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Department of Orthopaedics

Research Report

1993

1993 Research Report

Department of Orthopaedics

UNIVERSITY OF WASHINGTON

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SCHOOL OF
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Department
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COVER ILLUSTRATION: This striking work by Washington State glass artist William Morris is titled "Artifact Series #3 (Hunter)."

Contents

Chief Resident Abstracts

Foreword

We celebrate the excellence of UW orthopaedic traumatology with the 1993 Research Report. This theme is reflected in the cover illustration of glass art by William Morris, a work I call "Broken Bones in Glass." The lead article, "Orthopaedic Traumatology: Reflections Over Two Decades," by Ted Hansen, is followed by a wealth of articles from our trauma team and from the Harborview Orthopaedic Research Laboratory led by Allan Tencer.

By any measure, this has been an outstanding year for research. Let me describe several major highlights. Our department is second among orthopaedic departments nationwide in NIH research grant dollars awarded; only 16 of almost 200 orthopaedic departments receive any research support from NIH.

The broad spectrum of grants speaks volumes about our investigative strength: molecular imaging by oscillator-coupled resonance, regulation of gene expression in cartilage, pathology of inborn skeletal diseases, biochemistry of the intervertebral disc, spine pathology and low back pain determinants in identical twins, and development of an extremity trauma outcome scale.

The Centers for Disease Control and Prevention also will be funding departmental research through a grant on spinal canal geometry changes in vertebral fracture. The Veterans Affairs Department has funded major grants on subtalar and transverse tarsal joint mechanics, and synthesis and function of cartilage matrix molecules.

The depth and breadth of departmental research are recognized by our selection as a recipient of the prestigious five-year Bristol Myers-Squibb/Zimmer Institutional Grant for Excellence in Orthopaedic Research. This award will foster collaborative research among our molecular biology, collagen, morphology, kinematics, and biomechanics laboratories. In yet another honor, our department was chosen as the inaugural site of the AAOS/OREF Health Services Research Fellowship.

Additional indicators of our leadership in clinical research are two excellent new books by department faculty. Lynn Staheli's *Fundamentals of Pediatric Orthopaedics* provides a practical guide to the scientifically based management of the child's orthopaedic problems. *Orthopaedic Trauma Protocols,* edited by Ted Hansen and Marc Swiontkowski, condenses clinical research at the nation's leading trauma center into a practical "how to do it right the first time" guide useful to all traumatologists.

Honors continue to accrue to faculty members. Linda Sandell is the first woman in department history to achieve the rank of full professor. Stan Bigos chairs the U.S. Department of Health's AHCPR Low Back Pain Guidelines Panel to establish clinical practice guidelines in the care of acute back problems. Tom Trumble was chosen as an ABC Traveling Fellow. Carol Teitz was selected as an Asian Exchange Traveling Fellow by the American Orthopaedic Society for Sports Medicine. Marc Swiontkowski was elected member-at-large to the Board of Directors of the American Academy of Orthopaedic Surgeons.

Our residents also have distinguished themselves. In March the department hosted the 26th Annual American Orthopaedic Association Residents' Conference, an event superbly organized by Phil Kregor, Lyle Sorensen, and their fellow residents. Phil has received a Swiss National Science Foundation fellowship and the Shadyside Hospital Foundation International Traveling Fellowship in Pelvic and Acetabular Surgery. Jim Vahey received an Orthopaedic Research and Education Foundation resident grant. Peter Simonian has received the AOA/Zimmer Travel Award.

The 1993 Resident Research Days hosts Roby C. Thompson, Jr., this year's Shands Award winner, as guest professor. The two-day program, generously sponsored by our orthopaedic alumni, along with the Hark Lectureship Award from the OREF, showcases the research projects of our residents. Ed Laurnen has established a Spine Research Award that will be presented along with our two other resident research awards, named in honor of Esther Whiting and Victor Frankel.

Who is responsible for this success? The answer is many, many persons, including the faculty who provide the energy, vision, and resources, the Research Committee chaired by David Eyre, the Resident Research Program led by Bruce Sangeorzan, the alumni led by Bill Barrett, our able administrative, research and secretarial staff, and our generous individual and corporate donors. All should be proud of what we have accomplished this year! I salute each of you.

Frederick A. Matsen III, M.D.
Professor and Chairman

Orthopaedic Traumatology: Reflections Over Two Decades

Sigvard T. Hansen Jr., M.D.

Twenty years ago, a clinical research project began at Harborview Medical Center. It was not proposed or officially recognized as a clinical research project, it did not include statistically correct randomization of patients, and it certainly would not have been approved by the current review mechanism for clinical projects. Within the next ten years, despite these deficiencies, the results of our work on immediate internal fixation in multiply injured patients with musculoskeletal injuries defined orthopaedic traumatology as a new subspecialty.

Within 15 years, orthopaedic traumatology was recognized as a legitimate subspecialty by many hospitals as well as the American Academy of Orthopaedic Surgeons. The American Board of Orthopaedic Surgery included questions on the subspeciality in board certification examinations. In the early and mid-1980s, treatment of trauma received a great deal of attention, and television glorified paramedic teams and trauma hospitals. Within a decade, however, many trauma hospitals had closed and others were struggling to stay afloat. Solutions to the loss of these resources are difficult to implement and are overshadowed by the current crisis in health care funding.

The Harborview Trauma Program was a direct offshoot of the paramedic program started in 1970 by Dr. Leonard Cobb, a cardiologist, and Gordon Vickery, Seattle's Fire Chief. Originally aimed at training paramedics to perform cardiopulmonary resuscitation on victims of heart attacks and smoke inhalation, the focus of this program was soon expanded by Dr. Michael Copass and others to include emergent care for victims of trauma by all the services at Harborview.

Many polytraumatized patients had musculoskeletal injuries, which prompted active participation by the Department of Orthopaedics. Up to that time, musculoskeletal injuries were thought to require semi-emergent treatment rather than emergent surgery during the acute period. Immediate open reduction and internal fixation of fractures was not done. Standard treatment consisted of debriding and "washing out" open wounds and stabilizing the fracture with traction, splinting, or casting until patients were stabilized and could be prepared for surgery, at least five days post-injury.

We observed early on that many severely injured young patients, like some elderly patients with hip fractures, did not survive this period of enforced recumbency, constant pain, and high doses of pain medication. The hospital course of patients with severe soft-tissue trauma and multiple-system injuries was sometimes complicated by what we then called "fat embolism," a condition we now recognize as adult respiratory distress syndrome. In addition, the rate of wound infections in open fractures was high, particularly in multiply injured patients.

Under the leadership of Dr. Donald Gunn, we obtained daily post-injury paO_2 readings and found a subclinical but significant drop in arterial blood oxygen saturation in many patients during the second to fourth post-injury days. Concurrent hemorrhage and painful spasm in the femoral musculature made patients slightly febrile, and fracture reduction and nailing were difficult to accomplish.

By about five days post-injury, swelling, pain, and spasm decreased significantly, paO_2 levels increased, and, depending on the severity of the injuries, the condition of patients improved and internal stabilization was accomplished. Some multiply injured patients with severe injuries did not survive, and others took much longer to attain pulmonary and nutritional states adequate to allow femur fracture stabilization.

Of great significance was the effect of femoral nailing of patients in poor general condition. Femoral nailing greatly enhanced the general recovery of these patients, particularly those with head injuries or pulmonary problems. For example, one young patient's survival was in doubt due to a severe head injury and secondary pneumonia. We performed femoral nailing as a last resort and she quickly recovered.

A New Protocol

Such results stimulated the initiation of a protocol whereby all patients with open fractures and major long-bone fractures, particularly of the femur and the tibia, were stabilized immediately. This controversial approach won strong support from Dr. William Horton, the surgeon and anesthesiologist in charge of the surgical intensive care unit at Harborview in 1973. Frustrated by attempts to care for pulmonary insufficiency in patients placed in traction devices and casts, he and the intensive care nursing staff welcomed the opportunity to position these patients upright and to reduce the amount of sedative and narcotic medications.

In retrospect, our initial attempts at immediate internal fixation and soft-tissue management were somewhat crude. Nevertheless, it was obvious that immediate stabilization of major fractures did, indeed, have a positive effect on controlling pain, increasing mobility, and facilitating care provided by the intensive care specialists. The incidence and severity of pulmonary decompensation declined. Fear that the infection rate in orthopaedic wounds would rise did not materialize, and in fact, the infection rate declined.

The remarkable improvement in morbidity and survival rates during the trial run quickly convinced us of the value of this aggressive surgical approach. We were unwilling to subject patients to the conventional delayed approach merely to document a randomized study. Remembering the fates of patients who had served as unwitting historical controls for other procedures, we could not allow randomization from a moral standpoint.

Interestingly, some early studies that used randomized patients to verify the efficacy of this approach were done by young orthopaedists who trained here or were strongly influenced by our experiences. Papers by Kenneth Johnson and his associates at Parkland and Robert Meek and associates at Vancouver General Hospital are examples. They convinced surgeons trained in con-ventional approaches to allow a certain percentage of their patients to be treated by immediate stabilization. Their studies confirmed that immediate skeletal stabilization resulted in markedly less morbidity and mortality and decreased cost of care.

We were certain from the beginning that patients with pelvic and spinal fractures also would benefit from immediate stabilization, but it was precluded in these cases because the available technology and the techniques used in the early years did not provide a satisfactory risk-benefit ratio. Recent advances in technology, surgical technique, hardware, and instrumentation have improved internal fixation, not only in the long bones, but also in the pelvis and spine.

Technological advances included computerized tomography, magnetic resonance imaging, and improved image intensification. Better surgical technique emphasized delicate handling of soft tissues, indirect reduction of fractures, and improved methods of soft-tissue coverage, including single and composite vascularized free-tissue transfers.

New and specialized internal fixation devices have been introduced, including locked femoral intramedullary nails and locked tibial nails that can be inserted without reaming. Existing instruments were not suitable for handling acutely injured soft tissues, therefore delicate, sharp-pointed reduction clamps were designed to reduce undermining and stripping of soft tissues from bone.

