INTERNAL FIXATION IN OSTEOPOROTIC BONE
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To Q. Kay Kang, M.D.
Without her love, inspiration, and support, this book would not have been possible.
CONTENTS

FOREWORD ix
PREFACE xi
CONTRIBUTORS xii

SECTION I. ESSENTIALS OF OSTEOPOROSIS
1. Pathogenesis and Histomorphology of Osteoporosis—Helen E. Gruber 3
2. Biomechanics of Osteoporotic Bone and Fractures—Nozomu Inoue and Edmund Y.S. Chao 9
3. Biology and Biomechanics of Fracture Healing—William R. Walsh, Yan Yu, Jia Lin Yang, R. Hocking, P. Chapman-Sheath, and Warwick Bruce 22
4. Mechanisms of Internal Fixation of Bone—Allan F. Tencer 40
5. Imaging and Bone Densitometry of Osteoporosis—Sven Prevrhal, Christopher F. Njeh, Michael Jergas, and Harry K. Genant 51

SECTION II. CURRENT CLINICAL TECHNIQUES
7. Basic Principles and Techniques of Internal Fixation in Osteoporotic Bone—Ralph Hertel and Bernhard Jost 108
8. Internal Fixation of Osteoporotic Long Bone—Charles N. Cornell 116
9. Internal Fixation of Osteoporotic Spine—Kazuhiro Hasegawa and Toru Hirano 128
10. Internal Fixation of Osteoporotic Acetabular and Pelvic Fractures—Dana C. Mears and Simon C. Mears 137
11. Internal Fixation in Patients with Paget’s Disease—Frederick S. Kaplan and David L. Glaser 156
12. Internal Fixation in Patients with Osteogenesis Imperfecta—Lewis E. Zionts and Edward Ebranzadeh 162
13. Bone Fixation in Patients with Bone Tumors—Kamron Aflatoon, Deborah Anne Frassica, Nozomu Inoue, and Frank J. Frassica 178
14. External Fixation in Osteoporotic Bone—J. Carel Goslings 186
15. Fracture Prevention and Medical Treatment of Osteoporosis—Joseph M. Lane, Linda Russell, and Safdar N. Khan 194
SECTION III. NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: BONE SCREWS, PINS, AND AUGMENTATION

16. Norian SRS Resorbable Cement for Augmentation of Internal Fixation of Hip Fractures—Stuart B. Goodman and Sune Larsson

17. Fixation of Unstable Osteoporotic Intertrochanteric Fractures Using the DHS and a Glass-Ionomer Cement—Lutz E. Claes, Christiane Becker, Martin Sinnacher, and Ingolf Hoellen

18. Enhanced Stability of External Fixation with Hydroxyapatite-Coated Pins—Antonio Moroni

19. Internal Fixation of Osteoporotic Proximal Femoral Fractures Using a Novel Device Enhanced by Hydroxyapatite Granules—Kazuhito Hasegawa

20. An Interlocking Screw for Fixation in Osteoporotic Bone—Brodie E. McKoy, Geoffrey S. Connor, and Yuehuei H. An

21. An Injectable Cementing Screw for Fixation in Osteoporotic Bone—Brodie E. McKoy and Yuehuei H. An

22. A Cement Screw for Fixation in Osteoporotic Metaphyseal Bone—Peter A. Reynders and Luc A. Labey

SECTION IV. NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: BONE PLATES

23. Resorbable Implants as a Means of Augmenting Metal Plate Fixation in Osteoporotic Bone—Sylwester Gogolewski


25. LISS Plate Fixation of Periprosthetic Supracondylar Femur Fractures—Kyle E. Watford, Philip J. Kregor, and Langdon A. Hartsock

26. An Axially Mobile Plate for Fracture Fixation—Eric W. Abel, Jun Sun, and David I. Rowley

SECTION V. NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: INTRAMEDULLARY NAILS

27. The Huckstep Nail for Fixation of Mechanically Deficient Femoral Bone—Nasser M. Kurdy and Charles I. Ayekoloye


29. Synthes Spiral Blade Intramedullary Nail System for Proximal Humeral Fractures—Jeffrey M. Conrad, Michael S. Wildstein, and Langdon A. Hartsock

30. An Expandable Intramedullary Nail for Fixation in Osteoporotic Bone—Nadav Shasha, Nehemia Blumberg, Michael Tauber, and Shmuel Dekel

31. Improving the Distal Fixation of Intramedullary Nails in Osteoporotic Bone—Frederick J. Kummer

SECTION VI. NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: SPINAL FIXATION

32. Percutaneous Vertebroplasty Using Bone Cement for Compromised Vertebral Bodies—Bernard Cortet, Pierre Hardouin, and Anne Cotten

33. Vertebroplasty with Inflatable Bone Tamps and Calcium-Phosphate Cement—Jorrit-Jan Verlaan, F. Cumhur Oner, Abraham J. Verbout, and Wouter J.A. Dhert

34. Minimally Invasive Surgery for the Treatment of Vertebral Compression Fractures—Joseph M. Lane, Safdar N. Khan, Federico P. Girardi, and Frank P. Cammisa, Jr.

35. A Self-Guided Pedicle Screw for Anterior Fixation of Cervical Spine—Baoren Liu and Yuehuei H. An

36. TPS Devices for Treatment of Vertebral Tumors and Pathological Compression Fractures—Jean-Valéry C.E. Coumans, Connie P. Marchek, and Fraser C. Henderson

INDEX 359
Fractures in the elderly have recently seen a marked increase in frequency and severity. The subsequent pain and disability result in a diminished quality of life and suffering for the patient. For the community, these disabilities create substantial costs because, according to recent reports, a large percentage of patients with proximal femoral fractures, for example, remain bedridden or require ongoing assistance. In the acute phase immediately after the fracture, bed rest must be minimized to avoid the lethal risk of circulatory and pulmonary complications. Therefore, the main goal of treatment for fractures of the lower limb, pelvis, and spine is to achieve early ambulation. Clinical experience has shown that when the pain is reduced faster and mobility and ambulation is restored, the chances for survival are better. This in turn requires a high quality of internal fixation in a difficult setting.

Osteoporotic bone is not only less strong but also lacks toughness. Brittle bone is even less forgiving. The problem is compounded by the fact that at the same time as bone softens, the brain hardens; that is, it loses the control of the locomotor function resulting in increased incidence of fractures and, more importantly, in loss of control of loading after fracture treatment. The weakness and brittleness of the osteoporotic bone limit its load-bearing capacity, whereas the internal fixation must withstand higher, uncontrolled loads. Paradoxically, stronger implants do not help; they are usually more rigid and rigid implants increase the stress at the interface between implant and bone—a serious vicious circle. To improve this condition, therefore, animal models allowing research into internal fixation in osteoporotic bone are of basic importance. They should lead to finding the proper balance between stability for painless function and controlled instability for prompt healing.

The healing quality of the elderly with osteoporotic bone seems to be clinically a less important problem, provided the fracture can be fixed properly. However, any possibility to improve the healing process is desired. Furthermore, to reduce suffering and cost, research into avoidance of osteoporosis based on a better understanding of molecular biology to supplement knowledge of conventional biochemistry remains a priority.

This book deals extensively with both the biomechanical and the biological aspects of surgical treatment of fractures in osteoporotic bone. An outstanding balance between the “mechanistic” and “molecular” world and between clinical and research aspects has been achieved. The wealth of direct and quoted information provided is a valuable contribution to the researcher and clinician alike. The many methods of research and the often impressive variety of techniques, tools, and implants indicate that we are still in search of desperately needed improvements. In some areas, such as in fractures of the humeral head, the variety of procedures is proportional to the difficulty of the treatment. In respect to the frequent fractures of the forearm, interesting new developments allowing maintenance of mobility are reported.

The editor, Yuehwei H. An, has added one more outstanding contribution in the field of applied research and clinical treatment. We congratulate him and wish this book well-deserved success!

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Metabolic bone diseases, such as osteoporosis, osteomalacia, hyperparathyroidism, and Paget's disease, are usually associated with osteoporotic or soft skeleton, especially in the elderly patient. Orthopaedic procedures in elderly patients are costly and with the increasing age of the population these costs will continue to escalate. Great challenges are often encountered when internal fixation is needed for fractures or osteotomies in osteoporotic bone. This book is designed to present both current clinical techniques and cutting-edge knowledge in preclinical research on the internal fixation of osteoporotic bone. Potential readers include orthopaedic surgeons, orthopaedic residents, orthopaedic researchers, fellows, and graduate students, as well as implant designers who work in orthopaedic departments or companies. The book will also be of interest to anyone working in the fields of clinical orthopaedics, orthopaedic research, or implant manufacture, and to internal medicine physicians who see osteoporotic patients.

The book is organized into six parts containing a total of 36 chapters. Section I: “Essentials of Osteoporosis” introduces the nature, models, and measurements of osteoporotic conditions, fracture healing, and how internal fixation works; Section II: “Current Clinical Techniques” reviews the current status of routine clinical techniques for fixation of osteoporotic bone; and Sections III to VI: “New Clinical Applications and Novel Concepts” cover the new clinical and novel concepts of internal fixation in osteoporotic bone using screws, plates, and intramedullary nails and other fixation devices in osteoporotic spine and pelvis. The text is simple and straightforward. A large number of diagrams, tables, line drawings, and photographs are used to help readers better understand the content. Full bibliographies at the end of each chapter guide readers to more detailed information.

This is the first inclusive and organized reference book on internal fixation of osteoporotic bone, a topic not adequately covered by any existing books. The book is planned to stay at the frontier of internal fixation of osteoporotic bone. Future editions, hopefully every 5 to 10 years, will always introduce new development and novel concepts in the field. Readers will be able to follow the progress of every new concept from in vitro and in vivo stages to clinical applications.

Finally, I would like to acknowledge Kylie Martin for her tireless assistance in communication with contributors, manuscript review, and editorial assistance.

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SECTION I

ESSENTIALS OF OSTEOPOROSIS
Age-related bone loss and bone loss due to osteoporosis pose major problems for the orthopaedic fixation of bone not only because of diminished bone stock in which fixation devices must find anchorage, but also because future bone formation at the site may fail to solidify the construct or because future bone resorption may cause loosening and failure.

The statistics on osteoporosis presented in the platform statements for the Bone and Joint Decade are sobering: Current estimates are that the number of individuals older than 50 years will double between 1990 and 2020, and that for the first time in Europe in 2010 there will be more people older than 60 years than people younger than 20 years. Osteoporosis affects 10 million Americans and 18 million more are at risk; 80% of those at risk are women. Each year, 1.3 million fractures (including 500,000 vertebral fractures) are attributed to osteoporosis. One half of all American women older than age 50 years are expected to sustain an osteoporosis-related fracture in their lifetime. One in every six white women will have a hip fracture, and the rate of hip fractures increases exponentially with increasing age. After age 65, rates for both men and women double in each decade of life. Two thirds of the individuals who have a hip fracture do not return to prefracture level of function.

The objective of this chapter is to present a current perspective on the pathogenesis of osteoporosis and to relate traditional histomorphometric analyses of bone biopsies to current serum and urine biomarker assays of bone cell activities.

**Bone Cells and Bone Remodeling**

Bone remodeling consists of two phases: bone resorption by osteoclasts followed by bone formation by osteoblasts. This process occurs continually and simultaneously at different sites throughout the skeleton.

Bone matrix is produced by osteoblasts at sites of previous bone resorption (Howship’s lacunae; resorption cavities). Prior to this, an initial resorption stimulus signals and recruits osteoclast precursors to the site of bone resorption. Mature osteoclasts, rich in lysosomes with high tartrate-resistant acid phosphatase (TRAP) content, carry out the resorption process and leave behind empty resorption cavities (Howship’s lacunae). TRAP is a valuable enzyme marker used for the identification of osteoclasts. During remodeling, it is important to remember that although osteoclasts are not numerous in the iliac crests of postmenopausal osteoporotics, the individual cell activity of the osteoclast in removing bone matrix is much greater than the individual cell activity of the osteoblast in making new bone matrix. During resorption, signals recruit osteoblast precursors to the Howship’s lacunae. With the advent of mature osteoblasts, bone formation begins. Early osteoblasts are very active in depositing matrix and are plump cells with abundant alkaline phosphatase demonstrable in their cell membranes. These cells secrete procollagen, collagen fibrils are formed outside the cell, and collagen bundles are then laid down in an ordered arrangement at the bone surface. As a site of bone formation nears completion, osteoblasts become less active and appear more flattened and spindle-shaped; when formation has ceased, fibroblast-like cells line the quiescent bone surface.

There are two important components of the remodeling cycle: (1) the depth to which osteoclasts “excavate” the resorption lacunae, and (2) the efficiency with which osteoblasts are able to fill in this excavated site. If it is perfectly filled in, the amount of bone formed equals the amount of bone lost, and there is bone balance. When the amount of bone re-
sorbed exceeds the amount formed, however, net bone loss occurs. If the imbalance between formation and resorption is low and overall bone turnover is low, there will not be a big change in bone mass. If, however, there is an imbalance between formation and resorption, which favors resorption in the presence of high turnover (i.e., the presence of a large number of active remodeling sites throughout the skeleton, also termed a high activation frequency), large bone loss will result.

Following its synthesis and secretion, bone matrix must be converted into mature osteoid prior to the initiation of mineralization. Although bone matrix maturation is an important but poorly understood process, two processes are reasonably well established: proteoglycan loss and formation of intermolecular cross-links. Newly secreted matrix components can be considered to be at 0% maturation, and matrix in which mineralization is being initiated can be considered to be fully matured. The histologic benchmark for the evaluation of mineralization and determination of the quality of mineralization is tetracycline incorporation at the mineralizing front. Tetracycline in vivo labeling techniques have made possible the quantitative histomorphometric determinations of bone formation and mineralization indices. Most tetracycline antibiotics form stable tetracycline-calcium chelates, which fluoresce intensely at wavelengths readily obtained with the standard fluorescence microscope. These chelates are formed only at sites of new bone deposition where the matrix contains 20% or less of the maximum mineral content. These chelates are locked into bone during mineralization and remain there until that bone site undergoes bone resorption. When two time-separated doses of tetracycline are administered prior to a bone biopsy, the distance between these two labels can be measured with histomorphometry, and a variety of quantitative indices determined based upon the portion of the bone surface lined by osteoid and that marked with the tetracycline label (Fig. 1–1A).

**NEW INSIGHTS INTO BONE REMODELING**

Ducy et al. have recently reviewed current information on the cell biology of the osteoblast. The osteoblast, which derives from mesenchymal stem cells, produces transcripts that distinguish it from the fibroblast cell: Cbfa1 controls the directional information for a differentiation factor for the osteoblast lineage by regulating the expression of osteocalcin, a gene expressed in terminally differentiated osteoblasts. Following embryogenesis, Cbfa1 expression is limited to osteoblasts (with some expression also occurring in hypertrophic chondrocytes). OSE1 is another regulatory element present in the osteocalcin promoter; it appears to be found in poorly differentiated osteoblasts. Osteocalcin is secreted by osteoblasts and appears to inhibit osteoblast function. During osteoblast differentiation, each of the major families of growth factors plays a role in osteoblast embryonic differentiation, and the growth factors themselves become bound into the bone matrix and may be subsequently released during later bone resorption at that site.

**FIGURE 1–1**  Photomicrographs of (A) normal and (B) abnormal tetracycline incorporation. Clear separation of crisp, distinct labels is seen in the normal specimen. The patient received two courses of tetracycline prior to biopsy; the double labels show that this bone-forming site was active when the first (label 1) and second (label 2) courses of tetracycline were administered. In specimens from patients with osteomalacia, tetracycline labels are diffuse and smeared (B). (Undecalcified methyl methacrylate embedment, Fig. 1A, original magnification ×88; Fig. 1B, ×126.) (From Gruber and Singer, with permission.)
Teitelbaum has recently summarized the current understanding of the cell biology of the osteoclast. Maturation of osteoclasts from their macrophage precursors requires narrow stromal cells or their osteoblast progeny as shown by Udagawa et al. These cells produce macrophage colony-stimulating factor (M-CSF) and the receptor for activation of nuclear factor kappa b (NF-κB) (RANK) ligand (RANKL). M-CSF is essential for macrophage maturation, but formation of osteoclasts also requires contact between osteoclast precursors and stromal cells or osteoblasts. As described by Hofbauer et al, the quantity of bone resorbed depends on the balance between expression of RANKL and of its inhibitor, osteoprotegerin (OPG). Hofbauer et al suggest that the stimulation of the pool of M-CSF precursors to committed osteoclastogenesis by RANKL may be one of the central pathophysiologic pathways involved in increasing the number of osteoclasts in osteoporosis.

Osteoporosis

Osteoporosis is a common metabolic disease whose frequency is increasing because the elderly constitute a rapidly growing segment of our population. Osteoporosis is characterized by a decrease in bone volume within a normal periosteal perimeter. It is a condition of skeletal fragility in which reduced bone mass and microarchitectural deterioration of bone are associated with increased risk of fracture. World Health Organization classifications use the term osteoporosis to define a bone mass value greater than 2.5 standard deviations below the young adult mean. As reviewed by Heaney, low bone mass has a multifactorial etiology that includes genetic predisposition, failure to achieve peak bone mass during growth and development, excessive thinness, disuse, gonadal hormone deficiency, inadequate calcium and vitamin D intake, other medical factors (such as alcohol abuse, corticosteroid use, and smoking), and nutrition and lifestyle issues. The reader is referred to several recent reviews that have discussed the hormonal alterations in osteoporotic syndromes and the pathophysiology of osteoporosis in greater detail than space here allows.

Osteoporosis is classified into two major groups. Primary osteoporosis includes postmenopausal osteoporosis in women (type I), age related or “senile” osteoporosis, and idiopathic osteoporosis in juveniles and young adults. Secondary osteoporosis includes osteoporosis that is secondary to heritable or acquired abnormalities; this is a broad disease grouping that includes bone loss associated with Marfan’s syndrome, Morquio’s syndrome, homocystinuria, osteogenesis imperfecta, adult hypophosphatasia, Werner’s syndrome, lactase deficiency, male hypogonadism, gut malabsorption, renal hypercalciuria, renal tubular acidosis (type 2), cirrhosis, immobilization, multiple myeloma, conditions associated with low serum phosphate, selective deficiency of 1,25-dihydroxyvitamin D (adult onset), anticonvulsant drug usage, female hypogonadism, Cushing’s syndrome, thyrotoxicosis, chronic alcoholism, diabetes, chronic heparin treatment, chronic obstructive pulmonary disease, systemic mastocytosis, and mild vitamin-D deficiency. Treatment of secondary forms of osteoporosis is achieved by treating the primary cause or, as with glucocorticoid treatment, treatment with antiresorbers.

As reviewed by Teitelbaum, the most common form of osteoporosis is that due to decreased estrogen with menopause. Increased osteoclast numbers and increased bone resorption are associated with estrogen loss. Increased osteoclasts result from increases in a variety of cytokines that regulate this cell: RANKL, tumor necrosis factor-alpha (TNF-α), interleukin-1 (IL-1), IL-6, and IL-11; M-CSF, prostaglandin E, and osteoprotegerin.

Osteoporosis and Bone Histomorphometry

The fundamental basis of histomorphometry is that the histologic features of bone cells and the bone surface truly reflect the metabolic activity of that skeletal site and that these features can be quantitatively assessed in an unbiased manner. Intact cores of the anterior iliac crest can be obtained at a standardized sampling site 2 cm posterior to the anterior superior spine (Fig. 1–2); contralateral biopsies can be used for studies that require a baseline and posttreatment biopsy. Electric drills or large-needle biopsies help overcome problems with distortion and splintering. Multiple needle cores, obtained through a single incision site, are necessary if quantitative histomorphometry is desired and large drills are not available. Previous studies have discussed the influence of specific sampling sites on the iliac crest and the influence of the amount of bone tissue scored in the quantitative analysis. The general utility of histomorphometric assessment of trabecular bone in osteoporosis has been discussed by a number of researchers, including Compston and Croucher, Arnala, and Erikson et al.

Undecalcified processing of bone with methacrylates represented a major methodologic advance, which allowed assessment of both the amount of osteoid and the evaluation of bone formation and mineralization as reflected in tetracycline incorporation (see above).

The osteoporotic skeleton displays a great diversity with respect to cortical thickness and porosity,
trabecular pattern and bone volume, and formation and resorption indices. Biopsies from patients with several atraumatic compression fractures may show histologic bone biopsy features that fall within the range for normal age-matched subjects. Biopsies from other patients may show elevated resorption or normal, decreased, or increased osteoid surface. Quantitative bone histomorphometry relies on a good quality and appropriately sized bone specimen, which today is usually assessed with computer-assisted methods employing the standardized nomenclature. An example of the computer image of a bone biopsy from a postmenopausal osteoporotic patient is shown in Figure 1–3.

Both the primary and secondary osteoporoses show a varied histology, and usually these two types cannot be distinguished on biopsy (and are best distinguished by clinical tests).

Bone biopsy continues to have an important diagnostic role in answering the question of whether a patient has osteomalacia. Bone biopsy remains the only way to make this determination; this is accomplished by examining the quality of the incorporated tetracycline and by quantitatively determining osteoid maturation indices. Figure 1–1A shows a normal pattern of tetracycline incorporation; the crisp labels seen in normal bone contrast sharply with the diffuse, smeared label pattern seen in osteomalacia (Fig. 1–1B). Qualitative assessment of bone quality is also important; this uses polarized light microscopy and is carried out to determine the presence of abnormal woven bone matrix.

NEW BIOMARKERS OF BONE TURNOVER

Today the bone biopsy retains a useful role in helping to rule out the presence of osteomalacia and in specialized clinical studies of new therapeutic modalities. Biochemical assays for bone biomarkers of bone resorption and formation are becoming more common in the evaluation of patients with osteoporosis and other types of metabolic bone disease. These assays have recently been reviewed by Eyre and Hough.

Bone formation assays include bone-specific alkaline phosphatase, osteocalcin, and type I collagen propeptides. Eyre notes that with all bone-turnover assays, the correlation between assay values and the actual rate of bone formation may not be simple or constant within or between patients. Measurement of the bone-specific form of alkaline phosphatase is reported to be linked to osteoblast activity, but it
should be remembered that this assay probably measures excess alkaline phosphatase. Correlations of collagen propeptides with actual bone turnover in mild metabolic bone states is poor, and thus collagen propeptide markers are not widely used.

Bone resorption assays usually rely on measuring collagen degradation products in urine. It appears that the newer markers, which assess degraded products of cross-linking domains from collagen fibrils, may provide a higher specific reflection of bone resorption. The hydroxyproline assay was used in the past but is less specific than newer collagen markers. Biologic and technical variations are associated with both the urine-based and serum-based assays, although Hough has commented that the serum markers have a lower variability (5 to 10%). As commercial assays become more accurate and guidelines are formed on the use of bone biomarker assays in clinical practice, these new techniques may provide non-invasive methods for determining bone formation and bone resorption levels.

References


Osteoporosis is characterized not only by a reduction in bone mass but also by alteration in the architecture of the bone. Changes in bone mineral density have long been considered the most important factor in the diagnosis of osteoporosis and in predicting the risk of fractures caused by osteoporosis. However, recent studies have indicated that there is an overlap on bone mineral density between the groups with and without fracture due to osteoporosis and that bone density measurement alone is insufficient to evaluate the mechanical properties of osteoporotic bone. Changes in the trabecular architecture of the osteoporotic bone are well known, but quantitative analysis of trabecular structure has not been well studied until recently. Recent rapid progress in the noninvasive measurement of the bone density and structure, such as dual photon energy X-ray absorptiometry, quantitative computed tomography, and quantitative ultrasound measurement, provides better understanding of the characteristics of osteoporosis and indicates the potential for predicting the mechanical properties of osteoporotic bone and the fracture risk.

Mechanical properties of bone can be described at different levels of the bone structure, from a macroscopic level to an ultramicroscopic level, and under different mechanical basic assumptions, such as heterogeneous or homogeneous and isotropic or anisotropic assumptions. To correctly interpret the measurements from the various noninvasive techniques for osteoporosis, it is essential to understand the hierarchical structure of bone and different approaches to the biomechanical properties of osteoporotic bone.

This chapter describes the hierarchical structure of bone and the mechanical properties of osteoporotic bone determined by the changes in the structure at the different structural levels.

Bone exhibits hierarchical composite structure at different structural levels. The hierarchical structures are illustrated in Figure 2–1, which shows a contact radiograph of the longitudinal section of the distal femur. At the macroscopic level, the distal femur includes the diaphysis consisting of cortical bone, metaphysis where the cortex transforms to cancellous bone, and epiphysis consisting mainly of cancellous bone and shell-like cortical bone. In the epiphyseal region, higher-density cancellous bone areas are observed in the region between the cortex in the metaphysis and the loading area of the joint surface. The cancellous bone in these regions is highly oriented in the longitudinal axis of the femur. Density distribution is heterogeneous when the entire epiphysis is evaluated. However, trabecular structure can be assumed to be homogeneous within a small region of interest (ROI). Even though trabecular structure can be treated as homogeneous in a small region, clear directionality is still observed in the region. The approach considering the directionality, but not considering the microstructure of individual trabeculae, is called the heterogeneous-anisotropic approach. If the directionality is not considered, this approach is called the homogeneous-isotropic approach. Usually, material properties of metals are analyzed under the homogeneous and isotropic assumption. In the heterogeneous approach at the microstructural level of cancellous bone, the individual trabecular structure, such as thickness and connectivity of individual trabeculae, is of interest. At the ultramicrostructural level, bone tissue can be described as a composite material consisting of collagen fiber and hydroxyapatite.
The following sections describe the mechanical properties of the cortical bone and cancellous bone at each hierarchical structural level and their changes in mechanical properties associated with osteoporosis.

MECHANICAL PROPERTIES OF CORTICAL BONE

MACROSCOPIC APPROACH TO MECHANICAL PROPERTIES OF CORTICAL BONE

Age-related changes in macroscopic geometry of the diaphysis have been well studied. Bone resorption occurs with age on the endosteal surface of the diaphysis of the long bone. On the periosteal surface, the diameter of the diaphysis is increased with age by deposition of new bone. These age-related changes cause a change in a cross-sectional geometry of the diaphysis. When the increases in outer diameter and inner diameter are similar, the cross-sectional area remains almost constant but polar moment of inertia and area moment of inertia increase based on the increases of outer and inner diameters. When only the inner diameter of the diaphysis increases with age, the cross-sectional area decreases and moment of inertia also decreases. Although there are controversies on differences between gender in the changes in outer diameter with age, Ruff and Hayes demonstrated greater expansion of the outer diameter in men and noted that this age-related increase in bone cross-sectional geometry appears to “compensate” for age reductions in material properties of bone tissue at the microscopic level in men.

Regardless of the differences in gender, the changes in outer diameter and inner diameter with age cause changes in cross-sectional geometry, which in turn affect bending and torsional characteristics of the whole bone.

MICROSCOPIC APPROACH TO MECHANICAL PROPERTIES OF CORTICAL BONE

The direction of the primary osteons is generally parallel to the long bone axis. In the transverse plane, there is no specific directionality in terms of the arrangement of the osteon. It has been demonstrated that cortical bone is stronger and stiffer in the osteonal direction than in the transverse direction. The stress-strain behavior of cortical bone is dependent on the osteonal direction with respect to the loading direction. This type of material is called an anisotropic material. A composite model with isotropic assumption in the transverse plane and anisotropic assumption in the long axis of the bone based on the osteonal direction has been used to investigate the anisotropy of elastic modulus and strength of the cortical bone.

The osteoporotic change in the microstructure of the cortex is seen as an increase of the porosity in the microstructural level, which reflects a decrease of the bone mineral density. Linear relationships between the bone mineral density versus elastic modulus and bone mineral density versus ultimate strength were reported. Decreases with age in mechanical properties of cortical bone were reported by Burstein et al. Yield stress, ultimate stress, and elastic modulus in tension decrease 2.2, 2.1, and 1.5%, respectively, per decade over the age range 20 to 90 on femur. The anisotropic properties of elastic modulus and strength are not remarkably influenced by osteoporotic changes in microstructure of the cortex.

ULTRAMICROSCOPIC APPROACH TO MECHANICAL PROPERTIES OF CORTICAL BONE

In the ultramicroscopic approach, the structures of the osteon and interstitial lamellae, orientation of the

FIGURE 2–1 Soft X-ray image of a coronal section of the distal femur showing dense cancellous bone originating from the metaphysis and oriented toward the joint surface.
collagen fiber, and hydroxyapatite crystals are of interest. The strength of the interstitial lamellae is reported to be higher than that of secondary osteons. The number of secondary osteons increases with age. While osteons with longitudinally oriented collagen fibers are stronger in tension than osteons with transversely oriented fibers, the osteons with transversely oriented collagen fibers are stronger in compression than the osteons with longitudinally oriented fibers. Changes with osteoporosis in the collagen fiber orientation in the laminar structure of the osteon are still unknown.

**Fracture Mechanics of Cortical Bone**

Fracture can be classified by characterizing the factor that caused the fracture (Tables 2–1 and 2–2). Fractures caused by direct forces (Table 2–1) can be subclassified according to the magnitude and area distribution of the force, as well as according to the rate at which the force acts on the bone. Soft tissue injury and fracture comminution are related to the loading rate. Trauma energy is dependent upon the second power of loading rate. Trauma energy will be released when a bone fractures.

Fractures due to indirect forces are produced by force acting at a distance from the fracture site. When a long bone is loaded, each section of the bone will be subject to both normal and shear stress. When these stresses exceed the limit of the bone, the bone will fracture. Different loads will generate different normal and shear stresses along different orientation planes within the bone. Judging the morphology of fracture lines, it is possible to predict the type of indirect injury mechanism (Fig. 2–2; Table 2–2).

In general, depending upon the material strength influenced by the osteoporotic changes, the three principal stress planes (maximum tensile stress plane, maximum compressive stress plane, and maximum shear-stress plane) dictate the fracture plane and predict when and how the material will fail. Cortical bone as a material is generally weak in tension and shear, particularly along the longitudinal plane, due to the anisotropic characteristics of the strength. However, bone density change as a result of osteoporosis can also greatly reduce its material strength although the structural strength may be less apparent due to cortex geometry alteration.

The failure patterns of long bones follow basic rules. Under bending, the convex side is under tension and the concave side under compression. Because bone is more susceptible to failure in tension than in compression, the tension (convex) side fails first. Tension failure occurs progressively across the bone, creating a transverse fracture without comminution. Occasionally, the cortex under compression breaks due to shear stress before the tension failure progresses all the way across the bone: the resulting comminution on the compression side often creates a single “butterfly” fragment or multiple fragments. Under torsional injury, there is always a bending moment involved that prevents the propagation of endless spinal fracture line. Shear stress may cause small longitudinal cracks on the spinal fracture line. Under experimental conditions, an average fracture angle of spinal fracture is approximately 30 degrees of the lon-

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**Table 2–1 Classification of Fractures of Direct Injury Mechanism**

<table>
<thead>
<tr>
<th>Type of Force</th>
<th>Description of the Force</th>
<th>Fracture Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tapping force</td>
<td>Small force on a small area</td>
<td>Nightstick fracture of ulna</td>
</tr>
<tr>
<td>Crushing force</td>
<td>High force acting on a large area</td>
<td>Crush fracture and severe soft tissue injury</td>
</tr>
<tr>
<td>Penetrating force</td>
<td>High force acting on a small area</td>
<td>“Open” fracture and minimal to moderate soft tissue disruption</td>
</tr>
<tr>
<td>Penetrating-explosive force</td>
<td>High force acting on a small area at a high or extremely high loading rate</td>
<td>“Open” fracture and minimal to moderate soft tissue disruption and devitalized bone fragment</td>
</tr>
</tbody>
</table>

**Table 2–2 Classification of Fractures of Indirect Injury Mechanism**

<table>
<thead>
<tr>
<th>Fracture Type*</th>
<th>Example of Fractures</th>
<th>Injury Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transverse</td>
<td>Some transverse patella fractures</td>
<td>Tensile force</td>
</tr>
<tr>
<td>Oblique</td>
<td>Oblique or Y-fracture of the distal femur/ humerus</td>
<td>Axial compressive force</td>
</tr>
<tr>
<td>Spiral</td>
<td>Spiral fracture of the tibia/humerus with intermittent longitudinal crack lines</td>
<td>Torsional force</td>
</tr>
<tr>
<td>Transverse</td>
<td>Transverse shaft fracture of the humerus/tibia with small butterfly fragment</td>
<td>Bending force</td>
</tr>
<tr>
<td>Transverse oblique</td>
<td>Transverse shaft fractures of the tibia with large butterfly fragment</td>
<td>Axial compression and bending</td>
</tr>
</tbody>
</table>

*Fracture types are graphically demonstrated in Figure 2–2 from right to left.
The susceptibility of bone to fracture with a single injury is related to its energy-absorbing capacity and modulus of elasticity. The loading rate of bone affects its energy-absorption capacity. Bone undergoing rapid loading will absorb more energy than when loaded at a slow rate. However, at very high loading rates there is a decline in energy absorbed. The energy absorbed by bone during loading is released when the bone fractures. This phenomenon helps to explain why injuries with rapid loading involving higher velocities dissipate greater energy and result in greater fracture comminution and displacement.

Clinically, it is well known that spinal and oblique fractures tend to heal faster than some transverse fractures. This difference in the inherent healing rate has been commonly related to as the difference in the amount of soft tissue destruction; that is, in the difference of injury mechanism and fracture energy. Another variable is the increased surface area of fracture ends in oblique/spinal fractures. In vitro experiments have considered the difference in fracture energy under transverse and spinal failure of a loaded bone. Analysis of the load-displacement curves showed no statistically significant difference in the amount of energy absorption at failure (Fig. 2–3). However, this difference may change as the base material properties and geometry alter as a result of aging and osteoporosis. Such change is due to the different stiffness properties of the bone under torsion and bending. Regardless of bone material and geometry changes, the larger load under bending failure may cause the surrounding soft tissues and periosteum to sustain more damage and thus affect bone fracture healing potential. This information is useful in fracture fixation device design and in the care of patients whose bones have undergone significant osteoporotic changes.

The susceptibility of bone to fracture under fluctuating forces (or stresses) is related to its crystal structure and collagen orientation, which reflects the viscoelastic properties of the bone. Cortical bone is
vulnerable to both tensile and compressive fluctuating stresses. Under each cycle of loading, a small amount of strain energy may be lost through microcracks along the cement lines. Fatigue load under certain strain rates can cause progressive accumulation of microdamage in cortical bone. When such a process is prolonged, bone may eventually fail through fracture crack propagation. It is expected that osteoporotic bone will have poor fatigue resistance. However, it is still a living tissue and can undertake a repair process although such reparative process may be inferior when compared to that in normal bone. Periosteal callus and new bone formation near the microcracks can arrest crack propagation by reducing the high stresses at the tip of the crack. However, for this repair process to be effective, a relatively low level of stress must be applied and maintained on the bone.

**Mechanical Properties of Cancellous Bone**

Because osteoporotic change is generally initiated from cancellous bone and because fractures associated with osteoporosis occur more frequently in the cancellous bone-rich regions, such as vertebral bodies of the spine, distal radius, and proximal femur, more attention has been paid to investigating the osteoporotic changes of cancellous bone than cortical bone. In addition to the reduction of the bone mineral density, changes in trabecular pattern have been clinically observed in radiographs. The osteoporotic changes in the trabecular pattern were utilized for the clinical staging of the osteoporosis in the proximal femur. Despite the recognition of the changes in the trabecular architecture of the osteoporotic bone, quantitative analysis of trabecular structure and its correlation with mechanical properties have not been well studied until recently.

**Macroscopic Approach to Mechanical Properties of Cancellous Bone**

Proximal femur, vertebral body, and distal radius are the most common sites for fracture associated with osteoporotic changes in the cancellous bone. Macroscopic distribution of bone density and trabecular orientation have been studied in the various anatomical sites by dividing the epiphyseal region into small ROIs. While a microscopic approach is applied to analyze the bone density and trabecular orientation in each ROI (as described in the next section), distribution of these parameters in each ROI represents a heterogeneous feature of the trabecular structure at the macroscopic level. These parameters are often used in estimating the mechanical properties of the cancellous bone, which can be used as input data for the finite element stress-strain analysis.

Hagiwara et al analyzed the distribution of bone density and trabecular orientation in the osteoporotic human vertebral body. The bone mineral density and trabecular orientation were measured for nine different regions (3 × 3 matrices) for individual vertebral bodies on 39 vertebral bodies from 11 human cadavers. The anisotropy was defined as the intensity of vertical trabecular orientation to the intensity of horizontal trabecular orientation (vertical/horizontal) measured with the two-dimensional Fourier transform of the soft X-ray of the vertebral body (to be described in the next section). The results demonstrated a significantly lower bone mineral density and higher vertical trabecular orientation in anterior one-third regions of the osteoporotic vertebral body. This finding corresponds to the higher incidence of vertebral fracture associated with osteoporosis in the anterior part of the vertebral body (a wedge-shaped fracture).

For a prediction of the fracture, loading condition is another important factor in addition to the mechanical properties of the bones. The loading conditions in activities in daily living are being studied to predict fracture risk.

**Microscopic Approach to Mechanical Properties of Cancellous Bone**

An increasing number of studies indicate that trabecular microstructure, in addition to bone mineral density, is an important factor in the assessment of osteoporosis. The prediction of fracture risk in osteoporotic bone based on bone mineral density measurement alone has been reported to be insufficient. The prediction of fracture risk using bone mineral density measurement could be improved by incorporating the changes in trabecular orientation.

Following are three different approaches to investigate the mechanical properties of cancellous bone at the microscopic level (Fig. 2–4).

**Homogeneous and Isotropic Approach**

Within a small region, cancellous bone can be assumed as a homogeneous material not considering the structure of individual trabeculae. With this approach, only bone density is evaluated and directionality of the cancellous bone is ignored. This approach is commonly used to study mechanical properties of conventional materials like steel.

Bone density can be defined in several ways. An apparent density has been used for many investigations. The apparent density is defined as the mass of bone tissue divided by the bulk volume of the test specimen, including mineralized bone and bone mar-
row spaces. In histological studies, the bone density can be defined as a ratio of the bone area to the entire field area. Sometimes it is called an area fraction. Radiographic density is also often used to define the bone density with calibrating by known hydroxyapatite density or normalizing by density of the control area. While a micro-computed tomography (CT) uses the radiologic technique, the bone density can be defined in a different way (i.e., a volume fraction). The volume fraction is defined as the volume of the bony tissue to the bulk volume of the test specimen including the bone marrow space.

Nonlinear Relationship between Density and Mechanical Properties of Trabecular Bone

The classification of bone tissue as cortical and cancellous is based on relative density (i.e., the ratio of specimen density to that of fully dense cortical bone). The relative density of cancellous bone, described as porosity, varies from about 30% to more than 90%. The distinction between low-density cortical bone and high-density cancellous bone is arbitrary. However, the stress-strain properties of the cancellous bone are markedly different from those of cortical bone. While the relationship between bone density versus the strength and elastic modulus has been reported to be linear for the cortical bone, the nonlinear dependence of strength and elastic modulus of the cancellous bone on the bone density was demonstrated. This nonlinearity has been well described as a power-law by Carter and Hayes. Their studies indicated that the compressive strength of cancellous bone is related to the square of the apparent density and that the elastic modulus is also related to apparent density by a power-law function, with an exponent range between 2 and 3 (between a squared and a cubic relationship with density).

Homogeneous and Anisotropic Approach

It has been generally accepted as a Wolff’s law that the directionality and density of the cancellous bone are related to direction and magnitude of the load applied to the bone. Similar to the cortical bone, anisotropy of the microstructure and mechanical properties of the cancellous bone have been recognized by numerous investigators. Anisotropic features on the trabecular pattern can be observed even in plain radiographs. Changes in the trabecular orientation in osteoporotic patients are widely recognized by the clinician and sometimes evaluated in the staging system of osteoporosis in the proximal femur. Clinical investigations show the limitation of the density measurement in predicting fracture risk. Therefore, recent studies have indicated the importance of changes in anisotropy of the trabecular structure for the diagnosis of osteoporosis and for prediction of the fracture risk associated with osteoporosis, in addition to the bone density measurement.

Even though the importance of the trabecular orientation is recognized in determining the material properties of the cancellous bone and for the diagnosis of the osteoporosis, this parameter has not been introduced in the quantitative analysis or evaluation until recently because of technical difficulties in quantifying the trabecular orientation. The cancellous bone has an imperfect lattice structure and shows a variation of the orientation. This complexity makes the quantitative analysis of the trabecular anisotropy more difficult.

The anisotropic features of cancellous bone are similar to fiber-reinforced composite materials, and the models developed for characterizing the mechanical properties of the composites can be applied to describe those of the cancellous bone. As described in the previous section, the cancellous bone can be as-

![FIGURE 2-4](image-url) Three different assumptions to approach mechanical properties of cancellous bone.
Anisotropy of the trabecular structure is assumed as a homogenous material within the small region. Anisotropy of the trabecular structure can also be described from a statistical point of view without expressing the orientation of individual trabeculae. This homogeneous-anisotropic approach is frequently used in analyzing the anisotropy of elastic modulus and strength of the fiber-reinforced composite material. In this approach, principal directions of the trabecular orientation and intensities of the orientation along the principal directions are two major parameters to describe the anisotropy of the trabecular structure.

As a method to measure the anisotropy of the cancellous bone from an entire image data, not measuring the directionality of individual morphological elements, a two-dimensional Fourier analysis of the image was introduced. This technique was extended from an optical Fourier analysis to a digital Fourier transform using a Fast Fourier Transform (FFT) algorithm. This technique has been also applied to study a soft tissue anisotropy. In the two-dimensional FFT analysis, location information of an individual element is extinguished and, as a result, all image information is gathered around a spectrum field origin (center of the spectrum field) (Fig. 2–5). This feature of the two-dimensional FFT allows an easy and fast analysis of the directionality included in the image data by combining a polar analysis of the power spectrum. This technique also allows analysis of image data with a gray-level gradient without binalization of the gray-level. This feature is important to analyze radiographic data with wide range of density gradient (gray-levels). It should be noted, however, that the Fourier analysis does not allow analysis of geometrical characteristics of individual trabeculae such as connectivity and thickness of the trabeculae, even though some of the characteristics can be analyzed by spatial frequency analyses in the spectrum field. Therefore, this technique can be used to analyze trabecular structure under the assumption that the cancellous bone is a homogeneous-anisotropic material.

Osteoporotic Changes in Intensity of Trabecular Orientation

Anisotropy of cancellous bone based on three-dimensional trabecular orientation is more complex than that of cortical bone based on osteonal orientation. Ratios of the elastic modulus and strength of the cortical bone between the osteonal direction and the transverse direction are within a relatively narrow range. It has been recognized that the trabecular anisotropy varies with anatomical site and progress of the osteoporosis. Weaver and Chalmers compared the cancellous bone in calcaneous bone with that in the vertebral body and demonstrated less compressive strength in the calcaneal cancellous bone than in the vertebral body, even though the bone mineral density was higher in the calcaneous cancellous bone. They suggested that this discrepancy was caused by the stronger trabecular orientation toward the compressive force direction in the vertebral body.

The anisotropic features of the trabecular structure have been relatively well studied in the vertebral body. The longitudinal trabecular orientation and transverse trabecular orientation are well known in the vertebral body, and changes in ratio between the two trabecular orientations have been considered an important indicator in determining the initiation and progress of the osteoporosis in the vertebral body. Generally, the transverse trabeculi disappear as osteoporosis progresses and, as a result, the longitudinal trabecular orientation becomes more dominant. This change in the longitudinal and transverse orientations with osteoporosis is clearly demonstrated by the Fourier analysis of the radiographic image (Fig. 2–5). The increase in intensity of the longitudinal trabecular orientation appears to be beneficial for sustaining the compressive force applied to the direction of the longitudinal trabecular orientation with a limited bone mass. However, the change in intensity of the trabecular orientation associated with osteoporosis has a critical disadvantage as described in the next section.

Direction Dependence of Elastic Modulus and Strength of Cancellous Bone

In the majority of mechanical testing of cancellous bone in the literature, including the studies cited in the previous sections, test specimens were taken along the direction of the major trabecular orientation and loading axis was parallel to this direction. This type of testing is called on-axis testing. Under the homogeneous-anisotropic approach, the mechanical properties in the orthogonal direction (i.e., transverse direction) are as important as those in the longitudinal direction. Several investigators have studied the mechanical properties of osteoporotic bones in the orthogonal directions and reported a decrease in elastic modulus and strength in the transverse direction compared with those of the longitudinal direction. These findings correspond to an increase in intensity of the trabecular orientation in the loading direction in the osteoporotic bone. The ratio of the elastic modulus in a major principal axis (longitudinal direction) to that in the minor axis (transverse direction) was reported as 1.00 to 1.51 in osteoporotic vertebral body and 1.05 to 7.04 in bovine proximal tibia. Not only do the mechanical properties in the transverse direction represent the characteristics of the osteoporotic bone, but they also are necessary in
determining the mechanical properties in arbitrary directions with regard to the loading axis (off-axis properties).

Elastic modulus in arbitrary directions between the maximum principal axis and minimum principal axis can be determined by following homogeneous-anisotropic-elastic theory:

\[
\frac{1}{E(\theta)} = \frac{\cos^4(\theta)}{E_0} + \frac{\sin^4(\theta)}{E_{90}} + \cos^2(\theta) \sin^2(\theta) \left( \frac{1}{G} + \frac{2
u}{E_0} \right)
\]

where \( E(\theta) \) is Young’s modulus in arbitrary direction \( \theta \), \( E_0 \) is Young’s modulus in the longitudinal direction, \( E_{90} \) is Young’s modulus in transverse direction, \( G \) is shear modulus, and \( \nu \) is Poisson’s ratio.\(^{28,33}\)

Figure 2–6 shows the directional variation of the tensile Young’s modulus of cancellous bone taken from the proximal bovine tibia.\(^{28}\) The intensity of the trabecular orientation was defined as the ratio of the intensity of trabecular orientation in the maximum principal axis to that in the minimum principal axis (anisotropic factor).\(^{34}\) The Young’s moduli do not vary with direction in the specimens with low intensity of the trabecular orientation (low anisotropic factor; Fig. 2–6). This type of specimen can resist the load from any direction and has features of homogeneous-isotropic materials. This low-intensity trabecular orientation is seen in the normal vertebral body (Fig. 2–5). As the anisotropic factor increases, the directionality dependency increases. Young’s modulus decreases dramatically when the loading axis declines 15 to 30 degrees from the principal axis of the trabecular orientation. For example, when the intensity of the longitudinal trabecular orientation is four times higher than that in the transverse direction (anisotropic factor = 4; Fig. 2–6), Young’s modulus decreases to about one quarter when the loading axis declines 30 degrees from the longitudinal axis. Because the Young’s modulus at 45 degrees reflects on-axis shear modulus, the increase in the intensity of the trabecular orientation also causes dramatic reduction of the shear modulus. These findings indicate that the osteoporotic change in increasing intensity of trabecular orientation in the loading direction may be beneficial to sustain the load in the direction, but osteoporotic bone with high-intensity trabecular orientation is markedly weak for the loading with slightly different directions from the direction of the principal trabecular orientation or for the shear load.

**Ultrasound Properties of the Osteoporotic Bone**

An ultrasound technique is gaining popularity as a method of preference for the noninvasive, radiation-free assessment of osteoporosis. There is a growing need for correlating the ultrasound results with the
underlying mechanical properties and trabecular structure because this method has a potential to estimate elastic modulus for bone, which in turn allows prediction of the fracture risk of osteoporotic bones.

Previous studies of ultrasound measurement on the cancellous bone demonstrated the importance of trabecular orientation along the ultrasound measurement axis as a significant contributor to the ultrasound measurement results.\textsuperscript{35,36} Turner and Eich\textsuperscript{36} concluded that only 36\% of the variance in compressive strength of cancellous bone can be explained by apparent density without considering trabecular anisotropy.

Minakuchi et al\textsuperscript{37} investigated the correlation between the compressive stiffness or ultrasound velocity (USV) and the bone mineral density (BMD) as well as the intensity of the trabecular orientation using human calcaneal cancellous bone. The trabecular orientation was quantified with the two-dimensional FFT of the soft X-ray image of test specimens (Figs. 2–7A,B). Equivalent bone density oriented along the loading and ultrasound axis was calculated as the product of bone density and trabecular orientation intensity along the same axis (Fig. 2–8). The component of bone density oriented along the axis correlated significantly better than BMD with both compressive modulus and USV. This investigation suggests the importance of the trabecular orientation in estimating the mechanical properties of the cancellous bone in addition to the bone mineral density, and ultrasound results reflect mechanical properties of cancellous bone with information of anisotropy.

It should be noted, however, that ultrasound measures both the density and anisotropy simultaneously and that these parameters cannot be separated by the ultrasound measurement alone. The information about anisotropy could be obtained from the ul-
ultrasound measurement but the bone mineral density should be measured separately at the identical location where the ultrasound measurement is performed.

**Heterogeneous and Anisotropic Approach**

In the heterogeneous and anisotropic approach, the microscopic structure of the trabeculae is analyzed directly from the morphology of the individual trabeculae.
beculae. Histological studies have elucidated the morphological changes in osteoporosis. In addition to the two-dimensional histology, continuous sectioning technique allowed creation of a detailed three-dimensional reconstruction of the trabecular structure. Micro-CT has also been used to create the three-dimensional trabecular structure. These three-dimensional reconstructions of the trabecular structure enable quantification of morphological parameters, such as trabecular connectivity, individual trabecular volume, and surface area, and three-dimensional anisotropy. A microstructural three-dimensional finite element model (FEM) has been generated based on the three-dimensional microstructural geometrical data set. The microstructural FEM simulation of multidirectional mechanical testing provides not only three-orthogonal Young’s moduli but also shear moduli and Poisson’s ratios.

Connectivity of the trabeculae has been studied using the micro-CT technique. The relationship between the trabecular volume fraction and the connectivity of the trabeculae was investigated using micro-CT but the results were controversial. Most recently, Ding et al applied the micro-CT technique to study osteoporotic changes in anisotropy and connectivity of human proximal tibiae. They demonstrated a significant increase in the intensity of the trabecular orientation in the primary trabecular direction and a strong trend of decreasing trabecular connectivity with age. They indicated that the remaining trabeculae in the elderly support the mechanical load mainly in the primary direction to compensate for bone loss as the consequence of age and remodeling process. Ding et al. applied the micro-CT technique to study osteoporotic changes in anisotropy and connectivity of human proximal tibiae. They demonstrated a significant increase in the intensity of the trabecular orientation in the primary trabecular direction and a strong trend of decreasing trabecular connectivity with age. They indicated that the remaining trabeculae in the elderly support the mechanical load mainly in the primary direction to compensate for bone loss as the consequence of age and remodeling process.

Kabel et al. studied the relationship between the connectivity and the elastic properties of cancellous bone using the microstructural FEM and reported that the connectivity density parameter had no or very limited value for the assessment of the elastic properties by morphometric variables in normal bone. They indicated that the connectivity might be an estimator for mechanical properties for the pathological bones.

Because the size of the specimen for micro-CT is limited, these techniques are not applicable for in vivo human study at the present time.

Ultramicroscopic Approach to Mechanical Properties of Cancellous Bone

The ultramicrostructural features of cancellous bone have received less attention than those of cortical bone. While the microstructural FEM of the cancellous bone includes precise geometrical data on trabecular network, less attention has been paid to the bone tissue mechanical properties of the trabeculae. The effects of precise mechanical properties of bone tissue as an input data of the microstructural FEM of the cancellous bone have been presented recently.

Fracture Mechanics of Cancellous Bone

The porosity of trabecular bone is commonly expressed by the apparent density. In human cancellous bone, the apparent density ranges from approximately 0.1 g/cm$^3$ to 1 g/cm$^3$. The apparent density of cortical bone is about 1.8 g/cm$^3$. A cancellous specimen with an apparent density of 0.2 g/cm$^3$ has a porosity of approximately 90%. These physical values may or may not correlate with the fracture strength of the cancellous bone.

The compressive stress-strain behavior of cancellous bone exhibits a unique feature based on its porous structure. The stress-strain curve for cancellous bone under compressive loading shows an initial elastic region followed by yield. Yielding occurs as the trabeculae begin to fracture and fill the marrow spaces, and at a strain of approximately 0.50, most of the marrow space has filled with the debris of fractured trabeculae. Since such process is progressive, it is difficult to define the cancellous bone’s ultimate compressive strength as a material. Cubes or cylindrical specimens subjected to compressive load in different directions can help to establish cancellous bone mechanical properties including mechanical strength (Fig. 2-9).

When mechanical properties are used to study fixation strength involving cancellous bone, more detailed modeling using finite element method may be necessary. All cancellous bones are reinforced by the marrow content and the encasing cortical shell, which must be considered in the modeling effort. Cancellous bone healing mechanism after fracture is not well understood, and additional investigation must be conducted to establish the basic knowledge for both normal and osteoporotic conditions (Fig. 2-10).

Summary

Mass reduction of the bone in osteoporotic change causes structural changes of the bone, especially at the microstructural level. Subtle reduction in the bone mass in the transverse direction increases the intensity of the trabecular orientation in the loading axis. This structural change may be effective to resist the loading when the direction of the loading coincides with that of the trabecular orientation. However, this structural change narrows the tolerable loading directions, which in turn may increase the fracture risk. An investigation of the loading conditions to the bone in different anatomical sites in the
elderly population is another important approach for predicting the fracture risk associated with osteoporosis in addition to studies of the mechanical properties of the osteoporotic bone.

Different types of noninvasive techniques provide different information on the structural changes in osteoporosis. To interpret the information correctly and effectively, it is important to understand the structural level of the bone and the underlying assumptions on which the individual measurement is based.

Advanced noninvasive techniques may provide the structural changes of osteoporotic bone at the ultramicrostructural level and even at the molecular level. It would be important to integrate this lower-scale information with the higher-scale structural information to evaluate the mechanical properties of osteoporotic bone because biomechanical features at each structural level are closely linked with those at the upper-level structure.

REFERENCES


Osteoporosis is a systemic disease characterized by a decreased bone mass and reduction in mechanical properties. Osteoporotic fractures and related health problems and costs represent a significant and growing problem. An increase in age-adjusted incidence of all fragility fractures, hip, vertebral, and radius, has been seen in the Western world. The projected costs of osteoporotic fractures in white postmenopausal women during the next 10 years in the United States alone is estimated at more than $45 billion. More than 5.6 million fractures have been estimated to occur each year in the United States alone and somewhere between 5 and 10% of these result in delayed or impaired healing.

Fracture healing is a complex biological cascade characterized by the sequential expression of fibrous, cartilaginous, and bone-specific genes. Our understanding of the molecular events during fracture healing have benefited greatly with recent advances in molecular biology techniques. A thorough understanding of the cellular and molecular events and the correlating mechanical properties remains unknown. The events in fracture healing in the aged and osteoporotic patient are confounded by a known decrease in bone formation in osteoporotic patients compared to age-matched controls. The effect of estrogen deficiency on fracture healing remains controversial. The ability to augment or accelerate fracture healing has the potential to play an important role in the clinical treatment and economic considerations in fracture management. This chapter will examine fracture healing and the biological and mechanical factors that have been suggested to play an important role and to have the potential to provide a clinical treatment. The effects of estrogen deficiency on histology and immunohistochemistry fracture healing will also be examined.

Fracture healing has long fascinated and amazed researchers and clinicians. The unique concert of events that follow the initial injury play a vital role in the dynamic ability of bone to regenerate and repair itself and have been the source of a multitude of studies. Recent data suggest the regenerative capacity of adult bone may depend upon the reinduction of the pathways from fetal development of chondrogenesis and osteogenesis. Fracture regeneration aims to provide stability to the injury site to allow the infiltration of a new vascular system and ultimate remodeling to a mature and load-bearing construct.

The pathways for bone regeneration are related to the mechanical boundary conditions, stability and imposed loads, at the fracture site. Motion at the fracture site will lead to a cartilaginous pathway via enchondral ossification indirect, secondary healing, whereas a stable mechanical environment leads to bone formation without a cartilaginous intermediate direct, primary healing. Primary bone healing follows a similar sequence of events observed for filling of cortical bone defects. The initial phase provides a scaffold of woven bone that is later remodeled to Haversian or secondary bone. This type of healing has been observed following the principles of open reduction and internal fixation (ORIF).

Studies describing the histological features of secondary fracture healing have evolved from the early analogy of blastema production. Healing or regeneration of a low-energy long bone fracture via secondary healing has been described in five phases: immediate injury, intramembranous bone formation, chondrogenesis, endochondral ossification, and bone remodeling.
NORMAL FRACTURE HEALING

HISTOLOGY PHASES

Phase 1: Hematoma Formation, Inflammation, and Granulation Phase

Immediately following the mechanical insult and formation of hematoma there are two separate, but simultaneous events: (1) intramembranous ossification via proliferation of osteoprogenitor cells from the cambial layer of periosteum, and (2) endochondral ossification from the chondrogenesis of undifferentiated mesenchymal cells in the soft tissues adjacent to the fracture site and in the bone marrow. In simple terms, a fracture results in fragments of dead bone and disruption of soft tissues and local vascular and nutrient supply. Activated platelets release a variety of products to the local environment that have been thought to play a role in fracture healing and bone repair, including platelet-derived growth factor (PDGF), transforming growth factor beta (TGF-β), and osteocalcin.24

The ensuing influx of inflammatory cells that secrete fibroblast growth factor and additional PDGF and TGF-β and cytokine cascade interleukin (IL)-1 and IL-6 brings the cells of repair, fibroblasts, osteoblasts, and endothelial cells, into the fracture site, which may be important in regulating the early events in fracture healing.25

Some of the earliest changes as a result of the milieu of factors were reported by Brighton and Hunt in a rabbit model.26 These authors noted the early loss of normal architecture of the marrow and the disappearance of blood vessels in the region of high cellular density adjacent to the fibrin clot in the medullary callus; the enlargement and transformation of capillary and venous endothelial cells in the region of low cellular density adjacent to the normal, uninjured marrow; the appearance of polymorphic mesenchymal cells throughout the medullary callus; and the appearance of osteoblasts and new bone formation by 24 hours after the fracture.26

Phase 2: Intramembranous Bone Formation

New bone matrix is synthesized by osteoblasts adjacent to the fracture site and below the proliferating periosteal cells. This primary bone forms without a cartilaginous intermediate via an intramembranous pathway.

Phase 3: Chondrogenesis

This phase is characterized by chondrogenesis by mesenchymal cells and an enlarged cartilaginous matrix at the fracture site soft callus that provides some initial stabilization. The presence of fibrous tissue as well in the fracture site adjacent to the cartilaginous matrix is commonly seen.

Phase 4: Endochondral Ossification

The move into the formation of hard callus and union at the fracture site is achieved as a result in woven bone formation. This weak woven bone forms through a cartilaginous intermediate as the chondrocytes undergo hypertrophy7,27 and produce and release neutral proteases that degrade the cartilage matrix, including proteoglycans prior to mineralization.28,29

Phase 5: Bone Remodeling

The final phase of healing represents the final regeneration from disorganized woven bone to a return to Haversian bone prior to the initial event.

GROWTH FACTORS AND BONE MORPHOGENIC PROTEINS DURING FRACTURE HEALING

Improvements in clinical treatment of fractures may come as research into the molecular mechanisms behind the fracture cascade of events are understood. Many local and systemic regulators are involved in fracture healing, including growth and differentiation factors, cytokines, hormones, and extracellular matrix components.30–35 The expression of these factors appears to be spatially and temporally restricted, suggesting a fine level of control and balance during fracture regeneration and healing. The following summarizes a number of findings related to the proteins expressed during fracture healing. Collectively, these studies reveal the fine level of control of the biological mechanisms. A number of new and unique molecules have recently been identified that will no doubt bring about new questions and research. A number of excellent review articles are available for an overview of growth factors as they relate to fracture healing.4,25,30,36,37

EXTRACELLULAR MATRIX PROTEINS

The temporal expression of a number of extracellular matrix (ECM) proteins during fracture healing have been reported in the hard and soft callus,38,39 as well as the spatial expression of many of these molecules through in situ hybridization. These proteins include a variety of collagen types (Col I, II, V) as well as a number of noncollagenous proteins, including osteonectin (ON), osteocalcin, osteopontin, and alkaline phosphatase (ALP).

Using Northern analysis to determine the relative level of gene expression for intracellular matrix proteins gene, Jingushi and Bolander38 demonstrated that a temporal expression of different ECM protein genes can be correlated with cellular events and the phases of fracture healing, including the initiation of intramembranous bone formation, endochondral os-
sification, as well as bone remodeling. Changes in the ECM protein gene expression in the hard and soft callus differed further, demonstrating the differences between these tissues at the local molecular level.

**GROWTH FACTORS AND FRACTURE REPAIR**

The sequential expression of growth factors during fracture healing confirms the dynamic nature of the fracture cascade. A number of growth factors have been detected in the healing fracture including fibroblast growth factor (FGF), PDGF, insulin-like growth factor (IGF), and TGF-β. PDGF and TGF-β are among the first factors to be present following their release from degranulating platelets, followed by basic FGF and additional PDGF and TGF-β. A number of authors have reported using immunohistochemistry to detect the presence of growth factors as well as bone morphogenetic proteins (BMPs) during the fracture cascade in the standard closed fresh fracture model. Little data to date has been presented on a similar comparison in the estrogen-deficient fracture model.

**FIBROBLAST GROWTH FACTOR AND PLATELET- DERIVED GROWTH FACTOR**

Members of the FGF family have been reported to have a diverse range of functions that have been reviewed elsewhere. Both the acidic and the basic forms of FGF have been detected during the early stages of fracture repair and are implicated in the regulation of cartilage and bone.

PDGF, synthesized by a number of cell types, including platelets, macrophages, monocytes, and endothelial cells, has also been shown to be a potent mitogen for all cells of mesenchymal origin. PDGF has been detected during fracture healing using immunohistochemistry as well as in situ hybridization. Andrew et al have reported PDGF expression by a number of cell types for prolonged periods during fracture healing.

**TRANSFORMING GROWTH FACTOR-β**

Among these factors, the TGF-β/activin/BMP cytokine family has been implicated to play an important role in bone formation and healing. BMPs have been detected during ectopic bone formation in vivo, and they influence mesenchymal cell proliferation, differentiation, chondrogenesis, and osteogenesis in vitro, whereas TGF-β is involved in wound healing and tissue repair. Both factors initiate their biological effects from the cell surface through two related serine-threonine kinase receptors, the type I and II receptors. Upon ligand binding, the activated type II receptor phosphorylates/activates the type I receptor. In turn, the activated type I receptor propagates the signal to downstream substrates.

TGF-β’s role in fracture healing begins with the initial response and release from degranulating platelets. Joyce et al, using immunohistochemical and recombinant DNA techniques, have implicated TGF-β as an important regulator of cell proliferation, differentiation, and synthesis of extracellular matrix proteins during fracture healing. TGF-β has been localized in regions of cell differentiation and proliferation and is synthesized by these cells. TGF-β1 gene expression was noted to peak at day 13 in the soft callus, whereas the hard callus presented a maximal response at day 5 and a submaximal peak at day 15. Rosier and coworkers reported the temporal expression of different TGF-β isoforms in a chick fracture model. The pattern of TGF-β1 expression has been reported by many investigators.

Brager et al provided the local mRNA expression of a number of growth factors in the callus tissue at 7, 14, 21, and 28 days using the rodent fracture model. These authors did not differentiate between hard and soft callus. Expression levels were relative to a β-actin control revealed peak expression of TGF-β1–3 at day 14, which remained relatively high at day 21 and decreased by day 28. FGF-1, FGF-2, and FGF-9 were noted to peak on days 14, 21, and 28, respectively, whereas BMP-2 expression increased from day 7 to 14 and remained relatively constant.

Andrew et al investigated IGF-I and III mRNA expression in normally healing human fractures by in situ hybridization. Endothelial and mesenchymal cells at the early phases of healing granulation expressed IGF-II mRNA. Expression of IGF-I mRNA was detected during endochondral and intramembranous ossification. These results support a role for IGFs in local cellular regulation during fracture repair.

**MATRIX METALLOPROTEINASE-13 (COLLAGENASE-3)**

The presence of matrix metalloproteinase-13 (MMP-13) during fracture healing has recently been reported using a mouse rib fracture model. MMP-13 (collagenase-3) is a member of the MMP family, which degrades type II collagen about sixfold more effectively than type I or type III collagen. MMP-13 mRNA was present in the cells of the periosteum at day 1 as well as in the cells of the cartilaginous phase and hypertrophic chondrocytes and immature osteoblastic cells in the fracture callus.

**INDIAN HEDGEHOG**

Murakami and Noda reported the expression of Indian hedgehog (Ihh) in chondrocytes and osteoblasts
during fracture healing using a standard rodent fracture model\(^5\) at 1, 2, and 3 weeks following fracture. Ihh expression was known to be enhanced by TGF-\(\beta\), which provided motivation to examine its role in fracture healing.\(^5\) These findings indicated that this developmental factor is expressed during fracture healing and could participate in the regulation of enchondral bone formation at the fracture site.

**Neurotrophins**

Asaumi et al\(^6\) reported the expression of neurotrophins and their receptors in a mouse rib fracture model. Expression levels of three neurotrophins were increased during fracture healing. Peak levels were found as early as 3 days after fracture. Neurotrophins and their receptors exist in bone-forming cells, which suggests they may play an important role in the regulation of bone formation as autocrine or paracrine factors in vivo.\(^6\)

**Bone Morphogenic Proteins**

Since the key discovery by Urist,\(^57\) BMPs have been the source of great interest in fracture healing. BMPs are pleiotropic regulators of chemotaxis, mitosis, and differentiation.\(^58,59\) To date, at least 16 BMPs have been identified.\(^60,61\) Several studies have reported the presence of BMPs during fracture healing as early as 3 days using a rabbit mandible fracture model. Bostrom and coworkers\(^65\) have confirmed the presence, localization, and temporal expression of BMP-2 and BMP-4 using a standard closed adult rat fracture model\(^53\) at 2, 4, 6, 8, 10, 14, and 21 days following fracture. BMP-2 and BMP-4 expression appeared to be confined to primitive osteoblastic and chondroblastic tissues.\(^66\) Ishidou and coworkers\(^66\) have also reported the expression of BMP-2, BMP-4, and BMP-7 and osteogenic protein 1 (OP-1) during fracture healing. BMP-7 demonstrated a different localization and temporal expression pattern compared to BMP-2 and BMP-4. Individual BMPs may have different functions during the healing process, which has yet to be completely understood.

The expression of BMP receptors during fracture healing has also been reported using the adult closed fracture model.\(^53,66\) BMP type IA and IB receptors are expressed in osteoblasts and periosteum and are upregulated in the osteogenic cells of the periosteum near the fracture ends. These receptors also demonstrated a temporal and specific expression pattern, again suggesting different roles for these receptors during fracture healing.

**Activins and Follistatin**

Activins are multifunctional proteins that belong to the TGF-\(\beta\) superfamily and are thought to play an important role in modulating the formation of bone.\(^67\) Activins stimulate erythroid differentiation of hematopoietic progenitor cells of bone marrow\(^68\) and are involved in embryonic development.\(^69\) Activins are dynamically regulated by follistatins, which are monomeric glycoproteins. Activin A and follistatin have been detected using immunohistochemical techniques in ectopic bone formation in subcutaneous demineralized bone matrices.\(^67\) Activin A and follistatin are coexpressed in prechondrocytes, with the expression decreasing with maturity. Furthermore, the process of enchondral ossification has been shown to be inhibited by injections of rh-follistatin. The activin-follistatin system therefore may play an important role in bone development.

Nagamine and coworkers\(^70\) recently reported the immunohistochemical expression of activin A, follistatin, and activin receptors during fracture healing using the standard rat model.\(^53\) Activin and follistatin were not expressed in normal intact femurs of the rat. Activin and follistatin, however, were detected at the fracture site. Immunostaining for activin A was initially weak in the osteogenic cells and extracellular matrix of the thickened periosteum adjacent to the fracture site, as well as the fibroblast-like cells around the hemotoma on day 3. Staining for follistatin was strong in the periosteum. By day 7 after fracture, activin A expression decreased below levels of detection, whereas follistatin was weakly expressed. Activin staining also remained weak in the fibroblast-like cells located in the periphery of the cartilage islands on days 7 and 14. Follistatin was expressed moderately or strongly in the proliferating, mature, and hypertrophied chondrocytes on days 7, 14, and 28. Activin A staining was also noted in the osteoblasts and bone matrix of newly formed trabecular bone. Sakai et al\(^71\) reported that the local administration of activin promotes fracture healing in a rat fibula model.

**Smads**

The mechanism of action of BMPs has evolved following the identification of a novel family of proteins, the Smads, as TGF-\(\beta/\)activin/BMP signal transducers.\(^72,74\) Smads are the vertebrate homologs of Mad Mothers against decapentaplegic gene from *Drosophila* and/or Sma genes from *Caenorhabditis elegans*. They are categorized into three classes based on their different functions. Smad1, Smad2, Smad3, Smad5, and Smad8 belong to the receptor-regulated class (R-Smad), which is activated by the type I receptors.\(^72,74\) Smad2 and Smad3 are initiated by TGF-\(\beta\)/activin and induce the responses to their ligands, while Smad1, Smad5, and Smad8 mediate BMP responses. This class of Smads forms heteromers with the common-mediator class (Co-Smad): Smad4,
moving from cell surface to nucleus, positively regulates target gene function. Smad6 and Smad7 (inhibitory Smads or anti-Smads) perform negative regulatory or balancing roles in those processes.72–74

Smad1, Smad2, and Smad5 have been found to be highly expressed in proliferating chondrocytes, while Smad3, Smad4, Smad6, and Smad7 were strongly exhibited in mature chondrocytes in epiphysis of growing rats.46,75 In vitro studies by Fuji et al76 have shown Smad1 and Smad5 can induce alkaline phosphatase activity in C2/C12 mouse myoblast cells and chondrogenic differentiation of ATDC5 cells, whereas Smad6 and Smad7 repressed this activity. These studies suggest that Smads play a role in osteoblast and chondroblast differentiation and proliferation as well as endochondral ossification.59,60 Smad expression during fracture healing in normal or diseased states has not been reported. In a pilot study, we examined the expression of Smad1, Smad4, and Smad5 during fracture healing in normal and estrogen-deficient state (see below).

**Enhancing Fracture Healing**

Accelerating or enhancing fracture regeneration has the potential to influence the clinical decisions in fracture management as well as the economic burden on society. The aim of enhancement may be to accelerate a fracture that is likely to heal, or to assure the healing of a fracture that is not likely to heal without extraordinary measures.82 Either scenario has the potential to reduce clinical and socioeconomic problems associated with fracture healing. A number of noninvasive and invasive strategies that have been developed over the years will now be considered.

**Noninvasive Methods**

Noninvasive methods in fracture treatment through systemic injections or biophysical stimulation electromagnetic ultrasound have been examined. Systemic injections of l-dopa have been reported to enhance early fracture healing as well as nonunions.77,78 l-dopa is converted in the body to dopamine, which stimulates the secretion of growth hormone, which in turn can influence healing.

Holzer et al83 reported the effects of daily subcutaneous injections of parathyroid hormone in a rat closed fracture model.53 Treatment with parathyroid hormone resulted in a statistically significant increase in callus area and strength. Histology also showed an increase in the amount of new bone.

Biophysical stimulation, either electric, electromagnetic, or ultrasound, represents the most common clinically employed noninvasive method used to treat fractures. The development of electric and electromagnetic techniques has been based, in part, on the discovery of the piezoelectric properties of bone tissue. The foundation of these noninvasive strategies relates to strain-generated electric potentials acting as a signal for the regulation of cellular processes involved in bone repair and remodeling.80 A number of studies have examined the in vitro effects of electromagnetic stimulation.81,82 These authors have proposed that magnetic fields stimulate the secretion of IGF-II. Nagai and coworkers83 reported stimulation of TGF-β, BMP-2, and BMP-4/mRNA, respectively, following pulsed electromagnetic stimulation. Clinically beneficial effects of electrical stimulation have been shown over the past decade using a variety of stimulation techniques on nonunions and have been reviewed by Ryaby.84

Low-intensity ultrasound is another biophysical method that represents the sole intervention approved by the Food and Drug Administration to augment the healing of fresh fractures.85 A review of ultrasound-induced effects on fracture healing was reported by Hadjiargyrou et al.86 The general consensus from these studies supports the clinical use of ultrasound in fracture regeneration. Warden et al86 recently reported a review of the Sonic Accelerated Fracture Healing System (SAFHS, Exogen Inc., Piscataway, NJ). Despite the number of successful reports following ultrasound treatment in animal work, the physical process responsible for these effects still remains relatively unknown. This reflects the complexity of the fracture-healing cascade as well as limited understanding of how ultrasound signals are transduced in vivo to elicit a cellular response.

Kristiansen et al87 in a multicenter, prospective, randomized, double-blind, placebo-controlled clinical study recently reported that a specific ultrasound signal accelerated the healing of fractures of the distal radial metaphysis and decreased the loss of reduction during fracture healing. Heckman et al88 have reported acceleration of tibial fracture healing in humans following low-intensity pulsed ultrasound (Exogen, Smith and Nephew Endoscopy, Andover, MA).89 A significant decrease in time to clinical healing was observed (86 versus 114 days), which demonstrates the efficacy of low-intensity ultrasound stimulation in the acceleration of the normal fracture repair process. The economics in reduction in healing time of tibial fractures treated with ultrasound stimulation was examined by Heckman and Sarasohn-Kahn.89 Reduced healing time yielded a substantial cost-saving in fracture treatment.89

The mechanical environment is generally accepted as having a major influence on the course of the healing fracture. Mechanical stimulation can induce fracture healing or alter its biologic pathway. Mechanical stimulation through specific, controlled degrees of induced micromotion has been shown in preclinical
and clinical trials to enhance fracture healing\textsuperscript{90,91} as well as hypertrophy of bones or other connective tissues. The healing of osteotomies created in animal models have been shown to be influenced by the strain magnitude, strain rate, and stress applied to the tissues.\textsuperscript{3,90}

**Invasive Methods**

Invasive fracture treatment strategies include the use of autogenous bone grafting and has recently moved into the field of osteobiologics. The osteobiologic approach has been hampered, traditionally, due to a lack of detailed knowledge concerning the temporal and spatial distribution of growth factors and exogenous osteoinductive agents during fracture healing and a number of issues related to delivery and release kinetics.

**Autologous Methods**

The use of autologous bone graft remains the gold standard but has a number of well-recognized complications in terms of donor site morbidity, mechanical properties, blood loss, increased operating time, and limited supply. The choice of autogenous bone grafts or allograft bone represents a complicated clinical decision that needs to consider local biology and mechanical stability.\textsuperscript{92} Other techniques such as the use of marrow osteoprogenitor cells aspirated from the iliac crest and injected into the fracture offer other autogenous methods of invasive therapy. Another recent autologous strategy based on the isolation and concentration of platelets from the patient’s own blood has been applied to a number of bony sites. A few hundred milliliters of blood is taken prior to the procedure and the platelets and fibrinogen concentrated in a two-stage procedure known as Autologous Growth Factor (AGF) therapy (Interpore-Cross International, Irvine, CA). AGF has been examined in an ovine posterolateral spinal fusion model in combination with a resorbable ceramic and aspirated bone marrow.\textsuperscript{93} The addition of AGF to autograft increased the stiffness by nearly 15% compared to autograft alone, while the addition of AGF and aspirated marrow increased the stiffness nearly 50% compared to AGF + ProOsteon 500R (platelet concentrate and bone graft substitute; Interpore-Cross International, Irvine, CA) (P <0.05).\textsuperscript{93}

**Growth Factors**

The increase in osteobiologic strategies is not surprising considering the wealth of new knowledge concerning the fracture regeneration process at the molecular level. Lind\textsuperscript{37} recently reviewed a number of in vivo studies using invasive therapy through the addition of exogenous growth factors or BMPs (including PDGF, IGF, BMP-3, BMP-7, TGF-β) in a variety of animals (rat, rabbit, dog, sheep, baboons, monkeys).

Early studies on the effect of a single growth factor are plagued with questions concerning dose, timing, and release kinetics. Reddi\textsuperscript{58} reports increased understanding of the molecular cascade of growth factors following a fracture. Jingushi and Bolander\textsuperscript{38} have helped provide rationale behind the factor chosen and delivery method. The work of this group on correlating the changes in the histology of the fracture callus with changes in gene expression provides sound motivation for the delivery of different factors to the fracture site.\textsuperscript{38}

The effects of the application of a single growth factor or bioactive molecule have shown variable results. This in part reflects differences between the model, surgical site, method, animal, and age, as well as the endpoints used to evaluate the healing site (radiographic, histologic, and biomechanical). Bostrom et al\textsuperscript{44} reviewed many of the articles examining the effects of the exogenous application of a single growth factor on fracture healing. Many studies report some histologic or radiographic change, with overall poor results in terms of mechanical properties.

Researchers\textsuperscript{95–102} have reported the effects of different dosages of recombinant human basic fibroblast growth factor (bFGF). These authors report an optimal stimulator dose of 15 ng of bFGF per implant, whereas a higher dose had a marked inhibitory effect.\textsuperscript{95,102}

Local injections of acidic fibroblast growth factor (aFGF) have been reported by Jingushi et al\textsuperscript{103} to increase the cartilage proportion of the fracture callus in the rodent fracture model. Systemic administration of bFGF at 0.1 mg/kg/d to growing rats increased endosteal and endochondral bone formation while decreasing periosteal bone formation.\textsuperscript{83} Radomsky and coworkers\textsuperscript{45} examined the in vivo effects of 100 mg of bFGF incorporated in 50 µL of hyaluronan gel injected between periosteum and parietal bone in rats. Histologic sections revealed bFGF treatment significantly thickened the periosteum and caused proliferation of fibrous tissue at 3 days following injection. By days 7 and 14 intramembranous bone formation with continued remodeling was noted. Radomsky et al\textsuperscript{45} also reported the effects of 20, 50, and 200 µg of bFGF incorporated in 50 µL of hyaluronan gel and placed in a fresh fibula fracture model in rabbits. The fibulae treated with bFGF in a hyaluronan gel demonstrated a larger callus area, higher bone volume, and increased osteoblastic activity. The load at fracture in the bFGF-treated sites was greater than the control sites at day 23. Although not statistically significant, the mechanical strength
of the bFGF-treated fibula increased with bFGF dose. These studies are limited with respect to the release kinetics of the bFGF from the hyaluronan gel. They do however, support the in vivo effects of bFGF, whereas the mechanisms responsible remain to be determined.

Lind and coworkers\(^{104}\) reported the ability of exogenous TGF-\(\beta\) to stimulate bone formation in fracture healing using an adult unilateral plated midtibial osteotomy model introduced using a subcutaneous miniosmotic pump. Daily doses of TGF-\(\beta\) of 1 or 10 \(\mu\)g per day were examined compared to a control group with no TGF-\(\beta\) treatment. Both treatments result in enhanced callus formation but the increase to 10 \(\mu\)g per day did not result in any further increase in mechanical properties. This dose is nearly 1000-fold greater than the dosages reported for in vitro stimulatory effects of TGF-\(\beta\) as well as the effects of local injections of 1 \(\mu\)g of TGF-\(\beta\) in the calvarium as reported by Noda and Camilliere.\(^{105}\) Nielsen et al\(^{106}\) have shown that local injections of 40 ng of TGF-\(\beta\) in a standard intramedullary stabilized femoral fracture model resulted in a statistically significant increase in the mechanical parameters measured.\(^{106}\) Critchlow and coworkers\(^{107,108}\) reported no effect for exogenous application of TGF-\(\beta\)2. They examined the effect of TGF-\(\beta\)2 in a rabbit tibial model with and without plate fixation. Treatment with TGF-\(\beta\)2 revealed a slight increase in callus but no mechanical effect. Nash and colleagues\(^{109}\) examined the effects of PDGF-bb using a bilateral proximal metaphyseal rabbit defect model. A dose of 80 \(\mu\)g of PDGF in a type I bovine skin collagen carrier demonstrated some histological changes but no biomechanical effects compared to controls or carrier controls.

Studies on the effects of growth hormone by Bak and colleagues,\(^{110-114}\) using a rodent fracture model, have shown enhancement in fracture healing, whereas those of Carpenter et al,\(^{115}\) using a unilateral rabbit tibia osteotomy model, failed to show any effects of human growth hormone. The effect of IGF-I on fracture healing has been examined indirectly through the effect of growth hormone. The reported in vivo effects of growth hormone treatment are conflicting. Bak and coworkers report a positive effect of growth hormone in a young rat tibial fracture model,\(^{112,113}\) whereas no effect was observed in elderly rats.\(^{110}\) The effect of the local mechanical environment on in vivo IGF-I has been reported. Thaller and coworkers\(^{116-119}\) report the effects of systemic treatment in an unloaded calvarial model or loaded noncritical size zygomatic arch defect, whereas Kirkeby and Ekeland\(^{120,121}\) used a femoral osteotomy rodent model fixed with an intramedullary wire. The work of Thaller et al\(^{116,119}\) supports that continuous administration of IGF-1 enhances healing of bony defects, although Kirkeby and Ekeland’s\(^{120,121}\) work does not. This brings to light the importance of the mechanical environment, which may have an important role in the biological effects of certain factors.

**Bone Morphogenic Proteins**

A number of animal and human studies have reported the influence of BMPs on bone healing. The in vivo effect of BMP-7 (OP-1; Stryker Biotech, Natick, MA) in a variety of animal bone models has also been reported.\(^{122}\) Human pilot studies using rhBMP-2 or rhBMP-7 (OP-1) have been reported.\(^{61,123-126}\) This body of work confirms the osteoinductive nature of these molecules as well as the enormous clinical potential. The use of BMPs have also stepped beyond traditional bone healing to incorporate extraarticular tendon to bone healing using rhBMP-2\(^{127}\) as well as intraarticular tendon to bone healing using OP-1 in an ovine anterior cruciate ligament model.\(^{128,129}\)

Bax et al\(^{130}\) recently reported effects of rhBMP-2 on fracture healing in a stable and unstable rabbit model. Interestingly, when rhBMP-2 was injected, the callus of mechanically unstable fractures developed more rapidly compared to controls. However, the effect in the stable mechanical environment was minimal. The influence of the mechanical environment on rhBMP-2 appears to be directly opposite for that reported for IGF-1,\(^{116,119-121}\) where an effect was found in a mechanical stable environment rather than an unstable one. These experiments also highlight the importance of the carriers for these molecules as the use of bioerodible particles, and collagen gels in this study impeded callus formation and acted as a mechanical barrier. The size of the defect may also play an important role in the choice of delivery system and the clinical application.

Finally, Brager et al\(^{125}\) examined the effects of exogenous osteogenic growth peptide on healing of femoral rat fractures. Their results revealed osteogenic growth peptide treatment resulted in earlier organization and faster healing as evidenced by the larger and earlier appearance of cartilaginous soft callus and more rapid bridging of the callus. The effects of exogenous osteogenic growth peptide were thought to be related through its effect on the TGF-\(\beta\) family.

The above studies reflect the importance of the complex cascade nature of fracture healing. The natural healing process involves a number of factors, both intrinsic and extrinsic, that work together as well as against each other in orchestrating the biologic process of repair. It is unlikely that the application of any single molecule will hold the key to fracture repair strategies in the future. The dosage currently used in animal work as well as limited human trials is often far beyond those required in cell
culture. This again points to a greater need for understanding of the release kinetics and carriers for such strategies to be clinically successful in the future. The effect of multiple growth factors or BMPs and possible synergistic or antagonistic effects remains to be explored. Finally, the importance of the mechanical environment, stable versus unstable, remains a crucial factor when considering the in vivo effects of a growth factor and/or BMPs.

**GENE THERAPY IN FRACTURES, NONUNIONS, AND OTHER CLINICAL PROBLEMS ASSOCIATED WITH BONE LOSS**

Gene therapy offers the latest frontier with regards to treatment of fractures to influence the sequence and control of the fracture repair process. An attractive feature of gene therapy is that therapeutic proteins can be delivered locally to a fracture site in relatively high concentrations in a sustained fracture. A number of reviews on the potential for direct gene transfer have recently been published.\textsuperscript{131-133}

Goldstein and Bonnadio\textsuperscript{132} presented the concept of a gene-activated matrix where DNA is immobilized and incorporated into a three-dimensional structural matrix for local delivery. The structural matrix is placed in the wound site at the time of surgery. The local cells become in situ bioreactors through contact with the plasmid DNA and encoding the proteins as they infiltrate into the three-dimensional matrix. Initial experimental results using this concept have been reviewed by Goldstein and Bonnadio.\textsuperscript{132} Plasmid genes examined to date include a fragment of human parathyroid hormone (hPTH-1034) and BMP-4. The role of gene therapy in the clinical treatment of fractures remains to be seen. This area will no doubt be examined in greater detail in the future considering the enormous possibilities to overcome the difficulties and limitations with the exogenous application of osteoinductive molecules.

**MECHANISM OF GENE THERAPY**

Gene therapy, involving the manipulation of endogenous cells to generate specific proteins associated with the introduction of exogenous genetic material, offers a potential solution for the clinical problems associated with bone loss. By transferring genes into cells at a specific anatomic site, the osteoinductive properties of genetic factors can be used at physiologic doses for a sustained period to facilitate a more significant healing response. Successful gene therapy involves four key steps: transduction, transcription, translation, and expression.

**VECTORS**

To achieve gene transduction of a target cell, gene therapy models use vectors to enhance the entry and expression of exogenous deoxyribonucleic acid into the target cell’s nucleus in a treatment site to yield osteoinductive results. The vectors are either viral or nonviral class.

**TRANSDUCTION PATHWAYS**

The transduction of a gene can be performed via either an ex vivo or an in vivo approach. In vivo gene transfer involves a direct introduction of exogenous genetic material carried by vector into a host treatment site. Ex vivo gene transfer is described as autologous cells, which are pretransferred by exogenous gene material carried by a vector, delivering the transferred genetic material into an anatomical site.

**EX VIVO GENE THERAPY**

Different cell types of ex vivo gene therapy have been used to produce bone. These include a bone marrow stromal cell line, primary muscle-derived cells, primary bone marrow stromal cells, primary articular chondrocytes, and primary fibroblasts, etc. Musgrave et al\textsuperscript{134} found that after transduction by an adenovirus encoding for BMP-2, all of the above cell types were capable of secreting BMP-2. However, the bone marrow stromal cell line and muscle-derived cells showed more responsiveness to recombinant human BMP-2 than did the other cell types. In vivo injection of each of the cell populations transduced to secrete BMP-2 resulted in bone formation. Radiographic and histologic analyses corroborated the in vitro data regarding BMP-2 secretion and cellular osteocompetence.
Lieberman et al.\(^{135}\) applied ex vivo gene therapy for BMP-2 in a rat critical size segmental defect model via mesenchymal stem cells delivered to the fracture site in a demineralized bone matrix. Eight weeks following implantation into the critical size defects, 22 of 24 animals demonstrated complete bone formation. The segmental defects that had not received the transduced cells or that received non-transduced mesenchymal stem cells alone either did not heal or in some animals achieved a poor level of healing.\(^{135}\)

Boden and colleagues\(^{136}\) have reported the use of ex vivo gene therapy in a spinal fusion model. A novel osteoinductive protein, LIM mineralization protein (LIMP-1), is a transcriptional factor and can only have an effect if it is delivered intracellularly. In Boden and coworkers’ study,\(^{136}\) successful rat spine fusion was obtained in 9/9 (100%) of the sites receiving marrow cells transfected with the active LIMP-1 cDNA and in 0/9 (0%) of the sites receiving marrow cells transfected with the reverse inactive LIMP-1 cDNA. Radiographs and histology confirmed the manual palpation results, demonstrating new bone formation in the carrier and marrow transfected with the active LIMP-1 cDNA and essentially no bone induction in the sites treated with marrow cells that did not express the protein. These data confirm that local delivery of the novel LIMP-1 cDNA using bone marrow cells is feasible in vivo. Furthermore, these results demonstrate that posterior thoracic or lumbar spine fusion can be achieved in rats by local delivery of the LIMP-1 cDNA.

Lou and colleagues\(^{137}\) recently reported the use of ex vivo gene therapy using a mesenchymal progenitor cell line C3H/10T-1/2 and adenovirus BMP-2. Transduced cells exhibited differentiation to osteoblast phenotype, and injection into intramuscular sites (10\(^7\) cells into the thigh muscle in nude mice led to osseous development. The ossicles were observed on radiographs and confirmed histologically to be bone.

**TARGET CELLS**

Although there are many potential target cells for gene therapy, the specific anatomic site, the quality of the bone, and the soft tissue envelope will all influence the selection of the target cells for regional gene therapy.

Goto and coworkers\(^{138}\) demonstrated that meniscal cells can express a TGF-\(\beta\) transgene delivered by a retroviral vector and respond to the gene product by increasing matrix synthesis. In their study, monolayer cultures of human and canine meniscal cells were infected with retroviruses carrying either a human TGF-\(\beta\)/cDNA or marker genes. Transduction with the TGF-\(\beta\) gene, but not marker genes, increased the synthesis of collagen and proteoglycan by 8- to 15-fold. The synthesis of noncollagenous proteins was enhanced more modestly. Monolayers of meniscal cells synthesized types I, III, V, and VI collagen. The TGF-\(\beta\)\(1\) gene increased the synthesis of all types of collagen without altering the ratios between them. These findings encourage the further development of genetic approaches to the healing of meniscal lesions.

**IN VIVO GENE THERAPY**

In vivo gene therapy involves direct delivery of the vectors encoding therapeutic genes to the fracture site.\(^{133}\) Baltzer and coworkers\(^{139}\) recently reported that the injection of an adenovirus containing BMP-2/cDNA into the fracture site induced healing by 8 weeks after BMP-2 gene delivery. Biomechanically, the defects that did not receive the gene were inferior.

Goldstein and Bonnadio\(^{132,140}\) described an alternative method of in vivo gene transfer using localized transient gene therapy for the augmentation of fracture healing. They introduced a method\(^{132,140}\) involving the delivery of plasmid DNA via a three-dimensional matrix into a wound with in vivo transfection of wound repair cells, resulting in their subsequent expression of factors that condition the wound site and the promotion of healing. Initial experimental results using this concept have been reviewed by Goldstein and Bonnadio.\(^{132}\) Plasmid genes examined to date include a fragment of hPTH-1034 and BMP-4. The studies showed the potential of this technology not only to promote bone healing but also to repair or to regenerate other connective tissues.

The development of new clinically applicable methods for the delivery of bone morphogenic protein is an area of intensive research. Cell-mediated gene therapy approaches are being explored as a potential delivery vehicle. Primary muscle-derived cells isolated from an adult mouse were transduced with an adenoviral-BMP-2 construct. These cells were injected into the triceps surae of severe combined immune deficient (SCID) mice where they induced heterotopic bone formation. BMP-2 expression by these muscle-derived cell constructs was measured in vitro to estimate in vivo BMP-2 delivery. In vitro expression of BMP-2 by 3 × 10\(^5\) muscle-derived cells was 87.89 ng/72 h. These results suggest that the efficiency of muscle cell-based gene delivery of BMP-2 exceeds the direct delivery of recombinant BMP-2 protein.\(^{141}\)

**BIOMECHANICAL STAGES OF FRACTURE REPAIR**

Understanding the biomechanical properties of healing fractures is of great importance considering the
ultimate goal of solid skeletal union and rehabilitation of the soft tissues and/or injured joint. In vitro mechanical data provides a wealth of information related to the quality and progression of healing at the fracture site. A thorough understanding of the biomechanical and histological properties of fractures is required, especially in light of the new treatment options that may become available through gene therapy.

Quantitative methods are required to definitively prove that a certain treatment of stimulus has a beneficial influence on progression, quality, and rate of healing. While histology or radiographs provide insight into the properties of the healing fracture, they do not represent the ultimate endpoint for a fracture, which is the ability to bear load-bearing. Quantitative radiographic studies have shown a correlation with gains in strength and stiffness only until 50% of the intact bone has been reached. However, the greatest gain in strength and stiffness occurs during the callus remodeling by internal remodeling and cannot be detected using radiographs. Mechanical properties represent a quantitative endpoint that can be objectively assessed to examine the effect of a treatment. This section examines the biomechanical aspect of fracture healing, mechanical testing, and implications in this area.

The torsional biomechanical stages of fracture repair were initially reported by White et al using a rabbit midshaft osteotomy model tested in torsion. Rabbit tibias were tested in torsion and the maximum torque, angle, energy, and stiffness slope determined. This work provided the first objective measurement of healing bone and proposed four biomechanical stages.

- **Stage 1:** The bone fails through the original experimental fracture site with a low-stiffness, rubbery pattern.
- **Stage 2:** The bone fails through the original experimental fracture site with a high-stiffness, hard tissue pattern.
- **Stage 3:** The bone fails partially through the original experimental fracture site and partially through the previously intact bone with a high-stiffness, hard tissue pattern.
- **Stage 4:** The site of failure is not related to the original experimental fracture and occurs with a high stiffness.

### Biomechanical Testing of Fractures

Clinically, fractures can be induced through a number of different loading patterns reflected in the fracture pattern. The biomechanical data on fracture healing is confounded by differences in testing methodologies in terms of mode of testing and technique. Care must be taken when interpreting the biomechanical results following fractures due to the differences in tensile, compressive, bending, and torsional testing; testing rate; and the information obtained from each testing mode.

#### Structural and Material Properties

Biomechanical testing of fractures follows the same principles used in engineering to describe the properties of a material or structure. Load or torque and displacement or angle are monitored to provide the structural properties of the specimen because of the influence of specimen geometry. Load versus displacement graph provides a great deal of information on the properties of the healing fracture, which can be examined in a statistical manner. The main parameters usually reported for the structural properties include load to failure or torque, displacement to failure or angular displacement, stiffness gradient of the curve, and energy area under the curve. The structural properties (load versus displacement) can be converted to the material properties (stress versus strain) by taking into account the effects of geometry.

Mechanical testing of whole bones that have been fractured, such as the femur or tibia, can be performed in torsion, tension, or bending (3-point, 4-point, cantilever) protocols. Each testing protocol has its benefits as well as drawbacks, as reviewed by Black and colleagues.

#### Torsion Testing

Torsional testing of fractures in isolated long bones has been extensively reported in the literature. Although torsional testing provides information on the shear properties of bone, it does not provide information on the elastic properties. Sample preparation for torsional testing involves fixation of the proximal and distal ends of the bone in a resin or embedding medium for fixation into the testing machine. Care must be taken in proper axial alignment of the embedded bone sample to avoid bending of the sample during gripping and testing. The applied torque and angular displacement are recorded.

The original technique for torsional testing as reported by Burstein and Frankel actually does not apply pure torsion but axial-torsion. The use of testing machines that do not take into account the axial load results in a complex loading pattern of torsion in combination with tensile or compressive loading, depending upon which direction the sample is twisted,
clockwise or counterclockwise. As a result, the majority of the literature that reports the torsional properties of a fracture using the technique popularized by Burstein and Frankel does not report the pure torsional properties but a combined loading pattern with a combination of torque and bending moment. This has been neglected in the biomechanical literature until recently. To apply a pure torsional moment, the sample needs to be tested using a biaxial testing machine that can control the applied axial load during the application of the torque as noted by Funk et al.

TENSION TESTING

Tensile testing has been performed by many investigators and has been suggested to be a more reproducible measure of the properties of healing fractures. Tensile testing provides information on the elastic properties of the tissue. The whole bone is usually embedded in a similar fashion to that used in torsional testing. The same concerns regarding proper axial alignment and slippage as in the torsion test must be considered in tensile testing to avoid bending. The sample is distracted at a uniform rate and the load and displacement recorded. Uniaxial tension provides a uniform stress field to the sample, which helps simplify the interpretation.

Powell et al. reported the torsional strength of fractured metatarsals to reach that of the contralateral control by 24 weeks, whereas the tensile strength remained less than half of the contralateral controls. Walsh et al. reported the properties of healing fractures in tension were 50% weaker than the contralateral side, although in bending they had returned to control levels.

BENDING

Bending tests are often used because they are convenient and expeditious. Bending, however, involves complex stress fields that are strongly dependent on the operator’s testing skill and specimen orientation. Bending can be carried out in 3-point, 4-point, or cantilever testing modes and subjects the sample to a complex loading pattern of tension, compression, and possible shear, which complicates the interpretation. Additional parameters need to be considered such as the span between the supports and sample orientation. These different bending modes also differ with respect to the application of pure bending moments with and without a shear component. Bending tests are further complicated by the aspects concerning the moment of inertia and testing orientation, which need to be considered if the material properties of bone are to be reported. This requires measurement of the cross-sectional properties that can be made using calipers and assumptions being made regarding the geometry, or using computed tomography (CT) or sectioning and imaging following testing to obtain the native geometry to calculate the stress and geometrical properties of the healing fracture.

FRACTURE HEALING IN ESTROGEN-DEFICIENT OSTEOGENIC MODELS

Although many studies have shown that ovarectomy has a pronounced influence on bone mass and metabolism, the properties of healing fractures in diseased models such as osteoporosis have received little attention. This is surprising considering the clinical importance of osteoporotic fractures and the wealth of information regarding osteoporotic animal models. Blythe and Buchsbaum as well as Langeland did not demonstrate any effect of estrogen deficiency on the tensile properties of healing rodent tibial fractures. Walsh and coworkers reported the histologic and biomechanical properties of femora fractures following a 6-week estrogen-deficient state in 3-month-old female CD/COB rats with a normal diet using a standard closed fracture model. Tensile and 4-point bending mechanical testing results revealed a significant impairment in fracture healing in the estrogen-deficient state. Histology revealed the estrogen-deficient fractures to lag behind in healing. Hill and coworkers performed a similar study in terms of age and time of estrogen deficiency using torsional testing. These authors confirmed a reduction in the torsional mechanical properties in the estrogen-deficient state. Kubo and coworkers examined the effects of estrogen deficiency and a low-calcium diet in 30-week-old Wistar female rats who were estrogen-deficient for 12 weeks prior to fracturing. Tensile mechanical testing, dual energy X-ray absorptiometry, and light histology were performed. These authors reported that estrogen deficiency and low-calcium conditions did not markedly affect the early healing process, but largely affect the bones in the later period of healing. Newly generated bone formed at 12 weeks following the fracture showed histologic osteoporotic changes and a lower mineral density in the estrogen-deficient group compared to controls. Sakai et al. recently reported the effects of ovarectomy and the efficacy of activin, a member of the TGF-β superfamily, on female rats ovariectomized at 2 months of age and maintained for 6 to 8 months. Bilateral fibula fractures were induced and treated with activin or a vehicle control. Biomechanical analysis revealed topical application of activin for 2 weeks increased the 3-point bending properties but no com-
comparison to normal animals was provided. Jahng and Kim recently reported 3-point bending properties of healing fractures are impaired in the estrogen-deficient state in a 4-month-old Sprague-Dawley rat.

When performing a study using an estrogen-deficient model there are a number of factors to be considered that have been shown to have a significant influence on the level of osteopenia. Explantations for the diversity in biomechanical findings are complicated by the marked differences in the animal models in terms of age, length of estrogen deficiency, fracture site, and biomechanical testing conditions. The inferior rate of healing reported following a 6-week estrogen deficiency may reflect overall lower densities as suggested by Kubo et al as well as an inferior biological response due to some alteration in the normal healing cascade. Cesnjaj et al have suggested that changes in the bone matrix of
ovariectomized rats could be responsible for poor fracture healing in the estrogen-deficient environment. Altered production or availability of bone-inducing proteins or bone morphogenic proteins were offered as likely candidates for the cause of the delayed or impaired osteogenesis in estrogen deficiency.166 This area of research warrants further study and standardization of models and endpoints used to evaluate the effects of estrogen deficiency, as well as methods of noninvasive and invasive therapy.

**BMPs and Smads in an Osteopenic Fracture Model**

We have recently examined a hypothesis that the deficiency in fracture healing following ovariectomy may be related to the BMP-Smad interactions. In a pilot study, the expression levels of BMP and downstream regulators (Smads) following fractures in 3-month-old female Sprague-Dawley rats following a 12-week estrogen deficiency with a standard rodent diet were studied. Thirty rats (15 control and 15 ovariectomized) were fractured using standard techniques.53 Five animals per group were killed at 7, 14, and 28 days following fracture. Femurs were processed for decalcified histology and immunohistochemistry for BMP-2 and BMP-7 and Smad1, Smad4, and Smad5.

Histologically, healing in the ovariectomized group lagged behind the control animals. The expression of the R-Smads (Smad1 and Smad5) and the Co-Smad (Smad4) presented a temporal response in both groups. In general, Smad4 levels remained elevated to the control at 7 (Figs. 3–1A,B) and 14 days appeared weaker in the ovariectomized group compared to the control at 7 (Figs. 3–1C,D). BMP-2, BMP-4, and BMP-7 decreased with time. By day 28, BMP expression was minimal in both groups similar to control, nonfractured sections.

This pilot data suggests a possible deficiency or alteration in fracture healing in BMP expression as well as their downstream regulators (Smads) following a 12-week estrogen deficiency. This could account, in part, for the inferior histologic and mechanical properties observed following estrogen deficiency but further work is clearly warranted.

**Expression of BMPs**

In the nonfracture sections BMPs were either undetectable or in a low level in a small proportion of osteogenitor cells in the periosteum. The BMPs also presented a temporal response in both groups (Figs. 3–1E,F). BMP-2, BMP-4, and BMP-7 decreased with time. 

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The goal of this chapter is to explain the basic biomechanical principles of commonly used orthopaedic devices in the fixation of fractures, with focus on the bone-implant interface, since this is the specific part of the fixation system that is directly affected by osteoporotic bone. This chapter first briefly addresses specific mechanical changes in bone due to osteoporosis that affect its mechanical properties, to provide perspective when discussing the basic functions of fixation devices. Then, the conceptual mechanical principles of devices such as bone screws, plates, sliding screw-plate devices, intramedullary rods, external fixators, and spinal fixation devices will be presented.

The Effect of Osteoporosis on Fixation

Osteoporosis has specific effects on the mechanical properties of trabecular bone. It decreases the diameter of the trabeculae and produces a loss of interconnecting struts. This loss of bone mass leads to a decrease in the ultimate stress at which bone will fail in compression and shear. Compressive strength is important in resisting the toggling of vertebral screws with vertical loading (Fig. 4–1). Bone shear strength is important to resisting screw pullout forces. The relationship between loss of bone mass and decrease in

**FIGURE 4–1** (Upper) Loss of integrity in osteoporotic vertebra and (lower) result of loss of compressive strength on screw toggle and loss of shear strength on resistance of screws to pullout.
compressive or shear strength is not linear. In other words, a twofold decrease in density in bone due to osteoporosis will reduce the ultimate compressive stress by a factor of approximately four. This may be the most important effect when considering fixation in osteoporotic as opposed to normal bone.

Osteoporosis also affects bone cortex dimensions, particularly in the femur (Fig. 4–2). The outside diameter of the diaphyseal cortex of a long bone increases, as does the inside diameter, but not at the same rate. The result is a significant thinning of the cortex. Since screw pullout strength is directly related to the length of engagement of the screw thread, loss of cortical thickness directly decreases screw holding power. Further, the ability of load to be transferred across the cortex opposite that on which the plate is placed (buttressing), for example, the medial cortex of a subtrochanteric fracture, depends on the area of bone in contact, which directly decreases as bone becomes osteoporotic. Buttressing by the opposite cortex is very important in maintaining fixation stability (Fig. 4–2).

A fixation system is a bridge across a fractured region and as such consists of two generic components, the bone-implant interface device (such as screws, pins, or hooks) and the bridging device (rod, external fixation, or plate) and its connector to the bone-implant interface device. From this perspective, it is clear that the bone-implant interface device is the one directly affected by osteoporotic bone. The following discusses the mechanics of bone-implant interface devices first, followed by the mechanics of devices such as intramedullary rods, plates, external fixators, and spinal devices.

**Mechanics of Bone-Implant Interface Devices**

**Bone Screws**

A screw is a device that converts torque (rotary force) applied to its head into compressive force between the two surfaces it has engaged, as shown in Figure 4–3. The pullout strength of a screw in trabecular bone depends on the following (Fig. 4–4): its outside diameter, its length of engagement, the density of bone into which it is embedded, and its thread shape (and for very small screws, the material from which it is made). When a screw pulls out of trabecular bone it does so by cutting or shearing with it a core of bone, cutting the core as the threads move outward and trapping the core within the threads (Fig. 4–4). The properties of the outer surface of the core of bone define the screw purchase strength since failure occurs at this interface. If the outer core is smaller in diameter, shorter, or if the bone material at the interface has lower shear strength (due to loss of bone mass), the pullout strength of the screw will decrease. If the density of trabecular bone decreases to half that of normal bone, its shear strength decreases to nearly one quarter; therefore a screw of four times the diameter would be required to produce holding...
power equivalent to that of normal bone in this example (which is usually impractical). Increasing the number of screws or augmenting the density of bone around the screw are strategies that have been used to restore screw pullout strength.