Despite advances in instruments and techniques, the fundamental rationale behind immediate internal fixation remains valid after 20 years. Restoration of skeletal integrity at the earliest possible time restores soft-tissue viability and function and prevents systemic complications associated with severe musculoskeletal trauma. Experience has provided further insight into this rationale, however, and we have identified three guiding principles:

1. The more severe the injury, the more urgent the need for skeletal stabilization;
2. The more severe the local soft-tissue damage, the more rigid the fixation must be to prevent progressive necrosis and infection; and
3. Soft-tissue crushing or vascular deficiency beyond a certain point makes salvage unrealistic. In these cases, amputation should be done without delay to prevent systemic damage or metabolic threat from necrotic tissue.

These advances have led to the successful rehabilitation of severely injured patients with less morbidity and mortality and at lower cost. The only benefits of early internal fixation still to be formally documented are factors that are obvious to most traumatologists: patients recover more quickly and with fuller function and earlier return to work.

Is the Orthopaedic Trauma Team an Endangered Species?

Why then, have so many outstanding orthopaedic trauma teams disbanded after several years while relatively few survive? For example, excellent trauma centers in Tampa, Dallas, Los Angeles, San Francisco, and Baltimore (Maryland Shock Trauma) all closed approximately five years after their establishment.

One clue can be found in the composition of the trauma team. Trauma centers that continue operating at a proficient level have active traumatologist faculty who also participate in the administration of the medical center. Other factors that contribute to trauma center excellence include facilities for research and opportunities for advancement in an academic orthopaedic department.

Medical costs also play a role in the viability of a trauma center. The initial care of multiply injured patients is expensive, requiring 24-hour availability of emergency rooms, operating rooms, anesthesiologists, large intensive care units, sophisticated imaging, and other services. These services are not fully compensated by money received for caring for these patients, who frequently are uninsured. Arguments noting the young average age of these patients (34 years) and the cost-effectiveness of total recovery of a young, productive person compared to the cost of permanent disability or death must be presented to the makers of health care reimbursement policies.

Several conditions must be met for orthopaedic traumatologists to function in a trauma center. They must not work alone, but on a team with at least two additional orthopaedic trauma surgeons who can share call. Their colleagues in general surgery, neurological surgery, and anesthesiology also must make a commitment to provide excellent trauma care. The hospital administrator must provide an adequate emergency room, operating rooms, and intensive care facilities, sophisticated imaging, and other services 24 hours a day. Academic chairs must identify with and appreciate the singular demands of orthopaedic traumatology, and provide academic opportunities for the trauma faculty.

HMC Leadership

Harborview's orthopaedic trauma team has remained strong over the past 20 years. Our example has provided leadership in this area of patient care for the entire nation, if not the world. We are proud of our position as the role model for academic orthopaedic traumatology programs. We are continuing to document the cost-effectiveness of our protocols using our new Trauma Outcome Database Program developed by Marc Swiontkowski.

The Harborview orthopaedic traumatology program provides unparalleled resident training. Even residents who plan to specialize in other areas of orthopaedics find that the skills they learn in patient evaluation, preoperative planning, skeletal stabilization, soft-tissue handling, and overall patient management enormously enhance their clinical and surgical excellence. We continue to train future leaders in orthopaedic traumatology in hopes that they will set up and contribute to other trauma programs across the country and the world.

Supported by Harborview Medical Center and the University of Washington Department of Orthopaedics

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Fixation of Unstable Pelvic Ring Injuries with Percutaneous Iliosacral Screws

M.L. "Chip" Routt Jr., M.D.
Peter T. Simonian, M.D.

The management of complex pelvic ring fractures and dislocations is difficult. Associated genitourinary, neurological, and pulmonary system trauma, as well as severe local soft-tissue injuries complicate treatment.

Hesp described improved survivability in those patients treated with early pelvic ring stabilization. Treatment options range from conservative methods (pelvic slings, traction, and spica casting) to operative reductions using external or internal fixation. Mears popularized complex external fixateurs to stabilize the pelvis, allowing patient mobilization. These devices poorly control posterior pelvic ring instabilities. Kellam reported an alarming 25% rate of infection for posterior pelvic surgical incisions.

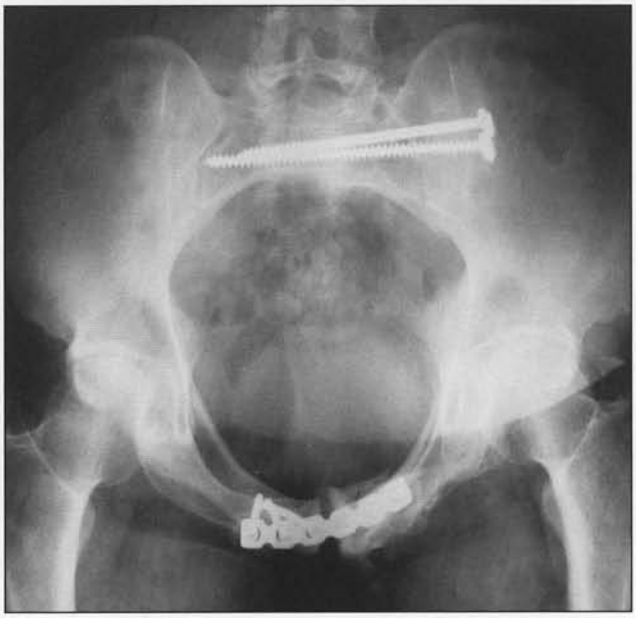

FIGURE 1: A construction worker fell three stories, sustaining spine fractures and a complex pelvic ring injury. He had a displaced left sacral fracture, a nondisplaced right sacral fracture, and a parasymphyseal fracture dislocation. The anterior pelvic ring injuries were treated with plate fixation after open reduction. The sacral fractures were reduced closed and stabilized using two iliosacral screws into the body of S1. Extra long screws were used so that both sacral fractures were immobilized by the screws. He returned to heavy manual labor at 11 months after injury. He complains of occasional low back pain.

Other authors advocate these posterior surgical exposures for accurate reduction and fixation. Letournel fixed sacroiliac joint dislocations using such exposures. After reduction, he would place his finger through the greater sciatic notch and direct a screw safely from the lateral ilium into the sacral ala. His technique was limited to sacroiliac joint disruptions since the screw would damage critical neurovascular structures if misplaced medial to the alar region.

Improvements in fluoroscopic imaging led Matta to build on this technique. With the patient prone, a posterior exposure allowed reduction of the fracture or dislocation. He then used fluoroscopic inlet and outlet pelvic images to guide an "iliosacral" screw from the lateral ilium, across the sacroiliac joint, through the sacral ala, stopping in the first sacral vertebral body. Performing this procedure percutaneously with the patient *supine* became attractive for many reasons. The supine position is familiar to all OR personnel and requires no special equipment. Numerous operative procedures can occur simultaneously (or in succession) with the patient supine, saving valuable OR time, especially for the polytraumatized patient.

The high rate of infection associated with posterior pelvic surgical wounds reflects the severity of the local soft tissue trauma that occurs

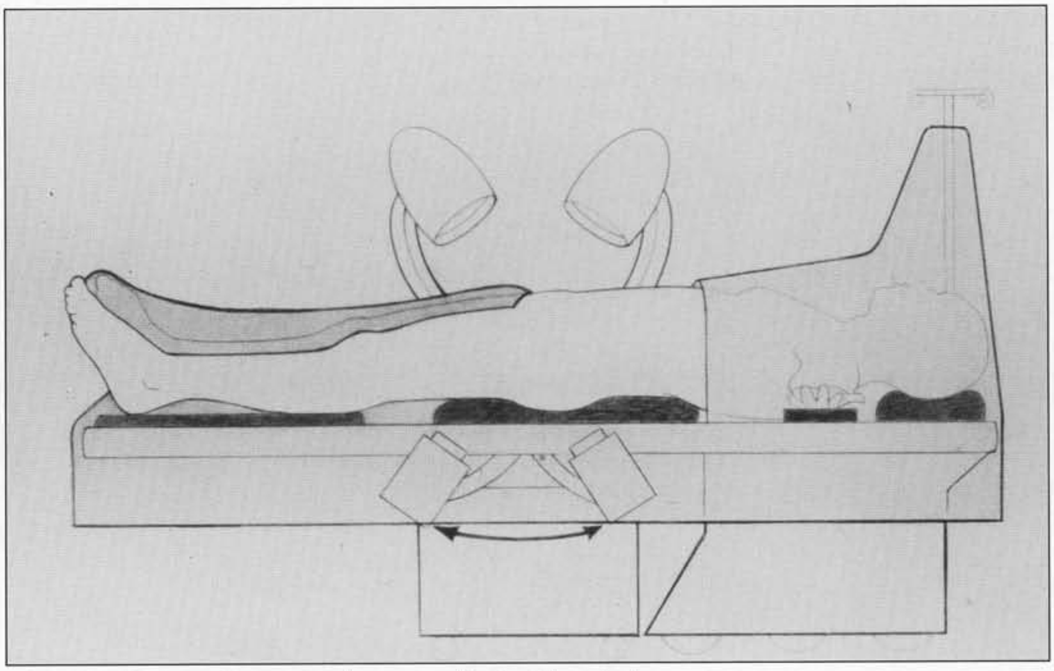

FIGURE 2: This diagram demonstrates the proper positioning of the patient.

with these fractures and dislocations. Closed manipulation and percutaneous screw placement avoids these injured soft tissues and should lower infection rates. Also, with the patient supine, the anterior pelvic ring injury can be reduced and fixed, allowing improved closed reduction of the posterior disruption.

If such "indirect" closed manipulation of the posterior ring injury is possible, then percutaneous iliosacral screws placed using fluoroscopic guidance can stabilize either sacroiliac joint dislocations or sacral fractures. Our studies are the first to investigate the technique of iliosacral screw placement with the patient supine as well as the limits of closed manipulation of the posterior pelvic ring.

Preliminary Studies

We used fresh cadaveric pelvic models mounted physiologically and simulating an "open book" pelvis injury (complete symphysis pubis dislocation and unilateral, anterior-only sacroiliac joint disruption) to compare the rigidity of this fixation method against other types. The disrupted pelvic specimens were loaded according to the following sequence of testing:

1. Intact
2. Symphysis pubis disruption
3. Unilateral anterior sacroiliac joint disruption
4. Ipsilateral sacrospinous and sacrotuberous ligaments division
5. Symphysis pubis fixation with a 4.5-mm DC plate, according to the technique of Lange and Hansen
6. Plate fixation of the SI joint, according to the technique of Simpson, along with pubis plating
7. Lag screw fixation of the SI joint, according to the technique of Matta, along with pubis plating
8. Plate fixation of the SI joint, without pubis plating
9. Lag screw fixation of the SI joint, without pubis plating.

The intact pelvic specimens demonstrated minimal changes with loading. Significant symphyseal displacements occurred with compression loading after symphysis pubis disruptions. In these specimens, the intact SI joint remained normal. With additional division of the anterior SI joint ligaments, both the SI joint and symphysis pubis demonstrated significant instabilities. Further disruption of the ipsilateral sacrotuberous and sacrospinous ligament complex produced some additional instability to compression loading.

Plate fixation of the symphysis pubis alone stabilized the symphysis pubis, but the motion at the disrupted SI joint was not decreased. The addition of either a plate or a lag screw across the disrupted SI joint significantly stabilized both the pubis and SI joint. There was no statistical difference in stabilization using the plate or lag screw to fix the disrupted SI joint, as long as the symphysis remained fixed with the plate. Removal of the symphyseal plate and fixation of the SI joint using either a plate or lag screw destabilized the symphysis significantly while the SI joint remained stable to compression loading. The contralateral normal SI joint demonstrated no changes during all phases of compression testing.

Clinical Trials

Our clinical series included 68 patients with complex, unstable pelvic ring injuries treated using fluoroscopically guided, percutaneously placed iliosacral screws. There were 37 males and 31 females ranging in age from 11 to 73 years. Injuries included 39 sacral fractures and 63 sacroiliac joint dislocations. Combination unilateral and bilateral injuries were more common than anticipated based on previous reports. Anterior pelvic ring injuries were mostly rami fractures and symphyseal dislocations.

The same surgeon (MLR) placed 103 iliosacral screws. Cannulated 7-mm cancellous screws were used to compress sacroiliac joint dislocations, while fully threaded 6.5-mm cancellous screws stabilized sacral fractures. Ninety-seven screws were targeted into S1, four were placed into S2, and two were placed into a transitional lumbosacral vertebra. The posterior reductions were within 5 mm of anatomical in 88% of the cases.

Seventeen complete sacroiliac joint dislocations required open reduction and percutaneous iliosacral screw stabilization due to inadequate closed reduction. Anterior sacroiliac joint disruptions were amenable to closed reduction using the femoral distractor/compressor between the two iliac crest tubercles. Unstable sacral fractures were well manipulated using a combination of iliac crest "joysticks," the femoral distractor, and distal femoral traction pins.

Patients with neural foraminal bony debris due to the sacral fracture were excluded since they required open decompression prior to fixation in the prone position. Obesity, intra-abdominal contrast agents, and flatus often made fluoroscopic imaging quite difficult.

Fluoroscopic times averaged 2.1 minutes. One obese patient sustained a transient L5 neuropraxia due to screw misplacement. Fixation failed in another patient with a severe closed head injury and spasticity. All of the posterior pelvic ring disruptions healed and there were no infections.

Percutaneous iliosacral screw fixation of the posterior pelvic ring with the patient positioned supine is a safe and useful technique. Quality fluoroscopic imaging is mandatory. Operative times and blood loss are diminished, and surgical wound complications are eliminated. Complete sacroiliac joint dislocations are exceptions and require *open* reduction prior to percutaneous iliosacral screw fixation. This technique should be added to the armamentarium of the orthopaedic trauma surgeon.

Supported by Harborview Medical Center and the University of Washington Department of Orthopaedics

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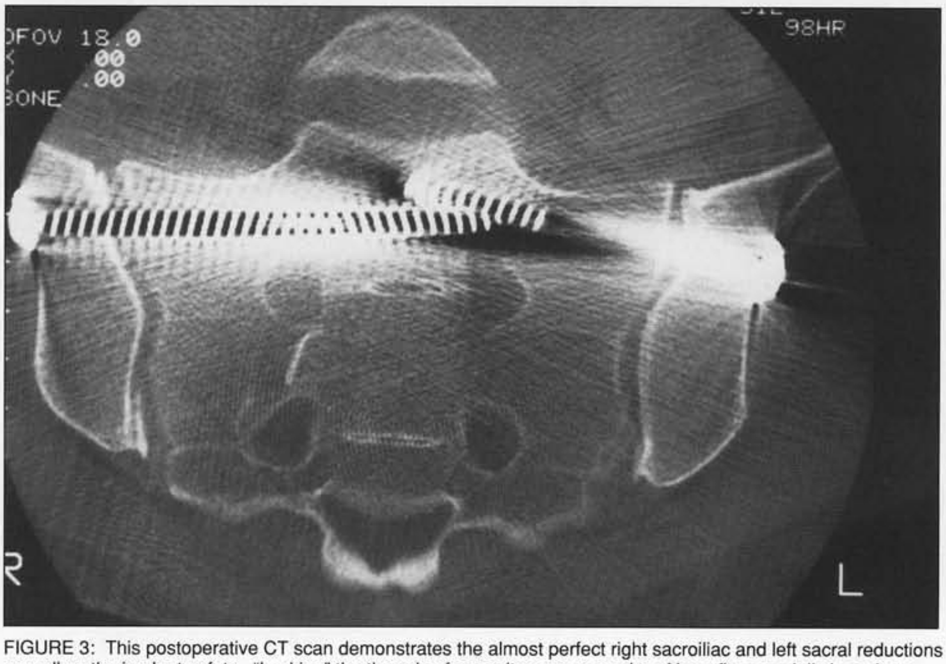

FIGURE 3: This postoperative CT scan demonstrates the almost perfect right sacroiliac and left sacral reductions as well as the implant safety. "Locking" the threads of opposite screws can be of benefit, especially in patients with poor bone quality.

Fracture Component Malalignment After Unreamed IM Nailing in a Proximal Tibial Fracture Model

M. Bradford Henley, M.D.
Mark Meier, M.D.
Allan F. Tencer, Ph.D.

FIGURE 1: Clinical examples of malreduction of a high proximal tibial fracture fixed with an unreamed interlocking tibial nail. LEFT: AO nail; RIGHT: Russell-Taylor nail. The distal component is translated posteriorly in both examples.

Prompted by our clinical observations of tibial fracture malalignment after insertion of small diameter unreamed nails in certain proximal tibial fractures (Figure 1), we studied the procedure of insertion, documented osseous displacement, and defined a mechanism for this occurrence in a cadaver proximal tibial fracture model.

Method

Eleven fresh lower extremities, including the distal femur and the ankle joint, were obtained from cadavers. To measure fracture site malalignment caused by nail insertion, we used a six-degree-of-freedom motion transducer mounted on the fracture components to track the relative positions of the proximal and distal tibial fracture components during and after complete insertion of the nail (Figure 2).

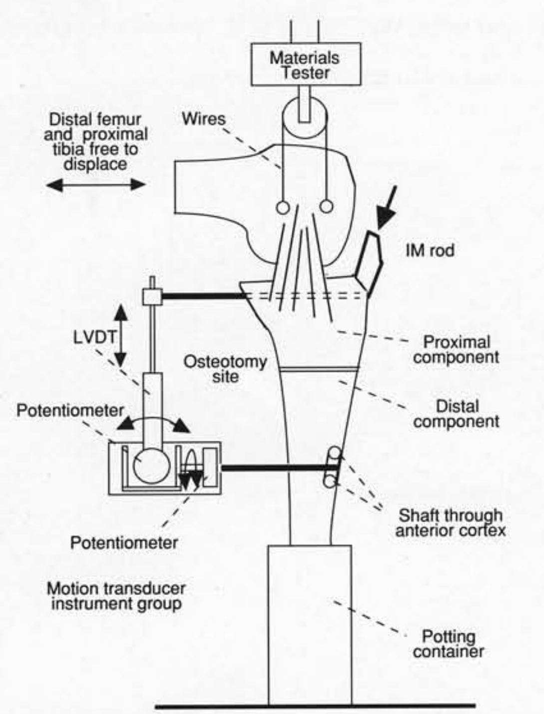

FIGURE 2: A lateral view diagram of the experimental apparatus for measuring three-dimensional motion of the proximal component with respect to the distal tibia during insertion of the IM nail.

With the specimen mounted on a test frame and the motion transducer attached, a standard osteotomy was created in a transverse plane, 2 cm below the location of the most distal of the proximal locking screws of the IM nail when fully inserted. We used a solid interlocking implant, 9 mm in nominal diameter and either 30, 31.5, 33, or 34.5 cm long (Synthes Ltd., Paoli, PA), and appropriately sized for the specimen.

The nail was inserted, using the standard starting position and technique as described by the AO group. To select a starting point on the anterior tibia, we determined the medial-lateral position by laying a guide rod on the anterior aspect of the tibia, centered along the axis of the intramedullary canal. In the coronal plane, the entry point coincided with the "soft spot" at the intersection of the tibial plateau and the anterior metaphyseal cortex. An entry portal into the canal was made using a 2.5-mm diameter guide pin inserted at an angle coincident with that of the proximal end of the nail. A hole was drilled with an 8-mm diameter cannulated drill bit placed over the guidewire.

As the nail was progressively inserted into the tibia, measurements of the relative positions of the proximal and distal tibial components were made as a function of nail insertion depth. The final relative positions with the nail fully inserted were used in the analysis. Prior to and following testing, each specimen was radiographed. Several parameters were measured either from the radiograph or directly from the specimen. Of those, the distance from the nail's anterior point of contact with the tibial medullary canal to its posterior point at the level of the osteotomy was correlated with the relative displacement between the proximal and distal fracture components.

Results

Significant relative displacement between the proximal and distal tibial components occurred in most insertion tests. Examination of the specimens showed that this may be due to impingement of the anterior edge of the nail against the anterior medullary cortex of the distal fracture component.