In cortical bone, loss of purchase strength due to thinning of the cortex affects fatigue properties due to the mechanism shown in Figure 4–5. In this example, a plate fixed with screws bridges a fracture. The bone can transfer load to the plate by two methods, friction between plate and bone and the direct interaction of the shaft of the screws against the plate. The preferable mechanism is frictional contact, because plate contact against the shaft of the screw causes the screw to bend and cyclic bending can result in rapid early fatigue failure of the screw. The ability to generate frictional force between the plate and bone, and therefore its fatigue resistance, is directly related to the torque that can be applied to the screw. Maximum screw torque, in cortical bone, is directly related to the length of engagement of the threads. Therefore cortical thinning reduces the length of engagement, the maximum screw torque that can be applied, and the frictional force between plate and bone, thus increasing the potential for fatigue failure.

**PINS**

Pins, such as K-wires or those used in ring-type fixators, are devices that resist tension and bending forces. The bending stiffness of a pin depends upon the material from which it is made, its diameter, its unsupported length, and the longitudinal tension applied to it. As Figure 4–6 shows, doubling the length of a pin decreases its bending stiffness by a factor of 8. More important, decreasing the diameter of a pin by one half reduces its bending stiffness by a factor of 16. This is because the moment of inertia of a pin is related to the fourth power of its radius. The moment
of inertia is a geometric property that defines how the material is distributed around a cross section of an object. The further the material is located away from the center, the stiffer the object will be (which explains the configuration of an I-beam). Pretensioning a pin applies an initial stress to it. Since bending a pin produces tension on one surface and compression on the opposite surface, when a prestress is applied, this superimposed tension must be overcome before the pin will bend, effectively stiffening the pin (Fig. 4–6).\(^\text{11}\)

\*FIGURE 4–5* Mechanism of fatigue failure of screws in cortical bone due to sliding of the plate and bending of the screw shaft.

\*FIGURE 4–6* (Upper) Bending stiffness of a pin decreases as its unsupported length increases and as its diameter decreases; (lower) applying tension along the pin creates a force that opposes the bending force acting on the pin.

**MECHANICS OF FIXATION DEVICES**

**EXTERNAL FIXATION**

External fixation consists of a construct of pins and crossbars that allow stabilization while minimally disturbing soft tissues. Figure 4–7A shows that to increase stiffness, the diameter of the pins used should be as large as practical and the sidebars should be located as close to the bone surface as possible, thereby
reducing the length of the exposed fixator pin.\textsuperscript{12-14} If the length of the pin decreases by one half, the resistance of the pin to bending increases by a factor of 8. Similarly, by placing the pins as close as possible to each other across the fracture site, the length of the sidebar spanning across the fracture site is reduced, increasing its rigidity. It should be appreciated that many fixator systems have a structure in only one plane, although most fixation situations require that the construct supports loads in multiple planes, including combinations of anterior-posterior or medial-lateral bending, compression, and torsion around the long axis of the bone. Therefore, different arrangements of multiplanar fixation, shown in Figure 4–7B, may be beneficial, depending on the application.\textsuperscript{14} In osteoporosis, a major concern, as with screws, is low strength at the pin-bone interface, resulting in pin loosening. The same factors, described above for screws, also affect the pullout strength of fixator pins. Enhancement of the pin-bone interface has been demonstrated by the use of hydroxyapatite-coated pins.

Another construct that has gained popularity is the hybrid external fixator, consisting of half or full rings with cross wires coupled to bars and fixator pins. Figure 4–8 summarizes the major factors affecting the stiffness of this construct, which include the number and angle of the cross pins, their pretension.
and diameter, and the configuration of interconnecting crossbars.15

INTRAMEDULLARY NAILING

The basic flexible intramedullary (IM) nail, if its curvature is different from that of the medullary canal into which it will be inserted, acts like a spring in bending to obtain fixation (Fig. 4–9). (This doesn’t apply to solid rods with locking screws.) A flexible nail, placed down the femoral IM canal, is forced to bend, and in doing so creates frictional force at the points where it contacts the inner surface of the canal. The working length is defined as the length of the nail that spans the fracture site between medullary wall contact areas. If the nail was well fixed by frictional contact, then as with other fixation devices, the greater the working length, the less rigid the fixation. In fact, frictional contact of the IM nail in the medullary canal is highly variable, and resistance to loads, especially compression causing shortening, is low. Current IM nails allow a variety of cross-locking screw configurations to accommodate different fracture patterns in various long bones and enhance fixation stiffness. The rigidity of these devices depends mainly on the cross-sectional shape and size of the nail itself. Since bending stiffness depends upon the third power and torsional stiffness, and the fourth power of the nail diameter, the difference in stiffness between, for example, a solid 11 mm and a solid 14 mm diameter nail is about 2 times in bending and 2.6 times in torsion (Fig. 4–9).

One problem with IM nails is splitting of the bone during insertion. In the femur, for example, the nail must travel along a curved path during insertion, due to the natural anterior bow of the femur. If the starting point for the nail is incorrectly placed, for example, too far anteriorly or medially, it is forced to bend excessively (Fig. 4–10A). As the nail deforms it pushes against the inner wall of the IM canal, resulting in bursting (hoop) stresses. Cracking significantly complicates management of the fracture.16,17 A second problem concerns the potential for breakage of the hardware. One particularly difficult condition is a very distal tibia or femur fracture. Because of the location, distal fractures apply large bending moments around the fracture site (Fig. 4–10B), and the fixation has only a small moment arm with which to counteract these forces. Large loads are applied also on the distal locking screws. Drilling pilot holes and placing the screws can cause nicks around the holes in the nail (Fig. 4–10C), leading to the possibility of fatigue fracture when combined with large loads.

PLATES, INCLUDING THE SLIDING HIP SCREW

Plates are very versatile devices that allow attachment to surfaces of highly varying shape (for example the iliac wing of the pelvis). The dynamic compression plate operates by forcing together the ends of two fracture components through the interaction of the heads of the screws and the holes in the plate.
The edges of the plate hole are actually wedge-shaped. As the head of the screw is driven into bone, it slides down the wedge-shaped corner of the plate hole (Fig. 4–11), and the bone fragment it is connected to is forced into the opposing one. Driving the fracture fragments together is important, not only to stimulate healing, which is retarded by gaps between the bone fragments, but also to maintain stability of the entire fracture construct (Fig. 4–11). Some newer plates with minimal periosteal contact surfaces were designed to reduce the biological effects of wide resection and disruption of periosteal blood flow that occurs when a wide surface plate is placed on the periosteum. These minimal contact plates still perform mechanically in the same manner as full-surface contact plates, although biological advantages have been demonstrated.

The sliding hip screw consists of a plate with a guide barrel attached (e.g., along the femoral cortex). A screw is placed through the guide barrel into the femoral head. Sliding hip screws are designed to permit sliding of the component to which the screw is attached (e.g., the femoral head) so that it impacts the fracture surface at the femoral neck. Several factors affect the performance of these devices. It is most important that the screw be allowed to slide to permit impaction of the femoral head. When the screw is not placed deeply into the barrel (Fig. 4–12A), loads acting through the femoral head cause the screw to pivot about the inferior and proximal edge of the barrel. Large frictional forces are set up between the screw and the barrel, inhibiting sliding. In addition, the angle of the barrel, if more vertical, enhances sliding (Fig. 4–12B).
SPINAL FIXATION

Unlike most of the other devices that have been described so far, a spinal fixator is more of a load-sharing device that must span across a flexible joint (the vertebral disc and facets), in contrast to other devices that directly fix bone fragments together. The spine has been conceptualized as comprising three load-bearing columns (Fig. 4–13A), which is helpful when considering the role of spinal fixation in supporting one or more damaged columns. The anterior column, which primarily resists extension and compression, is composed of the anterior longitudinal ligament and the anterior half of the vertebra-disc-vertebra of a spinal motion segment (two vertebrae and their interconnecting soft tissues). The middle column, which resists compression as well as shear and torsion (through the facets), is composed of the posterior half of the vertebra-disc-vertebra, the posterior longitudinal ligament, and the facet joints. The

FIGURE 4–11  (A) A dynamic compression plate functions by allowing the screw head, and the bone fragment it is attached to, to slide as the screw is advanced, because the plate hole geometry, when seen in cross section, is an inclined plane and the screw head is semicircular. (B) (left) Buttressing the plate against bending using opposite cortex contact is important in resisting bending loading of the plate and (right) resisting torsion.

FIGURE 4–12  (A) It is important to sink the compression screw of a sliding hip screw device fully into the barrel to enhance sliding. If the screw extends only partway into the barrel, then for the same force acting at its upper (proximal) end from the hip joint, the counteracting force against the screw within the barrel is increased because its moment arm is shorter. This force between the screw and barrel results in higher frictional force and greater resistance to sliding. (B) Increasing the angle between the barrel and the side plate enhances the ability of the screw to slide because a greater component of the hip joint force acts along the axis of the screw as opposed to across it.
posterior column, comprised of the spinous process, lamina, ligamentum flavum, and posterior ligaments, resists flexion.

A large variety of posterior fixation devices have been devised but recently these have become more uniform in design. They comprise, as the bone-implant interface, mainly screws placed through the pedicles, sometimes with supplementary hooks, especially if the vertebra is osteoporotic. Since posterior fixation devices function to replace the posterior and middle columns, they should be used in conjunction with anterior support, such as a bone graft, to prevent excessive flexion (Fig. 4–13B). The pedicle screws function as any other screws and are subject to the same limitations. Anterior fixation is mechanically best suited to supporting the damaged anterior column against flexion and compression (Fig. 4–13B).
The cage is a device that has found use in spinal applications, either alone or with supplemental fixation. The cage functions essentially as a screw, and so follows the same principles with respect to purchase strength, with one notable exception. Instead of being placed into a hole of fixed size, as it is placed into the disc, it engages the bone on both vertebral bodies, forcing them apart and tensioning the intervertebral soft tissues (Fig. 4–13B).26 Employing more than one cage (depending on their size) involves a compromise with respect to fixation stability. Inserting two cages, especially when placed at angles to each other, enhances stability and damages more of the soft tissues that they rely on for creating tension and thus for stability of the construct. Most significantly, if the facets are damaged during posterolateral insertion, the stability of the construct can be significantly compromised, especially in torsion.

**SUMMARY**

In this chapter, the basic functions of generic types of fracture fixation have been outlined. All devices consist of bone-implant interface components (usually screws) and components to bridge across the fracture (such as bars or plates, along with connector clamps to the screws). One major effect of osteoporosis is loss of trabecular bone mass, which results in decreased shear strength and loss of screw pullout force. A second effect is loss of cortical thickness, which decreases screw pullout strength because of a loss of length of thread engagement. In addition, this thinner, weaker cortical bone is less able to create a buttress on the opposite cortex, necessary for supporting plates or rods against bending forces. In subsequent chapters, the function of devices and methods, from materials to augment bone density to devices to support soft tissues that they rely on for creating tension and thus for stability of the construct. Most significantly, if the facets are damaged during posterolateral insertion, the stability of the construct can be significantly compromised, especially in torsion.

**REFERENCES**


The diagnosis of osteoporosis has always been a challenge to radiologists, clinicians, and other specialists alike, despite the wide range of instruments at hand today to aid decision making. The advent of devices that allow quantitative assessment of bone mineral density (the major determinant of bone strength and future fracture risk) has altered the field in clinical practice as well as research. Nevertheless, imaging of this disease with traditional radiological equipment has maintained its importance in the diagnosis of the manifestations of osteoporosis such as fracture and cortical thinning. In vivo radiography and densitometry are complemented by refined laboratory techniques including histomorphometry on histologic sections, computed microtomography, micro-magnetic resonance (MR) imaging, backscattered electron microscopy, and other techniques for detailed in vitro investigations. The purpose of this chapter is to provide perspectives on the available in vivo techniques, how they can be characterized, and their most important contributions to the field. According to its title, we have divided it into two subsections: radiographic techniques, as the more visual component of the radiologist’s armory, and densitometry, where results are presented not so much as images but as numbers characterizing the amount of bone or serving as numerical descriptors of its quality.

**RADIOGRAPHIC TECHNIQUES**

In this section, we give an overview of techniques based on plain-film radiography that are used in the evaluation of osteoporosis. Their significance has been altered by the advent of quantitative densitometric methods for the diagnosis of osteoporosis as it is currently defined by the World Health Organization (WHO), which is mainly based on bone mineral density. Thus, radiological techniques cannot be used for the diagnosis of osteoporosis without densitometry, but they remain useful and important for the detection of complications of osteopenia, a term that has been coined as a generic designation for radiographic signs of reduced bone density. Predominant features that are sought for on the radiograph in clinical practice are fractures or deformities of the spine.

**PHYSICAL AND TECHNICAL CONSIDERATIONS**

To obtain a radiological image, photons produced at a pointlike X-ray or other photon source must penetrate the object of interest and register on a detecting plane, which can be a conventional X-ray film, an imaging plate, or some sort of electronic X-ray-sensitive digital detector. A meaningful image is obtained when different tissues exhibit adequate contrast. Contrast, in turn, is the result of differences in X-ray attenuation characteristics between these tissues. How does tissue attenuate X-ray photons? A certain percentage of the incident photon flux is lost to interactions with the object by one of three processes: absorption by photoelectric effect, scattering (coherent or Raleigh scatter and incoherent or Compton scatter), and electron pair formation (only at photon energies above 1.022 MeV, thus not relevant for diagnostic imaging). These effects can be comprehensively described by the total attenuation coefficient \( \mu \), which is proportional to the incident flux \( I \) and the thickness of the object \( dx \):

\[
dl = -\mu I \, dx
\]  

(1)

\( \mu \) is dependent on the object and on the location of the interaction, because the composition of the object varies. Further, it is a function of the photon energy \( E \) because the constituent effects of \( \mu \) are dependent on \( E \). By integration with respect to \( I \) and \( x \) we can calculate the flux of exiting photons:
\[ I = I_0 e^{-\int_0^d dx \mu(x,E)} \]  

(2)

with object thickness \( d \) and incident flux \( I_0 \). Since the energy dependence of \( \mu \) is different for different materials, there is an X-ray energy that allows optimal contrast between bone and soft tissue. Attenuation of different tissues can be better compared in terms of mass attenuation \( \mu/\rho \), which is independent of tissue density \( \rho \).

Figure 5–1 shows that the difference between the mass attenuation coefficients for cortical bone and soft tissue is highest for lower energies, suggesting that radiographs be taken at very low energies to maximize contrast. On the other hand, the softer the radiation, the higher the relative contribution of photon absorption to the total attenuation. Since absorption has the same effect on contrast as scatter, but increases radiation dose substantially, photon energies need to be optimized to allow good contrast at a reasonable dose. For a lateral spine radiograph, tube energies at or around 90 kVp are typically chosen, yielding effective photon energies of about 70 keV.

Quantitative analysis of osteopenia (i.e., densitometry) based on planar X-rays without protocol modification is difficult. Numerous technical factors need to be controlled, including exposure time, film-focus distance, anode characteristics, voltage, beam filtration, film/screen properties, and film-processing parameters. The object itself contributes significantly to this uncertainty because the bone thickness, the soft tissue composition, and the scattering characteristics of both tissues are usually unknown. Consequently, the sensitivity of this technique to changes in bone density is low. It has been estimated that as much as 20 to 40% of bone mass must be lost before a decrease in bone density can be seen in lateral radiographs of the thoracic and lumbar spine. Unless an automated quantitative approach is used, the diagnosis of osteopenia from a radiograph is also dependent on the experience of the reader and her/his subjective interpretation. Therefore, main radiographic findings of osteopenia focus on qualitative features such as changes in trabecular structure, cortical thinning, and assessment of vertebral fractures and deformities. These are discussed in the following sections. Radiographic absorptiometry, a densitometric technique that is based on radiography but employs the imaging of a reference standard such as an aluminum wedge, will be presented in the “Densitometry” section.

**GENERAL RADIOGRAPHIC FINDINGS**

**Changes in Trabecular Structure**

Over the past decade, osteoporotic changes of trabecular structure have become an important focus in bone research as evidence mounted that bone density alone would not sufficiently explain the biomechanics of bone, and ultimately, the risk of fracture. Changes in the appearance of trabecular bone with the progression of osteoporosis had been documented radiographically much earlier (for instance by Singh in the proximal femur). Because trabecular bone has a much higher surface-to-volume ratio than cortical bone, it is eight times more metabolically active than cortical bone and thus much more susceptible to osteoporotic changes. Changes are most prominent in the axial skeleton and in the ends of the long and tubular bones of the appendicular skeleton such
as the proximal femur and the distal radius, ulna, and tibia. The patterns of these changes are predictable. In the beginning, non-weight-bearing trabeculae are thinned, then completely removed.\(^6\) This process can be offset by thickening of the remaining weight-bearing struts before these are affected as well.\(^7\) Figure 5–2 shows an osteoporotic spine demonstrating these features.

### Cortical Thinning

Although cortical bone is metabolically less active than trabecular bone, osteoporotic changes have wide ramifications because 80% of the skeleton consists of cortical bone.

All parts of the cortex can be affected by osteoporosis, depending on the metabolic stimuli. At the endosteal surface, resorption leads to cortical thinning. If this process affects the surface inhomogeneously, the result is “trabecularization” of the cortex. At the late stage of osteoporosis, the cortex appears very thin but typically smooth. Intracortical resorption, acting on Haversian and Volkmann channels, can be seen on X-rays as a longitudinal striation or tunneling. These striations are a typical sign of aggressive high-turnover osteoporosis, as for instance caused by oophorectomy, hyperparathyroidism, osteomalacia, renal osteodystrophy, or postmenopausal osteoporosis. Finally, subperiosteal resorption leads to an ill-defined outer bone surface, a finding that is pronounced in high-turnover osteoporosis. On the other hand, periosteal bone apposition is often seen in aging subjects in the long peripheral bones, for instance the femur.\(^8\) The subsequent increase in bone diameter partially offsets the loss of mechanical stability caused by cortical thinning (Figs. 5–3A,B).

### Radiographic Assessment of Trabecular Structure

Intuitively it is clear that the integrity of the trabecular structure is vital to the biomechanical competence of bone.\(^9\) Assessing it quantitatively with a projec-
tional technique such as radiography is challenging because of overlay effects, although spatial resolution would be sufficient. Nevertheless, attempts to analyze it have been recorded early.\textsuperscript{10,11} Radiographic techniques have been used exhaustively in vitro to assess trabecular texture\textsuperscript{12–15} and fractal dimension.\textsuperscript{16,17} The tenor of these studies is that structural parameters correlate significantly with bone mineral density, but tend to contribute independently, however weakly, when applied toward fracture discrimination.\textsuperscript{18} Recently, Majumdar et al\textsuperscript{19} confirmed these trends in an in vivo study. We have described radiographic assessment of trabecular structure only. There are a number of other techniques that are used in this field, and a thorough review would certainly require a separate chapter.

**Radiogrammetry**

Radiogrammetry signifies measurement of bone dimensions on radiographs. First descriptions of this technique date back to Barnett and Nordin,\textsuperscript{20} who introduced spine, femur, and hand scores, reflecting midvertebral and anterior height at the spine and cortical thickness at the femoral shaft and metacarpal.

Today’s major radiogrammetry applications include measurement of cortical thickness of phalangeal and metacarpal indices and measurement of hip axis length.\textsuperscript{21,22} Cortical thickness directly relates to osteopenia as the cortex becomes thinner with endosteal absorption. The small tubular metacarpal bones lend themselves well to this measurement because of ease of access and their high ratio of cortical bone. Besides cortical thickness, which is measured as the difference $(d_{\text{outer}} - d_{\text{inner}})$ of the outside diameter $(d_{\text{outer}})$ and the inside diameter $(d_{\text{inner}})$ of the bone, the cortical index $(d_{\text{outer}} - d_{\text{inner}})/d_{\text{outer}}$ is often used. It was shown that cortical thickness correlates fairly well with total body bone mineral density\textsuperscript{23} and has very high short-term precision.\textsuperscript{24} A commercial radiogrammetry system that assesses cortical thickness of the metacarpals has recently gained clearance for clinical use in the United States (Pronosco X-Posure, Nov. 2000, Pronosco, Vedbaek, Denmark).

In contrast to these cortical measurements, hip axis length does not relate directly to osteopenia, but it is intuitive from a biomechanical point of view that increased hip axis length (i.e., increasing the length of the lever through which forces from the pelvis are transmitted onto the femur) leads to reduced mechanical resilience. A significant association of hip axis length with hip fracture has been shown in the large study of osteoporotic fractures.\textsuperscript{22} Hip axis length can be acquired from standard hip radiographs and from dual X-ray absorptiometry (DXA) images or computed tomography (CT) scout views.

**Radiographic Assessment of Vertebral Fracture and Deformities**

Vertebral fractures are the hallmarks of osteoporosis, and even though one may argue that osteopenia per se may not be diagnosed reliably from spinal radiographs, spinal radiography continues to be a substantial aid in diagnosing and following vertebral fractures (Figs. 5–4A,B).\textsuperscript{25} Changes in the gross morphology of the vertebral body have a wide range
from increased concavity of the end plates to complete destruction of the vertebral anatomy in vertebral crush fractures. In clinical practice conventional radiographs of the thoracolumbar region in lateral projection are analyzed qualitatively by radiologists or experienced clinicians to identify vertebral deformities or fractures. For an experienced radiologist, this assessment generally is uncomplicated, and it can be aided by additional radiographic projections such as anteroposterior and oblique views, or by complementary examinations such as bone scintigraphy, CT, and even MR imaging.26–28

Vertebral fractures—the most frequent fractures in early postmenopausal women—have become the most important endpoints in epidemiological studies and clinical drug trials. In these settings conventional radiography is usually the only method used to assess vertebral fractures, and requirements and expectations differ considerably from the clinical setting.29 Examinations are frequently performed without specific clinical indications and without specific therapeutic ramifications. Evaluations for fractures are generally limited to lateral conventional thoracolumbar radiographs; the numbers of subjects are often quite large, requiring high efficiency; and the assessment may be performed by a variety of observers with different levels of experience. The detection of vertebral fractures may strongly depend on the experience of the reader. Experience with qualitative readings has shown considerable variability in fracture identification when radiologists or clinicians interpret radiographs without specific training, standardization, reference to an atlas, or prior consensus readings.30,31

Several approaches to standardizing visual qualitative readings have been proposed and applied in clinical studies. An early approach for a standardized description of vertebral fractures was made by Smith et al,32 who assigned one of three grades (normal, indeterminate, or osteoporotic) to a patient depending on the most severe deformity. The spinal radiographs were evaluated on a per patient and not on a per vertebra basis, a serious limitation for the follow-up of vertebral fractures and for the assessment of the severity of osteoporosis. Other standardized visual approaches allow for an assessment of vertebral deformities on a per vertebra rather than on a per patient basis, providing more accurate assessment of the fracture status of an individual and making follow-up of individual fractures possible. Meunier and co-workers33,34 proposed an approach in which each vertebra from T4 to L5 is assigned an individual score from 0 to 3 depending on the extent of the reduction in vertebral height and the type of vertebral deformity. This grading scheme is based on the reduction of the anterior, middle, and posterior vertebral heights, H_a, H_m, and H_p, respectively (Fig. 5–5). A vertebral deformity (to be graded 1 to 3) is present when any vertebral height, H_a, H_m, or H_p, is reduced by at least 4 mm or 15%. A vertebral deformity score of 0 is assigned to a normal vertebra with no reduction in vertebral height. A VDS 1 deformity corresponds to a vertebral end plate deformity with the heights H_a and H_p being normal. A wedge deformity with a reduction of H_a and, to a lesser extent H_m, is assigned a VDS of 2. A compression deformity, which is assigned a VDS of 3, is characterized by a reduction of all vertebral heights, H_a, H_m, and H_p. Grading all vertebrae T4 to L5 using this score, the minimum VDS for the whole spine would be zero when all the vertebrae are intact and the maximum score would be 42 when all the vertebrae are fractured. The vertebral deformity score still relies on the type of deformity (i.e., the vertebral shape), and changes in the vertebral shape would be required to account for incident vertebral fractures on follow-up radiographs. A quantitative extension of the VDS with measurements of the vertebral heights has been proposed by Kleerekoper et al35 to account for the continuous character of vertebral fractures.

This radiologist’s perspective on vertebral fracture diagnosis (i.e., considering the differential diagnosis as well as the severity of a fracture) is probably best reflected in the semiquantitative fracture assessment used by several investigators.25,37–39 The severity of a fracture is assessed solely by visual determination of the extent of the reduction in vertebral height and morphological change, and vertebral fractures are differentiated from nonfracture deformities. With this approach the type of deformity (wedge, biconcavity, or compression) is no longer linked to the grading of a fracture as with the other standardized visual approaches. Thoracic and lumbar vertebrae
from T4 to L4 are graded (Fig. 5–6) on visual inspection and without direct vertebral measurement as normal (grade 0); mildly deformed (grade 1, approximately 20 to 25% reduction in anterior, middle, and/or posterior height and a reduction of 10 to 20% of the projected vertebral area); moderately deformed (grade 2, approximately 25 to 40% reduction in anterior, middle, and/or posterior height and a reduction of 20 to 40% of the projected vertebral area); and severely deformed (grade 3, approximately 40% or greater reduction in anterior, middle, and/or posterior height and in the projected vertebral area).

From this semiquantitative assessment a spinal fracture index (SFI) can be calculated as the sum of all grades assigned to the vertebrae divided by the number of the evaluated vertebrae. In addition to height reductions, careful attention is given to alterations in the shape and configuration of the vertebrae relative to adjacent vertebrae and the expected normal appearance. These features add a strong qualitative aspect to the interpretation and also render this method less readily definable. Several studies, however, have demonstrated that semiquantitative interpretation, after careful training and standardization, can produce results with excellent intra- and interobserver reproducibility within the same school of training. In a further effort to provide definable, reproducible, and objective methods to detect vertebral fractures and to accommodate the assessment of large numbers of radiographs by technicians (in the absence of radiologists or experienced clinicians), various quantitative morphometric approaches have been explored and employed. Early studies using direct measurements of vertebral dimensions on lateral radiographs were described by Fletcher in 1947, Barnett and Nordin in 1960, Hurxthal in 1968,
Jensen and Tougaard in 1981, and Kleerekoper and coworkers in 1984, with the rationale being a reduction in the subjectivity considered intrinsic to the qualitative assessment of spinal radiographs.

Increasingly sophisticated morphometric approaches have been derived for the definition of vertebral dimensions. Most make 4 to 10 points on a vertebral body to define vertebral heights. Typically, $H_a$, $H_m$, and $H_p$ are measured (Fig. 5–5), as is the projected vertebral area. Newer techniques are based on digitally captured conventional radiographs to assess the vertebral dimensions. They rely on either marking points manually to define vertebral heights or finding those points and measuring in an automated or semiautomated fashion.

Hedlund and Gallagher used criteria such as percentage reduction of vertebral height, wedge angles, and areas in various combinations. Davies and coworkers employed two distinct morphometric cutoff thresholds for the detection of either vertebral compression or wedge fractures using vertebral height ratios that were defined by a radiologist’s assessment of vertebral deformities. Smith-Bindman and coworkers initially reported the use of vertebral level-specific reductions in anterior, middle, or posterior height ratios expressed as a percentage relative to normal data. Melton et al used this levelspecific approach, and Eastell et al subsequently modified it by applying height ratio reductions in terms of standard deviations rather than percentages. With this approach, each vertebral level has its own specific mean and standard deviation. Minne and colleagues developed a method by which vertebral height measures are adjusted according to the height of T4 as a means of standardization, and the resulting values are compared to a normal population. Black et al derived a statistical method for establishing normative data from morphometric measures of vertebral heights based upon deletion of the tails of the Gaussian distribution of an unselected population. McCloskey and coworkers used vertebral height ratios and introduced an additional parameter, defined as a predicted posterior height, in addition to the measured posterior height. Ross and colleagues further refined morphometric criteria for fracture by utilizing height reductions in standard deviations based on the overall patient-specific vertebral dimensions combined with population based level-specific vertebral dimensions.

Several comprehensive studies have compared the various methods or cutoff criteria in the same populations to examine the impact of methodology on es-

**FIGURE 5–6** Genant’s grading scheme for a semiquantitative evaluation of vertebral fractures. The drawings illustrate normal to mild to severe fractures (top to bottom). The size of the reduction in the anterior, middle, or posterior height is reflected in a corresponding fracture grade from 1 (mild) to 3 (severe). (Drawing courtesy of Dr. C.Y. Wu.)
timates of vertebral fracture prevalence and on identification of individual patients or individual vertebrae with fractures. Studies by various groups found the expected trade-offs between sensitivity and specificity. Two- to fourfold differences in estimates of fracture prevalence and generally poor or modest kappa scores between the different algorithms for defining fractures were reported. Despite these sophisticated, describable, and objective methods, the application and interpretation of the results are complicated by the large differences observed from one technique to the next.

Unfortunately, there is no gold standard for defining fractures by which the methods or their variable cutoff criteria could be judged. As a first approximation, there is some rationale for comparing visual assessment and morphometric data on a per vertebra basis to develop a consensus interpretation based on the expertise of experienced radiologists and highly trained research assistants. This may help to explain the concordant and discordant results and how best to utilize the strengths of the respective methods.

When relying solely on quantitative morphometry one has to consider that no real distinction between osteoporotic fractures and other nonfracture deformities can be made. Besides the uncertainties introduced by vertebral projection, the specific technique being used, and intra- and interobserver precision of quantitative morphometry, this lack of distinction between fracture and nonfracture deformities may have a substantial impact on attempts to determine the prevalence, and to a lesser extent, the incidence of vertebral fractures in a population.

Substantial differences have been reported when standardized visual approaches have been compared with quantitative morphometry; on the other hand, the agreement between different, centrally trained readers using the semiquantitative approach has been very good. This applies to the diagnosis of both prevalent and incident fractures, and at present, we feel that quantitative morphometry should be performed only in conjunction with a standardized visual assessment of vertebral fractures by an experienced radiologist or clinician.

**Morphometric X-Ray Absorptiometry**

Although morphometric X-ray absorptiometry (MXA) is implemented on DXA scanners, which are discussed later, the technique can be regarded as a quantitative imaging application and is thus presented here.

The relatively high resolution of DXA scanners (although the resolution is far inferior to that of conventional X-ray) allows clear depiction of anatomic details. For the MXA technique the scanner needs to be equipped with a rotating C-arm that enables taking lateral images of the thoracic and lumbar spine (T4 to L4) with the patient lying in the supine position. One advantage of DXA for obtaining lateral images of the lumbar spine is that the scanning beam, in contrast to conventional cone beam radiography, is always parallel to the vertebral end plates. This may improve the definition of vertebral dimensions for morphometric analysis in the diagnosis of vertebral deformities. This method has been referred to as *morphometric X-ray absorptiometry* (Fig. 5-7). Excellent correlation with radiographic vertebral morphometry has been reported for normal subjects, but vertebral deformities are more difficult to discern with MXA. Overlying osseous structures, including the ribs or the iliac crest, may have an adverse effect on the morphometric analysis. Technical modifications of the X-ray tube and the detector system may provide images with higher resolution and enhance the analysis of vertebral deformities, although this exposes the patient to a higher radiation dose. So far the method has not been adopted for routine examination in everyday practice or in clinical studies. Major reasons may be that the MXA technology is tedious to perform, is relatively expensive, and must be purchased in addition to regular scanning equipment for bone density. Furthermore, the general restrictions of quantitative morphometry apply, and the value of morphometric definitions of vertebral deformity versus a radiologist’s reading remains to be determined. The use of lateral DXA-based

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**FIGURE 5-7** MXA image and analysis.
spinal imaging for qualitative assessment of moderate to severe fractures, however, is becoming recognized as an important adjunct to standard bone densitometry for fracture risk appraisal.\(^72\)

**DENSITOMETRY**

**Basic Considerations**

**Nomenclature**

Nomenclature in densitometry can be misleading. The well-known and single most important parameter is bone mineral density (BMD). In contrast to the physical definition of the term density, which is mass per volume, BMD is mostly used for projectional techniques such as radiographic absorptiometry (RA), single photon absorptiometry (SPA), dual photon absorptiometry (DPA), SXA, or DXA, which actually measure areal density in units of g/cm\(^2\). BMD is also used for true (volumetric) density assessment by quantitative computed tomography (QCT) and peripheral quantitative computed tomography (pQCT) in units of g/cm\(^3\), but a direct comparison is difficult, because projectional BMD is dependent on bone size, whereas volumetric BMD is not. Furthermore, projectional methods are limited in their ability to separate trabecular and cortical bone compartments, whereas volumetric methods can yield trabecular BMD, cortical BMD, and integral BMD.

Bone mineral content (BMC), measured in units of grams, lends itself better to comparison between projectional and volumetric techniques. However, this parameter is definitely confounded by bone size and is thus less valuable for intersubject comparisons, including the categorization of bone status of an individual against a normative collective.

**T-Scores and Z-Scores**

Because of the availability of various densitometric techniques and the clinical importance of determining the high-risk patient for osteoporotic fracture, it is necessary to assess and compare the ability of these techniques to accurately discriminate the high-risk patient from the general population at risk. Because, as discussed in the previous section, projectional BMD and volumetric BMD are different things and methods like quantitative ultrasound do not even measure BMD directly, summary descriptive statistics for this discrimination include BMD-independent parameters like the T-score and the Z-score. The Z-score is defined as the deviation from the mean value of age-matched controls obtained with the same method divided by the standard deviation (SD) of that group. The T-score is defined similarly but uses young controls as the reference group. These parameters are simple to use and form the basis of the WHO's definition of osteoporosis (\(T \leq -2.5\)). For comparison of the diagnostic performance of two devices, they can be misleading. Here, machine precision and the magnitude of the observed age-dependent changes are the determinant parameters.

**Accuracy and Precision in Densitometry**

Accuracy is a systematic error and describes the difference between the actual measurement and the true physical value. In densitometry, it is sometimes used interchangeably with the term bias. Accuracy errors can be expressed in absolute or relative values. Precision, synonymous with reproducibility, is a random error and describes a system's ability to consistently deliver the same results under unchanged measurement conditions. Precision is commonly reported either as SD or as coefficient of variation (CV = SD/mean in \(\%\)) of the repeated measurements.

When evaluating or comparing precision data, it is important to understand the nature of precision in densitometry. One has to distinguish between phantom, in vitro, and in vivo precision, all of which can be measured with or without repositioning the phantom or subject between repeat scans, as well as between short- and long-term precision. Short-term precision is given by the root mean square (RMS) SD or CV of the repeat measurements. Consecutive phantom scans without repositioning typically yield minimum (short-term) precision errors, but more realistic errors can be obtained from short-term in vivo investigations with repositioning. To achieve sufficient statistical power, one should scan at least 27 subjects twice (or equivalently, 14 subjects three times each).\(^73\)

The measurement of long-term precision in vivo is more complicated because the quantity one is interested in (e.g., BMD) may change within the subjects over the course of the measurements. One strategy to separate this effect from machine imprecision is to fit a regression line to the data of each individual separately and then pool the residual errors.\(^73\) In vivo precision is also affected by the choice of the individuals. For example, it may be misleading to base the instrument's precision solely on young normals, since repositioning errors are larger in elderly and diseased patients. Reporting CVs instead of SDs facilitates the comparison of different devices but automatically increases apparent in vivo BMD precision errors in elderly people who have lower BMD than younger people. If the SD is constant and absolute BMD decreases, CV increases. Therefore, one must be careful when comparing CVs of different devices or techniques. For instance, significantly different precision errors were found for peripheral QCT (described later) for cohorts of healthy premenopausal, healthy postmenopausal, and osteoporotic women.\(^74\)
DEVICE PERFORMANCE CHARACTERIZATION

In clinical practice, high precision is more important than high accuracy because precision determines two important characteristics: the least significant change (LSC) and the monitoring time interval (MTI). LSC should be calculated using the long-term CV of a technique (CV_{long}):

\[ \text{LSC} = 1.96 \cdot \left( \sqrt{2} \cdot \text{CV}_{\text{long}} \right) \]  

(3)

LSC denotes the minimum true bone density change in a patient that can be measured by a densitometer with 95% confidence. In other words, if the change in the patient is smaller than the LSC then the chance of not detecting it will exceed 5%. If CV_{long} is unknown for the technique under consideration, it may be replaced by short-term in vivo precision. The MTI answers the question of how many years two measurements should be apart so that the change of a patient’s bone density is at least equal to the LSC.\(^5\) MTI is calculated by:

\[ \text{MTI} = \frac{\text{LSC}}{\left(\% \text{ yearly rate of bone loss}\right)} \]  

(4)

To be consistent, % loss and precision values must be derived from the same cohort. The healthy postmenopausal population is most relevant for the calculation of LSC and MTI, but the fact that published precision data are often based on young healthy volunteers is a potential pitfall. MTI should be interpreted cautiously as the rate of bone loss may vary in a population. Because it is important to identify patients who lose bone rapidly, it may be very appropriate to use measurement intervals shorter than the MTI. LSC and MTI values are given in Table 5–1 for all techniques that will subsequently be highlighted individually.

RADIOGRAPHIC ABSORPTIOMETRY

In RA, quantitative analysis of the optical density of the X-ray is made possible by including a known standard in the field of view, usually an aluminum or calcium hydroxyapatite wedge. The optical density of the standard is then compared to that of the object of interest, a step that is greatly enhanced by the use of computers. This technique is typically applied to peripheral measurement sites such as the metacarpals or the phalanges. Recently, this simple and inexpensive technique has gained renewed interest, and several devices are commercially available.

In the United States, RA devices are currently offered by CompuMed, Inc. (Manhattan Beach, CA) and Alara (Hayward, CA). The CompuMed system assesses bone mineral density by taking two radiographs of the left hand using direct exposure (non-screen) X-ray film at different radiographic settings with a special film cassette that has an aluminum alloy wedge placed next to the hand on conventional X-ray equipment. The Alara system assesses the hand the same way, but is based on computed radiography.

The parameters calculated from the reference wedge are applied to the bone image data from the middle phalanges of the index, third, and fourth fingers, and bone mineral mass is computed. Bone volume is estimated, based on the assumption that the bones are cylindrical in shape, and BMD is calculated. Corrections for soft tissue absorption, small errors in subject positioning, and variables associated with the film or exposure technique are incorporated into the analytical algorithms. As with densitometric techniques, interpretation of the results is based on comparison with a set of reference data.

SINGLE AND DUAL X-RAY ABSORPTIOMETRY

SXA with its high photon flux superseded the \(^{125}\)I isotope-based SPA, which was first introduced in the 60s.\(^6\) The replacement of the photon source by an X-ray tube has imparted better precision and improved spatial resolution of these systems and has reduced examination time. To correct for overlying soft tissue in an SPA or SXA scan, the anatomic site at which BMD is being measured has to be surrounded either

<table>
<thead>
<tr>
<th>Technique and Referenced Literature</th>
<th>Effective Dose (µSv)</th>
<th>Precision (%)</th>
<th>LSC (%)</th>
<th>% Loss/Year</th>
<th>MTI (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>min  max</td>
<td>min  max</td>
<td>min  max</td>
<td>min  max</td>
<td>min  max</td>
</tr>
<tr>
<td>pQCT (trab.BMD)(^74,115,116)</td>
<td>~1</td>
<td>1.6 1.8</td>
<td>4.4</td>
<td>5.0</td>
<td>1.0 4.4</td>
</tr>
<tr>
<td>Axial QCT(^117,118)</td>
<td>~50</td>
<td>2.0 4.0</td>
<td>5.5</td>
<td>11.1</td>
<td>2.6 2.1</td>
</tr>
<tr>
<td>Spinal DXA (L1–4,PA)(^117) (loss from Hologic reference values)</td>
<td>~3</td>
<td>0.5 1.5</td>
<td>1.4</td>
<td>4.2</td>
<td>0.78 1.8</td>
</tr>
<tr>
<td>Femoral neck DXA(^119,120)</td>
<td>~1</td>
<td>2.2 2.5</td>
<td>6.1</td>
<td>6.9</td>
<td>0.72 8.5</td>
</tr>
<tr>
<td>QMR (1/T2* at the distal radius)(^107)</td>
<td>0</td>
<td>3.8 9.5</td>
<td>10.3</td>
<td>25.7</td>
<td>0.81 12.7</td>
</tr>
</tbody>
</table>
by water, water bags, or water-equivalent moldable materials. SXA is used at the forearm for measurements of the radius and at the foot for measurements of the calcaneus. At the radius, BMD measurements are carried out at the ultradistal, distal (midradius), and shaft (1/3-radius). Because it is a projectional technique, separate measurement of trabecular and cortical bone is not possible, unless anatomical sites are chosen that solely consist of either one. For instance, a measurement of the radial shaft (often referred to as the *one-third radius* or *proximal radius*) includes mainly cortical bone and yields high precision. To include the metabolically more active trabecular compartment, the “ultradistal” radius measurement was introduced, but the trade-off is poorer precision of about CV = 2%. The calcaneus is also a site of interest because it is load-bearing and has high cancellous bone content. SXA has proven to be a valuable method in the diagnosis of osteoporosis, providing reasonable precision and low radiation exposure.

Sites with variable soft tissue thickness and composition such as the axial skeleton, hip, or whole body cannot be measured accurately using SXA. To correct for the unknown X-ray path length in the body, DPA and later (1987) DXA were introduced. DPA uses a radionuclide source, typically $^{153}$Gd. The fundamental physical principle behind DXA is the simultaneous measurement of X-rays with two different energies through the body. The dual X-ray spectrum can be generated using either K-edge filters or kVp switching. The main advantages of an X-ray system over a DPA radionuclide system are shortened examination time, greater accuracy, precision, and the removal of errors due to source decay corrections.

The preferred anatomic sites for DXA measurement of bone mineral include the lumbar spine (L1 to L4), the proximal femur (neck, trochanter, Ward’s triangle, and total hip), and the skeleton of the whole body. Figures 5-8 and 5-9 show typical screen shots of spinal and femoral DXA analysis.

DXA technology has seen the introduction of a new generation of fan beam scanners such as the Ho-logic QDR 4500 and Delphi (Hologic Inc., Waltham, MA) and the Lunar Expert-XL and Prodigy (Lunar Corp., Madison, WI). Fan beam scanners perform a single sweep across the patient instead of the two-dimensional raster scan required by pencil beam geometry. As a result scan times have been shortened from...
about 5 to 10 minutes for the pencil beam scanners to 10 to 30 seconds for the fan beam system, with a consequent higher patient throughput. Another advantage of the fan beam system is the higher image resolution. This allows easier identification of vertebral structures and artifacts caused by degenerative disease.

DXA is also employed for measurements of the appendicular skeleton. Most standard DXA densitometers allow for highly precise measurement of the radius or calcaneus using regions of interest like those derived from SXA measurements as well as user-defined subregions.79,80 Recently, peripheral DXA (pDXA) densitometers specially designed for forearm or calcaneal measurements have been introduced and may provide these measurements at a lower cost. Low radiation dose, availability, and ease of use have made DXA the most widely used technique for measurement of bone density in clinical trials and epidemiological studies, with a worldwide distribution of over 20,000 systems.81

**Quantitative Computed Tomography at the Spine**

QCT determines in three dimensions the true volumetric density (mg/cm³) of cancellous or cortical bone, in contrast to projectional techniques such as DXA that measure areal density and cannot separate cortical and trabecular bone. QCT can be performed on clinical CT scanners and theoretically at any anatomical location. Because of the high responsiveness of vertebral cancellous bone and its importance for vertebral strength, QCT has been principally employed to determine cancellous bone density in the vertebral body.82 A spinal QCT examination requires that an external bone mineral reference phantom be scanned along with the patient to calibrate the CT number measurements to bone-equivalent values. In carrying out the QCT examination, a sagittal scout view encompassing the lumbar spine is first obtained. Then, the sagittal location of the midplane of the vertebral bodies (typically L1 to L3) is marked.
and axial midvertebral slices are acquired (Fig. 5–10). Typically, automated analysis software is available that places regions of interest into the trabecular and the cortical compartment.

On some older scanners, dual energy QCT was available to correct for the influence of varying intraosseous fat content inside the vertebrae.83,84 Because it was found that this fat error is considerably smaller than biological spread, this technique has almost completely succumbed to the technically less demanding single energy QCT. Optimally, it is used at tube energies of around 80 kVp to minimize the fat error and maximize the difference of attenuation coefficients between water and bone.

QCT’s ability to selectively assess the metabolically active and structurally important trabecular bone in the vertebral body (Fig. 5–10) results in an excellent ability to discriminate vertebral fracture and to measure bone loss, generally with better sensitivity than projectional methods such as DXA.82,85 It has been found that the cross-sectional bone loss rate in females is typically 1.2% per year when measured with QCT and a little over half that value when measured with DXA. On the other hand, the precision of BMD measurement is poorer, which partly offsets the advantages (Table 5–1). QCT for measurement of vertebral cancellous bone is widely accepted and is used at over 4000 centers worldwide. Consequently, QCT has been used for assessment of vertebral fracture risk,96 measurement, and follow-up of osteoporosis and other metabolic bone diseases. However, a QCT scan is more expensive than DXA, and the radiation dose to the patient, while acceptable, is higher (Table 5–1).

PERIPHERAL QUANTITATIVE COMPUTED TOMOGRAPHY

To some extent, the high cost of and limited access to conventional all-purpose CT scanners has prompted the development of dedicated pQCT instrumentation specifically for measurements of purely trabecular and cortical BMC and BMD in the radius. pQCT at the forearm was introduced shortly after CT for medical imaging and several years before the development of spinal QCT.87 pQCT has the advantage of delivering a lower dose of radiation to the patient than standard spinal QCT because only the appendicular skeleton is irradiated. Unlike SPA or SXA, pQCT utilizes a transaxial image to allow separate measurement of the true volumetric density (mg/cm³) and cross-sectional area of trabecular and cortical bone without superposition of other tissues and provides exact three-dimensional localization of the target volume. The ability to measure the metabolically more active trabecular bone and to determine geometric parameters related to the cortical shell, such as moment of inertia and mean thickness, and its ease of use make pQCT an interesting alternative to SPA or SXA.81 However, despite the advantage of an early start and constant improvements of technology (e.g., the replacement of isotope sources used in earlier pQCT scanners by X-ray tubes) the clinical impact of pQCT in the field of osteoporosis has been rather small compared to the projectional techniques of SPA/SXA/DPA/DXA and volumetric assessment by axial QCT. This may in part be explained by the late commercialization of pQCT. In particular, in the United States pQCT devices are rarely used for the assessment of osteoporosis in patients and only a limited amount of data is available for pQCT.

On the other hand, the volumetric pQCT method is not affected by bone shape. This is important when determining BMD in the growing skeleton, when assessing biomechanical parameters like cross-sectional moments of inertia, or when measuring cortical bone thickness. The contribution of these parameters to fracture risk prediction has not fully been evaluated yet but the importance of compact bone may have been underestimated in the past. Here pQCT has a clear advantage over peripheral SXA and DXA. Because of its high spatial resolution, another application of pQCT is structural analysis of the trabecular network that complements densitometric information.

pQCT is also widely used for osteoporosis research in small laboratory animals, in particular in preclinical trials for the development of treatment strategies and pharmacological research.88–91 Dedicated devices have been designed for these applications.
QUANTITATIVE ULTRASOUND (QUS)

Ultrasound is usually defined as sound above human audible frequency of 20 kHz. The way ultrasound interacts with tissue can be used to characterize bone. Ultrasound variables of interest in bone assessments are speed of sound (SOS) and broadband ultrasound attenuation (BUA). BUA is defined as the gradient of the linear attenuation (in dB) as a function of frequency (in MHz) over the linear portion of this curve (from approximately 0.2 to 0.6 MHz). Most ultrasound measurements of bone use the transmission technique in which ultrasound transducers are positioned on opposite sides of the sample. Recently work has been done using axial transmission where sound is propagated along the surface of bone. QUS parameters are influenced by bone structure as well as bone density. However, the exact mechanisms of ultrasound interaction with bone and the physical properties that are measured remain unclear.

QUS, Bone Density, Structure, and Mechanical Properties

QUS parameters are significantly positively correlated with BMD in vitro and in vivo. Site-matched comparisons of BMD and QUS measurements have produced correlations of about 0.7 to 0.90. Both cross-sectional and prospective studies have demonstrated that QUS can be used to discriminate normal from osteoporotic subject groups as effectively as traditional bone densitometry approaches. The ability of QUS to discriminate between normal and osteoporotic patients is independent of BMD in some cases.

An important clinical question is how these parameters relate to bone strength. In vitro studies have demonstrated that BUA and SOS can be used to estimate the mechanical properties (Young’s modulus and strength) of cancellous bone samples. Generally, SOS has been found to be better than BUA for estimating the mechanical properties of cancellous bone. QUS correlates similarly to density in estimations of mechanical properties. However, when BUA and SOS are used together, their predictive power for mechanical properties is better than that of density. On in situ bone, the ability of QUS to predict the mechanical properties is not as good. This can be explained in part by confounding error sources that might weaken the association between QUS and bone strength. BUA of the heel correlates moderately with the strength of the calcaneus itself (r = 0.79) and with the strength of the proximal femur (r = 0.57 to 0.71). Femoral BMD is a significantly better predictor of femur strength (0.77 to 0.94) than heel QUS.

Evidence of the structural dependence of QUS has come mainly from anisotropic, histomorphometric, and fractal analysis studies. When cubes of cancellous bone are measured in the three orthogonal directions, both BUA and SOS show significant anisotropy that mirrors mechanical anisotropy. Acoustic anisotropy implies that structure affects acoustic properties independently of density, as the volumetric density of a given sample is independent of direction. These data indicate a relationship between QUS and bone density, structure, and strength, and suggest that this noninvasive approach has clinical utility in assessing osteoporotic fracture risk. However, its role in screening for osteoporosis and monitoring the efficacy of therapeutic intervention is still being investigated. There is also evidence to support the use of ultrasound to study skeletal status in children and other medical conditions such as rheumatoid arthritis.

Manufacturers have developed several different QUS systems since the late 1980s. Although all QUS devices measure either BUA and/or SOS, there are differences in the sites measured, coupling methods, calibration methods, analysis software, scanner design, and algorithm for BUA and SOS calculations. Because of these differences, different instruments will give different readings, even from the same site and on the same patient. Most of the commercial QUS systems measure the calcaneus submerged in a water bath or using ultrasonic gel as couplant, and they use a fixed single point transmission transducer system. Recent developments include calcaneal transmission imaging, phalangeal, tibial, and multisite measuring devices.

MAGNETIC RESONANCE IMAGING

To date, most MRI techniques have been limited to the study of soft tissue or of gross skeletal structure because compact bone does not generate any detectable MR signal. However, newly developed techniques focus on trabecular bone where marrow and fat provide the contrast. Quantitative analysis of bone density (QMR) is theoretically possible because the presence of bone alters the magnetic susceptibility of adjacent marrow in such a way that the apparent shortening of transverse relaxation time T2* in gradient-echo images should directly relate to the density and geometry of the trabecular structure. Thus, the transverse relaxation rate R2* = 1/T2* should correlate with BMD. Significant correlation has indeed been confirmed in vitro and in vivo. However, precision is far below that of other densitometry techniques (see Table 5–1). More recently, MR sequences to directly measure the reversible portion of the transverse relaxation rate R2', which is quantitatively related to magnetic susceptibility inhomogeneity of the measured tissue, have been introduced. A strong relationship of the transverse
signal-to-noise ratio are too low to discern individual standard clinical scanners, because spatial resolution and applied in vitro and in vivo. Standard stereological small radio frequency (RF) surface coils and can be lar architecture research. MR microscopy (µMR) uses practice does not seem likely in the near future. promising, an introduction of QMR to clinical prac-

tice does not seem likely in the near future. MR imaging has been on the forefront of trabecu-
lar architecture research. MR microscopy (µMR) uses small radio frequency (RF) surface coils and can be applied in vitro and in vivo. Standard stereological parameters are highly resolution-dependent on stan-
dard clinical scanners, because spatial resolution and signal-to-noise ratio are too low to discern individual trabeculae,111 thus researchers have used MRI to de-
scribe the overall texture of the trabecular network. Techniques like fractal analysis, power spectrum analysis, and other more sophisticated parameters have shown significant discriminatory power at the calcaneus, often independent of BMD.13,112,113 A more thorough discussion of MR-based bone structure analysis is beyond the scope of this chapter, but can be found in Majumdar’s study.114

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Most orthopaedic surgeons are not familiar with the history of bone fixation, and the literature on the issue is scant (either old or out of print). The authors had a difficult time trying to learn the historical development of osteosynthesis and found only a few publications on the topic. These are listed in the reference section for serious readers.1–7

The earliest technique of internal fixation of bone fractures was probably ligature or wire used in 1775 by Lapuyade and Sicre, surgeons from Toulouse.4,6 Other confirmed cases were the successful wiring of an un-united humeral fracture in 1827 by J. H. Rodgers of New York,6,8 fixation of an open humerus fracture with threaded suture in 1839 by Flaubert of Rouen,9 and fixation of a comminuted lower leg fracture using lead wire in 1851 by Dr. Long of Toulon.1,4 The use of screws for fixation in bone probably started in the late 1840s. In 1850, Cucuel and Rigaud described the use of screws for management of two fracture cases, a sternum fracture and an olecranon fracture.4–6 The first documented application of a plate for bone fixation was made by Hansmann in 1886.2,4 The plate was made of metal and was L-shaped with six screw holes. The plate was inserted into the fracture site through a skin incision and fixed to the bone across the fracture line. The screws were also inserted through the skin for easy removal. When the bone healed, the plate was pulled out by holding the part that had been left out of the skin (the bent end of the plate) (Fig. 6–1).

Albin Lambotte (1866–1955), a Belgian surgeon, is generally regarded as the father of osteosynthesis due to his pioneering work and tremendous contribution to the field.4,5 It was Lambotte who coined the term “osteosynthesis.” Through the 19th century, osteosynthesis was further developed and perfected by several famous surgeons, including W. Arbuthnot Lane, W. O. Sherman, and later, in the 1940s, Robert Danis (1880–1962).5

Robert Danis was regarded as the father of modern internal fixation.4 His three objectives of osteosynthesis4 (immediate mobilization of the injured limb, anatomical restoration of fractured bone, and primary bone healing) set the foundation for the late Arbeitsgemeinschaft für Osteosynthesefragen (AO) technologies developed by Maurice Müller in the 1960s.10 In the 1960s AO, headed by Müller, introduced its basic principles of fracture treatment: anatomical reduction, stable internal fixation, and early mobilization. More recently, plating methods have focused on the principles of “biological fixation.” These methods attempt to preserve the blood supply for improving the rate of fracture healing, decreasing the need for bone grafting, and decreasing the incidence of infection and refracture.7

According to the literature, little attention has been paid to the fixation of osteoporotic bone until recently.11 To briefly review the history, major methods for managing osteoporotic or mechanically compromised bone are listed in Table 6–1. Many methods are covered in other chapters in this book. The purpose of this chapter is to highlight major principles and methods in the field.
The biochemical and cellular defects associated with osteoporosis lead to structural changes in bone that are particularly applicable when considering traumatic fractures and their repair. Osteoporotic bone is characterized not only by a decreased amount of bone, but also by alterations in the architecture and composition of the affected osseous tissues. Structural changes predictably affect the physical properties of bone by lowering the level of maximum tolerable stress, decreasing elasticity, and reducing the potential for energy absorption. The final result is a bone that is not only thin but also weak and brittle.

Besides being more susceptible to incurring fractures, patients with osteoporosis tend to have significant difficulty associated with fracture fixation, more postoperative complications, and longer recovery times. The most constant feature of osteoporotic bone is a decrease in bone density. In fact, the World Health Organization defines osteoporosis as having bone mass 2.5 standard deviations below the mean bone density. An average person’s bone mineral density decreases by 50% between the ages of 20 and 80, so any superimposed osteoporotic changes could easily lower a patient’s bone density to a critical level.
density is associated with a decrease in maximal stress tolerance, elasticity, and energy absorption.\textsuperscript{45} In other words, density is directly related to the strength of bone. The loss of density is seen globally, affecting both cortical and cancellous bone, with the cancellous bone being affected to a much greater degree.\textsuperscript{45} The second aspect of bone that is affected by osteoporosis is the microarchitecture of the tissue itself. As osteoporosis decreases deposition and increases resorption of calcium, the trabecular framework of bone is affected. There is a decrease in cross-linking of subchondral bone, measured by the Singh Index. In this scale, bone quality is graded from 1 to 6 based on the trabecular bone pattern. Associated with the decrease in connectivity, there is a thinning of the trabeculae from resorption.\textsuperscript{45} So, not only are there fewer connections, but the existing ones are thinner than normal. The quality of these trabeculae is crucial to the interlocking of screws, pins, wires, or intramedullary nails.

This microarchitecture of bone tissues is critical because it determines the resistance to compressive forces. With increased thickness of the trabeculae and more cross-linking, bone is better able to withstand torsion and bending. Loading of bone plays an important role in maintaining structure and integrity. The stress absorbed by bone stimulates growth and maintenance of trabecular connectivity, ultimately increasing the cross-sectional area. Loading is actually an essential part of fracture repair and is lost when a patient becomes immobile from a fracture. Stable internal fixation allows patients to ambulate soon after surgery and begin this process of reforming and strengthening trabecular cross-links.

Along with these changes in microarchitecture, there are associated changes in the macroarchitecture as well. Osteoporotic bone has a thinner cortex and larger medullary canal than healthy bone. While the overall diameter of the long bones may remain the same, the ratio of cancellous to cortical bone is increased.\textsuperscript{50} The thin layer of cortex surrounding abundant cancellous bone is a weaker structural model and predisposes to low-energy fractures such as those through the femoral neck and greater trochanters. It is precisely these fractures that are most often seen in falls with the elderly. The abundance of cancellous bone will also adversely affect the fixation of osteoporotic fractures.

**Screws**

Fracture fixation is made possible through a vast variety of bone screws. Without screws, the use of many fixation devices, such as bone plates, intramedullary nails, and even some joint prostheses, would be less effective or even impossible. Each type of bone screw is uniquely designed for specific applications. The type of bone screw chosen most often depends on the general health of the bone at or near the fracture (normal versus osteoporotic), the location of the fracture (metaphysis, epiphysis, diaphysis), the density of bone (cortical versus cancellous), and the type and classification of fracture. Bone screws are designed around these parameters. Screws have many functions in orthopaedic surgery including bringing bone fragments together or fixing the fracture alone, fixing plate to bone, interlocking an intramedullary nail, working as anchors for wires, and fixing ligament or tendons to bone. This section will focus on common screw types and the relevance to internal fixation in osteoporotic bone.

**Types of Screws**

There are numerous types of screws available today. Each style possesses unique advantages in different applications. Bone screws may be categorized as cortical or cancellous, self-tapping or non-self-tapping, solid or cannulated, and fully threaded or partially threaded.

**Cortical vs. Cancellous**

The basic types of screws common to the average individual are wood and metal screws, which are two basic types of screws employed to attach objects together in everyday applications. If these two types of screws are placed side by side, variations in design can be immediately observed (Figs. 6–2A,B). The wood screw generally possesses a smaller core with larger threads spaced farther apart than its metal counterpart. This is no accident. The wood screw is used to penetrate materials with less density and resistance. The design of the wood screw offers deeper thread penetration, providing better stabilization in the wood. The metal screw, on the other hand, must have small threads closely spaced to pierce through the screw hole in the metal. This design does not provide as much thread penetration, but the small pitch assures that more threads are in contact with metal. It would not be possible to drive a wood screw with large threads into metal because the resistance would be too great. On the other hand, metal screws could be driven into wood, but the grip would not be nearly as strong and the screw would eventually fail (cut out) in most cases.

Similarly, cortical and cancellous bone screws possess different geometry based on the required function. The cancellous bone screw is analogous to the wood screw. It features larger, wider-spaced threads and a smaller core diameter. This enables the screw to easily penetrate and obtain a strong grip in less dense cancellous bone located in the metaphyseal
and epiphyseal regions of long bones. On the other hand, cortical bone most commonly located in the diaphyseal areas is analogous to metal in terms of density and resistance to penetration. Hence, smaller threads spaced closely together enable penetration while still maintaining a solid grip. As in the “real-life” example, it would not be possible to screw a cancellous bone screw into cortical bone. Similarly, a cortical screw could rather easily be driven into cancellous bone. However, the small threads would provide a limited grip in the less dense trabecular bone, and the screw would most likely be pulled out over time. Images of cortical and cancellous bones depicting the variation in thread size and quantity are shown in Figures 6–3A,B.

Cortical screws are fully threaded screws commonly used to attach plates to bone. Cortical screws may be used as lag screws if the near cortex is overdrilled. This technique allows the threads near the head of the screw to turn freely in the guide hole and the threads in the far cortex to take purchase and produce compression between the near and far cortexes.

**Self-Tapping vs. Non-Self-Tapping**

Depending on the nature of the fracture and the type of bone, surgeons may elect to employ self-tapping (Fig. 6–4) or non-self-tapping bone screws. For self-tapping screws, the surgeon first prepares a pilot hole using a drill bit slightly larger than the screw’s core diameter but smaller than the outer diameter of the threads. The screw is then driven into the pilot hole as the threads cut a shallow path into the cortex. Self-tapping screws are advantageous in thin cortical bone, according to Müller et al.10 However, these researchers recommend that self-tapping screws not be used in thick cortical bone due to the relatively high resistance they are subjected to. The large amounts of torque necessary to drive the self-tapping screw in cortical bone could result in the shearing of the screw or imprecise incision.

Non-self-tapping screws, on the other hand, do not cut their own path. After the pilot hole is drilled, a tap is used to cut deeper grooves matching the contour of the screw into the cortex. The result is deeper thread penetration and higher accuracy. Cortical
screws are typically non-self-tapping whereas cancellous screws are often self-tapping. Non-self-tapping screws work very well in thick cortical bone. However, Müller et al.\textsuperscript{10} suggest that non-self-tapping screws should not be used in thin flat bones such as those in the face, skull, pelvis.

**Solid vs. Cannulated Screws**

Most bone screws appear to be very similar to metal or wood screws at first glance. They possess a similar thread pattern, size, and overall shape. In addition, these screws usually have a solid core like the conventional screws. Another type of screw often used in fracture fixation is a cannulated screw. A cannulated screw has a hollow core. During surgery pins are initially inserted into bone at the area of the fracture. These pins temporarily represent the axis of the screw. Once the pins are manipulated to the desired configuration and alignment, the cannulated screw simply slides over the pin and is driven into the specimen. This feature provides optimum alignment and is advantageous where precise screw insertion is desired. Both small and large cannulated screws are available. According to Müller et al.\textsuperscript{10} large cannulated screws are commonly utilized in long bone fracture fixation in metaphyseal areas such as the femoral neck, femoral condyles, and tibial plateau. Smaller cannulated screws are typically used in similar regions of smaller long bones such as the distal radius and humerus, as well as the distal and proximal tibia.

**Fully Threaded vs. Partially Threaded Screws (Lag Screws)**

As in conventional screws, bone screws are offered in both partially and fully threaded versions. Surgeons use fully threaded screws mainly for affixing plates to bone. Partially threaded plates are advantageous when compression between the near and far cortex is desired. The latter have threads only up to a certain point on the shaft. The core is smooth from this point to the head. This allows for the smooth portion of the screw to glide through the near cortex while the threads are driven into the far cortex. This brings the fracture together through compression.

**Special Variants**

Special variants include Herbert screws, expansion screws or bolts, dynamic hip screws (DHS), dynamic condylar screws (DCS), and the recently developed cementing screws, interlocking screws, and hollow wall anchor. Correct implementation is achieved through a clear understanding of the advantages and disadvantages of each variant.

**Herbert Screws**

Herbert screws are unique in that they possess threads of different pitch on each end of the screw.\textsuperscript{51} The shank of the screw is unthreaded at the center, whereas the ends have threads of different diameters and different pitch. The leading end of the Herbert screw is used for penetration and thus has threads that are small in diameter. The thread at the proximal end of the screw has a smaller pitch than that of the distal end and a larger outer diameter. It is the difference of the thread pitch on the proximal and distal threads that create compression effect to the fractured proximal and distal fragments (Fig. 6–5). Herbert screws were originally designed for scaphoid bone fracture and later were also used for transarticular fractures and many other types of fractures.
**Pedicle Screws**

Pedicle screws are used in spinal fixation in conjunction with plates or rods, which will be discussed further below. Most pedicle screws are fully threaded. Although pedicle screws are biomechanically sound, their use is still very controversial, due mainly to the high complication rates. Reported complications include neurological deficits and vascular injuries caused by pedicle violation, epidural hematoma, device breakage, slippage, migration, and malpositioning. These complications can lead to infections, paralysis, and weakness of the lower extremities and bladder and bowel control problems. The solution is 100% accuracy of screw placement without pedicle violation. The newly developed concept of a self-guided pedicle screw (Fig. 6–6), invented by Dr. Baoren Liu and further developed in the authors’ laboratory (see Chapter 35), may bring a bright future to the use of pedicle screws.52

**Dynamic Hip Screws/Dynamic Condylar Screws**

Dynamic hip screws (DHS) are internal fixation devices used for femoral neck fractures in conjunction with “lateral plates” (Fig. 6–7A). More specifically, DHS are often used in intertrochanteric, subtrochanteric, and basilar neck fractures. These special screws are much more complex than other bone screws. DHS consist of a screw and bone plate assembly. Once proper alignment is obtained using Kirschner wires and angle guides, the canal for the screw is reamed and tapped if necessary. With the canal properly prepared, the DHS is then inserted followed by the chosen DHS plate. The DHS plate is fixed to the femoral surface using the screw of choice, typically cortical screws.

Dynamic condylar screws (DCS) are used for distal femoral fractures (Fig. 6–7B). DCS are structurally similar to DHS. They are comprised of a screw attached to a bone plate. Installation procedures for the DCS are very similar to the DHS. After Kirschner wires are used with an angle plate to achieve optimum alignment, a canal is created with a reamer and tapped if needed. The screw is inserted and a bone plate is attached to both the screw and bone.

**Cementing Screws**

Cementing screws are an experimental screw design currently being tested in Belgium by Reynders16 (see Chapter 22) and in the United States (at the authors’ laboratory) by McKoy and An15 (see Chapter 21). Cementing screws are unique in that they have through-holes spaced at intervals along the shank. These holes allow injected bone cement to flow through the screw into the surrounding bone, providing a more stable and robust fixation (Fig. 6–8). In the authors’ laboratory, we compared the ultimate holding power of a new cementing screw (8 to 10 holes, evenly spaced) injected with polymethyl-
methacrylate (PMMA) with a solid screw with the same dimensions secured with PMMA by the standard technique. Both screws were placed into embalmed and fresh-frozen lumbar vertebral bodies and pulled out using an MTS system. The cementing screw had 278% greater holding power compared with the standard screw. The cementing screw provided a dramatic increase in holding power in osteoporotic bone. This novel screw is promising for fixation in osteoporotic bone and warrants clinical evaluation. Dr. Reynders’ screw design has two side holes and has been effectively used clinically for metaphyseal fractures.16

**Interlocking Screws**

An interlocking screw was recently designed in the authors’ laboratory by McKoy and An (see Chapter 20).17 It features the interlocking of the inserted screw by a locking pin (Fig. 6–9). Mechanical testing showed a larger force was required to pull out the interlocking design than the standard screw. The locking screw not only helps to prevent screw backout but also adds additional bony purchase. This new interlocking screw for osteoporotic bone is very promising and warrants clinical evaluation.

**Expanding Bolts or Screws**

Lesoin et al12 published an early report on the expanding screw or bolt in 1983. It consists of an expanding cylinder and a screw. It was designed for anterior cervical spine fixation. The same principle has been recently adapted for a new design of pedicle screw (Fig. 6–10).14 The advantages of pedicle screw fixation depend on its ability to maintain bony purchase until the fusion mass is stable. The combination of osteoporotic bone with removal and replacement of pedicle screws in revision procedures substantially reduces screw mechanical fixation strength and can lead to clinical failure. The expanding pedicle screw design could be used to improve biomechanical fixation in bone of compromised quality. The mean axial pullout force in bone of all qualities was increased 30% when the expanding pedicle screw design was used.14 This included an appropriate 50% increase in pullout force in bone of poor quality (low bone mineral density). The preliminary clinical and radiographic results were supportive of the biomechanical design rationale and mechanical testing.

**Hollow Wall Anchor**

A hollow wall anchor recently tested in the authors’ laboratory has shown promise for fixation in osteoporotic bone.20 We compared the ultimate holding power of this expandable anchor (Fig. 6–11) with a standard solid screw of similar dimensions. The solid screw and the expandable anchor were both placed into fresh-frozen lumbar vertebral bodies and pulled out using a mechanical testing system. The expandable anchor had a holding power 74% greater than the standard screw. The expandable anchor provides a significant increase in holding power without the problems associated with cement. This prototype anchor is promising for fixation in osteoporotic bone and warrants further evaluation. A more theoretical and experimental analysis of this technique was reported previously and its performance was significantly better than conventional screws for fixation in osteoporotic bone.53

**PLATES**

Since the 1960s, both rigid fixation (AO principles) and biological fixation have evolved to provide for improved healing. Even with the widespread use of intramedullary (IM) nailing for diaphyseal bone frac-

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**FIGURE 6–9** The mechanism of the McKoy-An interlocking screw.

**FIGURE 6–10** Omega21™ expandable screw for spine fixation.
tures, plate osteosynthesis is still recognized as the treatment of choice for most articular fractures, many metaphyseal fractures, and certain diaphyseal fractures such as those in the forearm. Importantly, the evolution of internal fixation and specifically the emerging of the concept of biological fixation has been largely due to the development of plating techniques.

RIGID FIXATION AND BIOLOGICAL FIXATION

AO principles for internal fixation, based on Danis’ work,\(^5\) include anatomical reduction, stable fixation, and early limb mobilization.\(^10\) The first AO self-compressing plate was reported in 1963 and is still widely used.\(^54\) The oval screw holes and eccentrically placed screws provide self-compression to the fractured bone ends. Danis also designed a compression device for applying compression to conventional plates, which is not widely used today.\(^54\) The famous dynamic compression plate (DCP) was introduced in 1969 for fracture treatment (Figs. 6–12A,B).\(^55–57\) Besides its use for general rigid fracture fixation, it has been also used as a tension band, neutralization, and buttress plate.\(^10,27\) A similar design was reported by Mittelmeier in 1974.\(^27,58\) Using these rigid fixation techniques, bone healing is normally primary with scarce radiographic callus formation. However, to achieve anatomical reduction and stable fixation, excessive exposure of the fracture site and dissection of the periosteum are needed, which inevitably results in damage to the local blood supply. Another disadvantage of these techniques is the effect of stress protection, which causes local bone necrosis and osteopenia.

Due to the limitations of the early compression plate versions, with resulting damaged blood supply and bone loss adjacent to the plate caused by excessive exposure of the fracture sites and stress shielding (stress protection),\(^79\) a new concept of internal fixation evolved nearly 20 years ago that is termed biological fixation.\(^27\) Biological fixation can be defined as fixation that limits the injury to soft tissues and blood supply.\(^27\)

Several plate designs directly and indirectly supported the new concept, such as the wave plate by Brunner and Weber (Fig. 6–13)\(^60\) and the bridge plate by Heitemeyer et al.\(^61,62\) These plates bypass the fracture site to reduce the vascular disruption and allow easier bone graft at the fracture site. In 1990, Perren et
al27,63 published their new plate design for biological fixation, the limited contact dynamic compression plate (LC-DCP) (Figs. 6–12A,B). This design significantly reduces the effect of stress protection of the plate and the disturbance of blood supply, resulting in a lesser degree of local osteoporosis and clinically reduced nonunion and infection rates.

For addressing similar circulatory and stress concerns, the point contact fixator (PC-Fix) has recently been introduced (Fig. 6–14).30,31,64,65 In a sheep tibial fracture model, the strength values in the PC-Fix groups at 12 and 96 weeks were significantly higher than in the corresponding DCP groups.65 Healing of simple diaphyseal fractures treated by PC-Fix was superior to that achieved by conventional DCP. The histological evaluation suggested that the observed differences can be accounted for by the absence of implant-related cortical necrosis and by the circumferentially uninterrupted (if smaller) callus in the PC-Fix group.

Another recent development based on the same principle is a minimum contact plate (MCP) designed by Abel and Sun (Fig. 6–15).29 Four-point bending and torsion tests were conducted to compare the new MCP with the DCP and LC-DCP. Mechanically, the MCP plate was found to have adequate stiffness and strength for clinical application because it is at least as stiff and strong as one of the commonly used plates under both bending and torsional loading conditions.

**LC-DCP, MCP, and PC-Fix**

As mentioned above, LC-DCP, MCP,29 and PC-Fix reduce the contact area between the plate and the adjacent bone surfaces, leading to decreased effect of stress protection and clinically lower rates of delayed union and nonunion. They have great potential for treating osteoporotic fractures.

**Adhesive Plate**

The design of the adhesive plate was reported by Meyrueis in 1977 but it has not been well used and documented.24,66 The ridges on the undersurface of the plate increase the adherence of the plate to bone (Fig. 6–16). By increasing the coefficient of friction between the plate and the bone, the stresses on the screws can be diminished by one third. The ridges should not be such as to prevent the later removal of

**Special Designs That May Be Used for Osteoporotic Bone**

Based on their shapes, there are many special designs that fit the needs of osteoporotic bone fixation, including clamp-on plates, blade plates, less invasive stabilization system (LISS) plates, etc.
the plate. Further work both experimentally and clinically is needed for effective use of this plate design. It should be noted that the PC-DCPs may have similar effect to that offered by the adhesive plate, a factor that also warrants further investigation.66

Blade Plate
Blade plates are L-shaped plates consisting of the plate portion and the blade.67,68 They are commercially available (Synthes, USA) and can also be made from a standard bone plate as described by Dr. Palmer in Chapter 24 of this book. The plate portion is fixed to diaphyseal or metaphyseal areas of long bone and the blade is inserted into the end of the bone (epiphyseal or metaphyseal areas, such as humeral head, proximal and distal femoral condyle, upper or distal tibia) (Fig. 6–17). Blade plates offer stable fixation because of the fixed angle at the plate-blade junction.67,68

Buttress Plate
The condylar buttress plate is a broad dynamic compression plate with cloverleaf distal portion for accommodating up to six cancellous screws. It is suitable for fixing comminuted femoral condylar fractures. It does not provide rigid fixation as a DCS or blade plate. Also, the relationship between the screws and the plate is not fixed as in LISS.

Mennen Plate
A paraskeletal clamp-on plate has been developed that maintains the operatively reduced position of a fractured long bone during the healing phase while having a minimal effect on the healing procedure.26,69,70 The plate consists of a central ridge with paired fingerlike projections on each side, constructed in such a manner that in head-on projection the ridge and two projections form just slightly more than a semicircle (Fig. 6–18). The points of the projections, which are wedge-shaped and bent at right angles toward the center, are squeezed into the bone with a crimping tool. The technique is simple, the operating time significantly shortened, and the healing time notably reduced; fracture union is sound without signs of disuse osteopenia, stress protection, or damage to the bony architecture due to drill holes.59,70 The plate has been used for many different kinds of fractures of long bone,69–71 metacarpal bone,72 and even mandibular bone.73,74

The Mennen plate has been also advocated for femoral shaft and femoral periprosthetic fractures (Figs. 6–19A,B), as well as revision total hip surgery (combined with bone graft) for patients with severe...
bone loss. Mennen plate fixation provides an adequate and easy technique for femoral periprosthetic fractures and aseptic loosening of total hip replacement with severe bone loss. By preserving the periosteal blood supply, the time required for bone graft incorporation is shortened, resulting in an early final outcome.75–77 However, controversy exists with evidence claiming less adequate fixation of elderly femoral periprosthetic fractures.71,78 Therefore, the safest use of the Mennen plate may be non-weight-bearing tubular bones (Figs. 6–19A,B) and the mandible.

Zespol Plate
Developed by Ramotowski et al32 in Poland, Zespol is a system consisting of a plate, platform screws, and nuts that form a small clamp fixator (Fig. 6–20). In this procedure, the plate is not screwed onto the surface of the bone, but is fixed above the bone by special platform screw bolts. The ZESPOL system has less bending stability than DCP. However, the stability of the Zespol system can be regarded as being sufficient overall. The Zespol fixator can be used either internally or externally. Based on its design, Zespol features fixed-angle, self-compression, less soft tissue injury, and preservation of blood supply (if used externally).

Cushioned Plates
A cushioned plate includes a metal plate portion and a plastic part underneath the metal plate (cushion)79,80 or around screw holes (plastic washers, namely stress-relaxation plate),81 leading to less rigid fixation, although stable fixation is obtained. Less stress protection and resulting osteopenia under the plate is expected for this kind of device, making the fixation more “biological.”

Axially Mobile or Sliding Plates
A reduction in axial stiffness of fixators (or plates) has been shown to be beneficial to bone healing, and many external fixators have been designed that incorporate axial dynamization. Recently two similar axially mobile (sliding) plates have been designed for long-bone fracture fixation, to give the bone fragments a degree of axial mobility while maintaining bending and torsional stability after fixation.82–84 Mechanical testing data have shown that the sliding plates are comparable in both bending and torsion with conventional compression plates. Actually, plates with a sliding feature had been reported early in the history of internal fixation of bone fractures, including the Lambotte plate (1909), Townsend-Gillilan plate (1943), and Egger plate (1948). Theoretically, if the fixation is stable under bending and torsional loading, axial sliding will mechanically stimulate the fracture site for more “biological” bone healing (secondary callus formation).

Augmentation Methods for Plate Fixation
The Schuhli nut was originally designed for plate fixation in osteoporotic bone.22,85 It elevates the plate above the bone surface (Fig. 6–21), making less direct contact between the plate and bone and resulting in preserved blood supply. The nut can also reduce the mobility of the screw within the screw hole, leading to less motion between the screw and the plate.86 In addition, in the case of missing cortical bone, Schuhli nuts can serve as proximal cortices and make “bicortical fixation” feasible.87

Bioabsorbable strips are another kind of augmentation of screw/plate fixation (see Chapter 23).88 The strip is introduced into the medullary canal through the fracture site. Then, screws penetrate the proximal cortex, the strip, and finally the distal cortex, resulting in a stable “tricortical fixation” of the screw/plate (Fig. 6–22).88

Cement augmentation is a major technique and it will be discussed below in the “Cement and Composite” section.
MINIMALLY INVASIVE FIXATION TECHNIQUES

Minimally invasive percutaneous plate osteosynthesis (MIPPO) for distal femoral fractures, transarticular approach and retrograde plate osteosynthesis (TARPO) for distal femoral fractures, LISS, minimally invasive surgeries for foot and ankle fractures, and a recent development of percutaneous compression plating of intertrochanteric hip fractures are common types of minimally invasive plate fixation techniques. Here we use LISS as an example (see Chapter 25).

LISS is a recent development for fixation of long bone fractures, and features locked screws and minimally invasive surgical procedures (see Chapter 25). It is an internal fixator with the plate lying beneath the deep fascia and muscle but outside of the periosteum. The plate is anatomically preshaped (Fig. 6–23). The screw used for LISS is monocortical, self-drilling, and self-tapping, and fixes itself to the plate after complete insertion. It preserves blood circulation because the plate is inserted through a small incision at the epiphyseal level and no excessive soft tissue dissection is needed (biological fixation). The beneficial result has been shown in several publications. The LISS is indicated for the stabilization of fractures of the distal femur (distal shaft, supracondylar and intraarticular fractures). Clinical results have shown that LISS is beneficial for osteoporotic bones and periprosthetic fractures.

INTRAMEDULLARY NAILS

The internal fixation of long bone with IM nails has become one of the most frequently performed procedures in orthopaedics today. Although the operation is commonly used to stabilize complicated fractures of both the humerus and tibia, it is in the femur where it has truly proved its worth. With the development of new hardware and the refinement of technique since its introduction in World War II, IM nailing has become the new standard for the treatment of long bone fractures.

The theory underlying the procedure is simple. Placement of an internal fixation device aids in the transmission of forces from one end of the bone to the other. By allowing the implant to carry the majority of the stress, the damaged bone is better able to maintain alignment as well as lay down a proper matrix. With these two effects, IM nailing lowered the risk of pseudoarthrosis and infection, shortened hospital stay, and accelerated the return to function. Studies show that with femur fractures in trauma victims, early skeletal stabilization substantially reduces the incidence of pulmonary complications, shortens ven-
The merits of IM nailing are even more important when patients with osteoporosis present with femoral fractures. These patients often have complicated shatter fractures that require rigid stabilization. Nailing is particularly suited to osteoporotic bone because its central location in bone distributes loads more uniformly than do plates. Since the bone is already in a weakened state, this distribution reduces the risk of pseudoarthrosis and secondary stress fractures. Elderly patients also benefit from shortened hospital stays, reduced infection rates, and fewer pulmonary complications.

The diaphysis with its large medullary canal of osteoporotic long bone is not always amenable to stabilization with plating because the anchoring screws prefer a thick cortex to maintain purchase. Interlocking IM nailing can bridge the two sides of the cortex of osteoporotic bone to provide rigidity but maintains less stability than in normal bone.

Development of Intramedullary Nailing

The modern era of IM fixation is credited to Dr. Kuntscher of Germany. While he did not originate the concept of IM fixation, he was the first to systematically develop the technique based on basic science and clinical research conducted in the 1940s. Despite Kuntscher’s clinical success, IM nailing did not become a popular procedure until the late 1970s. This was in part due to the 1958 formation of the Swiss AO group and their organized study of methods of internal fixation. They focused their research on the plate and screw techniques and regarded IM nailing as a less rigid and inferior form of fixation. The group ultimately published their results in 1970 as the now-famous “Manual of Internal Fixation.” With the advent of improved imaging and cannulated lag screws later in the decade, it became easier to perform IM nailing as a closed procedure. As surgeons saw decreased blood loss and improved infection rates, interest in the procedure surged. At this time, Kuntscher performed a series of closed IM nailings that finally established the technique as the standard of care.

The next major development came around 1975 to 1980 when two competing groups released locking versions of the IM nail. The teams of Klemm and Schellman as well as Grosse and Kempf, both in Germany, were working on locking nails (Klemm-Schellman and Grosse-Kempf systems) to further stabilize complicated femoral fractures. At the time, extensive comminuted fractures and fractures located closer to the ends of bone were being poorly controlled with the standard Kuntscher nail. Subsequent trials at several medical centers established IM nailing with interlocking nails as the treatment of choice for not only femoral fractures but also traumatic humeral and tibial fractures. Grosse and Kempf originally worried that IM nails were “nonunion machines” that would prevent proper remodeling. They recommended dynamization (removal of the distal locking screws) at 6 to 12 weeks to expose the bone to the proper loading forces. Their concerns proved unfounded as other surgeons observed excellent results in patients who never returned for dynamization. Apparently static locking of the nail produces little stress shielding. Dynamization is now reserved for stimulation of fractures that have not healed at 6 months.

Until the early 1990s, most IM nailings were performed with reaming of the medullary canal prior to nail insertion. While the technique of unreamed nailing was not unknown, reaming was seen as the best way to obtain an adequate fit. The recent emergence of studies showing possible sequelae from the reaming procedure has increased the interest in the use of unreamed nailing. The Lottes nail for tibial fixation has been in use since 1960, but a comparable version was not developed for the femur until the Russel-Taylor and AO nails were released. They have both proved as effective for fracture union as their unreamed counterparts. Reduction of complications has been more difficult to show. Subsequent research has shown that one method is not superior to another and both techniques are commonly used today.

Over the years, there have been many modifications in design, technique, and materials, creating a whole host of other IM nailing devices. The flexible Ender pins and the retrograde interlocking nail represent the most radical departures from the original design. Most others are variations of the standard Kuntscher interlocking nail with different stabilizing screws, bends in the nail, or lag screws for the femoral head. These are often utilized for specialized circumstances such as in osteoporosis or femoral neck fractures. Development of IM nailing specifically for osteoporotic fractures has been sporadic at best. It has consisted of mainly adapting existing techniques to osteoporotic bone. Modifications include the use of cement to strengthen anchor sites, the Booker nail with its distal fins, and the spiral screw for locking cancellous bone.

Nail Types

As mentioned above, IM nailing is particularly suited to osteoporotic bone because the central placement distributes loads more uniformly than rigid plates. Since the nail will share the stress of body weight, the patient is able to ambulate earlier and begin the process of healing. There is less

tillator and intensive care unit times, and improves the overall survival rate.

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Nail Types

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pseudoarthrosis and healing times are quicker due to these effects.\textsuperscript{47} While the function of all IM nails is based on these principles, each nail has its own characteristics that make it more or less suitable for use in osteoporotic bone.

**Standard Nail**

The original nail that Kuntscher developed is considered the “standard” nail. This is a hollow nail inserted into the bone without any attachment hardware. Being hollow, it is necessary to perform medullary reaming out to the cortex to ensure proper fit. The goal is to use the largest nail possible without compromising the osseous tissue. Stability for the fracture is obtained with a combination of the size of the nail and the preciseness of the fit. In osteoporotic bone, there is a larger medullary canal and a thin cortex so use would be impractical. There are even problems with the reaming process that will be discussed later.\textsuperscript{98} The insertion of this nail is best suited for non-comminuted fractures that occur through the smallest part of the medullary canal. Fractures in osteoporosis are often comminuted and located at the ends of the bone in the femoral neck or trochanters. Standard nails cannot stabilize these fractures effectively.\textsuperscript{50}

**Interlocking Nail**

Interlocking nails were developed as a modification of the original Kuntscher nail. Screws were added that transverse both cortices through a premade hole in the nail. Cross-locking through both the bone and nail provides additional stabilization for the opposing pieces of the fracture. This modification is particularly effective in osteoporotic bone. The additional healing time of osteoporotic bone requires excellent stabilization for a proper callus to form and union to take place. Interlocking has proved its worth not only clinically, but also in axial loading tests where failure occurred only at four times body weight.\textsuperscript{100} The specific interlocking nails can be grouped according to their different modifications. First-generation nails are the Klemm-Shellman and the Grosse-Kempf, which are modifications of the original Kuntscher. Klemm and Shellman discovered that having a large proximal screw placed in an oblique orientation reduces the rotational movement and eliminates the need for a second screw.\textsuperscript{98} This feature has been incorporated into many subsequent designs. The Russel-Taylor is the best example of a second-generation nail. It uses the oblique lag screw and has a slight cloverleaf cross section for additional stability. They have also developed the Delta nail, intended for unreamed nailing. It is much smaller in diameter with a rounded, triangular cross section. Third-generation interlocking nails are currently in development. They are unreamed nails made of alternative materials such as titanium. The AO group has been the first to release such a nail.\textsuperscript{50}

Two other design modifications were developed with osteoporotic bone specifically in mind. The creators of the Booker nail added two distal fins instead of the distal interlocking screws. The fins were intended to prevent rotational torsion and improve stability in the soft cancellous bone. Unfortunately, the Booker nail cut out through the bone distally at only 1.5 times body weight.\textsuperscript{98} The Zickel supracondylar nail was designed for use in elderly patients with distal femoral fractures (Fig. 6–24).\textsuperscript{101} Like femoral neck and intertrochanteric fractures, distal femoral fractures are more common in osteoporotic bone. The nail was designed to be inserted open but can be used closed. The distal ends are transfixed in the condyles with screws. The Zickel nail provided good pain relief, postoperative function, and fracture union in these patients. Unfortunately, 96% showed some amount of shortening of the femur.\textsuperscript{101}

**Dynamic Nail**

Dynamism refers to a technique used to promote fracture union rather than a unique fixation device. A dynamic nail is simply an interlocking nail that has had its distal screws removed. This procedure allows the nail to control bending and rotational forces but requires the bone to support the axial loading during ambulation. As we know, the proper healing of bone requires stress forces to stimulate remodeling. Dynamism is particularly useful in axially stable frac-
tures, slow healing osteoporotic fractures, and nonunions. Dynamic loading is not routinely instituted unless there is nonunion after 6 months. By this time, adequate callus has formed to maintain alignment. Potential complications include shortening and malrotation.

**Retrograde Interlocking (Supracondylar) Nail**
The retrograde interlocking nail is a specific application used for conditions often associated with osteoporosis. Often, elderly patients have had previous hip replacements that hinder the antegrade placement of IM nails. The retrograde design is an interlocking nail that is inserted through the intercondylar notch of the distal femur rather than the traditional proximal site. There are no design features that cause it to excel in the treatment of osteoporotic fractures, and good clinical results have been reported. The nail can even be placed between the condyles of an artificial knee. Use is indicated for morbid obesity, ipsilateral femoral neck and shaft fractures, ipsilateral femoral and tibial fractures, and multiple trauma injuries. As its other name, supracondylar nail, implies, it is useful for the distal femoral fractures that are common in osteoporosis. Poor hold of the distal interlocking screws and difficult proximal locking are the two major technical problems encountered with this implant. Also, because it is inserted through the knee joint, there are potential risks of developing knee stiffness, patellofemoral degeneration, or sepsis.

**Titanium Nails**
Titanium nails have recently been developed by several companies including the AO Group of Switzerland. These nails are being designed as unreamed interlocking nails similar to the Russel-Taylor nail. Because of their popularity and initial success, they deserve special mention. In fatigue testing, titanium proves to be four times stronger than stainless steel. Therefore, a nail of the same design can have a 4 mm smaller diameter if made of tianium. Smaller nails of sufficient strength eliminate the performance benefits previously gained with the reaming of larger-diameter nails. These nails now match the strength of reamed nails while eliminating the complications of reaming such as acquired respiratory distress syndrome (ARDS) with comorbid pulmonary trauma. An additional benefit is that the elasticity of titanium closely matches that of normal bone. The decreased elasticity provides less shielding from forces that stimulate remodeling. Studies have shown less disuse osteoporosis and quicker fracture union.

**Huckstep Nail**
A nail design that did not directly develop from the original Kuntscher model was the Huckstep IM compression nail. This is a four-sided nail made of solid titanium alloy that has been designed and used specifically for complicated fractures of pathologic bone (see Chapter 27). The design of this nail is such that it has four oblique holes intended for femoral head lag screws and a series of holes spaced at 15 mm intervals throughout the body of the nail. A surgeon is thus able to stabilize the multiple pieces often seen in comminuted fractures of osteoporotic bone. The quadrilateral shape and the titanium alloy make for an extremely rigid device that is able to support the patient’s weight immediately after insertion.

Several clinical trials have shown the Huckstep nail to be as useful in practice as it is in theory. It has been used with success to treat comminuted osteoporotic fractures, oblique fractures extending the length of the femur, and other complicated fractures of pathologic bone. The union rates are excellent and there have been very few complications. The major drawback of the procedure is that it must be performed as an open procedure. For this reason, it is best used for severe fractures that would already be done as open procedures.

**Flexible Nail**
IM nailing has alternatively been performed with flexible rods and pins with small diameters, uniform curvature, and variable lengths. Multiple pins are inserted into the medullary canal and arranged such that they transverse the fracture site. Stability is achieved in two ways. First, the pin, with its curve and its elastic properties, creates a springlike mechanism that will cause the pin to wedge itself into the canal. Second, multiple devices are inserted into the canal until it is literally packed with pins. The friction from this packing stabilizes the fracture site.

Originally, Ender pins showed promising results for treatment of osteoporosis. It was later documented that the pins would leave behind unstable fractures and occasionally create an additional longitudinal cortical fracture. The problem is that the technique depends on the size of the medullary canal and the integrity of the outer cortex. If too few pins are used in a large canal, the fixation is unstable. If too many pins are inserted, the internal stress will overload the cortex and a secondary fracture will occur. It has also been noted that axial loading at less than body weight will push the pins back through the insertion. Of all available IM nailing, Ender pinning was found to have the worst prognosis for healing and complications when used in osteoporosis.

A rectangular IM nail was originally reported by a Chinese group. The study showed that excellent results were achieved with use of this flexible, rectangle-shaped IM nail (Fig. 6–25) in the treatment of 171 tibial and fibular shaft fractures in a series of 165 pa-
tients. Mechanical analysis showed improved fracture stability compared to fractures treated with Ender nails. This method suits osteoporotic tibial fractures because it does not need reaming, occupies the IM canal efficiently, and provides rotational stability.

**Expandable Nail**
The expandable Marchetti-Vicenzi IM nail may be beneficial in osteoporotic tibial fracture because its multiple pretensioned pins expand to occupy the outermost areas of the IM canal (Fig. 6–26). This feature adds rotational stability to the fixation.

**Inflatable Nail**
The newly developed FIXION™ IM nail (Disc-O-Tech, Israel) is an expandable stainless steel device designed for the fixation of long bone fractures. The nail is inserted in its narrow configuration to the bone medulla and expanded once in position (Fig. 6–27). The implantation procedure is shorter in comparison with that of other IM nails and X-ray exposure is minimized. The device has been CE marked for several years and is now cleared by the Food and Drug Administration for sale in the United States (see Chapter 30).

**Polarus Nail**
A special nail that needs to be mentioned is the Polarus nail, which is suitable for complicated osteoporotic proximal humeral fractures. With its distal locking screws the fixation is stable (Fig. 6–28). The multidirectional screw hole at the proximal end facilitates screw fixation of multiple fractured bone fragments.

**BIOMECHANICAL ISSUES IN OSTEOPOROSIS AND IM NAILING**

**Reaming**
Like many other medical procedures, IM reaming is routinely performed on patients receiving nails despite the existence of significant risk. It is well known that medullary cortical reaming weakens bone by decreasing torsional strength. There is damage to the endosteum at the drill site, which leads to damaged local blood supply and possibly microscopic damage to the surrounding bone. One study showed high IM pressures and increased temperature during the reaming process. These high pressures caused by reaming and nailing are thought to cause osseous necrosis, further contributing to weakness. Guidelines for reaming recommend that the cortex not be reamed to less than half its original thickness to pre-
serve strength. When an osteoporotic fracture is reamed, the decrease in strength is often associated with early fixation failure.\textsuperscript{100} A sufficient amount of damage may even lead to fracture comminution while reaming.

Evidence of other complications of cortical reaming is not so well delineated. One echocardiogram study found that “snow flurry” emboli were present in the right atrium with each passage of the reamer. The clinical significance of these findings is unknown but could lead to pulmonary complications. Indeed, supporting evidence claimed increased rates of ARDS in trauma patients who had comorbid pulmonary dysfunction. Evidence to the contrary has also been published, stating that cortical reaming caused no increases in time to union, time to weight bearing, pulmonary complications, or nail failures. These authors claimed that there was no real advantage for the patient to have an unreamed nail insertion.\textsuperscript{50}

One solution that has been developed is a reaming drill attached to a suction device. While this device does decrease IM pressures, the creation of emboli has not been studied.\textsuperscript{50} Despite some conflicting evidence, it appears that smaller, unreamed IM nails are the direction that internal fixation is heading. By nature, osteoporotic bone has a wider IM canal, which suits the use of unreamed nails. Also, with the development of titanium nails, there is no longer the concern of nail breakage that there was in the past.\textsuperscript{105} Unreamed nails appeal to surgeons especially for treatment of pathological fractures due to relative stable fixation, less blood loss, and faster operative time, although a higher incidence of perioperative complications is documented.\textsuperscript{105,115-117}

**FIGURE 6-27** Inflatable Fixion IM nail.

**FIGURE 6-28** Polarus nail fixation of a proximal humerus fracture.

**Attachment/Anchoring of Screws**

One of the most difficult problems surgeons have encountered in the nailing of osteopenic fractures is how to anchor the interlocking screws. The decreased bone density seen in osteoporosis reduces the strength and stability of the interface between the bone and screws used for internal fixation. Besides being less dense, the cortical layer that the screws depend on is much thinner in osteoporosis. With sparser trabeculation and a thinner cortical layer, the contact area between hardware and bone is greatly minimized.\textsuperscript{86} Interlocking screws either fail to gain purchase or cut out, especially near metaphyseal regions where cancellous bone cannot withstand high stresses of implant-bone interface.\textsuperscript{47} This loss of anchoring may lead to failure of internal fixation and subsequent delayed healing or non-union.\textsuperscript{98}

Past studies have evaluated screw configuration to maximize stabilization techniques. Screws should be located 2 cm from the fracture line for best stabilization. Placement this close to the defect resists axial and rotational deformation. It has also been proven that standard screws placed at a 30-degree crossing angle were more stable than either a step screw or an osteoporotic bolt. Apparently, cyclical loading forces cause the standard screws to become more stable due to load sharing.\textsuperscript{118} Proximally, where an abundance of cancellous bone exists, it was shown that two transverse proximal locking screws provide more certain fixation than the previously recommended oblique locking screw.\textsuperscript{119}

Cameron et al,\textsuperscript{38} Harrington,\textsuperscript{40} and Muhr et al\textsuperscript{41} had used polymethylmethacrylate cement to supple-
ment the metal implants. Most commonly used as an anchor for screws in osteopenic bone, the material can also be used to embed the entire nail or fill small defects in cortical bone. This technique has shown promising results for osteoporotic use.98

There have been several hardware developments that attempt to correct the screw pullout problem in osteoporotic bone. One is the osteoporotic nut and washer.118 The nut and washer can prevent screw pullout by increasing contact area between the screw and bone. Another method is the spiral blade made by AO/Synthes, which significantly increases the load-bearing surface of the screw (Fig. 6–29). It has a 75% greater projected surface area than previous locking screws, which should lower osseous stress at the bone-metal interface. Their studies show that the spiral blade interlocking device was 41% stiffer and 13 to 21% stronger than the traditional locking bolt.47 If cement is used an even stronger fixation can be expected (Fig. 6–30).

Another group made the anchoring screws from a copolymeric swelling-type material. These implants are particularly effective at inducing deposition of mineral matrix at the bone-implant interface. Compared with anchors of nonswelling material the copolymer screws had approximately a three-fold increased mean peak pullout load in vitro and in vivo.120

**Nonunion**
Nonunion of the fracture site is yet another possible complication that is more frequent with osteoporosis than with traditional traumatic fractures. The most likely explanation for this disparity in healing is that osteoporosis is a disorder of deposition and resorption, the same two processes necessary to remodel and repair a fracture. This remodeling process is affected by many factors including blood supply and loading forces.

A decrease in blood supply to bone will cause ischemia and necrosis as in any other tissue. Both cortical reaming and nail insertion injure the medullary vascular system and have the potential to cause osseous necrosis. Osseous necrosis is a pressure-mediated phenomenon. The pressure elevation created with the use of guide rods and reamers approaches 1000 mm Hg. In contrast, nailing of an unreamed bone only raised pressures to 200 mm Hg. Despite being the cause of vascular destruction, a rigid implant that immobilizes the site facilitates revascularization. It has been seen that unreamed bone, such as that fixed with the Russel-Taylor and AO titanium nails, shows an accelerated rate of revascularization.98 Although vascular damage is unavoidable in IM nailing, the unreamed procedure is less damaging and promotes better recovery.

The loading forces carried by the healing bone have a tremendous influence on the ultimate stability and strength of the union. The forces that most influence remodeling are bending rigidity, torsional rigidity, and axial loading. All of these forces have a spectrum of effects on the healing process. Axial rigidity varies with the amount of linear load the implant shares with the bone. While this loading stimulates remodeling and is necessary for a stable union, too much loading force on the bone will cause excessive remodeling and a brittle final structure. This concept has been addressed by dynamization of the interlocked nail. Dynamization has proved to be an effective technique in nonunions secondary to excessive shielding.50 The bending
rigidity of the nail has similar influences on fracture healing. If a nail is too flexible, abundant callus will form but the trabecular structure is unreliable. Without some lateral bending, however, only a scant callus will form. Torsional rigidity is perhaps the most difficult vector to control in IM nailing due to the length of the implants. Without sufficient control of torsion, there will be poor fracture fixation and pseudoarthrosis. This result was seen with the use of slotted IM nails.

The new generation of titanium nails have mechanical characteristics that are beneficial for balancing these forces. The elasticity of titanium closely matches that of normal bone and should prove to provide the ideal combination of both lateral and torsional rigidity for proper fracture union. The decreased rate of secondary fracture is evidence for this theory. Faster union rates and decreased disuse osteoporosis associated with titanium nails has meant lower rates of secondary fracture. This is particularly important in the comminuted fractures so common in osteoporosis where more stress is placed on the nail and the flexion characteristics become even more important.

The issues of reaming, anchoring of screws, and the causes of nonunion must be addressed for consistent results in osteoporotic fractures to emerge. There are several areas of research and development that hold great promise for the future of IM nailing in osteoporosis. Solutions already in development are the cementing of anchoring screws, copolymeric swelling anchors, dynamism techniques, and the newer titanium nails. These techniques must be evaluated and further tested in clinical trials. Other possible solutions may include a new form of biodegradable nail that is currently being developed.

**FIGURE 6-30** (A,B) Spiral blade interlocking of IM nails used with cement for fixation of proximal humerus fractures.

**FIGURE 6-31** Cerclage systems, including (A) hose clamp, (B) titanium cable, (C,D) stainless steel wires, (E) cable tie, and (F) Mersilene tape. (The image was kindly provided by Michael Wildstein, M.D., at the Medical University of South Carolina.)
Wire or cerclage may be the first device used for internal fixation of fractures, in a procedure used by Lapuyade and Sicre in the 1970s. It has played a very important role in fracture fixation and other aspects of orthopaedic surgery. Wires or cables are only in contact with bone over small areas, and this does not significantly interfere with the local blood supply. Cerclage is presented in various forms such as monofilament or twisted or braided multifilaments of stainless steel or titanium, or steel or nylon bands (Fig. 6–31). Methods for fastening cerclage include tied knot, twist, twist plus knot, twist plus tuck, bend (AO/ASIF), and screw-fastened bend (as in metal hose clamp), which obviously depend on the system used. For single filament wire, twist is the most common method in the clinical setting. There is evidence indicating that wire diameter and fastening system are the two most important factors affecting the mechanical properties of the resulting fixation using cerclage.

Cerclage can be used for making tension bends, direct fracture fixation (Fig. 6–32), fastening plate to bone, preventing rotational instability of intramedullary devices, fixing comminuted bone fragments in conjunction with IM nailing, fixing tendon or ligament to bone, bone graft fixation, and tightening spinal bone elements. Cerclage is specifically useful for fixation in osteoporotic bone in which preserving bone stock is the primary importance or where the use of screws is impossible. Cerclage systems are often used for plate fixation (bone graft or metal plate) of periprosthetic fractures because bicortical screws cannot be employed and the mechanical quality of the bone is poor (Fig. 6–33).

A newly developed unique application of twisted wire with screws has been reported for fixation of complicated fractures of metaphyseal areas of long bones (Fig. 6–34). Twisted wires can be manufactured with premade holes for screw insertion so that there is no significant motion at the wire-screw junction. Compared to other heavier devices, this system preserves local blood supply.

**PINS**

Direct pin fixation (or transfixation) of fractures is a well-established method. The pins are made of metal, bioabsorbable materials, or even allograft bone (Regeneration Technologies, Inc., Alachua, FL).
Method can be used alone or in combination with other devices such as wire for making tension bends. Pin fixation is mostly applied percutaneously although open procedures are often used. It does not significantly damage blood supply and has no significant stress-shielding effects. The disadvantage of this method is that the fixation is less secure, so other devices are often used for reinforcement. K-wires have been often used for fixation of small bone fractures, proximal humeral fractures (Fig. 6–35),112,128 distal radial fractures, and distal fibular fractures.129

There is a recent report on a creative use of K-wire with screws as a unique device: Fixclip (Fig. 6–36).130,131 The results of the first 280 fixations with the Fixclip systems are reported by Baker.131 The intended advantages of increased fixation accuracy and versatility have been realized. Two hundred fifty-four fixations have been followed-up to union; there have been three deep infections, two persistent nonunions, and 12 fixation failures requiring revision. A range of sizes has allowed use of the system with screws from the small and basic fragment sets with wires from 1.2 to 3 mm diameter. Its indications include the management of pediatric conditions, intraarticular fractures, fractures in osteoporotic bone, and as a blade plate substitute. It is a biologically and mechanically effective means of bone fixation.

**Memory Alloys**

Shape memory alloys (SMA) are a group of alloys having shape memory effect, the ability to return to their original shape after the environment temperature rises to a certain level (i.e., 37°C). Their shape...
can be changed easily at low temperature (i.e., 0 to 5°C). Buehler was among the first to find the shape memory feature of Ti-Ni alloy in the late 1950s. It was first used in oral and orthopaedic settings in China in the early 1980s.

SHAPE MEMORY ALLOY COMPRESSIVE STAPLES

An SMA compressive staple or clamp was designed by Yang et al in the early 1980s and has been used in their clinic with significant success. The device consists of a 1.5 mm diameter central portion with two legs made of Ti-Ni memory alloy (Fig. 6–37). It is suited for use in many kinds of fractures or osteotomies of non-weight-bearing and weight-bearing bones, or even intraarticular fractures. It has the advantage of preserving blood supply because periosteum stripping is not necessary for the procedures. A similar clamp was also used for bone fixation of mandibular fractures.