As shown in Figure 3, impingement causes the nail to wedge in the medullary canal instead of continuing to move distally down the canal into its fully inserted position. With further insertion force applied, the wedged nail carries the distal fracture component posteriorly and distally. To quantify this effect, we defined the effective diameter as shown in Figure 3. This value, the distance from the point of impingement on the nail anteriorly to its posterior surface at the level of the osteotomy, shows that if the bend of the nail is within the distal tibia, it acts like a wedge.

Figure 4 demonstrates that a highly significant (p = 0.006) correlation exists between the effective diameter (or the width of the wedge created by the angled tibial nail) and the recorded anterior shift of the proximal component from its anatomic initial position. The scatter in the data (r2 = 0.59) indicates that other variables affect fracture component displacement as well.

Discussion

Various mechanisms may contribute to the observed sagittal plane malalignment of the fracture components after nail insertion in proximal tibial fractures. One mechanism, described in our experiment, is the wedging effect of the nail in the distal component as the nail widens above the bend. When this happens, inserting the nail further causes the distal tibial component to be carried distally and posteriorly.

Another known mechanism for malalignment results from incorrect selection of the proximal starting hole. If the entry portal is too distal to the tibial plateau, the wide proximal end of the nail may engage the anterior cortex of the proximal component, driving the proximal component anteriorly. Clinically, this displacement can be minimized by choosing a very proximal entry portal and a vertical insertion angle that parallels the proximal slope of the nail and lies in the anterior tibial subcortical bone, just deep to the tibial tuberosity.

Anatomic reduction is not always possible using the small diameter unreamed nails despite choosing the appropriate nail path. In contrast to mid and distal diaphyseal and isthmic femoral fractures, an IM nail will not necessarily reduce proximal tibial fractures. Therefore, it is advisable to reduce the fracture before nail insertion and maintain reduction during insertion. If the anterior subcortical bone in the proximal fragment is soft, posterior translation may occur due to self-reaming of the nail posterior to its intended path during insertion. A component of the posterior translation may result from sagittal plane rotation (procurvatum) due to knee flexion and resulting soft-tissue forces. This may explain some of the variability in the experiment and scatter in the data.

In summary, biomechanical testing of unreamed tibial nails showed that in an experimental model with an osteotomy located proximal to the position of the bend in the nail when fully inserted, fracture malalignment may occur. Thus, care should be taken when fixing a high proximal tibial fracture to select an implant so that its bend will not be located within the distal fracture component.

Supported by Harborview Medical Center, the University of Washington Department of Orthopaedics, and an AO Foundation (Switzerland) grant

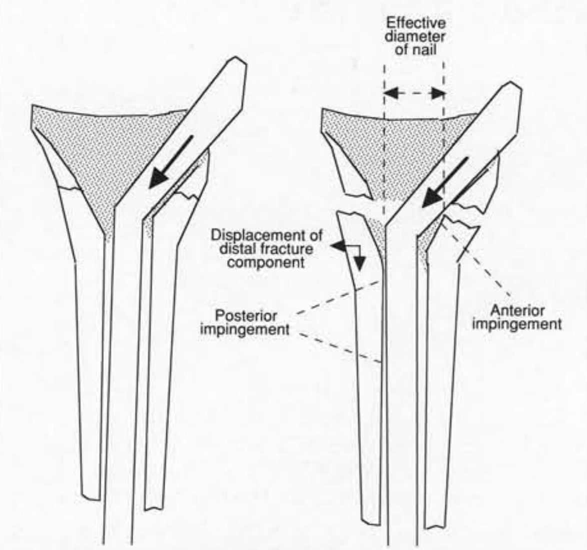

FIGURE 3: A schematic diagram showing how the IM nail can impinge against the bone of the anterior and posterior medullary canal of the tibia when the nail bend is within the distal fracture component. The effective diameter is the actual width of the nail at the fracture line due to its wedge shape. LEFT: Insertion of the nail without anterior impingement allows it to proceed distally down the medullary canal. RIGHT: With impingement, further insertion of the nail carries the distal component posteriorly.

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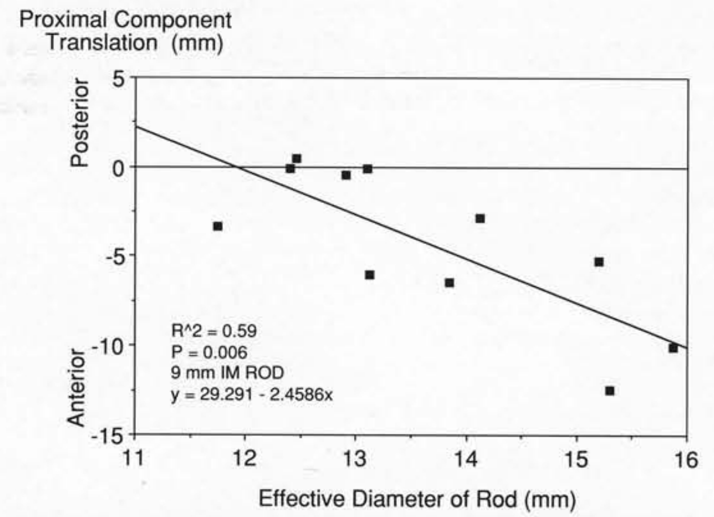


FIGURE 4: Correlation between relative translation between the fracture components and the "effective diameter" of the nail, which is defined in Figure 3. Note that anterior translation of the proximal component which we measured is equivalent to posterior translation of the distal component.

Hand Fracture Fixation with Titanium Implants

Douglas P. Hanel, M.D.

Rigid internal fixation is indicated for a variety of hand problems including intra-articular fractures, unstable fractures, fractures associated with massive soft-tissue injuries, arthrodeses, replantation of amputated fingers, and toe-to-hand transfers. Biomechanical studies demonstrate that stainless steel plates and screws provide the greatest fracture stability, but clinical studies report that the stainless steel implants are excessively large, difficult to apply, tend to interfere with overlying soft tissues, and have at times only limited advantage over less technically difficult methods of fixation such as Kirschner wire fixation.

The stainless steel plates and screws originally designed for the treatment of hand fractures were simply miniaturized versions of large bone implants. It has been suggested that the size, shape, and the material from which the implant was made could be responsible for limiting postoperative motion. Low-profile titanium implants specially designed for small bone fixation have been recently introduced. Titanium is a more biocompatible material than stainless steel, and should reduce soft-tissue reaction. In addition, the implants, with a smaller size and lower profile, should be less prone to mechanical interference between the implant and overlying soft tissues.

Over the last four years, 50 consecutive, skeletally mature patients with unstable hand fractures, end-stage finger joint arthritis, or toe-to-hand transfers were treated with implants from a prototype titanium mini-fixation set. Each patient was followed for a minimum of one year after treatment. The time to clinical and radiographic healing, complications, and finger motion were recorded. This report highlights the results of this series.

Acute Injuries

Thirty-five patients sustained 66 acute fractures. Twenty involved metacarpals and 46 involved the proximal or middle phalanx. Associated injuries included seven amputations, eight revascularizations, 12 isolated tendon lacerations, and eight soft-tissue coverage problems. The plates were usually placed along the dorsal surface of the metacarpal and middle phalanx and along the lateral side of the proximal phalanx. Tendon, nerve, and vascular injuries were repaired after fracture fixation. Open fractures with associated loss of skin cover were treated with local or distant flaps. Wounds usually were closed at the time of initial fracture fixation, including two cases of immediate free tissue transfer.

Chronic Injuries

Eight patients with either post-traumatic or inflammatory arthritis underwent a total of 22 metacarpal or proximal interphalangeal joint fusions using plates and screws. Three patients with chronic malunions underwent osteotomy, correction of alignment, and bony stabilization with plates and screws. Four patients, lacking thumbs or multiple digits secondary to old trauma, were treated with transfer of the second toe to thumb in two cases and to the metacarpal of the long finger in two cases. The transferred toes were secured with a modified "L" plate (Figure 1).

Postoperative Management

Unprotected motion was started within two days after fixation of isolated fractures or joint fusions. Similarly, fractures with associated tendon injuries were mobilized after two days but the tendon repairs were protected with dynamic splints. Replanted digits, toe-to-hand transfers, and cases requiring free tissue transfer for coverage were rested for seven days before digit motion was allowed.

Implants were removed only if they presented a mechanical block to motion, became prominent after resolution of wound edema, or were readily accessible during a secondary procedure such as tenolysis. Twelve implants were removed and the scar tissues surrounding the implants ware examined microscopically.

Results

Time to Healing and Complications:

Subjective healing, judged as the absence of pain at the fracture site, required four to six weeks in all but two cases. Radiographic healing usually occurred at six to eight weeks. In replantation cases radiographic healing was delayed until 12 to 20 weeks. The exceptions to timely healing occurred in the two complications of this series. An intra-articular proximal phalanx fracture became infected, required debridement, implant removal, and later joint fusion. The second complication occurred when a metacarpal fixation plate was bent during a fist fight. The implant was replaced with a larger plate and the fracture healed within six weeks of the second operation. Other than this single bent plate, there were no instances of mechanical failure.

Motion:

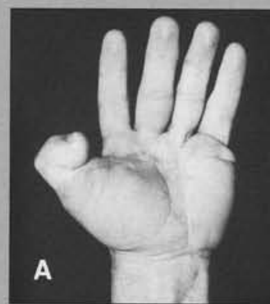
The functional outcome of fixation was reflected in the range of motion of the involved digits. We identified three trends:

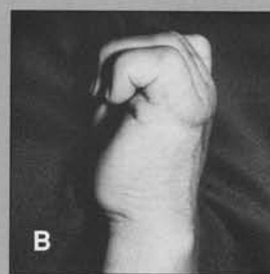
1. Metacarpal fractures without associated soft-tissue injuries regained complete motion within two to four weeks of treatment.
2. Phalangeal fractures, replantations, and joints adjacent to fusions had 70% of motion within eight weeks of repair and continued to improve over the next six months.
3. After fixation of intra-articular fractures, interphalangeal joint flexion usually approached normal, but an extension lag of 5 to 35 degrees persisted. The extension lag was not significantly affected by tenolysis, implant removal, splinting, or therapy, and more than likely represents the effects of joint capsular and extensor tendon scarring on extensor tendon pull-through.

A Case Study

A 20-year-old engineering student sustained an amputation of all fingers at the level of the metacarpophalangeal joints. The index, long, ring, and small fingers were reattached. The thumb was not salvageable. Six months after replantation, a second toe was transferred to the thumb position. The patient uses the hand for all activities including hunting, skiing, and baseball.

FIGURE 1: A radiograph of the hand one year after injury shows the straight plates used at the time of replantation and the "L" plate used for securing the toe-to-thumb transfer.





FIGURES 2A-C: The range of motion of the uninjured joints in the replanted digits and transferred toe is near normal.

Microscopic Findings:

Implants were removed after fracture healing for two reasons: at the request of patients who did not want to retain unnecessary foreign materials and as an incidental part of extensor tenolysis. Although the amount of subjective scarring about titanium implants appeared to be less than that encountered about stainless steel, there were no microscopic differences. The hope that titanium implants would result in less soft tissue scarring than caused by stainless steel was not substantiated by these limited findings.

Discussion

It was hoped that problems with size and tissue reaction could be circumvented by using titanium implants designed for finger fractures. This preliminary study indicates that implant design and early hand mobilization play a greater role in fracture management than the material from which the implants are fabricated. In the past, surgeons made an "educated guess" about the recommended screw and plate sizes based upon their experience treating long bone fractures. These large implants were bulky and interfered with the surrounding soft tissues.

The implants used in these 50 patients were smaller, lower profile, and just as successful in securing fracture healing as larger implants. Although the authors believe that small plates and screws are the best approach to unstable hand fractures, the proof will come from ongoing studies comparing the efficacy of these newly designed miniplates and screws with other methods of hand fracture treatment.

Supported by Harborview Medical Center and the University of Washington Department of Orthopaedics. Synthes/USA provided the implants used in this study.

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Biomechanical Predictors of the Stability of Femoral Neck Fracture Fixation

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Fracture of the hip, particularly in the elderly, is a significant and growing problem with a reported incidence of 18.9 to 105.5 per 100,000 population. Melton and colleagues emphasized that proximal fractures of the femur account for 30% of all hospitalizations for fractures and more than 50% of all hospital bed days used for fracture care.

The most important consideration in femoral fractures is functional outcome, which varies with age. Studies of patients less than 60 years of age show that 80% become ambulatory, 11% remain nonambulatory, and 9% die from related problems. In the 60 to 69 age group, these numbers are 75%, 12%, and 13% respectively, and between 70 to 79 years, 54%, 19%, and 37%. These rates contrast with the significantly higher survival rates for persons in these age groups in the general population.

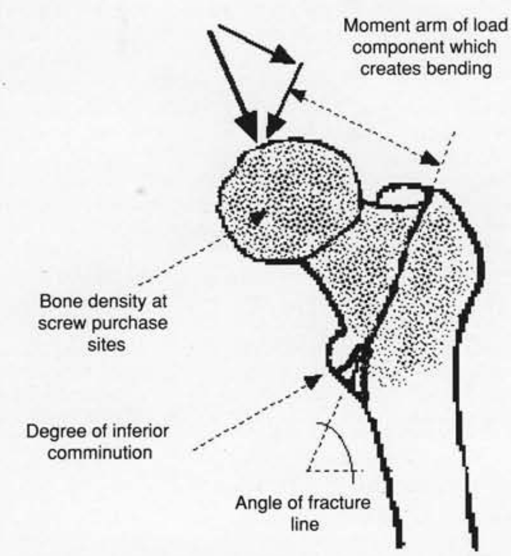

FIGURE 1: Four factors that may affect the biomechanical strength of femoral neck fracture fixation.

Two alternatives for management of these fractures are fixation and endoprosthetic replacement of the femoral head and neck. To assist decision making about which treatment to pursue, we quantitatively determined the biomechanical features that predict stable fixation of femoral neck fracture in a cadaveric model. We hope that this information will assist the surgeon in more accurately evaluating the potential for achieving biomechanically adequate fixation and minimizing the potential for displacement of the femoral head during healing.

Methods

We obtained 23 proximal femoral specimens and embedded the femoral shaft of each in potting plaster in a cylindrical fixture. Through plain radiographs as well as direct measurements we defined the femoral neck/shaft angle and the length of the femoral neck to determine the moment arm of the load applied to the femoral head (Figure 1). A hemispherical cup placed over the femoral head was attached to a rod used to guide a dropweight onto the femoral head. Weights ranging from 1 to 3 kg were dropped from a height of 3 meters at impact angles of 30 to 45 degrees. They produced a variety of fracture types with different degrees of comminution and orien-tation of the fracture line.

The fracture components of each specimen were fixed with three cannulated, 7-mm diameter, 32-mm threaded cancellous bone screws (Synthes, Paoli, PA) located parallel to the center axis of the femoral neck in a triangular fashion according to principles outlined by the AO group. As shown in Figure 1, the degree of comminution (ratio of cortical contact length to perimeter in the inferior half of the femoral neck), moment arm (perpendicular distance from center of the femoral head to the fracture line), and angle of the fracture line (with respect to a cross section perpendicular to the femoral shaft) were estimated independently by visual inspection of the specimen, plain radiography, and CT imaging. CT images were also analyzed for femoral head bone density.

Each specimen with its femoral shaft was mounted in a fixture on a materials testing system, shown in Figure 2. Cyclic axial force together with axial torsion was applied to the femoral head via the specimen's acetabulum mounted to the actuator of the materials tester. In addition, a transversely located actuator displaced the femur into flexion and extension during loading so that the angle of the applied axial force varied and to a certain extent approximated the gait pattern.

After 10,000 load cycles with a peak load of 2.2 times body weight, the test was stopped and axial load applied until the fixation failed. Both the average load that the fixation could withstand throughout the test and the failure load were correlated to the four variables identified above: moment arm, bone density, fracture angle, and percent comminution. We used a multiple regression analysis to determine the strengths of correlation of single and multiple variables to the strength of fixation.

Results

Comparing fracture patterns using plain films and direct measurement of geometric parameters from the specimens showed that fracture angle was closely correlated. However, radiographic determination overestimated the degree of comminution by 50%, since the medial-lateral film compresses the fracture surface into a two-dimensional plane. CT scan interpretation closely correlated to the fracture site comminution.

TABLE: Correlations between mechanical factors and the average load supported by a fixed femoral neck fracture during cyclic loading.

Average Force vs (variable)	Correlation (R^2)	Significance (p value)
density	0.074	0.347
comminution	0.106	0.256
density, comminution	0.506	0.021
density, comminution, moment arm	0.529	0.049
density, comminution, moment arm, fx angle	0.537	0.107

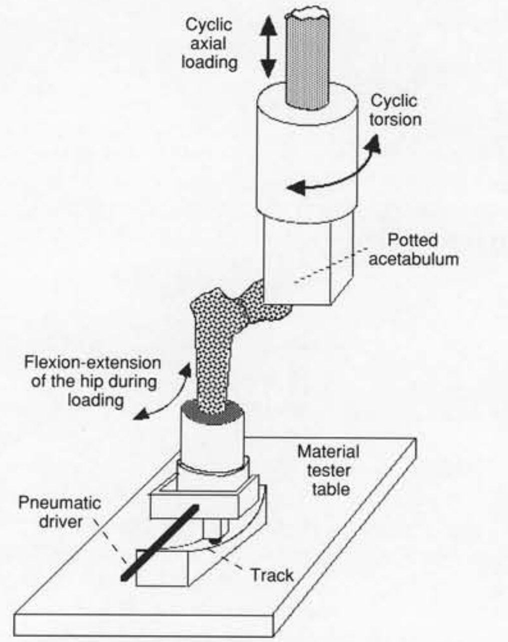

FIGURE 2: Schematic diagram of the method of loading the fixed femoral neck fracture. The pneumatic driver swings the femur through an arc of 30 degrees simulating flexion extension of the hip joint during gait. Cyclic axial load with a peak value of 2.2 times body weight (700 N is applied). In addition the actuator is rotated through an arc of 20 degrees, which results in torsion on the femoral head during axial loading.

Our data (Table) demonstrate that of the four factors identified in this study, bone density and percent comminution correlated most significantly ($R^2 = 0.506$, $p = 0.021$) with the average load supported by the fixation during cyclic loading. As shown in Figure 3, the strongest fixation under the conditions imposed in this study is most likely to occur with femoral head bone density greater than 1250 CT units and comminution of less than 30% of the perimeter of the inferior half of the femoral neck fracture line.

Conclusions

In current orthopaedic practice decisions on how to treat fractures of the femoral neck are often based upon rather arbitrary factors such as patient age and fracture configuration as interpreted from plain radiographs. Since successful treatment of these fractures depends heavily upon obtaining stable internal fixation, additional preoperative predictors would aid the clinician in decision making. Our biomechanical study indicates that bone density in the femoral head and percentage of comminution at the femoral neck fracture site, both obtainable from a simple CT-scan, may be more objective predictors of the potential failure of internal fixation in these patients.

Supported by Harborview Medical Center, the University of Washington Department of Orthopaedics, and a grant from the Orthopedic Trauma Association

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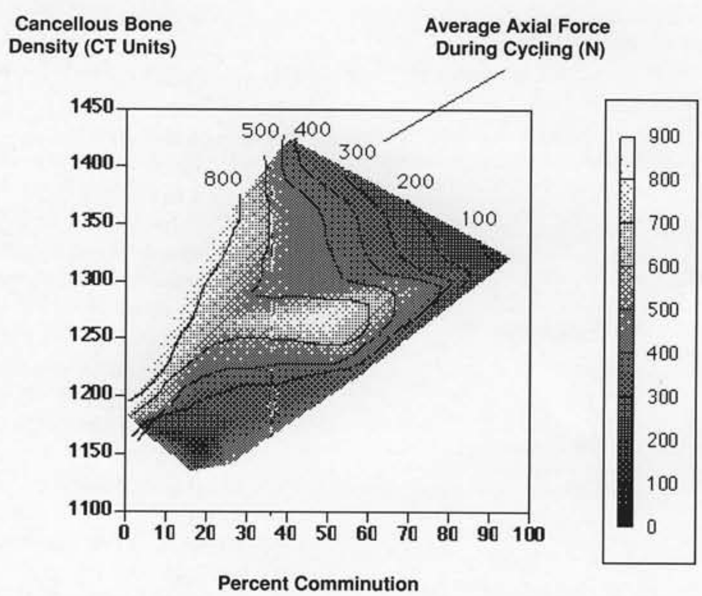

FIGURE 3: The relationship between average axial force during cycling, CT bone density, and percent comminution of the inferior half of the femoral neck. (Scale at right relates shading to average axial force that the fixed femoral fracture can withstand during loading).