SMA CLAMP-ON BONE PLATES (EMBRACING FIXATORS)

In the early 1990s, clamp-on bone plates (embracing fixators) made of memory alloy were first reported by two Chinese groups. The plate developed by Yang et al was specifically for treating short tubular bone fractures. It consists of a curved plate body with three finger-like projections on each side. The sawtooth-arm internal embracing fixator reported by Dai et al is made of Nickel-Titanium shape memory alloy and consists of three components: body, arms, and sawteeth (Fig. 6–38). In cross section, a two-thirds circumference is made by the body and arms of the fixator. The free ends of the arms are bent more medially so that the plate can match the requirement of fixation of long tubular bone whose cross section is not a regular circle. There are two types of embracing fixator: the cylinder type is for use in the middle part and the cone type is either for the proximal or distal one third of the shaft of long tubular bone. The animal experimental studies and in vitro mechanical tests demonstrated that the embracing fixator possesses good antibending and antitorsion effects, and its resisting compression effect was much lower than that of bone plate. These characteristics are beneficial for enhancing fracture healing, reducing postfixation osteoporosis, and providing a new, simple, and effective method for the treatment of long tubular bone fracture. The fixator has already been used in the treatment of femoral, humeral, radial, and ulnar fractures with promising results.

SMA LONG BONE FIXATORS

An upper limb tubular bone fixator made of shape memory alloy was designed by Zhang et al in 1987 and their clinical report was published in 1993. The device is made of two longitudinal compression limbs and two to eight semicircular fixation limbs (Fig. 6–39). Based on the design, these fixators have the advantage of preserving blood circulation with the effect of compression at the fracture site. Due to their slim size, they are mainly used for upper limb tubular bone fractures or osteotomies.

PATELLA FIXATOR

According to He, a patella fixator was designed by Zhang et al in 1986. The fixator is composed of one to two upper and two to three lower fixation limbs. It has been used for treatment of different types of patellar fractures.
Bone Grafts as Fixation Devices

Bone grafting is one of the most common methods of internal fixation. The graft can be used alone or in combination with internal and external fixation devices. The ideal graft for best healing is still the autologous bone graft. Due to the lack of autologous donor bone, allograft bone has been used widely. In certain applications, such as revision total hip surgery where large pieces of bone are required, allograft is still the number one choice because of its availability and reasonably good outcome. Revision of a femoral component in a patient who has severe bone loss is a complex problem that is likely to increase with the increasing numbers of patients who have multiple revision hip arthroplasties. Long stem prosthesis plus bone allograft is a common procedure for these conditions. Long-term results are good and encouraging. For knee revision with significant bone loss, large bone graft has been used but there is no long-term report yet available. There are many concerns about the long-term outcome of major bone grafting, but sometimes it is the only recourse for achieving satisfactory revision.

Cement and Composite

There are two kinds of bone cements for orthopaedic procedures, conventional cement (PMMA) and bioabsorbable composites. Both cements can be used for direct fixation of fractures, augmentation of fixation devices, and vertebroplasty.

Direct Fixation of Fractures

Bioabsorbable cement has been tested for fixation of compressed tibial and calcaneal fractures. Mechanical testing data by Yetkinler et al. have shown that the treatment of depressed tibial plateau fractures with calcium phosphate cement provides equivalent or better stability than conventional open reduction and internal fixation in pure depression tibial plateau fractures. If the fracture void is prepared by eliminating the cancellous bone under the subchondral plate, the results are further improved.

Augmentation of Fixation Devices

Cement augmentation is a very useful technique for fixation of implants such as screws, plates, or IM nails in osteoporotic bone. Generally, cement augmentation features increased strength of implant fixation, rapid restoration of patient mobility, and reduction of the complications of implant failures. Besides PMMA, bioabsorbable cements, such as Norian SRS cement, have also been used for augmenting implants.

The cement can be introduced into the medullary canal through the fracture site or through the screw hole. The screw hole can be made larger than the screw to hold cement before screw insertion. Often, the screw is inserted while the cement is still soft, and tightened after it is hardened. If cementing screws are used, the cement can be injected through the canal in the center of the screw (Fig. 6–41). The advantage of cementing screws is
the intimate screw-cement interface, which increases the holding power.15

An early report by Ker et al.153 showed the use of cement as an adjunct to medullary nailing in fractures of the distal third of the femur in elderly patients. Their results demonstrated that the use of cement with IM nails significantly enhanced fracture fixation, shortened hospital stay, and improved the quality of life.

**Vertebroplasty and Kyphoplasty**

Because current treatments of osteoporotic vertebral body fractures are less than adequate, there is a need for interventions that decrease the likelihood of occurrence of these fractures and improve the treatment options once they have occurred. One such intervention is cement augmentation of the vertebral bodies, vertebroplasty.43,154–156 In addition to prophylactically stabilizing osteoporotic vertebral bodies at risk for fracture, augmentation of vertebral bodies that have already fractured may prove to be useful

![Figure 6-40](image1)  
**FIGURE 6–40** Cement augmentation of screw fixation. The cement can be introduced into the medullary canal through (A) the fracture site or (B) the screw hole before (C) screws are inserted.

![Figure 6-41](image2)  
**FIGURE 6–41** Cement augmentation of screw fixation. Note the cement is injected through the canal of the screw. This is a new design by the authors for plate fixation, which has not yet been tested.
by reducing pain, improving function, and preventing further collapse and deformity. Vertebral body augmentation can also be used as an adjunct to fixation of internal hardware—for example, pedicle screws in osteoporotic spines.146

A number of products are now available or are in clinical trials. The most promising products are injectable materials, PMMA, or ceramic bone cements. The early clinical results using PMMA in percutaneous vertebroplasty for fractured vertebral bodies are encouraging.157 More injectable bioabsorbable cements or materials for vertebral body fortification have appeared in the recent literature, including calcium phosphate,158,159 glass-ceramic-reinforced Bis-GMA/BisEMA/TEGDMA matrix composite,160 carbonated apatite,161 and osteoconductive granular material.162

Compared to vertebroplasty, the advantages of kyphoplasty163 include better pain relief, more certain height restoration, better stabilization of acute fractures, and low risk of cement leak. It can be used as a first-line approach whenever technically feasible (see Chapter 34).

**Bioabsorbable Materials**

Since the beginning of the development of bioabsorbable materials by Kulkarni et al164 in the 1960s, bioabsorbable devices have been utilized and experimented in many aspects of orthopaedic surgery, including fixation of fractures, bone replacement, cartilage repair, meniscal repair, fixation of ligaments, and drug delivery.165–168 Absorbable materials have been used in the form of screws, pins, plugs, and plates for orthopaedic, oral, and craniofacial surgery. However, the major clinical orthopaedic applications thus far are fixation of fractures and osteotomies and interference screws for ligament repairs.167 Depending upon their constituent polymers, these materials can be tailored to provide sufficient rigidity to allow bone healing, retain mechanical strength for a period of time, and then eventually to undergo degradation. The material properties of the ideal polymer are a delicate balance between mechanical, thermal, and viscoelastic factors. The earliest and most commonly used absorbable materials include polyglycolic acid (PGA), polylactic acid (PLA), PGA-PLA copolymers, and poly(ortho esters).

Bioabsorbable fixation devices can be used in many fractured bones in adults, including glenoidal rim, proximal and distal humerus, olecranon, radial head, distal radius, hand bones, femoral head and neck, femoral condyles, patella, upper tibia, ankle bones, talus, calcaneus, metatarsal, and phalanges of the toes.

The advantages of bioabsorbable implants make them beneficial in management of osteoporotic conditions needing internal fixation. By using bioabsorbable devices, rigid metallic implants can be avoided, which could cause further osteopenic changes to the fixed bone. Bioabsorbable fixation devices have been in clinical use only for about 15 years. The cumulative number of operations with self-reinforced bioabsorbable implants in orthopaedics has exceeded 300,000 cases. It is likely that the number of surgical applications will continue to increase in both orthopaedics and other surgical specialties.167,168 Bioabsorbable devices have great potential in fixation of osteoporotic fractures but need more investigation.

**Fixation Devices for Osteoporotic Spine**

**Screws for Spine Fixation**

Screw fixation of the thoracolumbar spine has been a popular method of fixation for over a decade. The most common form of fixation has been posterior transpedicular insertion with attachment of the screw to longitudinal connectors such as plates or rods.169,170 Other forms of screw fixation that are less commonly used include facet screw fixation, external fixation, anterior screw fixation as a buttress for graft material, and transpedicular fixation into the adjacent vertebral body for spondylolisthesis.171,172 These other forms will not be discussed in this section.

The importance of the relationship between quality of screw fixation and bone mineral density has been observed in multiple clinical and mechanical studies. Some authors consider severe osteoporosis to be either a contraindication for screw fixation or a source of failed fusion.173,174 Others have reported immediate loss of fixation or inability to obtain fixation due to the presence of osteoporosis.175,176 In an early biomechanical study, Zindrick et al175 evaluated the pullout and cyclic loading characteristics of different screw sizes, designs, depths, and types of insertion. Although they found some differences related to other mechanical factors, they noted that the degree of osteoporosis, though very difficult to quantitate, was the factor that appeared to have the greatest effect upon screw fixation.175 They were unable in their study to fully quantify the bone density. Wittenberg et al177 characterized this relationship more clearly. They evaluated two fixation systems with different-size screws and types of insertion in a human cadaver model. Both pullout and cyclic loading were tested. Quantitative CT scanning was used to evaluate bone mineral density. Multiple screw loosening was noted in specimens with a density of 74 ± 17
mg/cc, single screw loosening with a density of 88 ± 12 mg/cc, and no screw loosening with a density of 114 ± 38 mc/cc. They concluded that “screw design is a less important factor for bone-screw interface strength than bone density.” In another study looking at various screw designs in fixation of synthetic long bones, DeCoster et al found a linear relationship between pullout force and synthetic bone density.

Catastrophic failure of screw fixation such as direct pullout can occur (Fig. 6–42), but the more common presentation is loosening at the bone-screw interface, likely due to cyclic loading rather than a single mechanical load (Fig. 6–43). As discussed above osteoporotic bone presents a significant obstacle to adequate screw fixation. Therefore, if a high clinical success rate is to be achieved all mechanical factors should be optimized in the osteoporotic patient.

Although the type of thread may be of little importance as it relates to osteoporosis, larger diameter screws should be used both to increase pullout strength and to allow for fixation to include the endosteal surface of the pedicle. This cortical surface is less severely affected by osteoporosis and may be more important than the cancellous bone of the vertebral body for screw fixation. Zindrick et al noted greater pullout strength for screws that obtained cortical purchase within the pedicle. Chiba et al, in a study looking at bending moments and supplemental hook fixation, felt that “fixation of the screws may depend more on interaction with the endosteal cortical bone in the pedicle than on fixation in the cancellous bone of the vertebral body.” These findings are disputed somewhat in a study by Brantley et al, who noted that the percent fill of a pedicle in osteoporotic vertebrae did not correlate with improved fixation. One weakness of this study is that all osteoporotic vertebrae came from a single specimen. All of these studies used a cadaveric model. Direct clinical verification of this concept is lacking.

Screw position in the vertebrae may also be relevant. Krag has described the “up and in” method of insertion. This allows longer screws to be placed, increasing the area of bone-screw contact, and enables them to be placed in a nonparallel fashion in two planes. Placement of nonparallel screws resists lateral shifting of the upper vertebrae in the construct (Fig. 6–44). If the surgeon feels comfortable with the technique, anterior penetration of the vertebral body with the screw also increases the pullout force in a cadaver model.

Hole preparation for screw placement becomes more important when osteoporosis is present. Undertapped or untapped screw holes lead to an increased pullout strength in osteoporotic bone. Al-
though the pullout strength was still far less than the values found in normal bone, the pullout strength more than tripled when a screw hole was under-tapped rather than tapped to the size of the screw in a cadaveric model.\textsuperscript{182} Maximal torque on insertion of the screw also seems to be a factor in stability of screw placement but this may be more dependent on the quality of the bone rather than insertion technique.\textsuperscript{183}

A number of augmentation techniques within the pedicle have been described to supplement screw fixation in the pedicle as well as for salvage of stripped screws. PMMA will restore pullout force to normal in a stripped screw hole in bone of normal density.\textsuperscript{175} When the cement was pressurized it was noted to “mushroom” under the pedicle, creating a mechanical environment similar to a toggle bolt inserted into drywall. The problem with this is that it will increase the risk of contact with neural elements if the pedicle has been violated during screw hole preparation. Soshi et al\textsuperscript{184} found that the addition of PMMA to tapped screw holes increases the pullout force in osteoporotic bone as well, but if the bone density was less than 0.5 g/dc\textsuperscript{2} the pullout force was low regardless of screw size or augmentation technique. Halvorson et al\textsuperscript{182} packed stripped screw holes with corticocancellous bone chips and found a significant increase in the pullout strength for normal bone but not for osteoporotic bone. Moore et al\textsuperscript{185} used calcium phosphate cement that hardens in situ and has been found to be biocompatible and resorbable. They used a stripped screw model and found that this cement compares favorably to PMMA in pullout testing. Two cc of each substance were injected using a nonpressurized technique. Although they did note that the vertebrae were “senile” they did not specify the density of the tested vertebrae.\textsuperscript{185} Lotz et al\textsuperscript{186} described the use of an injectable carbonate apatite cancellous bone cement in to a tapped screw hole. This cement has the advantage of being minimally exothermic. Pullout strength was significantly increased (70\%) when compared to a control screw inserted without cement. They noted that augmentation resulted in a 50\% decrease in stiffness and greater than 70\% increase in energy absorbed during cyclic loading. They found that bone mineral density did not play a statistically significant role in the variance \((P >0.09)\).\textsuperscript{186}

Coating of pedicle screws has also been reported. Lapresle and Missenard\textsuperscript{187} reported on their clinical use of a hydroxyapatite-coated screw for a number of different spinal pathologies. Included in this study were seven patients with “severe osteoporosis.” Although the bone density measurements are not reported, all seven patients were reported to have done well.\textsuperscript{187} A potential disadvantage of this technique may be difficulty of screw removal should it ever be indicated.

Another screw modification uses a cannulated, fenestrated screw through which PMMA is injected. This has compared favorably to a screw inserted into a tapped hole filled with PMMA immediately prior to screw insertion.\textsuperscript{15} A cadaveric model was used for this screw in vertebrae with documented low bone mineral density. Screws were placed in the vertebral body rather than via a transpedicular approach. Pullout testing showed a 278\% increase in pullout strength when comparing the cannulated screw to a solid screw placed in a tapped hole augmented with PMMA.

Anterior to posterior transpedicular screw fixation has been described both in a cadaver model and in a small number of patients.\textsuperscript{188,189} This technique has potential significant mechanical advantages but has yet to be tested as it relates to osteoporosis.

\textbf{HOOKS}

Hook fixation has a long history in surgery of the spine. Harrington popularized surgical correction of scoliosis using hooks attached to the posterior elements and multiple modifications have since been made.\textsuperscript{190} Hooks can be placed on the superior or inferior side of the lamina, the superior side of thoracic
transverse processes, or into the thoracic facet joints along the inferior aspect of the pedicle.

Mechanical studies have shown laminar hook constructs to be more resistant than both wires and pedicle screws to posteriorly directed pullout in the thoracic spine in the presence of osteoporosis.\textsuperscript{191,192} This may be due to the relative sparing of the posterior elements to severe bone density loss when compared with the vertebral body. An interesting finding in the study by Butler et al\textsuperscript{191} was that sublaminar wires failed at much lower stresses than had been previously reported (approximately 350 N vs. approximately 200 N).\textsuperscript{191} This was postulated to also be due to the lower bone density.

A number of studies have looked at the combination of hooks and screws (Fig. 6–45).\textsuperscript{179,193,194} All the studies demonstrated significant improvement in strength and stiffness when laminar hooks were added to constructs using pedicle screws, and it was felt their value is greatest in weaker bone such as that seen in osteoporosis. Although the design of the testing and the constructs varied between the studies, the finding of improved mechanical strength with this technique was consistent. Several explanations for this have been given including: (1) supplemental hook fixation reduces the stress on the screw-bone interface, (2) the posterior elements are less affected by osteoporosis and therefore maintain their structural integrity, and (3) the addition of supplemental hook fixation lengthens the construct, providing more resistance to bending moments.

**FIGURE 6–45** Infra- laminar hook added to pedicle screw construct.

**FIGURE 6–46** Sublaminar wire fixation.

**Wires**

Wire fixation without other mechanical support is not commonly used in the thoracolumbar spine. Wire fixation has a long history of success in the cervical spine, including its use in conditions such as rheumatoid arthritis, a disease that is often accompanied by decreased bone density.\textsuperscript{195} Clinical studies of wire fixation in the cervical spine generally do not discuss the relationship to osteoporosis.

Rod and wire constructs have been commonly used in the thoracolumbar spine for deformity correction, fracture fixation, and degenerative disorders. Wires can be placed in a sublaminar fashion or through the spinous process (Fig. 6–46). In the thoracic spine, where transpedicular fixation is less commonly used, sublaminar wires are a reasonable alternative to hook fixation. Although the mechanical testing reported by Butler et al\textsuperscript{121} argues against their use, it has been noted by Hu\textsuperscript{196} that sublaminar wires have been commonly used for correction of neuromuscular deformity, which is often accompanied by low bone mineral density.
Fixation Devices for the Osteoporotic Pelvis

The sacrum and pelvis present difficult problems regarding fixation when osteoporosis is present. Fracture of the osteoporotic sacrum is also reported but seems to be less common than in the mobile spinal segments. Little if any biomechanical testing of spinopelvic fixation has been performed as it relates to bone mineral density. The lamina of the sacrum is often quite thin, therefore screw rather than hook or wire fixation is generally used. Screw fixation can be transpedicular, directed laterally into the ala of the sacrum, into the iliac crest, or across the sacroiliac joint. Rod or screw placement into the ilium and the sacrum has also been employed to increase fixation. Allen et al described the “Galveston” technique of bending rods and placing them into the ilium at the level of the posterior superior iliac spine. Asher et al employ a bolt placed in a similar direction that can be attached to a rod (Fig. 6–47).

Other techniques include posterior sacroiliac screws connected to rods as well as rods impacted into the body of the sacrum. All of these techniques are intended to provide a stronger anchor to the pelvis by increasing bony purchase and providing a larger base for the remainder of the construct. Another technique has been described in which a contoured rod is placed over the sacral ala and held to the pelvis by distraction. This has the advantage of no violation of cortical bone and not needing any of the weaker cancellous bone for its support (Fig. 6–48). Although attractive for use in the osteoporotic pelvis, lumbar lordosis is jeopardized due to the distraction often required to seat the rod onto the ala.

Summary

Fracture fixation in osteoporotic bone has presented a challenge to orthopaedic surgeons since the fixation methods were first available. Major principles for fixing osteoporotic bone include devices with better bone purchase, long splintage, wide buttress, cement augmentation, IM nailing, and preservation of blood supply. Although tremendous efforts have been recorded to conquer the problem, there are no simple solutions. The evolution of techniques of internal fixation continues. Orthopaedists and researchers are continuously modifying existing procedures and trying to find new methods for fixation in osteoporotic bone. In the clinical setting, diagnosis of fragile bone conditions when using internal fixations is critical. Serious consideration and careful preparation and planning are essential for successful fixation in osteoporotic patients. Because easy surgical solutions or breakthroughs are less likely, prevention and medical treatment of osteoporotic conditions and osteoporotic fractures are the major hopes, if not the only ones.

References


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Restoration of best possible function is the common aim of fracture treatment. For the senior population special considerations are given to the possible ways to obtain the desired functional restoration. Treatment options can differ significantly from those applicable to a young adult. The main difference is the quality of the bone and hence the potential of obtaining a secure purchase of the available fixation devices. Further difficulties may arise if the patient’s ability to cooperate is reduced as overload of the compound system may lead to failure.

Preoperative planning begins with the definition of realistic goals. Rapid restoration of mobility should be the most important short-term goal in this group of patients. The relative merits of conservative versus operative treatment should be carefully weighted. If operative treatment is chosen, the procedure selected should be the least invasive, yielding a low complication rate and warranting an adequate long-term outcome.

As in general fracture treatment the correct balance between mechanical stability and preservation of bone perfusion is the key issue to obtain a successful osteosynthesis. This is embraced by the term “biological osteosynthesis.” The reader is referred to Mast and coworkers’ classic work where the essentials of minimal exposure and indirect reduction techniques are exposed.

Fractures of the lower extremity require a fairly stable fixation because early mobilization is the main concern. Operative treatment is generally indicated to avoid restrictive and dangerous immobilization. The main dangers of immobilization arise from cardiopulmonary and thromboembolic complications. Given the difficulties the elderly may have in complying with limited weight-bearing protocols, any osteosynthesis must be stable enough to resist the occasional uncontrolled full weight bearing. Alternatively the fixation must be externally protected, inevitably losing some of the benefits of early mobilization.

For fractures of the upper extremity conservative treatment is indicated in a large number of patients. Splints, casts, or bandages do not excessively limit ambulation, provided that the lower extremities are functional, although the marginally autonomous patient may become temporarily or permanently dependent and therefore requires special consideration. It may be necessary to treat upper limb injuries operatively to allow a marginally compensated patient to remain in his usual environment or to facilitate the use of crutches and similar devices in multiply injured patients.

**PRINCIPLES OF INTERNAL FIXATION OF OSTEOPOROTIC BONE**

Since the impaired anchorage of the implant jeopardizes osteosynthesis of osteoporotic bone, solutions are directed toward increasing the stability of the compound system by transferring more load to the bone thus relatively unloading the implant. The implant should be used in a load-sharing rather than in a load-bearing configuration. A complementary approach is the modification and adjustment of the implants to the specific requirements of osteopenic bone.

In the diaphysis, osteoporosis is associated with a reduction of cortical thickness and an increasing width of the medullary cavity. Also, the material properties of cortical bone deteriorate with increasing age and the bone becomes increasingly brittle, which may lead to micro- and macrocracking when standard screws are inserted. Both processes will reduce the holding strength of cortical screws. It has been shown that reduction of cortical thickness and the inclination of screw threads are directly propor-
tional to the holding strength. These findings have led to extensive basic research to optimize screw design. Morphologic and mechanical changes of cancellous bone are also of concern. The main process is rarefaction of trabeculae. Initially, a relative thickening of the mechanically relevant trabeculae might compensate for the general rarefaction. With time the remaining trabeculae will gradually be resorbed. It is essential to understand that screw purchase in advanced osteopenia relies essentially on the thin shell of peripheral cortical bone and not on the cancellous trabeculae. A pertinent comparison can be made with a fractured egg shell that requires a wide buttress (using an eggcup for instance) to provide adequate support. Oversized, stiff, and nonforgiving implants should be avoided. It is preferable to use elastic fixations that may temporarily give way and that are better adapted to the weak bone.

For practical purposes, basic principles of internal fixation in osteoporotic bone are: impaction, wide buttress, long splintage, bone augmentation, and bone substitution (Fig. 7–1).

The chosen method should be as forgiving as possible and should allow the inevitable occasional overload imposed on the construct by a marginally cooperating patient.

**Impaction**

Impaction is a key factor in stability. In many cases impaction is created by the trauma itself. A typical example is the valgus impacted abduction fracture of the femoral neck. The primary stability induced by impaction of the fragments may be sufficient for functional rehabilitation. Also valgus impacted fractures of the proximal humerus, impacted fractures of the distal radius, and compression fractures of the vertebral bodies generally have sufficient stability for functional rehabilitation. Taking advantage of the benefits of impaction is a useful concept that should be applied in the osteosynthesis of osteoporotic bone whenever possible. For instance, the strength of fixation of pertrochanteric fractures may be significantly improved when impaction of the main fragments is obtained previous to the application of the definitive fixation device. In practical terms this can be achieved by the following steps: (1) preliminary reduction of the main fragments (abduction and internal rotation); (2) preliminary fixation with Kirschner wires; (3) impaction of the main fracture fragments using a broad impactor (a conventional slotted hammer will do) placed over the trochanteric region and hit with a heavy mallet. Following impaction a suitable implant such as a hip sliding screw may be used. Controlled impaction can also be achieved by deliberately tensioning internal fixation devices (plate, wire, or nail). One should consider that compression of fracture planes dramatically increases the stability of the compound system. The concept is to shift from a load-bearing to a load-sharing constellation thus relatively unloading the implant.

Controlled impaction can also be planned to occur in the postoperative phase, as is the case for a number of K-wire fixations and endomedullary fixations. The concept of postoperative gradual and controlled impaction has several advantages. The main advan-

![FIGURE 7–1](image-url) Four basic principles to obtain stable fixation of osteoporotic bone.
The concept of wide buttress applies to epiphyseal and metaphyseal fractures. The aim is to support the weak bone with a wide internal fixation device, which will act like a spoon impeding dislocation. Special implants with large metaphyseal surface are available, such as the buttress plates for the proximal tibia and the distal radius.

Very efficient wide buttressing can also be obtained inside the bone. An example is the angled blade plate. As far as axial and rotational stability is concerned a blade is far better than a gliding screw. For supracondylar femoral fractures, which in the presence of osteoporosis typically have a long spiral element, the condylar plate is the implant of choice.

The antiglide plate as proposed by Ellis and Brunner and Weber is an excellent example of a simple buttress. It is used as a means of reduction, taking advantage of the mechanically most favorable position for the given fracture. The reduction is held by the springlike effect of the protruding plate segment. This principle can be applied to any epiphyseal fracture.

The tension band principle can also provide a wide buttress. Two K-wires, connected by a tensioned cerclage wire, provide excellent stability in the epiphyseal and metaphyseal areas, especially when compared to screw fixation. Should the bone be so soft that the wire cuts through, a cannulated screw may be used to augment the bore canal. The wire can then be passed through the cannulated screw, which dramatically augments the strength of the fixation.

LONG SPLINTAGE

For supraperiosteal fractures, which in the presence of osteoporosis typically have a long spiral element, the condylar plate is the implant of choice.

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screws. Long plates may compensate for the reduced holding power of screws in osteoporotic bone. Typical examples are long torsion fracture of the femur (Fig. 7–2) and the humerus (Fig. 7–3).

Intramedullary nailing represents a very efficient form of long splintage (Fig. 7–4). If used for the correct indication, it is the best option to achieve early weight bearing. Unfortunately, the ideal fractures for intramedullary nailing, that is short oblique and transverse fractures in the diaphysis, are rare in the elderly patient. The use of interlocked nails for metaphyseal fractures is critical. The broad cavity, the poor cancellous bone, and the thin cortical shell are relative contraindications for nailing in the metaphyseal segment. Fascicular nailing is more appropriate in soft bone, especially for metaphyseal stabilization. It is useful in fractures of the humerus where its indications can be extended to the proximal epiphysyal area. For fractures of the proximal femur fascicular nailing as proposed by Ender8 is losing popularity, due to its poor inherent stability. For the nonambulatory patient it remains a viable, minimally invasive alternative.

The principle of long splintage can be also applied to the osteoporotic spine. Fractures of the vertebral bodies that cause neurologic deficit, although rare in osteoporotic bone, need rapid decompression and stabilization. Transpedicular systems in osteoporotic vertebrae often have impaired screw anchorage, even when augmented with bone cement. Sufficient stability can be achieved with multisegmental fixation above and below the fractured vertebra.

**Bone Augmentation**

An increasing number of bone augmentation materials are proposed for treatment of osteoporosis-associated fractures.

The widest used and best known is bone cement or polymethylmethacrylate (PMMA). Although it has drawbacks such as monomer toxicity, exothermic polymerization reaction, and nonresorbability, PMMA can be used to enhance screw fixation or as a mechanical spacer to substitute for missing bone. When screw fixation is insufficient, the introduction of a limited amount of PMMA in the screw hole, locally filling the medullary cavity, is a very effective technique. After introduction of the cement using a narrow syringe, the screw is partially inserted then fully tightened after hardening of the cement.9 The torque that can be obtained is comparable to the torque in normal bone. When using bone cement in this manner10,11 fracture healing is essentially undisturbed. One must be aware that interposition of cement into the fracture zone will impede healing and should be avoided.
Metaphyseal and epiphyseal defects may become apparent only after reduction of the fracture. Bone cement may be used to fill these defects, particularly if the availability of good-quality autogenic bone graft is limited (Figs. 7–5 and 7–6). If a relevant cortical defect is filled with cement, a thin layer of autogenic cancellous bone should be laid on the exposed cement to encourage bridging consolidation. Again, cement should not be interposed in the main fracture planes, where it would prevent healing.

For larger defects it is preferable to include an intramedullary plate or nail in the cement bolus. This enhances primary and long-term stability, acting like an armature in a concrete wall. The technique has proven valuable for pathologic fractures in metastatic disease and is increasingly used for pathologic fractures in massive osteoporosis.

For compression fractures of vertebral bodies vertebroplasty represents a minimally invasive and efficient treatment option. Under image intensification and local anesthesia, a needle is placed transpedicularly in the vertebral body. The deformity may be corrected using an inflatable balloon, then PMMA is injected taking care to avoid penetration of the spinal canal (Fig. 7–7). The patient immediately feels the obtained stability.

Other bone augmentation materials, such as calcium phosphate/brushite cements, hydroxyapatite granules, glass-ionomer cements, and others, are currently in clinical evaluation. The improvement of screw fixation obtained with brushite cement compares favorably with PMMA. Hydroxyapatite has been used to fill bone defects and induce bone formation. The main disadvantage of hydroxyapatite for this purpose seems to be its poor mechanical properties. The glass-ionomer cement has theoretical advantages over PMMA, including low-temperature polymerization, little shrinkage, and excellent bone bonding. Clinical evaluation is still incomplete.

**Bone Substitution**

A special form of treatment in the osteoporotic bone of the elderly patient is the replacement of the fractured bone segment with a prosthesis. This option is particularly frequently used for fractures of the femoral neck and the proximal humerus (Fig. 7–8). Less frequently the knee and the elbow can require arthroplasty for treatment of fractures that cannot adequately be stabilized by conventional means. In humeral head replacement arthroplasty, adequate...
stabilization of the osteopenic tuberosities is a critical issue (Fig. 7–8). The use of simple sutures has been shown to be insufficient, although there is laboratory and clinical evidence that a wire cable tension band construction is able to withstand functional stresses. Should the cables have a tendency to cut through the bone, the additional use of cannulated screws can be useful.

Indication for prosthetic replacement in general must be carefully assessed. The expected functional benefit should be weighed against possible complications.

**FIGURE 7–5** Lateral tibial plateau impression fracture in a 78-year-old man. A large bone defect resulted after reduction of the articular surface. Filling the defect with autogenous bone graft is problematic in advanced osteoporosis because of the limited availability of the graft. Substitution of the missing bone with methylmethacrylate offers an adequate and primarily stable alternative.

**FIGURE 7–6** Lateral tibial plateau impression fracture in a 74-year-old woman. Reduction was preliminarily stabilized with screws. Filling the defect with methylmethacrylate afforded sufficient stability for functional rehabilitation.
FIGURE 7–7  Acute compression fracture of the second and third lumbar vertebrae in a 71-year-old man. The deformity was corrected with an inflatable balloon (kyphoplasty), and the resulting defect was filled with methylmethacrylate (vertebroplasty).

FIGURE 7–8  Four-segment fracture of the proximal humerus in an 81-year-old man. The osteoporotic and ischemic head was replaced with a prosthesis. Stable fixation of the tuberosities was obtained with cerclage cables.
DEVELOPMENT OF SPECIFIC IMPLANTS

Recently considerable effort has been made to adapt the implants to the specific needs of osteoporotic bone. Research has focused on possible ways to increase the purchase (holding strength) of screws, to better adapt the implants to the weaker bone and to strengthen the interface between implant and bone. The primary move was to modify the tread geometry of the screws. Interestingly, a finer, “metal screwlike” design was shown to be superior rather than a larger, “cancellous screwlike” design. This can be understood considering that the material properties of osteoporotic bone are more like glass than wood. A sharply cut fine tread in a brittle and relatively thin cortex affords better purchase than a wide tread, which may only engage half the tread in the thin cortical bone. Sharp mechanical cutting of the tread seems of importance to avoid cracks (and later crack propagation) in the brittle cortex.

Implants have been made with a broader metaphyseal buttress area but with less inherent strength. The choice of titanium as a working material has allowed an increased range of elastic deformation, thus increasing the safety interval of the fixation.

Research on the interface between bone and implant has primarily focused on avoiding additional vascular damage to the cortex. The use of screws that interlock with the plate was noticed to be beneficial in osteopenic bone mainly because backing out of screws was avoided. Nevertheless caution about the implementation of interlocking screws in osteopenic bone is required because the interface between screw and bone experiences increased strain and may become the weakest link in the system.

CONCLUSION

Obtaining stable fixation in osteoporotic bone is a major challenge. Uniformly valid solutions are still missing. Therefore there is a need for more basic research. For practical purposes the principles of impaction, wide buttress, long splintage, bone augmentation, and bone substitution, are useful and represent the common basis for further development.

REFERENCES


The impact of skeletal loss becomes most vividly apparent as the skeleton begins to fail in its ability to withstand the required loads of everyday life. When this occurs, osteoporosis becomes a disease impacting quality of life and challenging survival. The severe economic consequences of this disorder also become reality.

Osteoporosis currently affects 28 million Americans. With the elderly representing the fastest growing age group in the population, this epidemic grows yearly. It is believed that osteoporosis is related to 75% of the fractures that occur in the elderly. By the year 2020 there may be as many as 500,000 hip fractures annually in the United States alone. It is clearly documented that less than 50% of hip fracture patients recover fully following their injury and treatment.

These statistics emphasize the need for skilled fracture care in these patients. A reasonable return of function following fracture in the elderly often requires aggressive internal fixation and rapid rehabilitation. Conversely, prolonged immobilization of the patient through nonoperative care increases the risk of thromboembolic disease, pulmonary compromise, decubitus ulceration, and further generalized musculoskeletal deterioration from which complete recovery is unlikely. The need for stable internal fixation in osteoporotic bone is paramount. In this chapter, strategies to achieve these goals will be reviewed and analyzed.

**General Principles of Fracture Management in Patients with Osteoporosis**

Elderly patients are best served by rapid, definitive fracture care aimed at early restoration of function. In most cases, these patients are healthiest on the day of injury and are usually in the best condition to undergo surgery within the first 48 hours of their injuries. Nevertheless, many concurrent illnesses are often present and should be thoroughly evaluated prior to surgery. In some cases, judicious preoperative medical management to reverse medical decompensations causing or resulting from the injury benefits survival. Similarly, surgical procedures should be kept simple to minimize operative time, blood loss, and physiologic stress upon these patients.

The aim of the operative intervention is to achieve stable fracture fixation that permits early return of function. For the lower extremity this implies early weight bearing. Although anatomic restoration is important for intraarticular fractures, metaphyseal and diaphyseal fractures are best managed by efforts to primarily achieve stability rather than anatomic reduction.

The primary mode of failure of internal fixation in osteoporotic bone results from bone failure rather than implant breakage. Since bone mineral density correlates linearly with the holding power of screws, osteoporotic bone often lacks the strength to hold plates and screws securely. Furthermore, comminution can be severe in osteoporotic fractures. Internal fixation devices that allow load sharing with host bone should be chosen to minimize stress at the bone-implant interface. For these reasons, sliding nail plate devices, intramedullary nails, and tension band constructs are ideal for osteoporotic bone. Finally, whenever possible, the principles of biologic fracture fixation must be applied. Adherence to these principles improves the speed with which these fractures heal, improving the odds in the race against fixation failure.
BIOMECHANICS OF IMPLANT FIXATION IN OSTEOPOROTIC BONE

INTERNAL FIXATION USING SCREWS

Resistance to pullout of a screw placed in bone is dependent upon the length of the screw purchase, the thread diameter, and the quality of the bone into which it is inserted. Recent studies have also indicated that the trabecular orientation within the bone is also important. Bone is highly anisotropic. Screws placed parallel to the trabecular pattern have greater pullout strength than those placed across the trabeculae. In osteoporotic bone, the variable of bone quality becomes the prime determinant of screw holding power. When bone mineral content falls below 0.4 g/cm², the effect of varying thread diameter is lost. Therefore, when a surgeon plans to place screws into osteoporotic bone, he or she should strive to place screws as parallel to the cancellous trabeculae as possible and should use the largest thread diameter that is compatible with the scale of the fracture being fixed. Most importantly, he should try to secure fixation into cortical bone, if at all possible. In bone of poor quality, a smaller diameter cortical screw is definitely a superior choice over a larger diameter cancellous screw, which doesn’t secure a cortical “bite.”

In cases of severe osteoporosis, the surgeon should be ready to augment screw fixation with cement. Polymethylmethacrylate is currently the only cement that has been used for such a purpose but calcium phosphate cements that are bioreabsorbable and replaced by host bone are under investigation. Polymethylmethacrylate cement has poor adhesion to bone but by intruding into the cancellous structure it results in a vastly stronger composite after the cement sets. The surgeon can predrill a screw hole, fill it with cement, allow it to cure, then redrill the hole and tap it to insert the screw; or he or she can drill, insert the cement, and follow with the screw before the cement hardens. The latter method is easier on equipment and allows the surgeon the choice of only augmenting those screws that have inadequate purchase. If this latter method is used, the surgeon should tighten the screw in the cement and allow the cement to set completely without any additional screw manipulation. Once the cement has hardened, a final tightening of the screw can be performed. Manipulation of the screw while the cement is setting loosens the bond between the cement, bone, and screw, lowering the pullout strength. Kleeman et al describe a method for use of cement, which is similar to cement techniques used for fixation of intramedullary prosthesis. This technique is most useful for situations where poor screw fixation is combined with significant bone loss.

INTERNAL FIXATION USING PLATES

The security of plate fixation is affected primarily by the degree of comminution and the resulting size of any gap at the fracture site. In addition, the pattern of screw placement influences the strains experienced within the plate and its screws. The most important factor, which reduces strain in plated fractures, is the degree to which cortical contact at the fracture site can be achieved. Experimental fractures stabilized by plates spanning a gap experience three times the strain as fractures stabilized with secure cortical contact. In addition, for a given fracture pattern the spacing of screws is more important than the number of screws used for fixation. Strain within a plated construct is least when screws are placed as close to and as far away from the fracture site as possible. Intervening screws add little to the overall strength of fixation.

These principles become extremely important when dealing with osteoporotic bone. When using plate and screw fixation in osteoporotic bone the surgeon must try to achieve cortical contact at the fracture site. If moderate areas of comminution exist then the fracture should be shortened to achieve contact, especially in the cortex opposite the plate. In osteoporotic bone plates should be used as tension bands, which require an intact, load-sharing cortex opposite the plate. In osteoporotic bone longer plates with widely spaced screws should be used. In addition, the surgeon should try to place the plates to act as “antiglide plates” whenever possible. Antiglide plates are especially useful in short oblique or spiral oblique fracture patterns. In these situations the plate can be positioned to create an axilla with the cortex at the apex of the oblique tongue of the fracture (Fig. 8–1). This position of the plate acts to prevent fracture displacement, placing less importance on screw fixation, and positions the plate nicely for insertion of lag screws, which are so important for the oblique fracture pattern.

INTRAMEDULLARY NAILS

Intramedullary nail fixation is nicely suited for osteoporotic bone, especially for diaphyseal fractures. Interlocking nails provide broad areas of purchase, allow load sharing, and provide secure enough fixa-
tion to allow immediate weight bearing. There is no question that intramedullary nailing is the treatment of choice for diaphyseal fractures of the femur and tibia. The development of interlocking nails has extended the indications for intramedullary nailing to include metaphyseal fractures as well. Mechanically locked intramedullary nails provide greater strength in axial loading than condylar blade plates, but are significantly less stable in bending and torsion when applied to the distal femur. As such, although locked nails provide less stability than condylar blade plates in simple metaphyseal fractures, they are better suited for fixation of severely comminuted fractures with no reconstructable medial buttress in osteoporotic bone. The major weakness of locked intramedullary nails is the security of the distal locking screws. The distal locking screws can easily loosen, especially within the bone of the distal femur, leading to loss of control of the distal fragment. This often results in rotational and varus/valgus malalignment. Locking screw fixation can be improved by using different planes of screw orientation and by using locking bolts or cement to improve fixation.

**Augmentation of Fracture Healing and Stability**

Traditionally, surgeons have resorted to cancellous bone grafting to augment or ensure rapid and complete healing of fractures. In osteoporotic fractures, bone grafting plays several important roles. Cancellous bone grafts can be used to encourage rapid fracture healing, improving the odds of healing in the race against eventual failure of internal fixation. Cancellous bone is osteoinductive, osteoconductive, and osteogenic and will stimulate new bone formation periosteally, as well as in fracture gaps created by comminution. There is no current evidence that osteoporotic bone is an inferior graft material.

Bone grafting is also important in osteoporotic fractures to replace regions of skeletal loss due to comminution or crush injury. Bone grafts, which are corticocancellous, can replace structural loss and as such can help restore skeletal stability in fracture constructs. This is especially true in metaphyseal and joint depression-type fractures. Osteoporosis affects regions of cancellous bone more quickly than compact, cortical bone. Metaphyseal injury with joint depression is a typical fracture pattern associated with osteoporosis. Examples include split-depression tibial plateau fractures, intraarticular fractures of the distal radius, distal humeral fractures, and calcaneal fractures. Operative repair of these injuries requires elevation of the articular surface to restore joint congruity, with the use of structural bone graft to fill in the crushed, metaphyseal void to provide support to the subchondral region.

The donor source for autogenous bone graft is usually the iliac crest. The morbidity associated with the harvest of autogenous bone has recently become a concern. In the elderly this is a particularly important issue. Very often, the quantity and quality of bone available at the iliac crest is insufficient, requiring a larger exposure and increasing the risk of donor site complications (Fig. 8–2). Bone graft substitutes can provide an attractive alternative to autograft in osteoporotic patients.

In situations of severe skeletal loss complete replacement of comminuted areas by cement is often required. Polymethylmethacrylate has been used with success, especially in supracondylar fractures of the femur. Polymethylmethacrylate has also been used in intertrochanteric fractures. Although polymethylmethacrylate has proven useful, it is not an
ideal material for this purpose. It binds poorly to bone and can be difficult to inject accurately and to control. Over the long term, failure of healing and loosening of screws fixed with cement can lead to gross osteolytic damage to the surrounding bone (Fig. 8–3). Cements made from calcium phosphate have better adhesion to bone and have the advantage of being resorbed and replaced by host bone, avoiding the long-term consequences associated with polymethylmethacrylate. Calcium phosphate cements have been demonstrated to have usefulness in intertrochanteric, distal radius, and calcaneal fractures. These new cements can provide enough support to allow earlier load bearing and decrease the dependency upon the internal fixation devices. Although they are not approved for general use as yet, they will be available in the near future. It is expected that they will replace polymethylmethacrylate in this application.

Augmentation of the severely osteoporotic diaphysis can be accomplished using polymethylmethacrylate, but another useful approach is to place an augmentation device into the medullary canal, which can incorporate as bone or be resorbed. Fibular allograft struts can be used for this purpose (Fig. 8–4). The fibular strut improves local bone stock for screw purchase and can be incorporated to provide a span across regions of diaphyseal deficiency. Mainil-
Varlet and colleagues have proposed use of a re-
sorbable poly (L-lactide) material for the same pur-
pose. Creative strategies such as these can be ex-
tremely successful in osteoporotic diaphyseal frac-
tures and nonunions.

**PROVEN CLINICAL STRATEGIES**

**INTERTROCHANTERIC FRACTURES AND THE SLIDING HIP SCREW**

The development of the Sliding Hip Screw (SHS) has
tremendously advanced the results of treatment of
intertrochanteric fractures. The success of the SHS
is based upon its design. In many ways, it is the ideal
device for this typically osteoporotic fracture. The
SHS has a lag screw that gains broad purchase in the
highest-quality bone in the femoral head. The dy-
namic slide of the lag screw and side plate allow for
impaction at the fracture site with load sharing along
the plane of the fracture. The success of load sharing
is evident in the observation that the length of the
side plate and shaft fixation makes little difference in
the stability of an SHS construct. If the SHS is in-
serted correctly in all but the most unstable fractures,
the failure rate of fixation is universally observed to
be under 5%, even in grossly osteoporotic pa-
tients. No device can surpass the results observed
when a sliding hip screw is utilized.

Unfortunately, the SHS cannot claim equal success
in unstable four-part fractures, reverse obliquity frac-
tures, or in fractures with subtrochanteric extension
(Fig. 8–5). In these fracture patterns, the lack of a lat-
eral buttress and loss of posteromedial bone for load
sharing prevents the fracture from dynamically
achieving stability. As a result, the sliding hip screw
allows maximum medial displacement of the shaft,
leading to either unacceptable shortening at the frac-
ture site or cutout of the lag screw from the femoral
head because the lag screw threads have come to rest
upon the barrel of the side plate (Fig. 8–6).

In these unstable fracture patterns, devices are
needed that recreate a lateral buttress or allow verti-
cal, dynamic impaction. Fixed-angle devices such as
the 95-degree condylar screw can be utilized. This
type of device provides a lateral buttress but because

**FIGURE 8–5** Diagrammatic illus-
tration of fracture patterns that have a
high risk of poor outcome when
treated with the standard sliding hip
screw. (A) Reverse obliquity fracture
pattern; (B) highly comminuted frac-
ture with subtrochanteric extension
that lacks a lateral buttress.

**FIGURE 8–6** An example of the reverse obliquity frac-
ture that has been treated with a sliding hip screw. Lack of a
stable lateral buttress allows maximum slide of the lag
screw. No stable contact for load sharing is achieved. The
result is cut out of the lag screw from the femoral head.
it is a fixed-angle device, it cannot load share, unless an intact medial buttress can be reconstituted. Without this medial support opposite the plate, failure is almost guaranteed (Fig. 8–7). These devices have the additional disadvantage of not allowing weight bearing by the patient immediately following surgery.

Alternative devices for the unstable perirotrochanteric fracture include intramedullary hip screws, gamma nails, and vertically sliding plates. The intramedullary sliding hip screws provide the advantages of an intramedullary nail combined with a dynamic hip screw that allows impaction of the perirotrochanteric fracture. The intramedullary position decreases the lever arm on the device and creates its own lateral buttress that prevents excessive lateral migration of the proximal fragment. The strength of the device allows immediate weight bearing. Use of the long intramedullary nail avoids fracture of the femoral shaft that occurred in approximately 10% of cases when the short gamma nail was used. The insertion of intramedullary hip screws can be technically demanding. The surgeon must carefully develop the starting point, and the fractures must be reduced before reaming and nail insertion to avoid comminution of the fracture site and adjacent cortex. Open reduction of these fractures prior to initiation of the nailing procedure is recommended unless a near-perfect closed reduction can be achieved. Vertically sliding hip screws allow these fractures to impact without excessive lateral displacement (Fig. 8–8). Clinical experience with these devices is preliminary, but the initial results are encouraging. The primary advantage of this device is the ease of insertion as well as the ease of salvaging a routine sliding hip screw that has been complicated by lateral cortex comminution during insertion. Mechanically, the vertical sliding plate appears to perform as well as the intramedullary sliding hip screws.

**SUPRACONDYLAR FRACTURES OF THE DISTAL FEMUR AND THE 95-DEGREE BLADE PLATE**

In young individuals supracondylar fractures most often result from high-energy injury. In the elderly, however, the supracondylar region of the distal femur is weakened from osteoporotic bone loss, allowing even low-energy injuries to result in significant fractures. In the elderly intraarticular involvement and comminution of the metaphysis is
common. Historically, the challenge of these fractures prompted the development of closed methods of treatment using traction and cast bracing.\textsuperscript{54,55} However, the development of methods for internal fixation of these fractures that allow restoration of anatomy and early knee rehabilitation makes nonoperative management inappropriate in the majority of cases.\textsuperscript{56}

The 95-degree blade plate was designed for the treatment of the supracondylar fracture.\textsuperscript{57} The 95-degree blade plate has many features that make it ideal for fixation of these fractures in osteoporotic bone. Retrograde intramedullary nails can be utilized, but do not provide the same stability as the 95-degree devices\textsuperscript{33,58} and should be reserved for fractures around total knee replacements\textsuperscript{59} or those fractures with severe comminution into the diaphysis or with severe skin compromise around the knee. The 95-degree condylar screw was designed to make insertion of the device easier compared to the blade plate, but it has several disadvantages. The condylar screw sacrifices more bone from the distal femur with insertion and cannot be easily revised. It is also quite bulky and can painfully impinge upon the lateral soft tissues of the knee. In contrast, the blade plate is low profile and sacrifices very little bone with its insertion. The position of the blade can be revised without compromising its fixation. Although the blade plate is more technically demanding to insert, these advantages should not be overlooked.

The 95-degree blade plate can be used successfully as a buttress plate in younger individuals with good bone stock.\textsuperscript{57,58} However, in the elderly, the key to success is to use the plate only in a tension band fashion. This requires reconstitution of a load-sharing medial femoral cortex opposite the blade plate. For many fractures, this can be accomplished by shortening the fracture into a position of stability by impacting the fracture surfaces. Shortening as much as 1 to 2 cm can be accomplished without significant loss of function. Healing is usually quite rapid after shortening as the comminuted medial bone functions as bone graft.\textsuperscript{14,56} In severely comminuted fractures where sufficient stability cannot be accomplished by shortening, the surgeon can resort to double plating the distal femur\textsuperscript{28,60} or replacing the region of bone loss with cement. Finally, these cases represent an indication for a retrograde nail.

In most cases of supracondylar fracture of the osteoporotic femur, the 95-degree blade plate will serve the surgeon and patient well as long as the principles of its use are followed (Fig. 8–9).

\textbf{FIGURE 8–9} Two radiographs depicting clinical examples of supracondylar fractures that have been stabilized with 95-degree blade plates. (A) Slight shortening of the fracture combined with use of cement results in a stable construct. (B) The medial buttress has not been reconstituted and the plated construct has failed into a varus alignment. Notice the severe degree of bone loss within the medial femoral condyle around the lag screw. Less disruption of bone stock might have resulted with the use of a blade plate.
THE LATERAL TIBIAL PLATEAU FRACTURE AND THE RAFTER PLATE

In the osteoporotic patient, the split-depression or Schatzker type II (AO classifications B2, B3) lateral tibial plateau fracture is the most common variety of this injury. Fractures with less than 5 mm of joint-surface depression and a knee that is stable to varus/valgus stress can be managed nonoperatively. If the degree of joint depression exceeds 5 mm and if there is more than 5 degrees of varus/valgus instability, then surgical reconstruction is required. The classical approach to repair of the lateral tibial plateau fracture has been outlined extensively. Recently, Benirschke and Swiontkowski have suggested modifications of this technique that call for use of a small fragment plate specifically designed for the lateral tibial plateau. The small fragment plate is low profile and allows placement of proximal screws very close to the subchondral plate of the reduced tibial plateau. As many as four screws can be placed, providing extensive support of the reduced joint surface (Fig. 8–10). The small screws can be placed into opposing cortex, ensuring very secure cortical bite. Because the screws placed under the subchondral bone are reminiscent of rafters supporting a roof or a floor, this technique has been referred to as the rafter plate. This technique represents a useful modification of the classic technique for the osteoporotic patient.

ANKLE FRACTURES: THE DISTAL FIBULA AND THE ANTIGLIDE PLATE

Fractures of the ankle occur commonly in the elderly. In fact, ankle and foot fractures are among the most common fractures sustained by women, with the peak incidence of ankle fractures occurring in females between the ages of 75 and 84 years. Ankle fractures in the elderly have traditionally been noted to carry a poor prognosis. The principles of treatment of ankle fractures in the elderly are identical to those that apply to younger patients. Ramsey and Hamilton as well as Yablon and colleagues have demonstrated that even small residual displacements in the mortise markedly alter the load-bearing distribution on the talus, leading to poor clinical outcomes. As in younger patients, ankle fractures must be treated by anatomic reduction while healing.

Isolated fractures of the lateral malleolus without injury to the medial malleolus or deltoid ligament should be treated nonoperatively. Successful results in 96% of patients can be achieved with supportive immobilization and immediate weight bearing. Unstable ankle fractures require open reduction and internal fixation with particular attention to anatomic restoration of the fibula.

Operative fixation of the ankle in the elderly can be made more difficult by poor skin integrity, swelling, diabetes, and vascular disease. In addition, osteoporotic bone loss from the lateral malleolus can compromise the surgeon’s ability to secure internal fixation of the lateral aspect of the ankle. The majority of lateral malleolar fractures are short oblique or spiral oblique patterns with the apex of the fracture posterior and proximal. The most accepted technique for fixation of the lateral malleolus is placement of a plate on the lateral malleolus, approached through an anteromedial incision. Modifying this technique...
by placing the plate on the dorsal surface of the fibula puts it in the antiglide position with superior biomechanical stability (Fig. 8–11). In addition, with the plate placed dorsally the skin incision can be placed more posteriorly, allowing for better coverage of the fibula, if wound healing problems occur. The best advantage of the antiglide position is that the purchase of the distal screws is relatively unimportant, with the important screw fixation occurring in the more proximal cortical region of the fibula.

**FRACTURES OF THE PROXIMAL HUMERUS: TENSION BAND FIXATION**

Bone loss from the proximal humerus can be extensive in osteoporotic patients. As a result, proximal humerus fractures are most commonly seen in elderly females. Fortunately, 80% of these fractures are impacted or minimally displaced and heal well after a brief period of immobilization followed by an aggressive rehabilitation program. Unstable fractures usually are significantly displaced due to the pull of the musculature attached to the upper humerus. Unless reduced, unstable fractures will result in malunion with loss of range of motion, strength, and function in that shoulder girdle. Loss of significant shoulder motion reduces one’s ability to dress and perform personal hygiene. A poor outcome following proximal humerus fracture in the elderly leads to loss of independence with subsequent need for expensive social services. Open reduction and internal fixation of unstable two- and three-part fractures of the humerus that leads to improved functional outcome is advantageous in the elderly patient.

Repair of proximal humerus fractures is extremely challenging. Even in experienced hands, results are often disappointing. In four- or three-part fractures in which the head is only a deficient shell of subchondral bone, prosthetic replacement of the humeral head is indicated. However, functional results of two- and three-part fractures are better if open reduction and preservation of the humeral head can be accomplished. Traditional plating of the proximal humerus with plates and screws is often unsatisfactory due to poor screw purchase and acromial impingement caused by the bulkiness of the hardware. Hawkins and coworkers first described the advantage of tension band fixation for these fractures. He recognized that the tendinous attachment of the rotator cuff tendons to the tuberosities provides excellent purchase for figure-of-eight wires. The tendinous structures generally provide better anchorage than the soft bone of the humeral head, and the reduced bulkiness of wire constructs make tension band fixation ideal for this region. Excellent clinical results can be achieved with modifications of Hawkins’ original technique. The technique calls for exposure of the fracture site through an extended deltopectoral approach. The fracture is mobilized and the head and shaft are impacted to achieve stability along the fracture site. Intramedullary nails or a simple lag screw can be placed to provide initial stability while the tension band wires are placed. One wire is placed under the strong rotator cuff tendons and a second wire can be used to wire the tuberosities together. The wires are attached to the shaft through a drill hole placed laterally through the shaft (Fig. 8–12). The stability of this type of construct al-

**FIGURE 8–12** A diagram of the screw tension band construct used for fixation of two- and three-part fractures of the proximal humerus.
allows for immediate shoulder rehabilitation, optimizing outcome. 76–79 If there is extensive comminution of the metaphysis that would lead to excessive shortening with impaction at the fracture site, then this technique cannot be used alone. Excessive shortening of the metaphysis can cause subluxation of the shoulder due to laxity in the deltoid muscle. In these cases, a plate should be used to restore and maintain proper height. A modified cloverleaf plate works well due to its smaller bulk and option for multiple screws into the head and can be supplemented with a tension band wire for added support. 79

**SUMMARY**

Due to the evolving demographics of the world’s population, fracture surgeons now and in the future must become experts in the treatment of fractures in osteoporotic bone. Toward this end, fracture surgeons are learning to modify the classical techniques of internal fixation, adapting them to the elderly population. Using these techniques, excellent outcomes can be achieved even in patients of advanced age. Surgical repair of the fracture is the means by which aggressive rehabilitation can be started, which is crucial to achieve excellent outcomes in the elderly. To achieve consistently good results, interdisciplinary teams should be assembled to aid in pre- and postoperative management of these patients.

**REFERENCES**


As the life expectancy of the general population increases, there are increasing demands for the surgical treatment of various diseases in aged people. Tumor (primary as well as metastatic), trauma, infection, and degenerative disorders are common candidate diseases for spine surgery, and recent advances in the ability to support aged people by anesthesiologists and internists have decreased the risk of surgery. Spine surgery often requires fusion after decompression and/or correction of a deformity; therefore, some type of internal fixation is usually required. Although external immobilization, such as corset or brace, is an option, recent developments in internal fixation have greatly improved the outcome in correcting deformities, stabilizing the spine, maintaining alignment, and obtaining bony fusion. Internal fixation is also desirable for early mobilization without prolonged external immobilization, which is especially beneficial for decreasing complications in the elderly. Application of internal fixation, however, must be carefully considered in osteoporotic patients because of the higher rate of complications due to bone fragility.1 In this chapter, indications for internal fixation and recent advancements in spinal instrumentation (especially pedicle screwing and hook augmentation) are described.

**Indication for Internal Fixation**

Fundamentally, the indication for internal fixation in osteoporotic conditions is not much different from that in cases of nonosteoporotic conditions. Although some investigators suggest that spinal instrumentation should not be used for severe osteoporotic conditions,2,4 it is mandatory in some cases with spinal instability. For example, a patient with reconstructive surgery of the vertebra after removal of spinal tumor is a definite candidate for the use of internal fixation. In many trauma cases, internal fixation is also essential for reduction and stabilization of the unstable and/or dislocated spine. Other than these conditions, the use of spinal instrumentation for degenerative disorders is rather controversial. Most degenerative disorders require decompression and/or fusion, but elderly people are usually less active and decompression alone without fusion might be sufficient for successful outcome. Among the several degenerative disorders, unstable degenerative kyphoscoliosis is an indication for the use of spinal instrumentation.

**Spinal Instrumentation and the Augmentation Method for Osteoporotic Spine**

Currently, there are several kinds of spinal instrumentation available. Anterior instrumentation consists of vertebral screws connected to rods or plates. Most of the posterior instrumentation methods are combinations of hooks, wires, and pedicle screws connected to rods or plates. The use of either anterior or posterior instrumentation should be based on the patient’s pathology. Although basic principles and techniques of spinal instrumentation in the osteoporotic spine do not differ much from those in the younger spine, surgeons should be more prudent to prevent complications. Recent advances in spinal instrumentation provide several augmentation methods, which might be useful to overcome the bone fragility in osteoporotic spine. There are roughly three types of augmentation methods to enhance the initial construct stiffness of spinal instrumentation.

**Increasing the Strength of the Implant-Bone Interface**

Several methods have been used to increase the implant-bone interface, especially with pedicle screws.
The use of polymethylmethacrylate (PMMA) packed into the pedicle screw hole is the classic method to increase the screw pullout force. Zindrick et al\(^{12}\) reported that although unpressurized PMMA restored the pullout strength to within 5% of the original value, pressurized PMMA caused a twofold increase. A small amount of PMMA inserted in an unpressurized condition was reported to improve the pullout strength of a failed screw to approximately 1.5 times its original value.\(^6\) Soshi et al\(^{12}\) also investigated the effect of PMMA in pedicle screw pullout force and demonstrated that PMMA increases the pullout force in the moderate osteoporotic spine but failed to increase the pullout force in severe osteoporotic vertebra. Yamagata et al\(^{7}\) recommended the use of PMMA augmentation for pedicle screws in cases where the bone mineral density is less than 80 mg/cm\(^2\). Many ex vivo biomechanical studies support the use of PMMA in pedicle screw stability, but there are some potential adverse effects. Pressurization of PMMA into the pedicle screw hole can force the cement out of the pedicle, causing nerve root compression or irritation.\(^8\) PMMA evokes the formation of a membrane at the bone-cement interface, leading to bone resorption and resulting in loosening of the screw.\(^9\) Another concern is possible difficulty of screw removal or pedicle fracture during revision surgery. Although PMMA might enhance screw stability in severe osteoporotic spine, it should be used in an unpressurized manner, and surgeons should be aware of the possible complications regarding the use of PMMA.

Recently, newly developed biocompatible and biodegradable cements have been examined for potential use in increasing pedicle screw stability. Moore et al\(^{10}\) investigated the efficacy of calcium phosphate (Ca-P) cement for pedicle screw stability compared with PMMA in lumbar vertebrae of fresh human cadavers. They reported that both PMMA and Ca-P cement significantly increased pullout strength in revision screws by 147% and 102%, respectively. Most of the screws augmented with Ca-P cement were pulled out without causing any body fracture, whereas the pedicle fractured at or near its junction with the vertebral body in most of the screws augmented with PMMA. Lotz et al\(^{11}\) compared the pullout strength after cyclically loading with and without injectable biocompatible carbonated apatite cancellous bone cement (CBC). They reported a near doubling of the pullout strength with the use of CBC compared with controls. Yerby et al\(^{12}\) investigated the immediate effect of using hydroxyapatite cement (HAC) to augment revision pedicle screws after failure of the primary screw fixation. They demonstrated that the pullout strength of the 7 mm HAC-augmented screws was 325% of that of the 6 mm control screws. Although these data suggest that the newly developed biocompatible and biodegradable cements enhance immediate screw stability, there is little clinical data to support this method.

**Increasing Anchor Points to Prevent Stress Concentration**

Extending the fusion segment is the simplest way to increase the size of the anchor point. Gurr et al\(^{13}\) investigated the stability of spinal constructs with several types of instrumentation surgery after decompressive laminectomy. They reported that the flexion moment in the pedicle screw system with five levels was significantly superior (>1.5 times) compared with that in the same system with three levels. The long fusion, however, might result in greater exposure of the spine and a longer operative time, as well as the sacrifice of longer mobile segments.

**Use of Cross-Linking to Increase the Torsional Stiffness**

Ruland et al\(^{14}\) investigated the effects of a transverse plate (cross-link) connecting bilateral pedicle screws (Steffee VSP and CD). They concluded that even in osteoporotic spine CD and VSP screws with a transverse plate provided significantly greater fixation than the conventional pedicular or laminar hook-based systems. Dick et al\(^{15}\) also reported that the use of one cross-linkage increases torsional stiffness in a pedicle screw construct by 44% in a polyurethane spine model. Recently, several rod cross-linking systems were made available, and most were proven effective in clinical use.

**Combination Method of Pedicle Screw and Laminar Hook**

**Basic Biomechanics**

We have been trying to enhance initial stiffness of a spinal construct using a combination of the pedicle screw and laminar hook to the same vertebra in the osteoporotic spine. The pedicle screw-laminar “claw” is valuable and has been used clinically since 1990.\(^{16}\) Halvorson et al\(^{17}\) investigated the effects of using pedicle screws in conjunction with a laminar hook at one or two levels and evaluated the effect of bone mineral density on the quality of pedicle screw fixation. Although the results of their study were inconclusive because of the limited number of specimens used, the authors suggested that the use of pedicle screws in conjunction with a laminar hook at two levels improved pullout strength. Chiba et al\(^{18}\)
investigated the effects of augmentation hooks applied from the supralaminar at T11 and infralaminar at L2 to standard short-segment pedicle instrumentation constructs in a L1 burst fracture model. The results clearly indicated that supplemental offset hooks significantly increased construct stiffness and absorbed some part of the construct strain.

We conducted biomechanical testing to investigate whether adequate stiffness of short-segment instrumentation can be accomplished without invading the level adjacent to the instrumented vertebra in the osteoporotic spine. A laminar hook augmentation to the pedicle screw was used for this purpose. The effectiveness of a combination method of laminar hook and pedicle screw in comparison with that by pedicle screw alone in reference to bone mineral density of the vertebra under cephalocaudal cyclic loading were examined. Lumbar vertebrae were obtained.

**FIGURE 9-1** Experimental setup. (A) A shank of the pedicle screw is toggled by a specially designed connector, producing controlled wagging movement in cephalocaudal direction. Five cycles of loading are performed to the shank of pedicle screw 10 mm posterior to the end of the threaded portion with a crosshead speed of 3 mm/min under maximum load control of 29.4 N. (B) A laminar hook is then placed and connected to the pedicle screw via a rod. Cephalocaudal loading is performed in the same way.
from seven embalmed cadavers (average age ± SD = 73 ± 10.7, range 55 to 87 years). The embalming process affects the material properties of bone; however, all the vertebrae used in this experiment were fixed and preserved using the same procedure, and therefore the comparison made between the vertebrae was valid.19 Thirteen vertebrae, including one L1, two L2, seven L3, two L4, and one L5, with 26 pedicles, were available for this study. Bone mineral density (BMD) was measured using a dual-energy X-ray absorptiometer (DXA) in the anteroposterior direction. Both ends of a vertebra were placed in plaster to make the surfaces parallel. A pedicle screw was screwed into a vertebra. The vertebra was placed between two steel plates and fixed to an Instron-type testing machine.

The shank of the pedicle screw was toggled by a specially designed connector, producing a controlled wagging movement in the cephalocaudal direction. The shaft of the toggle was firmly connected to the load cell (Fig. 9–1A). Five cycles of loading in the cephalocaudal direction were performed with a crosshead speed of 3 mm/min under a maximum load of 29.4 N, which was within the elastic region of the screw-bone interface. We confirmed in a preliminary experiment that there was no deflection in any cycle during this loading range. This loading procedure imitates the mechanical testing of pedicle screw instrumentation system in a corpectomy model, and loading in the cephalocaudal direction to the pedicle screw is considered to be more realistic than simple pullout loading to the pedicle screw.20 Deformation of the screw end was recorded simultaneously using a laser measurement system. Because stability of a construct might best be described by its stiffness,21 the stiffness of the screw-vertebra interface ($K_i$), determined as the slope of the fifth hysteresis loop of the load-deformation curve, was used to evaluate the instrumentation stability. Then, a laminar hook (ISOLA drop entry hook, 6.5 mm throat, AcroMed Corp., Cleveland, OH) was attached to the lamina and connected to the pedicle screw via a rod (ISOLA rod, 6.35 mm in diameter, AcroMed Corp., Cleveland, OH; Fig. 9–1B). In each vertebra, uniform compression between the hook and the screw was applied by a compressor under strain gauge monitoring on the compressor. Mechanical testing was performed in the same way as before hook application, and stiffness of the screw-hook-vertebra interface ($K_f$) was determined as the slope of the fifth hysteresis loop of the load-deformation curve.

Improvement in the ratio of stiffness (%imp) by the combination method was defined as $\left(1 - \frac{K_f}{K_i}\right) \times 100$, where $K_i$ is stiffness obtained by pedicle screw alone, and $K_f$ is stiffness by the combination method using pedicle screw and laminar hook. $K_i$ and $K_f$ were compared using a paired $t$-test, and the relationship between $K_f$, $K_i$, or %imp and BMD was analyzed using linear regression analysis.

Representative load-deformation data from the fifth load cycles of the constructs of pedicle screw alone and a combination of pedicle screw and laminar hook are shown in Figure 9–2. A rigid claw made by the pedicle screw and laminar hook was effective irrespective of loading direction, flexion, or extension. Stiffness obtained by pedicle screw alone and the combination of pedicle screw and laminar hook were 60.2 ± 19.6 (mean ± SD) N/mm and 89.8 ± 35.0 N/mm, respectively. Stiffness obtained by the combination method was significantly greater than that by pedicle screw alone ($P <0.0001$, Fig. 9–3).

The stiffness obtained with the pedicle screw alone or the combination method was positively correlated with BMD ($R^2 = 0.614$, $P <0.0001$, pedicle screw only, and $R^2 = 0.645$, $P <0.0001$, the combination method, Fig. 9–4). There was no significant correlation between %imp and BMD ($R^2 = 0.132$, $P = 0.0748$, Fig. 9–5).

**THE COMBINATION OF PEDICLE SCREW AND LAMINAR HOOK FOR SHORT-SEGMENT INSTRUMENTATION IN OSTEOPOROTIC SPINE**

Because the ISOLA system is designed to address the full range of deformities and degenerative spine dis-

![Figure 9-2](loading_data.png)

*Figure 9-2* Load-deformation data of cycles of cephalocaudal loading in the constructs of a pedicle screw alone and a combination of the pedicle screw and laminar hook.
we prefer the combination method of pedicle screw and laminar hook. The patient is placed in the prone position on a Hall frame. Because kyphosis resulting from osteoporotic vertebral fracture is usually flexible, the spinal alignment is reduced to some extent just by placing the patient in a prone position. The vertebral level is confirmed using a C-arm image intensifier. The posterior elements, including laminae and facet joints above and below the fractured vertebra, are exposed. Pedicle screws are placed in the vertebrae cephalad and caudal to the fractured vertebra using the method described by Weinstein et al. The position of the pedicle screw is checked using the C-arm. Minimal flavotomy and hemilaminotomy necessary for placement of the caudal laminar hook are performed. The smallest hook is chosen with a throat depth that will pass over the caudal lamina, and the hook is angled into position (Fig. 9–6A). The rod is bent to fit the sagittal alignment. The prebent rod with two slotted connectors is applied to the pedicle screws and the laminar hook is held in place by a hook holder (Fig. 9–6B). Compression between the hook and the screw is applied in line with the rod using a compressor (Joe Gaines type, AcroMed Corp., Cleveland, OH). Our data indicated that the claw fixation was effective irrespective of loading direction (flexion-extension), suggesting that the hook application in the combination method does not just protect the pedicle screw during flexion moment, but forms a rigid claw. Sagittal configuration of the construct is confirmed with the C-arm (Figs. 9–6C,D). Decortication of the laminae and iliac bone grafting are performed before rod application. A suction drain is placed over the lamina and the wound is closed in layers.

**REPRESENTATIVE CASES**

**Case 1**
A 58-year-old woman suffered from an L1 compression fracture due to a traffic accident (Fig. 9–7A). Although she had been treated conservatively, the back pain did not subside. The kyphotic deformity became apparent during conservative treatment. Be-
cause of continuous back pain without neurologic deficit and progressive collapse of the L1 vertebra (Fig. 9–7B), surgical treatment was indicated. The surgery consisted of short-segment posterior fusion of T12 through L2 with the combination method of pedicle screw and laminar hook to L2. The duration of the surgery was 80 minutes and intraoperative blood loss was 150 mL. Back pain was improved immediately after the surgery. Thoracolumbar orthosis was applied for 4 months, and fusion was completed 12 months postoperatively.

Case 2
A 69-year-old woman with a diagnosis of rheumatoid arthritis, who had been treated with steroids for 20 years, experienced progressive pain in her lower back and left leg without any traumatic episodes. Walking gradually became difficult because of the leg pain. On presentation to our clinic, she had a gait disturbance because of the left leg pain, with muscle weakness of the left tibialis anterior and extensor digitorum, and sensory disturbance of the dorsal foot. X-ray revealed a defect in the caudal part of the L4 vertebra and minimal collapse of the cranial L5 vertebra (Fig. 9–8A). Magnetic resonance imaging indicated that the L4/5 disc space was replaced by granulous tissue involving both L4 and L5 vertebrae with concomitant canal stenosis (Fig. 9–8B). A diagnosis of steroid-induced L4 and L5 vertebral collapse with invasion of the rheumatoid nodule around the disc was
established and surgery was indicated. The surgery consisted of anterior decompression and fusion with iliac bone graft, and posterior instrumentation of L4 and L5 with the combination method of pedicle screw and laminar hook to the L5 vertebra. The pain in the low back and left leg pain dramatically improved and the unstable segment achieved a bony union 6 months after surgery (Fig. 9–8C).

**DISCUSSION**

As the elderly population increases, the use of spinal instrumentation in osteoporotic spine will also increase. Therefore, it is necessary to establish a strategy to overcome vertebral fragility to prevent complications such as implant loosening or reduction loss following surgery to the osteoporotic spine. Factors affecting pedicle screw fixation strength include screw penetration depth, screw diameter, screw orientation, screw insertional torque, bone mineral density, and screw insertion technique. In nonosteo-porotic bone, screw size and penetration depth conditioned by pedicle fill had a significant effect on fixation strength. On the other hand, screw size had little or no effect on fixation stiffness in osteoporotic bone and a larger screw can fracture the pedicle in the osteoporotic spine. Many studies have investigated the relationship between screw stability and bone mineral density of vertebra and concluded that stability was positively correlated with bone mineral density. The present study investigated whether stiffness of the pedicle screw system is improved by augmentation with a laminar hook to the same vertebra in reference to the bone mineral density of the vertebra. Augmentation of the pedicle screw by laminar hook improved the stiffness up to 49.2% on average. The combination method of pedicle screw and laminar hook can accomplish greater instrumentation stiffness compared to the stiffness obtained using the pedicle screw alone.

Using human cadavers instrumented with short-segment pedicle instrumentation, Yerby et al reported that the addition of offset laminar hooks to the pedicle screw construct significantly reduced screw bending moments and screw migration during in situ contouring. The mean screw bending moments decreased approximately 30% at the maximum bending angle of 30 degrees, and the mean screw migration during contouring decreased from 2 to 8 degrees. This study suggests that the protective effect of the hooks reduces the probability of long-term construct failure such as screw bending or breakage, bony fatigue failure, or screw migration.

When a combination method was employed in vertebra with BMD of 0.4 g/cm² measured by DEXA, which is considered to be osteoporotic (normal BMD at 70 years of age is 0.64 ± 0.21 g/cm² from the data of Departments of Orthopaedic Surgery, Hamamatsu University of Medicine and Kawasaki Medical School, Japan), the instrumentation stiffness approaches 41.2 N/mm, based on the regression equation used in this study. The use of a pedicle screw alone in such a vertebra, however, can produce a stiffness of approximately 33.7 N/mm. A
vertebra with 0.50 g/cm² in BMD, which is considered normal at the age of 70 years, is necessary to achieve 41.2 N/mm in stiffness using a pedicle screw alone. This suggests that some osteoporotic patients can be treated by the combination method as successfully as patients with normal bone density of the spine.

There was no significant correlation between the improvement ratio achieved by the combination method and BMD of vertebra (Fig. 9–5). This result is consistent with previous reports indicating no significant correlation between laminar hook pullout strength and bone mineral density of the vertebra, suggesting that the laminar hook is efficient even in osteoporotic spine.26,28,32 Although the combination method is different from single usage of the laminar hook, augmentation of the laminar hook to the pedicle-screwed vertebra was valuable irrespective of spinal osteoporosis, similar to the result of Halvorson et al.17

From the clinical point of view, Johnston et al16 reported that the indication for hook supplementation is when a screw is implanted very caudally and will be subjected to large flexion bending forces in the cantilever as a result of a deficiency of the anterior column, or when the screw is the distal anchor for a long construct crossing the thoracolumbar junction, where flexion bending forces emanating from the normally kyphotic spine will be transmitted via a long lever arm to this most caudal implant.16 In a severely osteoporotic spine, however, pedicle screw instrumentation is at risk of loosening even if the anterior column is not deficient or the screw is not subjected to a large flexion bending force. Because implant stiffness increases with hook augmentation to the pedicle screw irrespective of severity of osteoporosis or loading direction (Fig 9–2), the combination method of the pedicle screw and laminar hook will be effective for reconstruction of the severe osteoporotic spine.

**CONCLUSION**

A diversified approach is necessary for effective instrumentation to overcome bone fragility in spinal osteoporosis. The combination method using a pedicle screw and laminar hook is one of the promising options of instrumentation in the coming era of increased incidence of osteoporotic spine surgery. Application of the combination method, however, should be limited to the cases with anterior column deficiency or with severe osteoporosis in which the pedicle screw system alone is predicted to fail.

**REFERENCES**


Fractures of the acetabulum and pelvis represent uncommon injuries that, nevertheless, are growing rapidly in number. Historically, these traumatic insults have been viewed as the aftermath of major trauma, typically related to motor vehicles, and especially in young adults following exposure to alcohol and/or drugs. Many of these fractures follow minor trauma, such as a simple fall to the ground from a standing position. The minor traumatic injuries occur primarily in the elderly with osteoporotic bone, although they may arise in younger individuals with osteoporosis secondary to an inflammatory arthritis and steroid dependency. In many of the latter group, there is no history of a true accident, in which case the term insufficiency fracture is applied. With the rapidly aging population, and including those individuals with predisposing factors such as prior pelvic irradiation therapy or steroid dependency, the number of clinical presentations is soaring. For example, currently in the United States, annually there are approximately 300,000 hip fractures, 16,000 pelvic fractures, and 3000 acetabular fractures involving osteoporotic bone. Unless preventive measures are markedly improved, all of these figures can be expected to at least double during the next 20 years. This chapter outlines the clinical presentations, diagnostic features, biomechanical factors, and modified techniques of fixation as well as complications of these fractures.

The Impact of Osteoporosis on Clinical Presentations

Historically the hallmark of pelvic or acetabular trauma is a recent motor vehicular accident involving a young adult, typically after exposure to alcohol or drugs. Many pelvic fractures are accompanied by injuries to multiple organ systems. A somewhat special circumstance is the presentation of similar multiple traumatic insults in an elderly individual, over 70 years of age. Typically the more limited physiological reserves of the older person are further impaired by the presence of comorbidities such as ischemic heart disease, diabetes mellitus, and cerebrovascular disease. Overall, such a patient possesses a much higher mortality and a greater likelihood to sustain multiple complications from the event than is the case for his younger counterpart. The recovery period, including the duration of hospitalization, is likely to be much longer than for a young adult. Also, the elderly person has a higher likelihood of displaying permanent physical impairment than his younger counterpart. One such example in the elderly is where inadequately controlled hypovolemic shock precipitates a myocardial infarct. In turn, surgical reconstruction of an unstable pelvic ring or displaced acetabular fracture may be deferred indefinitely, so that the prognosis for the recovery is significantly impaired.

In the presence of marked osteoporosis, the types of acetabular and pelvic injury patterns that present clinically are different from those that occur in young, healthy adults. In part, the discrepancies follow the mechanisms of trauma that usually occur in younger and older individuals. Whereas the younger patients sustain major trauma, most of the elderly sustain minor traumatic incidents that would be unlikely to provoke a fracture in a young and healthy individual. Where an elderly, osteoporotic patient presents after major trauma to the pelvis, the fracture is likely to display marked comminution. If the acetabulum is involved, both the femoral head and the acetabulum may be highly impacted as well as fractured. Such complicating features unfavorably impact the prognosis. With such acetabular involvement, a surgical reconstruction may be unlikely to provide a correction of impaction so that posttraumatic arthritis is exceedingly likely to occur.
In part, the differences observed for pelvic injuries in younger versus older individuals correlate with the different mechanisms of trauma including the vectors of the provocative blow. As initially described by LeTournel and Judet,\textsuperscript{9} the characteristic pattern of an acetabular fracture depends upon the precise vector of the provocative blow. With a forceful injury, an associated or comminuted fracture pattern is likely such as a posterior wall-posterior column, a posterior wall-transverse, a T-type, or a both-column fracture. In an elderly, osteoporotic individual who sustains a simple fall to land on the side of his hip, a comminuted anterior column fracture is the most frequently encountered injury. The fracture site involves the thinnest and weakest portion of the acetabulum that is further compromised by the osteoporosis. One specific fracture pattern involves the anterior wall, column, and quadrilateral surface and is rarely observed in young adults.\textsuperscript{10} Another frequent injury in elderly individuals is a posterior wall fracture in which the wall undergoes so-called marginal impaction. The area of involvement varies greatly. Impaction or deep abrasive damage to the femoral head often accompanies the acetabular impaction and comminution. Ironically, this “simple” injury pattern possesses a poor prognosis that is much worse than certain associated fractures, such as the typical both-column fracture.

With respect to the pelvic ring, after a major trauma, an unstable injury of the posterior pelvic ring may involve a dislocated sacroiliac joint or a displaced fracture of the posterior ilium or sacrum.\textsuperscript{1} Following minor trauma or minimal trauma, such as an insufficiency fracture, the typical pattern of injury is the propagation of a minimally displaced fracture across the sacral ala, accompanied by uni- or bilateral ramus fractures.\textsuperscript{11,12}

One special manifestation of an insufficiency fracture is where the patient has a prior history of pelvic irradiation therapy, typically for uterine or prostatic carcinoma.\textsuperscript{13} Years later, in the face of an apparent cure, the pelvis is vulnerable to an insufficiency fracture, followed by a delayed union or nonunion. The compromised healing potential of the bone may lead to a prolonged symptomatic course. A similar clinical picture may follow steroid dependency, particularly for rheumatoid arthritis or lupus erythematosus. In this situation a complicating feature may be a prior history of a total hip replacement. Here, initially an insufficiency fracture of the sacral ala may propagate across the partly or completely fused sacroiliac joint into the posterior ilium. Then, the fracture advances across the acetabulum to create a periprosthetic fracture, possibly accompanied by loosening of the cup. Usually, such a fracture exits through the superior pubic ramus. A stabilization of the pelvic ring may necessitate a revision of the cup.

While most acetabular and pelvic fractures ultimately unite, after a conservative course of treatment, a small percentage progress to a nonunion.\textsuperscript{14,15} This likelihood increases enormously after prior pelvic irradiation therapy, which heavily compromises bony healing and remodeling. Where a nonunion persists, the principal symptoms are pelvic pain, aggravated by activity, and pelvic instability. The latter problem is highly disabling, whereby the patient perceives an unnatural motion of the nonunion site with sitting, transfers, ambulation, or even rolling in bed. In the presence of a sacral insufficiency fracture that becomes a nonunion, an insidious presentation of a pelvic deformity may ensue that is typified by a sagittal and internal malrotation of the involved hemipelvis. The injury hinges around the sacral nonunion so that the maximum deformity occurs at the sites of the ramus disruptions.

**Epidemiology**

The epidemiologic features of pelvic fractures in the elderly have been evaluated by Melton et al,\textsuperscript{3} Ragnarsson and Jacobsson,\textsuperscript{2} and Kannus\textsuperscript{4} in both the United States and Europe. The incidence of pelvic fractures in the elderly following minor trauma is increasing rapidly, especially in women. In the most recent study, from Finland,\textsuperscript{4} during the period from 1971 to 1997, the incidence of major pelvic trauma after motor vehicular trauma declined while the number of osteoporotic fractures in the elderly after minor trauma increased by 4.6 times. The authors predict an exponential increase in these numbers during the next two to three decades. Further studies are needed to reappraise these dire predictions and to evaluate preventive methods as well as potentially superior methods of definitive treatment.

**Diagnosis**

For the osteoporotic individual who presents for an evaluation of a presumptive pelvic fracture, one clinical scenario follows a major traumatic event, where a careful evaluation of multiple organ systems and timely initiation of a therapeutic protocol is necessary. These schemes are fully presented elsewhere.\textsuperscript{1} The more typical clinical picture is an elderly individual or a somewhat younger adult with known risk factors for osteoporosis, such as a steroid-dependent inflammatory arthropathy, chronic alcoholism, or prior pelvic irradiation therapy. A history of a simple fall or other minor injury may be present, followed by an inability to transfer or to ambulate. Alternatively, no traumatic event may have occurred or a senile patient may not be able to give an adequate history. Still another presentation is of an insidious onset of pelvic pain and a progressive deterioration
of ambulation and transfers. During transfers or possibly when rolling in bed, the patient may be aware of a sudden onset of focal pelvic pain and a sense of motion within the pelvis that is very unsettling. This history typifies pelvic instability.

On examination, the relevant portion of the pelvis may be tender. If a fall occurred recently, ecchymosis and soft tissue swelling may be evident, especially overlying the greater trochanter, ischium, or iliac crest. Unlike a patient with a hip fracture, the individual does not display a deformity of the relevant lower extremity, such as the typical external rotation and foreshortening. Whereas the hip fracture victim complains of severe pain with even minute motion of the hip, the pelvic and acetabular fracture victim does not complain of pain, at least with limited passive motion of the hip. The patient may even display limited active motion of the hip, which is highly unusual after a proximal femoral fracture. Usually the acetabular fracture patient has pain on passive motion of the hip, but no intrinsic deformity of the hip.

Standard radiographs of the pelvis and acetabulum include an anteroposterior (AP) view and 45-degree iliac and obturator oblique views, along with 40-degree outlet and inlet views. The former three are used to study the acetabulum while the last two supplement the AP view to permit an assessment of the pelvic ring. A computed tomography (CT) scan is needed to evaluate the posterior pelvic ring, especially the sacrum, along with the acetabulum and rami. In the assessment of the osteoporotic pelvic fracture, the CT scan is particularly helpful to permit the detection of an occult fracture of the sacral ala or transforaminal region. A minimally displaced fracture of the superior ramus, possibly extending into the anterior acetabulum, may be detected, along with an accompanying inferior pubic ramus or ischial fracture.

With respect to an acetabular fracture in the presence of osteoporosis, impaction of the subchondral bone is a frequent accompanying feature. Various patterns of posterior fracture dislocation are the most frequent injuries to display impaction, both of the acetabulum and of the femoral head. If impaction of the femoral head is visualized radiographically, usually the area of involvement that would be inspected during an open reduction is much larger than that impression which would be evident by a study of the CT scan. In the CT views, the degree of comminution tends to be exaggerated by the images of bony fragments that possess convoluted surfaces. Nevertheless, the conventional radiographs inadequately display comminution.

After a review of the images, the injury pattern is characterized by one of the available schemes. For both the pelvic ring and acetabulum, the alphanumeric Comprehensive Classification (CCF) System is the most detailed and represents an outgrowth of most prior classifications. As an alternative, the acetabulum may be characterized by the method of Le-Tournel and Judet into one of five simple or five associated injury patterns. A rigorous classification permits a determination of the prognosis, the available methods of treatment, and a guideline to a surgical plan, where appropriate. For unusually displaced fractures, especially of the acetabulum, a three-dimensional CT scan affords the optimal recognition of a complex multiplanar rotational deformity as a guideline to surgical planning.

**Occult Pelvic and Acetabular Fractures**

Many of the fractures after minor trauma are minimally displaced and unrecognizable by a review of plain radiographs or even a computerized tomogram. During the review of the history of the patient, and especially where the patient is a poor historian, the examiner needs to consider the potential diagnosis of an occult fracture of the proximal femur or acetabulum and pelvic ring. If an elderly or especially a demented patient is unable to transfer or ambulate, with apparent hip or pelvic pain and despite the presence of normal plain hip and pelvic radiographs, the presumptive diagnosis is a minimally displaced fracture, until proven otherwise. The optimal diagnostic method is either a technetium bone scan or magnetic resonance imaging (MRI). The latter method permits a detailed characterization of the injury site where the fracture propagates in an irregular manner across the involved segment of bone. During an inspection of the MRI, a careful scrutiny of the femoral neck and intertrochanteric regions for an occult fracture is needed for what may be the sole injury or an accompanying one. MRI also provides the most reliable diagnostic method to distinguish an insufficiency fracture from a malignancy or recurrent tumor in the bone, or to document an effusion of the hip.

**Indications and Contraindications for Surgical Treatment**

**Percutaneous Fixation**

For an acute minimally displaced fracture of the pelvic ring or acetabulum, conservative treatment suffices, with a resolution of symptoms during a 6- to 12-week period. Nevertheless, occasionally the occult fracture is an unstable or potentially unstable one that is vulnerable to displacement if the patient is mobilized less than 4 weeks after the injury. Exam-
amples include a minimally displaced transtectal transverse acetabular fracture, a high anterior column fracture, an anterior column-posterior hemitransverse fracture, or a vertical fracture of the posterior ilium. In any of these situations, a therapeutic alternative is percutaneous fixation under image guidance with the use of cannulated screws (Fig. 10–1). The method requires a familiarity with the appropriate pelvic columns of available bone and the techniques for intraoperative image guidance with either an image intensifier or a CT scanner. When properly used the method provides rapid relief of pelvic pain and the potential to mobilize the patient promptly.

**DISPLACED ACETABULAR FRACTURES**

Almost all displaced posterior fracture dislocations are unstable whereby any residual deformity is
poorly tolerated by the hip joint. Similarly, displaced, juxta-, and supratectal transverse fractures are poorly tolerated. Comminuted T-type and transverse posterior wall injuries likewise are indications for surgery. These and other injury patterns that possess an incarcerated fragment or an acetabular deformity that is incongruent with the femoral head merit consideration for an open reduction and internal fixation.

Contraindications to an Open Acetabular Reduction

For a displaced fracture with one or more of the previously described features that typically would be indicative of an open reduction, the most frequent contraindication is the presence of a comorbid condition that renders the patient unstable, such as uncorrected hemorrhagic shock or a recent myocardial infarct. In the osteoporotic elderly, this type of situation is much more common than arises with respect to younger individuals. With the technical complexity of many of these fractures, the possession of the appropriate surgical skills, training, and technical resources is essential. If the surgical procedure has to be deferred for more than 3 weeks, in view of unstable medical conditions or other considerations, then the surgical procedure becomes immeasurably more difficult. During the intervening period, erosion of the femoral head may eliminate any possibility for a favorable outcome. If the surgery has to be deferred, the use of skeletal traction may lessen the degree of erosive damage. Prior to such a delayed procedure, the imaging studies are repeated to determine the degree of erosion and the merits of an open reduction. In the authors’ opinions, once the femoral head is destroyed as a bearing surface, then an open reduction of the acetabulum is no longer indicated. Alternatively, the procedure of choice is a total hip arthroplasty performed before or after the fracture is fully united. Nevertheless, many elderly patients who undergo an open reduction and internal fixation of their acetabular fractures achieve a highly satisfactory outcome, especially in physiologically younger and more active individuals. Overall, the intrinsically poorer results that have been reported for progressively older patients appear to be related to the sizable subgroup of patients that are inactive and osteoporotic.

Total Joint Arthroplasty

In certain osteoporotic individuals, extensive areas of impaction to the femoral head and acetabulum may be present. Marked comminution may further hamper any attempt at an accurate and stable open reduction and internal fixation. If the procedure has to be deferred beyond 3 weeks, usually the outcome in such a patient is poor. Still other elderly patients present with preexisting severe degenerative arthritis. For any combination of these factors, another therapeutic option is primary conservative treatment. Once the acetabulum is healed and if the patient becomes symptomatic with posttraumatic arthritis, then a total hip arthroplasty can be considered. Another therapeutic option is an acute total hip replacement with concomitant internal fixation of the osteoporotic fracture. While the role for the latter solution remains somewhat controversial, nevertheless the method provides the shortest overall recovery period for the unusual case where either an acute open reduction or the use of conservative treatment possesses an abysmal prognosis.

The Pelvic Ring

An open reduction is recommended for most unstable pelvic ring disruptions with true posterior instability. Although the clinical outcomes after the treatment of unstable pelvic fractures with the use of internal and external fixation are optimized, some degree of residual disability and persistent pelvic pain is not uncommon. For minor trauma or after an insufficiency fracture that involves the pelvic ring, most of these minimally displaced injuries heal uneventfully after conservative treatment. In one of the few long-term studies on the recoveries of older patients, by Morris et al, there was an unfavorable impact on the patient’s mobility, at least for the short term. Over a longer period of up to a year, many of the patients displayed a need for increased levels of support by the community, or institutionalization. The in-patient mortality was 7% and the mortality at 1 year was 27%, secondary to the frequent presence of comorbidities. Some of the individuals remained symptomatic for periods of many months or longer. Explanations for the persistent pain included the presence of osteoporosis, a pelvic nonunion, and/or a history of prior pelvic irradiation. An extended period of incapacitating pelvic pain in the presence of a radiographic nonunion that fails to show signs of radiographic healing during a period of a few months or longer is an indication for an open reduction and internal fixation. Occasionally, such a nonunion undergoes an insidious onset of a deformity, with an internal rotation and sagittal malrotation that hinges around the involved side of the sacrum. In our experience, the onset of a deformity is an indication for surgical stabilization, prior to the origin of a major deformity that would impede the surgical reconstruction. Once a large fracture gap appears, at the time of an open reduction and in the face of osteoporotic bone and especially after a prolonged duration of the problem, reapproximation of the dis-
placed fragments with an obliteration of the fracture gap is exceedingly difficult.

PERIPROSTHETIC INVOLVEMENT

If an insufficiency fracture propagates across the acetabulum with radiographic loosening of the cup, an open reduction and internal fixation of the fracture including a revision of the cup is usually necessary to achieve symptomatic relief. Accompanying technical challenges may include the obliteration of a large acetabular defect.31 The surgical plan involves visualization of the hip joint and the site(s) of the pelvic nonunion or at least arrangements to perform appropriate percutaneous fixation of a stable acetabular fracture and cup.

BIOMECHANICAL CONSIDERATIONS

While many biomechanical factors pertaining to the fixation of osteoporotic bone were reviewed in Chapter 4, a few special considerations germane to the pelvis follow. Most conventional pelvic fixation techniques rely upon the use of isolated screws or screws employed with an accompanying plate. The fixation depends upon the holding power of the screws in the osteoporotic bone. Overall, the bony pelvis consists of two thin peripheral layers of cortical bone and a thicker intervening layer of cancellous bone. Screw fixation rests upon the anchorage of the screws in the cancellous bone. The holding power of a screw in a porous material such as cancellous bone or its resistance to pullout has been characterized by Tencer et al.32 These observations were derived from prior biomechanical studies.33,34 The resistance to pullout is dependent upon six factors, three of which are related to the geometry of the screw: its outer diameter, its length of contact with the bone, and its thread geometry. The other three factors pertain to the shear strength of the adjacent bone, the size of the pilot hole, and the features of tapping. In cancellous bone, tapping can be eliminated as a significant factor, along with the size of the pilot hole. From quantitative assessments, the relationships in Table 10–1 account for 97% of the variability of the pullout strength for nontapped screws that are inserted into a porous foam that is a mechanical equivalent to cancellous bone.

For virtually all types of pelvic fixation, generally one or more of four types of screws are used: a 6.5 or 7 mm (large) cannulated cancellous screw, a 6.5 mm (large) noncannulated cancellous screw, a 4.5 mm (large) cortical screw, or a 4 mm fully threaded (small) cancellous screw. It is useful to examine the relative holding power of these examples, in various lengths, and how varying degrees of osteoporosis influence their holding power. In Table 10–2, the geometric and mechanical features of these screws are listed. Since the 7 mm cannulated and 6.5 mm noncannulated screws possess nearly identical features referable to their holding power, only the latter is listed.

For the large cancellous screw, thread lengths of 16 mm and 32 mm are commonly stocked. While fully threaded models are commercially available, most hospitals do not routinely stock them. For the purpose of this discussion, the 4.5 mm and 4 mm screws are evaluated with thread lengths of 15, 30, 60, and 90 mm. These lengths are widely used in pelvic surgery, admittedly with the exceptional longer or shorter variants. In Table 10–3, the corresponding thread shear areas, As (mm²), for useful pelvic bone screws of assorted lengths are displayed.

Upon a review of the last table, a comparison of the thread shear areas of screws of similar lengths can be determined. The shortest 6.5 mm screw with a thread length of 16 mm is about 30 mm in the length of its shaft. Therefore its thread shear length is properly compared with that of the 4.5 mm and 4 mm screws of similar overall lengths. The thread shear area of the 6.5 screw is marginally greater than that of the 4.5 screw and merely 2.83 times that of the 4.0

<table>
<thead>
<tr>
<th>Table 10–1</th>
<th>The Determination of the Holding Strength or Predicted Shear Failure Force for a Screw in Bone</th>
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<tbody>
<tr>
<td>$Fs = S \times As = S \times (L \times \pi \times D_{major}) \times TSF$</td>
<td></td>
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</table>

Where

- $Fs$ = predicted shear failure force (N)
- $S$ = material ultimate shear stress (Mpa)
- $As$ = thread shear area (mm²)
- $L$ = length (mm)
- $D_{major}$ = major diameter (mm)
- $(L \times \pi \times D_{major})$ = area of a cylinder of diameter $D_{major}$ and length $L$
- $TSF$ = thread shape factor (dimensionless) = $(0.5 + 0.57735d/p)$
- $d$ = thread depth (mm)
- $D_{minor} = minor\ (root)\ diameter\ (mm)$
- $p$ = thread pitch (mm)

<table>
<thead>
<tr>
<th>Table 10–2</th>
<th>Geometric Features of the Commonly Used Pelvic and Acetabular Screws</th>
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<tbody>
<tr>
<td><strong>Screw Type</strong></td>
<td>OD (mm)</td>
</tr>
<tr>
<td>Large cancellous</td>
<td>6.5</td>
</tr>
<tr>
<td>Large cortical</td>
<td>4.5</td>
</tr>
<tr>
<td>Small cancellous</td>
<td>4.0</td>
</tr>
</tbody>
</table>

$d$, thread depth (mm); $p$, thread pitch (mm).
screw. In another comparison of the 4.5 mm screw with the 4 mm screw, both 60 mm in length, the former thread shear area is 2.64 times that of the latter. In theory, for screws of comparable length, the use of a larger diameter may improve the thread shear area by a maximum of 2.83 times. In practice, frequently, the selection of a smaller diameter permits the use of a longer screw, so that the apparent benefit of the use of a larger diameter screw is further diminished.

The other critical factor is the bone shear strength, and especially how that value is influenced by the presence of osteoporosis. The bone shear strength is related to the apparent density of the bone by the following power law relationship:

\[ S = 21.6 \rho^{1.65} \]  

(1)

where \( S \) = shear strength (MPa) and \( \rho \) = apparent density of trabecular bone (g/cm³).

If the bone density is decreased by 50%, then the screw holding power is diminished to 0.318 of that of normal bone. If the bone density is decreased by 75% to one quarter of its normal value, then the corresponding screw holding power is diminished to 0.10 of that of normal cancellous bone. The relationship of screw pullout strength versus bone density was assessed experimentally by Trader et al with the use of vertebral bodies. The observations are indicative of the precipitous deterioration of pullout strength that accompanies a progressive decrease in bone density. Once a significant degree of osteoporosis is encountered during pelvic surgery, with the power relationship of bone density and screw holding power versus the linear relationship of screw holding power and screw length or diameter, there is no practical way to modify the use of screws in osteoporotic bone to provide effective anchorage unless the apparent bone density itself is modified. One practical example is the use of methylmethacrylate cement to augment osteopenic bone around a screw. The practical utility of that method will be reviewed shortly.

Another fixation strategy is to replace or augment screw fixation with a technique that loads the overlying pelvic cortical bone. The latter is not compromised mechanically by the presence of osteoporosis nearly as much as the neighboring cancellous bone. One example is the use of a washer and a nut on a screw. Another example is the use of a cerclage technique achieved by the use of braided cables or wires. Load sharing on the cortical surface can be further improved by threading short plates onto the cable, which serve as washers to further distribute the load.

**Standard Methods of Acetabular and Pelvic Fixation**

Diverse methods of fixation have achieved an accepted role for the immobilization of acetabular and pelvic fractures. Most of them rest upon the use of screw fixation, with or without the use of an accompanying plate.

**Isolated Screws**

One or more isolated screws are a highly effective method to immobilize various patterns of acetabular or pelvic fracture. The technique relies upon the presence of a simple fracture line and an accurate reduction. With its ringlike structure and broad cancellous surfaces, the pelvis, unlike a lengthy long bone, permits the restoration of substantial frictional properties of an accurately reduced fracture to stabilize the bone. In a biomechanical sense, the sole use of pelvic or acetabular lag screws presupposes the presence of a truly anatomical reduction and tenacious purchase of the screws in dense bone. In the presence of a minor malreduction, comminution, or osteoporosis, the effectiveness of the screws declines precipitously. The assets of such lag screws include limited soft tissue stripping and ready radiographic visualization to confirm the optimal location of the screw so that it is across the fracture line and away from the hip joint, neural canal, or sacral foramen. More recently, the use of cannulated screws has provided an improvement in the technique that permits percutaneous insertion of screws even through thick layers of overlying soft tissue. With the preliminary insertion of a guide wire or lengthy drill bite, the small “footprint” of the guide wire supplements excellent imaging capabilities if its course is a faulty

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**Table 10–3**  
**The Thread Shear Areas (As) for Commonly Used Pelvic Screws in Assorted Thread Lengths and Overall Lengths**

<table>
<thead>
<tr>
<th>6.5 mm Screw</th>
<th>4.5 mm Screw</th>
<th>4 mm Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thread Length (mm)</td>
<td>As (mm²)</td>
<td>Thread Length (mm)</td>
</tr>
<tr>
<td>16 (30)*</td>
<td>389</td>
<td>15</td>
</tr>
<tr>
<td>32 (45)*</td>
<td>777</td>
<td>30</td>
</tr>
<tr>
<td>—</td>
<td>—</td>
<td>60</td>
</tr>
<tr>
<td>—</td>
<td>—</td>
<td>90</td>
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</tbody>
</table>

* The shortest available total lengths of screws with these thread lengths is shown in parentheses.

As, thread shear area (mm²).
Three types of plates are widely used on the pelvis. For acetabular fixation including the pelvic brim, the posterior column, and the iliac crest, the use of reconstruction plates is preferred. Such plates can be readily shaped to match the complex contour of adjacent bone. If the plate is somewhat misshapen as it is approximated to the bony surface by tightening the corresponding screws, it contours accurately to the bone, whereas in the presence of a stiffer plate that is malcontoured, an anatomically reduced fracture displaces as the anchoring screws are tightened. While the 3.5 mm plate is preferred for most situations, the larger 4.5 mm size is used for a large patient, in the presence of osteoporotic bone, or for an application across the posterior aspect of the sacrum and adjacent sacroiliac (SI) joints.

Conventional Plates
A standard straight plate may be applied primarily to two sites. Short plates of two to four holes are widely used to immobilize the anterior aspect of the SI joint. Generally two plates are used, with one principal anchoring screw inserted into the thick juxta-articular bone that is adjacent to the SI joint. The screws are directed parallel to the joint to permit the maximum length of about 60 mm. A larger plate extending across the sacral ala jeopardizes the overlying L5 nerve root while a corresponding screw is at risk to impale the S1 nerve root. In the authors’ experience, the optimal combination is the use of 4.5 mm cortical screws with a 3.5 mm plate. The narrow space between the screw holes in the 3.5 mm plate is the optimal interval to maximize the lengths of the screws in the limited columns of available bone. The plate can extend into the inter nal iliac fossa, although the corresponding screws diminish rapidly in length and holding power. Nevertheless, especially for a large or morbidly obese patient, the larger plate can be used as an aid to reduce the fracture. After contouring the plate, its medial end is secured to the sacral ala, then a tenaculum bone holding forceps is secured from the most lateral hole in the plate to the outer aspect of the iliac crest. Once the fracture is reduced, the more lateral screw holes in the plate are filled with screws.

A conventional plate, usually of a 3.5 mm size, also may be used effectively on the inner or outer table of the ilium. Many of the iliac portions of an acetabular fracture propagate across the ilium with a lengthy oblique course. During the reduction and fixation of the fracture, the opposing surfaces tend to override. The stiffness of the standard plate resists the deformity as an antiglide property and, thereby, maintains the anatomical alignment while the corresponding screws are tightened.

Bone Plates
Three types of plates are widely used on the pelvis for diverse applications.
Hook or Spring Plate

Both the posterior and acetabular walls are notable for the presence of thin layers of bone. Especially in the presence of comminution and osteoporosis, these areas are difficult to immobilize by lag screws or reconstruction plates. A supplementary hook or spring plate is a highly effective method of proven mechanical stability. A one-third tubular plate of appropriate length, usually three holes, is prepared by shaping two hooks in one end. A special wire cutter is used to cut the thin plate. The hooks are bent at right angles so that they imbed themselves into the capsule or underlying bone during the tightening of the corresponding screws. The plate is shaped with a convex contour over the bone. The plate is aligned with the hooks near the acetabular rim with its axis at right angles to the rim. One or more plates may be used, in combination with an overlying reconstruction plate to buttress a comminuted wall fracture (Fig. 10–2). Care needs to be taken that the hooks are not embedded into the hip joint itself. The method eliminates the need to insert screws near the acetabular rim where they are highly vulnerable to penetrate the hip joint. While the method has been employed for the quadrilateral surface, the plates are not stiff enough to resist the deforming forces, so a secondary protrusion of the hip ensues.

K-Wires

For a comminuted fracture, K-wires have been used to secure small, comminuted, and potentially osteoporotic fragments, especially of the posterior wall. In some cases short wires have been used to anchor free subchondral fragments of cancellous bone. The authors would discourage this method in view of the potential for a belated migration of the K-wire with penetration of the hip joint. Another liability of the method is the difficulty in removal of a buried K-wire at the time of a secondary total hip arthroplasty for posttraumatic arthritis.

Special Fixation Techniques for Osteoporotic Bone

Although the previously described methods are widely used, even in the presence of osteoporotic bone, certain modifications or supplementary techniques may be helpful to optimize the fixation of floridly soft bone.

Alterations with Screw Fixation

In light of biomechanical observations that were reviewed previously, the immobilization of osteoporotic bone is augmented by the use of screws that are of the maximum length and diameter. For an ir-
regularly shaped bone, such as the superior pubic ramus, the surgeon frequently may choose a screw that is either larger in diameter or longer in length than actually required. If the screw were larger in both dimensions, it would penetrate either the side or the far end of the bone. In other sites such as the ilium, a screw directed into the crest may achieve a length of 30 to 90 mm when an alternative one directed into the lateral ilium at a right angle to the crest would possess a maximum length of 12 to 20 mm.

Overall for the pelvis the role for a washer and nut is highly limited. Usually an exposure of the exit side of the screw is impractical or involves excessive stripping. While the method is more practical for the superior pubic ramus, not infrequently the florid nature of the osteoporosis limits its effectiveness.

**ALTERATIONS OF BONE PLATES**

In theory, one potential way to augment the fixation of osteoporotic bone is to switch to larger and longer plates that use screws of a correspondingly larger diameter. For the posterior column and to a lesser degree, the pelvic brim, the method is most effectively utilized. As the outside diameter of the screw increases, two problems are encountered. As reviewed previously, frequently the maximum length of the screw is correspondingly diminished. Also, as the screw diameter increases, the ability to angulate the screw in the screw hole diminishes. In the vicinity of the acetabulum, screws of a larger diameter are particularly difficult to use without a penetration of the hip joint. If a subsequent posttraumatic degeneration with joint space narrowing ensues, a large diameter screw that is in close proximity to the joint may penetrate the acetabulum, with precipitous destruction of the hip. Once the optimum orientation of the screw is compromised, the maximum length of screw may be significantly limited. Also, the path of a lag screw through the plate, thereby, may fail to achieve an orthogonal alignment with the plane of the fracture, the ideal relationship for fracture fixation with the use of a lag screw.

In the presence of a comminuted and osteoporotic wall, the use of spring plates is strongly recommended. Multiple spring plates and an overlying reconstruction plate afford the most effective fixation.

**THE USE OF CABLES OR CERCLAGE WIRE**

Although cerclage fixation of the acetabulum and pelvis have been used sporadically for many years, the method has never achieved widespread application. The technique is particularly effective for osteoporotic bone. Stainless steel wires of 16 or 18 gauge or braided cables of 2 mm are highly effective. The senior author has devised specialized Statinski cardiovascular clamps as passing tools. For passage of cables safely around the vulnerable structures, the cable needs to be kept immediately along the bony surface. The use of a Statinski clamp facilitates such a passage. Although an open exposure of the inner and outer pelvic tables is another feasible method, this technique compromises the blood supply to the bone and increases the risks of a postoperative wound infection and the formation of heterotopic bone. Where a less invasive passage technique is used, however, a clear knowledge of the hazardous sites for a neurovascular injury needs to be available. For acetabular immobilization, the cables can be passed through the greater or lesser sciatic notches and the obturator foramen, and between the anterior-superior and inferior spines. The cables can be passed through 2.5 mm drill holes at the base of the anterior-inferior spine or elsewhere. When the cable is passed through a drill hole and subsequently tightened, the drill hole helps to control the direction of the cable. Otherwise a tightening cable may slide along a flat or convex surface of the bone in an uncontrolled and undesirable fashion.

The senior author has described a technique to buttress the quadrilateral surface with cables in the presence of an anterior wall, column, and quadrilateral surface fracture that is a typical geriatric pattern involving osteoporotic bone (Fig. 10–3). Initially, through an ilioinguinal exposure, the anterior column, and wall are reduced and stabilized with a 3.5 mm reconstruction plate. The plate overlies the pelvic brim. A hook plate may be necessary to buttress the anterior wall. At this stage, the typical large quadrilateral surface fragment, often approaching a square of 5 cm², is reduced by the use of an eccentric or so-called Prince Tong forceps. The large jaw anchors the quadrilateral surface while the shorter jaw engages the outer pelvic table. A 2 mm cable or large wire is passed through 2.5 mm drill holes that are made from the pelvic brim into the quadrilateral surface. Each hole is centered in an empty screw hole in the plate. The plate is passed from the pelvic brim to exit on the quadrilateral surface. A rectangular corticocancellous structural graft of about 5 cm square is prepared from the iliac crest. Two drill holes are prepared in the graft. The cable is fed through the two holes in the graft and inserted into the other hole in the quadrilateral surface. With the Statinski-like passing tool, the cable is advanced until it exits from the other hole in the pelvic brim. The graft is optimally positioned to buttress the quadrilateral surface. Then the cable or wire is tightened and secured. Excess cable or wire is removed with a cutting tool.

A cable has been used to augment the fixation of bilateral iliosacral screws that traverse the entire
width of the posterior pelvis (Fig. 10–4). 36,39 This method has been used to immobilize unilateral or bilateral nonunions of the posterior pelvis including those where prior pelvic irradiation therapy contributed to the problem. Either a single transverse incision or a bilateral vertical incision can be used to expose the SI joints, intervening sacrum, and iliac wings. The former is preferred in view of its superior preservation of the cutaneous blood supply and cosmetic considerations. The nonunion site(s) are debrided and approximated. Autogenous or, if necessary, donor bone graft is used to obliterate a residual bone defect. Under image intensification with antero-}

**FIGURE 10–3** The use of a braided cable to buttress the quadrilateral surface for an anterior column, wall, and quadrilateral surface fracture in a woman of 79 years. (A) AP view. (B) Internal iliac three-dimensional CT view. (C) Pelvic model with the cabling technique including the use of a corticocancellous graft. (D) Postoperative AP view.

posterior, inlet, outlet, and direct lateral views, two guide wires for 7 mm cannulated screws are inserted through one lateral ilium. Either the primary transverse incision or one or two small supplementary incisions can be used to insert the cannulated screws. The guide wires are inserted into the S1 body or occasionally the S1 and S2 bodies. Considerable familiarity with the imaging technique for the iliosacral screw insertion is essential in view of the small target size and the proximity of significant hazards, notably the contents of the neural canal, the common iliac arteries, and veins and the rectum. 40 The guide wires are inserted so that they extend precisely across the
width of the pelvis, parallel to the S1 vertebral end plate and the anterior aspect of the S1 vertebral body. Where the S1 body is used, both wires may be superior to the S1 foramina or the wires may straddle the foramina. Not infrequently, sacral anomalies are encountered that may necessitate the use of a somewhat altered insertional technique. Once the guide wires are inserted, the depth gauge is used to document the optimal lengths of the screws, which typically are 120 to 130 mm in length. The holes are drilled to within 1 cm of the opposing lateral iliac outer table. Tapping of the osteoporotic bone is unnecessary. The two screws are fully inserted over the guide wires. Prior to its removal each guide wire is advanced so that it penetrates the opposing outer iliac table. A 2 mm cable is advanced along the cannula of one screw. When it exits from the opposing ilium, under direct vision, it is fed through the screw hole of a two-hole 3.5 mm plate, which serves as a “washer,” and then the cable is advanced in a retrograde fashion down the cannula of the second screw. A second two-hole plate is used as a washer for the two free ends of the cable, and then the cable is tightened and secured. A supplementary plate can be applied across the back of the pelvis.

**FIGURE 10–4** The use of a braided cable to augment iliosacral screws for bilateral sacral alar insufficiency fractures in a woman of 82 years. A supplementary plate stabilizes the posterior pelvic column. (A) Anterior three-dimensional CT view. (B) CT scan of the sacral body. (C) Postoperative AP view. (D) Postoperative inlet view.

**COLUMNS OF PELVIC FIXATION**

Particularly for a pelvic nonunion that is complicated by the presence of marked osteoporosis and potentially prior irradiation therapy, the concept of pelvic columns is helpful (Fig. 10–5). The pelvic ring can be perceived as possessing three supportive columns: an anterior one of symphysis and adjacent rami, a middle one with the lateral ilia, and sacral iliac joints including the ala and sacral bodies. The posterior column consists of the posterior sacral elements and adjacent sacroiliac ligaments. Fixation techniques are available for all three columns. For a conventional acute unstable pelvic ring disruption, typically two columns are immobilized either as the anterior and middle or anterior and posterior columns. For the formidable nonunion of osteoporotic and potentially irradiated bone, three
columns of fixation is recommended by the authors. For the osteoporotic pelvis, where the rami are the most osteopenic bone, for two columns of fixation, the middle and posterior are the preferred sites of immobilization.

**The Use of Methylmethacrylate Cement**

Supplementary methylmethacrylate cement has been widely used to augment the structural attributes of osteoporotic bone so that screws achieve a more robust fixation. The method is well accepted for the appendicular skeleton. From the authors’ experience, the method is somewhat less satisfactory for pelvic applications. Where the cement is injected into a pelvic screw hole, extrusion of the cement beyond the opposing pelvic table may create a potential for a significant complication as a thermal or mechanical source of injury to neighboring neurovascular structures or intraabdominal viscera. Similarly, errant extrusion of cement into the hip joint is another potential complication. Nevertheless, the method is potentially feasible for selective applications where a meticulous injection technique is used.

**External Pelvic Fixation**

In the presence of an acute unstable pelvic fracture, external fixation is widely used to immobilize the pelvic ring. The method is particularly attractive when a patient presents with hemodynamic instability that is secondary to an external rotational deformity of one or both sides of the pelvis. Not infrequently, with the application of an external frame and upon a closed reduction of the pelvis with reapproxiimation of the opposing rami at the symphysis, tamponade of the blood in the retroperitoneal space permits a rapid restoration of hemostasis. Where posterior pelvic instability is confirmed, the restoration of stability necessitates a supplementation or replacement of the frame with internal fixation. In this situation, fixation of either the anterior and middle or the anterior and posterior pelvic columns is recommended. In an osteoporotic, elderly individual, usually anchorage of the external fixation pins in the pelvis is effectively lost about 3 weeks after insertion. Unless a loose pin is removed, generally a pin track infection ensues as an additional complication. Ironically, in an elderly patient who presents with hemodynamic instability secondary to an acute unstable pelvic fracture, the minimally invasive nature of external pelvic fixation is particularly advantageous.

Once the fixation pins have been inserted and the frame has been loosely assembled, the optimal method to achieve a reduction of the pelvis is to temporarily reposition the supine patient in a lateral decubitus position, with the patient resting on his stable hemipelvis. The reduction of the deformity is undertaken by a combination of manual manipulation of the pelvis along with positioning of the uppermost leg, possibly with the use of longitudinal traction. Either as part of the same procedure or subsequently, percutaneous iliosacral screw fixation may provide an adequate mechanical supplementation. In such an elderly patient, the presence of comorbidities may inhibit a return to the operating room to augment the external fixation for a period of weeks or occasionally longer.

If a pin track infection occurs, the frame is detached from the pin to permit an assessment of the pin for signs of premature loosening. If the pin is loose, it is removed. Generally, there is no available bone to insert a replacement pin. If an infected pin site displays a well-anchored pin, the site is debrided and an appropriate antibiotic is given.

**The Presence of Prior Irradiation Therapy**

Currently the number of patients with long-term survival after treatment for malignancy by the use of pelvic irradiation therapy is increasing rapidly. Years after the nominally curative regime of treatment, insufficiency fractures of the pelvis may arise that are vulnerable to progress to one or more nonunions. Occasionally, the problem presents as an acute pelvic or acetabular fracture or periprosthetic fracture after minor or major trauma. For the inexperienced surgeon, this situation provides multiple potential problems. Surgical approaches to the acetabulum and pelvic ring are fraught with hazards, especially anterior exposures to the irradiated pelvic structures.
ring. With the scarified soft tissues and obliteration of the normal planes or intervals, the risk for iatrogenic injury to major neurovascular structures is greatly increased. Postoperative wound infections may be fulminating in nature with a progressive necrosis of the involved soft tissues. Closure of the wound may become a formidable challenge. If the entire hip joint previously was irradiated and an acetabular exposure develops a deep wound infection, a Girdlestone-type resectional arthroplasty may be necessary to eradicate the infection. When the irradiated bone is exposed, the necrotic tissue may involve a surprisingly extensive region. After sterilization of the wound is achieved, an obliteration of a massive soft tissue and osseous defect by the use of bone graft may be hampered by a poor likelihood for effective incorporation of bone graft into the avascular bed. A thorough review of plain radiographs and especially of CT scans may permit the delineation of the potentially extensive avascular area of bony involvement. Occasionally, such a patient presents with multiple insufficiency fractures and nonunions around the pelvic ring so that elimination of the pelvic pain is unlikely to be achieved. At the very least, such knowledge should be used to advise the patient about the potential surgical risks, complications, and the likelihood for a successful outcome. If the orthopaedic surgeon selects an anterior exposure, it is prudent to request the assistance of a general or vascular surgeon for the procedure. For immobilization of such a fracture, the recommendations provided here with respect to osteoporotic bone may be considered. In selective patients, particularly in the presence of significant medical comorbidities and despite the presence of incapacitating pelvic pain, a continued conservative therapeutic regime may be advisable.

**Primary Total Hip Arthroplasty for Selective Acetabular Fractures Complicated by Osteoporotic Bone**

Historically, for a displaced and incongruent acetabular fracture, the preferred treatment was an open reduction and internal fixation. If posttraumatic arthritis or avascular necrosis ensued with marked pain, a secondary total hip arthroplasty generally followed. In the experience of the authors, certain acetabular fractures, notably in the elderly with osteoporosis, possess an intrinsically abnormal prognosis irrespective of the initial method of treatment. If an open reduction is unlikely to improve the prognosis and if it inevitably introduces the potential for complications that would not occur after closed treatment, another option is closed treatment. If symptomatically indicated, a secondary total hip arthroplasty can be performed. Still another possibility for the acute case with a very poor outlook is a primary total hip arthroplasty. During the past 15 years, this method has been utilized by the senior author on 63 cases that were reported elsewhere. Of this group, 27 acute arthroplasties were undertaken in the presence of osteoporotic bone. In brief, the method appears to afford highly promising results. The technique has been used as a cementless or hybrid arthroplasty whereby a multiscrewed cup serves as a “hemispherical plate” to immobilize the fracture. The femoral head is available as a structural or morselized graft. Supplementary immobilization of the fracture has been achieved by the use of lag screws, plates, and cables. The cables are particularly helpful to buttress the quadrilateral surface and are consistent with the use of a standard total hip approach. An example of such a reconstruction is displayed in Figure 10-6.

**Periprosthetic Acetabular Fractures**

One of the more common types of acetabular fracture in an osteoporotic individual is a periprosthetic fracture following a total hip replacement. The fracture may be the sequel of major or minor trauma or an insufficiency fracture, possibly complicated by a prior history of pelvic irradiation therapy. There may be antecedent or concomitant loosening of the cup. In the former case a progressive, long-standing lysis of acetabular bone stock may have predated the fracture. In the presence of major trauma, a large periacetabular defect may complicate the picture. Clearly the details of management of such a problem are beyond the scope of this chapter, although such methods have been reported elsewhere. The general principles of treatment start with a complete diagnostic survey including multiple images to ascertain the extent and location of the bony defect and fracture. Where the process is of an insidious origin, the potential for an occult infection needs to be considered, with a possible evaluation including an aspiration arthrogram. Various methods to stabilize the fracture and obliterate the defect merit consideration, along with the preferred type of replacement cup. Techniques for the exchange arthroplasty may include the use of a jumbo cup, an acetabular cage, impaction grafting with mesh reinforcement, or a bulk allograft. For the more complex case, the availability of more than one method in the operating room is strongly recommended. Not infrequently, after a visual inspection of the defect site and despite extensive preoperative imaging, the defect is more extensive than anticipated so that modification of the preoperative plan is necessary. The preoperative plan should be devised on the basis of the principal site of the defect. Where the de-
fect is anteromedial, as best demonstrated in an obturator oblique view, proximity of the displaced or protruded cup to the external iliac vessels merits consideration. If such displacement is confirmed, a preoperative angiogram or three-dimensional CT vascular study is advised to determine whether an initial exploration of the relevant vessels is indicated. Similarly, where the cup is displaced posterior medially into the roof of the greater sciatic notch, and as best assessed in an iliac oblique view, the proximity

FIGURE 10-6 An acute total hip replacement for a highly comminuted acetabular fracture involving the anterior column, wall, and quadrilateral surface with extensive impaction of the articular surfaces in an osteoporotic woman of 81 years. (A) Anterior three-dimensional CT view. (B) Disarticulated anterior three-dimensional CT view to display the comminution and impaction. (C) Postoperative AP view. (D) Postoperative obturator oblique view.
of the cup to the sciatic nerve is a concern. Appropriate modifications in the technique may include intraoperative neurological monitoring with continuous electromyelographic monitoring or with the use of somatosensory evoked potentials.52–54 Alternatively the sciatic nerve may be explored primarily to carefully separate it from the adjacent displaced cup.

**Complications**

In common with other major acetabular and pelvic reconstructive procedures, a diverse array of complications may arise. Many of these follow the proximity of neighboring anatomical structures that are vulnerable to injury during the surgical exposures or the use of sharp tools. The more frequently encountered problems are reviewed.

**Neurological Injury**

Although various neurological injuries may occur including those to the femoral, obturator, pudendal, and gluteal nerves and the lateral femoral cutaneous nerve to the thigh, the most common occurrence is a traction injury to the sciatic nerve or lumbosacral plexus. Where the nerve is injured traumatically in a frank or occult manner, it is especially vulnerable to a major aggravation with minor traction or other form of injury that may accompany the pelvic reconstruction.55 Where the patient has spinal stenosis or degenerative disc disease with foraminal encroachment, possibly of a clinically occult nature, he or she possesses a markedly increased risk of a traction injury during pelvic surgery with manipulation of the sciatic nerve and ipsilateral lower extremity. The provocative position of flexion of the hip and extension of the knee is minimized by positioning the limb with the knee flexed beyond 90 degrees. Certainly in a case with known risk factors, the use of intraoperative neurological monitoring merits serious consideration.

If sciatic nerve palsy with a foot drop arises, splinting of the foot in a neutral position is recommended to avoid or minimize a fixed equinus contracture. In the presence of neurogenic pain, the use of amitryptiline may be helpful, along with a referral of the patient to a pain clinic. In about 50% of the cases, a full recovery occurs over a period of many months.

**Vascular Injury**

After a pelvic fracture, numerous problems and associated major injuries may contribute to the presence of uncontrolled hemorrhage of a life-threatening magnitude. The risk of early posttraumatic hemorrhage can be minimized by the use of standard protocols for resuscitation and an integrated team approach to management. From the perspective of the current review, iatrogenic causes of major hemorrhage during pelvic reconstructive surgery are uncommon but potentially serious complications that require prompt therapeutic intervention. If a large vessel is lacerated, rapid vascular control and consultation with a vascular surgeon to achieve a repair is indicated. In the elderly patient, potentially with pre-existing occlusive vascular disease, a more common event follows overenthusiastic traction and manipulation of the femoral or external iliac vessels during an ilioinguinal approach. A thrombus or embolus may form to jeopardize the viability of the relevant lower extremity. An urgent thrombectomy or embolectomy with the use of a balloon catheter is indicated. In the at-risk elderly patient, minimizing the intraoperative manipulation of the vessels is the single most critical preventive measure. This should be followed by a meticulous postoperative protocol that permits a prompt recognition of a delayed vascular occlusion with serial clinical assessments of the pulses in the relevant limb and the use of a Doppler device.

**Postoperative Wound Infection**

A predilection for a deep wound infection after pelvic reconstruction includes an extensile approach, morbid obesity, and a history of prior irradiation therapy.9,21,56 If a wound displays the presence of a draining hematoma or of increasing wound drainage possibly with purulent fluid, a deep exploration of the wound is strongly recommended, along with appropriate antibiotic therapy. A resection of necrotic tissue and pulsatile jet lavage is necessary. Generally, the wound is reclosed, although in the presence of continued drainage, a reexploration may be necessary. If the debridement(s) culminate in the creation of a deep dead space, obliteration with a suitable antibiotic-impregnated cement spacer is advisable. In the presence of prior irradiation therapy, a deep infection may necessitate a sizable resection of devitalized tissues before eradication of the infection is achieved. In the elderly in general, and especially in the presence of prior pelvic irradiation therapy, the use of an extensile pelvic exposure is strongly discouraged.

**Thromboembolism**

After a pelvic fracture, the incidence of deep venous thrombosis (DVT) is 35 to 60%.57–59 Such a clot may be situated distally or proximally, where the latter location is vulnerable for dislodgement with the potential for a subsequent pulmonary embolus (PE). After pelvic trauma, the incidence of a proximal clot is 25 to 35%. The incidence of a subsequent PE is 2 to 12%, with a risk of a fatal PE of 0.5 to 10%. In the presence of polytrauma and especially in an older patient, these rates may become even greater. After pelvic re-
construction in adults, including the elderly, routine therapeutic anticoagulation with low molecular weight heparin or coumadin is recommended.29 Unless the patient has a prior history of DVT/PE, a 3-week course is used. After major pelvic surgery, even minor excessive anticoagulation may predispose the patient to a wound hematoma that is vulnerable to a secondary infection. Careful regulation of the dose of anticoagulant, therefore, is necessary. If the patient possesses a specific contraindication for the use of therapeutic anticoagulation, the insertion of a filter in the inferior vena cava merits consideration as a therapeutic alternative.60,61

Failed Fixation and Persistent Nonunion
Where effective reduction strategies and internal fixation techniques are applied, late failure of the fixation is uncommon. Usually contributing factors are evident such as an inadequate fixation, insufficient columns of fixation, or impaired healing, such as occurs with prior treatment with irradiation therapy. Occasionally, the reduction and fixation are apparently satisfactory but a symptomatic nonunion persists with pain. The contributing factors in the problem need to be carefully identified and addressed. Where the fixation is intact, the nonunion site can be explored, debrided of intervening necrotic tissue, and obliterated with bone graft, preferably of autogenous cancellous bone. If pelvic irradiation therapy was previously employed, standard techniques of pelvic fixation and bone grafting may possess a high likelihood for failure, possibly complicated by a fulminant postoperative wound infection.

In the osteoporotic patient, the use of external pelvic fixation is marginally effective. Initially after their insertion, the pins achieve a modest purchase in the osteopenic bone. Within about 3 weeks, usually they undergo an effective loss of purchase in the bone with the onset of a pin track infection. Overall these shortcomings of external fixation seriously impair its usefulness in an elderly individual who sustains an acute unstable pelvic disruption, at least beyond the early posttraumatic and resuscitative period.

Persistently Pelvic Pain
About 60% of pelvic fracture victims have prolonged pelvic pain.1,15,62,63 Frequently the specific site of origin of the pain is difficult to determine. Especially in the elderly, a distinction of true pelvic pain from low back pain can be a formidable diagnostic problem, whereby the latter may be of posttraumatic or degenerative origin. Other sites of residual pelvic pain may be an associated neurological injury or posttraumatic arthritis or instability of the SI joint. For an evaluation of the problem, electromyelographic studies and nerve conduction velocities with MRI or myelography may be helpful to evaluate neurogenic pain. To assess the SI joint, plain radiographs, a CT scan with a CT-guided injection of local anesthetic, and a technetium bone scan are suggested. To implicate the SI joint as a source of persistent pain secondary to posttraumatic arthritis, multiple tests should provide confirmation of the diagnosis, including degenerative changes in the CT scan, temporary relief of pain with the CT-guided injection of local anesthetic, and increased activity in the bone scan. Otherwise, a SI fusion is unlikely to provide relief of pain.

For elderly patients with marked osteoporosis and a great likelihood for pelvic insufficiency fractures, these problems are likely to be a source of persistent pain. Where prior irradiation therapy was administered to manage a malignancy, a recurrence of the tumor is another possibility. As a single diagnostic test, an MRI provides the optimal technique to identify an insufficiency fracture and to distinguish it from recurrence of the tumor.

Symptomatic Hardware
The principal site for symptomatic hardware is a subcutaneous location such as the anterior iliac crest. Once the fracture is healed, metal removal is advised. Most retained hardware is asymptomatic. In the presence of discomfort, an occult nonunion is a potential explanation for which a CT scan, a tomogram, or technetium bone scan merit consideration. If such a nonunion is confirmed, then a revision of the fixation and bone grafting may be necessary to relieve the pain.

Conclusions
Most osteoporotic acetabular and pelvic fractures arise in elderly individuals or others who have a high likelihood to possess one or more medical comorbidities. If the fracture results from high velocity or major trauma, the management of the pelvic disruption may be heavily influenced by the greater systemic upset that usually occurs in such a patient. Most pelvic fractures in the elderly follow minor trauma, frequently as isolated injuries. When the fracture is obscured by the presence of osteoporosis, the use of a technetium bone scan or MRI may permit detection. Many of the occult injuries respond favorably to conservative treatment. Where operative treatment is selected, in view of an unstable fracture or other indication, the use of isolated screws or screws and plates is compromised by osteoporotic bone. In milder cases of osteoporosis, screws may be optimized by the selection of the maximum length and diameter. For more severe osteoporosis, special fixation techniques are available that employ supplementary cables or occasionally bone cement. For the
unusual acetabular fracture with extensive impaction, abrasion, or comminution, an acute conservative treatment may be used with a secondary total hip arthroplasty, if symptomatic degenerative change develops. Alternatively, an acute total hip arthroplasty can be undertaken. Neurovascular and thromboembolic complications can be minimized by a meticulous surgical technique and appropriate medical management. The treatment of other uncommon late problems such as a wound infection, nonunion, and posttraumatic arthritis also are reviewed.

REFERENCES

The orthopedic surgeon often manages the complications of Paget’s disease, especially when they manifest as arthritis, skeletal deformity, pathologic fracture, or malignant degeneration. The proper care of these patients involves a multidisciplinary approach, which may include primary care doctors, rheumatologists, physiatrists, physical therapists, and social workers. Indications for surgery in Paget’s disease are few and include unstable fractures, symptomatic arthritis, severe limb malalignment, and malignant degeneration. This chapter focuses on the treatment of orthopaedic complications of Paget’s disease requiring the use of internal fixation.1,2

**GENERAL TREATMENT CONSIDERATIONS**

Few who have Paget’s disease will require treatment. Nonsteroidal anti-inflammatory medications have an important role in treating the symptomatic arthritis associated with Paget’s disease (Table 11–1). Newer cox-2 inhibitors are likely to provide more specific anti-inflammatory relief with fewer gastrointestinal side effects. Narcotic agents should be avoided, if possible, particularly in the older population.1,2

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**Table 11-1**

**Pharmacologic Treatment of Paget’s Disease**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>Special Considerations</th>
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<tbody>
<tr>
<td>Pamidronate</td>
<td>60–90 mg intravenously slowly over 3 1/2 to 4 hours; patients with more severe disease may need 60 mg monthly or quarterly for variable periods</td>
<td>Transient fever (&lt;24 h) is common side effect</td>
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<tr>
<td>Alendronate</td>
<td>40 mg orally daily for 6 months; retreatment may be considered after 6 months</td>
<td>Must be taken in AM upon waking with an 8 oz glass of water; avoid eating for 45 minutes; do not lie down after taking medication; patients should be instructed to take adequate calcium supplementation (1000–1500 mg daily) and adequate vitamin D supplementation (800–1000 units daily) to avoid secondary hyperparathyroidism</td>
</tr>
<tr>
<td>Risedronate</td>
<td>30 mg orally daily for 2 months; retreatment may be considered following posttreatment observation of at least 2 months if relapse occurs, or if treatment fails to normalize serum alkaline phosphatase</td>
<td></td>
</tr>
<tr>
<td>Salmon calcitonin</td>
<td>50–100 international units subcutaneously daily; after symptomatic improvement, may reduce to three times weekly</td>
<td>Antisalmon calcitonin antibodies develop in 60% of patients; clinical resistance in &gt;20%</td>
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</table>
A cane can be a very important therapeutic device for patients with Paget’s disease of the lower limbs. A cane provides increased stability, prevention of falls, and load-sharing capability. The use of a cane makes good sense and should be standard treatment for the elderly patient who has Paget’s disease involving the lower limbs.

**General Surgical Considerations**

Indications for surgical intervention in Paget’s disease include unstable fractures, malignant transformation, and severe arthritis that is refractory to medical treatment. Relative indications for surgery include malalignment of a major weight-bearing bone or impending fracture, even though these may be treated with an orthosis. Spinal decompression for spinal stenosis is an important consideration, but there are few data on the management of this complication.

Surgical intervention in Paget’s disease is most often sought when degenerative arthritis of the hip or knee produces severe pain with movement. Anti-inflammatory agents usually produce little relief of symptoms in this setting. Diagnostic intraarticular injections with a local anesthetic often confirm that the pain is primarily articular, rather than osseous. Total hip replacement is highly effective in relieving hip pain and restoring mobility. Tibial osteotomy is equally effective in relieving knee pain in patients who have severe tibial bowing if the associated articular degeneration is not far advanced. The Ilizarov external fixator has been used successfully in limited application for treatment of deformities in Paget’s disease.

Before any operative procedure is performed, it is desirable, if possible, to reduce disease activity by drug therapy to prevent excessive blood loss. Preoperative medical treatment with bisphosphonates or calcitonin decreases intraoperative bleeding. A reduction in serum alkaline phosphatase activity to approximately 50% of pretreatment levels is probably adequate preoperative control. In elective cases it is desirable, therefore, to begin antipagetic medication at least 6 weeks before surgery. When osteotomy followed by bone healing is planned, bisphosphonates are the drugs of choice.

When total joint replacement is performed, long-term suppression of disease activity through use of bisphosphonates may be desirable to diminish excessive bone-remodeling activity and to prevent loosening of prosthetic components. In all circumstances requiring bone surgery, the patient must be aware that delayed bone healing may occur and that a lengthy rehabilitation program may be necessary.

**Fracture Fixation**

Pathological fractures are a common complication of Paget’s disease. Painful fissure fractures or pseudofractures and completed pathological fractures occur in areas of high mechanical stress, particularly in the weight-bearing bones of the lower limbs. Fracture healing is often complicated by delayed union. Complete immobilization of pagetic bone should be avoided because intercurrent osteopenia of immobilization further imperils the structural integrity of bone already weakened by Paget’s disease.

Exacerbation of pain in pagetic bone should raise suspicion of a pathological fracture, leading to prompt roentgenographic evaluation. Accelerated metabolic activity of active pagetic bone poses added complications when fractures occur, although none of the complications are specific to Paget’s disease (Table 11–2). In addition to following basic principles of fracture management, attention should be directed at decreasing metabolic activity in pagetic bone. Prolonged immobilization can further exacerbate osteopenia and provoke metabolic complications of hypercalcemia and hypercalciuria. Functional fracture bracing may be necessary to supplement open reduction and internal fixation.

Several series report the treatment of femur fractures in patients who have Paget’s disease. The use of modern intramedullary devices has yielded more predictable results. Several types of fractures, including proximal femoral fractures involving the subtrochanteric region, have been identified as problem fractures compared to subcapital, intertrochanteric, and femoral shaft fractures.

The selection of a fixation device in Paget’s disease is based on the same principles of fracture care used in nonpagetic fractures. Using longer plates may provide improved stability. Load-sharing devices with fixation extending outside areas of disease activity may offer help in improving construct stability. When using an intramedullary rod, the surgeon must assess overall bone alignment in all planes to ensure passage of the device in the canal. Severe bone deformity may not allow intramedullary fixation (Fig. 11–1). Reaming may be required to allow nail insertion.

**Table 11–2 Complications of Fractures in Paget’s Disease**

<table>
<thead>
<tr>
<th>Delayed union; nonunion</th>
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<tr>
<td>Malunion with increased deformity</td>
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<tr>
<td>Excessive bleeding</td>
</tr>
<tr>
<td>Compartment syndrome</td>
</tr>
<tr>
<td>Focal disuse osteopenia</td>
</tr>
<tr>
<td>Hypercalcemia</td>
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<tr>
<td>Hypercalciuria</td>
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</table>
Tibial Osteotomy

Tibial osteotomy is a useful procedure to realign the knee and decrease mechanical pain. Indications include disabling mechanical pain unresponsive to medical therapy. Tibial osteotomy is a relatively safe and effective procedure. Surgery should be performed only under preoperative cover of one of the newer bisphosphonates. Recently, some anecdotal success has been reported using the Ilizarov external fixator for tibial osteotomies in patients with Paget’s disease.

Total Joint Arthroplasty

Total joint arthroplasty has transformed the care of patients with advanced osteoarthritis and is a valuable adjunct in alleviating severe joint pain associated with Paget’s disease. The major indication for total hip arthroplasty is severe mechanical hip pain unalleviated by antipagetic medication. It is essential for the orthopedic surgeon to distinguish pathological bone pain from mechanical joint pain arising from the hip joint. In other words, it is important to determine if the pain is osseous or articular in nature. An intraarticular, diagnostic injection of lidocaine or a therapeutic trial of antipagetic medication may help distinguish bone pain from joint pain. The antipagetic medication will not substantially affect the mechanical component of pain.

Groin pain associated with Paget’s disease could be secondary to pagetic involvement of the pubis, stress fractures of the pelvic bones or hip, pathological fractures of the femoral neck, or associated visceral and/or neurological involvement. Further clarification of “hip pain” in Paget’s disease may include the use of nonsteroidal anti-inflammatory medication or intraarticular injections with an anesthetic agent to distinguish osseous from intraarticular pathology.

When a decision has been made to perform total joint arthroplasty, a thorough preoperative medical evaluation should be conducted. Anticipated dental or urological procedures such as tooth extraction or prostate surgery should be accomplished before total joint arthroplasty is performed to minimize risks for postoperative bacterial seeding of the endoprosthesis. The patient should be treated preoperatively with antipagetic medication to decrease bone remodeling and to minimize intraoperative bleeding. Autologous preoperative blood donation should be considered. Finally, as in all total joint arthroplasties, perioperative prophylactic antibiotics should be administered systemically.

Technical problems arising at the time of surgery include excessive blood loss, osseous deformity, intraoperative fracture, and sclerotic pagetic bone. Excessive blood loss can be reduced by judicious preoperative use of antipagetic medication. Special instrumentation needs should be anticipated if severe
osseous deformity or sclerotic bone exists. The decision to use cemented or noncemented prostheses remains controversial (Fig. 11–2).\textsuperscript{17,21,22,25,26} Custom femoral prostheses do not provide any advantage.\textsuperscript{27} Circumstantial evidence suggests that the newer bisphosphonates may delay prosthetic loosening, but long-term prospective studies are necessary.

Several studies have retrospectively evaluated long-term complications of total hip arthroplasty in Paget’s disease. In addition to the 1 to 2% risk of major perioperative complications encountered in most large series of nonpagetic total hip arthroplasties, increased risk of aseptic loosening, heterotopic ossification, acetabular protrusion, and varus deformity of the femoral components have been noted (Table 11–3). Mechanical failure requiring reoperation occurred in 10 to 15% of patients in several large series. Nevertheless, the results of total hip arthroplasty in patients with severe disabling pagetic arthritis of the hip have been encouraging and cited as good to excellent in 75 to 85% of patients based on well-accepted scales of pain relief and function.\textsuperscript{19,28–32}

### SPINAL DECOMPRESSION

Spinal stenosis is a common problem in Paget’s disease. In patients with Paget’s disease, one third have spinal involvement. One third of those with spinal involvement have evidence of symptomatic spinal stenosis. Half of those with spinal involvement have back pain. Both spinal stenosis and facet arthropathy are directly related to the bony structural changes of Paget’s disease. Facet arthropathy is often a major contributing cause of both back pain and spinal stenosis. The most common cause of neurological dysfunction from pagetic spinal stenosis is osseous compression by an enlarging vertebral body. Symptomatic pagetic spinal stenosis with neurological claudication has been shown to respond well to medical therapy with calcitonin and bisphosphonates.\textsuperscript{6} Surgical decompression rarely is necessary and can lead to complications of spinal instability.\textsuperscript{5,33–39}

Surgical decompression is difficult because obstruction can occur at multiple levels. The highly vascular pagetic bone poses significant risk for bleeding complications. Furthermore, the age group in which Paget’s disease occurs often makes these patients poor operative candidates. Frequently revision surgery is often required secondary to incomplete decompression. Operative mortality has been reported in about 11% cases.\textsuperscript{40}

<table>
<thead>
<tr>
<th>TABLE 11–3</th>
<th>COMPLICATIONS OF ARTHROPLASTY IN PAGET’S DISEASE</th>
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<tbody>
<tr>
<td>Aseptic loosening</td>
<td></td>
</tr>
<tr>
<td>Varus deformity</td>
<td></td>
</tr>
<tr>
<td>Heterotopic ossification</td>
<td></td>
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<tr>
<td>Excessive bleeding</td>
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</table>

A recent retrospective study of 98 Charnley low-friction arthroplasties performed on 76 patients reported 10-year follow-up demonstrating dramatic preoperative to postoperative improvement in both pain and functional scores despite multiple technical difficulties at operation. Intraoperative blood loss averaged 388 mL (range: 110 to 1730 mL), with minor heterotopic ossification occurring in 25% and major heterotopic ossification in four hips (4%). Aseptic loosening occurred in 10% of acetabular components and in 8% of femoral implants, but there was no evidence of progressive acetabular protrusion or femoral deformity after operation. Survivorship to revision was 98% at 10 years and 91% at 15 years for the acetabular component, and 93% and 89% for the femur. The only increased risk identified was nonunion of the trochanteric osteotomy (13%).\textsuperscript{29}
CONCLUSION

Internal fixation in Paget’s disease is often necessary for the management of pagetic complications. When possible, medical therapy should be attempted prior to surgical consideration. If surgery is required, preoperative treatment with bisphosphonates or calcitonin should be initiated to help reduce intraoperative bleeding. Surgeons should be aware of the increased morbidity and mortality of these patients.

Through medical and physical therapy modalities available to all physicians and through the judicious use of surgery in selected cases, the orthopedic surgeon often is able to preserve and restore function in this common disorder.

REFERENCES

30. Schai PA, Thornhill TS, Scott RD. Total knee arthroplasty with the PFC system. Results at a minimum of ten years and survivorship analysis [see comments]. J Bone Joint Surg Br 1996;80B:850–858.


Osteogenesis imperfecta is a heterogeneous group of inherited disorders caused by defective collagen synthesis, often leading to frequent fractures and the development of progressive deformity of the long bones. Osteopenia is a consistent finding with this disorder. Even in the most mildly involved patients, the bone mineral density averages approximately 30% lower than normal.1,2 In the early stages of the disease, fractures are usually managed nonoperatively. Operative intervention becomes necessary when recurring fractures or progressive deformity begin to limit function.

Of historical note, Seedorff3 suggested that Ivar Benlos (also known as Ivar the Boneless), who lived in the last quarter of the ninth century, may have been afflicted with osteogenesis imperfecta. Ivar, eldest son of the Danish king Regnar Lodbrog, is said to have had legs as soft as cartilage. Unable to walk, he had to be carried into battle on a shield. According to Tsipouras,4 complete verification of Ivar’s diagnosis is impossible because his skeletal remains are no longer available for study, having been exhumed and burned by William the Conqueror.

More tangible evidence of an early case of osteogenesis imperfecta can be found in an Egyptian mummy dating from about 1000 years B.C.5 The mummy had a tam-o’-shanter-shaped skull, radiographs of which revealed numerous Wormian bones. The long bones were deformed, with those of the lower extremity showing marked anterolateral bowing. Moreover, the teeth were amber in color, and the roots were disproportionately smaller than the crowns, both findings suggestive of dentinogenesis imperfecta.

In 1788, Eckmann provided what is now generally recognized as the first scholarly account of hereditary bone fragility through three generations.3,4 He termed this condition osteomalacia congenita. Seedorff5 wrote that osteogenesis imperfecta should be called Eckmann’s disease, “if at all one wants to practice the bad custom of naming a disease by its first describer.”

**Classification Systems**

Silence et al6,7 classified osteogenesis imperfecta into four distinct groups based on phenotypic features, radiologic appearance of the bones, and the mode of inheritance (Table 12–1). Their system is currently the most widely used.

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
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<tbody>
<tr>
<td>I</td>
<td>Autosomal dominant inheritance</td>
</tr>
<tr>
<td></td>
<td>Blue sclerae</td>
</tr>
<tr>
<td></td>
<td>Milder short stature</td>
</tr>
<tr>
<td></td>
<td>Milder short stature</td>
</tr>
<tr>
<td>II</td>
<td>Autosomal recessive inheritance or new dominant mutation</td>
</tr>
<tr>
<td></td>
<td>Lethal in perinatal or newborn period</td>
</tr>
<tr>
<td>III</td>
<td>Autosomal recessive inheritance or new dominant mutation</td>
</tr>
<tr>
<td></td>
<td>Severe bone fragility and progressive deformity</td>
</tr>
<tr>
<td></td>
<td>Severe short stature</td>
</tr>
<tr>
<td></td>
<td>May or may not have dentinogenesis imperfecta</td>
</tr>
<tr>
<td>IV</td>
<td>Autosomal dominant inheritance</td>
</tr>
<tr>
<td></td>
<td>Bone fragility and deformity more marked than type I</td>
</tr>
<tr>
<td></td>
<td>Short stature more marked than type I</td>
</tr>
<tr>
<td></td>
<td>Subtype A: dentinogenesis absent</td>
</tr>
<tr>
<td></td>
<td>Subtype B: dentinogenesis present</td>
</tr>
</tbody>
</table>

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1. Seedorff.3
2. Tsipouras.4
3. Sillence et al.6,7

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**Chapter 12**

**Internal Fixation in Patients with Osteogenesis Imperfecta**

Lewis E. Zionts and Edward Ebramzadeh
Types II and III are severe forms of the disorder. Type II osteogenesis imperfecta is characterized by extremely fragile bone, often resulting in perinatal or early infant death. Radiographs show crumpled (concertina-like) femora, angulated fractures of the tibia, fractures of the shafts of the upper limbs, platyspondyly, and a beaded appearance of the ribs (Fig. 12–1). Type III osteogenesis imperfecta causes severe bone fragility, and multiple fractures are usually present at birth. With age, these patients develop severely shortened stature and progressive deformity of the limbs and spine (Fig. 12–2).

Types I and IV osteogenesis imperfecta are milder forms of the disorder, with type I representing the mildest. Patients with type I osteogenesis imperfecta have distinctly blue sclera and generally fewer fractures, with less severe deformity of the limbs and spine than those with type IV (Fig. 12–3). In contrast, type IV is a moderately severe form of the disorder with wide phenotypic variability. Patients with type IV osteogenesis imperfecta have shortened stature and deformity of the long bones and spine, with intermediate severity between those of types I and III (Fig. 12–4). Managing fractures and deformities in type III and IV patients presents the greatest challenge to the physician. Shapiro proposed another classification scheme that may be used to predict the survival and walking ability of patients with osteogenesis imperfecta (Table 12–2). In this system, patients are classified according to the time of the initial fracture and the radiographic appearance of their long bones and ribs. Patients who have intrauterine or birth fractures are classified as osteogenesis imperfecta congenita (OIC). These are further subdivided into subgroups A and B. In subgroup A, radiographs show short, broad, crumpled femurs and ribs, whereas in subgroup B, radiographs show bones with normal contours. In contrast to OIC, individuals who sustain their first fracture after birth are classified as osteogenesis imperfecta tarda (OIT). These patients are further subdivided into subgroup A, who sustain their first fracture before walking has begun, and subgroup B, who suffer their first fracture after walking has begun.

Shapiro found that survival was poor in patients classified as OIC-A. In his report, 14 of 16 OIC-A patients died before 2 years of age. By comparison, survival of OIC-B patients was much better; however, many required a wheelchair for mobility. The prognosis for ambulation was better in OIT patients; that is, two thirds of OIT-A patients and all OIT-B patients were ambulatory.
SECTION II  CURRENT CLINICAL TECHNIQUES

FIGURE 12–2  (A,B) Anteroposterior and lateral radiographs of a 5-year-old girl with type III osteogenesis imperfecta, showing deformity and narrowing of the long bones of the lower extremities.

FIGURE 12–3  Radiograph of a 9-year-old boy with type I osteogenesis imperfecta. Osteopenia is present, but deformity of the long bones is minimal.

FIGURE 12–4  Radiograph of a 6-year-old boy with type IV osteogenesis imperfecta, showing moderate bowing deformity of the long bones of the lower extremities.
**Table 12–2**  
**Classification System of Shapiro**

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| OIC  | Intrauterine fractures and/or fractures at birth  
Subtype A:  
- Short, broad, and crumpled femurs  
- Small, bell-shaped rib cage  
- Multiply fractured, short ribs  
Subtype B:  
- Long bones of normal shape and length  
- Ribs of normal length, narrow or normal width, less extensive fractures  
- Rib cage with normal configuration |
| OIT  | Initial fracture after birth  
Subtype A:  
- First fracture before walking  
- Long bones and ribs normal in length, but somewhat narrow and osteopenic  
- Rib cage normal  
Subtype B:  
- First fracture after walking began  
- Long bones of normal shape, width, and length  
- Rib cage normal |

Data from Shapiro.9

**Fracture Management**

Closed methods of treatment are the mainstay of fracture management in children with osteogenesis imperfecta.8,10 Fractures usually heal at a normal rate, often with abundant callus that bears the same abnormal quality as the surrounding bone. Fractures through a deformed bone may provide an opportunity to obtain a straighter alignment. In managing fractures of these patients, it is important to minimize the disuse osteopenia that is associated with immobilization. Therefore, the duration of immobilization should be as short as possible. Early mobilization may be facilitated by using lightweight casts or splints.

In children with the milder forms of the disease, certain fractures are best treated using internal fixation. Olecranon apophyseal fractures in children with osteogenesis imperfecta may be treated using two parallel intramedullary Kirshner wires and a figure-of-eight tension band of stainless steel wire or absorbable suture11 (Fig. 12–5). Femoral fractures in older children and adolescents with the more mild forms of osteogenesis imperfecta may be managed by intramedullary nailing in selected cases (Fig. 12–6). The use of load-bearing devices, such as external fixators, is probably best avoided because these devices may impair the formation of bridging callus at the fracture site.

Although rare in normal children, a nonunion of a fracture may occur in a child with osteogenesis imperfecta, usually in those with the more severe form of the disorder.12 A nonunion is often associated with repeated fractures through a progressively bowed region of a long bone. When nonunion occurs in the upper extremity, it may limit the ability of the patient to transfer and can compromise hand function. A nonunion in the lower extremity can impair mobility. Treatment consists of excision of the nonunion, intramedullary nailing, and bone grafting (Fig. 12–7).

**Management of Long Bone Deformity**

**Indications for Operative Treatment**

In children with osteogenesis imperfecta, the disuse osteopenia and residual deformity that generally follows immobilization of a fracture increases the risk of a subsequent fracture and further deformity, creating a vicious cycle that can be stopped only by operative treatment. Most authors agree that indications for operative treatment in children with osteogenesis imperfecta include recurrent fractures and progressive deformity that impair function. The indications for surgery may be influenced by the severity of the disease. Specifically, in children with type III disease, Cole13 has recommended that surgery should be reserved for the prevention of repeated fractures and should not be performed for the correction of deformity alone in patients who are relatively free of fractures.

Some authors have proposed that surgical treatment will favorably influence motor development14 and will allow previously nonambulatory children to walk.15 In contrast, Millar16 suggested that the severity of involvement was more important than surgery in determining the probability of ambulation and recommended that ambulation should not be the primary objective of surgery. Both Cole13 and Shapiro9 have noted that the prognosis for independent ambulation was poor in patients with severe disease. Their observation was confirmed by Daley and colleagues17 who found that only 1 of 29 children who had type III osteogenesis imperfecta became a walker. Furthermore, their study suggested that intramedullary rodding had no major influence on motor development. In summary, although one may enhance the potential for walking in some children with osteogenesis imperfecta by correcting deformity and improving the stability of the long bones, the goal of achieving ambulation may not be realistic for those with severe disease.

In children with severe osteogenesis imperfecta, progressive deformity of the long bones of the upper
extremity commonly occurs. However, the upper extremities generally function quite well despite significant deformity, and thus there is usually no need for surgical correction. Still, surgery may be indicated for deformity that interferes with function or is associated with frequent fractures.18,19

The optimum age at which to begin operative management in children with osteogenesis imperfecta is controversial. Traditionally, deformity that may occur following closed treatment is accepted until the patient reaches the age of 5 years, after which corrective osteotomies are performed.8 This approach mini-

FIGURE 12–5  (A,B) Anteroposterior and lateral radiographs of a 4-year-old boy with type I osteogenesis imperfecta, showing an olecranon apophyseal fracture. (C) The fracture was treated by open reduction and internal fixation using two parallel intramedullary Kirschner wires and a figure-of-eight tension band of absorbable suture.
mizes the number of operative procedures that will be required over the lifetime of the patient. Operative intervention in infancy with “percutaneous” and “semiclosed” intramedullary rodding techniques has been described for the management of severely involved patients.20–22 These authors argue that in these very young patients, the benefits of deformity correction and internal stabilization of the long bones outweigh the risks of repeated procedures. This issue is still subject to controversy. As a result, the timing of operative management varies among practitioners based on their experience and philosophy.

FIGURE 12–6  (A,B) Anteroposterior and lateral radiographs of an 11-year-old boy with type IV osteogenesis imperfecta, showing a femur fracture. (C,D) Four months after closed reduction and stabilization using flexible intramedullary nails, radiographs show good bridging callus at the fracture site.
SURGICAL OPTIONS FOR CORRECTION OF LONG BONE DEFORMITY

In 1959, Sofield and Millar described fragmentation, realignment, and intramedullary nail fixation for the treatment of children who have osteogenesis imperfecta. They found that this procedure decreased the frequency and discomfort of fractures and corrected deformity. However, in time, the patients would outgrow the implant, allowing angulation or fracture to occur at levels of unsupported bone. The time between insertion and replacement of the nail averaged between 2 and 3 years in most series.23–27

To address this problem, in 1963, Bailey and Dubow introduced an extensible intramedullary device. The original implant consisted of an outer tubular sleeve and an inner obturator that telescoped together. At the outer end of each component was a small T-shaped piece that was seated in the epiphysis. The T-piece at the end of the sleeve portion could be unscrewed and replaced with a drill bit during insertion. The nail was designed with the intention that it could elongate as the child grew.

Although early clinical studies reported a low complication rate and generally favorable outcome with the Bailey-Dubow nail, more recent reports have indicated higher complication rates, generally greater than 50%.15,26,27,30–35 Somewhat lower complication rates have been reported by Luhmann and co-workers (39%) and by Stockley and colleagues (45%).37

Complications with extensible nails include those shared with solid nails, such as nonunion, migration, extrusion, fracture proximal or distal to a nail that has migrated, rotational deformity, and bending or breakage of the implant. In addition to these, the Bailey-Dubow nail has a number of unique problems inherent to its telescoping mechanism, namely, failure to elongate, loosening or detachment of the T-piece, backout of a component, and diminished strength at the junction of the sleeve and the obturator.

The most serious potential complication of extensible nail surgery remains growth arrest. Although rarely reported, traversing the growth plate with an extensible nail is not without risk of a subsequent growth disturbance, especially if the nail and T-piece migrate across the physis.35 This potential complica-
tion should be kept in mind when considering the use of an extensible device in the tibia, where the cross-sectional area of the distal growth plate is relatively small compared to the size of the sleeve component and T-piece, and in smaller, younger children.

Certain problems associated with the use of the Bailey-Dubow nail can be prevented or minimized by good surgical technique. Specifically, care should be taken not to place the T-piece too deeply into the epiphysis. Further, inserting the T-piece just below the articular surface of the knee or ankle joint and rotating it 90 degrees may minimize the risk of internal migration of the implant into the metaphysis. Scoring the T-piece before insertion or crimping the rod after the T-piece has been applied may minimize problems with loosening or detachment of the T-piece.

Other complications associated with the use of the Bailey-Dubow device, such as bending of the nail at the sleeve-obturator junction, may not be completely avoidable. Migration of one or both components of the Bailey-Dubow nail may sometimes occur after a period of uneventful elongation. Radiographs of these patients often reveal a subtle bending of the implant, which may lead to increased friction between the sleeve and obturator components, eventually causing the device to cease elongating. It is doubtful that this problem can be eliminated entirely given the current design of the implant.

Problems with the Bailey-Dubow nail, specifically loosening of the T-piece and migration of the nail into the metaphysis, led to the development of the Sheffield rod system. This system has a fixed and slightly larger T-piece and separate drills, of varying sizes, used to ream the medullary cavity. Wilkinson and colleagues found that the complications of loosening of the T-piece and migration of the T-piece into the metaphysis were eliminated by the use of the Sheffield rod. Furthermore, they observed no evidence of damage to the growth plate, a potential concern due to the use of a T-piece of larger surface area. However, these authors did note more problems with backout of the sleeve component in both the tibia and the femur compared to the Bailey-Dubow nail, but stated that this problem was more easily corrected than metaphyseal migration of the implant.

As an alternative to extensible devices, the use of overlapping Rush rods in the femur have been described by Luhmann and colleagues. They found this technique particularly useful in patients with relatively large femoral bony canals. In this technique, one rod is placed antegrade through the tip of the greater trochanter, and a second rod is placed retrograde through the central portion of the intercondylar area of the femur. Both rods are countersunk. These authors noted that the fixation provided by the combined diameter of two Rush rods was greater than that which would have been achieved by using the largest diameter Bailey-Dubow nail. They reported no complications related to the use of overlapping Rush rods at latest follow-up.

The choice of a solid or extensible nail remains a matter of personal preference for the treating surgeon. As noted above, extensible nails have a decreased replacement rate when compared to solid nails. However, extensible nails are weaker, are technically more demanding to insert, require a larger medullary canal, must traverse the growth plate, are more expensive, and are associated with more complications.

We prefer to use a solid nail for the femur in patients younger than 5 years of age because these nails are easier to insert and better accommodate a small medullary canal. As the child grows, these nails may later be revised to extensible devices. The extensible nail appears to be most advantageous in the femur, especially in children older than 5 years. Compared to the tibia, revision surgery in the femur is generally associated with greater blood loss. By increasing the time interval to revision, the extensible nail may help to delay the time to revision (Fig. 12–8).

We also prefer to use solid nails for the femur in patients younger than 5 years of age because these nails are easier to insert and better accommodate a small medullary canal. As the child grows, these nails may later be revised to extensible devices (Fig. 12–9). The extensible nail appears to be most advantageous in the femur, especially in children older than 5 years. Compared to the tibia, revision surgery in the femur is generally associated with greater blood loss. By increasing the time interval to revision, the extensible nail may help to keep the number of replacement surgeries to a minimum.

### Operative Techniques for Correction of Deformity

**Closed vs. Semiclosed Intramedullary Rodding**

Some authors recommend closed or semiclosed intramedullary rodding for severely involved infants who sustain frequent fractures despite careful handling. Middleton has performed this operation in patients as young as 8 weeks old. Closed intramedullary rodding is performed under general anesthesia. An image intensifier is used to guide the
(A,B) Anteroposterior and lateral radiographs of the tibia of a 9-year-old girl with type IV osteogenesis imperfecta, showing an anteromedial bowing deformity. (C,D) She underwent multiple osteotomy, realignment, and intramedullary fixation using a Peter Williams nail. Postoperative radiographs show the fixation from epiphysis to epiphysis. (E,F) Ten months postoperatively, satisfactory alignment has been maintained.
FIGURE 12–9  (A) Anteroposterior radiograph of both femora of a 6-year-old girl with type III osteogenesis imperfecta. Two and a half years earlier she had undergone multiple osteotomy, realignment, and internal fixation of both femora using Rush rods. (B) Lateral radiograph of the left femur showing protrusion of the implant out of the bone into the soft tissue. (C,D) The patient underwent staged removal of the Rush rods, multiple osteotomy, realignment, and intramedullary fixation of both femora using extensible nails. (E,F) Two years following the procedure on the left side and 1 year following the procedure on the right side, good alignment has been maintained and elongation of the nails has occurred.
placement of the rod. Visualization of the osseous structures may be very difficult, especially in very young infants and those with severe disease.

Femoral rods may be inserted either distally, through the knee, or proximally, through the greater trochanter or piriformis fossa. Deformity is corrected by osteoclasis at the tip of the rod as it is advanced along the medullary canal. Tibial rods are inserted through the heel. Correction of deformity is achieved by osteoclasis as described for the femur.

The rods may be cut just below the skin and removed once healing is complete, at which time braces are applied. Alternatively, the device may be left in for long-term stability. No problems have been encountered with leaving the nail across the ankle left in for long-term stability. No problems have been described for the femur. After subperiosteal exposure, the device may be moved once healing is complete, at which time braces are applied. Alternatively, the device may be left in for long-term stability. No problems have been encountered with leaving the nail across the ankle.

For this reason, open osteotomy may be preferable in older infants undergoing correction of their long bone deformities. Following closed osteoclasis and intramedullary nailing, the time interval to their long bone deformities. Following closed osteoclasis and intramedullary nailing, the time interval to the next operation to revise the implant has been reported to be between 1 and 3 years.

**Multiple Osteotomy and Intramedullary Fixation Using a Solid Nail**

Multiple osteotomy and intramedullary fixation have become the mainstay for treatment of recurrent fractures and progressive deformity in osteogenesis imperfecta. Despite the introduction of extensible nails, several authors still prefer to use solid nails for intramedullary fixation following multiple osteotomy procedures in patients with osteogenesis imperfecta, because these implants are less expensive, easier to insert, and have fewer associated complications.

Two types of solid nails are commonly used: the Rush rod and the Peter Williams nail. The Rush rod is a solid implant with a prebent hook on one end. The Peter Williams nail consists of two Steinmann pins that are screwed into each other to make one long nail with a point on either end. One pin has a male thread and the other pin has a female thread, allowing the two pins to be joined. The available sizes are 1/8-, 3/16-, and 1/4-inch diameter. In the tibia, the Williams nail allows fixation to span from epiphysis to epiphysis without the need for an arthrotony, thereby increasing the time to revision. If femoral and ipsilateral tibial procedures are planned at the same operative session, the tibia should be done first. By doing so, the tibial procedure can be done under tourniquet control. Performing bilateral femoral procedures at the same operative session may be associated with significant blood loss and thus is not recommended.

The procedure is performed under general anesthesia with the patient positioned on a radiolucent table to allow the use of an image intensifier. When operating on the femur, the entire extremity is prepped and draped. The femur is exposed through a postero lateral incision. The fascia lata is incised and the vastus medialis muscle is reflected anteriorly off the lateral intermuscular septum. Perforating vessels that can be identified are cauterized. The proximal femur is exposed up to the greater trochanter, either by extending the lateral incision or by making a separate lateral incision over the trochanter.

The bowed portion of the bone is exposed subperiosteally. Care is taken to preserve the periosteum for later closure. An osteotomy is made at the proximal portion of the deformity, usually just below the lesser trochanter. A second osteotomy is made at the distal portion of the deformity, usually just above the flare of the distal metaphysis.

The deformed portion of the femoral shaft is divided into as many pieces as necessary to allow the bone to be adequately straightened. The largest nail that will pass easily in the medullary canal is selected. If the canal is very small, it may be desirable to ream the fragments with a drill. It is best to progressively ream the fragments, starting with a small drill to avoid breaking the osteotomized segments. Slight overdrilling of the canal is recommended.

The length of the nail is determined using the image intensifier. The hooked end of the nail is laid over the greater trochanter and traction is then applied to the knee. The image intensifier is moved distally over the knee to determine the length of the implant. The nail is cut to allow the tip to lie at the midportion of the epiphysis.

The implant is inserted into the proximal fragment. Passing a guide pin or drill in a retrograde fashion, starting distally from the canal of the proximal fragment and exiting proximally just medial to the greater trochanter, facilitates accurate placement of the Rush rod. The rod can then follow the guide pin into the medullary canal of the proximal fragment. The osteotomy fragments are placed on the nail, and the end of the device is advanced into the distal fragment. It is usually necessary to omit one or more of the fragments to avoid excessive tension of the soft tissues. Proper position of the nail is confirmed using the image intensifier. After fixation of the bone is complete, the periosteum is closed. The fascia lata, subcutaneous tissue, and skin are closed over a drain and a spica cast is applied.

For the tibia, we prefer to use the Peter Williams nail. The procedure is performed on a radiolucent table under image intensifier control. A tourniquet is used whenever possible. The tibia is approached through an anterolateral incision. The bone is exposed from physis to physis.

The procedure for the tibia is similar to that described for the femur. After subperiosteal exposure, the bowed portion of the bone is sectioned at the
proximal and distal extent of the deformity. The deformed portion of the shaft is cut into as many pieces as necessary to obtain a straight alignment. The largest nail that will pass through the medullary canal is selected. If the canal is small or if none exists, the fragments must be progressively reamed as described for the femur. The nail is drilled up the proximal fragment to the metaphysis to assure that the nail will fit.

It may be necessary to remove a small segment of bone from the fibula, which can be done through a small incision in the reflected periosteum of the tibia. The length of the implant is determined using the image intensifier. The nail should extend from the proximal to the distal epiphysis while traction is applied to the foot. The female-threaded component of the nail is cut to the appropriate length.

The two components of the Williams nail are joined, forming a long nail with a point on the end of the male-threaded component and the cut portion of the female-threaded component on the other end. Next, the portion of the nail with the male thread is drilled antegrade into the distal fragment, beginning proximally at the medullary canal and exiting distally through the heel. The drill is then placed on the part of the nail that protrudes from the foot, and the implant is withdrawn until the female-threaded component lies just above the medullary canal of the distal fragment. The bone sections are then threaded onto this component as it is advanced. As in the femur, it is usually necessary to omit one or more of the fragments to avoid excessive tension on the soft tissues. Next, the device is advanced through the proximal fragment until the cut tip lies at the midportion of the proximal epiphysis and the other end lies in the midportion of the distal epiphysis.

Proper position of the nail is checked with the image intensifier. If satisfactory, the male-threaded portion of the nail is unscrewed and withdrawn from the foot. After fixation of the bone is complete, the periosteum is closed. The subcutaneous tissue and skin are closed over a drain and a long leg cast is applied (Fig. 12–8).

Postoperative management is similar following both femoral and tibial nailing. Six weeks following the procedure, the cast is removed, lightweight braces are applied, and physical therapy is begun based on the individual needs of the patient.

The procedure for the humerus is done through a lateral approach with care taken to identify and protect the radial nerve. Multiple osteotomies are performed as needed to obtain a straight alignment, and the bone sections are reamed and threaded onto a Rush rod. Placement of the Rush rod is facilitated by inserting a guide pin in a retrograde fashion, beginning distally at the medullary canal of the proximal fragment and exiting proximally through the humeral head. The Rush rod then follows the guide pin through the humeral head into the proximal fragment. The distal tip of the device is aimed toward the medial condyle to avoid cubitus varus.\textsuperscript{18,19} Proximally, the hook of the Rush rod should be seated on the bone to avoid catching the soft tissue under the hook, which could lead to migration of the implant.\textsuperscript{18}

Correcting a deformity of the forearm is technically demanding and the results are less predictable.\textsuperscript{18,43} This is primarily because intramedullary nails are difficult to insert in the small, deformed bones of the forearm. Root\textsuperscript{18} and Sofield and Millar\textsuperscript{23} recommend performing multiple osteotomies and placing the fixation in the ulna. The deformity of the radius may be corrected by removing an appropriately sized wedge of bone and allowing the fragments to align themselves with the ulna.

**Multiple Osteotomy and Intramedullary Fixation Using an Extensible Nail**

Two extensible nail systems are commonly used: the Bailey-Dubow nail and the Sheffield rod. The procedure described below is for the insertion of the Bailey-Dubow nail. The available sizes for the Bailey-Dubow nail are $\frac{5}{32}$-, $\frac{3}{16}$-, $\frac{7}{32}$-, and $\frac{1}{4}$-inch diameter. The instrumentation and technique for insertion of the Sheffield rod are described in detail by Wilkinson et al.\textsuperscript{39}

The procedure is performed under general anesthesia with the patient positioned on a radiolucent table to allow the use of an image intensifier. The surgical exposure of the femur is identical to that described above for insertion of a solid nail. It is important to expose the femur up to the greater trochanter, either by extending the lateral incision or by making a separate lateral incision over the trochanter.

An osteotomy is performed at the proximal and distal extent of the deformity. The deformed portion of the shaft is divided into as many pieces as needed to allow the bone to be adequately straightened. Any residual deformity that causes the implant to bend will impair its ability to elongate.

The largest nail that will pass through the medullary canal should be selected. To better accommodate the nail, the medullary canal of each fragment is reamed using the detachable drill point screwed into the tubular sleeve of the rod.

The image intensifier may be used to determine the length of the implant. The assembled nail should extend from the tip of the greater trochanter to the subchondral bone of the distal epiphysis at the intercondylar notch of the femur. The length of the sleeve component should be approximately 2 cm less than the desired length of the assembled nail.\textsuperscript{25}

The sleeve portion of the device is placed proximally. With the detachable drill point in place, the sleeve is drilled retrograde, beginning distally at the
medullary canal of the proximal fragment and exiting proximally through the tip of the greater trochanter. Through the proximal part of the incision, the drill bit is unscrewed and replaced by the T-piece. After the T-piece is screwed into place, the end of the sleeve is crimped to lessen the chance of later loosening. The distal fragment is prepared by anterograde drilling down to the level of the flare of the metaphysis. Excessive reaming of the distal metaphysis and epiphysis should be avoided.

The knee joint is exposed using a medial parapatellar incision. Using a drill, a small hole is made in the intercondylar notch slightly anterior and lateral to the insertion of the posterior cruciate ligament. The obturator component is passed through this hole into the medullary canal of the distal femur. After the osteotomy fragments are threaded onto the sleeve, the two components of the nail are telescoped together. One or more of the fragments should usually be omitted to avoid excessive tension on the soft tissue.

The T-piece of the sleeve component is then driven into the greater trochanter. It may be necessary to fashion a small window with a scalpel or small osteotome to facilitate seating of the T-piece just below the cortical or cartilaginous surface of the trochanter. The T-piece of the obturator component is carefully advanced through the articular surface into the subchondral bone. Again, it may be helpful to fashion a small window with a scalpel or osteotome to facilitate accurate placement of the T-piece. To lessen the risk of later migration into the metaphysis, it is important not to place the T-piece too deeply into the epiphysis. Once the end is within the subchondral bone, rotating the T-piece 90 degrees will help prevent the device from backing out into the knee joint.

Proper position of the nail is checked with the image intensifier. After fixation of the bone is complete, the periosteum is reapproximated and the wound is closed over a drain. A spica cast is applied to control rotation of the femur (Fig. 12–9).

The technique for the tibia is similar to that for the femur. The patient is positioned on a radiolucent table and a tourniquet is applied. The tibia is approached through an anterolateral incision. After subperiosteal exposure, the bowed portion of the tibia is sectioned at the proximal and distal extent of the deformity. Multiple osteotomies of the deformed portion of the shaft are performed as needed to obtain a straight alignment. The largest nail that will pass through the medullary canal should be selected. To better accommodate the sleeve, the sections of bone are reamed using the detachable drill point screwed into the sleeve component. The distal fragment is reamed down to the level of the flare of the distal metaphysis. Excessive reaming of the distal metaphysis and epiphysis is avoided.

The image intensifier may be used to determine the length of the implant. The assembled nail should extend from the subchondral bone of the proximal epiphysis to the subchondral bone of the distal epiphysis. As for the femur, the sleeve component should be 2 cm shorter than the desired length of the assembled nail.

The sleeve component may be placed proximally or distally depending on the size of the bone. We believe it is safer and easier to place the sleeve proximally, especially in smaller patients. The knee is exposed through a medial parapatellar incision. With the detachable drill point in place, the sleeve is drilled retrograde, beginning distally at the medullary canal of the proximal fragment and extending proximally at the base of the insertion of the anterior cruciate ligament. The drill bit is unscrewed and replaced by the T-piece. After the T-piece is screwed into place, the end of the sleeve is crimped. The ankle joint is exposed through a medial incision. The deltoid ligament and joint capsule are divided to provide access to the tibial plafond. In older children, an osteotomy of the medial malleolus is preferred. A small hole is drilled in the center of the tibial plafond through which the obturator component is passed. After the osteotomy fragments are threaded onto the sleeve, the two components are telescoped together. As in the femur, it is usually necessary to omit one or more of the fragments to avoid excessive tension on the soft tissues.

The T-piece at each end of the device is carefully advanced through the articular cartilage into the subchondral bone. It may be helpful to fashion a small window using a scalpel or osteotome to allow the ends to be accurately seated. As described for the femur, it is important to avoid placing the T-piece too deeply into the epiphysis. Once the ends of the device are within the subchondral bone, the T-pieces are rotated 90 degrees to help prevent the device from backing out into the joint.

Proper position of the nail is checked with the image intensifier. The periosteum is reapproximated and the wound is closed over a drain. A long leg cast is used to help control rotation.

Postoperative management is similar following both femoral and tibial nailing procedures. After 6 weeks, the cast is removed, lightweight braces are applied, and physical therapy is begun based on the individual needs of the patient.

**BIOMECHANICAL CONSIDERATIONS FOR BONE FIXATION IN PATIENTS WITH OSTEOGENESIS IMPERFECTA**

As with any long bone, those in patients with osteogenesis imperfecta are subjected to axial, bending,
and torsional loads. Although patients with osteogenesis imperfecta are not as active as normal patients, their bones are both smaller and lower in bone mineral density than normal patients. In biomechanical terms, their bones are both structurally weaker, evident by the smaller dimensions, and have weaker material properties, evident by lower mineral content. To make matters worse, the exaggerated curvatures in the bones of these patients serve as large moment arms. As a result, even relatively small axial loads, such as those generated during standing or walking, create very large bending moments in the long bones of these patients. Little wonder that they experience frequent fractures and refractures.

In normal patients, the goal in using implants for the fixation of long bones following fracture or osteotomy is to obtain anatomical reduction and to maintain stability to allow or facilitate osseous healing. Surely, if the implant fails the goal of osseous fixation will not be achieved. On the other hand, increasing the strength of the implant will usually also increase its stiffness, leading to other problems such as stress-shielding.

By necessity of its function, every implant that is used to fix a fracture or stabilize an osteotomy will reduce the stresses that a bone would normally experience without the implant. In biomechanical terms, the bone is being shielded or protected from stresses. Stiffer implants induce a greater degree of stress-shielding. Bone responds to stresses; that is, it modifies its structure and density to adapt to the new applied stresses. Accordingly, excessive stress-shielding is undesirable, as it will result in bone resorption.

In patients with osteogenesis imperfecta, the objectives of using intramedullary nail implants are principally different than in normal patients. In these patients, the primary objective is to prevent future fractures. As mentioned, the curvature in the long bones of these patients acts as a lever arm, causing large bending moments to be generated with normal axial loads. By correcting the deformity, the lever arm is reduced. Consequently, the bone becomes capable of withstanding much greater axial loads by distributing greater compressive stresses within the shaft of the long bone.

To discuss the stiffness or strength of long, cylindrical structures, it is helpful to introduce the area moment of inertia. The area moment of inertia is a property of the cross section of a beam that represents its resistance to bending loads. Two properties of the moment of inertia are relevant to the design of implants for the fixation of long bones. First, the moment of inertia of a circular cross section is related to the fourth power of its diameter. That is, doubling the diameter of a nail will increase its resistance to bending loads by a factor of 16. Second, the moment of inertia is affected to a much greater extent by the outside layers of material and very little by the layers closer to the center. As a result, given the same outside diameter, a solid intramedullary nail has only slightly greater resistance to bending than a thin-walled, hollow tube. Similar principles apply to the resistance of nails to torsional loads.

Since the critical loads on an intramedullary nail are bending and torsion, the moment of inertia plays an important role in defining their stiffness and strength. That is, compared to a solid intramedullary nail, a hollow one with the same outside diameter will offer practically the same structural stiffness and strength. This is because, as discussed, the moment of inertia of a solid tube and a hollow tube are nearly the same. Therefore, in comparing a solid nail, such as the Peter Williams nail, with an extensible nail, such as the Bailey-Dubow nail, factors other than bending stiffness contribute to a greater degree to the differences in strength. Specifically, an extensible nail is weaker at the location where the two parts of the device join (i.e., at the sleeve-obturator junction) because of stress concentration.

Several authors have noted cortical thinning around intramedullary implants. Some have attributed this finding to disruption of the medullary circulation or periosteal blood supply, or both, that may occur as a consequence of the nailing procedure. Others have attributed this finding at least in part to the stress-shielding effect of the implant. Frediani suggested that smaller-diameter nails are preferable to minimize damage to the medullary circulation and to limit the effects of stress-shielding. Unfortunately, a smaller-diameter nail may not be strong enough to withstand the loads. Given the materials that are currently used for intramedullary nails (mainly stainless steel), it is not possible to minimize stress-shielding without compromising the strength of the device in this patient population. Luhmann has attempted to address this problem using overlapping Rush rods, but this technique is not always possible in patients with small medullary canals.

Another complication associated with the use of Bailey-Dubow rods is failure to elongate. This could occur as a result of friction between the sleeve and the obturator, which could be increased by bending moments that occur in the limbs. Such bending moments could arise due to normal activities, by growth of the long bones into a more curved shape, or simply from residual bone curvature that was not corrected by surgery. A second potential reason for failure to elongate is migration of one or both of the T-pieces from the epiphysis into the metaphysis. T-pieces with a larger surface area, such as those used in the Sheffield nail, may help alleviate migration of the implant into the metaphysis by decreasing the contact stresses between the T-piece and trabecular bone of the epiphysis.
Two areas of potential improvement exist in the design of intramedullary nails for the fixation of long bones in osteogenesis imperfecta patients. First, the small-diameter femoral and tibial canals in these patients make it even more important than in normal patients to design a more flexible yet strong enough implant than those that are currently available. Second, a lower-friction sliding mechanism between the sleeve and the obturator in extensible nails could lead to more reliable elongation.

In summary, intramedullary nails have been efficacious in the management of deformities and prevention of fractures in the long bones of select patients with osteogenesis imperfecta. Extensible nails are useful as they continue to provide fixation as the bone grows, but are associated with a greater rate of complications. Future development in the design of these implants should address these complications by decreasing the friction between the components of the nail and by optimizing the design of the T-pieces.

**SUMMARY**

Our experience has shown beyond doubt that the operation of fragmentation and rodding in osteogenesis imperfecta is sound and offers the patient a new life, which is virtually free of fractures. (Peter Williams, 1965)

Multiple osteotomy, realignment, and intramedullary fixation of the long bones represented a major advance in the care of children with osteogenesis imperfecta. The introduction of the extensible nail increased the time between revision surgeries, although with a somewhat higher rate of complications. Continued refinement of the design of the extensible nail, such as the Sheffield rod, will hopefully diminish the number of complications associated with extensible nail surgery. Further investigation of the overlapping nail technique will better define the indications and long-term results of this procedure.

The care of children with osteogenesis imperfecta remains a challenge. The goals of management continue to be to improve long-term function, reduce the frequency and discomfort of fractures, and prevent and correct deformity of the long bones. Until promising research in gene therapy provides a cure for this disorder, operative methods of management will still be needed to help achieve these goals.

**REFERENCES**


The human skeleton is perfectly adapted to allow human motion and numerous activities. Bone also has the unique ability to repair without scar formation. The healthy skeleton will rarely fracture during normal physiologic motion, but fracture may occur when large loads are applied directly to the skeleton by events such as falls from heights, motor vehicular accidents, gunshot injuries, twisting injuries, or the contraction of large muscle groups. In addition, however, there are a number of conditions that may weaken the skeleton and predispose it to fracture with normal physiologic loading. These conditions cause either a focal loss of mineral in the skeleton, as in metastatic bone disease, or a very diffuse and symmetric loss, as in osteoporosis.

Metastatic bone disease is common. Each year in the United States there are approximately 1.3 million new cancer cases, and many of these patients will develop metastatic bone disease. The most common carcinomas that metastasize are those of the breast, lung, prostate, and kidney. These metastases typically occur in multiple bones and are usually distributed to the spine, ribs, pelvis, and long bones. There are three predominant patterns of skeletal involvement: (1) purely lytic bone destruction, (2) a mixed pattern of bone destruction and bone formation, and (3) purely blastic disease without bone lysis. These patterns are determined by the interaction between the metastatic cells and the host bone. Pure lysis occurs when the bone is resorbed and there is no concomitant bone formation; a mixed pattern occurs when there is both bone destruction and formation; and a purely sclerotic pattern occurs when there is extensive bone formation without a loss of mineral.

Patients with metastatic bone disease face a number of clinical problems, including pain, inability to ambulate, and pathologic fractures. For the cancer patient, uncontrolled bone metastases severely compromise the remaining quality of life (e.g., patients may lose the ability to ambulate and care for themselves). In the cancer patient, an untreated fracture results in severe pain; such patients often lose the will to live and spend their remaining days in despair.

Physicians play a major role in the treatment of patients with metastatic bone disease. The primary goals of treatment are to control pain, prevent pathologic fractures, and maintain patient independence. This chapter will address the effect of metastases on bone, the indications for prophylactic fixation, and the principles of surgical management.

**EFFECT OF METASTASES ON BONE**

The presence of a tumor in bone changes the mechanical properties of that bone. Existing data suggest that lytic lesions decrease not only the stiffness but also the strength of the bone in bending. In contrast, blastic lesions decrease only the bone’s stiffness, not its strength. The location of the lesion within the medullary canal also changes the strength of the bone. If the medullary defect is located within the center of the diaphysis, the strength reduction for a 50% loss in cross-sectional area is 60%. However, with the same amount of bone loss for an eccentrically located lesion, the strength reduction is greater than 90%.

Pathologic lesions in long bones also decrease the strength of the bone in torsion. Experiments on animal models have shown progressive reduction in torsional strength with increasing size of the cortical defect. The length of the lesion within the medullary canal does not substantially alter the bending properties; however, it does reduce the torsional strength. Biomechanical studies have shown that a lesion involving one third of the width of the bone reduces its torsional strength by 60%.
One of the most common radiographic criteria for operative management of a lesion is its size.\textsuperscript{6–12} It must be noted that plain radiographs tend to underestimate the amount of bone loss, and accurate determination of bone loss becomes more difficult when the lesion does not have clear boundaries.

In a report on 19 pathologic femoral fractures secondary to breast metastases, Snell and Beals\textsuperscript{7} noted that 58\% of those fractures were predictable when a lesion of 2.5 cm in diameter involved the femoral cortex or was painful, regardless of the bony location. Parrish and Murray\textsuperscript{13} reported on 104 pathologic fractures secondary to metastases and recommended prophylactic fixation in patients with increasing pain and loss of one third of the diameter of the bone.

In 1973, Fidler\textsuperscript{9} evaluated 19 pathologic fractures in long bones and analyzed the size of the lesion and level of pain before fracture. He recommended using prophylactic fixation if a lesion involved more than 50\% of the diameter of the bone and also advocated not using pain as an indication for prophylactic fixation. Harrington\textsuperscript{10} recommended prophylactic fixation for lesions 2.5 cm or larger, lytic destruction of 50\% or more of the cortex of a long bone, or persistent pain with weight bearing despite local radiotherapy. Fidler\textsuperscript{14} later evaluated 66 patients with 100 consecutive metastases in long bones, measuring the size of the defect and determining the risk of pathologic fracture. He concluded that fractures were unlikely when less than 50\% of the cortex was destroyed (2.3\%), likely when 50\% of the cortex was destroyed (60\%), and most likely when more than 75\% of the cortex was destroyed (80\%). However, most of the above indications cited in these studies were based on retrospective reviews of femoral lesions, and the specific criteria were based on general impressions rather than on precise biomechanical modeling or randomized prospective studies.

Mirels\textsuperscript{15} developed a classification system that incorporated the pattern of bone destruction, size and location of lesion, and degree of pain. He reviewed the files and roentgenograms of 38 patients with 78 metastatic lesions of long bones. In most cases (53/78, 68\%), the etiology was metastatic breast cancer. He analyzed the risk factors for pathologic fractures by evaluating four variables: the patient’s pain and the location, type, and size of the lesion (Table 13–1). In this system, each variable is scored from 1 to 3, with a maximum possible score of 12. A patient with a score of \( \leq 7 \) has a low risk of fracture, whereas a score of \( \geq 9 \) indicates a high risk. A score of 8 is suggestive, indicating a fracture risk of 15\% with a false-positive rate of 6\%. A score \( >9 \) is diagnostic for prophylactic fixation (Table 13–1). The most limiting aspect of this system is the subjectivity of grading the variables: characterizing the size of an individual lesion is difficult, and assessing pain is very subjective for both the patient and examiner.

### Indications for Prophylactic Intervention

Orthopaedic surgeons frequently evaluate patients with metastatic lesions and must make a determination of the risk of pathologic fracture. The amount of bone destruction is measured on both anteroposterior and lateral plain radiographs, and the pattern of metastatic bone involvement is graded as purely lytic, mixed lytic and blastic, or purely blastic (see above). Patients are also asked whether their pain occurs with rest or with weight bearing.

Patients with metastatic bone disease can lead fairly normal lives if the destruction of the skeleton can be controlled and limited, especially in terms of impending fracture (defined as a state in which the bone has been weakened to such an extent that normal physiologic loading will result in fracture). There are nonoperative and surgical modalities for accomplishing this goal.

### Nonoperative Management

There are several relative contraindications to managing metastatic bone disease surgically: (1) a patient who has a very short life expectancy (less than 2 to 4 weeks); (2) a patient who is too ill to survive a surgical procedure; (3) a patient with neutropenia; and (4) a patient with a low absolute white blood count and, thus, a high risk of postoperative infection, for whom surgery should be delayed until the immune system recovers. Such patients are best managed nonoperatively with external beam irradiation to control pain and limit disease progression.

#### Table 13–1 Characteristics of Metastatic Bone Lesions

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Type of Lesion</th>
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<tbody>
<tr>
<td></td>
<td>Lytic</td>
</tr>
<tr>
<td>Size</td>
<td>&lt;2/3</td>
</tr>
<tr>
<td>Location</td>
<td>Peritrochanter</td>
</tr>
<tr>
<td>Pain status</td>
<td>Mild</td>
</tr>
</tbody>
</table>
Surgical Management

If a patient has two or more of the following general criteria, we recommend prophylactic surgery: (1) >50% cortical bone destruction in a long bone; (2) long lytic lesions (length more than two or three times the bone’s diameter); (3) purely lytic pattern of bone destruction; (4) weight-bearing pain; or (5) pain after irradiation. The high stress areas at particular risk of fracture are the subtrochanteric region of the femur, the femoral diaphysis, the humeral diaphysis, the femoral neck, and the intertrochanteric hip area. Activity-related pain in these regions is often a harbinger of fracture.

Surgical intervention to strengthen the bone, prevent fracture, and allow full and painless weight bearing can be performed via a variety of advanced techniques. The method chosen should be durable to minimize the risk of fixation failure. Options include intramedullary rods, plates and screws, and prosthetic devices, and the choice is based on the amount of bone destruction and the location of the lesion. Acrylic (methylmethacrylate) cement is a useful adjunct to fixation because it hardens quickly and provides additional strength. Surgical intervention is usually followed by irradiation to prevent progression of the bone destruction.

Intramedullary Nails

Intramedullary nails, the most common internal fixation devices for patients with metastatic bone disease, are well suited to providing rigid fixation for several reasons (Fig. 13–1). First, an intramedullary nail is a load-sharing device because its neutral axis coincides with that of the long bone. Because the amount of deformation of the nail with weight bearing is small, it has a low risk of fatigue failure. Second, the second- and third-generation nails allow interlocking with cortical screws proximally and distally (static locking). This technique provides fixation from the subchondral region of the bone to the distal metaphysis of the opposite end, thus protecting almost the entire bone.

Plates and Screws

Plates and screws are used to reconstruct destructive lesions in the metaphysis and diaphysis of long bones (Fig. 13–2). In the presence of substantial metaphyseal bone destruction, intramedullary nails are

![A](image1.png) ![B](image2.png) ![C](image3.png)

**FIGURE 13–1** This patient had a destructive lesion in the proximal tibial diaphysis. (A) Preoperative anteroposterior radiograph showing >50% cortical bone destruction, indicating a bone at high risk for fracture. (B) Anteroposterior radiograph after intramedullary nailing with proximal and distal interlocking screws. Adjunctive methylmethacrylate was not used. (C) Lateral radiograph showing the nail fixation extending throughout almost the entire length of the tibia.
unlikely to achieve rigid fixation because the diameter of the rod is small compared with the width of the metaphysis. In these scenarios, plate fixation combined with methylmethacrylate results in a very rigid construct. The tumor is completely curetted and extensive areas of bone destruction are replaced with the cement.

**Prosthetic Devices**

Prosthetic devices are used in three scenarios. First, if articular surfaces have been destroyed, a prosthetic device is used to rebuild the joint. Second, if there is such extensive bone destruction that rigid internal fixation is not feasible, then the diseased bone is resected and the defect is reconstructed with a custom prosthetic device. Third, in the presence of progressive disease despite irradiation, the bone is resected and then reconstructed with a prosthetic device (Fig. 13–3).

**Acrylic Cement Augmentation**

Acrylic cement may be used to supplement intramedullary nail fixation, to increase the purchase of screws, or to fill large defects. With intramedullary nails, the medullary cavity is filled with the soft cement and then the nail is driven into the doughy cement; as the cement hardens, it locks the nail into place. To increase screw purchase (or to remedy a loose cancellous or cortical screw), the screw is temporarily removed, cement is injected into the screw track, the screw is replaced, and the cement is allowed to harden. This technique usually provides secure fixation. Alternatively, cement can be injected and allowed to harden, after which it is drilled and tapped, and the screw is then replaced. In this scenario, screw purchase is in the cement rather than in the diseased bone. When planning reconstruction with cement, it is important to ensure that the remaining bone, the acrylic cement, and the fixation device work together to resist loads. This application is quite strong when loaded in compression.

**Management of Lesions in Specific Locations**

**Femur**

The femur is the most common long bone affected by metastatic lesions (Table 13–2). The high mechani-

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**FIGURE 13–2** This patient had a forearm with a destructive lesion in the radial cortex secondary to metastatic lung cancer and experienced extreme pain with forearm rotation and with carrying objects. (A) Preoperative anteroposterior radiograph. (B) Anteroposterior radiograph after fixation with a 3.5 mm dynamic compression plate.
Cal loads placed on the femur during weight bearing render it a challenging area for reconstruction. Implants placed in the femur for subtrochanteric fractures have the highest incidence of fatigue failure. For example, Wedin et al. evaluated the long-term outcome of patients treated for metastatic carcinoma of the femur and found more complications and device failure in patients treated with internal fixation than in those managed with prosthetic replacement. Yazawa et al. noted a failure rate of almost 40% for femoral reconstruction at 5 years. These failures were secondary to mechanical problems resulting in early fixation failure and to disease progression after treatment.

Depending on the location and characteristics of the lesion in the femur, the orthopedic surgeon has a wide array of reconstructive options. To facilitate surgical planning, we divide the femur into several segments: femoral head and neck, intertrochanteric area, femoral shaft, and distal femur.

### Femoral Head and Neck

Isolated femoral head lesions are rare, but lesions that involve the femoral neck and portions of the head are common and may cause weight-bearing pain. Occasionally multiple cannulated screws can be used to stabilize small lesions (40 to 60% bone destruction) in the femoral neck and head. Hemiarthroplasty can provide good pain relief and improvement in function, and it is associated with a low risk of implant failure and postoperative complications. In this procedure, the proximal femur is exposed and the femoral neck is osteotomized. Any visible tumor is curetted with care to avoid removing cortical bone.

### Table 13-2

<table>
<thead>
<tr>
<th>Site</th>
<th>Incidence of Metastasis (%)</th>
</tr>
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<tbody>
<tr>
<td>Vertebrae</td>
<td>69</td>
</tr>
<tr>
<td>Pelvis</td>
<td>41</td>
</tr>
<tr>
<td>Femur</td>
<td>25</td>
</tr>
<tr>
<td>Ribs</td>
<td>25</td>
</tr>
<tr>
<td>Skull</td>
<td>14</td>
</tr>
<tr>
<td>Humerus</td>
<td>9.6</td>
</tr>
<tr>
<td>Scapula</td>
<td>5.7</td>
</tr>
<tr>
<td>Clavicle</td>
<td>4.1</td>
</tr>
</tbody>
</table>
The proximal femur is then reconstructed with a composite of cement and a femoral stem. The surgeon selects either a standard or long stem, based on the preoperative full-length anteroposterior view of the femur, so that the stem will extend beyond the areas of cortical bone loss. However, long-stem prostheses are not routinely used because they are associated with a substantial risk of fat embolism in metastatic patients. If a long stem is deemed necessary, care must be used to avoid overpressurizing the femoral canal during cement and prosthesis insertion.

**Intertrochanteric Area**

There are several treatment options, such as cephalomedullary nails, dynamic hip screws, and prosthetic reconstruction, for lesions in the greater trochanteric or subtrochanteric area. A dynamic hip screw with cement augmentation has a higher risk of failure than cephalomedullary implants (reconstruction nail or gamma nail) due to the high bending forces with weight bearing. Repetitive implant loading may lead to fatigue failure of both plate and rod constructs. For patients with severe bone destruction, failed internal fixation, and lesions that are not responsive to radiotherapy, the use of cemented modular replacement prosthesis is ideal.

**Femoral Shaft**

Most femoral shaft lesions are treated, without opening the tumor site, with intramedullary nails that are locked statically or just proximally. Currently available nails are quite rigid and strong, allowing immediate to full weight bearing, and usually fill the intramedullary canal so that the addition of cement would not increase the construct’s rigidity (Fig. 13–4). The medullary canals are usually reamed 1.5 to 2 mm more than the size of the femoral nail. Overreaming allows easier passage of the nail down the femur with a lower risk of intraoperative fracture or comminution.

**Distal Femur**

Distal femoral metaphyseal lesions may be treated with plate fixation or intramedullary nails. The closer the lesion is to the distal articular surface, the more one would choose a plate rather than an intramedullary nail. Plate fixation, performed through a cortical window in the area of bone destruction, is always augmented with cement to allow greater fixation and...
to reduce the stress on the implant with weight bearing. Although the cement can be added before or after the plate is applied, we generally apply the plate first. Intramedullary nail fixation can also be used in the distal femur, but as the femoral canal widens, it does not provide as rigid fixation as a plate.

When the distal articular surfaces have been destroyed or when rigid fixation cannot be achieved, the distal femur is resected and reconstructed with a custom prosthesis or a revision prosthesis with intramedullary stems. Normally, all the soft tissues (such as the capsule and the collateral and cruciate ligaments) are excised in this kind of reconstruction. Therefore, the prosthesis of choice would be a rotating hinge to restore stability and allow immediate weight bearing.

HUMERUS

The humerus ranks second among long bones, after the femur, in frequency of involvement by metastatic bone disease.17 The most frequent primary tumors metastatic to the humerus are (in decreasing order): breast, myeloma, renal, lung, prostate, and thyroid.23–25 Treatment should be tailored for each individual patient.

Small nonprogressive lesions (<50% bone destruction) may not require operative treatment. External beam irradiation, activity modification, and immobilization have been shown to provide substantial pain relief and (occasionally) healing.26,27

Proximal Humerus

When the lesion involves the humeral head as well as the greater and lesser tuberosity, it may disturb the rotator cuff attachment as well as the stability of the shoulder. Small and painful lesions that have failed to respond to irradiation may be treated with standard cemented endoprostheses. For patients in whom the involvement extends from the humeral head to the diaphyseal portion of the humerus, modular proximal replacement allows the surgeon to remove the segment of diseased bone, facilitating the reconstruction. Occasionally, deficient soft tissue may render the prosthesis unstable; in such patients, we augment the capsule with a Marlex mesh or Dacron vascular graft. The mesh is anchored around the glenoid and then sutured around the humeral head to keep it in place.

Diaphyseal Humerus

Destructive lesions of the humeral shaft could be stabilized with either an intramedullary nail or a plate. Our preferred technique is the use of an anterograde or retrograde locked intramedullary nail (via a closed or open technique) with or without cement augmentation.26,28 We use a closed technique when the amount of bone destruction is moderate (50 to 75%), and we lock the nail both proximally and distally. If the amount of bone destruction precludes obtaining rigid fixation with a statically locked nail, we open the diseased site and insert the nail with methylmethacrylate augmentation.26

The use of a dynamic compression plate with methylmethacrylate augmentation is possible, but there are some disadvantages to plate fixation. It requires a larger exposure, the remaining cortical bone may not be sufficient to secure rigid fixation of the cortical screws, and the stress riser effects at the screw holes increase the risk of fracture around the plate.28,29

Distal Humerus

The distal humeral anatomy precludes the use of a locked intramedullary nail because the supracondylar area is too narrow to allow nail insertion. Plate fixation is a more reliable technique. After thorough curettage of the lesion, two reconstruction plates (one on the medial column, one on the lateral column) are placed, preferably at 90 degrees to each other, to stabilize the area. The plates should be long enough to extend well above the lesion. The cavity is then filled with methylmethacrylate cement. For patients with insufficient bone stock for plate application, one Rush rod may be placed through each epicondyle, and then the cavity can be filled with methylmethacrylate cement.25 For patients with severe destruction of the distal humerus, another viable option is the use of a modular distal humeral replacement or a regular cemented total elbow arthroplasty.22,30

TIBIA

Metastatic disease is much less common in the tibia than in the femur. The approaches to stabilization of the proximal and distal tibial metaphyses are very similar. Preoperatively, radiographs of the entire bone to be fixed are obtained to rule out multiple lesions in the bone. The tumor is approached from the side with the most amount of bone loss. Curetting the lesion will produce substantial bleeding, which can be reduced with the use of a tourniquet during the debulking process, and which will stop after the bulk of the tumor is removed. The cavity is then filled with cement, and a long plate with screws is applied to the tibia.

Lesions that involve the diaphyseal portion of the tibia are best treated with conventional nailing. The nail is usually locked both proximally and distally with interlocking screws. Cement augmentation can be used in the distal or proximal diametaphyseal lesions in the presence of large destructive lesions. Because healing may not take place after fixation and ir-
radiation, the nail should be statically locked to prevent rotational instability. The goal is immediate weight bearing without pain.

**SUMMARY**

Treatment of metastatic disease differs from the treatment of acute fractures. For patients with metastatic disease, the surgeon needs to take into consideration the patient's comfort and need to use that extremity immediately; therefore, the reconstruction should be sound and rigid. Judicious use of cement is recommended in the treatment of such lesions, and all intramedullary implants should be locked statically to prevent rotational instability. Postoperative irradiation may be used to reduce pain. Patients should be discharged home as soon as possible so they can spend more time with family members in a serene environment.

**REFERENCES**


External fixation is a technique used to manipulate, align, and stabilize osseous fragments by means of pins or wires that connect the bone to a frame outside the body. The history of external fixation of fractures probably begins in the middle of the 19th century with Joseph François Malgaigne from France, who developed strapped-on metal points and claws to stabilize displaced fractures, as well as a clamp for the treatment of patellar fractures. Around the turn of the century Parkhill in Denver and Lambotte in Belgium both built external fixation devices with two unicortical screws in each bone fragment, connected by a clamp outside the skin. The introduction in the 1930s of transfixion pins, the concept of longitudinal distraction, and compression mechanisms led to the more sophisticated devices of Anderson, Stader, and Hoffmann. These devices not only provided a technique to immobilize the bone fragments but also to manipulate and adjust their position during and after application of the fixator, thereby creating a more practical clinical technique. The Russian surgeon Ilizarov and coworkers developed highly complex ring fixators for the correction of limb length discrepancies, malalignments, and segmental transport after corticotomy. In the 1970s De Bastiani and colleagues introduced the concept of dynamic axial fixation with a fixator frame that had a telescopic part, allowing the bone fragments to slide toward each other, thereby facilitating bone union.

**Fixator Design**

The fixator pins constitute the link between the external frame and the bone. Their diameter varies between approximately 2 and 6 mm with the strength and rigidity increasing with their diameter. Half pins have a terminally threaded segment that reaches just beyond the far cortex of the bone. In contrast, transfixion pins have a centrally threaded segment and can be connected to the fixator frame at both ends of the pin because the pin passes entirely through the limb. Transfixion pins therefore pose a greater threat to muscles, tendons, nerves, and vessels. Recently the concept of “pinless” external fixation has been reintroduced with pointed clamps that penetrate the cortex only minimally, similarly to a reduction forceps. Tensioned wires are used to connect bone fragments to a fixator with a ring construction. Purchase can be increased by an “olive,” a bulbous protuberance that anchors the wire to one cortex of the bone.

Clamps link the fixator pins (or wires) to the connecting rod. Simple clamps connect individual pins, whereas other fixator systems use clamps to connect a cluster of two or three parallel pins. The clamps are attached to the connecting rods, which are often made of stainless steel, aluminum, or carbon fiber. The construction of the frame can either be simple, with each pin connected directly to the rods, or modular, with clusters of pins held in a clamp that is connected to the rest of the frame (Fig. 14–1). Modular frames often allow pin placement before complete reduction of the fracture, thereby enhancing the possibility of adjusting alignment and length afterward. Uniplanar frame constructions have all pins and rods in the same plane, although the frame can be unilateral using half pins or bilateral using transfixion pins. Biplanar frames have pins entering the bone at different angles to each other (most often 90 degrees) and can also be built in a unilateral or bilateral mode. Ring fixators consist of wires and half pins connected to rings around the bone, which are subsequently attached to the fixator rods. The combination of a half pin frame with parts of a ring fixator results in a hybrid frame.
BIOMECHANICAL ASPECTS

With increasing clinical experience, the biomechanical properties of the external fixation devices have become the subject of research. The stability of the fixator, determined primarily by the properties of the pins and by the frame geometry, has been the main concern. The pins are the weakest component of the system but the stability of the construction is increased by a greater diameter and number of pins, preferably spread over the entire fragment length.13–15 Introducing the pin shaft into the proximal cortex has been said to double the stiffness of most pins, provide tighter pin-bone fit, decreased soft tissue irritation, and reduced stress at the pin-bone interface.16,17 Others instead have associated this technique with an increased rate of pin loosening and therefore recommend the use of larger root-diameter pins with bicortical threads for better purchase and decreased loosening characteristics.18

In a study comparing the healing pattern of osteotomies fixed with four-pin versus six-pin unilateral external fixation the axial, torsional, and bending stiffness of the four-pin configuration was 50 to 70% of that of the six-pin configuration. Bone porosity and pin loosening were significantly increased in the four-pin configuration.19 This suggests that a lower stiffness of the external fixator (i.e., a smaller number of pins) increases the risk of later pin-bone interface problems. Initially bending preload was advised to increase purchase in bone and to achieve compression at the fracture site,20 but Hyldahl21 demonstrated that radial preload is preferable to bending preload because resorption around the pin is reduced. Radial preload can be achieved by first drilling a pilot hole slightly smaller than the core diameter of the pin or by using pins with a conical, tapered thread to produce radial preload as the pin is introduced. However, insertion of fixator pins with misfits of greater than 0.4 mm can result in significant microscopic structural damage to the bone surrounding the pin.22

Biplanar frames increase bending and torsional stiffness as compared to uniplanar, unilateral frames.17,23 However, complex multiplanar configurations presently are rarely indicated since stronger unilateral frames with increased pin diameter have been designed.18,24 In addition, a smaller distance between the bone and the fixator frame is an effective method to increase strength: decreasing the distance between the bone and the rod by 1 cm can increase the frame stiffness by 40%.13,15,17,25 To allow image intensifier and X-ray views through the fixator and to reduce the weight of the construction, carbon rods are frequently applied. Although the carbon rods are stiffer than stainless steel rods, the bending stiffness of an external fixator construction with carbon rods is approximately 85% of the stiffness of standard frames. This is most likely due to the clamps being less effective in connecting the carbon fiber rods rigidly to the metal fixator pins.26

The stability of the frame together with the type of fracture, the accuracy of reduction, and the amount and type of stresses occurring at the bone ends are the most important factors determining the mechanical circumstances for fracture healing. These stresses are dictated by functional activity and loading at the fracture site. The amount of loading and the presence of a significant fracture gap resulting in oscillating fracture motion under loading are the most important factors in promoting callus formation.27 However, although less rigid configurations lead to earlier periosteal callus formation, there is an increased stress at the pin-bone interface and increased cortical porosity, both leading to an increased rate of pin loosening.19,23,25 Clinically, the amount of motion at the fracture site and thus the mode of fracture healing depend on the frame and pin configuration as well as on the type of fracture, the reduction, the amount of physiologic loading, and the performance of the pin-bone interface.15

INDICATIONS

Although in use for more than a century, external fixators have been applied with little consistency, with variable results, and with a high rate of complications.28 Among the properties that distinguish external fixators, other fixation methods are: stabilization at a distance from the injury, a greater versatility in accommodating a variety of bone and soft tissue lesions, ability to stabilize injuries extending across
joints, and adjustability of alignment after application of the device. In the presence of marked osteoporosis, external fixation may provide a method of obtaining adequate stabilization when effective internal fixation might be precluded by the degree of comminution or osteoporosis. Clinical indications include the following:

- Severe open injuries with massive associated soft tissue injury. Once (repeated) debridements have resulted in sufficient soft tissue coverage without contamination, external fixation can be converted to internal fixation techniques.

- Severe periarticular injuries, particularly in the proximal and distal tibia, when soft tissue conditions preclude emergent lengthy operative procedures for open reduction and internal fixation. External fixation in severe fractures around the distal articular surface of the tibia can provide time for soft tissue healing with subsequent internal fixation. This sequence does not have to lead to inferior results compared to primary internal fixation.

- Unstable and intraarticular distal radial fractures. This type of fracture is one of the few periarticular fractures that are not amenable to open reduction, anatomic reconstruction of the articular surface, and internal fixation. Specifically, in the presence of severe osteoporosis the purchase of screws in the metaphyseal area and in small fragments can be a problem. In these cases, realignment of the fracture fragments may be secured by the application of distraction across the adjacent joint, a technique based on the principle of ligamentotaxis. External fixation provides a method of neutralization and reduction maintenance for these frequently encountered fractures. To overcome some of the disadvantages of joint immobilization, articulating “dynamic” external fixation devices that permit early functional treatment have been developed.

- Unstable and severely polytraumatized patients. With the increasing aging of the population, elderly polytraumatized patients will probably be seen more frequently. In patients with injuries such as severe head injuries, pulmonary contusion, or hypothermia, after lifesaving measures have been taken, external fixators can be applied rapidly, providing fracture stability in expectation of improvement of the patients’ general condition.

- In patients with severe unstable pelvic ring injuries, retroperitoneal hemorrhage can often be controlled by decreasing the pelvic volume with external fixation.

- External fixation can be used for the management of posttraumatic complications and nontraumatic conditions such as osteomyelitis (Fig. 14–2), bone segment transport, and compression across joints in arthrodesis. In reconstructive surgery external fixation can be applied for immobilization following cross-leg flaps.

![FIGURE 14–2](image-url)

External fixation (Orthofix Inc., McKinney, TX, USA) in a 54-year-old woman with an infected pseudarthrosis of the tibia in the presence of osteoporosis and a previous history of rheumatoid arthritis. (Courtesy of J.S.K. Luitse, M.D.)
EXTERNAL FIXATION IN CLINICAL PRACTICE

Before the fixator pins are introduced three factors should be taken into consideration: the local anatomy of the limb, the adaptation of the frame to the specific injury, and the mechanical demands of the patient and the lesion. Since patients with osteoporosis are especially at risk for pin-related problems, care should be taken to optimize the stability of the external fixator construction, the position of the pins, and the technique of their placement. Pin insertion techniques should prevent necrosis of skin, soft tissue, and bone, unnecessary motion between pin and soft tissues, and neurovascular injury. In safe zones each limb segment has safe, hazardous, and unsafe zones through which pins can be inserted. In safe zones the bone lies subcutaneously. Hazardous zones contain musculotendinous units but no important neurovascular structures. Unsafe zones contain musculotendinous units and important neurovascular structures. Introducing the pins in safe zones can reduce pin tract infections and pin loosening by 50%. Since external fixation is often the first choice for treatment of a fracture, especially not in the presence of severe osteoporosis, special care should be taken to prevent complications associated with the technique.

Before application of a simple external fixator frame, the fracture is manually reduced as alignment of the fracture after pin insertion can produce tissue tension around the pins when the limb is aligned. Pins can generally be placed through stab incisions in the skin followed by blunt dissection through the soft tissues until the cortex is reached. The diameter of a pin must be limited to a maximum of 30% of the diameter of the diaphysis since a hole greater than 30% markedly increases the risk of pinhole fractures. In general, the diameter of the pins should be at least 5 mm in the pelvis, femur, and tibia; 4 mm in the humerus; 3 mm in the forearm, ankle, and foot; and 2 mm in the hand.

The most important factor in preventing thermal damage is predrilling of the holes before insertion of the pin. The use of self-drilling pins has been associated with microfractures and thermonecrosis at the pin-bone interface. Low drill speed and pin designs allowing for bone chip storage and extrusion with tip penetration can also reduce thermal effects. Therefore, all pinholes should be predrilled at low speed with a sharp, powered drill bit. Protective sleeves should be used during predrilling and introduction of the pin. In hazardous zones such as the forearm, a half-open technique for pin placement can prevent eccentric position of the pin and damage to nerves and tendons. This technique allows direct visualization of the bone to avoid injury to the soft tissues and redrilling due to pin placement (e.g., eccentric placement). An image intensifier helps to obtain correct pin placement and length. At the end of the procedure there should be no tension on the soft tissues around the pins and relaxing incisions may be necessary.