Contact Characteristics of the Subtalar Joint: Normative Data and the Effect of Fractures

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The subtalar joint is central to the biomechanics of the hindfoot (Figure 1). Like any diarthrodial joint, it requires a smooth load transfer throughout the range of motion. Ankylosis of this joint increases the peak pressures at heel strike, which presumably lead to increased degenerative changes in the more proximal lower limb joints.

Fractures of the calcaneus and talus may displace the cartilage surface. The amount of displacement that can be tolerated in the subtalar joint is unknown; thus it is often difficult to determine when surgical reduction of fractures is necessary. This study, by quantitatively determining the changes in articular contact characteristics, provides insight into the necessity for surgical treatment of displaced fractures of the subtalar joints.

We can measure the total contact area between two articulating bones as well as the amount of pressure in any given area of the joint. Changes in the contact area provide insight into whether a joint is functioning efficiently by using its available surface. Small pathologic changes that alter the contact area may be a subtle indicator of change in the mechanics of the joint, which may have long-term adverse effects.

Because excessive pressures can harm articular cartilage and lead to joint degeneration, the specific part of the joint subjected to high pressure is of interest as well. Changes introduced in the lab that are severe enough to alter the high-pressure zone probably reflect pathology that would lead to early degenerative changes in vivo.

We employed pressure-sensitive film combined with contemporary imaging techniques to study the contact characteristics of the human subtalar joint in cadaver specimens. We first studied the foot without any alterations in neutral, varus, and valgus positions under different loads. Then we determined the effect on contact characteristics of talar neck fractures and displaced intra-articular calcaneus fractures.

Part I: The Normal Joint

Method

The first part of this study examined the normal contact characteristics of the subtalar joint. The normative data included the effect of changes in position of the hindfoot and the role of weightbearing through the fibula. For this part of the study, 13 fresh cadaver specimens were stripped of the soft tissues down to the level of the hindfoot. We left intact the soft tissue envelope of the foot itself including the plantar pad and ligamentous structures about the foot. A small posterior arthrotomy was made to place the transducer in the posterior facet. After measuring the pressures in the posterior facet alone, we used a medial arthrotomy to enter the anterior and middle facets. We repeated the studies with both the posterior and the anterior and middle facets.

A pressure transducer was made of Fuji pressure-sensitive film, which is composed of two thin sheets with microspheres affixed to the film. Increasing pressure ruptures the spheres and produces coloration that is proportional to the amount of pressure applied. Pressure-sensitive film of low and super-low grades were superimposed and sealed in a waterproof packet for insertion into the joint.

We developed a loading jig that applied a vertical load simulating standing body weight. The load was transferred to intramedullary bars in the tibia and fibula. The two were connected by a small plate that allowed monitoring and adjustment of the amount of load carried through the fibula. The specimen was mounted on a plate that was in turn mounted on ball bearings to allow free rotation and translation of the foot in the horizontal plane so as not to impose artificial constraints on the motion of the subtalar joint.

Next, the posterior facet of the subtalar joint was distracted and the transducer was inserted into the joint and locked in place (Figure 2). We applied loads of 350, 700, 1,015, and 1,400 newtons, which were approximately to equal to one-half, one, one and a half, and two times body weight. We tested the foot in neutral, inversion, and eversion positions and determined the effect of loads of 0, 5, 10, and 15 percent of the total load through the fibula.

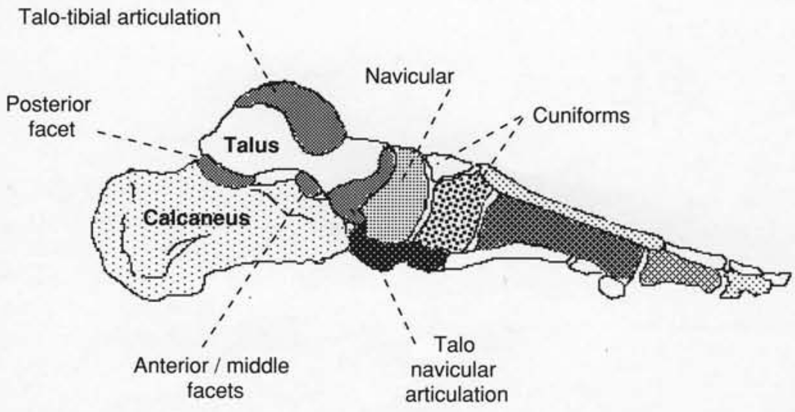

FIGURE 1: Anatomical diagram of the subtalar anatomy.

Results

In this initial study, we quantitatively demonstrated the part of the posterior facet used for weightbearing with the foot in neutral, inversion, and eversion (but not plantarflexion or dorsiflexion). The contact joint area increased significantly in the posterior facet with increases in the applied load. The proportion of the joint subjected to high-pressure loading (greater than 6 megapascals) also increased significantly with increasing contact pressures. The total area of the joint in contact was significantly lower in inversion than in neutral or eversion. Load distribution to the fibula had relatively little effect on contact characteristics. We found that the anterior facet supports proportionally greater load than the posterior facet, resulting in greater overall contact pressures.

The Effect of Talar Neck Misalignment on Contact Characteristics

Methods

We used the same basic methodology, but directed 90% of the load to the tibia and 10% to the fibula, and tested the foot only in the neutral position. After we tested the normal foot, we used a microsagittal saw to osteotomize the neck. An anatomically reduced osteotomized joint was then tested again to confirm that no changes had been introduced just by the osteotomy. The neck was then displaced 2 mm either dorsally, medially, or laterally, or displaced dorsally and in varus (complex displacement). All displacements were of the neck relative to the body of the talus.

Results

Measurements showed no significant changes in overall contact area or high-pressure area in the posterior facet, although four of the seven specimens demonstrated increased localization of the contact area into two discrete regions. The anterior and middle facets, on the other hand, were significantly unloaded by all but medial displacement of the talar neck fracture. From this finding, we postulated that small displacements in the talar neck alter hindfoot mechanics in a way that produces an extra-articular load path. Pressures did not increase in the posterior facet, but the anterior and middle facets became unloaded (Figure 3); thus, we presume that there is an increased load across the talonavicular joint or a load in the sinus tarsi from the displaced talar neck fragment that is off-loading the facets.

Contact Characteristics of Subtalar Joint Following Simulated Calcaneus Fractures

Methods

We used a similar methodology for this study. After initial loading, a "primary fracture line" was created using a microsagittal saw. The position of this simulated fracture was based on CT scans of the posterior facet after calcaneus fracture. Several large clinical studies

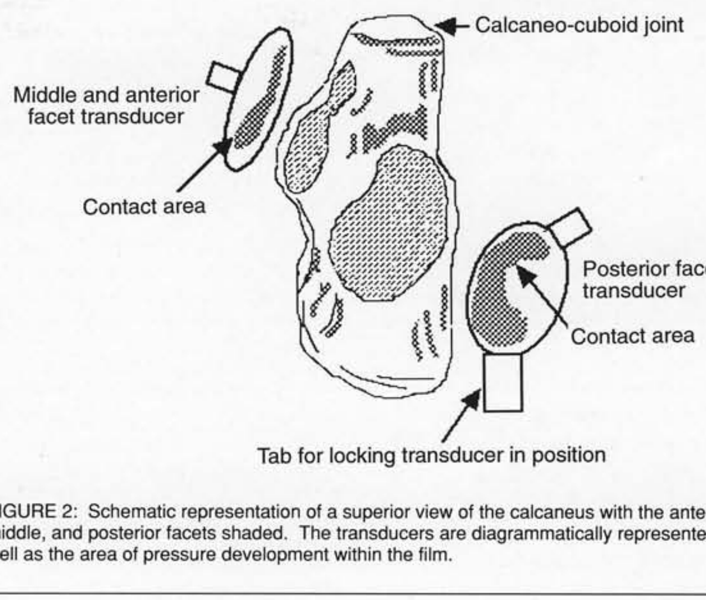

FIGURE 2: Schematic representation of a superior view of the calcaneus with the anterior, middle, and posterior facets shaded. The transducers are diagrammatically represented as well as the area of pressure development within the film.

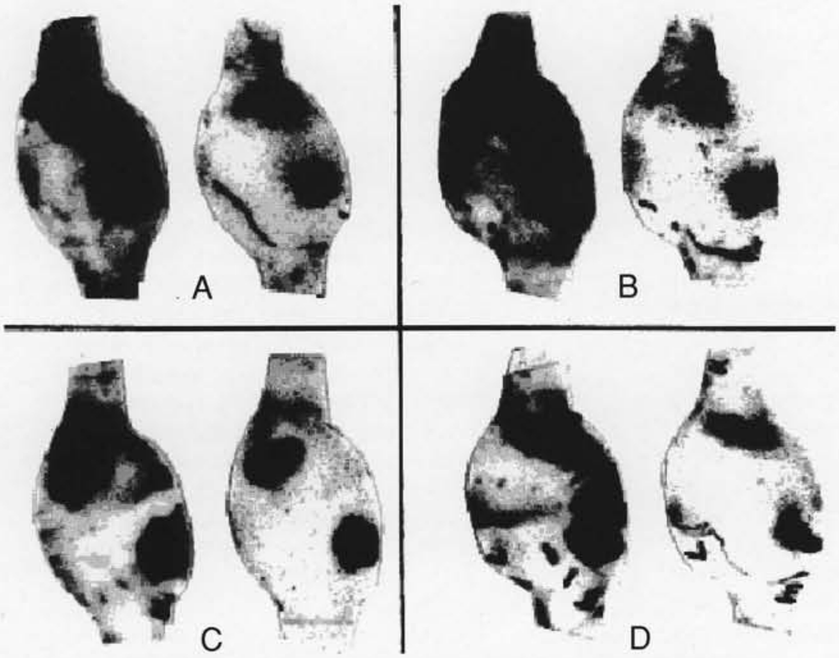

FIGURE 3: Example of pressure prints from the posterior facet of the talocalcaneal articulation. A: normal, B: anatomic, C: medial, D: complex.

showed that the primary fracture line or separation fracture appears to be the initial fracture line from which the others propagate. This primary fracture line proceeds from anterolateral to posteromedial through the posterior facet and divides the posterior facet and tuberosity from the sustentaculum tali and the middle and anterior facets.