The first pin is placed into one of the bone fragments as far as possible from the fracture site, and the second pin is placed at the greatest distance to the fracture in the other fragment, parallel to the first pin. The pins are then connected to clamps and the connecting rod, which should anticipate soft tissue swelling. The rod and extra clamps serve as guides for the introduction of additional pins in each bone segment, preferably close to the fracture to increase the distance between the pins and thus the stability of the frame. Once the clamps are tightened a second rod can be connected to the pins to increase stability of the frame. The application of modular frames allows the introduction of two or three parallel pins into each bone segment prior to reduction of the fracture. Once the clamps are attached to the rod and adequate reduction of the fracture is achieved, the clamps are tightened. The choice for a specific device depends on the type of fracture, the soft tissue injuries, and the preference and experience of the surgeon, but this choice should not limit the subsequent or definitive treatment plan. Severe traumatic limb injuries are probably best managed with a simple and strong unilateral frame that easily allows access for wound management.

Pin sites are best left open and patients should be comfortable with pin care and know how to recognize complications. Increased secretion and pin tract infection are often caused by excessive motion of the soft tissues against the pin and by excessive stresses at the pin-bone interface. There is no consensus as to what is the best method to clean pin sites, and most methods are based on doctor or nurse preference rather than research. Saline, hydrogen peroxide, alcohol, and iodine solutions have all been advised. Perhaps the most important thing is not the type of fluid as much as the removal of dried blood and debris from the pin-skin interface. There is no reason to prohibit showering and the use of tap water.

In the osteoporotic patient, especially those with an unstable fracture, weight bearing should probably not be allowed so as to reduce stresses at the pin-bone interface, which predisposes to pin loosening. Some dynamic external fixation devices, such as for the treatment of distal radial fractures, allow motion of the spanned joint to promote functional recovery (Fig. 14–3).
Many complications have been described as a result of the use of external fixation and most have a significant physician-related component. Clinical problems can relate to incorrect pin placement resulting in pin tract infections, pin loosening, iatrogenic soft tissue lesions, and obstruction of wound access by the frame. Mechanical complications can be caused by misuse of components or inadequate frame construction relative to the clinical needs. Manufacturing errors can lead to breakage, deformation, or malfunctioning of components. Delayed or inhibited bone and soft tissue consolidation, with reported rates up to 45%, can be caused by the severity of the initial injury, malreduction, failure to obtain prompt and adequate soft tissue coverage, and failure to recognize the need for additional procedures such as bone grafting.

Pin tract infection and pin loosening are the most frequent complications of external fixation. This can result in the need to replace or remove a pin or even in the need to remove the entire frame and switch to another method of stabilization. Factors influencing loosening include: stresses at the pin-bone interface, initial pin torque resistance, thermonecrosis and sub-

sequent bone resorption, the stability of the fracture, and infection. Histologically, loose pin tracts are characterized by excessive bone resorption and inflammatory infiltrates.\(^9\) In addition to the factors related to pin loosening, crust forming around the pin-skin interface, necrosis of skin and soft tissue, and motion between the pin and the adjacent tissues contribute to infection. The severity of these pin tract infections can be subdivided into serous drainage, superficial cellulitis, deep infection, and osteomyelitis.\(^18\) Reported infection rates vary widely from 1 to 60%, largely depending on the definition used.\(^18,51–54\) Initial management consists of rest, elevation, and increased pin care. Subcutaneous abscesses should be drained and the administration of oral or intravenous antibiotics is advised depending on the severity of the infection.\(^41,55\) Radiolucency around the pin of more than 1 mm is highly predictive of gross severity of the infection.\(^41,55\) Antibiotic-impregnated fixator pins used in an animal study showed reduced incidence of infection and pin loosening.\(^59\) In an in vitro study, the adherence of \textit{Staphylococcus epidermidis} strains on hydroxyapatite-coated pins was significantly lower than on stainless steel pins.\(^60\) Hydroxyapatite coating also results in a significantly improved pin-bone interface compared to titanium-coated and standard pins as measured by extraction torque and histological parameters such as bone resorption around the pin.\(^61–64\) This technique could therefore reduce the risk for pin tract infection and loosening.

**Summary**

External fixation is a versatile method for stabilization of fractures in elderly patients, and a variety of frame configurations can be chosen depending on the type of injury. The number, diameter, and position of the pins together with the geometry of the frame and the type of fracture are important factors in the stability of the construction, but exact data on the amount of stability required for a successful clinical outcome are lacking. Since the stability of the construct at the pin-bone interface is an important factor in pin loosening, the indication for external fixation in osteoporotic bone is limited primarily to severe and/or periarticular limb injuries and polytraumatized patients. A careful application of the fixator with particular attention to pin placement technique and a close follow-up are important determinants to prevent the well-known complications. The experience with hydroxyapatite-coated pins should be expanded, and future developments will have to focus on a further reduction of pin tract infection and pin loosening.

**References**


Osteoporosis is a common human bone disease characterized by decreased bone mass, microarchitectural deterioration, and fragility fractures. Based on World Health Organization criteria it is estimated that 15% of postmenopausal Caucasian women in the United States and 35% of women older than 65 years of age have frank osteoporosis. As many as 50% of women have some degree of low bone density in the hip. One of every two Caucasian women will experience an osteoporotic fracture at some point in her lifetime. There is a significant risk, although lower, for men and non-Caucasian women to also sustain osteoporotic fractures. Patients with fragility fractures create a significant economic burden with more than 400,000 hospital admissions and 2.5 million physician visits per year.

**Basic Pathophysiology**

The hallmark of osteoporosis is deficient bone density and connectivity. The trabecular bone in an individual with osteoporosis will be thinner in dimension and have evidence of osteoclastic resorption, leading to disconnectivity of the trabecular elements. There is a deficiency of bone and a deterioration of the structural integrity of the underlying trabecular bone. Because trabecular bone has a much greater surface area, it is more readily affected by osteoporosis than the cortical bone. The two major elements of cortical osteoporosis are tunneling resorption that can lead to stress fractures and the gradual thinning of the cortical bone. With aging, the body expands the cortical dimensions away from the epicenter of the bone. A 10% outward shift of bone can compensate for a 30% decrease in bone mass in terms of torque and bending, but it will not compensate for axial loading.

Males and females increase their bone mass with growth, achieving a peak bone mass by the age of 25. Thereafter, bone will be lost at a slow rate for men. Women have a precipitous drop around menopause, but after 60 years of age their rate of loss is identical to bone loss in men. In men and women there is a significant decrease in total bone mass as one approaches the age of 80, leading to a marked deficiency in mechanical properties. The summation of the strength of a given bone is related to the mass plus distribution, the relative ratio of trabecular to cortical component of the bone, and the structural integrity and connectivity of the trabecular and cortical elements.

Bone is a living tissue. It is constantly undergoing remodeling and repair. The process involves an identification of a molecular structural defect. Osteoclastic resorption then follows and resorption pits develop. This then is repaired with an ingrowth of osteoblasts replacing the bone. In individuals older than 40 years, the osteoblasts rarely bring the original bone surface back to the starting point, and, thus, every remodeling cycle leaves a small deficit of bone. The discrepancies in the rate of bone for resorption and formation lead to the gradual onset of osteoporosis (see below).

A bone has numerous functions. Besides providing structural support for humans, it is the main mineral bank in which 98% of the body’s calcium is maintained, and it also is the site where blood elements are produced. The body has developed a complex program to maintain calcium levels within the body of which bone is the major mineral repository. Vitamin D is produced in the skin. For a Caucasian individual, 1 hour of sunlight is sufficient for the skin to produce 400 units of vitamin D. This form of vitamin D lasts for approximately 2 months. Inadequate exposure to sunlight, such as in those individuals who are housebound or in individuals with dark skin, will compromise this process. Vitamin D then is converted to 25-hydroxy vitamin D in the liver. The
25-hydroxy vitamin D has a 3-day half-life, and is still an inactive vitamin D metabolite. It can be degraded by P450 hydrolase enzymes of the liver, which often are stimulated by numerous drugs, including barbiturates. When the calcium level is low, parathyroid hormone is released, which stimulates the kidney to convert the inactive 25-hydroxy vitamin D to the active component, 1α, 25-dihydroxy vitamin D. The kidney retains calcium from the glomerular filtrate. The 1α, 25-hydroxy vitamin D sets off a process in the intestine that leads to calcium absorption from the gut. This active metabolite, working with parathyroid hormone, ultimately leads to the resorption of bone. The cessation of this process results in an elevation of serum calcium. Children are extremely capable of extracting calcium from their diet. However, as one gets older, the efficiency of intestinal calcium absorption decreases. In elderly individuals, calcium deficiency often will lead preferentially to resorption of bone rather than an increased absorption from the intestine.

Peak bone mass is achieved at the age of 25 years. Individuals who have a calcium deficiency during their adolescence will not achieve this peak bone mass. Bone mass accretion not only depends on the presence of adequate calcium in the diet but also on an adequate array of all essential nutritional components. Calcium requirements depend on the age of the individual. A dairy portion, which consists of milk, cheese, ice cream, or yogurt, contains approximately 250 to 280 mg of calcium per portion. The recommended daily intake of calcium is as follows: children require 700 mg or three dairy products; adolescents from the age of 10 to 25 years (when peak bone mass is achieved) require 1300 mg; adults require 800 mg; pregnant women require 1500 mg; and patients recovering from a major fracture require 1500 mg. Girls who are 13 years of age often have inadequate calcium intake to achieve peak bone mass. Numerous drugs including isoniazid, corticosteroids, heparin, tetracycline, furosemide, and caffeine can decrease calcium retention. Drugs that are detoxified in the liver with P450 hydrolase system, particularly barbiturates, are suspected of decreasing calcium retention.

Hormonal status is critical in achieving and maintaining peak bone mass. Women who are premenopausal lose approximately 0.3% of their skeleton per year unless they are taking adequate levels of calcium. At menopause, or for every year that women are amenorrheic or oligomenorrheic, they will lose 1 to 3% of their skeleton. Women who are postmenopausal by surgical hysterectomy and oophorectomy, or who are naturally postmenopausal, will have equal amounts of bone loss when matched for length of time after cessation of normal cycles. Thus, rapid bone loss occurs when women stop having normal menstrual cycles.

Bone is extremely sensitive to exercise and mechanical load. Under a no-load situation bone will be lost. Low loads will maintain bone. High loads will remodel bone to withstand the new loads. Very high loads will lead to bone failure. Exercise, including impact and programs such as walking and dancing, when coupled with calcium intake has been shown to maintain or increase the appendicular skeleton in elderly individuals. Exercise is inadequate to protect the spinal trabecular bone in the woman who is perimenopausal, although it can clearly decrease the rate of loss as compared with the individual that does not exercise. Overexercise leading to amenorrhea is another issue. In one study of runners, Drinkwater et al reported that women who had amenorrhea had a bone mass of 1.12 g per cm², whereas eumenorrheic women who ran half the distance but maintained normal menstrual cycles had a bone mass of 1.30 g per cm² and statistically had more bone. In fact, women who did not exercise but maintained normal nutrition and menstrual cycles had a higher bone mass (1.20 g per cm²) than the women with amenorrhea who exercised. This showed that exercise to the point of developing amenorrhea is a deleterious state. Male long-distance runners also have low bone mass with an approximate decrease of 10 to 20% and an increased bone turnover. It is not clear whether the hormonal state is the cause or just a comarker. Warren and Stiehl think that just reestablishing menstrual cycles without adequate calories is ineffective.

**DEFINITION AND DIAGNOSIS**

Low bone mass is the most accurate predictor for increased fracture risk. An individual who has a bone mass that is one standard deviation below his or her peers will have a 1.9-fold increased risk of spinal fracture and 2.4-fold increased risk of hip fracture. These data are based on a slowly changing skeletal state. Acute changes in bone status, such as produced by steroids, can profoundly weaken bone before the bone mass reflects that finding. Bone mass is determined by numerous methods. The technique that has been used in most bone centers for the treatment of patients is based on dual energy X-ray absorptiometry (DEXA). In this situation the amount of mineralized tissue within an aerial section of the spine or hip is analyzed and expressed as grams per cm². Comparisons can be made with their peers and with a young, healthy adult population with peak bone mass. If the individual is more than 1.5 standard deviations below his or her age-corrected peer group (derived from cross-sectional studies in the...
United States), that individual probably has a secondary cause of osteoporosis that needs additional evaluation. The bone mass in the individual then should be compared with the peak bone mass in young adults, which characterizes whether the individual has osteoporosis according to criteria from the World Health Organization.5 If the individual is within one standard deviation, she or he is considered healthy. If she or he is between one and 2.4 standard deviations below peak bone mass, she or he is considered to have significant bone loss and osteopenia. If she or he is 2.5 standard deviations below peak bone mass, the patient is considered to have frank osteoporosis, and if the patient has a fragility fracture, she or he is considered to have severe osteoporosis.

There are alternate methods to determine bone mass besides the DEXA.8,13,14 These methods include a single energy X-ray absorptiometry and peripheral dual energy absorptiometry, which measures bone density in the forearm, finger, and sometimes the heel. A second method is radiographic absorptiometry. This is based on a standard radiograph, or computer-generated radiograph of the hand with a metal wedge in the same field. The quantitative computed tomography (CT) scan measures the trabecular bone at several sites, but most commonly is used to evaluate the spine. It uses 20 times the radiation and has a poorer precision compared with the DEXA. The ultrasound densitometry accesses the heel, patella, tibia, and peripheral sites, and measures several properties of bone. All the peripheral results are at a distance from the hip and the spine and only have a 0.75 correlation, at best, with those central readings. Second, their ability to recognize change with treatment is much more limited. These methods are excellent in identifying people who have osteopenia and are at risk for bone loss. However, in terms of treatment and follow-up of individuals the consensus at this time is to use DEXA.

Bone density determination14,15 is indicated for women who are perimenopausal and women who are postmenopausal to determine their need for hormonal replacement therapy and other antosteoporotic therapies, for individuals with known metabolic bone disorders who are taking agents that affect bone mass, for individuals with low energy fractures, and for individuals with a high number of risk factors for having osteoporosis develop. It also is indicated to monitor efficacy of treatment.

The bone mass determination shows the investigator the current skeletal mass, but does not provide information as to the metabolic activity.11 Several markers have been developed for bone formation and bone resorption. Bone formation markers are bone-specific alkaline phosphatase and osteocalcin. Markers for bone resorption are based on collagen breakdown products released into the urine. The most common products measured are the N- and C-telopeptides of the collagen cross-link area and the pyridinoline and the deoxypyridinoline cross-links. They are extremely sensitive to determining bone turnover rates. DEXA will provide the current bone mass state, and the resorption perimeters will indicate the rate of bone loss.

**RISK FACTORS**

Osteoporosis is associated with numerous risk factors, some that can be modified and some that cannot be modified.1,8 Major factors that cannot be modified are: personal history of a fracture as an adult or a history of a fracture in a first-degree relative. Minor factors include Caucasian race, advanced age, female gender, dementia, and poor health or frailty. The potentially major risk factors that can be modified are associated with current cigarette smoking and low body weight (<127 pounds). The minor factors that can be modified are estrogen deficiency, low calcium intake, alcoholism, impaired eyesight, recurrent falls, inadequate physical activity, and poor health and frailty depending on the cause. Health and frailty are related to risk factors that can be modified and risk factors that cannot be modified.

There is clear evidence of genetic predisposition to osteoporosis.1,6,8 Individuals who have blond hair, red hair, fair skin, freckles, easy bruisability, hypermobility, a small build, and adolescent scoliosis commonly are reported as having a genetic predisposition to develop osteoporosis.6 The major risk factors are independent of bone mass and their presence raises the level of concern for any given level of bone mass. Low body weight and recent loss of bone, a history of fracture (personal or in a first-degree relative), and smoking all should raise the concern for osteoporotic fractures.9

**DIAGNOSIS**

More than 65% of individuals presenting with a compression fracture will be asymptomatic.3,6 Most individuals will lose as many as 2 inches in height because of narrowing of the discs. Any height loss greater than 2 inches should raise suspicions for a compression fracture. The etiology for fractures could be trauma, localized lesion, or underlying metabolic bone disease. The predominant forms of underlying disease other than osteoporosis are bone marrow abnormality, endocrinopathy, and osteomalacia. A low hemoglobin, elevated sedimentation rate and abnormal immunoelectrophoresis should identify multiple myeloma. Approximately 1% of patients with osteoporosis will present with this disorder. Other than an
early menopause, the major endocrinopathies are Cushing’s disease, type 1 diabetes, hyperparathyroidism, and hyperthyroidism. Primary Cushing’s disease is rare. Iatrogenic Cushing’s disease is widespread because of steroid use for numerous medical disorders and can be determined easily by history. Osteoporosis associated with type 1 diabetes is worse in individuals under poor control with subsequent glucosuria. Hyperparathyroidism is best identified by an intact parathyroid hormone assay and elevated N-telopeptide collagen breakdown products. Most patients are diagnosed with hyperparathyroidism before kidney stones and brown tumors develop. Hyperthyroidism often is associated with overmedication and is a common presenting state for women of large girth with osteoporosis. One study indicated that these individuals frequently have hypothyroidism and take enhanced doses of thyroid medication in part to control their weight.6 Individuals who are at risk can best be identified with a suppressed thyroid stimulating hormone assay. Osteomalacia is present particularly in individuals who live in the urban northern United States. At New York Presbyterian Hospital, 8% of individuals with hip fractures have frank osteomalacia and more than 40% have some degree of malnutrition.16 The common laboratory abnormalities of osteomalacia are low calcium, low phosphate, low 25-hydroxy vitamin D, high alkaline phosphatase, and a high level of parathyroid hormone. Alkaline phosphatase will rise when an individual sustains a fracture, but it takes 5 days to do so. Therefore, a patient presenting with a fragility fracture and an initial high alkaline phosphatase level probably has an underlying high-turnover state disease until proven otherwise. Once the secondary causes of osteoporosis have been worked out, the clinician then must decide whether the osteoporosis is high or low turnover (see below).

**CONSEQUENCES OF HIP AND VERTEBRAL FRACTURES**

Hip fractures are the most debilitating problem in individuals with osteoporosis. Two thirds of the cost for the treatment of osteoporosis is for the treatment of patients with hip fractures.1 Sixteen percent of women will have a hip fracture in their lifetime.8 Hip fractures lead to a 15% increase in mortality within the first year, and more than 70% of survivors have a profound diminution of function. Men have less than 50% the risk of women for hip fracture but twice the mortality rate. Recent data also identifies an increase in mortality rate (25 to 35%) 5 years following vertebral crush fractures. Unlike hip fractures, the relative risk increases progressively with time.17  

The load to fracture correlates well with the femoral bone density.18,19 Therefore, decreased bone density profoundly increases the risk of weakening the bone. An older individual’s femur has one half the strength and one third the energy of absorption as compared with a femur in a younger individual. Given a direct blow to the trochanter, a young individual still has 20% more bone strength than the injury will impart. However, an elderly individual has passed her mechanical capability by 50%. The reason that there are fewer fractures than falls is that most individuals do not directly injure their trochanter. Studies have shown that more than 90% of fractures do occur from falls and that the majority of falls occur in the home between the hours of noon and 6:00 PM.20 Falls, in fact, are the primary risk factor for hip fracture. A fall to the side would increase the risk of a hip fracture by 5.7-fold in a patient who is ambulatory and by 21.7-fold in a patient in a nursing home. A decrease of one standard deviation of bone density will increase the femoral neck fracture risk approximately 2.7-fold. The lower the body mass index, the higher the risk of a hip fracture, particularly in the nursing home population. In a similar fashion vertebral fractures are directly related to falls (50%) and to lifting a load (20%).4 Thus, a fracture is related to the initial starting bone mass, the trauma to that bone, the ability to repair a microfracture before it becomes a macrofracture, the quality of the bone, the general health of the individual, and the age of the individual.

**CLASSIFICATIONS OF OSTEOPOROSIS**

Riggs and Melton21 have defined two forms of osteoporosis. Type 1 osteoporosis occurs in women six times more frequently than in men. It is related to estrogen deficiency, associated with vertebral fractures, and usually unrelated to calcium intake. Type 2 occurs in older individuals, approximately 75 years of age, and it is twice as likely to occur in women as in men. Trabecular and cortical bone hip fractures are the main problems in type 2 osteoporosis, and the fractures are related to a lifetime of inadequate calcium intake. It was presumed by Riggs and Melton21 that type 1 osteoporosis was high turnover and type 2 was low turnover, although it now is recognized that high- and low-turnover osteoporosis can occur in both age groups. In high-turnover osteoporosis there is an increased number and depth of osteoclastic resorption sites and the normal osteoblast effort, when repairing the site, cannot totally fill the defect. In low-turnover osteoporosis there are normal or decreased osteoclastic resorption sites; however, the osteoblasts are markedly inactive. This could be brought on by genetic etiology, senility, or drugs such as methotrexate. An excellent method to differentiate these types
of osteoporosis is through the collagen breakdown products. In the N-telopeptide assay, the normal is from 5 to 65 nanomoles of bone collagen equivalents per millimole of creatinine. However, in the healthy, younger individual, most N-telopeptide cross-link values are in the area below 35. Values greater than 35 indicate a higher resorption rate. Values in the order of 50 or higher are twice those of the young individual and provide evidence of a relative increase in this resorption rate.

**THERAPY**

There are numerous agents that have been developed to treat osteoporosis. The antiresorptive agents are estrogens, and selective estrogen receptor modulators, calcitonin, and bisphosphonates. Bone stimulators are all still experimental and have not been approved by the Food and Drug Administration (FDA). These include the fluorides, parathyroid hormone, and parathyroid hormone-related peptide analogs. The general recommendation for all patients with osteoporosis is to ingest a physiological level of calcium and vitamin D, perform an appropriate exercise program, and adopt fall prevention.

Calcium and vitamin D will decrease bone resorption and will mineralize the osteoid. Several studies have demonstrated that patients taking calcium and vitamin D have a higher bone mass and a lower fracture rate. Particularly in the nursing home population, calcium and vitamin D have been associated with a decrease in the hip fracture rate by 25% and less mortality. Calcium and vitamin D, however, will not prevent spinal bone loss in women who are peri-menopausal. Conversely, the appendicular skeleton will be maintained in all age groups in women who are premenopausal and in elderly women who obtain physiologic levels of calcium and vitamin D coupled with adequate exercise. There are various forms of calcium preparations; the most commonly used preparations are calcium carbonate and calcium citrate. Calcium carbonate requires gastric acidity to be dissolved. Numerous medications including H-blockers may interfere with this function. Calcium citrate, however, is digested easily by patients of all ages and patients with all gastric conditions. In terms of kidney stone production, calcium carbonate will increase the risk of kidney stones. However, calcium citrate actually is protective. It therefore is recommended that calcium citrate be used in elderly individuals, in individuals with dyspepsia, in men with a higher history of having kidney stones, and in patients with constipation. Magnesium is usually readily available in the normal diet; however, in individuals who are alcoholics or malnourished, magnesium may be beneficial. Moreover, magnesium leads to amelioration of constipation, and, therefore, 400 to 500 mg of magnesium during the day may prevent constipation in individuals who take calcium.

Estrogen has been the most studied and used agent for prevention of osteoporosis. Estrogen will decrease bone resorption. Estrogen at a dose equivalent of 0.625 mg of Premarin (Wyeth-Ayerst Laboratories, Philadelphia, PA) will increase bone mass approximately 2% per year. Once a woman stops taking estrogen, she will lose 2% of bone mass per year, and 7 years after terminating estrogen, bone mass will return to baseline levels unless the individual begins to take another antiresorptive agent. In cohort studies, estrogen has been shown at this dose to decrease fractures at all sites by approximately 30 to 50%. A recent study indicated that a lower dose (0.3 mg) was unable to show any efficacy in terms of hip fracture prevention within 3 years. Estrogen has numerous nonosseous effects, including a favorable modification of the cardiolipid profile, which has been translated into decreased risk for heart disease and longer survival. It also protects teeth from migration. Estrogen also improves the genitourinary physiology leading to fewer urinary tract infections and better vaginal function. There is some suggestion that it may ameliorate, to some degree, the effects of Alzheimer’s disease and improve cognitive functioning.

Estrogen is associated with an increased risk of thrombophlebitis. It causes as much as a 10-fold increase in uterine cancer if unprotected. The co-use of progesterones can totally eliminate this increased risk. Estrogen has been associated with approximately a 2.5% per year increased rate of breast cancer over the baseline, which translates after 10 years to a 30% increased risk. Thus, rather than 10 to 11 women per 100 getting breast cancer, estrogen will increase the rate to 14 to 15 per 100. Because the majority of patients older than 70 who have breast cancer are not dependent on estrogen, it has been thought that the relative added risk may decrease in the elderly patient when estrogen’s nonosseous benefits are best felt. Thus, estrogen therapy should be offered to the patient twice, once at menopause when bone loss will be greatest and second when the patient reaches age 70 when secondary benefits are desirous. There are various forms of estrogen. Most are beneficial, and equivalent doses to 0.65 mg of Premarin are effective in approximately 80% of patients. After a woman has been taking estrogen for 3 to 6 months, the N-telopeptide should have declined by 30%. If it has not, the question should be raised as to the dosage of estrogen. Patients who smoke and individuals who are very thin may require a higher estrogen dose. There often is breast engorgement in women, and, therefore, a slow buildup of estrogen may be important to allow the individual to tolerate the estro-
gens. A continuous combination of estrogens with 2.5 mg of progestins not only is very effective in terms of bone protection but also prevents menstrual cycles. There may be breakthrough bleeding within 5 years of menopause; however, when a woman starts taking estrogen beyond that point, breakthrough bleeding is very rare. Women taking estrogen require yearly follow-up by their gynecologist and yearly mammograms. The combination of estrogen with other antiresorptive agents may be synergistic (see below). Hormone replacement therapy has been approved by the FDA for the prevention and management of osteoporosis but not for treatment since the fracture data is based on cohort studies and not prospective randomized trials.

A series of estrogen-like agents have been developed. Originally, tamoxifen was used as an antiestrogen, particularly for patients with breast cancer. However, bone cells were shown to be responsive to tamoxifen. It has been identified that individuals taking tamoxifen have 70% of the benefit of estrogen in terms of maintaining bone mass. Tamoxifen has not been used as an osteoporotic agent because 70% of women have significant postmenopausal symptoms and a high incidence of uterine cancer. However, this observation contributed to the development of the selective estrogen receptor modulators. These are a series of agents that often can compete for the estrogen binding site and seem to function more like an estrogen with bone. The bone cells consider these agents to be estrogens. They work effectively as antiresorptive agents. They can change some of the lipid profile, particularly the triglycerides, but there is very little change in the high-density lipid fraction with these agents. There is no uterine hypertrophy and the risk of uterine cancer appears to be no more than normal. There are early data to suggest there is a decreased risk (possibly 73%) of breast cancer in patients using raloxifene who do not use raloxifene. A trial is now under way comparing selective estrogen receptor modulators with tamoxifen as to their preventive action against breast cancer. In terms of osteoporosis, raloxifene, which is the first release selective estrogen receptor modulator, can decrease the risk of vertebral fracture by approximately 40 to 50%. There is no reported protection in terms of the hip. There is an increase in bone mass, approximately two thirds the improvement related to estrogen.

Raloxifene (Eli Lilly, Indianapolis, IN) is associated with an 8% incidence of leg cramps and an increased risk of thrombophlebitis comparable with that of estrogen. Because raloxifene also enhances postmenopausal symptoms, it is not recommended in the first 5 years of menopause. The use of raloxifene for protection against breast cancer is now being considered.

Calcitonin is a nonsex, nonsteroid hormone that may play a role in the skeletal development of the embryo and fetus. It has been used effectively in patients with hypercalcemia and in patients with Paget’s disease. One study has shown that subcutaneous injection of calcitonin, approximately 100 units per day, is effective in treating patients with osteoporosis. A nasal spray form of calcitonin recently has been introduced and at the dose of 200 units per day seems to increase bone mass in the spine, comparable with estrogen, and decreases spinal fractures by 37%. There is no benefit in terms of hip fractures as of 5 years. Lower doses of calcitonin and higher doses of calcitonin may not be as effective in protecting against fractures. Whether this is a peculiarity of the study is not clear. Calcitonin does have the other benefit of providing some analgesia. It has been used in patients with painful osteoporotic fractures and does not interfere with fracture healing. Two percent of patients complain of dry nares.

Bisphosphonates are pyrophosphate analogs in which the linking central oxygen is replaced by a long carbon chain with either hydroxyl groups or a nitrogen group. The bisphosphonates are nondegradable analogs. They function by binding to the osteoclast-resorbing surface and act as a nondegradable shield. If absorbed by the osteoclast they have a secondary mode of inhibiting the osteoclast function. Short-chain bisphosphonates such as alendronate lead to interference with the Krebs cycle. The long-chain nitrogen-containing bisphosphonates such as alendronate interfere with the prenylation of the lipid membrane. Bisphosphonates have a very low bioavailability and less than 1% is absorbed when taken orally. The first bisphosphonate approved by the FDA for the treatment of osteoporosis is alendronate (Merck, West Point, PA). This has been shown to increase bone mass in the hip and spine, comparable with estrogen. It decreases the risk of all fractures by approximately 50% and 63% after 1 year and 18 months after treatment, respectively. Regardless of the degree to which bone mass is enhanced, there is an equal protection for all patients against fractures. Those individuals with the lowest bone mass gain, and those in the quartile of the highest bone mass gain had equal protection against fractures by alendronate, suggesting an improvement in bone quality. Alendronate has been associated with esophageal irritation and as many as 30% of individuals have had esophagitis. However, in a carefully controlled study, the rate seems to be comparable with the placebo group. The slow buildup of alendronate, such as one pill the first week and then two pills the second, until the patient is taking 10 mg daily, has led to over 98% compliance from patients who were treated at the author’s institution. The low
dose of alendronate, such as 5 mg per day or 10 mg three times per week, is used as a preventive dose. The higher dose is used successfully for the treatment of osteoporosis. Alternative dosage of 70 mg of alendronate once a week has full therapeutic activity and lower gastrointestinal upset and may be the preferred method of administration. In animal studies, alendronate seems to inhibit osteolysis around prostheses.

Risedronate is an alternative bisphosphonate and has a similar profile to alendronate. The 5 mg dose affords 80% of the hip protection of alendronate but may have less gastrointestinal symptoms.

Pamidronate has not been approved for treating patients with osteoporosis, but has been used for treating patients with metastatic disease, hypercalcemic malignancy, and Paget’s disease. At the author’s institution, intravenous doses of pamidronate have been successful in treating osteoporosis in this population group.

The first-generation bisphosphonate, etidronate, when used in doses of 400 mg daily for 2 weeks and followed by 11 weeks of calcium and multivitamins in a repeating cycle, has been reported to decrease fractures and increase bone mass when used repeatedly. Patients who take etidronate do not have the gastric side effects associated with alendronate. However, the data were best reported for the first 2 years and long-term use may produce a mineralization defect. There has been the question about its use, and the FDA has never approved it for use in patients with osteoporosis in the United States, but it is used in patients in Canada.

A series of new bisphosphonates has been released for treating patients with Paget’s disease and are being developed as osteoporotic agents, including intravenous agents that require very short administration time and numerous new oral agents. Although they have not been approved by the FDA for treating patients with osteoporosis, they will be used for those patients within the next year.

Combination agents have been tried. Ninety percent of individuals who did not respond to estrogen therapy have shown a benefit when they began taking alendronate. Twenty percent of individuals who did not respond to alendronate therapy have shown improvement when they began taking estrogen. A recent study indicated that a combination of alendronate and estrogen is superior to the single agents in terms of bone density augmentation. There were no data in terms of fracture-healing protection.

To date, the FDA has approved estrogen, alendronate, and calcitonin for the treatment of patients with osteoporosis and has approved low-dose alendronate and raloxifene for the prevention of osteoporosis. None of these has been labeled specifically for men; however, the bisphosphonates and calcitonin have been effective in men. Premenopausal women have to be evaluated and treated very carefully in terms of drug choices, including calcium and vitamin D. If menstrual cycles are becoming slightly irregular, some physicians have prescribed birth control pills or a postmenopausal dose of estrogen and progesterone, giving the patient at least 1 month off treatment each year to see whether she is postmenopausal. Alendronate has not been approved for the women who are premenopausal, particularly because of pregnancy. However, alendronate has been used by numerous centers for patients who are not pregnant and will not become pregnant, either as a
low dose for prevention of osteoporosis or high dose for treatment of osteoporosis. To date there is no approved method for bone stimulation, and trials of fluoride and parathyroid hormone and parathyroid hormone-related peptides still are in the experimental stage.

An algorithm is proposed by the National Osteoporosis Foundation (Fig. 15–1) for the treatment of patients who are at risk for having a fracture develop. If the individual has a known vertebral fracture, the use of hormone replacement therapy or alendronate or calcitonin would be recommended. If there is no fracture and the patient is not willing to consider treatment, then the recommendations would be calcium, vitamin D, exercise, and smoking cessation. If patients are willing to consider treatment and are older than 65 years of age, bone density should be measured and treated depending on level of bone loss. If the patient has osteoporosis, he or she should be treated for osteoporosis, and if the patient has osteopenia, he or she should be treated with preventive measures. A bone mineral density scan would be indicated if the patient is younger than 65 years of age, has positive risk factors, particularly low body weight, a personal history of fracture or a fracture in first-degree relative, or smokes. If the patient does not have risk factors, then calcium, exercise, and smoking cessation should be recommended. As an option a bone mineral density scan could be taken after menopause.

General recommendations should include physiologic calcium for their age and vitamin D, probably in the order of 400 to 800 units per day. Patients should consider taking estrogen twice in their lifetime, at menopause and at the age of 70 years. Appropriate exercise should be done including impact, strengthening, and balance training. In terms of balance training, effective programs include sports, dancing, and Tai Chi. One study revealed that Tai Chi is the best intervention in preventing falls. A 47% decrease in falls was reported. In terms of evaluating the status of osteoporosis, the two major elements besides risk factors include a bone density determination of apparent bone mass and a measure of bone markers, notably the collagen breakdown products to show the level of bone turnover. Treatments should be based appropriately. Finally, hip fractures are the major consequence of osteoporosis. Therefore, attempts should be made to prevent osteoporosis and to prevent falls. Clearly, prevention is much better than treatment for osteoporosis. The successful tools for the diagnosis, prevention, and treatment of osteoporosis are now readily available to eliminate this disorder.

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SECTION III

NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: BONE SCREWS, PINS, AND AUGMENTATION
Hip fractures are a serious health care problem. In 1994 in the United States alone, there were over 250,000 hip fractures, the majority of which occurred in women. Furthermore, the incidence of hip fractures is increasing due to the overall aging of the population as a whole and the increasing incidence of osteoporosis, which affects over 25 million Americans. The health care expenditures for hip fractures are astounding; in 1995, these costs totaled approximately $8.7 billion in the United States. Hip fractures are also associated with significant morbidity and mortality. The current 6-month mortality is approximately 10 to 20%, despite modern medical treatment and aggressive rehabilitation. If the patient survives a hip fracture, there are major implications for quality of life thereafter. Over two thirds of hip fracture patients do not return to their previous level of functioning. Forty percent of hip fracture patients require the use of a walking aid, and 60% can not perform their activities of daily living independently 1 year postoperatively. Cognitive level also diminishes after sustaining a hip fracture. This lack of cognitive function and independent living places a large social and financial burden on society.

Hip fractures are uniformly treated by optimization of the patient’s general medical condition, early internal fixation or prosthetic replacement of the fracture (within the first few days after injury), and comprehensive rehabilitation. The overall aim of treatment is to facilitate the patient’s early return to society in optimal fashion. Unfortunately, as the above statistics show, this goal has not been met for the majority of patients.

Internal fixation of hip fractures is predicated on the assumption that anatomical reduction of the fracture will lead to more normal hip biomechanics and therefore optimal function. Aside from the medical comorbidities associated with the elderly patient population, the main determinant of clinical outcome of hip fractures is the adequacy and maintenance of the fracture reduction. Hip fractures are notorious for impaction and displacement of the fracture fragments and loss of the reduction. Although closed reduction techniques, the use of multiple screws (for femoral neck fractures), and the sliding hip screw and plate device (for intertrochanteric fractures) have revolutionized the treatment of hip fractures, poor clinical and radiological outcomes are common. This is due in part to the disruption of the load-transmitting posteromedial calcar femorale and crushed cancellous bone in the femoral neck and intertrochanteric area postfracture. This places large axial, bending, and torsional loads on the fracture fragments and implant, leading to impaction, displacement, and implant failure.

Injectable materials that could supplement internal fixation in osteoporotic bone could potentially optimize the stability of hip fractures by resisting some of the loads mentioned above. In this regard, Norian SRS is a biodegradable, nonexothermic bone cement with physical and chemical characteristics similar to the mineral phase of bone. When injected in the form of a paste, Norian SRS quickly hardens in situ, augmenting structural bone deficits in areas of compromised cancellous bone such as in the proximal femur. Unlike polymethylmethacrylate, the material is biodegradable and able to undergo remodeling through normal biological processes. This chapter describes the clinical and experimental studies supporting the use of Norian SRS in the treatment of osteoporotic hip fractures. The general material and mechanical and biological properties of Norian SRS cement can be found elsewhere.
EXPERIMENTAL STUDIES WITH NORIAN SRS BONE CEMENT FOR HIP FRACTURES

Excessive shortening and altered hip biomechanics after fixation of femoral neck and unstable intertrochanteric fractures has been associated with poor functional results. Several biomechanical studies have been performed to assess the efficacy of Norian SRS combined with internal fixation in resisting physiological loads compared with the use of internal fixation alone.

FEMORAL NECK FRACTURES

Stankevich and colleagues studied the biomechanical effects of using Norian SRS to augment internally fixed, comminuted, femoral neck fractures. Pairs of fresh cadaveric proximal femora were harvested, stripped of soft tissue, and radiographed, then underwent dual-energy X-ray absorptiometry (DEXA) for bone mineral density and then were potted. A notch osteotomy was made at the midcervical level of the femoral neck using an oscillating saw; the fracture was completed using a materials testing machine (MTS, Indianapolis, IN). Thirty percent comminution at the inferior cortex of the fracture surface was created with an osteotome. The specimens were then randomly assigned into two groups of matched pairs that received internal fixation with cannulated screws with/without Norian SRS bone cement augmentation. The fractures were reduced anatomically (using direct vision and radiography) and three 7 mm diameter, 32 mm thread length cannulated cancellous bone screws were placed in an inverted triangle configuration. In the SRS treatment group, the drill holes and adjacent fracture were filled with SRS prior to insertion of each screw. After a 24-hour cement-curing period, the specimens were remounted on the testing machine (MTS), preconditioned, and tested using parameters simulating single-stance gait (1000 cycles of load to a peak compressive force of 611.6 N at 0.5 Hz). Stiffness of the construct was measured and then a quasi-static compressive load was applied at 10 mm/min until failure of fixation.

The fracture stiffness of the first loading cycle was found to be significantly greater in the SRS-augmented specimens compared to fractures fixed with screws alone (P < 0.05). Furthermore, SRS-augmented specimens failed at significantly higher loads than the contralateral controls (P < 0.01). On average, the addition of SRS improved the fixation strength of the fracture construct by approximately 170%. The relative improvement of fixation strength was not dependent on bone mineral density of the femoral neck. This study suggests a potential biomechanical advantage in augmenting comminuted, internally fixed femoral neck fractures with Norian SRS.

INTERTROCHANTERIC FRACTURES

Biomechanical Study #1

In the first biomechanical study, three-part intertrochanteric hip fractures were created in 10 matched pairs of osteoporotic human cadaveric femora. The femora first underwent radiographic analysis and dual energy X-ray absorptiometry (DEXA); only femoral pairs for which the density of the femoral neck was at least two standard deviations below that of young, gender-matched femora were chosen for inclusion in the study. The femora were stripped of soft tissue, potted, and two 45-degree strain gauge rosettes were attached to each femur along the femoral neck and immediately below the lesser trochanteric area. The femora were first loaded intact on a servohydraulic testing machine (MTS) using femoral head polymethylmethacrylate casts and parameters simulating single-leg stance (neutral flexion and 12.5-degree adduction). After preconditioning, a three-part intertrochanteric fracture was made by creating 2.2 mm stress risers at 6 mm intervals, including a wedged-shaped defect, and the femora were further loaded on the MTS machine. The femora were then anatomically reduced and fixed with a sliding hip screw device [Dynamic Hip Screw (DHS), Synthes, Paoli, PA] incorporating a 135-degree side plate and 4.5 mm bicortical screws. One of the randomly selected femora in each pair also received Norian SRS. Approximately 5 cc of SRS bone cement was injected into the proximal portion of the screw tract, prior to insertion of the sliding screw. After placement of all the internal fixation, an additional 10 cc of Norian SRS was injected and manually packed into the posteromedial defect left by the displaced lesser trochanter. After curing the cement for 12 hours, a uniaxial strain gauge was fixed to the side plate to measure tensile strains. Axial displacement of the sliding screw relative to the side plate was measured by attaching a linear variable differential transformer to the side plate during mechanical testing. The mechanical loading proceeded for 1000 cycles using 612 N compressive loads at 0.5 Hz and simulated single limb stance.

The addition of Norian SRS to the construct increased fracture stiffness (by approximately 165% after the first cycle and 75% after the thousandth cycle) and strength of fixation compared to nonaugmented contralateral controls (P < 0.05). There was decreased sliding hip screw displacement in the SRS treatment group (0.07 mm versus 1.18 mm, P < 0.05),
although the amount of sliding was very small in both groups because of anatomic reduction of the fracture. Medial bone surface strain remained closer to the intact femur and side plate in the augmented group \((P < 0.05)\). Thus the adjunctive use of Norian SRS enhanced the stability of three-part intertrochanteric fractures in osteoporotic femora.

**Biomechanical Study #2**

A second biomechanical study was performed to evaluate the use of Norian SRS augmentation of unstable three-part intertrochanteric femoral fracture fixation using a specific technique that could be applied at surgery.\(^{21}\) Two treatment groups were evaluated; namely (1) fixation of the fracture with a DHS alone and (2) fixation with a DHS and Norian SRS cement augmentation of the intertrochanteric fracture line and posteromedial lesser trochanteric region of the proximal femur. Paired, human cadaveric femora were first prescreened for anatomical deformities and bone mineral density (BMD) by radiographic examination and DEXA, respectively, prior to admission to the study. Six pairs of femora were subsequently entered in the study, cleaned of soft tissue, and potted in aluminum cylinders. An acrylic acetabular cup was molded using individual femoral heads to simulate in vivo loading conditions around the femoral head. The axial load was applied vertically to the femoral head with the shaft oriented in neutral flexion and 12.5 degrees of adduction to simulate the loads experienced in single-leg stance. A three-part unstable intertrochanteric fracture was created by generating stress risers along the proposed fracture lines and loading on an MTS machine. The two major proximal and distal fragments were reduced and fixed with the DHS. The lesser trochanteric fragment was not reduced. Prior to placement of the side plate in the SRS-treated femora, approximately 10 cc of SRS was injected into the intertrochanteric fracture area with a 12-gauge needle and syringe under radiographic image intensification. The side plate was applied, and all screws except the most proximal one were then inserted in the side plate. Using the proximal screw hole in the side plate, the posteromedial lesser trochanteric defect was then filled with 10 to 20 cc of Norian SRS using a 12-gauge curved needle and syringe under image intensification. The contralateral control femora were treated with a DHS alone without SRS. A linear variable differential transducer (LVDT) was then attached to the side plate using a custom fixture. After mechanical preconditioning, each femur was loaded to 1650 N \((2.5 \times \text{body weight})\) for 10,000 cycles to simulate postoperative load transmission across the fracture construct during normal gait. The load was further increased successively by one body weight for another 10,000 cycles until failure of the construct. Fixation was evaluated by measuring the amount of sliding of the lag screw of the DHS (shortening) and stiffness of the overall fracture construct (stability).

The mean sliding of the lag screw after the first 10,000 cycles was 0.73 mm (range 0.07 to 2.07) for the SRS cement-treated specimens and 18.76 mm (range 2.89 to 43.27) for the control specimens \((P = 0.026)\). First and 20th cycle stiffness was significantly greater in the SRS cement specimens \((P = 0.035\) and \(P = 0.026\), respectively). Thus, the addition of Norian SRS was associated with less femoral shortening and increased stability of three-part intertrochanteric fractures. Decreased proximal femoral shortening would be associated with improved hip biomechanics.

**Clinical Studies with Norian SRS Bone Cement for Hip Fractures**

As most patients who suffer a hip fracture are elderly, the surgical procedure should aim at providing adequate stability in the fracture area so that unrestricted weight bearing can be allowed directly after surgery. Restricted weight bearing is often difficult in elderly patients due to reduced muscle strength in the upper extremities, which makes efficient unloading of an injured hip during ambulation tiresome. If a stable fracture reconstruction is not achieved, rehabilitation will be prolonged and the risk for secondary fracture displacement will increase.

**Femoral Neck Fractures**

The main surgical options include either internal fixation or prosthetic replacement. The complications after internal fixation of femoral neck fractures can usually be divided into early mechanical loosening, nonunion, or avascular necrosis due to disturbed circulation to the femoral head. The revision rate following internal fixation of displaced femoral neck fractures is 20 to 35\%; complications after undisplaced femoral neck fractures are less than 10%. Even though primary circulatory disturbance of the femoral head at the time of injury is the strongest outcome predictor after internal fixation of displaced femoral neck fractures, fracture stability also correlates strongly with uneventful healing.\(^{22}\) Unfortunately the bone is usually osteoporotic, which makes it difficult for screws to achieve a good grip in the femoral head.\(^{23}\) Furthermore, comminution at the fracture site, most common in the posterior aspect of the fracture, adds to the difficulties when aiming for stable fracture fixation. As shown by Stankewicz et al.,\(^{19}\) augmentation with calcium-phosphate cement (Norian SRS) of experimental femoral neck fractures provided enhanced stability when loaded in a material testing machine and compared with fractures fixed with cannulated screws alone. It therefore
seemed of great interest to find out whether such an enhancement with calcium-phosphate cement could provide better stability and improved clinical outcome. Even if prosthetic replacement provided a good outcome in the short term, few would argue that successful internal fixation followed by uneventful healing would be a better option for the patient who has sustained a femoral neck fracture.

When using internal fixation for femoral neck fractures the conventional technique is closed reduction followed by fixation with two or three cannulated screws usually inserted without predrilling and with the screw tips ending in the subchondral bone of the femoral head. By adding cement there were two goals that were aimed for. The first aim was to create a cement mantle around the screw threads to enhance the holding characteristics of the screws. The second aim was to fill the fracture void, especially in the posterior part of the femoral head. During a pilot study, a surgical technique was developed that addressed these two aims. Predrilling was used to create tracts that could be filled with cement, after which the screws were inserted, before the cement hardened. A third drill hole was made through the lateral cortex located in between the two screws to provide a good access to the fracture area. A second cement injection was made through this separate drill hole for complete filling of the fracture void after insertion of the screws (Fig. 16–1).

As the specific aim with augmentation using resorbable cement was to enhance fracture stability, a study was performed in which a radiological technique called radiostereometric analysis (RSA), which allows very precise measurements of fracture stability in vivo, was used. A total of 60 ambulatory patients over 65 years of age, 42 women and 18 men, who had sustained a displaced femoral neck fracture, were included. Patients were randomized to either conventional surgical treatment with closed reduction and fixation with two cannulated screws, or closed reduction and fixation with two screws and augmentation with resorbable cement (Norian SRS). The first RSA examination was done within 12 hours after surgery, after which the patients were mobilized with unrestricted weight bearing. Additional RSA was performed at 1 and 6 weeks and at 6 and 12 months postoperatively.

The RSA study showed significantly improved stability [described as a significantly lower fracture movement from the first postoperative examination until 1 week ($P < 0.0002$) and 6 weeks ($P < 0.05$) after surgery] for fractures augmented with cement compared with fractures fixed with screws alone. At later time points, there was no statistically significant difference in fracture movement between treatment groups. Apart from describing overall total movement, the RSA technique also enables a precise description of the movement along and around three orthogonal axes, and therefore three-dimensional movement can be measured. The RSA data revealed significantly reduced varus angulation in fractures augmented with cement when compared with fractures fixed with screws alone at 1 week ($P < 0.0001$) and 6 weeks ($P < 0.01$) and at 6 months ($P < 0.01$). Furthermore, the cement-augmented fractures had significantly less distal displacement of the femoral head and neck fragment in relation to the greater trochanter at 1 week ($P < 0.001$) after surgery. In sum-

**FIGURE 16–1** Fixation of a femoral neck fracture with internal fixation supplemented by biodegradable bone cement. (A) Preoperative radiograph of a displaced femoral neck fracture. (B) Postoperative radiograph showing excellent reduction and fixation of the fracture with two Uppsala screws supplemented with Norian SRS bone cement. (C) One year later, the fracture has healed with minor impaction.
mary, the RSA study showed improved early fracture stability after surgery when cement was used for augmentation.

In another prospective study, 126 patients who had sustained a femoral neck fracture were enrolled to evaluate whether augmentation with resorbable cement would reduce the risk for reoperation and improve the clinical and functional outcome following internal fixation. Only ambulatory, self-reliant and nonsenile patients over 65 years of age were included. Patients with malignancy, pathologic fractures, arthritis, and multiple injuries or on treatment with drugs with a known effect on bone metabolism were excluded. A healthy, previously nonoperated contralateral hip was also a prerequisite for this study. The patients were randomly assigned to the same two treatment options as for the previously mentioned RSA study [i.e., closed fracture reduction followed by internal fixation with two screws alone (controls) or in combination with resorbable bone cement (augmented)] using the surgical technique previously described.

There were no serious adverse effects during surgery or follow-up that could be attributed to the use of the resorbable cement. Rehabilitation including unrestricted weight bearing was begun immediately after surgery, and follow-up evaluations were done on the first day after surgery and at 1 and 6 weeks and at 6 and 12 months after the fracture event. The functional outcome measurements included pain [standard Visual Analog Scale (VAS)], activities of daily living (ADL), and range of motion and isometric abductor muscle strength. Conventional radiographs were used to assess fracture reduction, implant position, secondary displacement, implant failure, and possible healing disturbances.

There was no statistically significant difference in the reoperation rate between the treatment groups during the 12-month follow-up period. Twelve of the patients in the cement-augmented group (12/62) were reoperated due to nonunion (eight) or avascular necrosis (four), and the corresponding reoperation rate in the control group was nine reoperations (9/64), due to nonunion (seven) or avascular necrosis (two). In 19/21 of the patients reoperated due to nonunion or avascular necrosis, the secondary procedure consisted of a total hip replacement; in two patients a resection arthroplasty was performed. In the control group two additional patients sustained a refracture that involved the subtrochanteric area. The lower screw hole probably acted as a stress riser, as the refractures seemed to evolve from this entry point. No refracture occurred in the cement-augmented group.

There were no significant differences in pain assessment between the two treatment groups at any of the time points either when given as an overall pain rating or as pain during walking. Patients in the cement-augmented group reported significantly less difficulty in walking 10 feet at 1 week ($P < 0.001$) when compared with the controls, although there were no significant differences in this parameter at other time points. The same tendency with better ADL function in the cement-augmented fracture group during the early rehabilitation period was also seen for activities such as getting in and out of the bath ($P < 0.001$), on and off of the toilet ($P < 0.001$), in and out of bed ($P < 0.001$), rising from a chair ($P < 0.001$), and putting on shoes ($P < 0.01$). From 6 weeks and onward, there were no statistically significant differences in ADLs between the two treatment groups.

The isometric muscle function during abduction, when measured with a handheld dynamometer, showed significantly better strength in patients whose fractures were augmented with the SRS bone cement until 6 weeks after surgery ($P < 0.03$).

When assessed by conventional radiographs, the cement-augmented fractures demonstrated less varus shift at 6 weeks ($P < 0.002$) and at 6 months ($P < 0.04$) after surgery.

**Trochanteric Fractures**

Two-part trochanteric fractures seldom present problems for the surgeon, and uneventful healing can almost always be anticipated no matter of what type of metal implant has been used. The complication rate following surgical treatment of multifragmentary unstable trochanteric fractures has also decreased due to development of sliding hip screw devices that allow secondary fracture impaction. Still, the results in terms of reoperation rate and sequelae due to insufficient recovery of the hip function are usually not as good as many surgeons tend to believe. There is definitely a need for improvement in the surgical treatment of unstable trochanteric fractures, especially if there is a lack of bone continuity on the medial side of the proximal femur due to displacement of the lesser trochanter.

Acrylic bone cement (polymethylmethacrylate or PMMA) has been shown to enhance the strength when used for augmentation of experimental trochanteric fractures fixed with metal implants in vitro. PMMA has also been used in vivo in a limited number of studies to enhance fracture stability when used in osteoporotic patients. Even given the favorable outcome in clinical series, augmentation with PMMA in hip fracture surgery has never gained widespread clinical acceptance. This is probably due to a number of potential side effects such as exothermic reaction during curing, inability of the cement to be remodeled, and the risk of inhibiting fracture healing if PMMA is interposed between adjacent fracture sur-
faces. PMMA may also be very difficult to remove if revision surgery becomes necessary.

Biodegradable bone cements have been studied with the goal of providing mechanical reinforcement at the fracture site during fracture healing, followed by progressive resorption over time when the healing bone will provide increasing structural support.27-32 As previously mentioned, two in vitro studies have revealed improved stability and strength for unstable trochanteric fractures fixed with a sliding screw device and augmented with calcium-phosphate cement when compared with fractures fixed with a metal device alone.20,21 Furthermore, SRS cement has been shown to compare favorably with PMMA in a single-cycle cutout test of augmented compression hip screws in senile trabecular bone.33

When using resorbable cement for augmentation of trochanteric fractures the overall goal is to improve the clinical and functional outcome for the patients by providing enhanced fracture stability during the course of healing.

During a pilot study, a surgical technique was developed that allowed the combined use of a conventional sliding screw device and augmentation with resorbable cement. The goal with the augmentation was not to fully prevent sliding but to avoid excessive sliding and thereby avoid major fracture displacement. If sliding was completely prevented and the combined metal-cement construct was rigid, the risk for healing disturbances would increase similar to fixed-angle implants previously used for unstable trochanteric fractures. Instead, the aim with SRS bone cement was to fill out the medioposterior defect in the proximal femur, thereby restoring a medial arch that would allow load sharing between bone and implant. Augmentation around the screw threads in the femoral head was considered less important, as loss of fixation of conventional sliding screws in the femoral head is a very uncommon complication in trochanteric fractures.

Following closed or, in some fractures, open fracture reduction, the sliding screw device was inserted using standard technique with the exception that the most proximal screw hole in the plate initially was left without a screw as it was used as a portal for cement injection. A separate cortical drill hole was made in the anterolateral aspect just distal to the base of the plate barrel. A curved probe was used to clear the fracture of small bone fragments and debris to create an empty space. The cement was then injected using curved needles with the same curvature as the probe, with the goal of completely filling the medioposterior void (Fig. 16–2). In most osteoporotic patients this part of the proximal femur is “empty” or only filled with very weak cancellous bone and fatty marrow. The whole injection procedure can be followed using fluoroscopic control due to the radiopaque nature of the SRS bone cement (Fig. 16–3).

As the specific aim with augmentation using resorbable cement in trochanteric fractures would be to enhance fracture stability during the course of healing, a study utilizing the RSA technique was performed.34 A total of 30 ambulatory patients (22 women and 8 men) above 65 years of age with an unstable trochanteric fracture that included a detached lesser trochanter fragment were included. Patients were randomized to surgical treatment with either a conventional sliding screw device alone or the same implant device in combination with resorbable cement for augmentation. The first RSA examination

FIGURE 16-2 Technique of fixation of intertrochanteric fractures with biodegradable bone cement. (A) The lag screw has been placed and the posteromedial calcar defect (due to a displaced lesser trochanteric fragment) is defined and cleared of debris. (B) After application of the lag screw, side plate, and screws, an anterior portal has been used to inject Norian SRS bone cement into the large posteromedial defect.
was done within hours after surgery, after which the patients were mobilized with unrestricted weight bearing. Additional RSA was done at 1 and 6 weeks, and a final examination was done at 6 months, a time point when a trochanteric fracture usually has healed.

The RSA examinations showed a significantly better overall stability at all time points after surgery ($P < 0.01$ to $P < 0.05$) in fractures augmented with cement when compared with fractures fixed with the metal device alone. For unstable fractures with a detached lesser trochanter there is a tendency for the fracture to displace into varus due to the lack of medial support. The RSA data revealed significantly reduced varus angulation in fractures augmented with cement when compared with fractures fixed with metal alone ($P < 0.01$). Furthermore, the cement-augmented fractures had significantly less distal displacement of the femoral head and neck fragment in relation to the greater trochanter at 1 week ($P < 0.003$) as well as at 6 weeks ($P < 0.03$) and 6 months ($P < 0.03$).

In a prospective multicenter study 102 patients were enrolled to evaluate whether augmentation with resorbable cement would reduce the risk for complications and improve the clinical and functional outcome following surgical treatment of unstable trochanteric fractures. Only ambulatory, self-reliant, and nonsenile patients above 65 years of age were included. Patients with malignancy, pathologic fractures, and multiple injuries or on treatment with drugs with a known effect on bone metabolism were excluded. The patients were randomly assigned to the same treatment options as for the previously mentioned RSA study. Fracture reduction was followed by internal fixation with a conventional sliding screw device alone (controls) or the hip screw device in combination with SRS bone cement (augmented) using the surgical technique previously described. Cement augmentation added on average 12 minutes to the total operation time. There were no serious adverse effects during surgery or during the time until fracture healing that could be attributed to the use of the resorbable cement. Rehabilitation including unrestricted weight bearing was begun immediately after surgery, and follow-up evaluations were done by an independent observer at 1 and 6 weeks and at 6 months after the fracture event. The functional outcome measurements included pain (standard VAS), ADLs, isometric abductor muscle strength, and quality of life (SF-36 Health Status Questionnaire). Conventional radiographs were used to assess fracture reduction, implant position, secondary displacement, implant failure, and healing disturbances.

All fractures healed and conventional radiographs did not show any difference in bone healing between treatment groups at any time point.

At 1 week after surgery there was no significant difference in pain either when given as overall pain rating or as pain during walking between patients in the cement-augmented group and controls. At 6 weeks the patients in the cement-augmented group had significantly less pain during rest ($P < 0.003$) as well as during walking ($P < 0.003$) when compared...
with the controls. At the final follow-up at 6 months there was no difference in pain rating between the two groups. The lack of difference between the treatment groups during the first week after surgery was interpreted as due to much of the pain being caused by the soft tissue injury and the surgery. Once the soft tissue pain declined, the difference in pain rating between the treatment groups was obvious as illustrated by the highly significant difference observed at 6 weeks. At 6 months all fractures had healed and the patients were therefore usually free of pain or reported only limited pain.

For several of the different ADLs that were measured, for instance getting on/off the toilet ($P < 0.05$), curb step difficulty ($P < 0.03$), and rising from a chair ($P < 0.05$), there was the same tendency with a significant improvement in the cement-augmented group at 6 weeks after surgery. At 6 months after fracture healing had occurred, there were no differences between the two groups for any element of the ADL evaluation.

There was no statistically significant difference in isometric abductor muscle strength between treatment groups at any of the time points. At 6 months the abductor strength was on average about 87% of the strength in the contralateral healthy hip for both treatment groups.

Perhaps most important, the quality of life assessment revealed that patients in the cement-augmented group showed significant improvement compared with the controls on four of the HSQ subscales at 6 weeks, including less pain ($P < 0.02$), better general health ($P < 0.006$), better vitality ($P < 0.004$), and health transition ($P < 0.02$). At 6 months the difference in life quality was even more pronounced, with the patients in the cement-augmented group reporting not only better physical functioning ($P < 0.04$), general health ($P < 0.02$), and vitality ($P < 0.02$) but also significantly better social functioning ($P < 0.002$), mental health ($P < 0.02$), and mental component scale ($P < 0.05$) when compared with the control group.

**Discussion and Conclusions**

Hip fractures still constitute a major health problem for society. The morbidity and mortality associated with hip fractures are still substantial despite modern surgical technique, anesthesia, and rehabilitation. The optimal outcome for these fractures is the return of the patient to his or her home environment soon after surgery, with their prefracture physical and mental status intact. This outcome has not yet been achieved for the majority of patients. This is due to the sequelae of the trauma on subsequent physical and cognitive function, the numerous medical comorbidities associated with elderly patients, and the prolonged rehabilitation outside of the patient’s home environment.$^{1,2,4,5}$

Comminuted femoral neck and intertrochanteric hip fractures are generally associated with loss of the structural integrity of the calcar femorale and crushing of the supporting cancellous bone. This often leads to progressive impaction and shortening of the fracture fragments and loss of normal hip biomechanics. The use of adjunctive methods of hip fracture fixation, such as Norian SRS, has the potential to enhance fracture stability and proximal femoral anatomy, thereby restoring more normal hip biomechanics. The goal is to allow the patient to ambulate quicker after surgery, with less pain and subsequently more optimal function. Biomechanical and ongoing clinical trials would suggest that some of these goals have been achieved with the use of SRS in the treatment of femoral neck and trochanteric fractures.

When comparing the RSA studies in trochanteric fractures and femoral neck fractures,$^{7,53}$ enhanced overall stability was seen in cement-augmented fractures as well as significantly less distal migration and less varus angulation of the femoral head fragment. Augmentation of the trochanteric fractures seemed to provide enhanced stability throughout the whole period of fracture healing, and the enhanced stability in the femoral neck fractures lasted for a shorter time period. Based on studies available at present it is not possible to fully explain this difference. One explanation might be that Norian SRS undergoes fatigue when used for augmentation of femoral neck fractures, as the time to healing appears to be longer for femoral neck fractures when compared with trochanteric fractures. Another possible explanation for the less sustained results when cement was used in femoral neck fractures might be that the circulatory disturbance caused at the time of fracture induced a resorption of avascular bone at the fracture site that reduced the strength of the bone surrounding the cement. In trochanteric fractures no such bone resorption is seen; instead callus formation will form around the cement and subsequently replace the cement over time.

A common finding when using resorbable cement for augmentation of hip fractures was leakage of cement into the surrounding soft tissue through the fracture. This was an expected finding as the cement has a fairly low viscosity until it hardens. This means that it will easily leak through the fracture into the surrounding soft tissue. For femoral neck fractures, cement was visible in the intracapsular area after surgery although in no case was there any cement in the weight-bearing portion of the joint space. There was no indication of an adverse effect due to cement in the soft tissue in any case. The cement in the soft tissue tended to disappear during the postoperative period.
The timetable for resorption of the calcium-phosphate cement Norian SRS when used in humans is not fully known. Once the fracture has healed, the presence or absence of a bone void filler like calcium-phosphate cement is not expected to have any clinical effect. However, based on clinical studies and biopsies recently retrieved from humans, the cement will be resorbed and replaced by bone although at a fairly slow rate. In the clinical hip fracture studies, with 6- and 12-month follow-up, the amount of cement as judged from radiographs was reduced at the final follow-up, although in no case had it been completely resorbed. It can therefore be concluded that the material will at least not be remodeled until the fracture has healed and the bone is restored to its load-bearing capacity.

The results from the first clinical studies using calcium-phosphate cement for augmentation of hip fractures suggest that in unstable trochanteric fractures the clinical effects are notable during the early healing period, with less pain and improved ability to perform activities of daily living in a more independent manner. The early clinical improvement also seems to have a positive, longer lasting effect on the quality of life. In femoral neck fractures augmentation with calcium-phosphate cement also improved stability of the fracture construct during the early healing period, and patients were able to perform activities of daily living more efficiently during this time when compared with control patients. However, it seemed that the effect of augmentation with biological cement in femoral neck patients was less pronounced when compared with patients sustaining a trochanteric multifragmentary fracture.

**Future Directions**

New surgical devices have recently been developed that may further improve the outcome of hip fractures. These new devices may be enhanced by the addition of Norian SRS to the fracture construct, and therefore further biomechanical studies are warranted. Norian SRS is an osteoconductive bone cement; methods to provide osteoinductive capabilities would be a great advance. Bone cements may provide a local delivery method for biological agents such as growth factors to hasten fracture healing, or antibiotics for the treatment of infection, etc. Bone cements such as Norian SRS can withstand substantial compressive loads. The development of a biodegradable bone cement that could withstand clinically important bending and torsional loads is also needed.

**References**

16. Frankenburg EP, Goldstein SA, Bauer TW, Harris SA, Poser RD. Biomechanical and histological evaluation


In the last 20 years, the number of femur fractures close to the hip has risen substantially, which is mainly due to the change in the age pyramid and the resulting increase in osteoporosis.\(^1\) Unstable intertrochanteric fractures in particular are very common in elderly people and pose a special problem because of the presence of advanced osteoporosis with a reduced mechanical bone quality, which makes it more difficult for implants to bond to bone in a sufficiently stable manner.\(^1\)–\(^3\)

The most frequently applied osteosynthesis technique for intertrochanteric fractures involves the dynamic hip screw (DHS, Synthes). Complication rates of up to 20% are reported for unstable femur fractures.\(^4\)–\(^6\) A common complication with mechanically weak osteoporotic bones is the migration of the screw through the femoral head, perforating the joint and causing the femoral head to tilt into a varus position.\(^4\),\(^7\) A reinforcement of the mechanically weak bone is desirable to avoid such implant migrations in the osteoporotic bone.

Adjunctive osteosyntheses such as those performed since the 1970s with the aid of polymethylmethacrylate (PMMA) bone cement can increase the primary stability.\(^8\)–\(^12\) There have been endeavors for some years to replace the PMMA bone cement with new cements as the PMMA cement releases monomers, undergoes fibrous sheathing, and does not form a permanent bond with the adjacent bone in vivo.

More favorable possibilities present themselves with a new cement on a glass-ionomer basis,\(^13\) which promises a chemical bond with the bone and thus a better and long-lasting adhesion to bone. However, before conducting in vivo trials, we had to establish whether an increased primary stability of the implant’s bond with the osteoporotic bone could be achieved with the aid of the new cement.

**Testing of the System**

**Anatomical Specimens**

The experimental investigations were performed on eight pairs of female cadaver femurs, with an average age of 76.9 (range 62 to 87) years. The mean degree of osteoporosis according to Singh was 2.9 (range 2 to 3). The average CCD angle was 120 ± 4.8 degrees. The femurs had been stored frozen at –30°C and were thawed at 37°C for 12 hours before the start of the experiment and were kept wet with Ringer’s solution.

**Glass-Ionomer Cement**

Glass-ionomer cements have been used for dental fillings for some 20 years; however, the experience so far with regard to applications in trauma surgery and orthopaedics is still inadequate. The cement consists of two components that have to be mixed in a fixed proportion before use. The powder consists of a calcium-aluminum-fluorosilicate glass with a particle size of 0.1 mm. The liquid component consists of an aqueous solution of a polycarboxylic acid (acrylic acid-maleic acid copolymer) and tartaric acid. The setting reaction is an exclusively ionic reaction and is based on a neutralizing reaction between the polycarboxylic acid and the alkaline glass powder.

The cured glass-ionomer cement (Ionos, Munich) consists of a solid insoluble aluminum-calcium-polycarboxylate matrix in which the glass particles and water molecules are embedded. Compared to the conventional PMMA bone cement, the glass-ionomer cement has the following advantages:
• No monomers occur.
• Ionic setting takes place, without any appreciable rise in temperature, in the physiological temperature range.
• Practically no loss of volume occurs during setting.
• It constitutes a hydrophilic system that can produce ionomeric bonds with the calcium in the bone.

Due to the glass portion, the cement’s resistance to pressure (110 MPa) is markedly higher than its flexural strength (19.8 MPa). As mixing must be performed in a precisely dosed proportion, the two components are supplied by the manufacturer in premeasured single-use packaging. After blending in a special mixer (Rolomix, Ionos, Munich), a manipulation time of some 4 minutes remains until curing.

**Implants**

For the stabilization of the intertrochanteric model fractures, we used DHS (Synthes) with an angle of 135 degrees and lengths of 95 to 105 mm. To guarantee a good distribution of the glass-ionomer cement when screwing the DHS into the femoral head, a groove of 2 mm width and 3 mm depth was cut into the thread part, parallel to the screw’s axis, across the entire length of the thread.

**Fracture Model**

To obtain experimental conditions as standardized as possible, the DHS implants were first implanted on the intact bone without cement, according to the recommendations of the AO, using the original set of instruments.

Subsequent radiological checks performed in two planes showed that all the screws had been put in place close to the calcar in such a way that their tips were located in a central position in the femoral head, directed against the dorsal-caudal quadrant, and within 5 to 10 mm of the cortex layer.

The implants were then removed again and standardized fracture conditions produced by osteotomies. The first osteotomy was performed at an angle of 45 degrees to the longitudinal axis of the femoral shaft from medial above the lesser trochanter to lateral toward the greater trochanter (Fig. 17–1). A deficient medial support was simulated with a second osteotomy running from the center of the osteotomy area to a point below the lesser trochanter (Fig. 17–1). This produced an instability of the kind developed under clinical conditions when a medial fragment is blown out. The two fragments of the femur were then stabilized with the DHS.

We randomly selected one bone of each pair for additional cement fixation. With these bones, 6 g of glass-ionomer cement was injected into the screw hole of the femoral head with an injection gun before the DHS was put into place. The fragment was repositioned, then the screw was screwed in and the osteosynthesis completed.

**Dynamic Load Test**

For clamping into a materials testing machine, the distal end of the femurs were embedded in steel cylinders with plastic (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany) up to 2 cm below the end of the DHS plate. With the aid of these cylinders, the femurs were fixed in the clamping device of the materials testing machine (Zwick 1454, Einsingen, Germany) at an angle of 25 degrees to vertical in the frontal plane (Fig. 17–2). For the application of a load on the femoral head, a force was applied through the crosshead of the testing machine. To achieve the ap-
The system’s accuracy of measurement is 0.2 mm for translations and 0.2 degrees for rotations. The coordinate system shown in Figure 17–2 was defined for the three translations and three rotations. To determine the interfragmentary movements under a dynamic load, 40 load cycles involving a vertical force of between 0 and 1400 N were applied to the femur, using a frequency of 0.2 Hz (cycles/s).

At the same time, we performed the measurement and recording of the force (with the measuring system of the materials testing machine) and the on-line measurement and evaluation of the relative movements of the femoral head fragment (with the goniometer measuring system with Rhothron computer, Homburg, Germany).

Having completed the test, the osteosyntheses were removed and the femoral heads were sawed through in the plane of the screws to assess the bony thread.

STATISTICS

In a bifactorial analysis of variance (ANOVA, StatView, Abacus Concepts, Berkeley, CA 1992), the measured values for the caudal shift and for the tilt into a varus position were tested for significant differences in terms of the influence of cementation and the number of load cycles. As one could not assume a normal distribution of data for the measuring results, it was not the means and standard deviations that were determined but the medians and maximum and minimum values.

RESULTS

We were able to perform a complete load test for seven of the eight pairs of femurs tested. With the uncemented femur of pair No. 6, the head was found to have tilted completely at a load of only 110 N. The irreversible deformation in caudal direction (z) was over 20 mm and the varusing rotation was over 20 degrees. Consequently, the dynamic pressure load cycles could not be performed on this bone, but the contralateral cemented femur endured the load without any higher-than-average irreversible deformation. Pair No. 6 was excluded from the evaluation.

Generally, the following can be said for both the cemented and the uncemented osteosyntheses: under the application of a cyclic load on the femur, cyclic motion amplitudes were measured in all degrees of motion of the femoral head (Fig. 17–2). Both elastic, reversible movements and irreversible deformations were observed. Irreversible deformations accumulated with each load cycle, which led to a permanent shift and tilt of the femoral head. Shifts in ventrodorsal direction (y) and rotations around the longitudinal axis (γ) were slight and reversible. Relatively low elastic and irreversible values were found for the rotation around the transversal axis (α) and the shift in medial-lateral direction (x). The greatest reversible and irreversible tilts (i.e., tilting of the head into a varus position) were observed for the rotation in the frontal plane (β) (Fig. 17–2). Tables 17–1 and 17–2 give the measured values for this and for the
### Table 17-1  Varus Tilt Angle ($\beta$), Cemented and Uncemented

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### Table 17-2  Irreversible Deformation in Caudal Direction (z), Cemented and Uncemented

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<td>3.3</td>
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<td>6.4</td>
<td>5.1</td>
<td>8.9</td>
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<td>10.1</td>
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transversal shift in caudal direction \((z)\), where great irreversible shifts were also observed. Cycles 1, 5, 10, 30, and 40 were evaluated for the presentation of results.

A comparison of osteosynthesis stability without and with the additional use of ionomeric cement reveals significantly smaller irreversible distortions \((\beta, P<0.001)\) and shifts \((z, P<0.031)\) for the osteosyntheses with an additional reinforcement of the spongy bone in the femoral head with ionomeric cement (Figs. 17–3 and 17–4) compared with the uncemented version.

What is particularly noticeable is that the irreversible deformations in these 2 degrees of motion \((\beta, z)\) are about twice as great in the uncemented osteosyntheses as in the cemented ones, and they increase steadily even after several load cycles (i.e., the process of shifting and tilting of the femoral head continues steadily), although no more irreversible deformations are observed with the cemented osteosyntheses after 10 load cycles.

These differences in the deformation behavior depending on the number of load cycles are statistically significant, both for tilting of the head \((\beta, P<0.005)\) and for the shift in caudal direction \((z, P<0.001)\).

Depending on the degree of osteoporosis, the irreversible shifts led to pronounced migrations of the screw in the femoral head. In two bones of the uncemented group, we found irreversible tilts of the femoral heads into varus positions of more than 11 degrees (Table 17–1) accompanied by a shift in caudal direction \((z)\) of more than 8 mm (Table 17–2). In such cases, a widening of the screw bed in the direction of the superior quadrant was observed in the sawed-through femoral heads at the macroscopic level.

With the cemented DHS, these effects were markedly rarer and less pronounced. The cement had penetrated approximately 2 to 3 mm into the spongy bone where it had led to a reinforcement of the weak trabeculae. Our observations showed that the cement did not touch the fracture zone (osteotomy).

**Discussion**

In vitro, the reinforcement of the osteoporotic spongy bone in the femoral head with 6 g of glass-ionomer cement led to a significant reduction of the DHS’ irreversible migration under dynamic load applied to an unstable intertrochanteric osteosynthesis. The same effects were found in a similar in vitro experiment\(^{15}\) in which the spongy bone in the femoral head was reinforced with bone cement (PMMA) or with a biodegradable cement consisting of polypropylene, tricalcium phosphate, and calcium carbonate. Both techniques proved an increase in the resistance until the onset of an irreversible deformation. However, it is doubtful whether an absorbable cement is suitable for this indication, as one cannot assume that an osteoporotic bone has formed new, dense bone trabeculae after the absorption of the cement.

Clinically, PMMA bone cement has successfully been used for the reinforcement of osteoporotic bones since the 1970s.\(^{2,8–12}\) The release of monomers involved in the use of PMMA bone cement, as experienced in prosthetic surgery, and the fibrous interface between PMMA and bone have led to the development of new cements designed to not have these disadvantages. The glass-ionomer cement used by us in this experiment does not release monomers, has a very low volume shrinkage when setting, and binds to the bone on an ionomer basis.\(^{15}\)

The good biomechanical results achieved with this cement indicate that the cement penetrates into the
The biomechanical model was chosen in such a way that a clinically critical form of instability (medial defect) was simulated under the conditions of a one-leg stance. The angle at which the force was applied in the frontal plane of 25 degrees to the femoral shaft axis is composed of a 16-degree angle of the adduction position resulting from the hip joint and a 9-degree physiological adduction position of the femoral shaft.16

The intensity of the force applied to the femoral head was chosen to be 1400 N, which, at just over twice the body weight, roughly corresponds to the target group of elderly females. Higher loads were not considered as a plastic deformation of the DHS implants can occur under these unstable conditions. The aim of the study, however, was to exclusively measure the irreversible deformations of the spongy bone in the femoral head. We limited the number of load cycles to 40 as preliminary experiments had shown that the major part of the irreversible deformation occurred during the first 10 load cycles. With the cemented screws, virtually no more irreversible deformations occurred after this, while further increases were found with the uncemented screws even up to the 40th load cycle. This difference in behavior was statistically significant and clearly proves the effect of cementing.

These results also confirm the experience so far with adjunctive osteosyntheses in osteoporotic bones for the new glass-ionomer cement. Due to its specific properties, we can expect a better and more durable bond with the bone, as distinguished from the PMMA cement. Clinical trials will have to show whether these more favorable material properties will turn out to be a significant advantage under clinical conditions, too. The growing number of intertrochanteric fractures in the elderly and their increasing life expectancy even after osteosyntheses indicate the significance of a suitable cementing technique.

Acknowledgments

The authors would like to thank Mrs. P. Horny and Mrs. A. Reindl for producing the graphics and the manuscript. Our thanks are also extended to IONOS for supplying the test material and the cementing technique.

References


9. Harrington KD. The use of methylmethacrylate as an adjunct in the internal fixation of unstable commin-


External fixation offers various advantages compared with other fixation methods.\(^1\) It is a fast, relatively simple, and atraumatic technique.\(^2\) It enables, in the majority of cases, easy reduction of the fracture, even under unfavorable soft tissue conditions, and secondary corrections can be made.\(^3\) Furthermore, it is possible to modify fixation stiffness during treatment.\(^1\) This enables proper management of the healing process.\(^4,5\) Technological evolution has been a significant contributing factor in improving the external fixator stiffness and eliminating its mechanical inadequacy, a major problem in the past.\(^6\) Finally, external fixation treatment is comparatively cost-efficient.\(^7\)

Despite these positive qualities, there persists a high incidence of complications due to the progressive mechanical deterioration of the bone-pin interface, which leads to pin loosening and infection.\(^8-12\) Often, these complications are severe enough to necessitate interruption of treatment due to a lack of fixation strength, or the spread of infection from the pin tracts causing osteomyelitis.\(^5,13-16\)

Deterioration of the bone-pin interface strength is an inevitable phenomenon with standard pins. Chao and Aro\(^5\) stated that “there seems to be a race between the gradually increasing loading capacity of a healing bone and failure of the bone-pin interface.” Pin extraction torque has been measured in many studies.\(^2,9,17,18\) In all studies of standard pin types, pin extraction torque was lower than pin insertion torque. This confirms that there is a progressive reduction of pin anchorage during treatment.

Aro et al\(^13\) demonstrated in an animal study that the extraction torque of Orthofix tapered pins decreased by approximately 80% at 12 weeks compared with the corresponding insertion torque (Orthofix, Bussolengo, Italy). Similar results were found using Apex cylindrical (Howmedica, Rutherford, NJ) and Superfixation bicylindrical (Citieffe, Lippo di Calderara di Reno, Italy) pins.\(^9,17,18\) In a clinical study on tibial fractures the extraction torque of Apex cylindrical and Superfixation bicylindrical pins was lower than the corresponding insertion torque. No difference in extraction torque was found between the two pin types.\(^10\)

The causes of pin loosening and infection are multifactorial. Thermal and mechanical damage of the bone during pin insertion and formation of fibrous tissue at the bone-pin interface have been identified as causes of pin loosening and infection.\(^18\) Both damaging factors can be limited but not completely avoided with standard pins. In many studies, fibrous tissue formation at the bone-pin interface has been identified as the most important factor in pin loosening.\(^9,11,19\) This fibrous tissue formation is thought to be an inevitable phenomenon with stainless steel and titanium pins.\(^11\) However, differences in bone-pin contact related to different metal types have been reported. A higher osteointegration was reported in pins coated with titanium compared with similar pins made of stainless steel.\(^11\)

To improve pin fixation and consequently avoid infection of the pin tracts, some authors developed the idea of coating the pins. The first example of coated pins dates back to 1913 when Lambotte coated the pins with nickel and gold to protect against rust.\(^20\) More recently, Manley et al\(^1\) used ultrahigh molecular weight polyethylene as a coating material. With these pins there was a reduction of approximately 50% in maximum compressive stress. However, ultrahigh molecular weight polyethylene is not an osteoconductive material, and furthermore, no in vivo study was performed.

Recently, thanks to technological progress in the science of biomaterials, a new technique has been devised. Pins coated with hydroxyapatite have been developed to improve osteointegration and consequently the mechanical stability of the bone-pin interface.
prevent bone-pin contact were seen in Group B (Fig. 18–2). At 60 magnification was 16 ± 9% (Group A, P < 0.001) and Group C (P = 0.003). Extraction torque was significantly lower compared to the corresponding insertion torque in both Group A (P < 0.001) and Group C (P = 0.003). In contrast, the hydroxyapatite-coated pins showed no significant difference between extraction and insertion torque (Table 18–1). No pin failed during removal.

Bone-pin contact at ×60 magnification was 16 ± 9% in Group A, 30 ± 12% in Group B, and 26 ± 15% in Group C (Group A vs. Group C, P = 0.042) (Table 18–2). At ×60 magnification, histological examination showed many areas of bone resorption, fibrous tissue encapsulation, and low bone-pin contact in Group A (Fig. 18–3). Better osteointegration and many areas of direct bone-pin contact were seen in Group B (Fig. 18–4). At ×60 magnification the osteointegration in Group C looked very similar to Group B but at
x10,000 magnification no real bone-pin contact was observed between titanium and bone (Fig. 18–5). In all titanium-coated pins a gap of 1 to 3 µm was found. In contrast, in Group B contact was seen between bone and hydroxyapatite even at ×10,000 magnification (Fig. 18–6).

No infection of the bone-pin tract was seen in the histological observations of any pin. There was no coating breakage or sloughing in the hydroxyapatite-coated pins.

Histological observations of the bone holes after pin removal showed no fractures in the bone surrounding the pinhole in any pin group. Neither the uncoated nor the titanium-coated pins left metallic particles in the bone after pin removal. The hydroxyapatite-coated pins left small fragments of hydroxyapatite approximately 10 µm thick in direct contact with the bone holes.

After removal of the hydroxyapatite-coated pins, the hydroxyapatite coating looked intact and the metallic substrate was not visible. Histologically, very few small bone fragments were seen between the threads of the hydroxyapatite-coated pins, and there were no hydroxyapatite-coating detachments from the metallic pin core.

### Clinical Study in Normal Bone

The purpose was to compare the clinical and biomechanical results of two groups of patients treated by hemicallotosis for medial osteoarthritis of the knee with external fixation with either standard tapered pins or hydroxyapatite-coated tapered pins. Nineteen patients were studied, 12 men and seven women, of mean age 54 years with medial osteoarthritis of the knee treated by hemicallotosis. Patients were randomized to receive either standard tapered or hydroxyapatite-coated tapered pins (Orthofix 6–5 mm Orthofix srl, Bussolengo, Italy). Two pins were implanted in the cancellous bone of the proximal tibia above the osteotomy, and two pins were implanted in the cortical bone of the tibial shaft. Pins were implanted after predrilling. Insertion torque was measured at surgery. A unilateral external fixator was placed anteriorly (Orthofix T-Garche). Nine patients received standard pins and nine patients hydroxyapatite-coated pins. The mean fixation time was 101 days. At the time of fixator removal, pin extraction torque was measured. There were no differences in pin insertion

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**Table 18–1  Biomechanical and Radiographic Findings**

<table>
<thead>
<tr>
<th>Sheep</th>
<th>Final Insertion Torque* (N•mm)</th>
<th>Initial Extraction Torque† (N•mm)</th>
<th>No. of Pin Tracts with Rarefaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A: uncoated pins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3390</td>
<td>165</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>4260</td>
<td>523</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>4440</td>
<td>320</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>3160</td>
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<tr>
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<td>6</td>
<td>6060</td>
<td>330</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>4360 ± 1050‡</td>
<td>253 ± 175‡</td>
<td>29§</td>
</tr>
<tr>
<td>Group B: hydroxyapatite-coated pins</td>
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<tr>
<td>7</td>
<td>4430</td>
<td>2430</td>
<td>1</td>
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<tr>
<td>8</td>
<td>3860</td>
<td>1960</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>3990</td>
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<tr>
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<td></td>
<td>3420 ± 676‡</td>
<td>3360 ± 1260‡</td>
<td>15§</td>
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<tr>
<td>Group C: titanium-coated pins</td>
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<tr>
<td>13</td>
<td>3160</td>
<td>1140</td>
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<tr>
<td>18</td>
<td>3390</td>
<td>975</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>3740 ± 643‡</td>
<td>1720 ± 1030‡</td>
<td>30§</td>
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</table>

* The values for individual sheep are given as the mean for the six pins.
† The values for individual sheep are given as the mean for five pins.
‡ The value is given as the mean (and standard deviation) for all the pins tested in the group.
§ The value indicates the total number for the group.

torque in both cancellous and cortical bone. In both bone types, the differences in extraction torque for the two types of pins were highly significant ($P < 0.005$). In the standard pin group, every pin implanted in the cancellous bone grossly loosened. Nineteen of twenty standard pins implanted in the cortical bone had an extraction torque of about half the insertion torque, showing deterioration of pin fixation over time. In the hydroxyapatite-coated pin group, the pins implanted in the cancellous bone had an extraction torque higher than the insertion torque, showing an improvement of pin fixation over time.

**FIGURE 18–2** Radiographs (A) at 6 weeks, showing tibiae with uncoated pins, (B) hydroxyapatite-coated pins, and (C) titanium-coated pins. Rarefaction can be seen around the uncoated and titanium-coated pins but not around the hydroxyapatite-coated pins. (Reprinted with permission from Moroni A, Toksvig-Larsen S, Maltarello MC, Orienti L, Stea S, Giannini S. A comparison of hydroxyapatite-coated, titanium-coated, and uncoated tapered external-fixation pins: an in vivo study in sheep. *J Bone Joint Surg Am* 1998;80:547–554.)

**FIGURE 18–3** Cross section at ×60 magnification of a specimen containing an uncoated pin. Severe bone resorption can be seen on the left. Very little bone-pin contact is visible. (Reprinted with permission from Moroni A, Toksvig-Larsen S, Maltarello MC, Orienti L, Stea S, Giannini S. A comparison of hydroxyapatite-coated, titanium-coated, and uncoated tapered external-fixation pins: an in vivo study in sheep. *J Bone Joint Surg Am* 1998;80:547–554.)

**FIGURE 18–4** Cross section at ×60 magnification of a specimen containing a hydroxyapatite-coated pin. No bone resorption can be seen. Many areas of direct bone-pin contact and newly formed trabeculae on the surface of the pin are visible. (Reprinted with permission from Moroni A, Toksvig-Larsen S, Maltarello MC, Orienti L, Stea S, Giannini S. A comparison of hydroxyapatite-coated, titanium-coated, and uncoated tapered external-fixation pins: an in vivo study in sheep. *J Bone Joint Surg Am* 1998;80:547–554.)
All 18 pins implanted in the cortical bone were well fixed (Figs. 18–7 and 18–8).

All pins were removed in outpatient facilities without general or local anesthesia. Removal of the well-fixed hydroxyapatite-coated pins seemed to be more painful than that of the loosened standard pins.

**CLINICAL STUDY IN OSTEOPOROTIC BONE**

Pin fixation problems are particularly severe in osteoporotic bone, which is usually considered as a contraindication for external fixation and a challenge for any fixation technique.25 Given the positive results obtained with the hydroxyapatite-coated pins in both cancellous and cortical normal bone, another clinical study was performed to address whether improvement of the bone pin fixation strength could be achieved in osteoporotic wrist fracture patients by using hydroxyapatite-coated tapered external fixation pins.26

Twenty female osteoporotic wrist fracture patients were selected. Patients were divided into two paired groups and randomized to receive either standard
(uncoated) tapered pins (Group A) or hydroxyapatite-coated tapered pins of the same diameter (Group B). The hydroxyapatite coating was identical to the coating used in the other studies.

Inclusion criteria were: female, age ≥65 years, AO type A2 or A3 wrist fractures, informed consent signed, and bone mineral density at the contralateral distal radius lower than –2.5 T score. A Pennig II wrist fixator was used in all the patients (Orthofix srl, Bussolengo, Italy). Two pins were implanted in the distal radius and two in the second metacarpal. Pin insertion torque was measured during implantation. All frames were removed 6 weeks after surgery. Pin extraction torque was measured at the end of treatment. Pin tract infection was graded according to Checketts and Otterburn.27

Average patient age was 75 ± 6 years in Group A and 74 ± 7 years in Group B. Mean final pin insertion torque was 461 ± 254 N·mm in Group A and 331 ± 176 N·mm in Group B (P = 0.01). Mean pin extraction torque was 191 ± 155 N·mm in Group A and 600 ± 214 N·mm in Group B (P <0.0001, Fig. 18–9). In Group A, the extraction torque was lower than the corresponding insertion torque (P <0.05), and in Group B it was higher than the corresponding insertion torque (P = 0.001). Pain during pin removal did not differ between groups. In Group A there were two Grade 1 pin tract infections, while in Group B there were none.

**DISCUSSION**

The results of these studies confirm that with the standard pins there is a severe deterioration of the bone-pin interface. This deterioration was more severe in the cancellous and osteoporotic bone than in the cortical bone.

In the animal study, radiolucency was significantly more frequent in the standard pins compared with the hydroxyapatite-coated pins. Extraction torque of the hydroxyapatite-coated pins was higher than that of the standard pins. Furthermore, the extraction torque of the hydroxyapatite-coated pins did...
not differ from the corresponding insertion torque and no bone-pin interface strength deterioration was observed. In contrast, extraction torque was significantly lower than the corresponding insertion torque and a severe bone-pin interface strength deterioration was observed in the standard pins.

Morphological observations revealed that bone-pin interface strength was maintained due to extensive close direct contact between bone and the hydroxyapatite coating, without fibrous tissue interposition. Conversely, no direct bone-to-pin contact but extensive fibrous tissue encapsulation was observed in the standard pins. Thus, the animal study showed that biomechanical results correlate with the morphological results. In the titanium-coated pins, both the biomechanical and morphological results were superior to those observed in the standard stainless steel pins but not as good as those observed in the hydroxyapatite-coated pins. The ability of pin surface material to establish a direct bone-to-pin contact proved to be the most important factor for the stability of the bone-pin interface strength.

Coating the pins with hydroxyapatite proved to be the best way of improving the bone-pin interface strength. The osteoconductivity of hydroxyapatite enabled bone remodeling and direct bony coverage of the pin surface and thus, mechanically improved the interface strength. The surface of the hydroxyapatite coating may also have been responsible for the improvement because it is rougher than the normal pin surface and may cause a higher initial mechanical stability. The higher fixation was also observed under unfavorable mechanical conditions.

There were no signs of hydroxyapatite degradation or failure of the hydroxyapatite metallic substrate interface. When the hydroxyapatite-coated pins were removed, the outer layers of the coating failed and only small fragments of hydroxyapatite remained in contact with the bone. The hydroxyapatite left inside the pin holes is not a potential risk for any adverse biological reaction preventing the hole from healing because this ceramic material is highly biocompatible.

The clinical studies confirmed the results of the animal study. The benefits provided by the coating were more evident in the cancellous bone than in the cortical bone. In the standard pins, there was a progressive deterioration of the strength of fixation in both bone types, expressed by a pin extraction torque lower than pin insertion torque. In the hydroxyapatite-coated pins, an increase in pin fixation was observed. This increase was higher in the cortical bone than in the cancellous bone.

In the study on osteoporotic bone, the hydroxyapatite-coated pins achieved optimal fixation. Pin extraction torque was three times higher in the hydroxyapatite-coated pins than in the standard pins, reflecting an enhancement of the strength of the bone-pin interface. In the standard pin group, there was a severe deterioration of the bone-pin interface strength. Extraction torque was two times lower than the corresponding insertion torque. In the hydroxyapatite-coated pin group there was an improvement of the bone-pin interface strength. Extraction torque was two times higher than the corresponding insertion torque. The higher strength of fixation of the hydroxyapatite-coated pins corresponded to a lower pin tract infection rate.

**Conclusions**

Before hydroxyapatite coating was introduced, many methods were recommended to improve the fixation strength of the bone-pin interface, but the literature has not provided evidence of their effectiveness. Conversely, studies with hydroxyapatite-coated pins showed that bone-pin fixation strength was always optimal, regardless of study design or bone type. This was due to extensive direct contact between bone and the hydroxyapatite coating. Excellent results were also obtained under unfavorable mechanical conditions. The hydroxyapatite-coated pins can be removed in outpatient facilities without general or local anesthesia. Removal of the well-fixed hydroxyapatite-coated pins seemed to be more painful than that of the loose standard pins.

There were neither signs of hydroxyapatite degradation nor failure of the hydroxyapatite metallic substrate interface. Optimal fixation was also achieved in the cancellous bone and in the osteoporotic bone.

For all these reasons, hydroxyapatite-coated external fixation pins represent the state of the art in achieving optimal fixation strength at the bone-pin interface. With this technique, a significant improvement in the clinical results of external fixation can be expected.

**Acknowledgments**

I wish to thank Antonio Sinopoli, Medical Illustrator/Research Associate, for his assistance in the preparation of this chapter.

**References**


As the general population ages with increasing life expectancy, an increase in the incidence of proximal femoral fractures is inevitable. There is no effective strategy, however, to prevent two major causes of the fracture in the elderly, bone loss and falling down. Therefore an effective surgical treatment of hip fracture in elderly osteoporotic patients, aiming to restore hip function as early as possible, is needed.

Zuckerman et al suggested that in elderly patients who are cognitively intact, able to walk, and living at home before the hip fracture, it is necessary to operate and initiate ambulation as soon as possible. In patients with severe osteoporosis, however, postoperative early ambulation following osteosynthesis of the hip fracture is difficult because of bone fragility, and sometimes results in failure of the fixation. In such cases, it is necessary to enhance the initial stability of the internal fixation.

In the present study, a double-sliding lag screw and plate system (Beak system) were used for superior initial stability. The Beak system has greater stiffness in compression and torsion compared to a conventional compression hip screw system (CHS). In addition to the new device, hydroxyapatite (HA) granules were used to augment cancellous bone around the lag screws. The purpose of the present report is to introduce preliminary results of osteosynthesis and to present the effect of HA granule augmentation.

**TESTING OF THE SYSTEM**

**METHODS**

Osteosynthesis was performed within a week after injury. Under an image intensifier, the fracture was reduced and osteosynthesis was performed using a double cannulated sliding lag screw and plate system (Beak system). Use of the Beak system was approved by the Ministry of Health and Welfare of Japan on Dec. 15, 1994. This system consists of a strong side plate, two cannulated lag screws (main and sub-screws), and cortical screws. The lateral cortex of the femur can be maximally preserved by omitting a barrel structure for the lag screw. The diameter of the main screw was 10 mm at its base with tapered shaft, and the diameter of the subscrew was 7 mm. These two lag screws were both engaged in the femoral head and realized telescoping following the initiation of loading to the fracture site with the locking mechanism after sliding 15 mm in length distally. After drilling and tapping a hole with a guide wire for the main screw, HA granules of 1 to 2 mm in diameter with a porosity of less than 20% (Apaceram, GL1, Pentax, Tokyo, Japan) were packed into the screw hole. Fibrin glue was used to adhere HA granules (Bolheal, Fujisawa Pharmaceutical Corp., Pentax, Tokyo, Japan) prior to packing HA granules into the screw hole. The main screw with a plate was screwed into the pretapped hole, affixing the plate to the femoral shaft. A self-tapping subscrew was then inserted using a guide wire (Fig. 19–1).

Patients were encouraged to initiate muscle exercise and ambulation as soon as possible after the operation. Patients were followed for 12 months on average (range 5 to 20 months) with regard to daily activity and X-ray findings. A simple evaluation system was used for grading daily activity of the patient before injury and at the follow-up period as follows:

1. bedridden (point 1)
2. able to walk to bathroom with support (point 2)
3. able to walk in house but not outside the house even with support (point 3)
4. able to walk outside the house with support (point 4)
5. normal activity, walking without support (point 5)
In all patients, final torque when the main screw was screwed into the hole was improved by augmentation using HA granules and excellent initial stability was achieved. In a separate series of nine patients with proximal femoral fractures (mean age ± SD = 81.9 ± 5.0 years, range 75 to 91 years), the torque of the main lag screw was measured when screwed to a full depth before and after packing HA granules into the tapped hole. The measurement was performed intraoperatively to verify the effect of HA granule augmentation on screw stability. Final torque before and after packing HA granules was compared using a paired t-test.

RESULTS

Although patient daily activity was slightly reduced at the follow-up period, this reduction was not statistically significant (3.0 ± 1.0 points before injury and 2.7 ± 1.3 points at follow-up; Fig. 19–2). This reduction in postoperative activity is considered acceptable if preexisting medical conditions (e.g., dementia, cardiovascular disease, or chronic lung disease) are taken into account. Thirteen fractures were united in situ and seven fractures were united with controlled collapse of the fracture site. There was no delayed union or nonunion in this series (Fig. 19–3). There were no major complications such as avascular

PATIENTS

Twenty patients (mean age ± SD = 82.0 ± 5.7 years, range 63 to 88 years) who suffered from proximal femoral fractures caused by minor trauma, such as falling down while walking, were subjected to our treatment protocol. There were 17 intertrochanteric fractures, including one revision case, one intracapsular, and two subtrochanteric fractures in this series. Of the 17 intertrochanteric fractures, six fractures were type I, six were type II, and the other four were type III, according to the classification of Kyle et al.7 X-ray grading of osteoporosis of the contralateral femoral neck (Singh’s index) indicated that seven patients were grade III, 12 patients were grade II, and one patient was grade I.8 A proximal fracture with osteoporosis (no more than grade III) diagnosed by Singh’s index of the contralateral femoral neck was an indication for surgery using our method.

FIGURE 19–1 Osteosynthesis procedure using a double cannulated sliding lag screw system and hydroxyapatite (HA) granules. A screw hole is drilled and tapped, then the main screw is inserted following packing of HA granules into the screw hole. Fibrin glue is used to adhere HA granules. The plate is then placed on femoral shaft and compressed by cortical screws, and finally a subscrew is inserted.

FIGURE 19–2 Result of the score of daily activity before injury and at the follow-up period. There is no statistically significant difference.
necrosis of the femoral head related to the operation during the follow-up period. Four patients died during the follow-up period at average 9.3 months, due to pneumonia ($n=2$) or acute heart failure ($n=2$). Augmentation using HA granules to secure the main lag screw significantly increased the final torque (before and after packing HA granules: $14.3 \pm 4.8$ Kgf·cm and $30.1 \pm 9.2$ Kgf·cm, $P<0.002$ by paired $t$-test; Fig. 19–4).

**ILLUSTRATIVE CASE**

An 80-year-old woman who had been living in a retirement home fell down while walking with a cane. She was able to walk in the house before injury, but not outside the house, even with support. Because she could not rise to her feet due to left hip pain, she was delivered to our clinic by ambulance. X-ray indicated a stable-type intertrochanteric fracture of the left femur, and grade II osteoporosis, using Singh’s index of the right femur (Fig. 19–5A). Her medical conditions included dementia and depression, which were treated with medication. Osteosynthesis was performed 3 days after the injury (Fig. 19–5B). Full weight bearing on the fractured extremity was initiated on the seventh postoperative day. She was able to walk to the bathroom with support. The solid bony union in situ was achieved 3 months after the operation (Fig. 19–5C). Her activity and the radiographic stability of the union site have been maintained 18 months postoperatively.

**DISCUSSION**

A decrease in bone volume is a critical factor in osteosynthesis of proximal femoral fractures with osteoporosis. On the other hand, fractures in the elderly patient should be treated as soon as possible to restore preoperative activity or reduce mortality. To resolve these conflicting factors, we performed an original osteosynthesis with a double lag screw system and HA granules, and we obtained excellent clinical results. Seventeen of twenty patients in this study had an intertrochanteric fracture of the hip. A relatively low trochanteric bone mineral density was associated with the intertrochanteric fracture.9 HA granules were implanted into the intertrochanteric region during the procedure and during insertion of the main screw; HA granules were considered to be pushed into the femoral head when the thread of the screw intruded into the subchondral bone. Thus, the torque measurement after HA granule augmentation indicated 110% increase on average compared to that before augmentation (Fig. 19–4). This supports the notion that HA granules augmented bone loss in the cancellous bone area of proximal femur, enhancing initial screw stability.

The HA granules were expected to not only supplement bone loss in the proximal femur but also to facilitate osteoconduction at the bone-implant interface, as reported in earlier studies.10–13 Because the biologic activity of bone reduces with age, new bone formation between the bone-implant interface was unlikely in elderly patients. We confirmed new bone formation, however, within and around the HA granules in one elderly patient, suggesting that physio-
logic bone conduction can be achieved even in elderly patients (Fig. 19–6).

Although a properly located sliding lag screw in compression hip screw system is stiff enough for most intertrochanteric fractures, the system is not strong enough for some fractures with severe osteoporosis. It is necessary to augment conventional CHS in such cases. Because the addition of a cancellous screw to CHS is not effective in biomechanical studies involving loading modes of torsion and/or bending, we used a double sliding lag screw with a plate (Beak system) to maximize implant stability.

A previous biomechanical study verified that the ratios of initial fixation stiffness achieved with the Beak system to that achieved by CHS were 176% in stable type fractures and 128% in unstable type fractures in compression loading, and 705% in stable type fractures in torsional loading. Using the Beak system, greater initial stiffness of the internal fixation would be expected than from simple addition of cancellous screws to CHS system.

Measurement of bone mineral density using a dual energy X-ray absorptiometer is precise and widely used. Singh’s classification is more simple.

FIGURE 19–5  (A) An 80-year-old woman suffered from stable intertrochanteric fracture of the left femur with grade II osteoporosis by Singh’s classification. (B) Osteosynthesis with a double cannulated lag screw and plate system and augmentation using HA granules was performed. (C) A solid bony union with controlled collapse of the fracture site was achieved 3 months after surgery.

FIGURE 19–6  Histological examination of HA granule specimen removed 2 months after surgery in a 77-year-old woman. (A) Most HA granules are fragmented and new bone is formed around or within HA granules (original magnification is ×5). (B) Osteoblast-like cells (cuboidal cells) are gathered on the surface of osteoid layer within HA granules (arrowheads; original magnification is ×50).
and practical, however, when the patient is distressed by hip fracture pain. Osteosynthesis augmented by HA granules is indicated for patients with osteoporosis no more severe than grade II in Singh’s classification. The fracture type should be taken into account in the decision-making process. If the fracture type is unstable with a porosity of grade III by Singh’s classification, the present method is preferable.

In conclusion, an original procedure was devised for osteosynthesis of the osteoporotic proximal femoral fracture. A double-sliding lag screw and a plate system and augmentation using HA granules enhanced implant stability and accomplished bony union in all cases in the preliminary series without major complications. This procedure is a promising method for treating osteoporotic femoral fractures.

**ACKNOWLEDGMENTS**

The author thanks Yoichiro Dohmae, M.D., for kind comments during development of the Beak system, and also appreciates Toshiaki Hara, Ph.D. for his support in the biomechanical study of the system.

**REFERENCES**

Osteoporosis constitutes a major health problem through its association with age-related fractures. Patients with fragility fractures create a significant economic burden with more than 400,000 hospital admissions and 2.5 million physician visits per year. Adequate screw fixation in osteoporotic bone is a difficult and challenging surgical problem. Screw loosening and subsequent implant failure are major complications. The quality of bone has been shown to be the most important factor determining the ability of a screw to resist loosening. As the bone mineral density decreases, screws are unable to obtain adequate purchase, leading to a decreased holding power.

In an effort to provide secure screw fixation, the effects of screw design, orientation, and cement augmentation on pullout strength have been evaluated. Polymethylmethacrylate (PMMA) and, recently, biodegradable calcium phosphate cements have been shown to increase the holding power of screws in osteoporotic bone.

However, the use of cement is not without problems. PMMA is exothermic upon polymerization and toxic monomers can cause bone necrosis, proliferation of a fibrous tissue layer, and adverse biological responses. Cement-induced osteolysis may lead to eventual screw loosening and failure. In addition, another problem with PMMA is its lack of adhesion to bone. Although ceramic cements that solidify in situ have excellent biocompatibility, the mechanical properties of these cements are weaker than those of PMMA. We have developed a new screw locked with a K-wire for fixation in osteoporotic bone that does not require cement augmentation. The purpose of this study is to evaluate the ultimate holding power of the interlocking screw compared to a standard solid screw.

### Screw Design and Testing

#### Screw Preparation

Twenty 6.5 mm × 45 mm, partially threaded, solid stainless steel cancellous screws were obtained (Synthes, Paoli, PA). All screws had a pitch of 1.50 mm. Ten screws were used as solid controls. The other 10 screws were modified to produce the new locking screw design (Fig. 20-1). Twenty millimeters from the head of each screw a 1.9 mm hole was drilled through the shaft of the screw at a 45-degree angle.

#### Specimen Preparation

Both embalmed and fresh-frozen vertebral bodies were used in this in vitro study. Four osteoporotic fresh-frozen lumbar vertebral bodies were obtained from a 73-year-old Caucasian female. A dual energy X-ray absorptiometry (DEXA) scan was used to document the bone mineral density and T-score for each of the fresh-frozen specimens. Only specimens with a
T-score of less than –2.50, which the World Health Organization defines as osteoporotic, were used in this study. The T-score compares the density of the bone being studied to that of a healthy 30-year-old female. Six embalmed lumbar vertebral bodies (L4 to L5) were also harvested from four cadavers with an average age of 70 years (three females and one male).

All soft tissues and posterior elements were removed from both the embalmed and fresh-frozen specimens. Two 4.73 mm diameter pilot holes were drilled 30 mm into each vertebral body from the anterior side. Although the anteroposterior (AP) diameter of each vertebra differed, no screw obtained bicortical purchase. One hole was drilled on the right side of the vertebral body, and the other hole was drilled on the left side the same distance from the midline. Both holes were drilled at a 30-degree angle toward the center of the vertebral body. Radiographs were taken to ensure neither hole crossed the midline.

The solid screw and the new locking screw were inserted into the predrilled holes. The screws were randomized to the right or left side. The same vertebral body was used to test both screws to limit the effects of variability in bone density. The locking pin (1.9 mm smooth K-wire) was inserted through the 45-degree hole in the shaft of the screw, obtaining bone purchase proximally and distally (Fig. 20–2).

The embalmed specimens were tested prior to the development of a guiding device. The concept of a right-angle triangle was used to free-hand the pin through the screw. The angle of the screw hole was drilled at 45 degrees, and the proximal portion of the hole was placed 1 cm from the bone surface, so the insertion site and angle for the pin were known. In the same plane as the mark previously made on the screw head, a K-wire was advanced 1 cm from the screw shaft at a 45-degree angle through bone, screw shaft, and bone. The pin was directed from medial to lateral in all cases. Before the fresh-frozen specimens were tested, a prototype guide to assist with pin placement was developed (Fig. 20–3). The guide was placed on the locking screw head after the hardware was inserted into the bone. This guide allowed all pins to be inserted on the first attempt without difficulty. To confirm the positioning of the screw and the interlocking pin, an X-ray was taken before mechanical testing (Fig. 20–4).

**MECHANICAL TESTING AND EVALUATION**

Axial pullout tests were performed using a servo-controlled hydraulic mechanical testing system (MTS Systems, Minneapolis, MN). A fixture with a hole in the superior aspect for pulling out screws was constructed to hold the specimen during testing. The ultimate load to failure for both screws was determined. The MTS was run in stroke control (actuator displacement). Screws were pulled out at a displacement rate of 5 mm/min. The same procedure was followed for all 10 vertebral bodies. The order of pullout was randomized between the solid and interlocking screws. The data were evaluated by using a paired Student’s *t*-test with each of the six
RESULTS

In the embalmed specimens, the mean pullout force for the solid screw was 202.5 ± 116 N and for the new interlocking screw was 412.5 ± 156 N. The interlocking design had a 104% increase in ultimate holding strength compared to the standard solid screw design in embalmed specimens. The Student’s t-test showed the difference to be statistically significant (\(P < 0.001\)). The pullout values for the six embalmed specimen pairs can be seen in Table 20–1. No interlocked screw could be backed out after failure. The K-wire had to first be removed to enable the screw to be removed from the specimen.

In the fresh-frozen specimens, the mean pullout force for the solid screw was 178 ± 19 N and for the new interlocking screw was 420 ± 203 N (Table 20–2). The mean BMD was 0.773 ± 0.047 g/cm\(^2\) (Table 20–3). Each specimen had a T-score of less than –2.50 (mean –3.07 ± 0.41 SD). In the fresh-frozen group, the interlocking screw exhibited a 136% increase in ultimate holding power (\(P < 0.04\)).

**POTENTIAL USES OF THE NEW SCREW**

With the aging population, osteoporosis and osteoporotic fractures are becoming more prevalent.\(^{23,24}\) Traditionally PMMA has been used to increase the purchase of screws in osteoporotic bone. Numerous problems with this inert material\(^{17,18}\) have led to the development of biodegradable calcium cements. However, these cements are biomechanically weaker than PMMA\(^{21,22}\) and often difficult to handle. Our new locking screw may help overcome the current problems with cement and internal fixation in osteoporotic bone. In this study, we evaluated whether adding a locking pin to a screw would significantly increase the screw’s ultimate holding power in document osteoporotic bone.

The results validated our hypothesis that a significantly larger force would be required to pull out the interlocking design than the standard screw. In every specimen tested, the new design proved superior in ultimate holding power (Tables 20–1, 20–2). The locking screw not only helps to prevent backout, but the additional bony purchase proximally and distally...

**TABLE 20–1** **ULTIMATE TENSILE LOAD TO FAILURE IN EMBALMED SPECIMENS (N)**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Solid Screw</th>
<th>Interlocking Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 L5</td>
<td>100</td>
<td>330</td>
</tr>
<tr>
<td>#2 L4</td>
<td>90</td>
<td>315</td>
</tr>
<tr>
<td>#2 L5</td>
<td>125</td>
<td>300</td>
</tr>
<tr>
<td>#3 L5</td>
<td>220</td>
<td>320</td>
</tr>
<tr>
<td>#4 L4</td>
<td>340</td>
<td>530</td>
</tr>
<tr>
<td>#4 L5</td>
<td>340</td>
<td>680</td>
</tr>
<tr>
<td>Mean</td>
<td>203</td>
<td>413</td>
</tr>
<tr>
<td>SD</td>
<td>116</td>
<td>156</td>
</tr>
</tbody>
</table>

**TABLE 20–2** **ULTIMATE LOAD TO FAILURE (N) IN FRESH-FROZEN SPECIMENS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Solid Screw</th>
<th>Interlocking Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>#5 L2</td>
<td>300</td>
<td>720</td>
</tr>
<tr>
<td>#5 L3</td>
<td>175</td>
<td>280</td>
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<tr>
<td>#5 L4</td>
<td>155</td>
<td>320</td>
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<td>80</td>
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<td>178</td>
<td>420</td>
</tr>
<tr>
<td>SD</td>
<td>91</td>
<td>203</td>
</tr>
</tbody>
</table>

**TABLE 20–3** **T-SCORE AND BMD (G/CM²) OF FRESH-FROZEN SPECIMENS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>T-Score</th>
<th>BMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>#5 L2</td>
<td>0.829</td>
<td>–2.51</td>
</tr>
<tr>
<td>#5 L3</td>
<td>0.715</td>
<td>–3.52</td>
</tr>
<tr>
<td>#5 L4</td>
<td>0.770</td>
<td>–3.41</td>
</tr>
<tr>
<td>#5 L5</td>
<td>0.778</td>
<td>–2.85</td>
</tr>
<tr>
<td>Mean</td>
<td>0.773</td>
<td>–3.07</td>
</tr>
<tr>
<td>SD</td>
<td>0.047</td>
<td>0.41</td>
</tr>
</tbody>
</table>
with the K-wire significantly increases the screw’s overall holding power.

The 136% increase in holding power of the interlocked screw is higher than published data on both PMMA and ceramic cement augmentation. Kleeman and colleagues\textsuperscript{25} compared the pullout force of screws in trabecular bone before and after reinforcement with either PMMA or ceramic cement. In this study, the pullout force after PMMA augmentation increased by only 43% and after ceramic cement augmentation increased by 68%. The ultimate pullout strength of ceramic cement tested in polyurethane foam models with a density close to trabecular bone was 61%.\textsuperscript{10}

Only one other published study has evaluated a screw with a locking pin. Griffith et al\textsuperscript{26} performed a biomechanical comparison of a novel plate system for use in anterior spinal surgery using a tapered thread screw with a locking pin. Significant differences exist between their design and outcomes and our screw. The proximal opening of their pin hole in the shaft was not embedded in bone, and thus they only had purchase distally where the pin exited the screw shaft. In addition, the angle of their locking pin was very narrow. Locking pins with a greater angle will undoubtedly increase the holding power of the screw. They found no increase in pullout strength between their prototype screw with a locking pin and an unlocked screw. In contrast, our new screw has an angled hole through the midshaft of the screw. After insertion of the screw, the pin hole is completely embedded in bone. This unique design allows the interlocking pin to obtain bone purchase both proximally and distally. This is a key component to increasing the holding power and rotational stability of the screw. The angle of our pin is 45 degrees. Our interlocking screw proved to have a 136% increase in holding power.

In the current study, both screws were tested in the same vertebral body to limit variations in bone density. Meticulous care was taken to ensure that both screw holes were prepared in the same fashion with the screws angled the same direction. The standard screw and the locking screw were randomized to either the right or left side for insertion in each vertebra to limit bias. Vertebral bodies are a good choice to assess the right or left side fixation in osteoporotic bone. The use of a locking screw will bypass the current problems encountered with cement. If the screw needs to be taken out, the K-wire can be withdrawn and the screw easily removed. Currently, we are evaluating ways to secure the K-wire to a plate if this is used in conjunction with the screws to prevent migration of the pins. In future studies, we will evaluate this novel screw design with fatigue and stability testing. Because of the biomechanical superiority of the interlocking screw, it warrants clinical evaluation for fixation in osteoporotic bone.

REFERENCES


AN INJECTABLE CEMENTING SCREW FOR FIXATION IN OSTEOPOROTIC BONE

Brodie E. McKoy and Yuehuei H. An

Osteoporosis is a common bone disorder characterized by decreased bone mass and fragility fractures. According to the World Health Organization, 35% of women over 65 years of age in the United States have frank osteoporosis. One of every two Caucasian women will have an osteoporotic fracture during her lifetime. These osteoporotic fractures are a significant concern and account for the majority of the money spent on this condition.

With the aging population, the prevalence of osteoporosis is expected to escalate. Not only is the population aging, but people are remaining healthy and active later in life. Nonoperative treatment of fractures in this age group is no longer the only treatment choice. Many orthopaedic surgeons are now performing internal fixation of fractures in octogenarians. However, because of the microarchitectural deterioration seen in this type of bone, adequate screw fixation is a difficult and challenging surgical problem. Several authors have reported on screw loosening and subsequent implant failure in osteoporotic bone. The most important factor determining the ability of a screw to resist loosening is bone quality. As bone mineral density decreases, so does the holding power of screws.

In response to the difficulties of fixation in osteoporotic bone, surgeons have evaluated the effects of screw design, orientation, depth of penetration, and cement augmentation on pullout strength. Polymethylmethacrylate (PMMA) and, recently, biodegradable calcium phosphate cements have been shown to increase the holding power of screws in osteoporotic bone. If PMMA is used to augment screw fixation, a pilot hole is drilled, and the bone cement is injected prior to inserting a screw. However, this leads to variable cement mantles and poor penetration of the cement into the bone. PMMA has been shown to have poor adhesion to bone. Thus, cement that penetrates into the trabeculae may increase the holding power of the screw.

Injectable cements have been used to provide screw fixation in osteoporotic bone. Vertebroplasty has been evaluated not only for treatment of compression fractures in osteoporotic vertebra but also as an adjunct to internal fixation of hardware. In this method, PMMA is injected into the vertebral body percutaneously. Brantley and Mayfield investigated a cannulated pedicle screw injected with cement for fixation in osteoporotic bone. We have modified this technique for use in other areas in osteoporotic bone, such as anterior spinal surgery. To further increase the holding power, our modifications consisted of adding holes to the shaft of the screw to allow cement to penetrate into the trabeculae of the bone. The purpose of the current in vitro study is to evaluate the ultimate holding power of the new cannulated screw injected with cement compared with a solid screw of the same dimensions augmented with cement.

SCREW DESIGN AND TESTING

SCREW PREPARATION

Twenty-six 7.3 mm × 40 mm, fully threaded, cannulated stainless steel screws were obtained (Synthes, Paoli, PA). All screws had a pitch of 1.50 mm with identical internal diameters. Thirteen of the screws were filled with PMMA to serve as solid controls, because a solid stainless steel screw with these dimensions was not commercially available. Thirteen of the cannulated screws were modified to produce the new screw design. Ports were made along the shaft of the screw between the threads with a 1.9 mm drill bit. Holes were only made through one wall of the cannulated screw. Consecutive ports were made along the entire shaft of the screw by rotating the
screw approximately 30 degrees for a total of eight holes (Fig. 21–1).

**SPECIMEN PREPARATION**

Nine embalmed lumbar vertebral bodies (L3 to L5) were harvested from seven cadavers with an average age of 73 years (five females and two males). Four lumbar vertebral bodies (L1 to L3) were harvested from two fresh-frozen cadavers (two females; 65 and 67 years old). All soft tissues and posterior elements were removed from the specimens. Two 4.73 mm diameter pilot holes were drilled 30 mm into each vertebral body from the anterior side. The midline of each vertebral body was clearly marked. One hole was drilled on the right side of the vertebral body, and the other hole was drilled on the left side, both 20 mm from the midline measured with a digital caliper. The same distance was used for all specimens. Both holes were drilled at a 20-degree angle toward the center of the vertebral body. The holes were drilled with a drill press attached to a secure table. A wooden block with a 20-degree angle was secured to the drill press platform. The vertebral bodies were attached to the wooden block with the cut pedicles facing the platform. In this manner, all holes were drilled with a 20-degree angle plus or minus 3 degrees. Radiographs were taken to insure neither hole crossed the midline.

A dual energy X-ray absorptiometry (DEXA) scan (Hologic, Bedford, MA) was used to document the bone mineral density of each fresh-frozen specimen. All fresh-frozen vertebral bodies had a T-score of less than –3.00. The World Health Organization defines osteoporotic bone as having a T-score less than –2.50. The T-score is the number of standard deviations from the mean bone density of a healthy 30-year-old female. In addition, the absolute numbers for the bone mineral density (g/cm²) and bone mineral content (g) were recorded for each fresh-frozen specimen.

Tygon® tubing was attached to a 20 cc syringe for injecting the cement into the pilot hole of the solid screw. PMMA (Surgical Simplex P, Howmedica, Rutherford, NJ) was mixed for 2 minutes according to the manufacturer’s instructions to a viscosity that would allow injection (20 g powder + 10 mL of liquid monomer). The pilot hole for the solid screw was injected with approximately 0.5 to 1.5 mL of PMMA followed by insertion of the screw. Next, the pilot hole for the cannulated screw was injected with 0.5 to 1.5 mL of PMMA followed by insertion of the screw (Fig. 21–2). After insertion, 3.0 to 5.0 mL of PMMA was injected under pressure through the central canal of the vertebral body.
canal of the screw. The cement was allowed to harden for 30 to 40 minutes before testing in the embalmed specimens and 24 hours for the fresh-frozen specimens.

MECHANICAL TESTING AND EVALUATION

Axial pullout tests were performed using a servo-controlled hydraulic mechanical testing system (MTS Systems, Minneapolis, MN). A fixture with a hole in the superior aspect for pulling out screws was constructed to hold the specimen during testing. The ultimate load to failure for both screws was determined. The MTS was run in stroke control (actuator displacement). Screws were pulled out at a displacement rate of 5 mm/min. The same procedure was followed for all 13 vertebral bodies. The order of pullout was alternated between the cannulated and solid screws. The data were evaluated by using a paired Student’s *t*-test with each of the 13 vertebrae representing a pair. Statistical significance was set at *P* < 0.05. Each fresh-frozen vertebral body was sectioned after mechanical testing to document the penetration of cement into the bone. The reproducibility of this experimental setup was evaluated by pulling out a 4.5 mm cancellous screw from eight polyurethane blocks. The coefficient of variation was found to be only 3.7%.

The mechanical properties of the new cannulated screw design were assessed. Three-point bending tests were performed on two cannulated screws and two of the modified cannulated screws to determine how much the screw was weakened by the addition of side ports. The tests were performed on the MTS in a stroke control mode with a compression rate of 1 mm/min. The two inferior posts of the three-point bending apparatus were placed 29 mm apart.

RESULTS

In the embalmed specimens, the mean pullout force for the solid screw was 572.2 ± 542 N and for the new cannulated screw was 1011.1 ± 583 N. The cannulated design had a 77% increase in ultimate holding strength compared to the standard solid screw design. The paired Student’s *t*-test showed the difference to be statistically significant (*P* = 0.01). The pullout values for the nine specimen pairs can be seen in Table 21–1. Radiographs taken before mechanical testing confirmed the screw position and the areas of injected cement (Fig. 21–3). The gross specimens revealed a substantial cement mantle surrounding the entire shaft in the cannulated screws with radial cement spokes from each port extending into the surrounding trabeculae. The solid screws had variable amounts of cement along the shaft with almost no extrusion of cement into the trabeculae of the cancellous bone.

The fresh-frozen vertebral bodies all had a T-score less than −3.0 with an average bone mineral density of 0.692 g/cm² by DEXA scan (Table 21–2). In the fresh frozen specimens, the mean pullout force for the solid screw was 781.3 ± 151 N and for the new cannulated screw was 2956.3 ± 567 N (Table 21–3). The cannulated design had a 278% increase in ultimate holding power (*P* = 0.006).

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Solid Screw</th>
<th>Cannulated Screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 L3</td>
<td>325</td>
<td>1325</td>
</tr>
<tr>
<td>#2 L4</td>
<td>350</td>
<td>525</td>
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<td>825</td>
<td>900</td>
</tr>
<tr>
<td>#5 L3</td>
<td>1925</td>
<td>2125</td>
</tr>
<tr>
<td>#6 L5</td>
<td>250</td>
<td>1650</td>
</tr>
<tr>
<td>#7 L3</td>
<td>200</td>
<td>350</td>
</tr>
<tr>
<td>#7 L5</td>
<td>425</td>
<td>575</td>
</tr>
</tbody>
</table>

Mean 572 1011
SD 542 583

*p* = 0.01.

![FIGURE 21–3](image-url) Macroimage of cross section of a fresh-frozen vertebral body demonstrating depth of penetration of cement. The control screw (a cannulated screw filled with cement, used as a solid screw) is on the left with limited cement mantle. The new cannulated screw with side holes on the right, demonstrating substantial cement mantle penetrating into the bone. Arrows show holes in screw with cement extruding).
Sectioning of the fresh-frozen specimens revealed a cement mantle around the entire shaft of the new cannulated screw. The cement penetrated the trabecular bone an average of 12.1 mm from the screw (Table 21–4). The control screws only had a mantle of approximately 1.0 to 4 mm around the screw (Fig. 21–4).

Mechanical testing of the cannulated screw and the new cannulated screw design revealed a 24% decrease in strength of the new screw design. The ultimate load to failure during three-point bending for two standard cannulated screws was 1975 N and 1950 N. The load to failure for the two new cannulated screw design was 1475 N and 1525 N.

### Table 21–2

<table>
<thead>
<tr>
<th>Specimen Density</th>
<th>T-Score</th>
<th>Bone Mineral Density (g/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 L1</td>
<td>-3.10</td>
<td>0.693</td>
</tr>
<tr>
<td>#1 L2</td>
<td>-3.50</td>
<td>0.643</td>
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<tr>
<td>#2 L1</td>
<td>-3.06</td>
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<td>Mean</td>
<td>-3.20</td>
<td>0.692</td>
</tr>
<tr>
<td>SD</td>
<td>0.20</td>
<td>0.40</td>
</tr>
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### Table 21–3

<table>
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<tr>
<th>Specimen Density</th>
<th>Solid Screw</th>
<th>Cannulated Screw</th>
</tr>
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<tbody>
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<td>#1 L1</td>
<td>2600</td>
<td>650</td>
</tr>
<tr>
<td>#1 L2</td>
<td>3750</td>
<td>750</td>
</tr>
<tr>
<td>#2 L1</td>
<td>2975</td>
<td>725</td>
</tr>
<tr>
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<td>1000</td>
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<tr>
<td>Mean</td>
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<td>781</td>
</tr>
<tr>
<td>SD</td>
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<td>151</td>
</tr>
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</table>

### Table 21–4

<table>
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<th>Solid Screw</th>
<th>Cannulated Screw</th>
</tr>
</thead>
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<tr>
<td>#1 L1</td>
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</tr>
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<td>#1 L2</td>
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<td>13.0</td>
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<tr>
<td>#2 L1</td>
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<td>12.5</td>
</tr>
<tr>
<td>#2 L2</td>
<td>0.9</td>
<td>11.5</td>
</tr>
<tr>
<td>Mean</td>
<td>1.0</td>
<td>12.1</td>
</tr>
<tr>
<td>SD</td>
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</table>

With the aging population, osteoporosis and osteoporotic fractures are becoming more prevalent. The most immediate concern regarding screw fixation in osteoporotic bone is the problem of hardware pullout. Traditionally PMMA has been used to increase the purchase of screws in osteoporotic bone. The current method of injecting cement into a pilot hole prior to inserting a screw does not ensure implant stability. Although PMMA does have adhesive properties, it functions more as a filler than a true adhesive material. In fact, PMMA has been shown to have poor adhesion to bone. Thus, it is important for the cement to penetrate into the bone to provide the strongest fixation. Our new cannulated screw, which can be injected with PMMA, allows the cement to infiltrate into the bone. In this study, we compared the ultimate holding power of a new cannulated screw design to a solid screw of the same dimensions in osteoporotic bone. Both screws were augmented with PMMA.

The results validated our hypothesis that a significantly larger force would be required to pull out the cannulated design than the standard screw. In every specimen tested, the new design proved superior in ultimate holding power (Tables 21–1 and 21–3). The cement mantles including the radial spokes of cement in our cannulated design led to a statistically stronger holding power when compared to the technique currently used. Because PMMA adheres poorly to bone, the radial spokes extending from the screw undoubtedly accounted for the increased holding power.
The variability in the ultimate tensile load to failure for the cannulated and solid screws in the embalmed specimens was most likely due to the differences in bone mineral density between specimens. The pullout values were much closer between vertebrae from the same cadaver than between vertebrae from separate cadavers. To limit the effects of these differences in densities, both screws were tested in the same vertebral body. The screws were also alternated between the right and left sides. A paired Student’s t-test was used for statistical evaluation with each vertebral body representing a pair. The P-value revealed this difference to be statistically significant (embalmed specimens \( P = 0.01 \)).

Because of the influence of formalin fixation on the mechanical properties of bone specimens, four fresh-frozen cadaveric vertebral bodies were evaluated as well. A DEXA scan was used to determine the bone mineral density of each fresh-frozen vertebral body. Only osteoporotic bones with a T-score less than \( -2.50 \) were used. A much smaller variability in pullout strengths was seen in the fresh-frozen group, because bone density was controlled. Though the sample size was too small for a statistical correlation, a trend was seen in the density of the bones and the pullout strength of the new screw design. The vertebral body with the lowest bone mineral density had the largest ultimate load to failure, and the vertebral body with the highest density had the lowest pullout strength (Tables 21–2 and 21–3). The specimens with a lower bone mineral density allowed more PMMA to infiltrate into the trabecular bone (Table 21–4). This increased cement mantle may help explain the stronger fixation. The cement penetration was greatest for the specimen with the lowest density.

The increase in pullout strength for the fresh-frozen specimens was significantly higher than the difference seen in the embalmed specimens. Several factors may help explain the difference. Firstly, the cement was allowed to harden for 24 hours in the fresh-frozen group and only for 30 minutes in the embalmed group. Depending on the temperature, a longer setting time may lead to a higher tensile strength of the cement. Secondly, bone mineral density was not assessed in the embalmed specimens. Dense bones, which would not allow a substantial penetration of cement needed for the new screw design to be superior, may have been included.

Brantley and Mayfield\(^\text{22}\) evaluated a cannulated pedicle screw for fixation in osteopenic bone. PMMA and a resorbable bone cement were both used to augment fixation. The purpose of this group’s cannulated screw was to prevent cement extravagation into the spinal canal. Their screw had radially extending slots distally, which prevented cement from migrating proximally. The initial stiffness of their new screw design was not different from solid screws.

Our modification of Brantley and Mayfield’s cannulated screw design may be used in other areas of osteoporotic bone, such as anterior spinal surgery. In the pedicle, cement that extends back on the shaft of the screw may be detrimental. In other areas, this cement proximally has a beneficial effect on the holding power. The current technique of placing cement in a predrilled hole allows cement to extend only in variable amounts back on the shaft. In addition, this method does not provide the penetration of cement into bone necessary in osteoporotic bone to provide an increased holding power.

Because of problems with PMMA\(^\text{28,29}\) such as its exothermic nature upon polymerization, biodegradable calcium phosphate cements have been investigated. However, these cements are biomechanically weaker than PMMA initially until they are replaced by bone.\(^\text{30}\) The use of our cannulated screw with biodegradable cements may help overcome this initial weakness. However, future studies are needed to evaluate the biomechanical properties of this new screw design with biodegradable cements.

In this study, both screws were tested in the same vertebral body to limit variations in bone density and to allow for a paired comparison. A limitation of this design would be the effect of one pullout test on the holding power of the other screw. The destroyed cancellous matrix surrounding the screw may have decreased the holding power of the other screw. To limit this effect, the order of pullout was alternated between the two screws. In testing spinal instrumentation, the only other option is to test the implants in adjacent vertebral bodies. However, the bone mineral density can vary considerably between adjacent vertebral bodies leading to differences in pullout strengths.

The superior holding power of the cannulated screw is encouraging. In this study, the screw has proven effective for increasing the holding power in osteoporotic vertebral bodies. It is likely that similar effects may be seen in other areas of spongy bone with low mineral density and a thin cortex. Because of the biomechanical superiority of the cannulated screw, it warrants clinical evaluation for fixation in osteoporotic bone.

**References**


A CEMENT SCREW FOR FIXATION IN OSTEOPOROTIC METAPHYSEAL BONE

Peter A. Reynders and Luc A. Labey

Chapter 22

THE SCREW DESIGN AND TESTING

IMPLANT DESIGN AND TESTING

The structure of our society in the coming decades will include a higher number of elderly people, which will increase the consumption of a substantial proportion of the health care resources. Although recent research suggests that the incidence of osteoporotic fractures has experienced either a leveling off or a slight downturn in North America and Europe, the number of patients with osteoporotic fractures will continue to rise in all continents, as a result of aging. New implant and surgical techniques need to be developed to improve treatment and allow rapid rehabilitation for the patient. When bone quality is impaired and stable fracture fixation is impossible, augmentation of the osteosynthesis is advocated. For fixation of screws, cement based on polymethylmethacrylate (PMMA) or ceramics and resins has been used with success.

The use of plates for the treatment of osteoporotic fractures is often problematic as the purchase of screws in the bone is reduced and the precarious soft tissue situation makes surgical dissection impossible.

Another option to overcome these problems is the use of oversized plates that span the fracture over a long distance. Another approach to improve stability of a plate osteosynthesis is the application of an intramedullary rod made of resorbable polymers that produces adequate purchase for screws. To prevent the detrimental effects of PMMA injected in the fracture site, we investigated the usefulness of PMMA, injected through side holes situated in the threaded portion of a modified cannulated 7.3 mm AO screw (Mathys, Belgium) to enhance the purchase of these screws in the epimetaphyseal region of long bones (Figs. 22–1A,B).

THE SCREW DESIGN AND TESTING

Implant design and testing

The “cement screw” is a partially cannulated, self-drilling, and self-tapping 7.3 mm AO screw with a thread length of 32 mm. The screw is made of implant-quality stainless 316L steel. The top of the cannulated screw is closed by insertion of a press-fit metal plug. In the threaded portion, three side holes of 2 mm are drilled. Through these side holes the injected cement (Palacos LV 40, Shering-Plough, Brussels Belgium) can flow sideways into the cancellous bone, surrounding the threaded portion of the screw (Figs. 22–2A,B,C).

Bending test was used to evaluate the modified cement screw versus the regular cannulated screw. Two groups of four screws were loaded in a three-point fixture. The support distance was 40 mm. The force was applied via a steel roller of 8.3 mm diameter and was applied at a test velocity of 1 mm/min.

Pullout test was used to evaluate the pullout strength of both screw types. Fifteen cold-preserved distal human femurs were selected from a pool of 60 fresh-frozen bones. The surrounding soft tissue was removed, and the bones were wrapped in moist cloths impregnated with 6% glutaraldehyde, put in a watertight container, and stored at −40°C until thawed 24 hours prior to testing. For mechanical testing, the femurs were sawed through, 15 cm above the proximal end of the incisura femoris. For easy handling in the testing machine, the sawed-off portion was placed in a steel pot and embedded in PMMA. The osteoporotic state was evaluated with a computed imaging tomograph (Hologic QDR-
Only bones with a mean density below 1 g/cm³ were used.

The 15 specimens were divided randomly into three groups each consisting of five femora (Fig. 22–4).

- Group I, cannulated screw (65 mm length and 32 mm threaded length) inserted in the lateral epicondyle at right angles to the shaft and the frontal plane of both condyles. The screw head was left 3 mm from the cortex, so that the clamp of the

**FIGURE 22–1**  (A) Loosening of a plate osteosynthesis in a 67-year-old male, 4 months after surgery. Revision of the osteosynthesis was done using large amounts of bone cement. The bone cement is protruding into the fracture site, preventing the sound healing of the fracture. (B) An example of the detrimental effect of bone cement injected into the fracture site. This 70-year-old female had a fracture above her knee prosthesis. The retrograde nail was reinforced with bone cement with the undesirable presence of bone cement in the fracture and surrounding tissue. The fracture did not heal and became infected, necessitating a resection arthroplasty.
FIGURE 22–2  (A) The modified 7.3 mm cannulated screw. (Reprinted with permission from Broos PL, Robijns FM. Fractures of the distal femur. In: Obrant K, ed. Management of Fractures in Severely Osteoporotic Bone. London: Springer; 2000:280–293.) (B) Injection of Palacos LV 40 through the ported screw in a block made of calcium sulphate. (C) Magnification of the section through the cement plug, showing the flow of the cement into the porous material.

FIGURE 22–3  Example of cadaveric femora after insertion of a cannulated 7.3 mm screw (group I), insertion of a cannulated screw in a plug of bone cement (group II), and insertion of the modified cannulated screw (group III).
servohydraulic testing machine could be fitted for pullout testing.

• Group II, ported screws of the same length inserted in the same manner. After screw insertion 5 cc of liquid cement was injected with a medical plastic syringe (Braun®, Germany) through the head of the screw.

• Group III, cannulated screw of the same dimensions as the previous ones, potted in a cylinder of PMMA (15 × 80 mm). This cylinder was created by a metal punch with a diameter of 15 mm. The cement was allowed to harden for 2 days.

Pullout force was measured by a load cell having a capacity of 30 kN (Model 2511–317, Instron Corp., Canton, MA) at a constant crosshead speed of 5 mm/min. The maximum force was determined for each test and defined as the pullout test.

**Prospective Clinical Study**

Starting in February 1998, we used these screws to reinforce plate osteosynthesis in 63 patients with 70 nonpathological fractures (45 subcapital humerus fractures, 5 distal femur fractures, 13 tibial fractures, 3 os calcis, and 4 ankle fractures) (Figs. 22–5A through D) were treated with plate osteosynthesis using these screws supplemented with PMMA. All patients were operated and reviewed by the author (P.R.) until bone healing occurred (minimum follow-up 11 months). Special attention was given to mechanical complications in the bone implant complex and bone healing problems due to the inappropriate use of the PMMA. Our technique of using this reinforced ported screw consists of open reduction of the fracture after which one of the different available plates is used to treat a particular fracture. The epimetaphyseal area of the plate is loaded with one ported screw. After the plate is fixed to the bone, 5 cc of liquid bone cement (Palacos E-flow; Schering-Plough, Germany) is injected through the head of the ported screw (Fig. 22–6). To prevent injection of bone cement into the adjacent joint, the injection is monitored by an image intensifier. Backing out of the bone cement was observed in three cases. This was corrected by waiting until the bone cement was more viscous before further injection was done. After the cement hardened, the screw was tightened until a firm resistance was felt. Postoperative care was no different from fractures treated with normal plate osteosynthesis. Immediate mobilization of the fractured limb was advocated if the patient was able to do so.

**Results**

**Mechanical Properties of the New Screw Design**

The results show no difference between the mechanical properties of both types of screw (Table 22–1). Mean stiffness for the ported cannulated screws was 1.81 kN/mm (SD: 0.17 kN/mm), and failure load was 1.19 kN (SD: 0.078 kN). Failure load in this experimental setup is defined as the force to permanently deform the screw 0.2 mm after releasing this force.

**Pullout Strength**

There was a significant difference between the mean pullout force of the regular cannulated screw without PMMA augmentation (105 N, SD: 122) versus the ported cannulated screw with injected PMMA (935 N, SD: 272) and cannulated screw embedded in a cylinder of PMMA (1373 N, SD: 792).

The mean difference between group I versus group II was significant (two-tailed P-value = 0.0003, t = 6.3). The mean difference between group II versus group III was not significant (two-tailed P-value = 0.2759, t = 1.169).

The data of the three groups are shown in Table 22–2 and Figure 22–7.

**Clinical Data**

Results were assessed at a minimum follow-up of 11 months. In our series, plate osteosynthesis with reinforced ported screws was performed for 45 subcapital humerus fractures, 5 distal femur fractures, 13 tibial fractures, 3 os calcis fractures, and 4 ankle fractures. The average age at the time of fracture was 78.9 years (range 72 to 94). There was a predominance of female patients (53 female versus 10 male). In two patients accidental injection of bone cement into the joint occurred (one shoulder and one knee).
The lump of bone cement was easily retrieved from the joint without influencing the clinical result. In one patient with a severe fracture dislocation of the shoulder, avascular necrosis of the humeral head developed with implant failure necessitating a hemiarthroplasty of the shoulder 1 year after the initial surgery. In two patients with proximal humeral fractures, loosening of the plate was seen, necessitating revision surgery. In one patient the implant failure was due to alcohol withdrawal delirium 5 days after surgery. In another patient, loosening and breakage of the screws happened because of nonunion.

**FIGURE 22–5** (A,B) Radiographs of an os calcis fracture in a 62-year-old female treated with the modified cannulated screw. (C,D) Intraoperative view of an ankle fracture with the use of the small version of ported screws (4 mm cortical screw).

**TABLE 22–1** RESULTS OF THE THREE-POINT BENDING TEST; COMPARISON BETWEEN THE CANNULATED SCREW VERSUS THE MODIFIED CEMENT SCREW

<table>
<thead>
<tr>
<th>Screw Number</th>
<th>Bending Stiffness (kN/mm)</th>
<th>Bending Strength (kN)</th>
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<tr>
<td>1</td>
<td>2.08</td>
<td>1.29</td>
</tr>
<tr>
<td>2</td>
<td>2.04</td>
<td>1.28</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>1.51</td>
<td>1.31</td>
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<tr>
<td>6</td>
<td>1.75</td>
<td>1.13</td>
</tr>
<tr>
<td>7</td>
<td>1.82</td>
<td>1.30</td>
</tr>
<tr>
<td>8</td>
<td>1.66</td>
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The coexistence of an unstable fracture with advanced osteoporosis materially worsens the prognosis for successful internal fixation. The incidence of loss of reduction and malunion ranges from 36 to 54%. The use of PMMA in internal fixation of these difficult fractures is an accepted method. Mechanical studies reveal that the compression strength of bone cement is high, but its ability to resist shear and torsion is minimal. Therefore, when used to fix fracture fragments it must be augmented by implants capable of withstanding the shear and torsion stresses involved.

Slooff demonstrated the proliferation of periosteal callus throughout the length of the femoral shaft in dogs without fractures when PMMA was injected into either end of the medullary canal. Enis et al demonstrated in dogs that the interposition of PMMA in the fracture site resulted in 75% of the

**Table 22-2** POROTIC STATUS AND MECHANICAL PROPERTIES IN GROUPS I, II, AND III

<table>
<thead>
<tr>
<th>No.</th>
<th>BMD (g/cm³)</th>
<th>Pullout Strength (N)</th>
<th>Displacement (m)</th>
<th>Stiffness (kN/m)</th>
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<td>Group I</td>
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<tr>
<td>17</td>
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<td>0.636</td>
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<td>12</td>
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<td>26</td>
<td>0.0004</td>
<td>152</td>
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<tr>
<td>18</td>
<td>0.676</td>
<td>44</td>
<td>0.0005</td>
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<tr>
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<tr>
<td>2</td>
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<td>0.0013</td>
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<td>3</td>
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<td>851</td>
<td>0.0009</td>
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<tr>
<td>1</td>
<td>0.867</td>
<td>816</td>
<td>0.0010</td>
<td>1275</td>
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</table>
cases (6/10) in a nonunion. Using fluorescent techniques the authors showed the diminished bone formation in areas immediately adjacent to the bone cement.\(^1\)\(^8\) Previously we used the classical technique of digital packing of bone cement in a longitudinal slot created in the shaft, after which a plate was applied to the shaft surface with screws drilled throughout the cement plug. Often lumps of bone cement were pressed through the fracture into the surrounding soft tissues, increasing the risk of iatrogenic thermal injuries to the adjacent neurovascular structures. Another drawback of the latter technique is the poor infiltration of PMMA into bone. With the proposed technique, forceful injection of less PMMA compared with the older technique into the cancellous bone is possible, thereby improving the holding power of the screw.

Brantley and Mayfield\(^2\)\(^2\) evaluated a cannulated pedicle screw for fixation in osteoporotic bone. PMMA and a resorbable bone cement were both used to augment the screw fixation. To prevent backing out of the cement into the spinal canal, these authors designed radially orientated slots distally on the screw.

To prevent injection of PMMA into the adjacent joint, we deliberately blocked the hollow screw tip, so as to force the cement sideways through the side ports into the cancellous bone. Side ports are situated in the threaded portion of the screw to prevent extravasating back on the shaft of the screw. The bending stiffness of this screw design was no different from the original cannulated screw. With the axial pullout test higher forces were required to pull the cannulated screw without side ports out of the cylindrical cement plug than with the modified screw and injected cement. This difference was not significant. On the other hand, there was a clear difference in pullout strength between the cemented screw compared with the noncemented screw.

We applied this technique of injection of bone cement through these modified screws in 70 patients with 70 nonpathological fractures: 45 subcapital humerus fractures, 5 distal femur fractures, 13 tibial fractures, 3 os calcis fractures, and 4 ankle fractures. In two patients accidental injection of bone cement in the joint occurred. Probably this was due to an unin-
tentional drilling through the subchondral bone plate. The lump of bone cement was easily retrieved from the joint without influence on the clinical result. In one patient with a severe fracture dislocation of the shoulder, avascular necrosis of the humeral head developed with implant failure, necessitating a hemiarthroplasty of the shoulder (Fig. 22–8). In two patients with proximal humeral fractures, loosening of the plate was seen, necessitating revision surgery. In one patient the implant failure was due to extreme agitation as a result of alcohol withdrawal delirium 5 days after surgery. In another patient, loosening and breakage of the screws happened because of nonunion. Our clinical experience was in favor of this technique because of efficacy of increasing the holding power of the screw without the need for the application of an abundance of bone cement. This meant we could avoid the interposition of the cement in the fracture site. The ease of handling the simple equipment (plastic syringe and a bowl of liquid cement) makes this technique more likely to ensure adequate screw fixation in osteopenic bone.

REFERENCES

NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: BONE PLATES
RESORBABLE IMPLANTS AS A MEANS OF AUGMENTING METAL PLATE FIXATION IN OSTEOPOROTIC BONE

Sylwester Gogolewski

The treatment of bone fractures in patients with osteoporosis is a problem. Conservative techniques involving casts or skeletal traction are associated with well-appreciated drawbacks. Standard metal internal fixation devices fail frequently when applied in brittle, osteoporotic cortical bones. Hence, methylmethacrylate (MMA) cement is often used to improve the purchasing power of screws and the stability of fixation of osteoporotic bone fractures.1–20 The main disadvantages of this treatment modality are associated with the high temperature developed when MMA monomer sets, bone necrosis, release of toxic residual monomer, and the difficulty of removal of solid polymethylmethacrylate (PMMA) in the case of infection.

An alternative to MMA cement for the reinforcement of osteoporotic bones could be provided by ceramic cements based on calcium phosphates. These cements solidify without the exothermal effect, can be osteoconductive, and can be produced with mechanical properties comparable to those of MMA cement.21–30 Yet another approach to augment screw purchase in osteoporotic bone might be to use medullary inserts produced from resorbable polymers.31,32

GENERAL REQUIREMENTS FOR BIOMEDICAL POLYMERS

Biomedical polymers for implants should not have adverse effects upon the recipient of the device, should not induce adverse inflammatory or foreign body reactions, and should not be carcinogenic, mutagenic, teratogenic, or toxic. Biomedical polymers should be pure and reproducibly produced, and have final properties adequate for the intended application. Hence, flexural strength, bending strength, shear strength, Young’s modulus, fatigue resistance, and wear resistance are critical for internal fixation implants. Tensile strength and tear, burst, and fatigue resistance are essential for implants intended for use in the reconstructive surgery of soft tissues and in cardiovascular surgery. The physical and chemical properties of implantable materials should not undergo changes in the biological environment, unless they are designed as resorbable or degradable materials.33

RESORBABLE POLYMERS FOR IMPLANTS

The potential of using resorbable polymers for medical devices has been recognized since the early 1970s. At present, the main clinical applications of resorbable polymers are for wound closure, internal fixation of bone fractures, tissue engineering, and drug delivery devices, to mention just a few. There are various definitions of resorbable polymers. In general, they are polymers deliberately designed to be degraded in vivo to nonharmful by-products. Such by-products are usually present in the body as metabolites and/or tissue components. The former are finally eliminated from the body by normal metabolic routes; the latter can be incorporated into the tissues. In vivo degradation can be described as the structural and chemical changes in the implant resulting from the interaction between components of the living tissue and the implant material, which acts as a foreign body at the implantation site. Resorbable polymers can be of natural or synthetic origin. The latter, mainly commercial polyhydroxyacids, are more suitable for implants subjected to the action of mechanical stress or load.34–59

CRITERIA FOR SELECTING RESORBABLE POLYMERS

Resorbable polymers for implants should be commercially available in high-purity, reproducible
grades. The batch variations may have an impact on material processing, final implant performance, and biocompatibility. Polymer processing and implant sterilization should not affect its molecular or mechanical properties. The polymers chosen for implants should have proven biocompatibility in soft tissue and/or in bone. The time for complete material resorption in vivo should be known to ensure that the particular device intended for the given application is produced from the material with an optimal or at least acceptable resorption rate. This means that the rate of implant degradation should not be too slow to avoid prolonged inflammation, yet it should not be too fast to allow for an effective metabolism of the degradation products formed upon implant degradation. Ideally, the resorbable implant should maintain its mechanical properties and remain in place only for the time required for tissue healing.\textsuperscript{34}

**COMMERCIAL RESORBABLE POLYMERS**

Commercial resorbable polymers are primarily polyhydroxyacids, including various polylactides based on l-lactide, d-lactide, meso-D,L-lactide, racemic D,L-lactide; polyglycolide, copolymers of lactides with glycolide, \(\varepsilon\)-caprolactone, or trimethylene carbonate; copolymers of glycolide with trimethylene carbonate or \(\varepsilon\)-caprolactone, poly(p-dioxanone), and to a lesser

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**FIGURE 23–1** Chemical structures of selected resorbable polymers. (A) Polylactide; (B) polyglycolide; (C) poly(lactide-co-glycolide); (D) poly(glycolide-co-trimethylene carbonate); (E) poly(dioxanone); (F) poly(\(\varepsilon\)-caprolactone); (G) poly(hydroxybutyrate); (H) poly(hydroxyvalerate); (I) tyrosine-derived diphenolic diol used in the syntheses of polycarbonates.
extent poly(hydroxybutyrate) and poly(hydroxybutyrate-co-hydroxyvalerate) with various content of the valerate unit (Figs. 23–1A through I). In addition, poly(ortho esters), poly(esteramides), and poly(tyrosine carbonates) are considered as materials for implants. More recently, triblock copolymers of L-lactide, D-lactide, and glycolide have been pursued as materials for implants for cranio- and maxillofacial applications.

**Degradation of Resorbable Polymers**

Polymeric materials placed in liquids undergo changes due to chemical and electrical interactions. These changes can be reversible if only secondary bonds are affected, or irreversible when upon hydrolysis the covalent bonds are cleaved. In the latter case, the products of degradation are small-chain fragments and monomers.

Degradation of polyhydroxyacids in the aqueous media proceeds via a random, bulk hydrolysis of ester bonds in the polymer chain with the formation of carboxylic acids. Degradation in vivo may be enhanced by the presence of tissue enzymes, peroxides, cellular activity, lipids, and traces of elements. Lysis may also contribute to the degradation process. Carboxylic acids are finally transformed into carbon dioxide and water (Krebs cycle). The chain scission takes place in the amorphous regions first as they are more permeable to liquids, followed by degradation of the crystalline regions. This is accomplished by a significant reduction in mechanical properties. For semicrystalline polymers the crystallinity of the material initially increases, to be reduced again at the final stage of degradation. If polymers contain impurities, these are released into the surrounding tissue together with the degradation products. Impurities can be accumulated at the implantation site, transported by macrophages, or moved passively through the tissue and the circulatory system. The amount and biological quality of degradation products will finally affect the tissue reaction to the implant.

Degradation of polymeric implants in vitro and in vivo depends on a number of factors related to their inherent characteristics and/or properties achieved upon processing. Chemical structure, chain regularity, molecular weight, polydispersity, surface chemistry, hydrophilicity, and glass transition temperature belong to the first category. The molecular orientation, overall crystallinity, presence of pores, defects, size, shape, presence of impurities, and additives are introduced upon processing. Yet more factors affecting degradation include load and stress acting on the implants, the aggressiveness (pH) and temperature of the environment, the site of implantation (vascularity), and bacterial contamination. In general, the rate of degradation of resorbable polymers decreases with increasing chain regularity, molecular weight, chain orientation, crystallinity, and number of cross-links. The presence of monomer and catalyst residues, voids, and hydrophilic moieties facilitates polymer degradation. The rate of degradation is also mass-dependent (i.e., the greater the amount of polymer, the slower its clearance). Although the body of published literature on in vitro and in vivo degradation of resorbable polymers is rich, comparison of the data is difficult. Test samples from polymers having the same chemical composition are often claimed to lose mechanical properties at different rates and resorb completely at different times. These discrepancies may result from the fact that samples used by various investigators differed in molecular weights, overall crystallinity, chain orientation, the presence of voids, and purity.

**Processing of Resorbable Polymers into Implants**

Implants from thermoplastic resorbable polymers for trauma and orthopaedic applications are mainly produced using common melt-processing methods such as injection-molding, extrusion, and compression-molding.

Melt processing requires heating of resorbable polymers to high temperatures, which is necessary to obtain a homogenous melt. This is accompanied by thermo-oxidative and/or thermo-mechanical degradation of the material. The extent of degradation is higher for materials with very high molecular weight as higher shear forces develop during the melt flow. Degradation upon melt processing is accelerated by the presence of impurities and moisture in the raw material. In consequence, the melt-produced implants available at present have mechanical properties far from optimal. In some cases, implants are also machined from as-polymerized material or from elements prepared by melt processing. Mechanical properties of such implants are poor due to inferior properties of the starting material and the possibility of introducing cracks upon cutting.

Various means were applied to produce implants with improved mechanical properties. Compression-molding of commercial sutures at temperatures below their melting temperature provided implants with enhanced mechanical properties, yet such implants tended to delaminate. Solid-state extrusion, ram extrusion, or hydrostatic extrusion (i.e., the techniques initially developed for nonresorbable polymers) are also successfully used for producing
high-strength, high-modulus implants from resorbable materials. Other methods of producing resorbable implants with enhanced mechanical properties involve gel-spinning and solvent-welding of highly oriented monofilaments and/or films.

**Mechanical Properties of Resorbable Polymers**

Various factors affect the final mechanical properties of resorbable polymeric implants. These include the polymer molecular weight, polymer chemical composition, chain regularity, chain orientation and crystallinity, the presence of reinforcing additives, and material purity. Increasing the polymer molecular weight and the chain orientation and crystallinity enhances the mechanical properties of implants. Homopolymers usually have better mechanical properties than copolymers with disturbed chain regularity. The use of reinforcing polymeric or ceramic additives may initially improve the mechanical properties. Such composites, however, are prone to delamination. This leads consequently to a dramatic loss of implant strength and Young’s modulus. The presence in the implant of particulate impurities, nonreacted monomers and voids reduces its mechanical properties. Resorbable implants produced by injection-molding have bending strengths in the range of 40 to 140 MPa and bending moduli in the range of 2 to 5 GPa. Solid-state extrusion provides implants with a bending strength in the range of 200 to 300 MPa and bending moduli up to 13 GPa.

**Resorbable Polymeric Inserts as a Means of Enhancing Fracture Fixation in Osteoporotic Bones**

An alternative to MMA or ceramic cements as a means of augmenting the stability of fracture fixation in osteoporotic bones with metal plate and screw systems may be offered by the use of intramedullary inserts produced from bioresorbable polymers. In a recent study, AO 3.5 mm titanium screws were inserted into the tapped holes drilled in cylindrical medullary inserts of 8 x 40 mm. The inserts with a viscosity-average molecular weight of 153,000 Daltons were produced by melt-extrusion from poly(l-lactide). The screw/insert samples were aged at 37°C in a phosphate buffer solution for 1, 2, 3, 4, and 6 months and, subsequently, the pullout force of the screws from the inserts was measured. It was found that the pullout force at time zero varied between 1.4 and 3.2 kN, which corresponds to the pullout force of such screws from healthy cortical bone with a thickness of 6 to 7 mm. The viscoelastic properties of the inserts at 37°C resembled those of bone. Although the molecular weight of the inserts decreased by 20% during the first 4 weeks of in vitro aging and was only 40% of the initial value after 6 months, the pullout force did not change for the whole period of the aging experiment. This indicates that for the time period usually required for bone fracture healing, the polymeric inserts provided an adequate purchase for the screws.

In another study, osteotomies were carried out on nine matched pairs of human osteoporotic humeri divided randomly into three groups each consisting of three pairs. In group I, the osteotomies of three nonreinforced humeri were fixed using a five-hole titanium T plate. The remaining contralateral three humeri in group I were reinforced with poly(l-lactide) inserts and holes were drilled through the bone and the insert. The holes were tapped and the osteotomies were fixed with plates. In group II, the osteotomies of three nonreinforced humeri were plated using a standard procedure. The osteotomies of the remaining contralateral three humeri in this group were plated after reinforcing the bone with PMMA cement. In group III, the osteotomies of three humeri were reinforced with a polylactide medullary insert and plated using a standard procedure and the osteotomies of the remaining three humeri were plated after reinforcing the bone with PMMA cement (Figs. 23–2A through D). It was found that the pullout force of the screws from bones reinforced with polylactide inserts was identical to the pullout force of the screws from bones reinforced with PMMA cement. The torsional stiffness of the bones reinforced with the polylactide inserts was, however, higher than the torsional stiffness of unreinforced bones and those reinforced with PMMA cement.

The results of the studies indicate that the bioresorbable polymeric inserts used in conjunction with metal fixation systems may provide a means of reinforcing osteoporotic bone and enhancing the stability of fracture fixation. Inserts can be produced by melt-extrusion, injection-molding, or compression-molding. Their mechanical properties can additionally be improved by using solid-state extrusion or solvent-welding techniques. Applying various implant geometries can reduce the amount of polymer to be used in the intramedullary inserts. The inserts may have starlike or corrugated cross sections or be tubular in form. The latter could be produced by extrusion or by rolling up uniaxially or biaxially oriented foils, which would provide implants with enhanced mechanical properties. The introduction of the insert into the medullary cavity can be done either from the fracture site or like a standard medullary nail. When using such intramedullary inserts it should be kept in mind that their function is not to act as a medullary nail but to enhance the stability of the standard.
metallic plate/screw system fixation. The fact that resorbable inserts can be drilled in situ and that the debris produced upon drilling does not have to be removed from the medullary canal is an additional advantage.

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Osteoporosis is thought to affect 15 to 20 million people in the United States. A significant proportion of these will be females affected by type 1 or perimenopausal osteoporosis, which has the effect of reducing the amount of cancellous bone in the axial and appendicular skeleton while leaving the cortical bone relatively unaffected. Localized osteoporosis affecting metaphyseal bone is also seen in infiltrative conditions such as leukemia, multiple myeloma, and metastatic bone disease.

These pathological conditions predispose individuals to predominantly metaphyseal fractures (e.g., distal radius, vertebrae, proximal humerus, proximal and distal tibia). Such fractures may be difficult to treat because of comminution, joint proximity, reduced metaphyseal bone volume, and malignant infiltration. Nonunion of such fractures makes treatment more challenging because of increased local osteopenia and joint stiffness following prolonged immobilization. Also, surgical exposure is restricted to that used in previous attempts at internal fixation, and the overall quality of the soft tissue envelope may be compromised. There may be technical difficulties with internal fixation because of preexisting deformity, and infection may be present. Fortunately this situation is uncommon because of the enhanced vascularity and the large cross-sectional area available for healing in the metaphysis.

The theoretical resistance to screw pullout is described in the equation:

\[ F = \left( \frac{L}{P} \right) \times (C \times S) \times G \]  

where \( F \) is the pullout force, \( L \) is the length of engagement of the screw, \( P \) is the pitch, \( C \) is the outer circumference of the screw, \( S \) is the shear strength of the bone, and \( G \) is a geometric factor and accounts for the volume of bone into which the screw has purchase. Patients with poor bone stock will have reduced \( S \) values and a reduced absolute volume of bone behind the pitch of the screw (\( G \)). Various authors have confirmed poor pullout strengths of screws in osteopenic bone, thus standard fixation techniques used to achieve secure fixation and allow early functional recovery may be found wanting.

The blade plate is a rigid device providing a broad surface area of contact within metaphyseal bone. It is therefore capable of resisting considerable torsion and bending moments. Its use has been described in the treatment of fractures and nonunions in the proximal tibia, proximal humerus, and the subtrochanteric and supracondylar regions of the femur. Biomechanical studies have confirmed improved loads to failure of blade plates over conventional screw-plate devices. The use of an angled-blade plate device rather than a screw-plate device is recommended as the bone is impacted by the blade rather than removed by the reaming process required for screw insertion, which would be undesirable in bone that is already of poor quality.

Despite the advantages of blade plates, failure by pullout is seen when satisfactory fixation to protect from varus or valgus strain cannot be achieved. This is seen in patients with particularly poor bone stock. In this situation the use of an interlocked angled-blade plate may be considered. This is a technique of blade plate fixation that allows extra stability to be achieved without the need for extra soft tissue dissection or fixation hardware.

**Operative Technique**

Preoperative planning with radiographs and templates is essential to decide on the appropriate plate length and shape. There should be at least 10 holes in the plate to allow a minimum fixation of six cortices in the diaphyseal fragment and two holes to sit within the weak metaphyseal bone (Fig. 24–1). A 3.5 mm dynamic compression plate (DCP) is suitable.
for the humerus and a 4.5 mm DCP is adequate for the proximal tibia. The plate is prebent to the planned acute angle in an industrial vice. The angle of the bend of the plate will determine the number of interlocking screws that can be inserted (i.e., more than a right angle usually allows two screws to be successfully interlocked) (Fig. 24–2). The plate-to-plate interlocking screws are tested before sterilization of the implant and the appropriate screw lengths determined.

The fracture is approached through the appropriate exposure with minimal soft tissue dissection. The proximal humerus is exposed through a deltopectoral approach. The proximal tibia is approached through a midline extensile approach. This ensures future access for joint athroplasty is not compromised. The distal tibia is approached anteriorly. The entry site is chosen, usually in the middle of the metaphyseal fragment, and checked with an image intensifier. Using a small chisel or multiple drill holes, a small cortical aperture is created to accept the shaped “blade” of the plate. The plate is inserted with hand pressure or light hammer blows. The distal fragment is then reduced onto the vertical limb of the plate and held with a bone clamp. The distal fragment is compressed onto the proximal fragment in the standard way. Bone-grafting techniques are performed as appropriate. Two holes just distal to the acute angle of the plate are left free to accommodate the interlocking screws. Drill holes are made through these holes and into the proximal fragment to meet the holes of the horizontal limb of the plate.

Engagement of the drill and screw into the holes in the plate are monitored on the image intensifier with the beam perpendicular to the plate. The plane of the plate is obvious to the surgeon.

Appropriately sized cortical screws are then inserted and are felt to “bite” on the holes in the blade. These are checked on the image intensifier and gently tightened. In the author’s experience an excellent purchase of the interlocking screws can easily be obtained.

**Clinical Results**

Nine patients with problem fractures are described (Table 24–1). Four of the patients treated had acute fractures (Fig. 24–3). Five of the patients had nonunions (Fig. 24–4); three of these had undergone previous unsuccessful surgical intervention.

There were no intraoperative complications and no postoperative wound infections. Postoperatively all the patients with tibial fractures were mobilized in a cast brace, touch-weight bearing for 3 months before progressing to full-weight bearing once callus was seen on X-ray. The patients with shoulder frac-
tures were mobilized with active assisted exercises for 6 weeks, increasing to active resisted exercises once callus was seen.

The mean follow up was 7.2 months (range 4 to 10 months). All nine patients achieved clinical and radiological union during the period of follow-up (mean 6.1 months). All patients were satisfied with their outcome at follow-up although a formal evaluation of outcome was not used. The only complication was that of subacromial impingement of the proximal blade plate in a 91-year-old patient (case 3; see Fig. 24–2) causing restricted abduction to 80 degrees. However, the patient was satisfied and did not wish to have any further surgical intervention.

### Biomechanics

From the theoretical resistance to screw pullout Eq. (1), one can see that as the interlocking screws pass into the proximal metaphyseal bone and then lock into the plate the shear strength against pullout is increased (i.e., $S$ is increased). Because the screws are inserted in an oblique direction, $L$ is increased. Also the volume of bone "behind" the screw is increased, thereby theoretically increasing the value of $G$ (i.e., the construct is more able to resist pulloff in a direction perpendicular to the bone).

Another important concept is that of "toggle." In the clinical situation bone screws are usually subjected to cyclical lateral loading, which over time has been shown to reduce stability of a fixation and reduce screw pullout strength. The toggling occurs around a fulcrum that is the insertion point of the screw into the cortical bone. This has biological consequences of local osteoporosis and loosening, which leads to a reduction in stability and ultimately mechanical failure. The use of the interlocked blade plate results in the formation of a triangular structure within the bone. This theoretically reduces toggle and prevents loss of stability of the construct over time, preventing mechanical failure.
A recent biomechanical study analyzed the effect of an oblique screw through a lateral condylar buttress plate in the treatment of supracondylar femur fractures and although there was no interlocking technique, there was an improvement in the strength of the overall construct and a resisted tendency to varus.12

All these factors suggest methods by which the interlocked blade may improve the stability of fracture fixation. This may allow early mobilization and encourage fracture healing before mechanical failure of the plate. This is borne out by the clinical results of a small group of patients. The results of biomechanical testing of this construct, however, are awaited.

**DISCUSSION**

This technique is presented not as a routine tool of internal fixation but rather for the treatment of problem fractures or nonunions in patients with osteoporotic metaphyseal fractures.

These fractures are difficult to treat and numerous methods have been described. These broadly fall into three categories: standard plates and screws, intramedullary devices, and external fixators.

The problems of standard plates and screws have already been mentioned in the discussion of pullout strengths and toggle. To improve the stability of such a construct an increase in the size of the plate and number of screws in the metaphyseal fragment is often employed. This requires increased soft tissue dissection and leads to an increase in the “footprint” of the plate on the bone, which necessarily enlarges the contact area of a plate, and the underlying area of periosteal compression further damages the blood supply to the already compromised bone. Biomechanical studies do not show any mechanical advantage of these plates over blade plates.9-10

The use of intramedullary nails in these fractures is limited because of the small metaphyseal fragment, which is often multifragmentary. The presence of deformity and intramedullary callus often makes insertion of such devices difficult and reaming further damages bone stock. Intramedullary devices in such a situation have poor rotational and axial control of the fracture, although the “miss-a-nail technique” may address varus/valgus instability to some degree. Intramedullary spread of infection from an already contaminated fracture site is a possibility when treating nonunions after previous surgical intervention. Theoretical advantages include less soft tissue stripping and disturbance of the fracture site, although technical difficulty usually precludes the use of intramedullary devices by most surgeons.

Standard external fixation devices are of little use for the same reasons that standard screw fixation is inadequate. Fine wire fixation and ring external fixa-
tors undoubtedly have a role to play but expertise in this technique is required. Infected nonunions with deformity and soft tissue/osseous defects are best treated with the Ilizarov technique. The disadvantages of this technique are the complications (e.g., pin tract infection, which may lead to septic arthritis if the wire is too close to the joint), length of treatment, and cost.

The customized interlocked blade plate is an alternative for the fixation of metaphyseal fractures or nonunion in patients with poor bone stock. Blade plates have a good track record in the literature in the treatment of these difficult fractures. Theoretically and clinically the interlocked blade plate appears to improve the quality of fixation. Early mobilization and the avoidance of “fracture disease” are therefore possible. The technique is easy to learn and does not require expensive or unusual equipment. The soft tissues are respected and the biological potential of the fracture is preserved as much as possible. The technique is not presented as a routine fixation method but rather as a useful technique to be added to the armamentarium of the trauma surgeon for the treatment of problem fractures.

Acknowledgments

The authors acknowledge that this modification to the DCP plate is not recognized by the manufacturer and the acuity of the plate bend must substantially weaken it for normal purposes. To date implant failure as a result of this has not occurred.

References


It is currently estimated that over 200,000 primary total knee arthroplasties (TKAs) are performed each year in the United States. With widening indications, increasing surgeon familiarity with the procedure, and the aging of the U.S. population, this number is expected to increase dramatically over the next decade. TKA continues to be one of the most cost-effective and successful of all operative procedures performed. There has been much mention in the literature of complications such as patellofemoral malalignment, infection, and thromboembolic disease. One of the more rare complications of TKA is periprosthetic fracture. The reported incidence of periprosthetic supracondylar femur fracture is between 0.5 and 2.6% \(^1\). Even though this complication is rare, as the rate of TKA increases over the next few years this will become a relatively common problem. Controversy still exists over the appropriate management of these fractures as the complication rate with both open and closed treatment approaches 20 to 30% \(^2\). Three major factors complicate the treatment of these fractures: (1) typically there is a very small distal fragment with little room for placement of fixation devices, (2) loosening of the femoral component may be hard to assess, and (3) the bone is typically osteoporotic.

In addition to the more conventional plating and intramedullary devices used in supracondylar femur fractures, there is currently a great deal of interest in minimally invasive osteosynthesis, which minimizes periosteal stripping and soft tissue dissection. Leaving fracture fragments undisturbed theoretically allows for shorter time to union and greater union rates. This can be vitally important in caring for fractures when one is essentially trying to “win the race” in achieving bony union before failure of fixation. There is also a need for devices to provide adequate purchase in a distal fragment that is typically deficient in both the quality and quantity of bone. One device that combines the concept of minimally invasive osteosynthesis and the concept of a locked internal fixator is the Less Invasive Stabilization System (LISS) developed by the AO Group and produced by Synthes. The possible role of this device in solving some of the more common problems encountered with distal femoral periprosthetic fractures shows great promise.

**RISK FACTORS FOR PERIPROSTHETIC FRACTURES**

Periprosthetic supracondylar femur fractures typically occur in well-defined patient groups. Osteoporosis seems to be an important risk factor. This is attested to by the fact that supracondylar femur fractures in younger patients without a prosthesis are usually the result of high-energy trauma. However, with periprosthetic fractures the history usually involves low-energy trauma such as a fall from standing height. In a series reported by Cain et al. \(^3\) 12 of 14 fractures resulted from a simple fall. There is a significant preponderance for the fractures to occur in women in nearly every series reported. The Mayo Clinic joint registry shows that 129 of a reported 161 cases of femur fractures around total knee prostheses were in women. \(^4\)

Other risk factors for periprosthetic supracondylar femur fractures include any factors that impair mobility or lead to decreased bone stock. Among these would be neurologic conditions such as seizure disorders, ataxia, Parkinson’s disease, or disability secondary to cerebrovascular accident. Disorders that affect bone stock such as rheumatoid arthritis, prolonged use of corticosteroids, or osteolysis also leave the patient at an increased risk for fracture. These factors also tend to make fixation of the fracture more difficult, as adequate purchase in the osteoporotic bone is difficult to obtain.
Another risk factor that is more controversial is notching of the anterior femoral cortex. Because of the multifactorial nature of these fractures and their relative rarity, it is difficult to establish the causative nature of notching the anterior femoral cortex in periprosthetic fractures. A recent biomechanical study by Lesh et al. noted that notching the anterior femoral cortex reduces bending strength by 18% and torsional strength by 39.2%. This provides excellent evidence that notching reduces the strength of cortical bone and may leave the patient at increased risk for supracondylar fracture.

Classification of Periprosthetic Supracondylar Femur Fractures

The most common classification scheme referenced by most authors is the modified Neer classification. In this classification a type I fracture is an extraarticular fracture that is nondisplaced or minimally displaced. Type II fractures are extraarticular fractures that are displaced. Typically types I and II are associated with stable components if there are no subjective or objective signs of loosening of the femoral component prior to the fracture. Type III fractures involve comminution at the fracture site and often are associated with a loose prosthesis. Figure 25–1 shows a modified classification based on the three fracture types as described by Neer.

Conventional Methods of Treatment of Periprosthetic Fractures

A great deal of controversy still exists regarding appropriate treatment of periprosthetic supracondylar femur fractures. Even as operative treatment of supracondylar femur fractures not associated with a prosthesis has been demonstrated to be superior to nonoperative treatment, the same is not true for periprosthetic fractures. Nonoperative treatment remains a viable option. Long leg casting, cast braces, and traction have all been reported with good results, especially with type I fractures. Other authors point out that a TKA has no hope of surviving long term without optimal alignment. They would argue this optimal alignment is difficult if not impossible to achieve with closed treatment. Conventional open treatment options available to the orthopaedic surgeon include 95-degree blade plates, dynamic condylar screws, lateral buttress plates, and external fixation. Each of these options has its own set of pros and cons, with no one method showing itself clearly superior in the literature.

Closed Treatment

Closed treatment remains a viable option in many patients with periprosthetic supracondylar femur fractures. Chen et al. reviewed the literature on periprosthetic supracondylar femur fractures in 1994 and found 83% of patients with type I fractures (i.e., those that are minimally displaced or nondisplaced) did well with nonoperative treatment. In this study they included casting, cast bracing, traction, and any combination of these in their category of nonoperative treatment. Results were based on final range of motion, patient satisfaction, and achieving bony union. When type II fractures were investigated this rate of satisfactory results fell to 67%. In their discussion they point out the high complication rate with operative treatment (approaching 30%) in some series and note that most studies show no statistical difference between open reduction and internal fixation (ORIF) and closed treatment. McLaren et al. in a series of 223 cases showed satisfactory results in 56.8% of patients treated closed and in 66.7% of those treated with ORIF using intramedullary rod fixation. This difference was not statistically significant.

Chen et al. concluded that closed treatment was satisfactory for most type I fractures and many type II fractures. They came up with six criteria for open reduction and internal fixation: (1) patient cannot tolerate bed rest, (2) good bone quality, (3) surgeon is technically capable of performing ORIF, (4) patient has multiple fractures, (5) acceptable alignment can-
In group I, all fractures treated closed resulted in satisfactory results. In group II, treatment of eight of the nine fractures treated closed resulted in malunions, and two cases required knee revisions. Displaced fractures treated with open reduction/internal fixation (group III) resulted in two malunions and three reoperations. Culp et al13 investigated 61 supracondylar femur fractures above TKAs in 58 patients. The patients were divided into two groups: group I, managed by open reduction/internal fixation, and group II, treated with casting or traction followed by cast bracing. In the nonoperative group of 30 fractures, there were seven malunions and six nonunions. The operative treatment of 31 fractures (group I) resulted in 25 unions, but also three malunions, one nonunion, and two above-knee amputations. Healy et al14 treated 20 fractures with open reduction and internal fixation. All fractures eventually healed, but 15 bone graftings were performed (six autogenous), and two reoperations were necessary. The use of retrograde nailing has resulted in higher union rates (without bone grafting) and fewer complications. McLaren et al10 treated seven fractures successfully without complications. Henry15 treated 48 fractures with the Green-Seligson-Henry (G-S-H) retrograde supracondylar nail. This resulted in one nonunion and the need for two bone grafts. Although treatment of these fractures with the retrograde intramedullary nail has proven efficacy, it is not adaptable to all total knee designs. Thus, although surgical treatment of supracondylar femoral fractures above TKAs is beneficial, it is not without complications. Adverse events include infection, decreased range of motion, need for bone grafting, malunion, and nonunion.

Ideally, the treatment of a supracondylar femur fracture above a TKA would be characterized by:

- The ability of the patient to return to preaccident function
- A surgical technique that is minimally invasive
- Ability for immediate motion
- No need for postoperative bracing
- No need for bone grafting
- Low risk of infection
- Adaptability to various total knee designs

**Basic Biomechanics of Conventional Plate Fixation**

The LISS plating system is designed to overcome some of the disadvantages faced by conventional plating systems. This becomes especially important when dealing with fixation in osteoporotic bone. Conventional plates act as load-sharing devices that
rely on the friction between the inner surface of the plate and the cortical bone that lies underneath (Fig. 25–2). As one inserts cortical screws through the plate and cortical bone, the torque applied is used to preload and tension the plate, and this force holds the screws to the plate and the plate to the bone. As an axial load is applied to the bone, the friction between the plate and the bone is what resists this force.

When a load is applied parallel to the long axis of the plate and perpendicular to the axis of the screws, the tendency is for the screws to toggle within the plate and allow for motion at the fracture site. (Courtesy of Synthes, USA.)

FIGURE 25–3 When a load is applied parallel to the long axis of the plate and perpendicular to the axis of the screws, the tendency is for the screws to toggle within the plate and allow for motion at the fracture site. (Courtesy of Synthes, USA.)

Applied Load

Bicortical

Unicortical

FIGURE 25–4 Toggle of screws when screws are not locked to the plate. (Courtesy of Synthes, USA.)
cortical screws are used a much smaller force may lead to displacement.

In osteoporotic bone, the applied load is constant but the purchase of the screws is decreased dramatically. This results in a smaller force holding the plate to bone and thus in failure of fixation with a smaller applied load than in normal bone. The load applied is essentially a feature that cannot be altered. Therefore, to improve fixation the holding power of the screws must be augmented. Some have attempted to do this by placing polymethylmethacrylate (PMMA) into the screw holes prior to tightening. Zehtner and Ganz16 reported on six cases of successful fracture fixation using lateral buttress plates and PMMA cement injected into the screw holes. All fractures healed with excellent alignment within 12 weeks of injury.

Conventional means of improving fixation in small fragments of bone have led to such concepts as blade plates, spiral blades, and dynamic condylar screws. These devices have met with much success, but their widespread use in periprosthetic supracondylar femur fractures often is precluded by the presence of the prosthesis. For example, the already challenging insertion of a blade plate is made even more so when having to deal with the box of a posterior stabilized knee or even the pegs of a cruciate retaining knee. The ideal implant for periprosthetic supracondylar femur fractures would be one that provides excellent fixation in osteoporotic bone, maintains the normal valgus alignment of the distal femur, and is flexible enough to work around the prosthesis. The 95-degree blade plate provides excellent fixation in osteoporotic bone and is designed to maintain the normal valgus alignment of the distal femur. However, its point of insertion must very precise to maintain this alignment. Surgeons generally like the lateral buttress plate for its flexibility and numerous distal screw holes, but it is notorious for providing paltry fixation. It is very clear that periprosthetic supracondylar femur fractures remain an “unsolved fracture” with the need for better implants and better fixation.

ADVANTAGES OF LISS PLATE

The LISS from Synthes provides promise by combining the flexibility of lateral buttress plates with adequate fixation in the small, osteoporotic distal fragments encountered in periprosthetic supracondylar femur fractures. The system acts like an internal fixator in which all screws are unicortical and lock to the implant. Thus, the implant no longer relies on friction and intimate contact between plate and bone for stability. Instead, the bone is fixed at each point along the length of the fixator. This provides for a very stable construct as there is no toggle at the
plate-screw interface. There are several features of the plating system as well as the accompanying screws that differ from conventional plate and screw fixation.

**LISS Screw Features**

The screws that accompany the LISS plating system are 5 mm screws with a self-drilling and self-tapping tip (Fig. 25–5). The tapered head of each screw is threaded so that it locks into the corresponding hole on the LISS plate (Fig. 25–6). The screws come in lengths from 26 mm to 85 mm. The diaphyseal screws are all 26 mm and do not need to be measured as they are unicortical and need only to be long enough to ensure that the self-drilling/self-tapping tip penetrates the near cortex. To size for the screws that are placed in the metaphyseal aspect of the distal femur, a Kirschner wire is place in hole A (the central hole in the aiming arm) and advanced to the far cortex. A depth gauge is used to measure this Kirschner wire and then a template (provided by Synthes) gives the appropriate lengths for the remaining metaphyseal screw holes. This prevents screws from being placed into the patellofemoral joint or from penetrating the far cortex of the distal femur (Fig. 25–7). The screws may be placed with a power screwdriver and then definitively tightened with a torque-limiting hand screwdriver. The diaphyseal screws are placed using saline irrigation through a portal in the drill sleeves to prevent thermal necrosis of the diaphyseal cortical bone.

**LISS Plate Features**

The LISS plating system for the distal femur consists of right and left titanium precontoured plates. Each has seven holes distally for metaphyseal screws and a choice of 5, 9, or 13 holes for the diaphysis. The plate may be placed either through a small lateral incision for extraarticular fractures or after the joint surface of an intraarticular fracture that has undergone ORIF through a formal lateral parapatellar approach. A radiolucent aiming arm attachment allows for percutaneous placement of the diaphyseal screws (Fig. 25–8). Because the plate acts as an internal fixator it does not act as a reduction tool. The fracture must be reduced and held with traction, a femoral distractor, or external fixator prior to plate application.
The seven distal holes provide for a high degree of flexibility when placing the metaphyseal screws as well as provide for stable fixation in the distal fragment. A recent biomechanical study compared the stability provided by a 95-degree blade plate, a lateral condylar buttress plate, and a locked buttress plate. The locked buttress plate provided 2.8 to 3.1 times greater stability than the lateral condylar buttress plate and 2.25 to 2.65 times greater stability than a 95-degree condylar blade plate in axial loading. The locked buttress plate also provided consistently more stability in torsional loading than the other two constructs; however, this difference was not statistically significant. The locked buttress plate is superior to the conventional buttress plate because there is no toggle at the screw-plate interface and the screws are able to transfer the axial load directly to the plate because of their fixed-angle configuration. The locked buttress plate is superior to the blade plate because the blade plate relies on one fixation point, the blade within the metaphyseal bone. In contrast, the locked buttress plate has multiple points of fixation throughout the metaphysis.

**Clinical Experience with LISS Plate**

Preliminary results of use of the LISS for treatment of supracondylar/intercondylar femur fractures have demonstrated efficacy. There is one published series in the English literature of patients treated with the LISS for distal femur fractures. This is a prospective nonrandomized account by Schandelmaier et al18 of 29 fractures in 28 patients in which there was no need for supplemental bone grafting and no incidence of nonunion. The average age of the patients was 54 years and the time to fracture healing was 3.1 months. There were two cases in which proximal (diaphyseal) screw pullout occurred. There were no instances of failure of the implant in the metaphyseal bone and this included two patients with periprosthetic femur fractures. Out of this and other experience grew the concept of the treatment of periprosthetic distal femur fractures with the LISS.

The LISS is currently in clinical trial for treatment of distal femur fractures above TKAs. Its initial results have been encouraging, but preliminary. Thirteen fractures in eleven female patients were treated by one of the senior authors (P.J.K.) with the LISS at the University of Mississippi Trauma Center during a 3-year period. The average age of the patients was 75 years (range: 58 to 84). Average surgical time was 140 minutes, with average time for placement of the LISS fixator of 47 minutes. One patient required bone grafting as a secondary procedure, and one patient required revision TKA for loosening of the femoral component. Eventual range of motion averaged 2 degrees (range: 0 to 5) of extension to 90 degrees (range: 80 to 115) of flexion. The mean time for full weight bearing was 13 weeks. No cases of varus collapse and/or distal femoral condyle screw loosening occurred. No infections developed. Therefore, in initial clinical trial advantages appear to include high union rates with a low need for bone grafting (8%), low infection (0%), and maintenance of distal femoral fixation (Figs. 25–9A through F).

**Discussion**

The newly developed LISS from Synthes shows a great deal of promise in treating many problematic distal femur fractures. Its unique characteristics make it an ideal implant for use in osteoporotic patients where more conventional methods often fail. The characteristics include: (1) multiple fixed-angle screws that lock into the plate at the metaphyseal end, (2) a radiolucent insertion device that allows for percutaneous placement of screws, and (3) submuscular plate placement. Biomechanical studies have thus far borne out the fact that the LISS internal fixa-
A 67-year-old woman was involved in a high-speed motor vehicle collision. She sustained a significant pulmonary contusion necessitating intubation, a left intertrochanteric hip fracture, a type II open supracondylar femur fracture above left total knee arthroplasty (A,B), and a type I open supracondylar femur fracture above right total knee arthroplasty (C,D). Because of her initial significant hemodynamic instability, she underwent fixation of her left intertrochanteric hip fracture with a dynamic hip screw, irrigation and debridement of both open wounds, and placement of spanning external fixators across the knee joints for provisional stabilization. After the patient’s hemodynamic status improved and she was deemed able to tolerate further surgery, she returned to the operating room for repeat debridement and definitive fixation of her supracondylar femur fractures using the LISS method (E,F).
tor provides more stable fixation than conventional plating methods. It also does this while allowing a more biologically favorable environment for fracture healing to prevail. Current prospective clinical studies are under way to evaluate the performance of the LISS internal fixator in long-term results. Early reports indicate that this system performs well in elderly patients and those most at risk for osteoporosis.

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Fracture healing is greatly influenced by the biomechanical environment at the fracture site. In terms of fixator design, this is determined by the type of fixation method and the structural properties of the fixator. In plate fixation, there has been considerable interest in recent years in assessing the effects of plate stiffness on fracture healing. This has arisen for two reasons. Firstly, the traditional rigid plate is known to give rise to stress-shielding of the bone at the fracture site, causing bone resorption and local bone weakness. Secondly, fractures supported by standard compression plates heal by primary bone healing and there has been concern about unacceptable rates of refracture for primary healed bone after the removal of the implant. Bone porosity and loss of strength at the fracture site have also been associated with vascular impairment due to the presence of a bone plate, but low-contact plates are now available or being evaluated to help alleviate this problem.

**BIOMECHANICAL CONSIDERATIONS**

From a biomechanical standpoint the superiority of secondary bone healing has been emphasized as it provides an earlier restoration of the strength of the fractured diaphysis to its former level. Secondary bone healing and bone remodeling can be promoted by reducing the stiffness of the fixator. When considering plate design, it is generally agreed that a high torsional stiffness is necessary for maintaining alignment and should not be compromised. The use of fixators with reduced bending stiffness has proved to be effective in stimulating callus formation, but the risks of delayed union, fixator failure, and fracture dislocation have made the routine use of such fixators unsafe. Much experimental and clinical work has shown the beneficial effect on bone healing from reduced axial stiffness of fixators and from intermittent axial compression provided by a device attached to an external fixator. In fact, axial dynamization has become one of the most important functions of modern external fixators. In comparison, much less work has been done on internal fixators.

**AXIALLY FLEXIBLE PLATES**

Two examples of plates designed for axial flexibility are the tubular plate and the axially flexible plate, both of which have been shown in animal experiments to produce healing bone that has superior mechanical and structural properties to bone fixed with rigid plates. The tubular plate has a rigid tubular cross section that is filled with a flexible polymeric material. Its low axial stiffness, obtained from the small cross-sectional area of the metal tube, permitted the underlying bone to take a greater proportion of the load than did stiffer plates. This enabled improved postunion healing. The axially flexible plate is made from stainless steel. A low-modulus elastic insert, made of a polymer, fits into each of its six screw holes. Screws pass through holes in the inserts, providing a structure that is flexible axially. In a study using dogs, four plates with different axial stiffnesses were tested. In all cases healing was found to be superior to that obtained with the dynamic compression plate in terms of bone stiffness. The rate of healing was affected by the stiffness of the flexibility of the plate.

**SLIDING PLATE FIXATION**

An axial sliding plate offers freedom of axial movement and full axial load carrying by the bone at the fracture site. This of course limits its use to fractures that are not comminuted, because they lack bony support after fixation. The earliest sliding plate design was the “Eggers Splint,” developed in 1948.
This has two long slotted screw holes into which screws are tightened against the plate and then backed off one turn. The author believed that muscle forces would produce compression and that the bone ends would be guided toward each other through the slotted plate mechanism. This simple plate has more recently been tested on femora in canine subjects and found to produce a stronger bone in the earlier stages of healing, with less intracortical resorption. The uncertainty of the sliding mechanism, however, means that the plate is unlikely to find future clinical use.

An axially mobile plate (AMP) has been designed by the authors to allow the bone fragments free axial movement after fixation while maintaining bending and torsional stability. It is expected that the use of such a plate for long bone fracture fixation would remedy some of the shortcomings of other internal fixation plates, particularly the fracture fragment resorption that has been noted in flexible plate fixation and the stress-shielding that occurs with rigid fixation. This would result in a quicker healing process and a stronger healed bone.

**DESIGN OF THE AMP PLATE**

Figures 26–1A through C show a schematic diagram of the AMP. There are two parts, which together form a sliding mechanism. One part has two holes set into a raised elongated column; the other has a matching elongated hole such that the parts can slide longitudinally while constraining movement in other directions. Two screws with large heads connect the two parts. The depth of the elongated column is slightly greater than that of the matching section with the elongated hole, so when the screws are fully tightened there is a set clearance for the components to slide. The maximum sliding distance is 2 mm. All components are made from surgical grade stainless steel (316L). The AMP plate dimensions are similar to those of commonly used plates so its bending and torsional stiffness will also be similar. The dimensions shown on the representative plate in Figure 26–1 would make it suitable for tibial or humeral fixation.

**MECHANICAL PERFORMANCE**

Bending and torsional tests were carried out on the AMP and for comparison on the eight-hole stainless steel narrow dynamic compression plate (DCP) 4.5 (135 mm × 12 mm × 3.6 mm) and the pure titanium narrow limited contact dynamic compression plate (LC-DCP) 4.5 plate (135 mm × 13.5 mm × 4.6 mm), both from Synthes, Switzerland. These plates were chosen for comparison because of their popularity in tibial fracture fixation.

The bending stiffness and bending strength of the AMP were determined by four-point bending tests, which were conducted in accordance with specifications given by International Standards Organization, ISO 9585:1990. Their equivalent bending stiffness and bending strength were calculated according to formulas given in ISO 9585. The equivalent bending stiffness is a measure of the stiffness of the plate and is effectively the product of the modulus of elasticity and the second moment of area of the plate and gives a measure of the overall stiffness of the plate. Figure 26–2 shows the arrangement for mounting a test.
Further details of the test are given in the paper by Jun et al.\textsuperscript{27} Figure 26–3 shows the mean and standard error values (which were very low) for bending tests on two samples of each of the three plates. The AMP plate produced the largest mean value of equivalent bending stiffness (10.73 Nm\(^2\)), which was found to be significantly greater than values for both the DCP (5.38 Nm\(^2\)) and the LC-DCP (4.31 Nm\(^2\)). The mean value of bending strength of the AMP (16.7 Nm) was less than that of the LC-DCP (22.0 Nm) but greater than that of the DCP (16.1 Nm).

There is no ISO or other standard torsion test for bone plates, so the testing methods used followed those most frequently reported in the literature,\textsuperscript{28–32} but with the plates fixed to synthetic tibias (Sawbones Europe AB, Malmo, Sweden) rather than bones in situ or fractured bone models, to ensure standardization of tests. These are made of a composite material and have a stated flexural modulus of 20.6 GPa and a tensile modulus of 27 GPa, which are representative of these properties in cortical bone.

Each plate was fixed on to the middle part of the anteromedial surface of a synthetic tibia by fully threaded 4.5 mm cortical screws (Synthes, Switzerland). Longitudinal compression was not applied to the DCP and LC-DCP, and a 1 mm gap was left at the bone ends of the “osteotomy” site to avoid contact friction between them during testing. The ends of the synthetic tibia were held in a torsion-testing machine using high-strength cement. Further details are given in Jun et al.\textsuperscript{27}

Under torsion, all failures occurred in the plates as a permanent twist of the central portion of the plate. Figure 26–4 shows torsional stiffness and torsional strength values based on tests on three of each type of plate. The AMP plate, which has a torsional stiffness of 1.30 Nm\(\text{deg}^{-1}\) and torque at failure of 31.2 Nm, was stronger than the LC-DCP (0.94 Nm\(\text{deg}^{-1}\) and 18.8 Nm), although it was not as quite as stiff or as strong as the DCP (1.42 Nm\(\text{deg}^{-1}\) and 33.1 Nm).

**FURTHER DESIGN CONSIDERATIONS**

In all cases the new AMP was stiffer and stronger than at least one of its counterparts. There are no universally accepted values for minimum stiffness and strength of fixators for producing successful union of fractured bone so, from the viewpoint of fixation safety, if a new fixator has a stiffness and strength
comparable with those of currently used conventional ones, it can reasonably be treated as a "safe" fixator.

Fatigue testing of the plate would also need to be undertaken at a later stage, once a production prototype has been developed, as fatigue failure is highly dependent on the specific geometry of an item and its method of fabrication. Wear of the sliding contact surfaces is also an important issue in the design of a sliding plate. Axial motion, however, would only be expected to occur during the first 2 or 3 weeks, after which the bone should have started to unite and stiffen, thereby reducing and eventually stopping altogether the amount of sliding movement that can take place. The number of movement cycles envisaged that could contribute to fatigue and wear would therefore be very few.

Finally, the design of the sliding mechanism is important. Figures 26–5A and 5B show other versions of sliding plates considered by the authors. The plate in Figure 26–5A is made from two contoured sheets, one sliding within the other. Corrugations enhance its bending stiffness. The plate could readily be fabricated, but under torsion and bending deformation of the contact surfaces would impede sliding. In Figure 26–5B, dovetail sliding mechanisms are used. This plate would be more costly and bulky to make than the chosen AMP prototype design.

Another design of sliding plate has recently been reported and tested on sheep radius bones, with good results. This, like the AMP, is a two-part plate, with a circular rod on one part, sliding within a tube on the other part. Rotation is prevented by a protruding spigot. In the animal study the modulus of elasticity of the healing bone increased much more rapidly than for the DCP for the first 4 months after application. Additionally, the ultimate bending strength of the bone from the sliding plate was 40% higher in the fourth month than that from the DCP. At 6 months, once the fractures had healed both plates gave similar results. The authors conclude that the fast maturation of callus is a clear advantage of their sliding plate.

**FUTURE PROSPECTS FOR SLIDING PLATES**

Eggers' original study on his splint remains the only clinical trial to be conducted on axially flexible or axially sliding plates. Trials on other plates have not passed the animal stage. A clinical trial on the AMP is planned after further mechanical tests to determine fatigue strength and wear on the sliding surfaces. The published evidence to date suggests that sliding plates offer considerable potential in long bone fracture fixation.

**ACKNOWLEDGMENTS**

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SECTION V

NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: INTRAMEDULLARY NAILS
The interlocking intramedullary nail remains the gold standard fixation device for femoral shaft fractures in adults. With improvements in design and locking options, the new generation nails have extended the indications for nailing to include complex and comminuted shaft fractures, subtrochanteric fractures, and combined femoral neck and shaft fractures. When choosing a fixation device, the presence of mechanical deficiency is an important factor that needs special consideration.

Mechanical deficiency of the femur commonly results from either generalized bone loss due to osteoporosis or from focal bone loss due to metastatic deposits, with both conditions being more prevalent in the older age group. In theory, the use of an intramedullary device in this group of fractures should allow significant uniaxial bending and torsional loads to be carried by the reconstituted bone, which is usually of inadequate quality to allow reconstitution with screws and plates. However, most of the literature on intramedullary fixation of femoral fractures involves young adults suffering high-energy trauma and does not address age-related comorbidity factors or the quality of bone. The literature on outcome of this type of surgery in the elderly population is sparse.

As life expectancy continues to increase, the incidence of insufficiency femoral neck fractures also continues to increase. Even though not as common, fractures of the femoral shaft do occur in the elderly population and usually result from low-energy trauma such as a fall from standing height. These fractures present a major challenge as in a high proportion of cases, they are associated with significant comminution and can occur anywhere from the subtrochanteric to the supracondylar area of the femur. Morbidity and mortality following femoral fractures in this group of patients are very high and are influenced by coexisting premorbid medical factors in addition to cardiopulmonary complications associated with immobility. The fixation device considered should therefore address early weight bearing as well as early mobilization to reduce the complications associated with these fractures in the older age group.

The osteoporotic comminuted femur presents two specific problems when choosing a fixation device. Firstly, osteoporotic bone does not support fixation well as the security of fixation is directly dependent on the bone mineral content. As such, it is necessary for the fixation device to involve long segments of the bone. Secondly, in the presence of comminution, the construct is inevitably load bearing. Most intramedullary nails in current use have a maximum of two proximal and two distal locking screws, thus risking poor purchase and cutout of the osteoporotic bone. Therefore, an intramedullary fixation device that distributes the locking mechanism through long segments of the bone would reduce this risk.

Fractures of the femur in the elderly can also be associated with metastatic disease. In this situation, focal bone loss combined with osteoporosis makes stabilization especially difficult. The reduction of mechanical strength of the bone at the site of metastatic involvement is well documented. In the femur, a common location for metastatic deposits is the calcar and subtrochanteric area, where loss of the medial cortex results in an adverse biomechanical environment for extramedullary devices, which regularly fail either from screw cutout or fatigue failure of the implant. Therefore, in the presence of a mechanically deficient femoral bone, the fixation device must be able to:

1. Achieve early definitive stabilization to allow early mobilization.
2. Provide a strong enough construct that allows early weight bearing.
3. Last the remaining life of the patient or until union of the fracture, without loss of fixation or failure of the implant.

From our reported experience, the Huckstep intramedullary compression nail can achieve these goals. This device was designed by Professor R. Huckstep and has been available since 1967. The essential characteristics of the Huckstep nail are strength, rigidity, versatility, and inertness. It combines the mechanical advantage of an intramedullary nail with the rigid fixation of a compression plate, providing a strong fixation construct in difficult mechanical circumstances. It has in fact been referred to as an intramedullary plate.

THE HUCKSTEP NAIL AND INSTRUMENTATION

NAIL DESIGN

The Huckstep nail was designed as a straight solid nail with a rounded square profile and is bullet-tipped. The standard nail is 12.5 mm in diameter, which is the most commonly used size for femoral nailing, and is available in different lengths from 15 to 60 cm. Along its length, the nail has 4.6 mm transverse holes at 15 mm intervals for 4.5 mm fine-threaded locking screws. At its proximal end, the standard reconstruction nail has four oblique holes at 130 degrees that allow 4.5 mm lag screws to be passed into the femoral neck. An alternative reconstruction nail is available with an expanded proximal end of 14 mm diameter, allowing insertion of 6.5 mm lag screws into the femoral neck. There is also an 11.5 mm diameter nail for use in the smaller femur, but it is not strong enough for early weight bearing.

The nail is made of titanium alloy (4% vanadium and 6% aluminum). This alloy has a low modulus of elasticity (about 50% that of cobalt chrome and stainless steel) and is much nearer the modulus of elasticity of bone. The nail has been shown to be 1.1 to 1.8 times stronger than the average femur, and can therefore permit early weight bearing in most cases. As with most implants, this alloy is inert and the nail seldom requires removal after union.

The square design is thought to lead to less interruption of the endosteal blood supply, and as with most current nail designs, it does not depend on interference fit for fixation.

Transverse locking screws at 15 mm intervals allow for secure fixation over a long segment of osteoporotic bone. This design of multiple transverse holes also allows for bone fragments to be secured onto the nail, adding to the mechanical integrity of the fixation. The transverse locking screw is a 4.5 mm fine-threaded titanium screw, and three screws have been shown to be equal to the strength of the nail. The nail therefore can be applied to most oblique, spiral, and comminuted fractures of the femur and is strong enough to be used in the presence of segmental bone loss, providing secure fixation while maintaining length. In metastatic disease, bone defects can be held to length and the nail can be used with cement augmentation in the fixation of pathological fractures.

As with most reconstruction nails, the Huckstep nail has proximal oblique holes extending its use to high subtrochanteric fractures with or without deficient medial cortex and to fixation of associated trochanteric and neck fractures. The standard 12.5 mm nail features 4.5 mm lag screws, while the larger 14 mm proximally expanded nail allows 6.5 mm lag screws. An additional feature of the nail is the ability to apply compression at the fracture site if desired. Transverse fractures can be compressed using a special compressor device placed over the insertion site at the level of the greater trochanter.

NAIL CHOICE AND ASSEMBLY

Figure 27–1 illustrates the five important components of the Huckstep nail assembly. The jig is de-
signed to permit nail insertion without the need for a special operating table or X-ray control, unless reconstruction screw placement is required or closed nailing is being carried out. The length of nail to be chosen should extend from the tip of the greater trochanter and allow four screws below the fracture. There is no indication for the choice of an excessively long nail as the risk of anterior cutout of bone increases the more distally the nail extends and the unfilled transverse holes can act as stress risers, risking implant failure.

The inserter compressor is screwed onto the nail and the alignment jig is then attached to its side arm. Both attachments are secured before checking the alignment of the nail with the jig. Drill bits are passed through the holes in the jig and these should pass smoothly through corresponding holes in the nail. All the drill holes should match (Fig. 27–2). Instrumentation for the Huckstep nail is simple (Fig. 27–3), but may be unfamiliar and the instruction manual is handy in the operating room before embarking on this procedure.

**NAILING TECHNIQUE**

The procedure can be carried out either closed or open. As with most antegrade nailings, the proximal femur is approached via a lateral gluteal incision and perforation of the pyriformis fossa. For closed nailing and for placement of oblique screws into the femoral neck, the patient is placed supine on a fracture table and an image intensifier is necessary. If augmentation is needed with either bone graft or acrylic cement, an open procedure may be preferred. In open nailing, the patient can be placed on an ordinary table and an image intensifier is not strictly necessary. However, in view of the straight profile of the nail, the proximal femoral entry is best done under image intensifier guidance as an anterior entry portal risks proximal comminution of the femur. Straight handheld reamers are then used to ream the medullary canal up to 13 mm.

**THE HUCKSTEP NAIL IN OSTEOPOROTIC AND PATHOLOGIC FRACTURES**

In our series of 14 acute femoral fractures,11 seven patients with complex osteoporotic fractures were treated using the Huckstep nail. All procedures in this series were carried out open, and no patient required bone grafting. This nail was specifically chosen for its design, which allowed for long segments of bone to be held with transverse screws. It was possible to insert at least four screws in each of the proximal and distal fragments, allowing for early mobilization and weight bearing without failure of fixation (Figs. 27–4A,B). The nail simplified the management of this group of patients and resulted in a satisfactory outcome without implant failure. In view
of its straight profile, the nail penetrated the anterior cortex of the distal femur in one patient with a distal fracture (Fig. 27–5). We did not experience a problem of poor purchase of the distal screws as noted by Moran et al\(^6\) in their series using a conventional intramedullary nail with two distal locking screws.

In our series of pathologic fractures, the Huckstep nail was selected primarily for its strength. It was possible to augment some of the nailings with acrylic bone cement, and stable fixation was achieved in all six patients (Fig. 27–6). Even though two patients had significant involvement of the proximal femur with loss of the medial cortex, both patients remained relatively ambulant without implant failure until they succumbed to their malignancy.

The Huckstep nail design allowed adequate purchase of osteoporotic bone and was sufficiently strong to permit weight bearing in the presence of a bone defect. Our experience with osteoporotic and pathologic fractures compared favorably with Huckstep’s original series\(^12\) of 122 nailings (including nonunions), with only three nail failures and one anterior cortex penetration. The strength of the nail also proved valuable in the management of difficult cases of nonunion as reported in a number of series.\(^11,12,15\)

Even though this nail was designed more than 30 years ago, it incorporated a number of biological and mechanical features that are now common for many nails in current use. Firstly, from a technical perspective, the surgical technique for inserting the nail is straightforward, and the surgical instrumentation is reliable and easy to use. Despite its relatively small diameter the nail is strong, making extensive reaming unnecessary, and the square design is thought to lead to less interruption of the endosteal blood supply. The use of titanium alloy reduces the modulus of elasticity of the nail, thus reducing the effect of stress-shielding and improving callus formation and fracture healing. This early nail incorporated proximal oblique locking holes, allowing a reconstruction mode with either 4.5 or 6.5 mm screws (Fig. 27–2). The strength of the transverse locking screws is improved by having a large diameter and a fine thread, making three screws equal to the strength of the nail.
The straight profile of the nail, however, merits the following comments. It is important to use the supplied solid reamers as flexible reamers will create a curved intramedullary path through which the nail will not pass. Care should be taken when assessing patients with a narrow medullary cavity or excessive anterior bow as the straight nail may perforate the anterior cortex (Fig. 27–5). Despite this relative drawback, most reported series have shown the Huckstep nail to be a useful implant for the femur. Furthermore, the straight profile in combination with the ability to apply compression makes the Huckstep nail useful for arthrodesis of the knee as well as pantalar arthrodesis.16,17

SUMMARY

Stabilization of the osteoporotic femur in the presence of mechanical deficiency dictates that the fixation device will be load bearing. The majority of present nailing systems feature a maximum of two holes for distal locking, which may not be strong enough to allow early mobilization and weight bearing. The Huckstep nail has a particular advantage in that transverse locking screws can be placed at 15 mm intervals along the length of the nail. In our experience with osteoporotic and pathologic fractures, the nail design allowed adequate purchase of osteoporotic bone and the construct was sufficiently strong to permit weight bearing in the presence of a bone defect. Instrumentation for this nail is simple and the insertion technique is straightforward. In view of its straight profile, care should be taken in the presence of a narrow medullary cavity or excessive anterior bow as the nail may potentially perforate the anterior cortex.

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In the majority of the proximal humeral fractures, satisfactory results can be expected with either conservative or operative treatment. However, in cases of elderly patients with advanced osteoporosis, there have been some problems obtaining a successful outcome. These fractures in the elderly patients with advanced osteoporosis are usually unstable. As a rigid and appropriate fixation cannot be easily obtained even using a plate and screws, conservative treatment has been considered superior to open reduction and internal fixation.\(^1\text{-}^3\) Conservative treatment, however, sometimes requires a long period of immobilization that causes the limitation of range of motion. We believe that sufficient range of motion is necessary even for elderly patients. Unfortunately, with conventional osteosynthesis, early mobilization cannot be achieved. As augmentation with methylmethacrylate has been helpful in osteoporotic fractures of distal femur,\(^4\) distal radius,\(^5\) and calcaneus,\(^6\) we have performed an intramedullary cement fixation procedure for proximal humeral fractures in the elderly since 1997. The improved stability achieved by cement augmentation allows immediate mobilization, so we believe this procedure is suitable treatment for elderly patients with advanced osteoporosis.

Patients over 75 years old with advanced osteoporosis who have sustained proximal humeral fractures that are unstable due to insufficient bone stock have an absolute indication for this procedure.

**Surgical Technique and Postoperative Care**

The patient was placed in the beach chair position with a sandbag under the shoulder. Using a deltopectoral incision (Fig. 28–1), the fracture was carefully reduced. Temporary fixation with a Kirschner wire was added where needed (Fig. 28–2). With the aid of a fluoroscope, an eight-hole plate was placed lateral to the bicipital groove. The proximal fragment was then fixed with cancellous screws using two holes, and the distal shaft was fixed with cortical screws using two holes to keep the alignment. If there was no perforation, the cortex of the fracture area was incised over an area about \(15 \times 10 \text{ mm}\). In the osteoporotic bone of the elderly, the medullary cavity is commonly almost empty. After careful irrigation of the cavity (Fig. 28–3), it was filled with dough-type bone cement using a pressurized cement gun (Fig. 28–4). Using the remaining four holes of the plate, cancellous screws should be inserted into the intramedullary bone cement before polymerization of the methylmethacrylate is complete. To prolong the working time, the cement is cooled before the operation.\(^7\) Used in this manner, bone cement acted as an...
internal fixation material and as an anchor for the screws.

Postoperatively, the patients were permitted to have a sling to support the arm in case of need. Physical therapy including assistive passive movement was started on the first postoperative day and consisted of an active range of motion exercise of the elbow, wrist, and fingers, and passive movement of the shoulder. Active movement of the shoulder was started within a week after surgery.

**Clinical Study**

From November 1997 to October 1999, 12 patients (average age 80 years, range 75 to 86) in Saiseikai Yamagata hospital with advanced osteoporosis who had sustained acute traumatic fractures of the proximal humerus were treated by this procedure. They included three men and nine women. Preoperatively, two plane views were used in radiographic diagnosis, an anteroposterior view and a lateral view in the scapular plane. The fracture types were classified according to Neer; seven patients had type II fractures, four patients had type III fractures, and one patient had a type IV fracture. Using fluoroscopy, they were all determined to be unstable at the time of surgery. We defined fractures that would not be stable after reduction and internal fixation with the plate and screws as unstable. These fractures were treated by intramedullary augmentation with bone cement in combination with plate and screw fixation. The postoperative range of motion expressed by percentage of motion to the healthy side, clinical results, and radiographic findings were evaluated at 3 months and at 1 year. The clinical results were assessed using a part of the Constant scoring system (total: 75 points).

All patients showed a good range of motion and good clinical and radiographic outcomes at 1 year after surgery. Mean follow-up period was 16 months. At 3 months postoperatively, average results showed 74% of the motion of the healthy side was obtained in anterior elevation, 68% in abduction, and 35% in external rotation. At 1 year after surgery, that increased...
to 77% in anterior elevation, 70% in abduction, and 44% in external rotation. The clinical results according to a part of the Constant score at 3 months were 48 points (range 34 to 59), and those at 1 year were 49 points (range 34 to 64). Radiographic cortical bone healing was completed in 10 weeks. There were no failures of osteosynthesis in our series (Figs. 28–5 through 28–8). There was neither infection nor avascular necrosis in our follow-up, which was up to 31 months after surgery.

**DISCUSSION**

In the majority of proximal humeral fractures, satisfactory results can be expected with either conservative or operative treatment. Paavolainen\textsuperscript{10} reported the use of plate osteosynthesis in the treatment of proximal humeral fracture has proved to be successful. In young or middle-aged patients with good quality of bone, internal fixation is usually a better choice. However, fractures in the osteoporotic elderly are generally unstable, because the humeral head is highly mobile due to insufficient bone stock. And even if the fracture can be reduced and well fixed, early failure and loosening of the implant occur fre-
quent. As immediate mobilization is risky in elderly patients, a long-term external fixation would be usually applied that limits the range of motion. For elderly patients, the ultimate goal is a rigid internal fixation to allow immediate mobilization. Benum first reported good results by using bone cement as an adjunct to internal fixation of supracondylar fractures of osteoporotic femurs. Kiyoshige and co-workers reported cement augmentation also gave good results in distal radial fracture and calcaneal fractures in elderly patients. With the intramedullary bone cement augmentation procedure described here, the plate osteosynthesis of the osteoporotic proximal humeral fracture was stable and made early mobilization safe. In our previous study, the average shoulder motion postoperatively with this procedure was similar to equally treated younger patients who had no osteoporosis, and the early recovery of motion remained for a long period without complications. We believe that the advantage of the cement augmentation procedure is that it gives good stability and range of motion, which is a great benefit to the elderly with these fractures.

**REFERENCES**

Osteoporosis is a significant health care problem facing American men and women. It is estimated to be responsible for 1.5 million fractures each year. Up to 50% of women over the age of 50 years and 33% of men over the age of 70 years will have a fracture secondary to osteoporosis. Rose et al. investigated the incidence and other epidemiological aspects of humeral fractures in an American community. They reported an incidence of 105 fractures per 100,000 person-years for the population of Rochester, Minnesota; furthermore, 76% occurred in postmenopausal women. Treatment of proximal humerus fractures is no easy task. One must consider the fracture classification, bone quality, age of the patient, and activity level to determine the best treatment plan. The poor quality of bone in osteoporotic patients presents the surgeon with difficult decisions for treatment. Most of these fractures can be treated nonoperatively; however, internal fixation is required in those patients with displaced or comminuted fragments, instability of the glenohumeral joint, or neurovascular injury. Other possible indications for operative intervention depend not only on the fracture personality, but also on the patient’s age, other associated injuries, preinjury activity level, and occupational demands.

**Anatomy**

The proximal humerus can be divided into four segments: humeral head, greater tuberosity, lesser tuberosity, and the humeral shaft. The anatomic neck is located at the junction between the tuberosities and the humeral head, and the surgical neck is found between the tuberosities and the humeral shaft. The main blood supply to the humeral head is via the ascending branch of the anterior humeral circumflex and its intraosseous continuation, the arcuate artery. Inserting onto the tuberosities are the four tendons forming the rotator cuff muscles. The supraspinatus, infraspinatus, and teres minor all insert on the greater tuberosity, while the subscapularis inserts onto the lesser tuberosity.

The most widely used classification for proximal humerus fractures is the Neer Classification. Neer used radiographic appearance of proximal humerus fragments, specifically the four major anatomic segments, to classify the fracture type (two-, three-, or four-part). He also noted that a fracture was considered minimally displaced (regardless of level or number of fracture lines within the humerus) as long as no segment is displaced more than 1 cm or angulated more than 45 degrees. The universal acceptance of this classification can be attributed to its ability to describe the fracture pattern, determine treatment, and predict prognosis.