In our model, after osteotomy, we anatomically reduced the posterior part of the calcaneus and loaded the joint again. It was then displaced 2 mm, 5 mm, and 10 mm using a laminar spreader and spacer blocks.

Results

The contact area of the posterior facet significantly decreased with all displacements of the simulated fracture. The high-pressure areas in the posterior facet were significantly greater only when displaced 5 and 10 mm. There were no significant differences for any parameters in the anterior and middle facets.

This suggests that for a simple calcaneus fracture, the joint area available for function diminishes significantly even with 2 mm of displacement. However, the area of the joint subjected to significant increases in high pressure does not increase until displacement has exceeded 2 mm. Since the former is presumably a more sensitive indicator of abnormal mechanics, and the latter by definition is an area of cartilage pressure known to cause degeneration of cartilage, we concluded from this study that a 2-mm threshold for open reduction of a calcaneus fracture is appropriate in this simple fracture pattern.

Summary

This study was limited to static loading of the neutral foot, and did not consider muscle actions. Nonetheless, we noted significant changes in the contact characteristics for small misalignments of the talar neck or posterior part of the calcaneus. Essentially, misaligning the talar head unloads the anterior and middle facets by which it articulates with the calcaneus. When there is a small displacement in the talar neck, the posterior facet remains intact. This suggests that for subtle injuries, it is important to look closely at displacement in the middle facet.

These subtle changes may explain Hawkins' finding that nondisplaced talar neck fractures can have substantial subtalar joint pain. On the other hand, displacing part of the calcaneus increases pressures on the remaining part left in contact, but does not affect the anterior and middle facet articulations. The clinical corollary is that small displacements along the primary fracture line probably do not warrant open treatment when there is no secondary fracture line separating the posterior facet from the anterior and middle facets.

Transverse plane CT scan is probably the best method of identifying such fracture lines. Even misalignments as small as 2 mm create these measurable changes. Many questions remain, such as identifying any extra-articular load paths and evaluating the effects of joint misalignment in other positions of the foot.

Supported by Veterans Affairs Research and Development, Harborview Medical Center, and the University of Washington Department of Orthopaedics

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Tensions in the Palmar Ligaments of the Wrist

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The wrist is one of the most complex joints of the body. There are no muscles that directly stabilize the wrist with respect to the forearm, so stability must come from compressive contact between carpal bones and tensions in their interconnecting ligaments.

The aim of this study is to identify key ligamentous stabilizers of the wrist. This information will form a basis for developing anatomical methods of ligament reconstruction as an alternative to fusing carpal bones to regain stability in the wrist.

The functions of the palmar carpal ligaments, shown schematically in Figure 1, are a subject of controversy. Of particular interest are the functions of the proximal radiocarpal ligaments, the radioscaphocapitate (RSC), the ulnolunate (UL), and the radiolunate (RL). The RSC ligament is taut in extension, ulnar deviation, and pronation. Disagreement arises as to whether it relaxes as the wrist deviates radially, or whether tension is maintained since the scaphoid palmar flexes during radial deviation, bowing the RSC outward. The radiolunate (RL) prevents ulnarward displacement of the lunate and captures the proximal pole of the scaphoid, preventing its palmar displacement. However, it is uncertain whether the RL also continues to the triquetrum and how this affects its function.

Recently, Savelberg and colleagues showed that the palmar ligaments elongate in extension but not in flexion. In ulnar deviation, the RSC and the distal part of the RL elongate, while the proximal RL shortens. The in situ tensions in the carpal ligaments have not been directly measured, only inferred indirectly from measured strains.

To provide further insight into the functions of some ligaments of the wrist carpus, we developed a technique to measure their in situ tensions. With this technique we are able to address several questions related to the relative distribution of tensions in the ligaments in various positions, their roles as passive stabilizers, and the effects of injury on tensions in the remaining ligaments. Knowledge of ligament function may provide insight into developing reconstructive procedures that better restore anatomical function to the injured wrist than fusing carpal bones.

Methods

In each of five upper extremity specimens, we identified the eight ligaments on the palmar side of the wrist, shown in Figure 1. The specimens were then mounted on a positioning frame that permitted controlled and measurable orientation of the hand in each of seven functional positions and provided a stable platform for the ligament tension measurements.

We developed a technique to measure tensions in the small ligaments of the carpus in situ (Figure 2). If a cable (or ligament) under axial tension whose end points are fixed is deformed perpendicular to its long axis, its axial tension can be determined from a force balance if the magnitudes of the perpendicular deformation and the deforming force are known. Based on this principle, we designed a transducer to measure the perpendicular deforming force and displacement. The length of the ligament was defined from caliper measurement of the distance between insertion sites.

We examined several potential sources of error such as nonperpendicular pull on the ligament, movement of the bones to which the ligament connects, and stress relaxation in the ligament during testing. Extensive testing occurred in two stages. We used nylon line with known axial loads applied to verify the basic theory, followed by bone-ligament-bone preparations to determine actual errors. Errors between the known and measured axial tensions ranged from 5.9% in nylon line to 9% in bone-ligament-bone preparations.

For intact specimens, the tension in each of the carpal ligaments was measured twice in seven functional

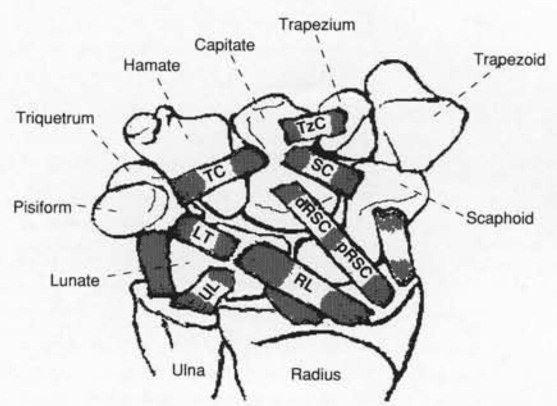
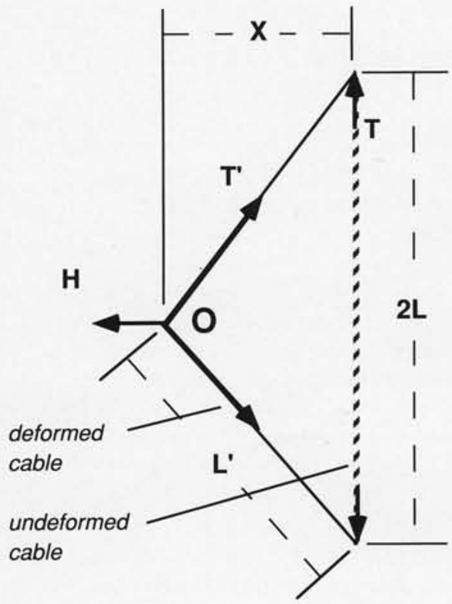


FIGURE 1: A schematic diagram of the major palmar ligaments of the wrist (adapted from Taleisnik J, *The Wrist.* New York: Churchill Livingstone, p 14, 1985).



T' = T + K (L' - L)

where:
T' = tension in the deformed cable
T = tension in the undeformed cable
K = stiffness of the cable
L' = length of the deformed cable
L = length of the undeformed cable
*cable is deformed by pulling it laterally

At point O where the perpendicular deforming load is applied:

$$T' = 1/2 * (L' / X) * H$$

where:
X = imposed perpendicular deformation
H = applied perpendicular force

The tension in the cable is:

$$T = 1/2 * (L'/X) * H - K (L' - L)$$

FIGURE 2: A schematic diagram of the method by which tensions in the wrist ligaments can be estimated from pulling them laterally and measuring the magnitude of the lateral pull and the deformation.

positions. The scapholunate interosseus ligament was then sectioned and the measurements repeated. To reduce interspecimen variations, the tension in each ligament was divided by the sum of tensions of all the ligaments tested for that position for each specimen. Therefore, the data are expressed in percent of the total tension.

Results

Repeatability of the mean ligament tensions between the first and second measurements was within 0.02%. Measurable tensions were detected in all ligaments in the neutral unloaded position of the hand. As the hand was moved from radial to ulnar deviation, UL tension increased significantly while RL tension decreased (Figure 3). Moving from ulnar to radial deviation caused the opposite effect. Overall, in the normal wrist, the tensions were greatest in the UL, RL, and RSC ligaments, confirming their importance as key stabilizers on the palmar side.

With isolated sectioning of the scapholunate interosseus ligament, a redistribution of ligament tensions occurred. The tension in the proximal part of the RSC increased in neutral, ulnar deviation, and radial deviation (Figure 4) compared with the intact wrist in the same positions. In contrast, tension in the RL decreased in neutral, radial deviation, and extension.

Discussion

Our study shows that measurable tensions exist in the palmar carpal ligaments in the unloaded wrist. These passive tensions may be important in maintaining the spatial relationships of the carpal bones. The RL was a main stabilizer to limiting radial deviation motion of the hand and the UL to ulnar deviation. In radial deviation the lunate moves ulnarward, which should tighten the RL and slacken the UL. In ulnar deviation, the lunate moves radialward, tightening the UL and slackening the RL.

We found no significant passive stabilizers to extension among the ligaments tested. The flexor tendons probably assume this role, so it may not be necessary to have additional ligamentous stabilizers. The pRSC appears to be the dominant passive stabilizer to pronation. In supination the UL and TC are the main participants. The reasons are not completely clear, but depend upon the axis of supination/pronation rotation within the carpus and forearm, a mechanism that has not been well defined.