**Existing Methods of Internal Fixation**

There are many options for internal fixation: percutaneous screw or pin fixation, tension band, intramedullary fixation (with or without tension band), buttress plate, 90-degree condylar plate, or hemiarthroplasty. The ultimate goal of treatment is full function without pain. There are also significant complications with fixation of proximal humerus fractures. Interruption of the blood supply to the humeral head can lead to avascular necrosis. Nonunion is also a significant problem especially in the two- and three-part fractures. This can be due to soft tissue interposition, excessive soft tissue/periosteal stripping, or poor fixation. In addition, with the use of buttress plates in the elderly patient, there is a significant chance of screw cutout due to the poor quality of bone in the proximal humerus.
Closed reduction and percutaneous pinning is indicated in two-part surgical neck fractures with minimal comminution, minimal displacement, and good bone quality.7 This form of treatment is appealing as it is less invasive and avoids compromising the blood supply to the head of the humerus.5 Usually the head is abducted or in neutral position and the shaft is displaced medially due to the pull of the pectoralis major. Although closed reduction and percutaneous pin fixation of three-part fractures have been reported, the fixation is challenging and not as stable as other forms of treatment.7,13

Open reduction and internal fixation is necessary for those fractures that cannot be adequately reduced by closed methods. The use of plates and screws can obtain good results in younger patients; however, in elderly patients with osteoporosis the screw purchase can be less than optimal. The use of buttress plates has fallen out of favor due to the extensive soft tissue exposure necessary for adequate reduction, placing the blood supply at risk.5,13 In addition, there is a risk of secondary impingement when the hardware is placed too high.13

Hawkins et al8 reported a retrospective review of 15 patients who sustained three-part fractures of the proximal humerus. Fourteen of fifteen patients were treated with a tension band wiring technique. The other patient was treated with a buttress plate. It was recommended that buttress plating not be used in older osteoporotic patients. Tension banding allows incorporation of the healthy rotator cuff tissue in the fixation, and in this study there were no reports of fixation failure in those treated with the tension band.

The use of intramedullary devices in the treatment of proximal humerus fractures has distinct advantages over other forms of treatment. The use of a limited approach allows for the preservation of the soft tissues, which means that the blood supply is not disturbed. In addition, with stable fixation there is an advantage of early range of motion and mobilization. This allows for preservation of the strength of the rotator cuff and other supporting muscles. Finally, the intramedullary nail is a load-sharing device, which allows for appropriate bone remodeling and early callus formation.11 Intramedullary fixation has been associated with some problems with nonunion possibly associated with a lack of rotational control.11,13 Ingman et al10 reported that locked intramedullary nailing was indicated in osteoporotic fractures to provide stable fixation.

**Intramedullary Fixation with Interlocking Spiral Blade**

The focus of this chapter is on the use of an intramedullary device with a proximal interlocking spiral blade for internal fixation of proximal humerus fractures in osteoporotic patients (Figs. 29–1A,B). Intramedullary fixation of proximal humerus fractures is a minimally invasive technique that preserves the

**FIGURE 29–1** (A) Illustration of Synthes humeral intramedullary nail and spiral blade system (courtesy of Synthes, USA), and (B) radiographic image of the system used for a proximal humeral fracture.
blood supply of the periosteum and soft tissue while simultaneously providing strong fixation. Before the introduction of the spiral blade, the use of intramedullary nailing in proximal humerus fractures in osteoporotic patients did not provide ideal fixation.\textsuperscript{16–18} With the addition of the spiral blade, the humeral nail is an effective proximal interlocking component that improves rotational stability.\textsuperscript{18}

With the addition of the spiral blade to the intramedullary construct, one achieves an increase in surface area contact in the proximal humerus, which allows for a stronger construct. Wheeler et al\textsuperscript{18} performed a comparison study on the cyclic stability in rotation and abduction, as well as the ultimate failure load in abduction, of three devices used to stabilize cadaveric three-part proximal humerus fractures. The three fixation methods tested were the percutaneous K-wire fixation, cloverleaf plate, and intramedullary nailing with proximal interlocking spiral blade. The results of this study revealed that in abduction and external rotation the stiffness and stability of the spiral blade with intramedullary fixation was better than the cloverleaf fixation and was far superior to the percutaneous fixation with K-wires. The K-wire fixation specimens were noted to have lost fixation and fracture reduction with cyclic loading; specifically, the greater tuberosity fragment displaced up the K-wire. The cloverleaf plate was noted to be stable with cyclic abstraction forces but not in external rotation forces. The distance between the humeral head and shaft increased to >2 mm within the first 100 cycles. This was thought to be due to screw cutout from poor bone quality of the specimens tested.

The spiral blade with humeral intramedullary nail was reported to obtain stable fixation with minimal fragment movement and an increased stiffness when compared to the other forms of fixation. Specifically, there was <0.2 mm displacement of the greater tuberosity fragment during rotation and abduction cycle loading. Upon exposure of the fixed proximal humeri to supraphysiologic loads during the failure tests, the spiral blade was again the strongest, most stable construct. It was two times stronger than the cloverleaf plate and it was three times stronger than the K-wire fixation. Furthermore, the spiral blade construct was able to withstand loading 30 times that seen with normal physiologic conditions.

**CLINICAL DATA**

The Medical University of South Carolina series of spiral blade intramedullary nails represents a diverse population both in terms of age of patients as well as mechanism of injury. To date in our center, 12 spiral blades have been utilized in the treatment of proximal humerus fractures. Patients in the study are grouped according to the Neer classification of their fractures as two-, three-, or four-part fractures. Our patient population ranged in age from 18 to 79 years (median = 27). In our series, eight (67%) suffered three-part fractures (Figs. 29–2A,B), one (8%) suffered a four-part fracture, and two (17%) sustained proximal shaft fractures, which are not included in the Neer classification scheme. The majority of cases (42%) were injuries secondary to motor vehicle accidents. The next most common mechanism of injury was gunshot wounds (25%) followed

**FIGURE 29–2** (A) Preoperative radiograph of an elderly patient who sustained a three-part proximal humerus fracture. (B) Postoperative radiograph demonstrating proper placement of spiral blade system.
Positioning of the patient is crucial in the fixation process as image intensification plays a prominent role in anatomic reduction of these difficult fractures. The patient is placed in a position amenable to easy and frequent transitions of the image intensifier to and from the anteroposterior and lateral views. In standard fashion, the C-arm is placed opposite the surgeon. In this way, the surgeon is most able to manipulate the C-arm to provide all three views (anteroposterior/lateral/scapular Y), which are necessary for assessment of fracture fragments. An anterior acromial incision is the suggested mode of insertion, as the lateral approach has the potential for varus displacement of the humeral head. The optimal entry site for nail insertion is preacromial. This is best facilitated by the aforementioned incision.

Once the correct size of intramedullary nail has been selected, the standard insertion handle is attached with a connecting screw. A separate driving head is attached to prevent damage to the nail head, and the preacromial incision is made. The supraspinatus fibers are identified and split longitudinally, and an entry portal is obtained between the articulator cartilage and the greater tuberosity using a cannulated awl. C-arm images are taken throughout the process to ensure proper positioning of the component. Once complete, the nail/insertion handle assembly is moved into position and advanced by hand. Once the surgeon has positioned the nail to an acceptable depth, the aiming arm is fastened to the insertion handle. A guide-wire is passed through the proximal hole in the aiming arm. This indicates the final height of the intramedullary nail (with end cap) and ensures that the nail is appropriately subosseous in the humeral head. Next, protection and drill sleeves and a trocar are inserted through the aiming arm. A laterally oriented incision is made adjacent to the trocar tip followed by blunt dissection of the deltoid fibers to expose the humeral cortex. Anteroposterior and lateral C-arm images are obtained and the spiral blade-measuring device is then utilized to obtain an accurate measurement of the blade size to be inserted. A cannulated drill is inserted into the sleeve and a hole is drilled through the lateral cortex. Once the spiral blade has been attached to the guide and connecting screw, the cannulated spiral blade is passed over the tip of the 2 mm guide-wire and advanced.

Some surgeons prefer to use tension band sutures in the repair, and if this is desired, sutures are passed through the portal in the rim of the blade at this point. Finally, the blade is advanced under fluoroscopy using light mallet blows. The ideal location for the spiral blade is in the inferior half of the humeral head. After the aiming and insertion hardware has been removed, a spiral blade end cap may be placed. This ensures a secure fit of the spiral blade into the humeral nail and prevents blade migration. Finally the tension band sutures are tied to the blade. To reduce rotator cuff tension while closing, the arm may be abducted as the sutures are tied. The distal holes of the intramedullary nail may now be fixed with locking screws if the fracture is still felt to be rotationally unstable. Postoperative radiographs are obtained to assess reduction and instrument placement (Figs. 29–2A,B).

**DISCUSSION AND FUTURE STUDIES**

The Synthes spiral blade and intramedullary nail system is currently under clinical trial. At this time we have used this device on 12 patients with proximal humerus (two-, three-, or four-part) fractures. Due to the osteoporotic state of many of the patients who sustain this fracture, we feel that further modifications can be made to this apparatus. Our hypothesis is that cement augmentation of the humeral head,
previous to the insertion of the spiral blade, will significantly improve the strength at the fracture site. We plan on testing this hypothesis with the injection of Norian cement into test cadaveric bone, in which a surgical neck fracture will be created to each of the humeral bones via an osteotome. The cement will be injected with the use of a specifically designed applicator into the site of fixation. After the fixation is stable the entire assembly is subjected to bending and torsional test. We will compare this data to fixation without cement augmentation.

REFERENCES

The changes in long bone caused by osteoporosis are well described and include alterations in the proximal, metaphyseal, and diaphyseal areas. Fixation of fractures in osteoporotic bones is characteristically fraught with complications and problems. As the internal fixation devices are stronger than the bone, cutout, fracture below the implant, or implant failure are commonly observed.

Fractures that have occurred in the midshaft of the long bone are not amenable to stabilization with either plating or external fixation. Intramedullary nailing with or without interlocking screws is currently the standard treatment of these fractures, a procedure that also entails complications mainly due to the large medullary canal that is pathognomonic in patients with osteoporosis. In addition, weakening of the bone by the use of interlocking screws may cause further fractures below the end of the nail.

Despite the larger diameter of the medullary canal in osteoporotic bones, reaming is still necessary to introduce the largest intramedullary nail in the canal. Reaming, however, injures the medullary vascular system, resulting in relative avascularity of significant portions of the diaphyseal cortex. It also reduces the strength of the bone by 15 to 64%, depending upon the extent to which it is carried out. The drilling of a hole in a bone inevitably reduces its breaking strength. The presence of a screw also weakens the bone to the same extent as an unfilled hole, but this effect diminishes with the production of new bone.

The osteoporotic bone in the distal femoral metaphysis can compromise distal locking screw purchase. Moran and coworkers supplemented their distal locking screws with intramedullary polymethylmethacrylate in several cases. However, because of the differences of stiffness that had been created, further fracture below the intramedullary nail became unavoidable.

The need for reaming and fixing a distal locking screw significantly prolongs operative and fluoroscopy time. The threat of thromboembolism increases with the duration of the surgical procedure, as does the wound infection rate. Excessive radiation exposure to the surgeon’s hands and body are a major concern with closed intramedullary nailing; several studies have shown that the greatest dose of radiation occurs during nail insertion and distal targeting. The avoidance of both reaming and the use of an interlocking screw would directly reduce operative and fluoroscopy time and associated complications. An inflatable nail that can adapt itself to the changing diameter of the medullary canal and produce a satisfactory grip along the fractured bone would make reaming and interlocking screws unnecessary.

**THE INFLATABLE NAIL**

The inflatable intramedullary nail expands within the medullary canal and does not require reaming or interlocking screws. It is a stainless steel, sealed pressure tube consisting of four longitudinal bars connected radially by four thinner stainless steel membranes. The implant is supplied in its small diameter configuration. Upon expansion, the nail is capable of increasing its diameter by more than 65% (range from 6.5 through 14 mm to 10 through 22 mm, for pre- and postinflation, respectively). The nail with the reduced diameter has flexible characteristics and is easily inserted into the medullary canal. Once in position, it is reexpanded by inflation under controlled pressure with saline (up to 70 bar). This expansion of the nail within the medullary canal causes abutment of the longitudinal bars to the inner surface of the canal along its entire length. The expanded nail adapts to the different shape and diame-
ter of the medullary canal, resulting in excellent fixation of the fracture (Fig. 30–1).

**THE DESIGN**

The inflatable nail is a single-use system that features three main components (Fig. 30–2):

1. The nail is a stainless steel construct with the shape of a thin-walled annealed tube with four longitudinal bars for reinforcement. The tube is sealed with a conically shaped cap at the distal end, and a female threaded cap containing an internal check valve at the proximal end (Fig. 30–1). The inflatable nail is provided with a specific longitudinal curvature for use in individual long bones (humerus, femur, or tibia), as well as different diameters and length. Sterile inflation liquid (saline), which is inserted into the nail through its check valve under fluoroscopy and controlled pressure, is used to expand the nail to the desired diameter.

2. The driver is a stainless steel tube that is cut at its distal end to create a male thread for connection to the nail implant’s proximal end. This tube is connected to the driver’s plastic handle. To prevent relative rotation movement between the driver and the nail during its insertion, a locking mechanism is activated on the driver’s plastic handle. A quick connector is located on the driver’s handle close to its distal end for connection to the inflation device.

3. The nail inflation pump is manually operated by rotation of its handle’s screw. An analog pressure gauge and a pipe joint, which is designed for quick connection to the driver, are installed at the pump outlet. Accessories to these components are the multiuse nail removal handle and the extractor, which when required enables the nail to be removed after deflation.

**IN VITRO BIOMECHANICAL STUDIES**

Compared to other commercially available intramedullary fixation devices, the expandable nail’s bending stiffness was higher, its bending strength was similar (Table 30–1), and the torsional stiffness was equivalent or even greater (Table 30–2).\(^{17}\) Its torsional
Strength was tested in cadaveric bone and was found to be equivalent to that of the other intramedullary fixation devices.

The saline solution within the nail is a noncompressible liquid and, as such, causes the nail to expand, causing plastic deformation of its thin wall membranes. Once the nail is expanded, it assumes a final stable condition. Thus, the biomechanical properties of the nail after solution evacuation were found to be close to those of the intact inflated nail. Due to characteristics of the nail and the noncompressible saline, any leak of saline from the nail, however small, will cause its immediate internal pressure to drop to atmospheric pressure, without bone or tissue damage.

The bone-nail interface was also measured. Inflation of the nail up to 120 bar (170% of the manufacturer’s recommendation of 70 bar) caused no harm to the bone. The stresses exerted on the canal inner wall during inflation were significantly below the bone force resistance limits. The inflatable nail’s fatigue strength (500,000 cycles) was more than the expected duration of use until bone healing (assuming 1000 walking steps for patient per day for 1.5 years after implantation \[1000 \times 365 \times 1.5 = 547,500\]).

**ANIMAL STUDY**

Twenty-six healthy sheep were used for the animal experiment. A fracture was created in the midshaft of either the femur or tibia and fixed with the inflatable nail. Several observations were made during the nail’s insertion. First, inserting the nail in its narrow configuration was easy due to the small diameter. There were a few fracture angulations, which were possibly due to the small dimension of the nail, and they disappeared after inflation and expansion of the nail. Second, the nail often assumed the shape of an hourglass configuration; thus it expanded more in the wider part of the canal and less in the narrow part, adapting itself to the maximal diameter (Fig. 30–3).

All surgical procedures were carried out uneventfully and all the sheep were able to bear weight on the second or third postoperative day. Full weight bearing was achieved after 7 to 10 days after surgery. The first sign of healing of the fracture was evident at 10 to 14 days postoperatively, and complete healing was achieved after 50 days postoperatively. All the fractures healed uneventfully without loss of reduction.

One of the anticipated problems was the extraction of the nail after the fractures had healed but no

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**TABLE 30–1** Bending Performance Results of Inflatable Intramedullary Nail

<table>
<thead>
<tr>
<th>Nail</th>
<th>Average Bending Stiffness (N • m²)</th>
<th>Average Bending Strength (N • m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflatable 8/12.7 mm, humeral nail</td>
<td>29.8</td>
<td>54.5</td>
</tr>
<tr>
<td>Inflatable 10/16 mm, tibial nail</td>
<td>61.6</td>
<td>92.5</td>
</tr>
<tr>
<td>Inflatable 12/19 mm, femoral nail</td>
<td>78.1</td>
<td>172.5</td>
</tr>
</tbody>
</table>

Note: The nail sizes in the table appear in abbreviation, \(x/y\) mm (\(x\) stands for the reduced nail diameter and \(y\) stands for the maximal inflated diameter).

**TABLE 30–2** Torsion Performance Results of Inflatable Intramedullary Nail

<table>
<thead>
<tr>
<th>Nail</th>
<th>Average Torsional Stiffness (N • m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflatable 8/12.7 mm, humeral nail</td>
<td>4.0</td>
</tr>
<tr>
<td>Inflatable 8.5/13.5 mm, tibial nail</td>
<td>5.4</td>
</tr>
<tr>
<td>Inflatable 10/16 mm, tibial/femoral nail</td>
<td>9.7</td>
</tr>
<tr>
<td>Inflatable 12/19 mm, femoral nail</td>
<td>16.2</td>
</tr>
</tbody>
</table>

See Table 30–1 for nail size abbreviations.

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**FIGURE 30–3** Hourglass appearance of inflated nail in experimental fracture of sheep femur. Note the larger diameter of the nail in the proximal part compared to its distal part.
such problem was encountered. This was due to the rapid decrease of pressure within the nail while removing the valve as well as to the ability of the nail to "collapse" along the narrow and thin walls. The low contact area between the nail and the intramedullary cavity also contributed to the ease of extraction.

Microscopic examination of the callus and the intramedullary cavity did not reveal any bone necrosis around the longitudinal bars, and a normal fracture repair was observed in all the examined calluses.

**Intramedullary Pressure during Nail Insertion and Inflation**

In four intact bones, measurements of the intramedullary pressure were done in vivo during nail insertion and inflation. A 5 mm hole was drilled at the distal end of the medullary canal and a sealed pressure gauge (Koganei GS 520, Japan) was connected to that hole. Those measurements were done without performing fracture so it represents the worst case of pressure rise. The results showed that a very moderate increase in pressure was found during insertion alone (283 ± 203 mm Hg), and this value increased during inflation to 310 ± 130 mm Hg as the nail was inflated up to 80 bars (more than required). These values, which were obtained in an intact bone, were far less than those recorded during medullary canal reaming of the tibia and femur (mean levels of 1125 mm Hg and 752 mm Hg, respectively).19–21

This is due to the fact that the nail is inserted in its reduced diameter, then gradually expanded until full expansion when only the longitudinal bars (and not the membranes) are attached to the medullary canal wall. During the whole insertion-expansion process there is enough space between the nail and the inner wall to allow pressure distribution. The pressure measured in this study, however, was significantly lower than the pressure caused by conventional reaming.

The favorable results of the animal experiment led to several more conclusions. First, the lack of reaming and the low contact area minimized the injury to the endosteal blood supply on one hand, and the unique cross-sectional shape allowed rapid revascularization of the fracture site on the other hand. These combined phenomena contributed to the rapid union that had been achieved in all the animals. Second, the engraved grip of the inflatable nail, together with the hourglass configuration that had been seen in many of the animals, made reaming and interlocking screws unnecessary, and thus preserved the bone strength. By obviating reaming and interlocking screws fluoroscopy time was reduced to a minimum. Third, the capability of the nail to expand to 65% more of its original shape made it easier to insert, even in very narrow canals, and probably make it likely that fewer nails would be enough to fix a specific bone with different sizes. Also we believe the homogenous grip force created all around the longitudinal bar eliminates the stress concentration and breakage area as seen with interlocking screws.

The encouraging results that emerged from the animal experiment provided the basis for conducting a human clinical trial in fixation of fractures of the humerus, tibia, and femur.

**Human Clinical Trial: Preliminary Results**

The self-locking inflatable intramedullary nail was used for internal fixation in more than 230 cases, of which most were traumatic fractures (n = 183).22 The other indications were pseudarthrosis, pathologic fracture, or impending fracture. All the traumatic fractures were in long bones (humerus, tibia, and femur). One half of them (53%) were at the midshaft, and the rest were equally divided between the proximal and distal thirds. The operation was carried out by different surgeons worldwide. Of 183 patients 60% were male, the mean age of the cohort was 37.7 years (range 13 to 89), and 25 (14%) patients were older than 65 years. They had varying degrees of osteoporosis, and one patient had recurrent tibial fracture due to familial osteoporosis.

Of 67 humeral fractures, 42 (63%) nails were inserted in a retrograde direction. Partial reaming was performed according to the physician’s preference in only 20 (30%) fractures. The average total surgical time was 51.6 minutes (range 20 to 120), with a mean fluoroscopy time of 3.5 minutes (range 0.3 to 6.6). Anatomical reduction was achieved during surgery in 90% of the cases, and the rest at mild angulation (less than 7 degrees). Nineteen patients were available for follow-up (14.8 weeks, range 3 to 52 weeks): 10 of them (53%) demonstrated full union, all in anatomical position (Figs. 30–4A through D), and another 7 (37%) showed moderate callus formation.

The nail was used for the fixation of 83 tibial fractures of which limited reaming was performed in 27 (32%) and anatomical reduction was achieved in all. The mean surgical time was 36.7 minutes (range 10 to 100), with a mean fluoroscopy time of 3.5 minutes (range 0 to 20). Of 11 patients available to date for follow-up (mean 8.5 weeks, range 3 to 12 weeks), five fractures (46%) had united in anatomical position, another four (36%) demonstrated moderate callus formation, and the remaining two (18%), followed for 3 weeks only, had no sign of callus formation.

Thirty-two patients with femoral fractures were treated by antegrade inflatable nails and some reaming was performed in 10 of them (32%). Anatomical
reduction was achieved in 82%, with acceptable valgus deformity among the others. The mean operative time was 58 minutes (range 15 to 180), and the mean fluoroscopy time was 5.5 minutes (range 0 to 24.7). Of six patients available for follow-up (mean 11.8 weeks, range 3 to 26 weeks), the fractures of four (75%) had united in anatomical position (Figs. 30–5A through C), one (17%) demonstrated moderate callus formation, and one, 3 weeks from operation, had no sign of callus formation.

In no case did inflation cause an adverse effect on the patient or the fracture and it improved reduction in a few of them. Reaming of the medullary canal was carried out based upon the physician’s preference and experience.

Since the nail is capable of being inflated to different diameters, it can accommodate a changing canal diameter and thus create the radiological appearance of hourglass. Therefore, the inflatable nail can be used to treat fractures that are not confined to the isthmus. A significant reduction in operating time was achieved, due to the absence of or minimal reaming and the obviating of interlocking. The absence of reaming on the one hand and the low contact area between the nail and endosteum on the other contributed to minimizing the injury to the blood supply. Thus, rapid union and callus formation was observed in many patients, in some as early as 6 weeks. Despite the hourglass shape of the nail, extraction after deflation was easy and without complication in six cases, probably due to the collapsibility of the thin wall of the nail and the limited extent of nail-endosteum contact.

**Fracture of the Proximal Femur**

Three devices were developed for fractures of the proximal femur. These include models that are suitable for subcapital, pertrochanteric, and subtrochanteric fractures.

Multiple pin fixation has been advocated as the simplest method of internal fixation of femoral subcapital fractures. However, the weak bone in patients with significant osteoporosis cannot support this means of fixation, leading to a high failure rate. Furthermore, insertion of the pins creates a rise in stress in the subtrochanteric area of the lateral cortex, thus causing the fractures in this area that are secondary to weakening of the bone by the screw holes. Cannulated screws do not provide significant mechanical advantage over pin fixation.

Skinner and Powles concluded that the sliding compression hip screw is an excellent means of fixation due to the relatively low nonunion and avascular necrosis rates (17.5 and 24.3%, respectively).
Placement of an accessory pin or screw is needed to stabilize the fracture before screw insertion, thereby preventing rotation during insertion. However, the quality of the trabecular bone in the femoral neck is apparently the major factor in the fixation of femoral subcapital fractures. Using a nail with an inflatable tip and a small plate may be more suitable for subcapital fractures. Insertion of the nail at its narrow configuration will prevent the need for an accessory stabilizer during insertion because there is no rotation. Bone condensation from inflation will provide an excellent degree of axial and rotatory stability by virtue of its unique expanded tip architecture.

The incidence of comminuted unstable intertrochanteric fractures is increasing, probably due to the growing proportion of elderly people in the general population. Severely depleted cancellous bone in the femoral head and neck prevent stable proximal purchase. Sliding nail plate devices comprise the preferred treatment, but the implant failure rate remains high in osteoporotic femora, mainly seen as upward penetration of the sliding screw and shortening of the femoral neck. Using an inflatable hip screw, currently under development, may overcome those major problems. The new device consists of an inflatable distal end and a plate with optional controlled collapse.

Condensation of the depleted cancellous bone in the femoral head during inflation of the device, rather than removing it while drilling (as is done with the traditional hip screw), contributes to the preservation of bone stock and strength. By providing a better grip and a larger contact area, it may also prevent cutout of the nail.

The treatment of subtrochanteric fractures in the elderly is challenging. They are mainly composed of cortical bone, and the large biomechanical stresses are responsible for both the slower rate of union and the higher rate of malunion in these fractures, thus highlighting the need for stable internal fixation. Nails and plates do not provide sufficient support, thus precluding early weight bearing. Intramedullary nails, such as the Grosse-Kempf, Zickel, Gamma, and the Russell-Taylor reconstruction ones, have been confirmed to improve stability and early weight bearing. However, the large diameter of those nails can cause comminution at the insertion point, be it piriformis fossa or trochanter, in a considerable number of patients. Other complications include implant

FIGURE 30–5  A 32-year-old male with midshaft fracture of right femur, treated with antegrade inflatable intramedullary nail. (A) Preoperative lateral radiograph. (B) Anteroposterior radiograph made immediately postoperatively. Note the hourglass appearance at the proximal femur. (C) Anteroposterior radiograph made 11 weeks postoperatively, demonstrating radiographic union in anatomical position.
failure, fractures occurring below the implant, problems related to reaming, and diminished distal locking screw purchase. The expandable nail that is currently under development will include an inflatable distal part and an optional proximal supplementary screw fixation through the nail into the femoral head and neck. Decreasing the diameter of insertion while maintaining postexpansion bone-nail complex stability and strength can overcome some of these complications: this nail can be inserted through a diameter as small as 14 mm (compared with 17 to 18 mm in others). An expanded diameter (more than 17 mm) can be achieved, a good grip can be provided even without distal interlocking screw fixation, and there are the added advantages of an inflatable intramedullary nail.

**ADVANTAGES OF THE INFLATABLE NAIL**

**BIOLOGICAL FIXATION**

The absence of reaming and the low contact area minimize the blood supply injury on the one hand, and the unique cross-sectional shape allows better and rapid revascularization on the other hand. These features contributed to the rapid union achieved in the experimental fracture in a sheep model (50 days after surgery) and confirmed by the preliminary clinical results in humans. Providing a firm grip without the need for an interlocking screw preserves bone strength and prevents failure associated with the drill hole adjacent to insertion and removal. With no interlocking fixation, the axial pressure between the broken parts of the bone stimulates callus formation. Homogenic load distribution along the bar-bone interface, rather than centering at the interlocking area only, may decrease the stress concentration and implant-related problems such as failure and fractures occurring below the implant.

**REDUCTION OF OPERATIVE AND FLUOROSCOPY TIME**

The absence of reaming and interlocking significantly reduces operative time, and, as a result, minimizes the use of fluoroscopy, as had been observed in human clinical trials.

**THE POSSIBILITY OF CHANGING THE DIAMETER**

The implant insert is provided in its smallest diameter, thus permitting a smaller entrance portal than that needed for contemporary intramedullary nails, a factor that moderates the decline in bone strength secondary to drilling. Furthermore, a large portal increases the risk of iatrogenic damage to the vascular arcade at the base of the femoral neck; the inflatable nail is capable of increasing its diameter by more than 65% after insertion. The nail adapts to the changing dimensions of the canal diameter, as demonstrated by its hourglass appearance on X-ray in the human clinical trial. Osteoporotic bone deformities, such as bowing, which grossly change the canal diameter and form obstacles to the traditional intramedullary nailing, may be treated with the inflatable nail. The capability of expansion optimizes the final diameter of a given canal and reduces the number of required devices due to the availability of different nail diameters in one product.

**THE CROSS SECTION OF THE INFLATABLE NAIL**

The small cross section of the inflatable nail means it is more flexible, allowing easier insertion. Expansion of the nail in the medullary canal causes abutment of only the longitudinal bars to the inner surface of the canal. The small contact area between the endosteum and these bars minimizes the injury to the blood supply. Furthermore, the nail’s cross-sectional shape positively influences the return of circulation after nailing. Channels within the nail allow better revascularization than a nail that occupies the majority of the medullary cavity. Thus, the large spaces between the bars allow rapid revascularization.

**CONCLUSION**

It is well known that fixation of an osteoporotic fracture can be problematic, and implant failure and bone refractures are very common. This is mainly due to the inherent nature of weakened bone and the relative strength of the implant that is introduced into it. The introduction of inflatable intramedullary nails offer a highly significant advantage in treating osteoporotic bones. They can adapt to the medullary cavity without reaming, thus obviating further weakening of the bone. There is no need for interlocking screws that weaken the bone even more and that may precipitate a fracture below or above the intramedullary nail. The lack of interlocking screw loads axial compression on the fracture site, which is favorable for rapid callus formation. The nail changes its diameter according to the diameter of the medullary canal. An excellent grip is achieved and makes the fracture very stable to rotation as well as to bending forces. The intramedullary nail at its constrained diameter is very flexible and can be introduced into a relatively very small hole in the piriformis fossa, after which it can expand by an additional 65%. The smaller the hole, the lower the risk of fracture via the piriformis fossa.
Many additional developments were made on the basis of the expandability of this nail, including several new devices. One of them is a nail that can be used for a peritrochanteric fracture and that has the capability of expanding in the head of the femur. This will very likely afford a better grip of the nail in the femoral head and make cutout of the nail far less common. In addition, the same principle can be used for fixation of subcapital fractures. One narrow nail, which can adjust into a very small plate, can create a very good fixation of the femoral head as well as eliminate rotation by virtue of its expandability.

Subtrochanteric fracture can also be treated by this nail design. The nail can be introduced into a very narrow configuration through the piriformis fossa or the trochanter, requiring few screws to fix the femoral neck, while the distal part is expandable and requires no interlocking screw fixation.

In addition to the above, these devices combine expandable and interlocking parts in the same nail. Thus, the distal part can be expanded and the proximal part can allow for interlocking screws, vice versa, or both, addressing very proximal or very distal fractures. Achieving better grip in less time and with less invasiveness can be a breakthrough in the treatment of the increasing number of osteoporotic fractures.

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25. Swiontkowski MF, Harrington RM, Keller TS, Van Patten PK. Torsion and bending analysis of internal fixa-


Intramedullary nailing is a common treatment of diaphyseal fractures. Its advantages include immediate fracture stabilization with early weight bearing and relative preservation of the soft tissue envelope. The addition of interlocking screws affords additional control of alignment, length, and rotation for unstable fracture patterns. Finally, dynamization by interlocking screw removal may allow for enhanced rates of fracture union. One clinical problem with use of these devices in osteoporotic bone is distal locking screw backout or cutout with subsequent loss of fracture reduction. Most of the commercially available nails have a transverse, medial-to-lateral distal locking screw orientation; there are several new locking screw designs that are purported to provide better nail-screw stability. Although some authors suggest the use of one distal screw, two are recommended for osteoporotic bone. The purpose of the following studies was to examine the fixation stability of several types of these distal locking screws and alternative screw fixation configurations in osteoporotic femoral bone and simulated tibial fracture composite models.

**TESTING OF SCREW TYPES IN OSTEOPENIC FEMURS**

Twenty-four mildly osteoporotic femurs were selected based upon a bone density of 0.30 to 0.45 g/cm² as determined by dual energy X-ray absorptiometry (DEXA). The distal femurs were osteotomized at 20 cm from the distal condyles and the distal 5 cm were fixed in metal holders using a low melting point alloy. They were distributed into four randomly selected groups of six femurs. For each group, supracondylar intramedullary nails (GSH, Smith & Nephew Richards, Memphis, TN) were inserted in a retrograde manner and locked with two distal, 5-mm screws using either standard cortical screws, step screws, standard screws with osteoporotic nuts and washers, or standard 5-mm screws inserted at a 30-degree crossing angle using a modified drill guide and nail (the screw holes in the nail were redrilled). These constructs are illustrated in Figure 31–1.

The specimen holders were fixed in an angle vise at a 10-degree lateral tilt to create a slight varus bending moment when the nail was loaded. Testing was performed using an MTS machine (Model 810, MTS Corp., Minneapolis, MN). First the proximal end of the nail was axially loaded to 1000 N with a flat-faced applicator (the proximal nail end was not constrained) at a rate of 100 N/s, and resistance to motion of the nail was determined from the slope of the load displacement curve. The specimen was then radiographed to measure any screw movements. The specimen was remounted on the MTS and sinusoidally cycled to 10⁵ cycles with a 500-N load, radiographed, and retested for axial stability. Unpaired t-tests between and paired within each test group were used to analyze the data.
The resistance to motion for the four test groups before and after cycling is given in Table 31–1. The standard screw fixation became significantly more stable (P < 0.01) after cycling; the other screw configurations developed less stability or remained unchanged. Precycling, the cross-screw configuration was significantly more stable than other methods of locking screw fixation (P < 0.01). Postcycling, the cross-screw configuration had the same stability as the standard locking screws; both were significantly (P < 0.05) more stable than the osteoporotic bolt and step screw. No gross inferior screw movements were detected radiographically, regardless of locking screw type or configuration; one of the standard distal locking screws backed out approximately 2 mm during cycling.

There are two factors that could have affected the screw stability measurements: (1) the inherent screw rigidity, which is a function of the screw length, core diameter, and end fixation conditions,10,11 and (2) the amount of osseous compaction. Screw length has a third-order effect and was similar for all screws. Screw diameter has a fourth-order effect, but only the step screw had a larger diameter (one side only). A screw that is fixed at both ends has 40% of the deflection of a screw that is simply supported at its ends; only the osteoporotic bolts were locked at both the proximal and distal cortices. However, all of the screws had at least some fixation within the distal cortex. Therefore none of these intrinsic screw-related parameters adequately explains the precycling results, particularly for the cross screws, which theoretically should have behaved in a manner similar to the standard screw configuration. With cycling, the more rigid constructs (i.e., osteoporotic bolts and step screws) might have more highly loaded the bone fixation (less load sharing between the two screws), resulting in greater loosening at the interface and greater displacements. Except for the cross screws, the two fixation screws were oriented parallel to each other. A mechanical interaction was therefore possible between these screws due to effects on the surrounding bone; presence of the distal screw hole may have enhanced movement of the upper screw. After cycling, the standard screws became more stable. This increased stability may have occurred secondary to the greater amount of inherent motion of the standard screws, which could have compacted the bone at the cortex interfaces. This did not occur with the crossed screws, possibly due to the previously described effect of the aligned standard screws.

This experiment did not determine stability in the anterior-posterior and medial-lateral loading modes. Attempts to measure these loading modes were confounded by nail contact with the endosteal femoral cortex during testing. However, the cross screws did appear to provide better stability in medial-lateral loading, as expected from studies of wire orientation on external fixator frame stability.12

A lateral-medial, crossed screw configuration for the distal locking screws of intramedullary nails appears to offer enhanced fixation stability in osteoporotic bone when compared with the standard lateral-medial, parallel screw configuration. The following experiment sought to determine the intrinsic causes of stability by comparing parallel to perpendicular locking screws.

### Stability of Tibial Nails with Parallel or Perpendicular Locking Screws

Perpendicular and parallel distal interlocking screws were evaluated in a distal tibial shaft fracture model using a simulated bone to determine response to applied medial, lateral, anterior, posterior, and torsional loads that were not tested in the previous study. Solid titanium-alloy tibial intramedullary nails (11 mm diameter, 330 mm length; Depuy, Warsaw, IN) having three distal interlocking holes were implanted in antrigade fashion in each of six composite fiberglass pipes to simulate a distal tibia (outer diameter 25 mm, inner diameter 17 mm). The nails received two parallel (medial to lateral) and two perpendicular (one medial to lateral, one anterior to posterior) distal interlocking screws (4.5 mm diameter) in a random order (Fig. 31–2). A straight-edged reference stylus was placed at the proximal tip of each tibial nail. The distal tibia construct was secured in a vise with the nail projecting horizontally.

A 70-N load was applied to the most proximal hole of each nail. Calipers were used to measure the deflection between a fixed proximal point on the nail and stylus in response to the applied load. This was performed with 90-degree rotations of the construct
within the vise to simulate anteriorly, posteriorly, medially, and laterally directed forces.

For torsional loading, a rigid, stainless steel rod was inserted through the most proximal hole of the nail. A 70-N load was applied to the rod, 11 cm from the longitudinal axis of the nail, and the movement of the tip of the rod with respect to the stylus was measured. A support was placed beneath the nail just distal to the hole to minimize any effects of angular displacement due to nail bending.

As a control, an unimplanted tibial nail was secured in a vise and tested in a similar fashion as described above to determine the amount of bending or torsion of the device itself.

Angular deflections were calculated using trigonometry. Student’s t-test was used for statistical analysis for comparison of the two screw positions. A P-value of 0.05 or less was considered statistically significant.

Load application in the medial, lateral, anterior, and posterior planes resulted in average angular deflections of 2.6 degrees (range 2.4 to 2.9 degrees) and 2.2 degrees (range 1.9 to 2.3 degrees), respectively, for the perpendicular distal screw orientation group, and 1.8 degrees (range 1.7 to 1.8 degrees) and 1.5 degrees (range 1.3 to 1.6 degrees), respectively, for the parallel distal screw orientation group (Table 31–1). Although average angular deflection was less for the parallel group, this was not statistically significant (P >0.5).

Torsional loading resulted in average angular deflections of 8.1 degrees (range 7.8 to 8.2 degrees) for the perpendicular screw orientation group and 9.9 degrees (range 9.5 to 10.2 degrees) for the parallel screw orientation group. These results were not significantly different (P >0.3). Torsional loading of the unimplanted nail demonstrated an average angular deflection of 7.1 degrees (range 6.4 to 7.6 degrees).

This study demonstrated no statistical differences in nail stability between the two screw patterns in anterior, posterior, medial, or lateral directions or torsional loading. The cause of the measured nail instability is the mismatch between the diameter of the locking screws and the distal screw holes. Figure 31–3 shows that there are two types of screw movement within the hole that can affect nail tilt depending on the initial screw position and diameter mismatch. It is possible to mathematically calculate the tilt and torsional movement for a worst-case scenario (using the measured dimensions of the nails and screw). For example, this was found to be 2.2 degrees, which is similar to the 2.4 to 2.6 degrees observed values for the medial-lateral tilt of the parallel screws.

The torque applied (7.7 N·m) in this investigation is approximately one third the physiologic torques observed during normal activities.13 The observed increases in angular deflection with torsional loading as compared to values observed with sagittal and coronal plane loading can be explained by the torsional rigidity of the nail itself, which, upon torsional loading, resulted in an average angular deflection of 7.1 degrees (range 6.4 to 7.6 degrees). If this deflection is taken into consideration, the magnitudes of angular deflection values are similar to those observed in the other planes.

This biomechanical model assumed an unstable fracture pattern in a worst-case scenario of cortical bone loss or extensive comminution in which angular deflection would be limited only by distal interlocking screw configuration and position. Cortical apposition with fragment interdigitation would contribute to fracture stability and may limit angular deformity. Additionally, an interference fit between the nail and tibial cortex would limit translation of the nail within the medullary canal, thus providing additional fracture stability.

With perpendicular screw orientation, angular deflection is limited by the more eccentrically placed
screw, as screw offset within the hole results in earlier impingement with angulation. However, with parallel screws, coronal plane offset must also be considered, as screw eccentricity in opposite directions (anterior and posterior or superior and inferior) may further limit angulation. Additionally, with parallel screws, a greater interhole distance results in greater limitation to angulation.

There are several limitations of this investigation: central screw placement (which allows for greater nail angulation until screw impingement as compared to an eccentrically placed screw), a wide intramedullary canal with an undersized component, and no fragment apposition or proximal nail-cortical contact. This study did not investigate the possibility of coronal plane translation, with sliding along parallel locking screws nor angulations other than 90 degrees.

This study indicates that regardless of the configuration of distal interlocking screws, due to design limitations and technical considerations, such as provision of a beveled screw hole of sufficient diameter to allow ease of intraoperative placement, there exists a small degree of angular motion with distal interlocking. Geometrical considerations dictate that, as the distal interlocking screws represent the apex of angular deflection in response to load, the more proximal the fracture, the greater the linear displacement of the fracture allowed. Based on this, a 2-degrees tilt may cause a 1 mm fracture gap in a distal third fracture of the tibia.

Despite recent enthusiasm for the use of perpendicular, distal interlocking screw fixation, they possess no clear advantages over parallel screws with regard to fixation stability. Moreover, due to the risk to neurovascular structures in proximity of the tibia, we believe that the use of two medial to lateral distal interlocking screws is optimal. It appears that some amount of angulation between these screws increases fixation stability.

**CONCLUSION**

Although the preceding studies have evaluated locking screw orientation as one aspect of intramedullary nail fixation in osteoporotic bone, there are other potential solutions to this problem such as improving the strength of the bone by injecting cements and designs that increase the fixation area to reduce interface stresses that have not been evaluated in the laboratory. Injection of acrylic bone cement and more recently biodegradable Ca-P cements have been found to augment screw fixation in poor-quality bone. Laboratory studies of pedicle screw fixation have shown significant enhancement of screw pull-out strengths. There are also nail designs (not available in the United States) that incorporate an expanding component such as multiple pins or fins contained in the distal nail. In one design, the nail body itself expands to engage the medullary canal due to internal pressurization with saline. The use of larger or a greater number of screws can weaken the bone or increase operative time.

**REFERENCES**

SECTION VI

NEW CLINICAL APPLICATIONS AND NOVEL CONCEPTS: SPINAL FIXATION
Percutaneous vertebroplasty (PVP) using polymethylmethacrylate cement (PMMA) consists of injecting PMMA into the vertebral body by a percutaneous route to provide strength and support.1 The bone cement is injected into the vertebrae under X-ray guidance using a hollow needle, and the PMMA hardens within 15 minutes. First described in 1987 by Pierre Galibert and coworkers,2 this technique has found increasing recognition and is now used worldwide in several diseases involving the spine, including vertebral metastatic diseases,3–5 nondegenerated hemangiomas,6–8 and vertebral osteoporotic fractures.9–11

CHRONOLOGICAL ACCOUNT OF VERTEBROPLASTY

PMMA is well known among orthopaedic surgeons who have used this acrylic cement for joint prosthesis fixation since the work of Charnley 40 years ago.12 More recently PMMA has been used in spine stabilization for metastatic diseases13–15 and for the treatment of hemangiomas16 and giant cell tumors.17 The use of PMMA by a percutaneous route for the treatment of hemangiomas was pioneered by Galibert and colleagues in 1984. They added tantalum powder to the PMMA powder to obtain a good radiopacity of the cement when using fluoroscopic guidance. The first description of this technique was published in 1987,2 then several French teams made use of it in the next few years especially in Lyon,3,18 Lille,4,7,8,11 and Paris,5 with the Lyon group using some minor modifications such as injection under computed tomography (CT) scan, rather than under fluoroscopic guidance. Initially the aim of PVP was to strengthen the vertebral body weakened by an aggressive hemangioma. Thereafter the method was extended to other weakening lesions such as vertebral myeloma, osteoporotic crushed fractures, or metastatic lesions.

Today the technique is used worldwide, several thousand PVP procedures have been performed, and many hospitals are giving information about PVP on their web sites.

PERCUTANEOUS VERTEBROPLASTY TECHNIQUE

RADIOLOGIC ASSESSMENT

Radiography and CT must be performed in the days preceding vertebroplasty to assess the extent of vertebral collapse, the location and extent of the lytic process, the visibility and degree of involvement of the pedicles, the presence of cortical destruction or fracture, especially of the posterior wall, and the presence of epidural or foraminal stenosis caused by tumor extension or bone fragment retropulsion. These assessments may influence the way the procedure is performed, but none is an absolute contraindication for vertebroplasty. The presence of cortical destruction or epidural or foraminal stenosis should lead to the exercise of extreme caution during cement injection to prevent new or further neurologic compression.

PROCEDURE

Vertebroplasty is usually performed under anteroposterior and lateral fluoroscopic guidance, although some authors have emphasized the use of CT for needle positioning or injection assessment.20,21 General anesthesia or neuroleptanalgesia is needed because pain may intensify during cement injection.

Ten- or fifteen-gauge needles are frequently used for cement injection, with the diameter and length of the needles chosen depending on the spinal level involved. However, the use of thinner needles has been
reported. The choice of needle route depends on the experience of the radiologist. For the cervical spine, although some radiologists prefer transpedicular injections,20 anterolateral access is frequently performed. The fingers are placed in such a way as to push the large vessels laterally, and the needle is advanced between the vessels and the pharyngolarynx. Either transpedicular or posterolateral route is used for the thoracic and lumbar spine. The transpedicular route avoids spinal segmental nerve injury and decreases the risk of leakage of PMMA into the paravertebral tissue. However, this access is not possible when osteolysis involves the pedicles and does not allow their adequate visualization under fluoroscopic guidance. The posterolateral route is easy to perform for the lumbar spine but is more difficult for the thoracic spine due to the risk of pneumothorax.

When the needle is in the desired location, methylmethacrylate polymer (20 mL powder, 5 to 7 mL solvent) is mixed with tungsten powder (2 g) or barium powder20 to increase its radiopacity. The viscosity of the mixture progressively increases due to polymerization of the methylmethacrylate. The main difficulty at this point is choosing the appropriate viscosity of the cement to be injected. A paste consistency is preferred to a liquid consistency as the latter may result in leakage of methylmethacrylate into adjacent structures. The methylmethacrylate is then injected until resistance is met or until cement reaches the posterior wall. However, injection is stopped immediately if epidural, foraminal, or venous leakage is detected at fluoroscopic guidance. This initial access usually allows an injection of 2 to 9 mL of cement. Depending on the distribution of cement in the vertebral body, one or more injections may be performed. The distribution of methylmethacrylate is frequently homogeneous in hemangiomatous or osteoporotic vertebral bodies, and a single injection may be sufficient. The degree of lesion filling is much more varied in cases of metastatic and myelomatous lesions, probably because of the different texture of these lesions. The procedure usually lasts from 1 to 2 hours unless cement is injected into two or more vertebral bodies. CT, which allows assessment of vertebral body filling and depicts leakage of methylmethacrylate, must be performed in the hours following cement injection.

**INDICATIONS**

**OSTEOLYTIC METASTASES AND MYELOMAS**

Osteolytic metastases and myelomas (Fig. 32–1) constitute the main indications for vertebroplasty, as patients usually experience severe pain that is frequently resistant to drug treatment. Vertebrectomy followed by strut grafting or intraoperative use of methylmethacrylate is rarely undertaken because of the multifocal nature of the disease. Radiation therapy affords partial or complete pain relief in more than 90% of the patients after a delay of 10 to 20 days, but results in minimal, delayed (2 to 4 months after the start of irradiation) bone strengthening, which is usually more effective in patients with myeloma than in those with metastases. However, this delay in bone reconstruction increases the risk of vertebral collapse and consequently of neural compression.

Some studies have reported the effect of vertebroplasty in patients with osteolytic metastases and myeloma. In studies of 101,22 37,4 and 335 patients, complete or marked pain relief was obtained in 80, 68, and 73% of the patients, respectively. Pain relief occurred within hours or days (mean 24 hours) after the procedure. Only 2.5 to 6% of the patients demonstrated no improvement in pain. It also may be hypothesized that vertebroplasty provides bone strengthening, preventing new or further collapse of the vertebral body, as cement hardens as polymerization occurs. This has to be confirmed, however.

**VERTEBRAL HEMANGIOMAS**

Vertebral hemangiomas (Fig. 32–2) are common benign lesions of the spine that are often asymptomatic and discovered incidentally during radiologic evaluation. Rarely, they may be painful, and there must be
a close correlation between clinical findings and radiologic features to ensure that the patient’s pain is due to the vertebral hemangioma. In such cases, vertebroplasty is performed to provide pain relief. In 38 painful hemangiomas, Deramond et al\textsuperscript{22} reported a disappearance of the pain in more than 90% of the cases.

Exceptionally, vertebral hemangiomas are aggressive and result in spinal cord or nerve root compression. Decompressive surgery such as laminectomy or excision of epidural hemangioma (when present) is usually required, generally preceded by vertebroplasty, which may obviate more aggressive surgery. Methylmethacrylate is then injected for pain relief, bone strengthening, and direct embolization of the hemangiomatous body. This combination approach may be preceded by embolization of arteries feeding the vertebral hemangioma or used in conjunction with other percutaneous injections.\textsuperscript{6–8,22,23}

**VERTEBRAL COMPRESSION FRACTURES DUE TO OSTEOPOROSIS**

Osteoporotic vertebral compression fractures (Fig. 32–3) are common, occurring in 16% of postmenopausal women (i.e., with a frequency comparable with the two other main osteoporotic fractures, wrist and hip fractures). Vertebral fractures are usually responsible for back pain, disability, and decreased height.\textsuperscript{24} Conservative therapy including bed rest, analgesics, calcitonin therapy, and sometimes external bracing are usually sufficient for control of pain. However, in some cases, despite these treatments, vertebral fractures are responsible for persistent and debilitating pain. Due to the high benefit/risk ratio of percutaneous vertebroplasty with PMMA in both vertebral hemangiomas and metastatic neoplasms, this procedure has been proposed in osteoporosis.

The results of vertebroplasty in osteoporosis are summarized in Table 32–1. To our knowledge the first authors reporting the interest of vertebroplasty in osteoporosis were Lapras et al.\textsuperscript{19} They evaluated a small group of four patients leading to the performance of 11 vertebroplasties. Although the authors considered that the treatment was of interest with a mean follow-up of 7 months, they did not state what kind of criteria they used for assessing the efficacy of the procedure. In 1991, Debussche-Depriester et al\textsuperscript{25} reported their experience in osteoporosis for the first time. They studied five patients suffering from severe pain due to vertebral fractures. Before vertebroplasty all the patients were unsuccessfully treated by conventional therapy including bed rest and analgesics. Pain was suppressed in all the cases within a few hours after the procedure was done and results remained stable after a prolonged follow-up (mean 13 months; range 12 to 18). In 1994, Gangi et al\textsuperscript{21} also reported satisfying results with vertebroplasty by using a combination of CT and fluoroscopy. Indeed,
they performed eight vertebroplasties in four patients suffering from pain due to vertebral fractures. Twenty-four to 48 hours after the procedure, patients reported that their pain had markedly decreased. Results remained stable with a mean follow-up of 9 months (range 4 to 15). Jensen et al. in 1997 published a large series about vertebroplasty in osteoporosis. They performed vertebroplasty in 29 patients with 47 compression fractures. Their patients had severe pain that limited their mobility. Furthermore, all their patients were receiving narcotics either on an as-needed basis or continuously. Within 24 hours after vertebroplasty two patients were free of pain and pain relief was noted for 26 patients (90%). Unfortunately, data about prolonged follow-up are lacking in this study. Mathis et al. described the case of a 36-year-old woman suffering from pain due to multiple vertebral compression fractures secondary to corticosteroid-induced osteoporosis. The authors performed vertebroplasty in 29 patients with 47 compression fractures. Their patients had severe pain that limited their mobility. Furthermore, all their patients were receiving narcotics either on an as-needed basis or continuously. Within 24 hours after vertebroplasty two patients were free of pain and pain relief was noted for 26 patients (90%). Unfortunately, data about prolonged follow-up are lacking in this study.

The same year we published our own results. Our prospective series included 16 patients for whom 20 vertebroplasties were performed. Inclusion criteria were: one or two vertebral fractures responsible for severe pain and evolving for more than 3 months despite the use of conventional therapy including bed rest and analgesics. Three days after vertebroplasty, pain was markedly decreased (~53%). The results remained stable over time (6 months of follow-up for all the patients). Quality of life, as assessed using the Nottingham Health Profile score, was also markedly improved after the procedure was done since 5/6 of the dimensions showed a significant improvement. Cortet et al. prospectively studied 20 patients with vertebral fractures responsible for severe pain evolving for less than 1 month and requiring the use of narcotics. Twenty-three vertebrae were treated by vertebroplasty performed under CT guidance. Within 24 hours, all the patients showed a marked improvement of their pain and 15 patients (75%) were free of pain. Within a few weeks after vertebroplasty 15 patients had minimal pain and five had moderate pain. Barr et al. retrospectively studied 38 patients in whom they performed 70 vertebroplasties. Within 48 hours they observed a marked pain relief for 24 patients (63%) and a moderate pain relief for 12 patients (32%). Pain did not change for two patients (5%). After a mean follow-up of 18 months (range 2 to 42), five patients had recurrent pain. For one patient pain was related to an incident vertebral fracture adjacent to the vertebra treated. This new fracture was successfully treated by vertebroplasty. Although this latter study included a relatively high number of patients, the results must be interpreted cautiously due to the study design (retrospective study), particularly for the long-term follow-up. Grados et al. have shown the most prolonged follow-up after vertebroplasty (mean 48 months; range 12 to 84). They retrospectively studied 25 patients in whom 34 vertebroplasties were performed. Visual analog scale decreased from 80 mm at baseline to 37 mm at the 1-month evaluation. The results were stable over time since the level of visual analog scale was 37 mm at the maximal follow-up.

<table>
<thead>
<tr>
<th>Author</th>
<th>Patients (n)</th>
<th>VP (n)</th>
<th>Efficacy</th>
<th>Pain Improvement (%)</th>
<th>Mean Follow-up</th>
</tr>
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<tr>
<td>Lapras et al.</td>
<td>4</td>
<td>11</td>
<td>+</td>
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<td>7 months</td>
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<tr>
<td>Debussche-Depriester et al</td>
<td>5</td>
<td>5</td>
<td>+</td>
<td></td>
<td>13 months</td>
</tr>
<tr>
<td>Gangi et al</td>
<td>4</td>
<td>8</td>
<td>+</td>
<td></td>
<td>9 months</td>
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<td>Jensen et al</td>
<td>29</td>
<td>47</td>
<td>+</td>
<td>Complete or partial pain relief: 97%</td>
<td>24 hours</td>
</tr>
<tr>
<td>Mathis et al</td>
<td>1</td>
<td>7</td>
<td>+</td>
<td>Complete pain relief: 89%</td>
<td>9 months</td>
</tr>
<tr>
<td>Martin et al</td>
<td>11</td>
<td>40</td>
<td>+</td>
<td>Complete pain relief: 53%</td>
<td>14 months</td>
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<tr>
<td>Cortet et al</td>
<td>16</td>
<td>20</td>
<td>+</td>
<td>Complete or partial pain relief: 100%</td>
<td>6 months</td>
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<tr>
<td>Cyteval et al</td>
<td>21</td>
<td>23</td>
<td>+</td>
<td>Complete or partial pain relief: 95%</td>
<td>6 months</td>
</tr>
<tr>
<td>Barr et al</td>
<td>38</td>
<td>70</td>
<td>+</td>
<td>Mean pain decrease: 54%</td>
<td>18 months</td>
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<td>Grados et al</td>
<td>25</td>
<td>34</td>
<td>+</td>
<td></td>
<td>48 months</td>
</tr>
</tbody>
</table>
CONTRAINDICATIONS

Vertebroplasty is contraindicated in coagulation disorders due to the large diameter of the needles used for injection. If emergency decompressive surgery cannot be performed, neither should vertebroplasty be performed because it carries the potential risk of epidural or foraminal leakage of methylmethacrylate. Extensive vertebral destruction and significant vertebral collapse (i.e., vertebra reduced to less than one third of its original height) may lead to a technically difficult vertebroplasty procedure and may therefore constitute a relative contraindication. Neurologic symptoms related to compression by the abnormal vertebral body or by tumor extension require a very cautious injection to avoid any leakage of cement that could increase the compression. However, such symptoms do not constitute an absolute contraindication for the procedure.1

SIDE EFFECTS AND COMPLICATIONS

Transitory worsening of pain and fever can occur in the hours following injection as a consequence of inflammatory reaction due to the heat generated by polymerization of the methylmethacrylate. To minimize these side effects, nonsteroidal or steroidal anti-inflammatory drugs may be administered for 2 to 4 days.

Leakages of methylmethacrylate into adjacent structures during vertebroplasty represent the main complication of the procedure, especially epidural (Fig. 32–2), foraminal, or venous leakage (Fig. 32–4) that can lead to spinal cord or nerve root damage. PMMA may also leak into the paravertebral soft tissue (Fig. 32–5) and adjacent intervertebral disc (Fig. 32–6), usually without clinically relevant consequences. Fortunately neurologic complications are uncommon and a study30 showed that of 258 patients who underwent vertebroplasty for tumoral lesion (n = 113), vertebral hemangioma (n = 78), or painful os-
teoporotic vertebral collapse (n = 67), spinal cord compression was seen in only one patient who had a tumoral lesion. Furthermore, neurologic complications subsequently resolved with decompressive surgery. Radicular pain was seen in 13 patients, but surgery was necessary in only three cases. One case of pulmonary embolism of cement also has been recently reported by Padovani et al\(^{29}\) in a 41-year-old man. In the same manner Jensen et al\(^{19}\) and Grados et al\(^{29}\) have also noted this side effect in 4.3 and 2.9%, respectively.

Finally an increased risk of new vertebral fracture adjacent to the vertebra treated by vertebroplasty was reported by Grados et al\(^{29}\) in their osteoporotic patients. Indeed these authors found that the relative risk of vertebral fracture adjacent to a vertebra not treated by vertebroplasty was 1.44 [95% confidence interval (CI) 0.82 to 2.55] during a mean follow-up of 48 months. On the other hand the relative risk of vertebral fracture adjacent to a vertebra treated by vertebroplasty was 2.27 (95% CI 1.11 to 4.56). This side effect must be confirmed in larger prospective studies with long-term follow-up.

**Perspectives**

PVP takes advantage of a quite simple interventional radiologic technique that has been available for a long time. Good pain relief with a low complication rate is reported by most of the authors, and PVP affords immediate good mechanical resistance. However, a number of crucial issues about the clinical indications, the technique, the explanation of pain relief, and the long-term results have been left unanswered. Practitioners often modify the procedure for PMMA preparation, especially by adding tungsten or barium powder, or by increasing the recommended monomer-to-powder ratio. Leakage of PMMA is often observed, the exothermic polymerization process may cause thermal damage, and PMMA remains in bone as a permanent implant with a higher mechanical strength than adjacent bone. Moreover, the Food and Drug Administration currently approves no cement for use with the PVP procedure.\(^{32}\)

The first perspective is a better understanding of PVP. More studies are being performed to get information about the mechanical properties,\(^{32,33}\) temperature elevation,\(^{34}\) and pathological consequences\(^{35}\) of PVP, and prospective evaluations have recently been published.\(^{11,27}\) For the future we absolutely need to know more precisely in which cases PVP is useful and what the consequences are of PVP, especially in common diseases such as osteoporosis. Also PVP will strongly benefit from prospective multidisciplinary studies aiming to assess the benefit/risk ratio of this procedure.

A second perspective is an evolution of the PVP procedure. For example, an anterior route has been described for cervicothoracic junction PVP,\(^{36}\) and a special syringe has been proposed to standardize and facilitate the injection.\(^{37}\) Another procedure, so-called “kyphoplasty,”\(^{38}\) using a balloon inflated in the vertebral body, has been proposed to correct the deformation of the collapsed vertebra and to decrease the frequency of PMMA leakage. This technique is described in another chapter of this book.

A third perspective is to improve the injected biomaterial to avoid some deficiencies of PMMA. A bioactive, glass/ceramic-reinforced composite material has been developed for use in PVP.\(^{32}\) This cement exhibits a lower setting exotherm and is more radiopaque than current commercially available PMMA cements, but is not resorbable.\(^{32}\) In this aim resorbable cements and especially aqueous mixtures of calcium phosphate and other calcium salts could be used.\(^{39}\) Lemaitre\(^{40}\) developed calcium phosphate cements consisting of a mixture of β-tricalcium phosphate (β-TCP) and monocalcium phosphate monohydrate (MCPM) to which calcium sulfate hemihydrate is added. The setting reaction produces dicalcium phosphate dihydrate (DCPD) and hardening occurs because of the bonding between β-TCP grains and the precipitated DCPD crystals. Bone morphogenetic proteins can be added with these brushite cements.\(^{41}\) Constantz et al\(^{42}\) studied cement made of a mixture of MCPM, β-tricalcium phosphate, and calcium carbonate. A sodium phosphate solution is added and the paste hardens by crystallization of dahlite. This cement has been proposed for intravertebral body reconstruction with a hope of better clinical results than those obtained with current PVP.\(^{43}\) Coral granules have been injected percutaneously into vertebral bodies, and the osteoconductivity of the material was observed in an experimental in vivo model.\(^{44}\)

As exciting that these potential improvements may be, they should not lead us to forget the difficulties encountered developing a new cement that works better than PMMA.

**Conclusion**

PVP is an opportunity to do something really good for patients.\(^{45}\) The technique is easy to perform, and satisfactory results with a low rate of complications are usually obtained. However, appropriate training is required, and PVP must be associated with the other treatments of the disease (cancer, osteoporosis). Moreover, a controlled evaluation of long-term results is still needed, and sometimes one may be frightened by a careless enthusiasm to develop this technique,\(^{46}\) especially in osteoporosis. In addition,
the expected benefits of PVP have to be compared with those of other treatments. The development of PVP could be a chance to help patients: let’s do it well.45,46

**REFERENCES**


In 1987 Galibert et al. described a procedure, “vertebroplasty,” in which polymethylmethacrylate (PMMA) cement was injected into the vertebral body for the treatment of painful hemangioma using a percutaneous, transpedicular approach. Deramond et al. reported acute pain relief in 80% of the patients treated with PMMA vertebroplasty for osteoporotic vertebral compression fractures. Other applications of the procedure included treatment of pain and imminent vertebral collapse in malignancies, myelomas, and metastases. The complication rate was low (1%), but included leakage of cement to surrounding tissue, pulmonary embolism, rib fracture, blood loss, radicular pain, and damage to the spinal cord. The method has been adopted on a larger scale in the early 1990s for the treatment of osteoporotic vertebral compression-type fractures (VCF), producing similar results in prospective studies. The mechanism of pain relief is not elucidated completely. Both mechanical and chemical properties of the PMMA cement may account for the beneficial effects. The stability provided by the cement prevents the painful micromotion of bone in the fractured vertebral body. Additionally, pain reduction could result from thermal destruction of nerve endings or tumor tissue in the vertebra. Shortcomings of vertebroplasty are the requirement for high-pressure injection of the cement, thereby increasing the risk of cement leakage, and the inability to restore vertebral body height. These shortcomings have been addressed by the so-called “kyphoplasty,” a technique described in 1998, for the restoration of collapsed osteoporotic vertebral bodies. In this technique, inflatable bone tamps are percutaneously inserted transpedicularly in the vertebral body prior to cement injection. By inflating the balloons, fracture reduction and height restoration of the vertebral body can be achieved. After deflating and removing the bone tamps, PMMA cement can be injected. The first prospective studies (maximum follow-up 18 months) showed good clinical outcome with 90% of the treated patients reporting acute pain relief and the same risk for complications as with traditional vertebroplasty.

PMMA is the most used cement for injection in the vertebral body, but the use of this cement as a bone defect filler in vertebroplasty is under discussion. The advantages of this cement are the well-described chemical and mechanical characteristics, the pain reduction ascribed to the exothermal nature of polymerization, and the mechanical stability (resistance to compressive force) provided after vertebroplasty. However, insufficient data exist on the long-term behavior of a large volume of the biologically inert cement in a vertebral body. Several studies suggest that the osteolysis, frequently seen in PMMA-cemented total hip replacement, is caused by a PMMA-induced, inflammatory (increased macrophage/osteoclast activity) response. With respect to the exothermal polymerization reaction, supraphysiological temperature causes tissue necrosis. Although thermal damage of the spinal cord is a rare complication, Deramond et al. showed temperatures to rise above 50°C in cadaveric vertebral bodies, underlining the need for prevention of cement leakage. Furthermore, during practice, many physicians found the viscosity of PMMA too high for controlled injection. Deviating from the manufacturer’s preparation instruction in search of less viscosity can significantly impair mechanical stability of PMMA cement.

**Traumatic and Osteoporotic Vertebral Compression-Type Fractures**

VCF, resulting from axial impact, can be treated conservatively or surgically, depending on the severity as assessed by radiological and neurological exami-
nation and on the opinion of the surgeon. Patients with osteoporosis, regardless of the cause of the disorder, leading an active life for an extended period are exposed to an increased risk of suffering one or more traumatic VCF during their lifetime (Fig. 33–1).\textsuperscript{17} Traumatic fractures involving a burst of the vertebral body (A3-type fracture according to AO classification\textsuperscript{18}) are treated preferably by surgical intervention in our center. Posterior stabilization using rods and pedicle screws has gained popularity over the last years, due to the relatively simple procedure, the limited number of motion segments that are fixed, and the good clinical outcome.\textsuperscript{19} Speth et al\textsuperscript{20} reported on complications of this treatment, such as failure of the instrumentation during the postoperative period or recurrent kyphosis after removal of the instrumentation (Figs. 33–2A through C). Oner et al\textsuperscript{21} concluded that narrowing of the intervertebral disc space was characteristic for patients in which treatment failed. From a serial publication by Oner,\textsuperscript{22} it was also concluded that recurrent kyphosis and narrowing of the disc space are a result of creeping of the disc into a central depression of the bony end plate, rather than degeneration of the disc itself.\textsuperscript{22} The basis for this mechanism is formed by the anatomy: the disc is contained by the annulus fibrosis and by the end plates. Traumatic changes in the containing structures of the disc space probably result in a redistribution of disc tissue, due to the swelling pressure, into the available space. Following this hypothesis optimal reduction of the fracture, especially the end plate, would prevent this morphologic change. Restoration of the central part of the end plate is performed, ideally after distraction of the fracture with pedicle screws through a transpedicular approach. The void that results in the vertebral body could be augmented with an injectable osteoconductive or osteoinductive material, which supports the intervertebral disc and prevents migration of disc tissue into the vertebral body. Since the material will be used in combination with a posterior fixation device, it will not be under full load bearing during the healing period.

**INJECTABLE CALCIUM-PHOSPHATE CEMENTS IN VERTEBROPLASTY**

It is our opinion that the patient who suffers a traumatic or osteoporotic VCF and has a long active period ahead benefits when a more biocompatible ce-

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**FIGURE 33–1** CT scan of a 56-year-old male 7 years after successful treatment of multiple myeloma with chemotherapy, irradiation, and bone marrow transplantation, showing severe osteoporosis and multiple collapsed vertebral bodies.

**FIGURE 33–2** (A) Preoperative radiograph of a 32-year-old female with a traumatic vertebral compression fracture due to a car accident. (B) Postoperative radiograph of the same patient after reduction and posterior instrumentation. (C) Recurrent kyphosis following removal of the hardware 1.5 years after initial trauma.
ment, as compared with PMMA cement, is used as a bone void filler. This bone void filler would ideally augment the vertebral body, conduct new bone formation, and eventually be replaced by bone. Previous studies demonstrated that augmentation of the defect with autologous cancellous bone does not provide sufficient initial stability and can be a potentially dangerous procedure.23,24 Due to vascular insufficiency, the graft becomes ischemic and necrosis may result in time. Furthermore, the harvesting of an autologous graft is associated with well-known donor-site morbidity. The choice for calcium-phosphate bone cement in the experimental procedure is justified by its biomechanical and chemical properties.25 Such bone cements are currently being used in neurosurgery and ENT surgery.26,27 It serves as an osteoconductive and possibly as a biodegradable bone substitute in defects too large to be covered by the natural process of bone healing (“critical size defect”) and where initial mechanical stability (compression forces) is required. In an aqueous environment, the main (powder-form) components of the cement react to form hydroxyapatite as a final product, which is the principal mineral in bone (and teeth). This property makes calcium-phosphate cement (Ca-P) bio-compatible with both soft and hard tissues. In animal studies, this cement is resorbed over time by osteoclastic activity and replaced with bone. The cement’s consistency before hardening gives the opportunity to preform the cement before application. Ca-P is isothermal in its hardening phase, thereby decreasing the risk of thermal damage to neural structures in case leakage occurs. The mechanical properties (resistance to compressive force and stiffness) of Ca-P as compared to PMMA did not show significant differences after in vitro vertebroplasty.28 However, shear forces are not very well tolerated by Ca-P, making it more suitable for applications in which it is “contained” and thus is exposed mainly to compressive forces.

This chapter describes a new technique in which Ca-P cement is used for vertebroplasty, in combination with inflatable bone tamps, and directed at traumatic spinal conditions.

**Studies on Human Cadaveric Spines**

**Experimental Fracture Device and Creation of Fractures**

A device has been developed in which part of a cadaveric osteoligamentous human spine can be mounted in polyurethane cups. To create type A fractures (according to the AO classification by Magerl et al18), the device allows for an axial impact on the specimen by dropping a weight (10 to 20 kg) from a height of 1.50 m on the top cup. A wedge, bolted to the weight, hits the anterior part of the spine first before axial impaction, to simulate the impact that results in a wedge-formed vertebral compression-type fracture. In a first study, we used a total of five fresh human cadaveric spines (T8 to S1) from donors 60 to 69 years of age. All soft tissue, except the ligaments, was removed. All spines were divided at the L1-L2 level, which resulted in a total of nine specimens (five thoracolumbar and four lumbar) that were used to create compression-type fractures. Magnetic resonance (MR) imaging (T1 and T2 weighted with a 0.5 Tesla scanner) was performed for prefracture assessment of the spine (T1). To confirm and classify the fractures that were created with the device, plain radiographs [anteroposterior (AP) and lateral] and MR images were obtained (T2). Subsequently, all fractures were treated, using the standard surgical procedure in our center, by short-segment posterior fixation and distraction using titanium pedicle screws and rods (BWM system, Stryker-Howmedica-Osteonics, Rutherford, NJ). Again, plain radiographs and MR images were obtained (T3).

**Direct Repositioning of Fractures Using Inflatable Bone Tamps**

As we previously demonstrated, posterior fixation after distraction is insufficient to prevent the redistribution of disc tissue after a compression-type fracture. Therefore, a transpedicular vertebroplasty in combination with inflatable bone tamps was performed. The principle of this procedure is that a direct restoration of the impressed vertebral body is performed followed by augmentation of the resulting vertebral body defect. First, to achieve a direct restoration, two inflatable bone tamps (Kyphon Inc., Sunnyvale, CA) were inserted simultaneously through the pedicles into the vertebral body, after piercing the pedicles with an orthopaedic awl. Frequent high-resolution fluoroscopy imaging was performed to monitor the introduction of the bone tamps and for visual feedback of possible displacement of loose bone fragments. The bone tamps were forwarded until final placement in the anterior third of the vertebral body, adjacent to the midline. Both bone tamps were inflated by forcing a radiopaque fluid into the balloons (Fig. 33–3A). The pressure generated to accomplish this expansion was monitored very carefully. After each milliliter of added volume, a fluoroscopic check was performed. It appeared not unusual to register a pressure drop in the bone tamps after expansion, which is explained by movement of bone fragments (actual restoration). Inflation of the balloons was continued until fluoro-
scopic reduction of the fracture or the occurrence of a restriction. Restrictive conditions included posterior displacement of bone fragments in the direction of the spinal canal, exceeding the maximum pressure rating of the bone tamp, or poor visualization of the operating field. After ascertainment of the best possible reduction, both balloons were actively deflated and the bone tamps were removed (Fig. 33–3B). At this moment, insufficient data are available to evaluate the extent of possible relapse of the vertebral body after deflation.

AUGMENTATION OF VERTEBRAL BODY DEFECT USING INJECTABLE CA-P CEMENT

To prevent a recurrent prolapse of the reduced fractured end plate(s) into the vertebral body, the void was filled using an injectable Ca-P bone cement (BoneSource, Stryker-Howmedica-Osteonics). The Ca-P was prepared after satisfactory reduction of the fracture had been achieved with the inflatable bone tamps. Dicalcium phosphate and tetracalcium phosphate in equimolar amounts were mixed with saline (3 mL saline added to 10 g of powder), forming hydroxyapatite:

\[
\text{CaHPO}_4 + \text{Ca}_4(\text{PO}_4)_2 \text{O} \rightarrow \text{Ca}_5(\text{PO}_4)_3 \text{OH}
\]

Reducing the powder/liquid ratio will produce a more fluid consistency, but this will affect the porosity of the end product, thereby compromising compressive strength. Care should be taken to keep the vertebral body as dry as possible before injection of the cement for the same reason. As shown above, the saline will dissolve the reactants and induce precipitation.\textsuperscript{25} The time for Ca-P to harden varies with conditions, including reactant particle size, powder/liquid ratio, and temperature but is approximately 20 minutes. Only a small amount of hydroxyapatite is formed at this point. Approximately 4 hours after preparation the reaction is completed with the formation of hydroxyapatite as the only end product.\textsuperscript{29}

In our cadaveric study, after mixing the powder and liquid components, the viscous cement was transferred into two 10 mL syringes with large (3 mm) nonflexible needles, which were then inserted into the vertebral body, through each pedicle. Fluoroscopic guidance was used to ensure proper positioning at the anterior third of the corpus adjacent to the midline. Injection of cement was continued until complete radiographic filling of the defect had been achieved or until the occurrence of an undesirable event. This included cement leakage outside the vertebral body, a buildup of pressure necessary to inject the cement, and poor visualization of the operating field. The needles were removed and final fluoroscopic imaging was performed (Fig. 33–3C). Subsequently, plain radiographs and MR images were obtained (T4).

QUALITATIVE AND QUANTITATIVE RADIOLOGICAL PROCEDURES

As mentioned previously, plain radiographs (AP and lateral) and MR images were made at T1 (before fracture), T2 (after fracture), T3 (after instrumentation with distraction and posterior fixation), and at T4 (after vertebroplasty with bone tamps and injection of Ca-P; Figs. 33–4A through D).

Using both the plain radiographs and the MR images, the fractures were classified according to the system described by Magerl et al.\textsuperscript{18} In addition, the plain radiographs were used for general overview and confirmation of the fractures, and to assess possible complications of the treatment (e.g., improper placement of pedicle screws, localization of Ca-P outside the vertebral body). The MR images were used particularly for quantitative assessment of changes in vertebral body and disc space morphology. First the
two central sagittal slices, at a 3 mm distance from
each other, were digitized. Subsequently, images
were analyzed using dedicated software (NIH Image
for Windows, Beta 4.0.2 Scion Corporation, Frederi-
ck, MD) by measuring the following parameters at
T1, T2, T3, and T4: Anterior bulging (AB) of the verte-
bral body, defined as the maximum length of the line
perpendicular to the line drawn from the anterior, in-
ferior margin of the adjacent cranial vertebral body
to the anterior, superior margin of the adjacent caud-
al vertebral body; posterior bulging (PB) of the ver-
tebral body, defined as the maximum length of the line
perpendicular to the line drawn from the poste-
rior, inferior margin of the adjacent cranial vertebral
body to the posterior, superior margin of the caudal
vertebral body; proximal end plate impression (PI),
defined as the largest depression measured perpen-
dicular to a line drawn from the anterior, superior
margin to the posterior, superior margin of the verte-
bral body; distal end plate impression (DI), defined
as the largest depression measured perpendicular to
a line drawn from the anterior, inferior margin to the
posterior, inferior margin of the vertebral body (see
Fig. 33–5 for a graphical explanation).

From the quantitative MRI data, AB, PB, PI, DI,
means, and standard errors were calculated for each
time point. Subsequently, we investigated whether
an effect of the vertebroplasty in combination with
inflatable bone tamps was found with respect to
these four parameters. Therefore, single tailed,
paired t-tests were performed comparing T3 and T4
with respect to a possible decrease of PI and DI and a
possible increase of AB and PB ($P \leq 0.05$).

**RESULTS**

A total of nine fractures were created of which eight
were classified as A3 fractures and one as A1 frac-
ture. All fractures were successfully stabilized using
the posterior pedicle screw and rod instrumentation.
The mean intravertebral volume of each bone tamp
after fluoroscopically satisfactory fracture reduction
was 3.3 mL (range 2 to 5.5 mL) at a mean pressure of
7.2 atm (range 4 to 14 atm). The amount of injected
Ca-P cement was between 6.0 and 12.1 g (mean 9.9 g;
mean powder-saline ratio of 2.6) to achieve a fluoro-
scopically complete filling of the defect. Neither radi-
ographically nor after macroscopic inspection of the
specimens was cement leakage outside the vertebral
body detected.

Data from the quantification of the MR images are
presented in Figures 33–6A through D. It is clear that
for all parameters the impact of the fracture, as repre-

**FIGURE 33–4**  (A) Prefracture magnetic resonance (MR) image of a thoracolumbar specimen, T1. (B) Postfracture MR
image of the same specimen, T2. (C) MR image after distraction and posterior stabilization, T3. (D) MR image after verte-
broplasty using inflatable bone tamps and Ca-P, T4.

**FIGURE 33–5**  Graphical explanation of the MRI para-
eters measured.
sent by the bars at T2 versus T1, had a major influence upon each of the four parameters. In Table 33–1, the results from the statistical analysis of the effect of the experimental procedure on each of the four parameters are presented. No significant displacement of the anterior and posterior walls could be detected, but as a result of the vertebroplasty with inflatable bone tamps a significant decrease in impression of both the proximal \( P \leq 0.025 \) and distal \( P \leq 0.05 \) end plates was measured. Individual judgment of the MRI data did not reveal displacement of bone fragments that could result in neurological damage (one specimen had a positive PB of 1.3 mm following the experimental procedure).

**DISCUSSION**

So far, various publications featuring clinical outcome of vertebroplasty procedures in patients suffering from symptomatic osteoporotic VCFs have been presented. From the number of patients treated and the results presented, it can be concluded that vertebroplasty is an efficient and relatively safe procedure, reflected by the large proportion of patients experiencing immediate and permanent pain relief and the low incidence of complications. For acute osteoporotic VCFs, kyphoplasty addresses most of the

**TABLE 33–1 RESULTS FROM SINGLE-TAILED T-TESTS ON EFFECT T3–T4**

<table>
<thead>
<tr>
<th>Difference</th>
<th>( T3–T4 ) (mm)</th>
<th>( P )-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI (proximal impression)</td>
<td>1.4</td>
<td>0.0157</td>
</tr>
<tr>
<td>DI (distal impression)</td>
<td>0.6</td>
<td>0.0326</td>
</tr>
<tr>
<td>AB (anterior bulging)</td>
<td>0.1</td>
<td>0.5884</td>
</tr>
<tr>
<td>PB (posterior bulging)</td>
<td>–0.1</td>
<td>0.3248</td>
</tr>
</tbody>
</table>

**FIGURE 33–6** Graphs showing (A) the mean proximal impression (PI in Fig. 33–5) for T1 to T4, and (B) the mean distal impression (DI in Fig. 33–5).
shortcomings of vertebroplasty such as the incapacity of correcting the spinal deformity and the need for high-pressure injection of cement. The first studies on the subject suggest the clinical results to be at least as good as for vertebroplasty, boasting the benefit of spinal deformity correction. The incidence and nature of the complications are comparable for vertebroplasty and kyphoplasty. The few severe acute complications (radicular pain and damage to the spinal cord) can possibly be attributed to the exothermal nature of the PMMA polymerization reaction. Both procedures have proven to be technically feasible, and clinical outcome after prolonged follow-up will probably also be determined by specific cement-bone interactions.

We described in a first in vitro study the use of Ca-P cement as a bone void filler for vertebroplasty in combination with inflatable bone tamps as an alternative to PMMA cement in traumatic spinal conditions. Ca-P cement has the potential property of being remodeled into bone over time, is biocompatible and osteoconductive, and does not present with thermal side effects during hardening. In the current study, we demonstrated that direct repositioning of the compressed vertebral body using inflatable bone tamps, followed by transpedicular injection of Ca-P cement, is feasible with respect to a decrease in both proximal and distal end plate impression. Based upon our previous studies on recurrent kyphosis (i.e., the result of a redistribution of disc material into the vertebral body due to end plate impression), this is considered to be an advantageous additional treatment to posterior reduction and fixation for traumatic VCFs. Although at this stage we report on only nine fractures, we did not find serious adverse effects with respect to possible anterior or posterior wall displacements or a false route of the cement during or after injection. Potential advantages of using Ca-P ce-
ment instead of PMMA cement include better biological compatibility and resorption characteristics, which are of particular importance for patients with a long life expectancy, and the absence of heat production during hardening of the cement. A deliberate choice for creating and treating type A fractures was made on the basis of the incidence of the condition and the morphological similarity to osteoporotic fractures. All fractures created were classified as type A (axial compression) fractures. In this type of fractures, the integrity of the posterior longitudinal ligament (PLL) may be a crucial factor for the risk of cement leakage into the vertebral canal. The PLL may be damaged more frequently in type B and C fractures. Additional studies need to be performed in which type B and C fractures, with an axial compression component, are to be created and treated according to the described procedure. Thus, additional cadaveric studies to increase the knowledge on feasibility and risk factors as well as in vivo biocompatibility studies for this particular location near the intervertebral disc are required. These subjects are currently under investigation at our center.

Notwithstanding the encouraging clinical results of vertebroplasty with PMMA, the exceedingly large and diverse population of potential patients with VCFs will prompt practitioners to continue to refine the treatment. Although osteoporosis is a disease primarily diagnosed in the elderly, they continue to live longer and lead more active lives that will, without doubt, result in more traumatic fractures in this group. The same holds true for the increasing group of young patients with iatrogenic osteoporosis induced by the long-term use of corticosteroids. In these instances a treatment directed at good, long-term clinical results is indicated.

**FUTURE DEVELOPMENTS**

To explore future directions for the treatment of traumatic and osteoporotic VCFs the various drawbacks and questions that emerge from the current practice have to be examined. Firstly, the described experimental procedure will have a limited application in traumatic fractures due to an assumed higher risk of cement leakage and posterior bulging in non-type A fractures. Thus more information needs to be obtained on this specific topic. Secondly, in those fractures where direct contact between bone substitute (PMMA cement or Ca-P) and the intervertebral disc is present, it will be necessary to obtain information on the long-term effect of these bone substitutes on the integrity of the intervertebral disc. This is, of course, of particular importance in those patients who will undergo this procedure at a relatively young age. Thirdly, the considerable exposure to X-rays for both the patient and medical staff due to the need for intensive intraoperative fluoroscopic monitoring will need attention in the future. In recent years, medical imaging has benefited greatly by the increase in computer processing power. Computer-assisted interventions promise a high accuracy and reproducibility in a variety of clinical applications. Vertebroplasty in combination with inflatable bone tamp, in which excellent visualization and accuracy is a prerequisite, is a potential procedure to perform in close conjunction with this new technique as soon as real-time intraoperative updating of the operating field, in a minimally invasive fashion, can be implemented in the hardware.

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The incidence of pathological vertebral fractures in the United States is approximately 700,000 per annum, 85% of which are associated with osteoporosis.1 The prevalence of osteoporosis of the lumbar spine in women aged 50 years or more is approximately 16% and, after correction for skeletal size, is similar for all ethnic groups.2 Osteoporotic fractures of the vertebrae have become increasingly recognized as a source of significant morbidity and mortality in an expanding elderly population.3

The clinical manifestations of osteoporotic vertebral collapse include pain, immobility, deformity (particularly in the sagittal plane), and rarely neurologic compromise. The negative emotional impact of vertebral fractures is more difficult to quantify but may be even more important determinant of reduced quality of life.4 Traditional wisdom has declared that approximately two thirds of vertebral fractures are not symptomatic; however, this may have been underestimated. One study showed that 84% of patients with radiographically evident vertebral fracture reported associated back pain.1

The morbidity associated with osteoporotic fractures in general is considerable and it is estimated that 6.7% of women are rendered dependent in the basic activities of daily living because of osteoporotic fracture during their lifetimes.5 The association between hip fracture and decreased survival is now well established. Up to 20% of patients die in the year following hip fracture, representing a 5 to 20% reduction in expected survival.6 Recent studies indicate that vertebral fractures may also adversely affect survival. Clinically evident osteoporotic compression fractures were shown to be associated with a 15% age-adjusted increase in mortality not associated with clinically evident osteoporotic distal radial fractures.1 Kado et al7 prospectively studied 9575 women aged 65 years or more for a mean follow-up period of 8.3 years. Twenty percent of women were found to have one or more vertebral fractures. Compared to women who did not have fractures, these women had a 23% increase in age-adjusted mortality. The mortality risk was even greater (34%) for the 13.1% of women with severe fractures.

Conventional treatment of osteoporotic vertebral collapse fractures has been almost exclusively nonoperative. Bed rest, analgesia, nonsteroidal anti-inflammatory agents, and physical therapy with external bracing have been the mainstays of treatment. Operative reconstruction of the spinal column has traditionally been reserved for actual or impending neurological compromise and in the elderly population carries significant perioperative risk. Despite this conservative approach, or perhaps because of it, vertebral fractures in patients aged 65 years or older account for 150,000 hospital admissions in the United States each year.

The monetary cost of treating osteoporotic fractures is enormous and is likely to increase with increased longevity of the population. The number of people in the United States aged 65 or more is expected to more than double from 32 million in 1990 to 69 million in 2050, and those aged 85 years or more are expected to increase fivefold from 3 million to 15 million.2 Direct medical expenses for osteoporotic fractures alone were estimated at $13.8 billion in 1995.8 Most of this (63%) was for treatment of hip fractures, although vertebral fractures accounted for only 5%. Any changes in treatment of vertebral fractures, particularly the use of new minimally invasive reconstruction techniques, are likely to have considerable cost implications.

Osteoporotic vertebral fractures in addition to being a source of considerable distress to the individual patient may signify decrease survival, and this presents a challenging public health issue for the future. The purpose of this article is to review some of the newer, minimally invasive surgical tech-
niques that have evolved for treatment of this condition.

**SURGICAL TECHNIQUES**

The terms *vertebroplasty* and *kyphoplasty* refer to percutaneous structural reinforcement of the vertebral body using polymethylmethacrylate acrylic cement (PMMA). This technique was initially pioneered in France by Galibert and colleagues9 over a decade ago for the treatment of vertebral hemangioma. Over the past 13 years the indications have been expanded to include metastatic disease of the spine and osteoporotic vertebral collapse. The procedure was first performed in the United States for osteoporotic vertebral fracture in 1995.10 Despite a small number of studies in the literature and the lack of prospective randomized trials, this procedure has gained increasing acceptance, particularly as a palliative measure in metastatic disease of the spine. One of the reasons for this has been the universal experience of prompt relief of pain in approximately 90% of patients treated using this method.9,11–14

Percutaneous vertebroplasty can be performed under general anesthesia, diazananalgesia (midazolam and fentanyl combined with local anesthesia), or local anesthesia.11 Prophylactic antibiotics are used in some centers but not universally.14 The percutaneous approach to the thoracic spine may be transpedicular or extrapedicular. The transpedicular approach is safe as long as the wall of the pedicle is not violated and in general is preferred if the diameter of the pedicle is large enough to accommodate the instruments. This approach minimizes the risks of cement tracking back along the path of the needle and, in the thoracic spine, minimizes the risk of pneumothorax. An extrapedicular approach may be used if the pedicles are too narrow or cannot be cannulated for whatever reason. This can result in pneumothorax or leakage of cement along the needle track, which potentially could injure the nerve root exiting the foramen below. The transpedicular approach is essential in the lumbar spine to minimize the risk of cement tracking back around the exiting nerve roots.

The patient is positioned prone on the operating table, which should incorporate a radiolucent spinal frame. High-quality biplanar imaging using fluoroscopy alone or a combination of fluoroscopy and computed tomography (CT) is essential. The pedicles are identified and an 11-gauge needle is introduced into the vertebral body using one of the approaches described. A spinal biopsy may be performed at this time using a trephine if required. Contrast medium is then injected into the vertebral body. This gives some indication of the local anatomy and venous drainage; however, it does not necessarily predict the casting of the cement, which has a different viscosity. The needle is advanced under fluoroscopic guidance to the anteroinferior border of the vertebral body to be treated. The cement, which must have been previously brought to room temperature, is then prepared. The cement is supplied as a liquid monomer and cement powder containing some polymer and must be mixed in sterile conditions. An agent to increase the radiodensity of the cement (such as tantalum powder) is added at the mixing stage. Once the cement has reached the consistency of a thin paste, it is loaded into 2 or 3 mL Luer-Lok syringes. The cement is allowed to solidify until it is just at the point where it can still be injected and is then injected under strict lateral fluoroscopy. The more viscous the cement, the less likely it is to migrate in an uncontrolled fashion. Injection is stopped immediately if cement encroaches on the posterior vertebral wall or is seen to migrate outside of the confines of the vertebral body.

After vertebral filling, the stylet of the needle is reinserted and the needle slightly withdrawn to the cortical wall of the vertebra. Careful attention to the position of the needle during curing of the cement is essential to prevent fixation of the needle and rendering subsequent removal difficult. If 50% or less of the vertebral body has filled with cement, the procedure can be repeated on the opposite side. In general, a total of 2 to 6 mL of cement is injected at each level.

The technique described above does not attempt to restore vertebral body height and thus correct the kyphotic deformity of vertebral collapse. This, at least in theory, may have pain implications from persisting deformity or abnormal biomechanical loading at adjacent levels. A procedure known as *kyphoplasty* has evolved to address this issue. This technique involves cannulation of the vertebral body using the trans- or extrapedicular approaches described above and insertion of an inflatable balloon tamp into the

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**FIGURE 34-1** Balloons are inflated simultaneously under fluoroscopic guidance.
center of the collapsed vertebral body (Fig. 34–1). The balloon is then inflated using a device (Fig. 34–2) that delivers a controlled volume of radiopaque liquid (Figs. 34–3A through D). Inflation pressure is constantly monitored as inflation of the balloon is visualized on fluoroscopy. The object of this technique is to impact cancellous bone circumferentially around the tamp, exerting forces on the end plates above and below and thus reducing the deformity. Packing cancellous bone against an intact posterior vertebral wall should also decrease the likelihood of cement leakage into the spinal canal. The bone tamp is then deflated and removed. The central defect is then filled with PMMA cement (Figs. 34–4, 34–5, 34–6). Filling of this defect should require less force than necessary for vertebroplasty, as the defect will offer no resistance to the insertion of cement.

The total duration of the procedure depends on the number of levels treated, the quality of the imaging, and the experience of the physicians and usually does not exceed 2 hours (Figs. 34–7, 34–8, 34–9). Postoperatively, patients can mobilize out of bed as tolerated and are usually prescribed a nonsteroidal anti-inflammatory agent for a short time. Patients are usually discharged from hospital within 48 hours.

**BIOMECHANICAL CONSIDERATIONS**

PMMA has been used extensively in spinal reconstruction for tumor or trauma since the 1950s. Several studies have shown that mechanical integrity of the cement is maintained in the long term when cement is loaded in compression. The forces on cement within the vertebral body are predominantly compressive in nature. While use of PMMA in osteoporotic patients is not strictly comparable to its use in the tumor population, the majority of whom are young adults with normal bone density, there is no reason to believe that osteoporotic bone cannot be successfully augmented with PMMA. Cemented
total hip replacements fail at a lower rate in osteoporotic patients than in any other subgroup.17 Nevertheless, long-term follow-up of its use specifically in the osteoporotic spine is required to establish resistance to mechanical failure and any effects on adjacent vertebrae.

Polymerization of PMMA is an exothermic reaction resulting in temperatures as high as 70 to 80°C at the cement surface as the cement cures in air. The temperature reached depends on the amount and rate of heat production and the rate of heat dissipation. Potentially harmful sequelae of this thermal property of cement, given the proximity of nervous tissue in the event of a cement leak, are one of the main concerns with this technique. It has been established that the heat generated by the polymerization process is proportional to the size of the cement block. Thermal necrosis of bone occurs when it is exposed to temperatures in excess of 50°C for more than 1 minute. Injury to sensory nerves has been reported at 45°C with exposure in excess of 30 minutes. The thermal effects of vertebroplasty using PMMA have not been studied in vivo and few in vitro studies are available. Deramond et al18 found that the temperature recorded in the spinal canal did not exceed 41°C following injection of 10 mL of cement into cadaveric vertebral bodies. Temperatures in excess of 50°C were recorded at the center of the cement mass. The authors concluded that the spinal cord and nerve roots are not at risk from this procedure. Extrapolation of these results to the clinical situation is difficult. This experiment did not attempt to simulate leakage of cement around the neural elements. The cerebrospinal fluid surrounding the neural elements will dissipate some heat and provide some protection, but how much? Further in vivo studies are necessary to assess potential injury to neural elements following direct application of polymerizing cement to the dura, as may occur in the event of a cement leak.

**Efficacy**

Relief of debilitating back pain is the primary treatment goal in patients with osteoporotic vertebral collapse. In this respect the results of vertebroplasty have been quite dramatic. Several authors have reported significant improvement or complete relief of pain in 80 to 90% of patients following vertebroplasty for tumor or osteoporotic vertebral fracture.11,14,19,20,21

Symptomatic relief of pain is usually evident within 24 hours of the procedure, although there may be a transient worsening of the pain. Cotten et al19 reported partial or complete pain relief in 36 of 37 patients with metastases or myeloma within 6 to 72 (mean 36) hours. Pain relief was not proportional to percentage filling of the lesion with cement. Martin et al21 reported complete pain relief in seven of nine patients with osteoporosis following vertebroplasty. Analgesic medication was stopped in all but one pa-
tient and all patients reported recovery of mobility. In a prospective study of 16 patients with osteoporotic fractures, a mean decrease in pain of 53% was recorded on a visual analog scale 3 days following vertebroplasty. Jensen et al reported improvement in pain and mobility in 90% of 29 patients with osteoporotic compression fractures refractory to analgesic therapy. Pain relief appears to be sustained over time although the follow-up time in most studies is less than 2 years and the longest reported follow-up is 3 years.

The adequacy of the tools used for outcome measurement is critically important in the evaluation of this new technique. Pain relief measured on a visual analog scale may be the simplest and perhaps the most important outcome measure; however, this does not address the more obscure parameters of functional outcome or improvement in general health and well-being. Cortet et al used the Nottingham Health Profile to assess changes in quality of life following treatment. The utility of this instrument has already been demonstrated in spinal osteoporosis. A significant improvement was found in scores for four of the six dimensions measured (pain, physical mobility, emotional reaction, and energy). Augmentation of the vertebral body with cement has also been found to prevent further collapse. Lieberman reported on his first 70 patients undergoing kyphoplasty. Seventy percent of fractures underwent with 47% (mean) restoration of height. By SF-36...
score, bodily pain and physical function were significantly improved. Only 8.6% of vertebral had cement leakage.22

The mechanism of pain relief following vertebroplasty is obscure. A number of mechanisms have been suggested:

1. Stabilization of the vertebral body by immobilization of microfractures
2. Destruction of sensitive nerve endings by the thermal effect of the curing cement
3. Load sharing by the cement, reducing transmission of load by the bone23

In the small number of studies of patients with osteoporotic vertebral fracture, vertebroplasty was generally performed in patients who failed to respond to more conservative measures and was usually performed 3 months or more following fracture. At this stage one would expect the fracture to be stable if not healed, suggesting that the denervation theory may be the most plausible. It is particularly important to resolve this issue and identify the relative therapeutic contributions of mechanical stabilization and denervation respectively, if new products without the exothermic effects of PMMA are to be developed for this application. Percutaneous stabilization of the vertebral body using agents that do not have thermal effects is an attractive concept, since it avoids potential complications associated with the exothermic effect. The usefulness of these agents will obviously be limited if the thermal effect is in fact the therapeutic one.

### Complications

Complications related to percutaneous augmentation of the vertebral body using acrylic cement have in general been associated with the surgical approach or migration of cement. General medical complications of this minimally invasive technique have been few and are certainly much less than the morbidity and mortality associated with open spinal surgery.

Complications of vertebroplasty for any indication include transient increase in pain, pulmonary embolism, fat embolism, pneumothorax, and neurological injury.10,19 Uncontrolled migration of the cement into the spinal canal is the main safety concern using this technique. Posterior defects in the vertebral body may be missed on axial CT and routine radiographs. Deramond et al11 estimated that 50% of their patients

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**FIGURE 34-8** T1/T2-weighted MRI showing bone marrow edema at L1, L2, and L3 demonstrating acute vertebral body fracture.

**FIGURE 34-9** T1, L1, L2, and L3 kyphoplasties performed under same anesthesia.
treated with vertebroplasty had some degree of posterior wall destruction. The group did not consider this an absolute contraindication to vertebroplasty, but proceeded as deemed appropriate following multidisciplinary discussion.

Leakage of cement outside of the margins of the vertebral body is common during vertebroplasty for tumor as might be expected due to the high likelihood of vertebral body defects in these patients. Cotton et al reported cement leakage in 72% of patients with osteolytic metastases or myeloma, with leakage into the spinal canal or foramina in more than half the cases. Two of eight foraminal leaks required surgical nerve root decompression. The incidence of cement leakage outside the vertebral body during vertebroplasty for osteoporotic vertebral fracture is also high. Cortet et al reported leakage of cement in 65% of cases. In this series, leakage into the peridural space was found in only 3 of 16 patients (18%) and there were no neurological sequelae.

Postoperative paralysis has not been reported following vertebroplasty for osteoporotic vertebral fracture, but paralysis following leakage of cement into the spinal canal has been reported during surgery for metastatic tumor. In one case, cement was injected through an anterior drill hole in a vertebral body, which had an unrecognized posterior defect allowing cement to flow into the spinal canal. The patient’s neurological status deteriorated from Frankel grade D preoperatively to grade B postoperatively. Deramond et al reported spinal cord compression following vertebroplasty in one patient with tumor invading the epidural space. The patient was operated on immediately and recovered from his neurologic deficit. Radiculopathy following leakage of cement through fractures, venous channels, or the needle track into the intervertebral foramen is more common (4 to 20%). Overall the complication rate has been estimated at 6% for vertebroplasties.

Postoperative paralysis has not been reported following vertebroplasty or kyphoplasty for osteoporotic vertebral fracture, but paralysis following leakage of cement into the spinal canal has been reported during surgery for metastatic tumor. In one case, cement was injected through an anterior drill hole in a vertebral body, which had an unrecognized posterior defect allowing cement to flow into the spinal canal. The patient’s neurological status deteriorated from Frankel grade D preoperatively to grade B postoperatively. Deramond et al reported spinal cord compression following vertebroplasty in one patient with tumor invading the epidural space. The patient was operated on immediately and recovered from his neurologic deficit. Radiculopathy following leakage of cement into the spinal canal has been reported during surgery for metastatic tumor.

While most cement leaks have no apparent detrimental effects, the potential for neurological injury is obviously cause for concern. These procedures should only be undertaken under optimal conditions including adequate preoperative imaging to identify any defects in the vertebral body. Injection of cement must be stopped if leakage is seen on biplanar imaging during the procedure. Several authors have recommended that a spinal surgeon should be available during the procedure in the event that emergency spinal decompression is necessary.

### Future Directions

Minimally invasive surgical technology for the treatment of vertebral fracture is still in its infancy. Research in this area should be directed toward improvements in the safety and accuracy of the surgical technique, together with developing alternatives to PMMA that are biocompatible, biodegradable, and similar in crystalline structure to bone. Image-guided surgical navigation systems should improve the accuracy of needle placement and reduce the necessary radiation dose. Exciting advances in the development of calcium-phosphate bone substitutes have resulted in products that are injectable, biocompatible, and biodegradable, without the exothermic effects of PMMA. The rate of new bone formation and bone remodeling of these agents has shown some variability in animal models, and the long-term mechanical integrity of these agents will need to be established.

### Summary

The indications for vertebroplasty or kyphoplasty in osteoporotic vertebral fracture are still evolving (Table 34–1). Most symptomatic patients respond to analgesic therapy and rehabilitation, and to date these procedures have been reserved for patients whose symptoms have been refractory to these measures. A multidisciplinary approach to the treatment of the osteoporotic spine is essential to afford patients maximum benefit with minimal invasion. Minimally invasive surgery should be considered as one of several modalities for treatment of this condition and used judiciously until long-term results become available.

### References


THE PROBLEM

ANTERIOR PLATE SYSTEMS

The anterior cervical plate screw was developed to give a more direct fixation method and to overcome progressive posterior protruding deformity, instability, and graft dislodgment in the treatment of various conditions of the cervical spine.1–3 There are two main types of designs: nonconstrained (such as Orozco plates by Synthes, Paoli, PA) and constrained or locked systems (such as Orion system by Sofamor Denek USA, and AO titanium cervical spine locking plate [CSLP] by Synthes).4,5 Constrained or locking systems significantly increased the rigidity of the tested screw plate systems both initially and after cyclic loading.6 Based on screw purchase, there are unicortical or bicortical screws. The bicortical screws (such as Caspar system, or AcroMed system, Cleveland, OH) have more holding power than that of unicortical screws.6 The failure rates are also affected significantly by the length of the segment needing fixation. For example, the failure rates of two-level fixation were lower than that of three- (or more) level fixation.7

For most anterior fixation systems, screws are fixed in the vertebral bodies, which consist of mainly cancellous bone with very thin cortex, so the holding power is not great and the potential exists for loosening of the screw. Morscher et al4 created the AO titanium hollow screw-plate system, which gave good immobilization between screw and plate or screw and vertebral body. Constrained systems, such as Morscher’s CSLP system, prevent motion at the junction between the screw and plate.4,8 However, they do not increase holding power between screws and bone. With bicortical screw systems, such Caspar or AcroMed, screws are inserted through both anterior and posterior vertebral cortices, so the holding power of the screw is much higher but possible spinal cord injury remains as a major concern. Again, hardware failure in this kind of system is not uncommon. Paramore et al9 reported that 11 of 49 patients treated with Caspar plating suffered hardware failure, defined as any amount of screw backout or breakage, plate pullout, or pseudoarthrosis. These authors also concluded that Caspar plate failures are more likely to occur in the elderly and in patients who need longer constructs.

Most reports on new systems have relative low failure rates,8,10–12 probably due to the short follow-up periods as stressed by Lowery and McDonough.5 There have been some longer-term reports on the high failure rate of anterior spinal fixation using the

<table>
<thead>
<tr>
<th>TABLE 35–1</th>
<th>FAILURE RATES OF SELECTED REPORTS ON ANTERIOR FIXATION SYSTEMS FOR CERVICAL SPINE</th>
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</thead>
<tbody>
<tr>
<td>System</td>
<td>Cases (Failure)</td>
</tr>
<tr>
<td>Nonconstrained</td>
<td>Orozco</td>
</tr>
<tr>
<td></td>
<td>Orozco</td>
</tr>
<tr>
<td>Constrained</td>
<td>CSLP*</td>
</tr>
<tr>
<td></td>
<td>Orion</td>
</tr>
</tbody>
</table>

*CSLP, cervical spine locking plate.
above-mentioned methods. Common modes of failure include broken and loosened screws or plates. The hardware failure rate reported by Lowery and McDonough was as high as 35% (44% of the nonconstrained and 18% of the constrained or locked systems) (Table 35–1).

**POSTERIOR PEDICLE SCREWS**

For more powerful fixation, pedicle screws have been used through a posterior approach, which has become increasingly popular in recent years. It is a technically challenging procedure although several reports have shown promise. The insertion of pedicle screws is associated with a relatively high complication risk and its success strongly depends on the experience of the surgeon. Incorrectly drilled holes or malplacement of the screws can result in nerve root injuries and fracture of the pedicle. A cadaver study using two screw insertion techniques demonstrated a high percentage of screws violating the pedicle despite creation of a laminotomy “window” to directly determine the superior, medial, and interior borders of the pedicle. A “blind” technique, using only bony topographical landmarks and a predetermined 30-degree medial and 20-degree superior trajectory, was associated with a violation rate of 47% (Table 35–2). The “window” technique reduced the violation rate to 25%. In a recent similar article, the critical breach rate using three methods (i.e. surface landmarks, laminoforaminotomy, and computer-assisted guide system) were 66, 40, and 11% respectively.

Clinically, studies have reported high complication rates with substantial neurological implications after posterior pedicle screw fixation. According to Esses et al, the overall rate of complication in their 617 cases was 27%. They also found that the rate was significantly higher in patients with previous spine surgery (45%). In addition, data from the thoracolumbar pedicle screw literature may help to predict the potential high complication rates of cervical pedicle screw procedures. Matsuzaki et al found that of 57 patients who received lumbar pedicle screw fixation, 20% had neurologic problems postoperatively and 3.5% had severe sensory impairment. It is known that when a critical breach happened, no matter which surgical technique was used the vertebral artery was likely to be injured in 73%, whereas the exiting nerve root was likely to be injured in 41%.

**LATERAL MASS SCREWS**

Lateral mass screws (or transverse process screws) in conjunction with plates have been used for posterior cervical spine fixation. One advantage is they do not cause as much neurovascular injury as pedicle screws. Bicortical lateral mass screws are less likely to loosen than unicortical screws. However, the holding power of these screws is not as great as that of pedicle screws and the procedure is not without complications, such as screw loosening, plate breakage, nonunion, and neurovascular injury.

**THE HYPOTHESIS**

Based on the brief literature review, the problems are obvious, including the relatively low screw holding power of most anterior plating systems and the high rates of pedicular violations for posterior pedicle screw systems. Where do we go from here? Most clinical cervical spine conditions originate from the instability of the anterior portion of the spinal column, including congenital conditions, neoplasms, and fractures of vertebral bodies or degenerative changes of vertebral bodies and discs. Biomechanically, a stable anterior fixation should be superior to posterior fixation. Another major improvement could be increasing screw holding power. If unicortical and bicortical screws are believed not to be strong enough, what could be stronger? The hope may lie in a well-designed pedicular screw system inserted through an anterior approach. Our hypothesis is that a newly designed pedicle screw can be inserted by an anterior approach, first through the vertebral body and then anchored in the pedicle.

Although the concept of an anterior pedicle screw is not novel, there has been no report on the design and use of anterior pedicle screw for cervical spine fixation. For thoracic and lumbar fixation, Hertlein et al inserted a pedicle screw through an anterior approach without a mechanical guide and achieved an accuracy of 81%, and the technique was also successfully used in a patient suffering from a

**TABLE 35–2 VIOLATION RATES OF SELECTED REPORTS ON EXPERIMENTAL PEDICLE SCREW INSERTION IN CERVICAL SPINE**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Violation Rate (%)</th>
<th>First Author, Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Blind” technique</td>
<td>47</td>
<td>Miller, 1996</td>
</tr>
<tr>
<td></td>
<td>66</td>
<td>Ludwig, 2000</td>
</tr>
<tr>
<td>“Window” technique</td>
<td>25</td>
<td>Miller, 1996</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>Ludwig, 2000</td>
</tr>
<tr>
<td>Computer-assisted</td>
<td>11</td>
<td>Ludwig, 2000</td>
</tr>
</tbody>
</table>

*aBlind* technique: using only bony topographical landmarks.  
*bWindow* technique: creation of a laminotomy “window” to directly determine the superior, medial, and interior borders of the pedicle.  
*cComputer-assisted: computer-assisted image-guided procedure.*
lumbar vertebral metastasis. Marchesi et al. tested anterior insertion of pedicle screws using a direction finder (a mechanical guide). They stated that the anterior transpedicular screw technique appeared relatively safe (88% success rate) and encouraged the development of the new plate system for anterior spinal stabilization. Our concern is the 12 to 19% inaccuracy rate. What we want is 100% precision. How can we achieve this? The answer may be, as in our design, a mechanical guide and a self-directing screw.

**The New Screw**

In our search for a secure method of anterior fixation and to conquer the high cortical violation rate of the existing posterior pedicle screws, a self-guided transpedicular screw (or anterior pedicle screw) was designed specifically for cervical spine fixation. Radiographs of low cervical spine were used to measure the parameters needed for designing the screw and the drill guide. The screw was tested in cadaver bone for accuracy.

**The Screw**

The screw consists of three parts: head, neck, body, and tail (Fig. 35–1). The dull round head and the flexible neck can guide the advance of the screw itself in the correct direction within the pedicle. The diameter of the head is less than the threaded outer diameter of the screw body. The head’s surface is glossy, and it is somewhat ovoid in shape. The flexible neck is thinner than the head and the body. The body portion is threaded. The tail is notched for a screwdriver. Without counting the 1.5 to 2.0 mm tail, the length of the screw ranges from 20 to 29 mm. The diameter of the head is 1.9 to 2.5 mm and the length is 2.5 to 3 mm. The diameter of the neck is 1.5 mm and the length is 2.5 to 4.5 mm (for use in vertebral bodies of different sizes). The outer diameter of the screw body is 3 mm. The diameter of the tail is 4.5 to 5 mm.

**Measurements of Vertebral Body Dimensions and Insertion Angle**

To test the effectiveness of a new pedicle screw for anterior transpedicular fixation, 50 sets of flexion lateral view radiographs (26 males and 24 females, average age 38 years, range 19 to 71 years) and 42 sets of axial radiographs were examined for the axial direction (angle) of the pedicle, the internal and external height and width of the narrowest portion of the pedicle, the distance from screw insertion point to anterior central line, and the distance from the screw insertion point to the posterolateral cortex of the lamina (Fig. 35–2). The angle of the mechanical guide for the pilot hole is based on the axial direction (angle) of the pedicle. This angle was called the best estimated guide angle (BEGA) (angle $\alpha$ in Fig. 35–3).

**Screw Insertion**

Sixty new screws were driven into the 60 pedicles of 30 vertebrae of the lower cervical spine (C3 to C7) using a specially designed guide (Fig. 35–3). The angle of the guide for the pilot hole is based on the axial direction (angle) of the pedicle, a lateral angulation of about 35 degrees, which is the same as the suggested medial angulation for posterior insertion of conventional pedicle screws. From the X-ray measurements, it was found that there was not a best angle that would fit all the angles of the pedicular axis at different levels. However, because of its self-guiding characteristics (dull head and flexible neck), the screw can automatically orient its track along the axial line of the pedicle. As shown in Figure 35–3, three shallow holes are drilled first for anchoring the guide. With the guide in place (basically perpendicular to the anterior surface of the vertebral body), the pilot hole for one pedicle is created using a smooth-pointed pin (probe). Then the guide for the other side...
is used for making the pilot hole toward the other pedicle. After the pilot holes are made, the screws are inserted using a screwdriver.

**EXPERIMENTAL RESULTS AND DISCUSSION**

According to the X-ray evaluation, the BEGA (or $\alpha$ angle) for the lower cervical vertebrae (C3 through C7) is 35 degrees lateral angulation. The axis of the pedicle is basically vertical to the anterior surface of the vertebral body. Therefore, the guides for the initial pilot holes are made with a flat surface that will be in contact with the anterior vertebral surface. The level of the starting point of the pilot hole is estimated to be 1.5 to 2 mm below the anterosuperior edge or border of the vertebral body.

The results showed that 57 screws (95%) were successfully inserted through the pedicles of the cadaver vertebrae (Figs. 35–4A through E). With the use of the pilot hole guide, even if a screw is not well lined up with the pedicle axis, it can still advance accurately within the pedicle because of the bending of its neck (Figs. 35–4D, 35–5, and 35–6). The mechanism is simple. When the screw head hits the central axis of the pedicle, it will continue to advance without bending its neck. If the pilot hole is deviated several degrees away from the central axis, the head of the screw will be forced to slide into the canal of the pedicle, which may cause angulation of the screw neck.

Only three screw insertions failed. All of these were because of sclerotic changes of the pedicle,
which virtually closed the pedicle in the path of the screws. A similar finding was observed in a recent experiment for testing a new lumbar pedicle screw based on the same principle (Fig. 35–7). This is a potential problem using this new screw design. Therefore, detailed preclinical preparation, including CT.

FIGURE 35–4  Radiographic images of cervical vertebral bodies inserted with the new pedicle screw.

FIGURE 35–5  The insertion mechanism of the new pedicle screw.

FIGURE 35–6  Radiographic image showing the successful positioning of anterior pedicle screws in a lumbar vertebral body (L2). Bending of the screw neck is evident.
scan at the pedicle level, is critical. Current research is aimed to solve this problem by using a specific method of instrumentation.

**POTENTIALS AND FUTURE DEVELOPMENT**

The new self-guided pedicle screw can be accurately driven into cervical pedicles through an anterior approach. During the initial stage of experimentation, 57 screws were successfully inserted into 57 pedicles without the assistance of computerized imaging. There was no pedicle violation found in the experiment. The accuracy of the procedure is 100%. Therefore, the data strongly indicates further investigation in fresh cadaveric bone.

The new screw will be used in conjunction with a plate, rod, or cable, which is currently in the design stage in our laboratories. The screw could also be used to fix a spinal fusion cage in place. The devices we are currently working on include an anterior plate and a fusion cage for fixation in cervical spine. With its unique design, the new screw could also be used through a posterior approach and as a pedicle screw for fixation in thoracic and lumbar spine, a method that is also in development in Dr. An’s laboratories (Figs. 35–6 and 35–7).

This is no doubt an innovative screw design that would have many potential uses. The ultimate development of this novel device could lead to revolutionary changes in spine instrumentation.

**REFERENCES**


There are 8 million Americans with osteoporosis in whom 1.5 million fractures are diagnosed each year. Of these, 750,000 occur in the spine. Though most common in postmenopausal women, vertebral compression fractures occur in both sexes, every age group, and all races. The risk of fracture for a reduction in bone density of one standard deviation is 10% and is twofold for every reduction in standard deviation beyond. The cost of osteoporosis is great: $14 billion in 1995 alone. Most cases arise in the elderly. Other risk factors include positive family history, poor diet, immobilization, alcohol use, smoking, caffeine, use of anticonvulsants or methotrexate, hyperthyroidism, elevated glucocorticoids or steroid use, neoplasm, chronic inflammatory disease, and poor nutrition. Other causes of bone softening should be ruled out, such as osteogenesis imperfecta, osteomalacia, rickets, osteitis fibrosa, and Paget’s disease. Patients present most commonly with back pain, usually of a nonradicular nature. Most cases of osteoporotic fracture are treated with bracing and pain control, but patients with progressive deformity, instability, or loss of alignment may be candidates for vertebroplasty or surgery. Endoscopic or percutaneous vertebroplasty (the injection or instilling of polymethylmethacrylate or other bone substitutes into the vertebra) is a reasonable treatment for preventing further collapse of one or several vertebrae and in some instances for reestablishing vertebral height. However, there are real risks of vertebroplasty, including extrusion of compound with epidural compression of the spinal cord or nerve roots, systemic embolization of particles and consequent death, immune reaction to the injected compound, and infection.

When stability, severe pain, or neurological deficit is an issue and when the patient is deemed a reasonable surgical risk, then more definitive surgical treatment should be considered. Posterior stabilization and fusion is appropriate in many cases of instability or severe intractable pain. However, anterior column instability with progressive kyphosis, loss of vertebral height and alignment, ventral compression, or impending compression of the spinal cord or nerve roots might best be treated anteriorly, and vertebrectomy may be the treatment of choice.

Similarly, vertebrectomy and anterior column stabilization is often the treatment of choice for metastatic disease of the spine. Metastatic disease of the spine is common; the spine is the most common site for osseous for metastatic deposits, with 5 to 10% of all cancer patients ultimately developing epidural disease. While most patients are treated with palliative radiation and steroids, those with intractable pain, instability, and neuraxial compression are suitable candidates for tumor resection and stabilization. Vertebrectomy from an anterior approach is most often preferred as 85% of metastatic disease arises ventral to the spinal cord in the vertebral body. Other indications for surgery include recurrence of tumor after radiation and chemotherapy, patients with solitary lesions where resection may be curative, and patients in which open biopsy is required.

There are four major problems encountered with most anterior stabilization devices, particularly when treating soft or osteoporotic bone. First, the “piston effect” or subsidence of the graft or device into the adjacent vertebra, which causes loss of vertebral height. There may be loss of alignment with increased kyphosis, and often persistent pain from microinstability; secondly, the inability to provide inline distraction to safely accomplish reduction of fracture and kyphosis; thirdly, the inability of the construct to engage and incorporate the strongest parts of the vertebra; fourthly, the inability to place the instrumentation in regions difficult to access, such as the cervicothoracic junction and the upper cervical spine.
This chapter will discuss the telescopic plate spacer (TPS). The TPS provides in-line distraction to restore vertebral height and alignment and increases stability and fusion through integration of constrained screws, flanges, and large spacer surface area. The TPS is approved by the Food and Drug Administration for use from C3 to T2 in patients with metastatic disease. This chapter is broken into three parts: biomechanical theory underlying the design of the TPS, particularly as it applies to use in potentially soft bone, biomechanical and animal testing, and finally the early clinical experience with the TPS, including four different anatomical approaches to the high cervical and cervicothoracic spine for treatment of neoplastic disease. A brief preview of the thoracolumbar TPS device, which is currently undergoing preclinical testing, is appended.

**BIOMECHANICAL THEORY UNDERLYING THE TELESCOPIC PLATE SPACER**

Instrumentation failure occurs commonly in poor-quality bone in consequence to screw pullout, subsidence of construct, and graft failure. Successful fracture reduction, stabilization, and fusion require a strategy that enjoins natural anatomical features into a rigid, load-sharing construct. Four design features of the TPS (Figs. 36–1A,B) exploit the natural anatomical and biomechanical features of the spine, which are permissive to reconstruction of poor-quality bone.

The first anatomic feature availing itself to construction is the ventral anterior edge of the vertebra (the “ventral lip” of the vertebra). While the soft cancellous core of the vertebra is incapable of resisting pistoning of a device or fusion substrate, the ventral lip of the vertebral body, hardened through Wolff’s Law, provides an excellent platform for reconstruction. The “boundary effect” of Benzel refers to the ability of the edge of the vertebra to carry a greater load than the softer centrum. To avoid pistoning of spacer or graft into osteoporotic bone, the surgeon therefore must incorporate the “boundary” into the construction. The fully integrated flanges of the TPS maintain the position of the spacer at the edge of the vertebral body (Fig. 36–1A) to utilize the boundary effect. The flanges are furthermore load bearing and anatomically contoured to minimize translational movement.

A second anatomical feature, the slope of the end plate of the vertebra above, lends itself to bracing the upper end of the graft or spacer. The ventral lip of the vertebra above, which in part covers the disc space, is too often resected by the surgeon to create an inter-space that is more perpendicular to the spine; removing this ventral lip permits the surgeon to more easily place the graft or implant. However, the sloped upper surface of the TPS accommodates this natural feature as a brace to avoid kick out (Fig. 36–1A). The cephalad surface of the TPS device, angled at 15 degrees, conforms to the diagonal slope of the vertebral end plate above. With distraction, this bevel locks the device in place behind the vertebra above, providing the “bracing effect.”

A third feature is the relationship of the screws (angled at 45 degrees) to the instantaneous axis of rotation (IAR). The IAR is the axis perpendicular to the plane of motion and passing through a point that does not move for a given motion at a given instant. The IAR, or the point around which the vertebra rotates in flexion and extension, lies toward the ventral inferior aspect of the vertebra. Altering the rigidity of any spinal motion segment results in a change in

**FIGURE 36–1** (A) The fully integrated flanges of the TPS maintain the position of the spacer at the edge of the vertebral body to utilize the boundary effect. Translational movement is minimized by the flanges. In addition, the upward bevel and flange create a “bracing effect.” (B) Screws are angled at 45 degrees, away from the path of movement, and therefore subject to less pullout force.
the IAR. A rigid, load-bearing device under compression (such as the TPS), placed into the anterior part of a corpectomy defect, changes the point around which the spine pivots. The center of rigid load bearing and the IAR thus move ventrally and inferiorly in the upper vertebra and ventrally and upward in the lower vertebra of the construct. Movement in flexion/extension occurs in an arc around each respective IAR. The vector of pullout force, and therefore pullout tendency, is greatest along any tangent to the path of rotation around the IAR. A screw placed perpendicular to the path of movement will see zero pullout force, though shear forces will be maximal. TPS screws are angled at 45 degrees away from the path of movement and are therefore subject to less pullout force (Fig. 36–1B). That is, the screw angle is advantageous in resisting screw pullout, by virtue of the trajectory of the screw with respect to the vector of pullout force.

The fourth anatomically useful feature relates to the thicker cortical mantle of the ventral inferior lip of the vertebra. The screws angled at 45 degrees are placed through the ventral lip and are afforded the most sound screw purchase.

The TPS has several other design features that enhance construct stability in osteoporotic bone. The strength of any columnar construct relates in part to the number of intermediate stays or supporting elements. By providing in-line distraction to the collapsed spine, the TPS is able to entrain the support of paraspinal ligaments. This restoration of paraspinal ligament tension is paramount in maintaining stability of long constructs.

Secondly, the 45-degree screw angle allows for longer screws. A 45-degree angle permits a longer screw purchase by a factor of sine 45 degrees (Fig. 36–1B). Thus at the 45-degree angle, 20 to 22 mm screws may be safely used without violating the posterior cortex. These longer screws have a significant advantage in soft bone as screw pullout strength is proportional to screw length.

Central to the design of any spine device is the concept of subsidence, the settling or loss of vertebral height following fusion due to pistoning of graft or intervertebral spacer into adjacent vertebral end plates. All constructs undergo subsidence with loss of construct height. The result is a glacial (or not so glacial) tendency toward kyphosis. Most of the settling of the construct takes place within the first few weeks after implantation. "Permissive spine deformation," which normally occurs and which does not result in instability or excessive loss of correction, has been termed dynamism by Benzel. Failure of an instrumentation system to minimize or take into account subsidence, however, results in excessive kyphosis, possibly graft fracture, pseudoarthrosis, and/or screw pullout.

The TPS was designed to minimize subsidence through load sharing, multiple points of fixation, longer screws, and incorporation of the strongest part of the anatomy, the ventral lip. Fully constrained screws, integral flanges, and nonorthogonal surfaces with large contact surface area confer resilience against compression, rotational, and translational forces. The toggling and translational movements between plate and graft (or graft spacer) do not occur in the TPS, because of the integration of plate and spacer.

The most important feature of the TPS is the ability to provide in-line distraction. In-line distraction accomplishes restoration of vertebral height, alignment, and tightening of the paraspinal ligaments. The forces of distraction are applied anterior to the IAR, allowing for restoration of lordosis. With soft bone, there is minimal risk to the vertebral body, because of the broad surface area through which the distraction takes place.

Restoration of lordosis is of great importance. Apart from the adverse consequences relating to load bearing, posture, and gait, there is growing evidence that loss of the normal lordotic curvature of the cervical spine results in increased adjacent segment disease. More important than disc degeneration, however, are the deleterious effects of kyphosis (stretch and shear) on the spinal cord. To wit, the wall of the anterior canal increases from 9.5 cm in extension to approximately 11.5 cm in flexion; thus, the spinal cord shortens and thickens on extension and lengthens and thins on flexion. Through the dentate ligaments, this increased excursion of the spine imparts a stretching force on the spinal cord. Kyphosis, therefore, generates increased axial tension on the spinal cord. The lower cervical cord at the C8 to T4 level is most subject to stretch and movement, elongating up to 18 mm in flexion. Stretching of the cord results in altered blood flow, particularly in the lateral most tracts. The pathological consequences to the spinal cord from repetitive stretch injuries have been implicated in clinical studies and demonstrated in numerous animal models. By restoring lordosis to the spine, the TPS lessens tensile stretch, and thereby stretch injury, to the spinal cord.

**Mechanical Testing**

Mechanical testing is essential to evaluate the structural integrity of spinal instrumentation. The mechanical results of new implant designs are often compared to instrumentation clinically available. The TPS and a clinically successful anterior cervical plating system were both mechanically tested and compared using the *Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy*
Model (ASTM F1717–96). Three static tests and one dynamic test were performed to evaluate the structural integrity of the spinal construct in each system.

The static mechanical tests included compression bending, tension bending, and torsion. For compression bending and tension bending tests, the ASTM standard implements the worst-case loading scenario that includes both axial and bending loads. All testing was completed on fully extended (fully distracted) TPS™ spinal constructs and anterior cervical plates of equivalent size to the TPS™. The tests were continued until ultimate failure of the construct was achieved. Each test utilized a total of five implant assemblies of each spinal system. The load displacement curve was recorded during compression bending and tension bending. From the load displacement curves the construct stiffness, yield load, and ultimate failure load were determined and recorded. The torque angular displacement curve was recorded for each torsion test, and the construct torsional stiffness and yield torque were determined.

The dynamic mechanical test was a compression bending fatigue test. The tests were performed using increasing loads until the construct failed, or the tests were run out to 5,000,000 cycles. A fatigue curve reflecting the bending load versus number of cycles at failure was plotted for each spinal system.

The average stiffness, yield load or torque, and the ultimate failure load for the TPS™ spinal implant and the anterior cervical plate were determined from the force vs. displacement or torque vs. angular displacement curves and are summarized in Table 36–1. All test results have been normalized to maintain confidentiality of proprietary information.

As shown in Table 36–1, the average ultimate compression bending failure load and the average stiffness of the TPS™ spinal construct is more than three times the values determined for the anterior cervical plate. In addition, the average yield load of the TPS™ implant is more than twice the stiffness of the cervical plate, and the tension bending yield loads for both implants are statistically equivalent. It is important to note that tension bending is not a normal physiological load observed in the cervical spine. There were two modes of failure observed when the TPS™ spinal construct underwent tension bending. Either the tab of the female component sheared off completely or the threads of the set-screw sheared off when the tab of the female component was bending in the anterior direction. During the static tension bending test, the failure mode for the plate spinal construct occurred when the plate pulled away from the bone screws. In addition, all plates were permanently deformed, reducing the lordotic curvature of the plate.

The average ultimate tension bending failure load of the TPS™ spinal construct, as shown in Table 36–1, is 86% of the value for the anterior cervical plate. The stiffness of the TPS™ implant is more than two times the stiffness of the cervical plate, and the tension bending yield loads for both implants are statistically equivalent. It is important to note that tension bending is not a normal physiological load observed in the cervical spine. There were two modes of failure observed when the TPS™ spinal construct underwent tension bending. Either the tab of the female component sheared off completely or the threads of the set-screw sheared off when the tab of the female component was bending in the anterior direction. During the static tension bending test, the failure mode for the plate spinal construct occurred when the plate pulled away from the bone screws. In addition, all plates were permanently deformed, reducing the lordotic curvature of the plate.

The yield torque of the TPS™ spinal construct is over twice that of the anterior plate construct, while the torsional stiffness is statistically equivalent. The male and female components of the TPS™ spinal construct permanently deformed or twisted in the direction of the applied torque. Fracture of the male component occurred across the bone graft hole. Similar to the TPS™ implant, the anterior cervical plate permanently deformed in the direction of the applied torque. Yielding of the thin wall lateral to the middle screw holes and thinning, cracking, or fracture of the thin wall near the locking mechanism was observed.

The compression bending fatigue run-out load for the anterior cervical plate is three quarters of the run-out load of the TPS™ spinal construct. The fatigue failure mode for the TPS™ spinal construct is similar to the failure mode observed during the static com-

| Table 36–1 | Average Stiffness, Yield Load, or Torque and Ultimate Failure Load (Standard Deviations in Parentheses) |
| Test Method | Stiffness | Yield Load or Torque | Failure Load |
| | TPS | Plate | TPS | Plate | TPS | Plate |
| Compression bending | 3.14 (0.25) | 1 | 2.29 (0.12) | 1 | 3.25 (0.08) | 1 |
| Tension bending | 2.42 (0.25) | 1 | 1.10 (0.04) | 1 | 0.86 (0.07) | 1 |
| Torsion | 1.06 (0.13) | 1 | 1.80 (0.08) | 1 | N/A | N/A |
expression bending test. The fatigue failure for the anterior cervical plate was a fracture across the center hole in the plate.

The TPS™ Spinal System outperformed the anterior cervical plate during the compression bending and fatigue testing outlined in the ASTM F1717 mechanical testing standard. The TPS™ Spinal System also performed better in torsion and tension bending; however, the torsional stiffness and tension bending yield loads are equivalent for the two systems. In addition, the average ultimate tension bending load is greater for the anterior cervical plate. The tension bending loading condition is not as significant compared to the compression bending, torsion, and fatigue as it is not a normal physiological load seen in the cervical spine.

**Telescopic Plate Spacer: In Vivo Caprine Model**

Prior to implantation in humans, the TPS was tested for safety and efficacy in an animal model. The caprine model was chosen because of the upright posture of the goat, in which the mechanical and biochemical properties of the disc are similar to those in humans. Also, the large range of motion of the goat neck offers a worst-case scenario for any fusion model. The caprine model had been previously demonstrated to have fusion rates similar to humans: 50% for two-level fusion with autograft. In this study, the TPS was compared to a plate/graft construct. Two groups of six animals each underwent a C4 corpectomy, then stabilization and grafting either with an anterior plate and autologous rib (controls) or with the TPS filled with autologous bone. There were no complications; in both groups all animals were without pain and neurological deficit postoperatively. At 28 weeks, X-rays in the live animals and then manipulation of the retrieved specimens (C3 to C6) suggested fusion throughout 5/6 of the controls and 6/6 of the TPS constructs. Histological evaluation demonstrated pseudarthroses of the grafts in two animals stabilized with rib and plate; however, in the group stabilized with the TPS, substantial bone growth was demonstrated through the ends and sides of every TPS (Fig. 36–2). Bone appeared to grow from the periphery of the TPS toward the center. Bone growth occurred right up to the titanium mesh of the TPS.

The success of the TPS in achieving fusion was thought to reside in its greater stability and larger surface area. The large flat surfaces of the TPS may have an advantage over round and cylindrical cages where the arc of contact is more limited.

**Clinical Experience with the Telescopic Plate Spacer: Illustrative Cases**

The following four cases illustrate different approaches to the cervical and upper thoracic spine. In each case, following corpectomy and tumor resection, the telescopic spacer was used to restore vertebral height, alignment, and lordosis.

**Case 1—High Cervical Metastasis: McDonnell’s Extrapharyngeal Approach**

A 48-year-old male with a history of metastatic renal cell cancer presented with a 6-week history of gradually progressive neck pain radiating to the left shoulder. At the time of admission he rated his pain as 10 out of 10. Neurological examination was significant for diffuse hyperreflexia and trace lower extremity weakness. A radiographic bony survey revealed a pathologic fracture of C3 with 30 degrees of kyphosis (Fig. 36–3A).

The patient was reduced with 15 pounds of cervical traction. He then underwent a C3 corpectomy and stabilization through an extrapharyngeal approach. McDonnell’s extrapharyngeal approach affords exposure from the anterior tubercle of C1 to lower C4 with minimal tissue distraction. The patient was placed supine and his head rotated 30 degrees contralaterally, slightly extended. A transverse skin incision was made parallel and 2 cm inferior to the mandible. The subcutaneous space was undermined 1 cm. The platysma was divided transversely and undermined. The submandibular gland was identified and retracted superiorly, exposing the an-

![FIGURE 36–2](image) Histological section of a TPS implanted into a goat, 6 months postoperatively. Bone growth is seen throughout the construct.
terior belly of the digastric muscle and its tendon; the latter attaches to the hyoid bone by way of a fascial sling. The digastric muscle was released from its attachment to the hyoid bone and reflected superiorly. The hypoglossal nerve was identified and gently retracted superiorly. The superior laryngeal nerve was retracted inferiorly. The internal carotid artery and greater cornu of the hyoid bone were palpated. The fascia overlying the hyoid bone was dissected, and the hyoid was displaced contralaterally. The superior pharyngeal constrictor muscle was identified and retracted medially to reveal the precervical fascia and longus colli muscles. The tubercle of C1 and the converging longus colli muscles were palpated. The longus colli were undermined with monopolar cautery, allowing placement of the retractor blades. The intervertebral discs flanking the C3 vertebral body were then cut with a scalpel, and the diseased body was removed piecemeal down to the posterior longitudinal ligament. Under the surgical microscope, the posterior longitudinal ligament was removed with Kerrison rongeurs. The end plates were decorticated with a high-speed drill to bevel C2 slightly and to square off C4. The telescopic spacer was filled with graft, placed into the corpectomy defect, and distracted 5 mm to restore vertebral height, alignment, and lordosis (Fig. 36–3B). The lock pin was tightened. The screws were inserted at 45 degrees superiorly and 15 degrees inferiorly. The lock pin was broken off, and additional bone substitute was packed into the device. The wound was closed in two layers, and steri-strips were applied.

Histopathologic examination of the specimen revealed poorly differentiated carcinoma, positive for keratin and vimentin by immunocytochemistry. Postoperatively, he was pain-free and ambulatory, and remained so until his death 8 weeks after surgery.

CASE 2—MIDCERVICAL SCHWANNOMA: THE TRANSCERVICAL APPROACH WITH CONTROL OF THE VERTEBRAL ARTERY

A 66-year-old female presented with a palpable, left cervical neck mass, associated with mild pain (2 out of 10). Examination was significant for a nodular, firm, slightly mobile, and nontender mass in the midcervical region. There was hypoesthesia over the left side of the lower face and neck. Motor examination was normal; she was hyperreflexic. The magnetic resonance imaging scan revealed an expansile, lytic lesion from C3 to C4 (Fig. 36–4A). The vertebral and carotid arteries appeared wrapped by the tumor.

Due to the potential necessity of sacrificing the vertebral artery, the patient underwent a preoperative endovascular trial occlusion of the left vertebral artery. No deficits were observed during or following the 25-minute test.

A standard Cloward approach was used.20 A transverse skin incision was made at the level of the thyroid cartilage. The subcutaneous space was undermined, and the platysma was sharply divided transversely. The medial border of the sternocleidomastoid muscle was exposed, and the alar fascia was dissected. This exposed the tumor, which displaced the carotid sheath laterally. The carotid sheath was
freed from the mass. The vertebral artery was exposed at C5 by removing the overlying costal process of the lateral mass. The tumor formed a bilobed mass around the vertebral artery, but was separable from the artery. The tumor component lateral to the vertebral artery was excised. The longus colli muscles were exposed and retractors were inserted. The C3 to C4 and C4 to C5 intervertebral discs were removed, and C4 corpectomy was performed. Under the operating microscope, the posterior longitudinal ligament was removed, and tumor attachments were resected. Extradurally, tumor was resected around the C4 and C5 nerve roots. The C3 and C5 end plates were drilled down to conform to the beveled superior edge and flat inferior edge of the telescopic spacer. The telescopic spacer was filled with autologous bone (harvested from C4) and placed into the corpectomy defect. Two 18 mm screws were used superiorly in the 45-degree holes, achieving bicortical fixation, and two 14 mm screws were used inferiorly in the 80-degree holes. The wound was closed in two layers.

Histopathology revealed a schwannoma. Postoperatively, the patient enjoyed complete resolution of her neck pain, and at 3 months she was neurologically intact. Radiographs demonstrated normal vertebral height, alignment, and lordosis (Fig. 36–4B).

Case 3—Cervicothoracic Metastasis: The Low Anterior Cervicothoracic Approach

A 41-year-old male with history of renal cell carcinoma metastatic to the C6 vertebra presented with progressive left-sided neck pain and weakness. Two years earlier, he had undergone a radical nephrectomy. A single C7 metastasis was treated with 6 MV photon beam radiation (40 GY) in a single posterior field. Nine months before admission he underwent a C6 and C7 laminectomy and Luque rod fixation from C4 to T2 at another institution. The surgery was aborted because of massive blood loss. Despite immunotherapy, his tumor progressed, and he presented with progressive left-sided hemiparesis and sensory loss. On admission, his pain was 3 out of 10. A myelogram revealed cord compression at C7 with radicular impingement of C7, C8, and T1 roots (Fig. 36–5A).

Following preoperative embolization, he underwent a C6 and C7 corpectomy via a cervicothoracic approach. He was placed supine, with his neck in slight extension. A transverse incision was made 1 cm above the clavicle. The platysma was divided transversely and undermined. The sternal and clavicular heads of the sternocleidomastoid muscle were detached and reflected superiorly. In this case, it was not necessary to resect the manubrium. The alar fascia was then dissected down to the prevertebral fascia. The longus colli muscles were then undercut with cautery and the retractors inserted. The exposure spanned C5 to T1. The corpectomy of C6 and C7 were performed expeditiously. In an attempt to further devascularize the tumor, the dissection was extended laterally to the anterior scalene muscle, next to which the costocervical and thyrocervical trunks were identified and ligated. The phrenic nerve was identified and preserved. The corpectomy was then completed under the operating microscope. Using a
high-speed drill, the inferior end plate of C5 was beveled to accommodate the telescopic plate. The superior plate of T1 was drilled flat. The telescopic spacer was filled with coralline hydroxyapatite and demineralized bone matrix, placed into the corpectomy defect, and distracted 4 mm. The 45-degree screw guides were selected superiorly and inferiorly: 16 mm screws were used at C5 and 22 mm screws were used at T1. Additional bone substitute was packed into the device to fill any remaining voids. The wound was closed in two layers. The patient was kept intubated overnight. Two weeks later, the tumor behind the spinal cord was resected from a posterior approach. The left C7, C8, and T1 nerve roots were decompressed. He was stabilized with posterior instrumentation from C4 to T3 and rib grafting. Postoperatively, his pain and hypoesthesia decreased significantly, and his strength returned to normal (Fig. 36–5B).

**CASE 4—T2 PLASMACYTOMA WITH PARASPINAL COMPONENT RESECTED THROUGH A HIGH THORACOTOMY**

A 70-year-old male presented with a 6-month history of right shoulder pain, neurologically intact. CT showed destruction of T2 and a large paraspinal tumor over the second and third ribs (Fig. 36–6A). Biopsy revealed a plasmacytoma. Radiation therapy (40 GY) had failed to diminish the tumor mass. The large paraspinal component of tumor necessitated a high thoracic exposure to the T2 body. He was intubated with a dual lumen endotracheal tube and placed in the left lateral decubitus position. A posterolateral thoracotomy incision was made over the fifth intercostal space and extended posteriorly through the latissimus dorsi, serratus anterior, and superiorly through the trapezius and rhomboid muscles. The scapula was reflected superiorly. The second and third ribs were exposed and resected along with the overlying tumor, back to the costovertebral process. Using single lung ventilation, the T2 vertebral body was then exposed and drilled away. The posterior longitudinal ligament was resected with Kerisson rongeurs, under the operating microscope. The T1 and T3 end plates were then prepared, beveling the T1 end plate 10 degrees with a high-speed drill. The telescoping plate was filled with allograft and demineralized bone matrix and placed into the corpectomy defect. It was tightly distracted. Four 22 mm screws inserted, using the 45-degree holes cephalad and the 10-degree holes caudal. Propylene mesh was used to close the chest wall defect. A chest tube was inserted and cryoanalgesia was performed using a −60° cryoprobe for 2 minutes over the fourth, fifth, and sixth intercostal nerves. The rib cage and the latissimus dorsi, serratus anterior, trapezius, and rhomboid muscles were reapproximated with suture. The skin and subcutaneous tissues were closed in two layers. Postoperatively, the patient was intact neurologically, and despite the thoracotomy, is pain-free (Figs. 36–6B,C).
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FIGURE 36–6  (A) Preoperative CT of a 70-year-old male with plasmacytoma involving the right upper chest wall and T2 vertebra. A high thoracotomy approach was used to resect part of the chest wall and the T2 vertebral body. (B,C) Postoperative radiographs showing restoration of vertebral body height and alignment.


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Index
Augmentation of fracture fixation (continued)
resorbable implants, 259–263
proximal femoral fracture, internal fixation, hydroxyapatite granular devices, 232–236, 233–235
spinal fixation
anchor point size, stress concentration prevention, 129
cross-linking for torsional stiffness, 129
implant-bone interface, 128–129
screws, 99
vertebroplasty procedures, injectable calcium-phosphate cement, 328, 328
Autogenous bone grafting, augmentation of healing and stability, 118–120
Autologous bone grafting
enhanced fracture healing, 27
osteoporotic fracture fixation, 95
Autologous Growth Factor (AGF) therapy, enhanced fracture healing, 27
Axial displacement, distal fracture fixation, intramedullary nails, 311, 311
Axially mobile plates (AMP)
biomechanics, 279
design criteria, 280, 280–282, 282
flexible vs. sliding plates, 279–280
osteoporotic fracture fixation, 83
performance evaluation, 280–281, 280–281
Axial pullout tests
cement screw mechanics, 248–255, 254
injectable cementing screw analysis, 244
interlocking screws, 238–240
B
Bailey-Dubow nail, osteogenesis imperfecta, long bone fractures, 168–169
complications, 175–176
multiple osteotomy, 173–174
Balloon tamps, vertebral compression fractures, minimally invasive techniques, 335–337, 335–337
Basic fibroblast growth factor (bFGF), enhanced fracture healing, 27–28
Beak system, proximal femoral fracture, internal fixation, hydroxyapatite granular devices, 232–236, 233–235
Bending tests
axially mobile plate mechanics, 280–281, 281
cement screw mechanics, 248–255, 252
expandable intramedullary nail, 302–303, 303
fracture healing, 32
Benzel boundary effect, telescopic plate spacer (TPS) biomechanics, 350, 350–351
Best estimated guide angle (BEGA), self-guided pedicle screws, dimensions and insertion angle, 344–345, 345
Bioabsorbable materials
augmentation of plate fixation
bioabsorbable strips, 83–84
resorbable implants, 259–263
intertrochanteric fractures, internal fixation, Norian SRS resorbable cement, 212–214
osteoporotic fracture fixation, 95–97, 96
Biologic fracture fixation
expandable intramedullary nail, 307
osteoporotic fractures
long bone fractures, 116
plate fixation and, 80–81
Biomarkers, bone turnover analysis, 6–7
Biomechanics
acetabular and pelvic fractures, 142–143, 142–143
expandable intramedullary nail, 302–303, 303
fracture testing, 31
hydroxyapatite-coated pins, 225, 226
interlocking blade plates, 268–269
intertrochanteric fractures, internal fixation, Norian SRS resorbable cement augmentation, 208–209
LISS plating system, 274–276, 275–276
osteogenesis imperfecta, fixation techniques, 174–176
osteoporotic bone fractures
bone mechanics, 9–10, 10
cancellous bone mechanics, 13–19
fracture mechanics, 19
macroscopic analysis, 13
microscopic analysis, 13–19
ultramicroscopic analysis, 19
cortical bone mechanics, 10–13
fracture mechanics, 11–12, 11–13
macroscopic analysis, 10
microscopic analysis, 10
ultramicroscopic analysis, 10–11
external fixation, 187
implant fixation, 117–120
intramedullary nailing, 88–91
plate fixation, 273–274, 274
spinal fracture fixation, pedicle screw/laminar hook combination, 129–131, 130
telescopic plate spacer (TPS), 350, 350–351
vertebral compression fractures, minimally invasive techniques, 336–337
Biophysical stimulation, enhanced fracture healing, 26–27
Biplanar frame, external osteoporotic fracture fixation biomechanics, 187
Bisphosphonates, osteoporosis therapy, 200
Blade plates
internal fixation, osteoporotic bone, wide buttress principle, 110
osteoporotic fracture fixation, 82, 82
interlocking blade plates, 266–270
supracondylar fracture fixation, distal femur, 121–122, 122
BMD. See Bone mineral density
BMP. See Bone morphogenic proteins
Bone biopsy, osteomalacia/osteoporosis diagnosis, 6
Bone cells, osteoporosis histomorphology and pathogenesis, 3–5
Bone cortex dimensions, osteoporosis, 41
Bone density. See also Bone mineral density (BMD)
osteoporosis pathophysiology, 194–195
osteoporotic bone and fracture mechanics
fracture fixation and, 74–75
homogeneous-isotropic analysis, cancellous bone, 13–14, 14
quantitative ultrasound (QUS) measurement, 64
screw devices, bone shear strength, 143
Bone failure, osteoporotic long bone fractures, 116
Bone biopsy, osteomalacia/osteoporosis diagnosis, 6
Bone cells, osteoporosis histomorphology and pathogenesis, 3–5
Bone cortex dimensions, osteoporosis, 41
Bone density. See also Bone mineral density (BMD)
osteoporosis pathophysiology, 194–195
osteoporotic bone and fracture mechanics
fracture fixation and, 74–75
homogeneous-isotropic analysis, cancellous bone, 13–14, 14
quantitative ultrasound (QUS) measurement, 64
screw devices, bone shear strength, 143
Bone failure, osteoporotic long bone fractures, 116
Bone biopsy, osteomalacia/osteoporosis diagnosis, 6
Bone cells, osteoporosis histomorphology and pathogenesis, 3–5
Bone cortex dimensions, osteoporosis, 41
Bone density. See also Bone mineral density (BMD)
osteoporosis pathophysiology, 194–195
osteoporotic bone and fracture mechanics
fracture fixation and, 74–75
homogeneous-isotropic analysis, cancellous bone, 13–14, 14
quantitative ultrasound (QUS) measurement, 64
screw devices, bone shear strength, 143
Bone failure, osteoporotic long bone fractures, 116
Bone formation assays, bone turnover analysis, 6–7
Bone grafts
  acetabular and pelvic fracture fixation, cable and cerclage wire devices, 147–148
  long bone fractures, healing and stability augmentation, 118–120, 119
  osteoporotic fracture fixation, 95
Bone-implant interface
  fixation of fractures
    bone screws, 41–42, 42
    pins, 42–43, 43
    hydroxyapatite-coated pins, 224–230
Bone mass
  fracture fixation, 40–41
  osteoporosis definition and diagnosis, 195–196
  osteoporosis pathophysiology, 195
Bone matrix, production of, 3–5, 4
Bone mineral content (BMC), densitometric measurement, 59
  single and dual x-ray absorptiometry, 60–62, 61–62
Bone mineral density (BMD)
  cement screw mechanics, 251, 251
  densitometric measurement, 59
  accuracy and precision, 59
  quantitative computed tomography (QCT), 63
  interlocking screws, testing protocols, 238–239, 239
  magnetic resonance imaging (MRI), 64–65
  osteoporosis definition and diagnosis, 196, 196
  osteoporotic cancellous bone, 17–18, 18
  quantitative ultrasound (QUS) measurement, 64
  spinal fixation
    epidemiology and demographics, 134–135
    pedicle screw/laminar hook combination, 131
    screw devices, 97–99, 98–99
  T-scores and Z-scores, 59
Bone morphogenetic proteins (BMP), fracture healing mechanics
  enhanced fracture healing, 28–29
  ex vivo gene therapy, 29–30
  normal fracture healing, 25
  osteopenic fracture model, 33, 34
  in vivo gene therapy, 30
Bone plates. See Plate devices (rigid fixation)
Bone remodeling
  components of, 3–5, 4
  normal fracture healing, 23
Bone resorption assays, collagen degradation measurement, 7
Bone screws, fracture fixation, 41–42, 42
Bone shear strength
  fracture fixation, 40–41
  screw devices, 143
Bone stimulator therapy, osteoporosis management, 198
Bone substitution, internal fixation, osteoporotic bone, 112–113, 114
Bone tumors
  fixation techniques
    femoral tumors, management of, 181–184, 182–183
    humoral tumors, management of, 184
    metastases, effects of, 178–179, 179
    nonoperative management, 179–180
    prophylactic intervention, indications, 179–181
  specific locations, lesion management, 181–185
  surgical management, 180, 180–181
  tibial tumors, management of, 184–185
  vertebral tumors, TPS devices for treatment of, 349–357
  Booker interlocking nail, development of, 86
  Bridge plate, osteoporotic fracture fixation, 80–81
  Broadband ultrasound attenuation (BUA), quantitative ultrasound (QUS) measurement, 64
Buttress plate
  acetabular and pelvic fracture fixation, 144, 144
  LISS plate biomechanics, 275–276, 276
  osteoporotic fracture fixation, 82
  supracondylar fracture fixation, distal femur, 122
C
Cable fixation devices, acetabular and pelvic fractures, 147–149, 148
Calcitonin, osteoporosis therapy, 199–200
Calcium, osteoporosis therapy, 198
Calcium phosphate
  internal fixation, osteoporotic bone, healing and stability augmentation, 119–120
  spinal fracture fixation, implant-bone interface, 129
  vertebroplasty procedures, 326–332
Cancellous bone
  fracture fixation, screws, 74–76, 76
  hydroxyapatite-coated pin stability, 226–228, 227
  osteoporotic bone and fracture biomechanics, 13–19
    fracture mechanics, 19
    internal fixation principles, 109
    augmentation of healing and stability, 118–120, 119
    macroscopic analysis, 13
    microscopic analysis, 13–19
      heterogeneous-anisotropic approach, 18–19
      homogeneous-anisotropic approach, 14–18, 14–18
      homogeneous-isotropic approach, 13–14, 14
    ultramicroscopic analysis, 19
Cancellous bone cement (CBC), spinal fracture fixation, implant-bone interface, 129
Cannulated screws
  acetabular and pelvic fracture fixation, 143–144
  cement screw mechanics, 249–255, 250, 252
  injectable cementing screws, 245
  osteoporotic fracture fixation, 77
  pelvic and acetabular fractures, percutaneous fixation, 140, 140
Caprine model, telescopic plate spacer (TPS), 353
CBC. See Cancellous bone cement
Cbfa1 expression, bone remodeling, 4–5
Cementing screws, osteoporotic fracture fixation, 78, 78–79
Cement materials
  bone tumor management, 181
  injectable cementing screw, 242–246, 243–245
  internal fixation, osteoporotic bone
    augmentation principle, 111–112, 113–114
    healing and stability augmentation, 119–120
  intertrochanteric fractures, unstable fracture fixation, glass-ionomer cement, 217–218
  intramedullary cement fixation, proximal humeral fractures, 292–295
Cement materials (continued)
Norian SRS resorbable cement, hip fracture internal fixation, augmentation using, 207–215
osteoporotic fracture fixation, 95–97
cement screw, metaphyseal bone, 248–255
spinal fracture fixation, implant-bone interface, 129
vertebroplasty procedures, calcium phosphate cement, 326–332
Cervical bone cements, osteoporotic fracture fixation, 97
Cervical systems
acetabular and pelvic fractures, 147–149, 148
osteoporotic fracture fixation, 91–93, 92
screw devices, bone shear strength, 143
Cervical metastases, telescopic plate spacer (TPS), management with, 353–356, 354–356
Cervical spinal fixation, self-guided pedicle screw, 342–347
Cervical spine locking plate (CSPLP), failure rates, 342
Chondrogenesis, normal fracture healing, 23
Clamp-on bone plates, shape memory alloys (SMA), 94, 94
Closed fracture management
osteogenesis imperfecta, 165
vs. semiclosed intramedullary rodding, 169, 172
periprosthetic supracondylar femur fractures, 272–273
Coefficient of variation (CV), densitometric analysis, 59
Collagen, normal fracture healing, 23
Collagenase-3. See Matrix metalloproteinase-13 (MMP-13)
Columns of pelvic fixation, acetabular and pelvic fracture fixation, 148, 149
Composite materials, osteoporotic fracture fixation, 95–97
Compression hip screw (CHS) system, proximal femoral fracture, internal fixation, hydroxyapatite granular augmentation, 232–236, 233–235
Compressive staples, shape memory alloys (SMA), 94, 94
Compressive strength, fracture fixation, 40–41
Computed tomography (CT) scan
acetabular and pelvic fracture fixation, 139
osteoporosis definition and diagnosis, 196
Condylar plate
internal fixation, osteoporotic bone, wide buttress principle, 110
intertrochanteric fracture fixation, 120–121
Copolymer swelling materials, osteoporotic fracture fixation, attachment/anchoring problems, 90
Cortical bone
fracture fixation
bone screws, 41–42, 42
screws, 74–76, 76
hydroxyapatite-coated pin stability, 226–228, 227
osteoporotic bone and fracture biomechanics, 10–13
fracture mechanics, 11–12, 11–13
internal fixation principles, 108–109
macroscopic analysis, 10
microscopic analysis, 10
ultramicroscopic analysis, 10–11
radiographic imaging
mass attenuation coefficient, 51–52, 52
radiogrammetry, thickness assessment, 54
thinning, images of, 53, 53
Cross-linking techniques, spinal fracture fixation, 129
Cushioned plates, osteoporotic fracture fixation, 83
CV. See Coefficient of variation (CV)
Cyclic loading/cyclic motion, intertrochanteric fractures, unstable fracture fixation, 219, 219

D
DCP. See Dynamic compression plate
DCS. See Dynamic condylar screws
Deep venous thrombosis (DVT), acetabular and pelvic fracture fixation, complications, 152–153
Degradation mechanics, resorbable polymers, 261
Densitometry, osteoporosis, 59–65
accuracy and precision, 59
magnetic resonance imaging (MRI), 64–65
nomenclature, 59
performance evaluation, 60, 60
peripheral quantitative computed tomography (pQCT), 63
quantitative computed tomography (QCT), spinal sites, 62–63, 63
quantitative ultrasound, 64
radiographic absorptiometry, 60
single and dual x-ray absorptiometry, 60–62, 61
T-scores and Z-scores, 59
DHS. See Dynamic hip screws
Diaphyseal humerus, bone tumor management, 184
Direct force mechanism, cortical osteoporotic bone fracture mechanics, 11–12, 11–12
Direct fracture fixation, cement and composite materials, 95
Direct injury mechanism, cortical osteoporotic bone fracture mechanics, 11, 11–12
Displaced fractures, acetabular fractures, clinical signs, 140–141
Distal femur
bone tumor management, 183–184
femoral mechanic deficiency, Huckstep nail fixation, 289–291, 290
fracture fixation, intramedullary nails, 310–313
supracondylar fractures, 121–122, 122
Distal fibula, antiglide plate fixation, 233–235
Distal radial fractures, external osteoporotic fracture fixation, 188
Double-sliding lag screw and plate system, proximal femoral fracture, internal fixation, hydroxyapatite granular devices, 232–236, 233–235
Dovetail sliding plate, 282, 282
Dual x-ray absorptiometry (DXA)
femoral fractures, internal fixation, Norian SRS resorbable cement augmentation, 208
injectable cementing screw analysis, 243–246
interlocking screws, testing of, 237–240
intertrochanteric fractures, internal fixation, Norian SRS resorbable cement augmentation, 208–209
osteoporosis definition and diagnosis, 195–196
osteoporotic bone measurement, 60–62, 61–62
hip axis measurement, 54
vs. morphometric x-ray absorptiometry (MXA), 58–59
spinal fixation
epidemiology and demographics, 134–135
pedicle/screw/laminar hook combination, 131
DVT. See Deep venous thrombosis
DXA. See Dual x-ray absorptiometry
Dynamic compression plate (DCP)
axially mobile plate mechanics, 280–281, 281
interlocking blade plates, 266–267
osteoporotic fracture fixation, 80, 80–81
Dynamic condylar screws (DCS), osteoporotic fracture fixation, 78, 78
Dynamic hip screws (DHS)
bone tumor management, intertrochanteric region, 183
intertrochanteric fractures, unstable fracture fixation
anatomical specimens, 217
dynamic load testing, 218–219, 219
fracture model, 218, 218
glass-ionomer cement, 217–218
implants, 218
irreversible caudal-oriented deformation, 219, 220
osteosynthesis stability comparisons, 221, 221
statistical analysis, 219
tilt angles, cemented/uncemented, 219, 220
osteoporotic fracture fixation, 78, 78
internal fixation techniques, 110
Dynamic load testing, intertrochanteric fractures, unstable fracture fixation, 218–222
Dynamic nail, osteoporotic fracture fixation, 86–87
nonunion complications, 91
Dynamism, telescopic plate spacer (TPS) biomechanics, 351

E
“Eggers splint,” axially mobile plate device, 279–280
Elastic modulus
cancellous osteoporotic bone fracture mechanics, 15–16, 17
cortical osteoporotic bone fracture mechanics, 12
Electromagnetic stimulation, enhanced fracture healing, 26–27
Embracing fixators, shape memory alloys (SMA), 94, 94
Endochondral ossification, normal fracture healing, 23
Energy-absorption capacity, cortical osteoporotic bone fracture mechanics, 12
Estrogen-deficient osteopenic models, fracture healing biology and biomechanics, 32–34
Estrogen receptor therapy, osteoporosis, 198–199
Exercise, osteoporosis pathophysiology, 195
Expandable intramedullary nail, osteoporotic fracture fixation, 88, 88
animal studies, 303, 303–304
biological fixation, 307
biomechanical studies, 302–303, 303
clinical trials, 304–305, 305
cross section, 307
diameter alterations, 307
inflatable nail design, 301–302, 302
operative and fluoroscopic time reduction, 307
proximal femur fracture, 305–307, 306
Expanding bolts and screws, osteoporotic fracture fixation, 79, 79
Extensible nails, osteogenesis imperfecta, long bone fractures, 169, 170–171
multiple osteotomy, 173–174
External fracture fixation
acetabular and pelvic fractures, 149
hydroxyapatite-coated pin stability

INDEX • 363

animal studies, 225–226
degradation analysis, 229–230
normal bone, clinical studies, 226–228, 227–229
osteoporotic bone, clinical studies, 228–229, 229
research background, 224–225, 225
interlocking blade plates and, 269–270
mechanics, 43–45, 44
osteoporotic bone
biomechanics, 187
complications, 190–191
design criteria, 186, 187
indications for, 187–188, 188
osteoporotic bone, clinical practice, 189, 190
Extracellular matrix (ECM) proteins, normal fracture healing, 23–24
Ex vivo gene therapy, fracture healing, 29–30

F
Fan beam scanners, dual x-ray absorptiometry (DXA), 61–62
Fast Fourier Transform (FFT) algorithm, homogeneous-anisotropic analysis, cancellous bone, 15, 16
FEM. See Finite element model (FEM)
Femoral osteotomy, osteogenesis imperfecta, long bone fractures, multiple osteotomy, solid nails, 172–173
Femur
tumor management in, 181–184, 182–183
distal femur, 183–184
head and neck region, 182–183
intertrochanteric area, 183
shaft region, 183, 183
fracture fixation
distal fixation, intramedullary nails, 310–313
expandable intramedullary nail, 304–306, 306
internal fracture fixation
Norian SRS resorbable cement, 208–211, 210–211
proximal femoral fractures, hydroxyapatite granular devices, 232–236, 233–235
intertrochanteric fractures, unstable fracture fixation, 218–222
mechanical deficiency fixation, Huckstep nail, 287–291
osteoporosis and bone density in, 197–198
periprosthetic femoral fractures, LISS plate fixation, 271–278
FGF. See Fibroblast growth factor
Fibroblast growth factor (FGF), fracture healing mechanics
enhanced fracture healing, 27–29
normal fracture healing, 24
Fibular allograft struts, internal fixation, osteoporotic bone, healing and stability augmentation, 119–120
Finite element model (FEM), osteoporotic cancellous bone analysis, 19
Fixation of fractures
axially mobile plate device
biomechanics, 279
design criteria, 280, 280–282, 282
flexible vs. sliding plates, 279–280
performance evaluation, 280–281, 280–281
bone-implant interface devices
bone screws, 41–42, 42
pins, 42–43, 43
Fixation of fractures (continued)

bone tumors
- femoral tumors, management of, 181–184, 182–183
- humoral tumors, management of, 184
- metastases, effects of, 178–179, 179
- nonoperative management, 179–180
- prophylactic intervention, indications, 179–181
- specific locations, lesion management, 181–185
- surgical management, 180, 180–181
- tibial tumors, management of, 184–185

device mechanics
- cement screw, 248–255
- external fixation, 43–45, 45–46
- hydroxyapatite-coated pin stability, 224–230
- hydroxyapatite granules, 232–236
- injectable cementing screw, 242–246
- interlocking screws, 237–240
- intramedullary nailing, 45
- plate devices, 45–47, 47
- spinal fixation, 47–49
- distal fixation, intramedullary nails, 310–313
- failure of, acetabular and pelvic fractures, 153
- internal fixation, osteoporotic bone
  - acetabular and pelvic fractures, 137–176
  - augmentation of healing and stability, long bone fractures, 118–120, 119–120
  - basic principles, 108–114, 109
  - bone augmentation, 111–112, 113
  - bone substitution, 113–114, 114
  - impaction, 109–110
  - implant development, 115
  - intramedullary nails, 117–118
  - long bone fixation, 116–125
  - long splintage, 110–111, 111–112
  - plates, 117, 118
  - screws, long bone fractures, 117
  - spinal fractures, 129–135
  - wide buttress, 110
- osteogenesis imperfecta, biomechanics of, 174–176
- osteoporotic bone, 40, 40–41
  - bioabsorbable materials, 97
  - bone grafts, 95
  - cement and composite, 95–97
  - augmentation of fixation with, 95–96, 96
  - direct fixation, 95
  - vertebroplasty/kyphoplasty, 96–97
  - cerclage systems, 91–93, 92
  - current trends in, 73–101, 74
- intramedullary nails, 84–88
  - attachment/anchoring complications, 89–90, 90–91
  - dynamic nails, 86–87
  - expandable nail, 88, 88, 301–308
  - flexible nail, 87–88, 88
  - Huckstep nail, 87
  - inflatable nail, 88, 89
  - interlocking nail, 86, 86
  - nonunion complications, 90–91, 91
  - polarus nail, 88, 89
  - reaming issues, 88–89
  - research and development, 85
  - retrograde interlocking (supracondylar) nails, 87
- standard nails, 86
- titanium nails, 87
- patella fixator, 94
- pelvic fixation, 101, 101
- pin fixation, 92–93, 93
- plates (rigid fixation), 79–84
  - adhesive plate, 81–82
  - augmentation methods, 83–84, 83–84, 259–263
  - axially mobile or sliding plates, 83
  - blade plate, 82, 82
  - buttress plate, 82
  - cushioned plates, 83
  - LC-DCP, MCP, and PC-fix, 81
  - Mennen plate, 82–83, 83
  - minimally invasive techniques, 84, 84
  - resorbable implants, augmentation with, 259–263
  - vs. biological fixation, 80–81, 81–82
  - Zepol plate, 83, 83
  - screws, 74–79
  - attachment/anchoring complications, 89–90, 90
  - cementing screws, 78, 78–79
  - cortical vs. cancellous, 74–76, 76
  - dynamic hip screws/condylar screws (DHS/DCS), 78, 78
  - expanding bolts/screws, 79, 79
  - fully threaded vs. partially threaded, 77
  - Herbert screws, 77, 77
  - hollow wall anchor, 79, 80
  - interlocking screws, 78
  - pedicle screws, 78, 78
  - self-tapping vs. non-self-tapping, 76–77, 77
  - solid vs. cannulated screws, 77
  - shape memory alloys (SMA), 93–95, 94
  - spinal fixation, 97–101
  - hooks, 99–100, 100
  - screws, 97–99, 98–99
  - wires, 100, 100
- Paget’s disease, 157–158, 158
- proximal humeral fractures, intramedullary cement fixation, 292–295
  - vertebroplasty procedures, inflatable bone tamps, 327–332
- Fixclip system, osteoporotic fracture fixation, pin devices, 93, 93

Fixed-angle devices
- intertrochanteric fracture fixation, 120–121
- LISS plate biomechanics, 275–276
- FIXION™, osteoporotic fracture fixation, 88, 89
- Flexible intramedullary nail, osteoporotic fracture fixation, 87–88, 88
- Fluoroscopic analysis, expandable intramedullary nail, 307
- Follistatin, normal fracture healing, 25
- Four-part fractures, sliding hip screw fixation, 120, 120–121
- Fracture mechanics. See also Fixation of fractures
  - healing biology and biomechanics
    - enhanced healing, 26–29
    - autologous techniques, 27
    - bone morphogenic proteins, 28–29
    - growth factors, 27–28
    - invasive techniques, 27
    - noninvasive techniques, 26–27
    - estrogen-deficient osteopenic models, 32–34
gene therapy, nonunions and clinical bone loss problems, 29–30
normal healing, 23–26
extracellular matrix proteins, 23–24
growth factors and bone morphogenic proteins, 23–26
histology phases, 23
repair states, 30–31
testing biomechanics, 31–32
osteogenesis imperfecta, 165
osteoporosis diagnosis, 197
osteoporotic bone
cancellous bone, 19
cortical bone, 11–12, 11–13
long bone fractures, 116
radiographic assessment, vertebral fracture/deformity, 54, 54–58, 56–57
vertebroplasty procedures, 327–332
Fracture models, intertrochanteric fractures, unstable fracture fixation, 218, 218
Fully threaded screws, osteoporotic fracture fixation, 77
High activation frequency, osteoporosis histomorphology and pathogenesis, 4–5
Hip axis, radiogrammetry, osteopenia analysis, 54
Hip fractures
internal fixation, Norian SRS resorbable cement augmentation, 207–215
osteoporosis and risk of, 197–198
Histomorphometry, osteoporotic bone, 5–6, 6
Hollow wall anchor, osteoporotic fracture fixation, 79, 80
Homogeneous-anisotropic analysis, osteoporotic bone and fracture mechanics, 9–10, 10
cancellous bone, 14–18, 15–18
Homogeneous-isotropic analysis, osteoporotic bone and fracture mechanics, 9–10, 10
cancellous bone, 13–14, 14
Hook devices
acetabular and pelvic fracture fixation, 144, 144–145
cable and cerclage wire techniques, 147–149, 148
spinal fracture fixation, 99–100, 100
pedicle screw/laminar hook combination, 129–134, 130–135
Hormonal status, osteoporosis pathophysiology, 195
Howship’s lacunae, bone remodeling process, 3–5
Huckstep intramedullary nail
design and assembly, 288–289, 288–289
femoral mechanical deficiency, fixation with, 287–291
osteoporotic fracture fixation, 87, 289–291, 290
techniques using, 289
Humerus
tumor management, 184
fracture fixation, expandable intramedullary nail, 304–305, 305
proximal humeral fractures
intramedullary cement fixation, 292–295
Synthes spiral blade system, 296–300
Hybrid external fixator, mechanics, 44–45
Hydroxyapatite cement (HAC)
coated pin stability, external fixation
animal studies, 225–226
degradation analysis, 229–230
normal bone, clinical studies, 226–228, 227–229
osteoporotic bone, clinical studies, 228–229, 229
research background, 224–225, 225
internal fixation, osteoporotic bone
augmentation principle, 112
proximal femoral fractures, granular devices, 232–236, 233–235
spinal fracture fixation, implant-bone interface, 129
Hyperparathyroidism, osteoporosis diagnosis, 197
Hyperthyroidism, osteoporosis diagnosis, 197
Iliac bolt fixation, osteoporotic pelvis, 101, 101
Impaction, internal fixation, osteoporotic bone, 109–110
Implant devices
biomechanics, osteoporotic long bone, 117–120
augmentation of healing and stability, 118–120, 119
intramedullary nails, 117–118
plate devices, 117, 118
screws, 117
cement screw mechanics, 248–255
internal fixation, osteoporotic bone, 115
Implant devices (continued)

intertrochanteric fractures, unstable fracture fixation, 218
resorbable implants, augmentation of plate fixation, 259
spinal fracture fixation, implant-bone interface, 128–129
Indian Hedgehog (Ihh), normal fracture healing, 24–25
Infection, external fixation complications, 190–191
Inflammation, normal fracture healing, 23
Inflatable bone tamps, vertebroplasty procedures, 327–332, 328
Inflatable intramedullary nail, osteoporotic fracture fixation, 88, 89
animal studies, 303, 303–304
biological fixation, 307
biomechanical studies, 302–303, 303
clinical trials, 304–305, 305
cross section, 307
design, 301–302, 302
diameter alterations, 307
operative and fluoroscopic time reduction, 307
proximal femur fracture, 305–307, 306
Injectable fixation devices

cementing screw, fixation mechanics, 242–246, 243–245
vertebroplasty procedures, calcium phosphate cement, 326–328
Instantaneous axis of rotation (IAR), telescopic plate spacer (TPS) biomechanics, 350–351
Insulin-like growth factor-1 (IGF-1), enhanced fracture healing, 27–29
Interleukins, normal fracture healing, 23
Interlocking nails

internal fixation, osteoporotic long bone fractures, 118
osteoporotic fracture fixation, 86
proximal humerus fractures, Synthes spiral blade system, 297–300
retrograde (supracondylar) nail, 87
Internal fracture fixation

hip fractures, Norian SRS resorbable cement augmentation, 207–215
ostegenesis imperfecta

biomechanics, 174–176
classification, 162–165, 162–165
clinical signs, 162
closed management techniques, 165
long bone deformity management, 165–174, 166–168
closed vs. semiclosed intramedullary rodding, 169, 172
multiple osteotomy and intramedullary fixation, 172–174
surgical options, 168–169, 170–171
osteoporotic bone

acetabular and pelvic fractures, 137–176
augmentation of healing and stability, long bone fractures, 118–120, 119–120
basic principles, 108–114, 109
bone augmentation, 111–112, 113
bone substitution, 113–114, 114
impaction, 109–110
implant development, 115
intramedullary nails, 117–118
long bone fixation, 116–125
long splintage, 110–111, 111–112
plates, 117, 118
proximal femoral fractures, hydroxyapatite granular devices, 232–236, 233–235
screws, long bone fractures, 117
spinal fractures, 129–135
wide buttress, 110
Paget’s disease

complications, 157–158, 158
spinal decompression, 159
surgical considerations, 157
tibial osteotomy, 158
total joint arthroplasty, 158–159, 159
treatment protocols, 156, 156–157
periprosthetic supracondylar femur fractures, 273
proximal humerus fractures, Synthes spiral blade system, 296–300
Internal rotation, internal fixation, osteoporotic bone, 109
Intertrochanteric fractures

bone tumor management, 183
internal fixation, Norian SRS resorbable cement, 208–209, 211–214, 212–213
sliding hip screw (SHS) fixation, 120–121, 120–121
unstable fracture fixation

anatomical specimens, 217
dynamic load testing, 218–219, 219
fracture model, 218, 218
glass-ionomer cement, 217–218
implants, 218
irreversible caudal-oriented deformation, 219, 220
osteosynthesis stability comparisons, 221, 221
statistical analysis, 219
tilt angles, cemented/uncemented, 219, 220
Intramedullary (IM) nails

bone tumors, 180, 180
cement fixation, proximal humeral fractures, 292–295
femoral mechanical deficiency, Huckstep nail, 287–291
fracture fixation, 45, 45–46
interlocking blade plates, 269–270
intratrocchanteric fracture fixation, hip screws, 121
ostegenesis imperfecta, 165, 167
closed vs. semi-closed intramedullary rodding, 169, 172
fracture biomechanics, 175–176
long bone fractures, 167–169, 168
multiple osteotomy

extensible nails, 173–174
solid nails, 172–173
ostoporotic fracture fixation, 84–88
attachment/anchoring complications, 89–90, 90–91
cement/composite augmentation, 96
distal fixation, 310–313
dynamic nails, 86–87
expandable nail, 88, 88, 301–308
flexible nail, 87–88, 88
Huckstep nail, 87
inflatable nail, 88, 89
interlocking nail, 86, 86
internal fixation

implant biomechanics, long bone fractures, 117–118
long splintage principle, 111, 112
nonunion complications, 90–91, 91
polarus nail, 88, 89
reaming issues, 88–89
research and development, 85
retrograde interlocking (supracondylar) nails, 87
standard nails, 86
titanium nails, 87
Synthes spiral blade system, proximal humeral fractures, 296–300

Intramedullary pressure, expandable intramedullar nail insertion and inflation, 304
Intramembranous bone formation, normal fracture healing, 23
Invasive techniques, enhanced fracture healing, 27
In vivo gene therapy, fracture healing, 30
Irradiation. See Radiation therapy
Irreversible deformation, intertrochanteric fractures, unstable fracture fixation, cemented vs. uncemented, 219, 220, 221
Ischemia, osteoporotic fracture fixation, 90–91
Isola rods, spinal fixation, pedicle screw/laminar hook combination, 130–131

K
Kirschner wires, fracture fixation
acetabular and pelvic fracture fixation, 145
common applications, 42–43
internal fixation, osteoporotic bone, 109
wide buttress concept, 110
osteogenesis imperfecta, management, 165, 166
osteoporotic bone
dynamic hip/condylar screws, 78
pin devices, 93, 93
proximal humerus fracture fixation, spiral blade fixation vs., 298
Klemm-Schellman intramedullary nail system
development of, 85
interlocking nail, 86
Kuntscher intramedullary nail, development of, 85–86
K-wires. See Kirschner wires, fracture fixation
Kyphoplasty
osteoporotic fracture fixation, cement/composite augmentation, 96–97
vertebral compression fractures, 335–340
vs. vertebroplasty, 340

L
Lag screws, osteoporotic fracture fixation, 77
Laminar hooks, spinal fracture fixation, pedicle screw combined with, 129–134, 130–135
Lateral mass screws, cervical spinal fixation, 343
Lateral tibial plateau fracture, rafter plate fixation, 123, 123
LC-DCP. See Limited contact dynamic compression plate
L-Dopa, enhanced fracture healing, 26–27
Least significant change (LSC) characteristic, densitometric measurement, 60
Less invasive stabilization system (LISS) plate applications, 276–278, 277
osteoporotic fracture fixation, 81, 84
periprosthetic supracondylar femoral fractures, 271–278
Limb measurements, single x-ray absorptiometry (SXA), 61–62
Limited contact dynamic compression plate (LC-DCP)
axially mobile plate mechanics, 280–281, 281
osteoporotic fracture fixation, 80, 81
LIM mineralization protein (LIMP-1), fracture healing mechanisms, ex vivo gene therapy, 30
LISS plate. See Less invasive stabilization system (LISS) plate
Liu’s self-guided pedicle screw, osteoporotic fracture fixation, 78, 78
Load-displacement curves
cortical osteoporotic bone fracture mechanics, 12, 12–13
fracture healing, 31
plate fixation biomechanics, 273–274, 274
spinal fixation, pedicle screw/laminar hook combination, 131, 131
Long-bone fractures
osteogenesis imperfecta
T-piece devices
complications, 175–176
extensible nails, 173–174
osteoporotic bone
cortical bone fracture morphology, 11–12, 11–12
internal fixation, 116–125
augmentation, 118–120, 119–120
plate fixation devices, impact mechanics, 117, 118
shape memory alloys (SMA), long bone fixators, 94, 95
shape memory alloys (SMA), fixation with, 94, 95
Long splintage principle, internal fixation, osteoporotic bone, 110–111, 110–112
Lordosis restoration, telescopic plate spacer (TPS) biomechanics, 351
LSC. See Least significant change (LSC) characteristic

M
Macrophase colony-stimulating factor (M-CSF), osteoclast cell biology, 5
Macroscopic analysis, osteoporotic bone and fracture biomechanics
cancellous bone, 13
cortical bone, 10
Magnetic resonance imaging (MRI)
bone density measurement, 64–65
occult pelvic and acetabular fractures, 139
vertebroplasty procedures, qualitative and quantitative analysis, 328–329, 329
Marchetti-Vicenzi expandable intramedullary nail, osteoporotic fracture fixation, 88, 88
Mass attenuation coefficient, radiographic imaging, osteoporosis, 51–52, 52
Material testing machine (MTM), femoral neck fractures, internal fixation, Norian SRS resorbable cement augmentation, 208
Matrix metalloproteinase-13 (MMP-13), normal fracture healing, 24
McDonnell’s extrapharyngeal technique, cervical metastases, telescopic plate spacer (TPS), management, 353–354, 354
MCKOY cementing screw, osteoporotic fracture fixation, 78–79, 78–79
M-CSF. See Macrophage colony-stimulating factor
Mechanical load, osteoporosis pathophysiology, 195
Mechanical stimulation, enhanced fracture healing, 26–27
Mechanical testing system (MTS)
  axially mobile plates, 280–281
  cement screw mechanics, 248–255
  injectable cementing screw analysis, 244
  interlocking screws, 238–240, 239
  telescopic plate spacer (TPS), 351–353, 352
Melt processing, resorbable polymers, 261–262
Memory alloys. See Shape memory alloys
Mennen plate, osteoporotic fracture fixation, 82, 82–83
Metaphyseal/epiphyseal defects
  internal fixation, osteoporotic bone, augmentation principle, 112
  osteoporotic fracture fixation
    cement screw, 248–255
    interlocking blade plates, 266–270
Metastatic disease
  bone tumors, 178–179, 179
  femoral mechanical deficiency, Huckstep nail fixation, 289–291, 290
  incidence, 182
  telescopic plate spacer (TPS), management with
cervical thoracic metastasis, low anterior cervical approach, 354–355, 355
  midcervical schwannoma, transcervical approach, 354–355, 355
  plasmacytoma, paraspinous component resection, 356–357, 357
Methyl-methacrylates
  percutaneous vertebroplasty, side effects and complications, 321, 321–322
  resorbable implants, augmentation of plate fixation, 259–263
  undecalciﬁed bone processing, 5–6
Meyrueis’ adhesive plate, osteoporotic fracture fixation, 81, 81–82
Micro-CT analysis, osteoporotic cancellous bone, 19
Microscopic analysis, osteoporotic bone and fracture biomechanics
  cancellous bone, 13–19
    heterogeneous-anisotropic approach, 18–19
    homogeneous-anisotropic approach, 14–18, 14–18
    homogeneous-isotropic approach, 13–14, 14
  cortical bone, 10
Minimally invasive percutaneous plate osteosynthesis (MIPPO), osteoporotic fracture fixation, 84
Minimally invasive surgery, vertebral compression fractures (VCF), 334–340
Minimum contact plate (MCP), osteoporotic fracture fixation, 81
MMP-13. See Matrix metalloproteinase-13 (MMP-13)
Monitoring time interval (MTI), densitometric measurement, 60
Morphometric techniques, radiographic assessment vertebral fracture/deformity, 56, 56–58
Morphometric x-ray absorptiometry (MXA), osteoporotic bone imaging, 58, 58–59
MTI. See Monitoring time interval (MTI)
MTS. See Mechanical testing system (MTS)
MXA. See Morphometric x-ray absorptiometry
Myelomas, percutaneous vertebroplasty, 318, 318
N
Necrosis, osteoporotic fracture fixation, 90–91
Neer classiﬁcation
  periprosthetic supracondylar femur fractures, 272, 272
  proximal humerus fractures, Synthes spiral blade system, 296
Neurological injury, acetalabular and pelvic fracture fixation, complications, 152
Neurotrophins, normal fracture healing, 25
NF-κB. See Nuclear factor kappa b
Noninvasive techniques, enhanced fracture healing with, 26–27
Nonlinearity, trabecular bone density and mechanics, 14
Non-self-tapping screws, osteoporotic fracture fixation, 76–77, 77
Nonsteroidal anti-inﬂammatory drugs, Paget’s disease, 156, 156–157
Nonunion complications
  acetalabular and pelvic fractures, 138, 153
  gene therapy for, 29–30
  osteoporotic fracture fixation, 90–91, 91
Norian SRS resorbable cement, hip fracture internal ﬁxation, augmentation using, 207–215
  clinical studies, 209–214
  femoral neck fractures, 208–211
  intertochanteric fractures, 208–209, 211–214, 212–213
Nuclear factor kappa b (NF-κB), osteoclast cell biology, 5
O
Occult pelvic and acetabular fractures, diagnosis, 139
OIC. See Osteogenesis imperfecta congenita
OIT. See Osteogenesis imperfecta tarda
Olecranon fractures, osteogenesis imperfecta, management, 165, 166
Omega21™ expandable screw, osteoporotic fracture ﬁxation, 79, 79
On-axis testing, cancellous bone elastic modulus and strength, 15–16, 17
Open reduction and internal ﬁxation (ORIF) protocol
  acetalabular fractures, contraindications, 141
  external osteoporotic fracture ﬁxation, 188
  fracture healing biology and biomechanics, 22
  periprosthetic supracondylar femur fractures, 272–273
Orthofix pins, stability analysis, 224
OSEL expression, bone remodeling, 4–5
Osteosclerotic bone, osteoporotic fracture ﬁxation, 90–91
Osteobiologics, enhanced fracture healing, 27
Osteoblasts
  bone formation, 3–5, 4
  cell biology, 4–5
Osteocalcin
  bone remodeling, 4–5
bone turnover analysis, 6–7

Osteoclasts
bone resorption, 3–5, 4
cell biology, 5

Osteogenesis imperfecta, internal fixation
biomechanics, 174–176
classification, 162–165, 162–165
clinical signs, 162
closed management techniques, 165
long bone deformity management, 165–174, 166–168
closed vs. semiclosed intramedullary rodding, 169, 172
multiple osteotomy and intramedullary fixation, 172–174
surgical options, 168–169, 170–171

Osteogenesis imperfecta congenita (OIC), classification, 163

Osteogenesis imperfecta tarda (OIT), 163

Osteogenic growth peptide, enhanced fracture healing, 28–29

Osteolytic metastases, percutaneous vertebroplasty, 318, 318

Osteomyelitis, external osteoporotic fracture fixation, 188, 188

Osteopenia
distal fixation, intramedullary nails, 310–313
in osteogenesis imperfecta, 162, 164
radiographic imaging, quantitative analysis, 52

Osteopenic models, fracture healing biology and biomechanics, 32–34

Osteoporosis
acetabular and pelvic fractures, clinical presentation, 137–138
biochemical and cellular defects, 74–75
bone biochemistry and cellular characteristics, 74–75
bone mechanics, 9–10, 10
cancellous bone, 13–19
fracture mechanics, 19
macroscopic analysis, 13
microscopic analysis, 13–19
ultramicroscopic analysis, 19
classification, 198
cortical bone, 10–13
fracture mechanics, 11–12, 11–13
macroscopic analysis, 10
microscopic analysis, 10
ultramicroscopic analysis, 10–11
densitometry, 59–65
accuracy and precision, 59
magnetic resonance imaging (MRI), 64–65
nomenclature, 59
performance evaluation, 60, 60
peripheral quantitative computed tomography (pQCT), 63
quantitative computed tomography (QCT), spinal sites, 62–63, 63
quantitative ultrasound, 64
radiographic absorptiometry, 60
single and dual x-ray absorptiometry, 60–62, 61
T-scores and Z-scores, 59
epidemiology, 5
fracture fixation, 40, 40–41
bioabsorbable materials, 97
bone grafts, 95
cement and composite, 95–97
augmentation of fixation with, 95–96, 96
direct fixation, 95
vertebroplasty/kyphoplasty, 96–97
cerclage systems, 91–93, 92
current trends in, 73–101, 74
external fixation
biomechanics, 187
complications, 190–191
design criteria, 186, 187
hydroxyapatite-coated pin stability and, 228–230, 229
indications for, 187–188, 188
osteoporotic bone, clinical practice, 189, 190
injectable cementing screw, 242–246
interlocking screw device, 237–240
internal fixation, 108–114, 109
long bone fixation, 116–125
proximal femoral fractures, hydroxyapatite granular devices, 232–236, 233–235
intramedullary nails, 84–88
attachment/anchoring complications, 89–90, 90–91
dynamic nails, 86–87
expandable nail, 88, 88
flexible nail, 87–88, 88
Huckstep nail, 87
inflatable nail, 88, 89
interlocking nail, 86, 86
nonunion complications, 90–91, 91
polarus nail, 88, 89
reaming issues, 88–89
research and development, 85
retrograde interlocking (supracondylar) nails, 87
standard nails, 86
titanium nails, 87
patella fixator, 94
pelvic fixation, 101, 101
pin fixation, 92–93, 93
plates (rigid fixation), 79–84
adhesive plate, 81–82
augmentation methods, 83–84, 83–84
axially mobile or sliding plates, 83
blade plate, 82, 82
buttress plate, 82
cushioned plates, 83
LC-DCP, MCP, and PC-fix, 81
Mennen plate, 82–83, 83
minimally invasive techniques, 84, 84
resorbable implants, augmentation with, 259–263
vs. biological fixation, 80–81, 81–82
Zespol plate, 83, 83
screws, 74–79
attachment/anchoring complications, 89–90, 90
cementing screws, 78, 78–79
cortical vs. cancellous, 74–76, 76
dynamic hip screws/condylar screws (DHS/DCS), 78, 78
expanding bolts/screws, 79, 79
fully threaded vs. partially threaded, 77
Osteoporosis (continued)

Herbert screws, 77, 77
hollow wall anchor, 79, 80
interlocking screws, 78
pedicle screws, 78, 78
self-tapping vs. non-self-tapping, 76–77, 77
solid vs. cannulated screws, 77
shape memory alloys (SMA), 93–95, 94
spinal fixation, 97–101
hooks, 99–100, 100
screws, 97–99, 98–99
wires, 100, 100
fracture healing biology and biomechanics
enhanced healing, 26–29
estrogen-deficient osteopenic models, 32–34
genotype, nonunions and clinical bone loss problems, 29–30
normal healing, 23–26
repair states, 30–31
testing biomechanics, 31–32
fracture prevention and medical treatment
definition, 195–196, 196
diagnosis, 197
hip and vertebral fractures, 197–198
pathophysiological principles, 194–195
risk factors, 196–197
histomorphology and pathogenesis
bone cells and bone remodeling, 3–5, 4
bone histomorphometry, 5–6, 6
bone turnover biomarkers, 6–7
metaphyseal bone, cement fixation screw, 248–255
radiographic imaging, 51–59
cortical thinning, 53, 53
morphometric x-ray absorptiometry, 58, 58–59
physical/technical issues, 51–52, 52
radiogrammetry, 54
trabecular structure analysis, 52–54, 53
vertebral fractures and deformities, 54, 54–58, 56
therapy, 198–201
vertebral compression fractures
inflatable bone tamps and calcium-phosphate cement, 325–332
minimally invasive surgery for, 334–340
percutaneous vertebroplasty, 319–320, 320
Osteoporotic nut and washer, osteoporotic fracture fixation, attachment/anchoring problems, 90
Osteoprotegerin (OPG), osteoclast cell biology, 5
Osteosynthesis stability
cement screw mechanics, 248–249, 249
intertrochanteric fractures, unstable fracture fixation, 221, 221
proximal femoral fracture, internal fixation, hydroxyapatite granular devices, 232–236, 233–235
Osteotomy procedures
femoral neck fractures, internal fixation, Norian SRS resorbable cement augmentation, 208
osteogenesis imperfecta
intramedullary fixation, extensible nails, 173–174
intramedullary fixation, solid nails, 172–173
resorbable polymer augmentation, 262–263, 263
tibial osteotomy, Paget’s disease, 158

P
Paget’s disease
bisphosphonate therapy, 200
internal fracture fixation
complications, 157–158, 158
surgical considerations, 157
treatment protocols, 156, 156–157
spinal decompression, 159
tibial osteotomy, 158
total joint arthroplasty, 158–159, 159
Pain management
acetabular and pelvic fractures, 153
femoral neck, internal fracture fixation, Norian SRS resorbable cement augmentation, 211
Paget’s disease, fracture fixation, 157–158, 158
vertebral compression fractures, minimally invasive techniques, 337–340
Pamidronate, osteoporosis therapy, 200
Parallel locking screws, distal fracture fixation, intramedullary nails, 311–313, 312
Parathyroid hormone, enhanced fracture healing, 26–27
Patella fixator, shape memory alloys (SMA), 95
PC-Fix. See Point contact fixator
PDGF. See Platelet-derived growth factor
PE. See Pulmonary embolus
Pedicle screws
osteoporotic fracture fixation, 78, 78
spine fixation, 98, 98–99
posterior screws, 343
self-guided pedicle screw, cervical spinal fixation, 342–347
spinal fracture fixation
implant-bone interface, 128–129
laminar hook combined with, 129–134, 130–135
Pelvic fractures
external fixation, osteoporotic bone, 149
fixation, osteoporotic patients, 101, 101
internal fixation, osteoporotic bone biomechanics, 142–145 143–144
isolated screws, 143–144
plate fixation, 144–145
bone plate alterations, 146–147
cable/ cerclage wire fixation, 147–149, 148
clinical presentation, 137–138
diagnosis, 138–139
epidemiology, 138
methylmethacrylate cement, 149
occult fractures, 139
pelvic columns, 149
screw fixation, alterations, 145–146
surgical indications/contraindications, 139–142
displaced fractures, 140–141
open reduction, contraindications, 141
pelvic ring disruption, 141–142
percutaneous fixation, 139–140, 140
periprosthetic involvement, 142
total joint arthroplasty, 141
irradiation therapy, fixation in presence of, 149–150
total hip arthroplasty, osteoporotic bone, 150–153
complications, 152–153
periprosthetic fractures, 150–152
Pelvic ring
  external osteoporotic fracture fixation, 188
  internal fracture fixation, 141–142
Percutaneous fixation
  osteogenesis imperfecta, 167
  pelvic and acetabular fractures, 139–140, 140
  vertebroplasty
    bone cement, compromised vertebral bodies, 317–323
    minimally invasive techniques, 335–340
Periarticular injury, external osteoporotic fracture fixation, 188
Peripheral dual x-ray absorptiometry (pDXA), forearm and calcaneal measurements, 62
Peripheral quantitative computed tomography (pQCT), osteoporotic bone measurement, 63
Periarticular fractures
  acetabular and pelvic region
    prosthetic replacement, 150–152, 152
    surgical management, 142
  supracondylar femoral fractures, LISS plate fixation, 271–278
Perpendicular screws, distal fracture fixation, intramedullary nails, 311–313, 312
Peter Williams nail, osteogenesis imperfecta, long bone fractures, multiple osteotomy, solid nails, 171, 172–173
Photon flux principles, radiographic imaging, osteoporosis, 51–52, 52
Pin devices
  external fixation, 43–45, 44
    hydroxyapatite-coated pins, stability
    animal studies, 225–226
    degradation analysis, 229–230
    normal bone, clinical studies, 226–228, 227–229
    osteoporotic bone, clinical studies, 228–229, 229
    research background, 224–225, 225
    osteoporotic bone, 186–191, 187, 190
  fracture fixation, 42–43, 43
  osteoporotic bone, 92–93, 93, 186–191, 187, 190
Plasmacytoma, cervical metastases, telescopic plate spacer (TPS), management of, 356–357, 357
Plate devices (rigid fixation)
  acetabular and pelvic fractures, 144–145
  cable and cerclage wires with, 147–149, 148
  fixation alterations, 146–147
  axially mobile plate device
    biomechanics, 279
    design criteria, 280, 280–282, 282
    flexible vs. sliding plates, 279–280
    performance evaluation, 280–281, 280–281
  biomechanics, 273–274, 274
  bone tumors, 180–181, 181
  fracture fixation, 45–46, 47
  interlocking blade plates, osteoporotic metaphyseal fractures, 266–270
  osteoporotic fractures, 79–84
    adhesive plate, 81–82
    augmentation methods, 83–84, 83–84
    resorbable implants, 259–263
    axially mobile or sliding plates, 83
    vs. biological fixation, 80–81, 81–82
  blade plate, 82, 82
  buttress plate, 82
  cushioned plates, 83
  implant biomechanics, long bone fractures, 117, 118
  LC-DCP, MCP, and PC-fix, 81
  Mennen plate, 82–83, 83
  minimally invasive techniques, 84, 84
  Zespol plate, 83, 83
  shape memory alloys (SMA), clamp-on bone plates, 94, 94
Platelet activation, normal fracture healing, 23
Platelet-derived growth factor (PDGF), fracture healing mechanics
  enhanced fracture healing, 28
  normal fracture healing, 23–24
Point contact fixator (PC-fix), osteoporotic fracture fixation, 81
Polarus nail, osteoporotic fracture fixation, 88, 89
Polymer characteristics, resorbable implants, augmentation of plate fixation, 259–263
Polymethylmethacrylate (PMMA)
  acetabular and pelvic fracture fixation, 149
  cement screw mechanics, 248–255
  injectable cementing screw, 242–246
  internal fixation, osteoporotic bone
    augmentation of healing and stability, 118–120
    augmentation principle, 111–112, 113–114
  intertrochanteric fractures, internal fixation, Norian SRS
    resorbable cement, 211–214
  intertrochanteric fractures, unstable fracture fixation, 217–222
  osteoporotic fracture fixation
    attachment/anchoring problems, 90
    cement and composite materials, 95–97
    cementing screws, 78, 78–79
    interlocking screws, 237–240
    spinal fixation, screw devices, 99
  percutaneous vertebroplasty, 317–323, 321–322
  resorbable implants, augmentation of plate fixation, 259–263
  spinal fracture fixation, implant-bone interface, 129
  vertebral compression fractures, minimally invasive techniques, 335–340
  vertebroplasty, inflatable bone tamps and calcium-phosphate cement, 325–332
Polytrauma, external osteoporotic fracture fixation, 188
Porosity
  cancellous bone, 14
  cement screw mechanics, 252, 253
Posterior fixation devices, fracture fixation mechanics, 48, 48–49
Posterior longitudinal ligament (PLL), vertebroplasty procedures, 332
Postoperative autoimpaction, internal fixation, osteoporotic bone, 109–110
Power law relationship, screw devices, bone shear strength, 143
pQCT. See Peripheral quantitative computed tomography
Precision parameters, densitometric analysis, 59
Prince Tong forceps, acetabular and pelvic fracture fixation, 147–148
Prophylactic management procedures, bone tumors, 179–181
nonoperative management, 179–180
surgical management, 180, 180–181

Prosthetic replacement techniques
acetabular and pelvic fractures, periprosthetic involvement, 142, 150–152, 152
bone tumors, 181, 182
internal fixation, osteoporotic bone, 112–113, 114

Proximal femur
bone tumor management in, 182–183
femoral mechanic deficiency, Huckstep nail fixation, 289–291, 290
fracture fixation, expandable intramedullary nail, 305–306, 306
internal fracture fixation, hydroxyapatite granular devices, 232–236, 233–235

Proximal humerus
bone tumor management, 184
fracture
intramedullary cement fixation, 292–295
Synthes spiral blade system, 296–300
tension band fixation, 124, 124–125

Pullout strength measurements
cement screw mechanics, 251–255, 252–254
interlocking blade plates, 266–270

Pulmonary embolus (PE), acetabular and pelvic fracture fixation, complications, 152–153

Q
QCT. See Quantitative computed tomography
Qualitative analysis, vertebroplasty procedures, 328–329, 329

Quantitative analysis
biomechanical repair stages, fracture repair, 31
magnetic resonance imaging (QMR), 64
vertebroplasty procedures, 328–329, 329

Quantitative computed tomography (QCT), osteoporotic bone measurement, 62–63, 63
Quantitative ultrasound (QUS), osteoporotic bone density measurement, 64

R
RA. See Radiographic absorptiometry (RA)
Radial preload, external osteoporotic fracture fixation biomechanics, 187
Radiation therapy, acetabular and pelvic fracture fixation
clinical presentation, 138
complications, 149–150
Radiogrammetry, osteoporotic bone analysis, 54
Radiographic absorptiometry (RA)
hydroxyapatite-coated pins, 225, 226
osteoporotic bone analysis, 60
Radiographic imaging
osteoporosis, 51–59
cortical thinning, 53, 53
morphometric x-ray absorptiometry, 58, 58–59
physical/technical issues, 51–52, 52
radiogrammetry, 54
trabecular structure analysis, 52–54, 53
vertebral fractures and deformities, 54, 54–58, 56
percutaneous vertebroplasty, 317
vertebroplasty procedures, qualitative and quantitative analysis, 328–329, 329
Radiological vertebral index (RVI), vertebral fracture/deformity, radiographic assessment, 55–58
Radiostereometric analysis (RSA)
 femoral neck, internal fracture fixation, Norian SRS resorbable cement augmentation, 210–211
intertrochanteric fractures, internal fixation, Norian SRS resorbable cement augmentation, 213–214
Rafter plate, lateral tibial plateau fracture fixation, 123, 123
Raloxifene, osteoporosis therapy, 199
RANK/RANKL. See Receptor for activation of nuclear factor kappa b (NF-κB)(RANK) ligand (RANKL)
Reaming process, osteoporotic fracture fixation, intramedullary nailing, 88–89
Receptor for activation of nuclear factor kappa b (NF-κB)(RANK) ligand (RANKL), osteoclast cell biology, 5
Reconstruction plates, acetabular and pelvic fracture fixation, 145
Repair mechanics, biomechanical stages, fracture repair, 30–31
Resorbable polymers
degradation, 261
implants, augmentation of plate fixation, 259–263
mechanical properties, 262
poly (L-lactide) material, internal fixation, osteoporotic bone, healing and stability augmentation, 120
Retrograde interlocking nail, osteoporotic fracture fixation, 87
Reverse obliquity fractures, sliding hip screw fixation, 120, 120–121
Rheumatoid arthritis, spinal fixation, wire devices, 100
Ring fixators, osteoporotic fracture fixation, external fixation, 186
Risedronate, osteoporosis therapy, 200
Risk factors
osteoporosis, 196–197
algorithm for, 201
periprosthetic fractures, 271–272
Root mean square (RMS) analysis, densitometric precision, 59
Rush rods, osteogenesis imperfecta, long bone fractures, 169
multiple osteotomy, solid nails, 172–173
Russel-Taylor interlocking nail system
development of, 86
nonunion complications, 90–91
RVI. See Radiological vertebral index (RVI)

S
SAFHS. See Sonic Accelerated Fracture Healint System (SAFHS)
Schanz self-drilling screw, osteoporotic fracture fixation, 76–77, 77
Schuhli nut, osteoporotic fracture fixation, plate augmentation, 83, 83
Sciatic nerve palsy, acetabular and pelvic fracture fixation, complications, 152
Screw fixation devices
acetabular and pelvic fractures
fixation alterations, 145–146
isolated screws, 143–144
biomechanics, 142–143, 142–143
bone tumors, 180–181, 181
distal fracture fixation, 310, 310–313
geometric features, 142
holding strength or predicted shear failure force, prediction of, 142
injectable cementing screw, 242–246, 243–245
intertrochanteric fractures, internal fixation, Norian SRS resorbable cement augmentation, 212–213, 212–214
LISS plate biomechanics, 275, 275
locking pins, 240
osteoporotic fractures, 74–79
attachment/anchoring complications, 89–90, 90
cement/composite augmentation, 95–97, 96
cementing screws, 78, 78–79
cortical vs. cancellous, 74–76, 76
dynamic hip screws/condylar screws (DHS/DCS), 78, 78
expanding bolts/screws, 79, 79
fully threaded vs. partially threaded, 77
Herbert screws, 77, 77
hollow wall anchor, 79, 80
interlocking screws, 78, 237–240
internal fixation, 109
implant devices, 115, 117
long bone fractures, 117
metaphyseal bone, cement screw for, 248–255
pedicle screws, 78, 78
self-tapping vs. non-self-tapping, 76–77, 77
solid vs. cannulated screws, 77
spinal fixation, 97–100, 98–100
self-guided pedicle screws, cervical spinal fixation, 342–347
telescopic plate spacer (TPS) biomechanics, 350–351
thread shear areas, 143
SD. See Standard deviation
Self-drilling pins, external osteoporotic fracture fixation, 189, 190
Self-guided pedicle screw, cervical spinal fixation, 342–347
Self-tapping screws, osteoporotic fracture fixation, 76–77, 77
Semi-closed techniques, osteogenesis imperfecta, 167
vs. closed intramedullary rodding, 169, 172
Shape memory alloys (SMA), osteoporotic fracture fixation, 93–95, 94
clamp-on bone plates (embracing fixators), 94, 94
compressive staples, 94, 94
long bone fixators, 94, 95
patella fixator, 94
Sheffield rod system, osteogenesis imperfecta, long bone fractures, 169
complications, 175–176
multiple osteotomy, 173–174
Short-segment instrumentation, spinal fixation, pedicle screw/laminar hook combination, 131–132
SHS. See Sliding hip screw
Singh index, tissue architecture, osteoporotic bone, 75
Single x-ray absorptiometry (SXA), osteoporotic bone measurement, 60–62, 61–62
Skeletal loss, internal fixation principles, osteoporotic bone, augmentation of healing and stability, 118–120, 119
Skeletal measurements, dual x-ray absorptiometry (DXA), 62
Sliding hip screw (SHS)
fracture fixation, 45–46, 47
intertrochanteric fracture fixation, 120–121, 120–121
Sliding plates
axially mobile plate device, 279–280
future design criteria, 281–282
intertrochanteric fracture fixation, 121
osteoporotic fracture fixation, 83
Smads protein family, fracture healing biology and biomechanics
normal fracture healing, 25–26
osteopenic fracture model, 33, 34
“Snow flurry” emboli, osteoporotic fracture fixation, intramedullary nailing, 89
Solid nails, osteogenesis imperfecta, long bone fractures, 169, 170–171
Solid screws, osteoporotic fracture fixation, 77
Sonic Accelerated Fracture Healint System (SAFHS), enhanced fracture healing, 26–27
Speed of sound (SOS), quantitative ultrasound (QUS) measurement, 64
Spinal decompression, Paget’s disease, 159
Spinal fixation
case studies, 132–134, 133–134
epidemiology and demographics, 134–135
internal fixation, osteoporotic bone
indications for, 128
instrumentation and augmentation techniques, 128–129
long splintage principle, 111
pedicle screw/laminar hook combination, 129–134, 130–135
mechanics, 47–49, 48
Omega21™ expandable screw, 79, 79
osteoporotic spine, fixation devices
hook fixation, 99–100, 100
screws, 97–99, 98–99
wire fixation, 100, 100
self-guided pedicle screw, anterior fixation with, 342–347
Spinal fracture index (SFI), radiographic assessment vertebral fracture/deformity, 56, 56
Spinal measurements, dual x-ray absorptiometry (DXA), 61–62
Spiral blade
osteoporotic fracture fixation, attachment/anchoring problems, 90, 90–91
proximal humerus fractures, Synthes spiral blade system, 296–300
Standard deviation (SD), densitometric analysis, 59
Statistical analysis
intertrochanteric fractures, unstable fracture fixation, 219
vertebroplasty procedures, 329–330, 330–331
Steinmann pins, osteogenesis imperfecta, long bone fractures, multiple osteotomy, solid nails, 172–173
Stiffness measurements
axially mobile plate mechanics, 280–281, 281
Stiffness measurements (continued)
  femoral neck fractures, internal fixation, Norian SRS resorbable cement augmentation, 208
  spinal fixation, pedicle screw/laminar hook combination, 131, 132
  telescopic plate spacer (TPS), 352–353
Stress concentration, spinal fracture fixation, prevention, anchor point size, 129
Subtrochanteric extension, sliding hip screw fixation, 120, 120–121
Supracondylar fractures
  distal femur, blade plate fixation, 121–122, 122
  periprosthetic femoral fractures, LISS plate fixation, 271–278
Supracondylar retrograde interlocking nail, osteoporotic fracture fixation, 87
Surgical management techniques
  acetabular and pelvic fractures, indications/contraindications, 139–142
  displaced fractures, 140–141
  open reduction, contraindications, 141
  pelvic ring disruption, 141–142
  percutaneous fixation, 139–140, 140
  periprosthetic involvement, 142
  total joint arthroplasty, 141
bone tumors, fixation techniques, 180, 180–181
expandable intramedullary nail, 307
interlocking blade plates, 266–267, 267
intratrochanteric fractures, internal fixation, Norian SRS resorbable cement, 212, 212–214
osteogenesis imperfecta, long bone deformity management, 168–169, 170–171
Paget’s disease, 157
percutaneous vertebroplasty, 317–318
proximal humeral fractures
  Synthes spiral blade fixation, 299–300
vertebral compression fractures (VCF), minimally invasive procedures, 334–340
Symptomatic hardware, acetabular and pelvic fracture complications, 153
Synthes spiral blade system, proximal humerus fractures fixation, 296–300

T
Tamoxifen, osteoporosis therapy, 199
Target cells, gene therapy, fracture healing, 30
Tartrate-resistant acid phosphatase (TRAPase), bone remodeling process, 3–5
Telescopic plate spacer (TPS), vertebral tumor and compression fracture management, 347–357
biomechanics, 350, 350–351
mechanical testing, 351–353, 352
metastatic disease, case studies, 353–356, 354–357
in vivo Caprine model, 353, 353

Tension band fixation
  internal fixation, osteoporotic bone, wide buttress concept, 110
  osteogenesis imperfecta, management, 165, 166
  osteoporotic fracture fixation, external fixation, 186
  proximal humerus fracture, 124, 124–125
Tension testing, fracture healing, 32

Tetracycline labeling, osteoporosis histomorphology and pathogenesis, 4, 4, 6
TGF-b. See Transforming growth factor beta
Thoracotomy, spinal metastases, telescopic plate spacer (TPS), management of, 356–357, 357
Thromboembolism, acetabular and pelvic fracture fixation, complications, 152–153
Tibia
  bone tumor management, 184–185
  fracture fixation
    distal fracture fixation, intramedullary nails, 311–313
    expandable intramedullary nail, 304–305
Tibial osteotomy
  osteogenesis imperfecta, long bone fractures, multiple osteotomy, solid nails, 172–173
  Paget’s disease, 158
Tilt angles, intratrochanteric fractures, unstable fracture fixation, cemented vs. uncemented, 219, 220
Tissue injury, external osteoporotic fracture fixation, 188
Tissue microarchitecture, osteoporotic bone, 75
Titanium intramedullary nail
  nonunion complications, 90–91
  osteoporotic fracture fixation, 87
  resorbable polymer augmentation, 262–263
TKA. See Total knee arthroplasties
“Toggle” concept
  interlocking blade plates, 268–269
  LISS plate biomechanics, 274–276, 275–276
  plate fixation biomechanics, 273–274, 274
Torsional biomechanics
  axially mobile plate mechanics, 280–281, 281
  biomechanical repair stages, fracture repair, 31
  expandable intramedullary nail, 302–303, 303
  fracture healing, 31–32
  spinal fracture fixation, cross-linking and, 129
  telescopic plate spacer (TPS), 352–353
Total attenuation coefficient, radiographic imaging, osteoporosis, 51–52, 52
Total joint arthroplasty (TJA)
  acetabular and pelvic fractures, 141
  osteoporotic complications, 150–153, 152
  Paget’s disease, 158–159, 159
Total knee arthroplasties (TKAs), LISS plate fixation, 271–278
T-piece devices, osteogenesis imperfecta, long bone fractures, 168–169
  complications, 175–176
  multiple osteotomy, extensible nails, 173–174
TPS. See Telescopic plate spacer
Trabecular bone
densitometric analysis, quantitative computed tomography (QCT), 63, 63
density and mechanical properties, 14
fracture fixation, bone screws, 41–42, 42
homogeneous-anisotropic analysis, 14–18
magnetic resonance imaging (MRI), 65
orientation intensity, osteoporotic changes, 15, 16
radiographic imaging
  osteoporotic structural changes, 52–53, 53
  structural assessment, 53–54
Transarticular approach and retrograde plate osteosynthesis (TARPO), osteoporotic fracture fixation, 84
Transcervical technique, cervical metastases, telescopic plate spacer (TPS), management, 354–355, 355
Transduction pathways, gene therapy, fracture healing, 29
Transfixion pins, osteoporotic fracture fixation, external fixation, 186, 187
Transforming growth factor beta (TGF-b), fracture healing mechanics
enhanced fracture healing, 28
gene therapy, target cells, 30
normal fracture healing, 23–24
T-scores
densitometric techniques, 59
injectable cementing screw analysis, 243–246, 245
interlocking screws, 238–239, 239
Tubular plate, axially mobile plate device, 279
Twisted wires, osteoporotic fracture fixation, cerclage systems, 92, 93
Tygon® tubing, injectable cementing screw analysis, 243–246
Type I collagen, bone turnover analysis, 6–7

U
Ultimate load to failure
interlocking screws, 239, 239
telescopic plate spacer (TPS), 352, 352–353
Ultimate tensile load test
injectable cementing screw analysis, 244, 244–245
interlocking screws, 239, 239
Ultramicroscopic analysis
cancellous bone mechanics, 19
osteoporotic bone and fracture biomechanics, cortical bone, 10–11
Ultrasound
enhanced fracture healing, 26–27
osteoporotic cancellous bone analysis, 16–18
Ultrasound velocity (USV), osteoporotic cancellous bone, 17–18, 18
“Up and in” insertion method, spinal fixation, screw devices, 98, 99
USV. See Ultrasound velocity

V
Valgus impacted fracture, internal fixation, osteoporotic bone, 109–110
Vascular injury, acetabular and pelvic fracture fixation, complications, 152
VDS. See Vertebral deformity score (VDS)
Vectors, gene therapy, fracture healing, 29
Vertebral compression fractures (VCF)
inflatable bone tamps and calcium-phosphate cement, 325–332
minimally invasive surgical procedures, 334–340
complications, 339–340
percutaneous vertebroplasty, 319–320, 320
TPS devices, management with, 349–357
Vertebral deformity score (VDS), radiographic assessment, vertebral fracture/deformity, 55
Vertebral fracture and deformity
osteoporosis and risk of, 197–198
radiographic assessment, 54, 54–58, 56–57
self-guided pedicle screws, dimensions and insertion angle, 344, 344
Vertebral hemangiomas, percutaneous vertebroplasty, 318–319, 319
Vertebral tumors, TPS devices, management with, 349–357
Vertebroplasty
complications, 339–340
inflatable bone tamps and calcium-phosphate cement, 325–332
internal fixation, osteoporotic bone, augmentation principle, 112, 114
vs. kyphoplasty, 340
osteoporotic fracture fixation, cement/composite augmentation, 96–97
percutaneous vertebroplasty (PVP)
bone cement fixation, 317–323
complications, 321, 321–322
contraindications, 321
vertebral compression fractures, minimally invasive surgery for, 335–340
Vitamin D
osteoarthritis pathophysiology, 194–195
osteoporosis therapy, 198

W
Wave plate, osteoporotic fracture fixation, 80, 80–81
Wide buttress concept, internal fixation, osteoporotic bone, 110
Wire fixation
osteoporotic fractures, cerclage systems, 92
spinal fixation, 100, 100
Wolff’s law
cancellous bone directionality and density, 14
telescopic plate spacer (TPS) biomechanics, 350, 350–351
Wound infection, acetabular and pelvic fracture fixation, postoperative complications, 152
Wu rectangular intramedullary nail, osteoporotic fracture fixation, 87–88, 88

Y
Young’s modulus
cancellous bone elastic modulus and strength, 16, 17
resorbable polymer mechanics, 262

Z
Zespol plate, osteoporotic fracture fixation, 83, 83
Zickel supracondylar nail, development of, 86, 86
Z-scores, densitometric techniques, 59