These data show that there are definite differences in tensions between the ligaments. In general, the UL and RL ligaments possessed the greatest tensions while the SC, TzC, and LT had the least. Tensions in the pRSC, dRSC, and TC were variable. Since the UL and RL, both key stabilizers of deviation motions of the hand, are connected to the lunate, its role as an anchoring point appears to be important. With sectioning of the scapholunate interosseus ligament, the pRSC tension increased in most positions while conversely, the RL tension decreased. These changes may be attributed to loss of the scapholunate ligament, allowing the proximal pole of the scaphoid to move distal and ulnar, while the lunate moves proximal and radial.

Supported by Harborview Medical Center and the University of Washington Department of Orthopaedics

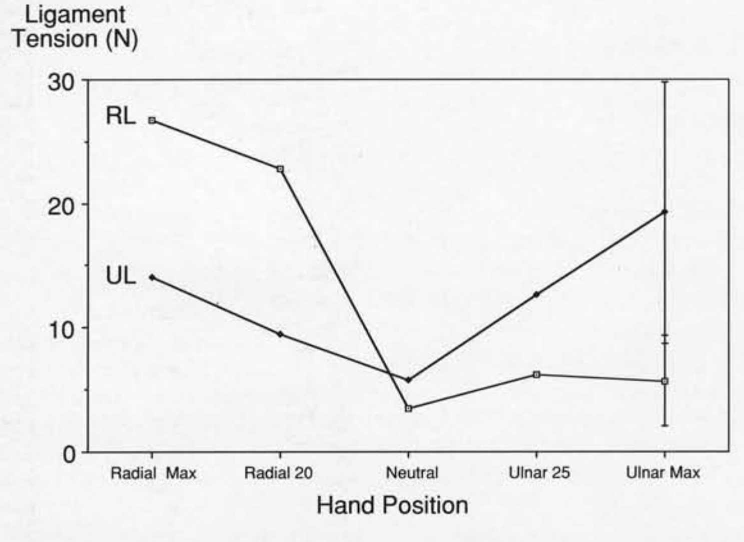


FIGURE 3: Changes in the tensions of some of the carpal ligaments with movement of the hand from radial to ulnar deviation (UL-ulnolunate, RL-radiolunate).

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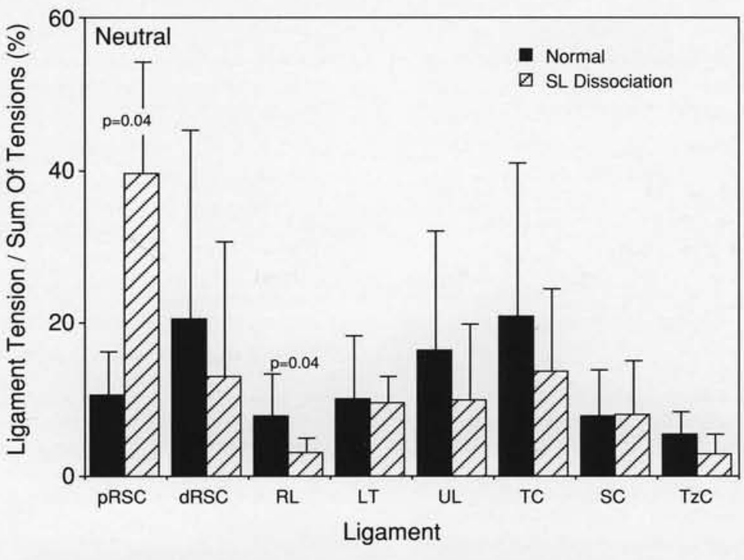

FIGURE 4: Effects of sectioning of the scapholunate interosseus ligament on tensions in the palmar ligaments of the wrist carpus, in the unloaded, neutral positioned upper extremity (refer to Figure 1 for nomenclature of ligaments).

Prosthetic History and Functional Outcome of the Traumatic Below-Knee Amputee

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Previous studies evaluating prosthetic use and functional outcome following below-knee amputation have reported on elderly, dysvascular, and diabetic patients. Outcome data are usually narrowly focused on one successful prosthetic fitting and achieving minimal ambulation. By contrast, traumatic below-knee amputees are typically younger patients who have greater functional expectations. Our report documents the prosthetic history, prosthetic costs, and a detailed, standardized functional outcome of 20 traumatic, below-knee amputees.

From the Harborview Medical Center amputee support group files we identified 20 persons who at least four years previously had suffered trauma requiring a unilateral below-knee amputation. Subjects in this select group had no other medical problems or injuries. They ranged in age from 19 to 58, with an average age of 34. The average time since amputation was 5.5 years, with a range of four to nine years.

Each person's prosthetic history and cost analysis were determined from the medical record and the billing records of the prosthetist. Exact costs were calculated for 15 of the 20 patients. Of the five patients where costs could not be accurately determined, two had used prosthetists who subsequently went out of business, one patient's records were unavailable from the Navy, and two patients had received experimental prostheses as part of research studies and thus were excluded from the calculations for cost and for average number of prostheses.

We assessed functional outcome through the SF-36 Health Status Profile developed by the Medical Outcomes Study Group. The SF-36 is a standardized health status evaluation tool designed to be self-administered in 10-12 minutes. It provides a measure of eight categories of functioning and well-being:

1. physical functioning
2. role limitations due to physical health
3. role limitations due to emotional problems
4. social functioning
5. mental health
6. energy/fatigue
7. pain
8. health perception.

This type of instrument provides insight into outcome that is beyond the usual scope of commonly used measurements, such as healing rates, radiographic changes, range of motion, or muscle strength. Health status tools are concerned with the effects that a disease or injury has on a person's performance in everyday activities, social interactions, mental health, the patient's perception of health in general, and appraisal of his or her well-being.

Results

The first prosthetic fitting occurred an average of 15 weeks after amputation. Between three and seven visits to the prosthetist were needed for each limb. During the first three years, the mean number of prostheses acquired per patient was 3.4 (range 1-5) with an average total cost of $10,829 (range $2,558-$15,700). Over the first five years the mean number of prostheses acquired per patient was 4.4 (range 2-8) with an average total cost of $13,945 (range $6,203-$20,070).

All of the patients had mastered the ambulatory skills necessary to function without aids other than their prosthesis. Patient estimates of the time to plateau in walking ability was one to 1.5 years from amputation. Only two patients felt that they could run farther than 100 yards without incurring significant residual limb trauma; however, neither ran regularly.

Patients wore their prostheses an average of 12.5 hours per day (range 3-16 hours). Five patients routinely alternated use between two different prostheses. Of this group, two used a waterproof prosthesis, two changed legs to alter residual limb wear pressure distribution, and one used the additional prosthesis for sports only.

All patients experienced phantom sensation, but only 12 stated that the sensation was sometimes painful. Of these 12 patients, four had less than one episode per week, five had one episode per day, and three had several episodes of phantom pain per day.

Nine patients were employed full time, five in office jobs, and four in construction work. Three patients were students, one an active housewife, and one retired. The six unemployed patients all felt that their status was due to their amputation. Of the five unemployed patients who desired employment, three cited recurrent skin breakdown from the prosthesis as their impediment to working.

To evaluate the Health Status Profile scores we used the Wilcoxon matched pairs signed rank sum test to compare an amputee's scores to published scores of normal aged-matched controls. The scores of traumatic amputees are significantly decreased in the three categories of physical functioning (p=.0001), role limitations due to physical health (p=.0004), and pain (p=.006).

Interestingly, the scores were not significantly different from normal aged-matched scores in the other five categories of role limitations due to emotional problems, social functioning, mental health, energy/fatigue, and health perception. Outlier analysis of the 20 patients revealed that only one had outcome scores that, in every category, were significantly worse than aged-matched normalized data.

Summary

Rehabilitation and prosthetic fitting following traumatic amputation can be a costly and time-consuming process. An average of approximately 1.5 years elapsed between the definitive amputation and a point when the patients felt they had reached a plateau in ambulation. By this time the average patient was using a second or third prosthesis and had accumulated about $7,000 in prosthetist's bills. By three years most patients were comfortable on their third or fourth prosthesis and had invested more than $10,800 in prosthetic hardware and labor. At five years this figure had typically climbed to an average of 4.4 limbs and $13,900.

The SF-36 Health Status Profile is a standardized survey designed to assist research in medical outcome analysis. The results in our study show relatively little deviation from normal patient scores in the categories of role limitations due to emotional problems, social functioning, mental health, energy/fatigue, and health perception. We believe that these data are encouraging and give insight that the emotional and social aspects of life are not as drastically affected by traumatic below-knee amputation as might be assumed. Scores were lower in the categories of physical functioning, role limitations due to physical health, and pain. We believe that these scores indicate that many below-knee amputees do have some real physical limitations.

In conclusion, while the accomplishments of this group of traumatic below-knee amputees are impressive, we feel that new below-knee amputees should be informed that recovery can take longer than one year, and that prosthetic fitting can be a costly process. Since in all but three cases, prosthetic replacement was due to loss of fit and not component failure, modular systems that allow replacement of only the socket might be more cost effective.

Furthermore, while the traumatic below-knee amputee probably will attain a different level of physical function than prior to the amputation, the outcome in the areas of social function, mental health, energy, and general health perceptions is usually good. The use of newer functional outcome tools such as the SF-36 provides insight into many areas of functioning and well-being and should help tremendously to evaluate the impact on a person's life of medical treatments, such as limb salvage versus amputation.

Supported by Harborview Meedical Center, the University of Washington Department of Orthopaedics, and the Prosthetics Research Study

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Arthroscopic Labral Repair to the Glenoid Rim

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The open Bankart procedure is the preferred technique for repair of traumatic labral and capsular ligament avulsions from the glenoid rim. This procedure has provided consistent and reliable results in the hands of experienced orthopaedic surgeons.

Although the open Bankart repair may seem safe, reliable, and cosmetic, many orthopaedic surgeons find it technically demanding with significant potential complications. Only about 5% of patients develop recurrent stability after an open Bankart repair. Unfortunately, the failure rate for arthroscopic Bankart repairs averages 12%, more than double the failure rate for the open procedure.

We designed this study to rigorously test our new arthroscopic method in vitro prior to clinical application. The technique we devised attempts to duplicate the "inside-out" open surgical repair described by Thomas and Matsen. Our new approach anatomically repairs the labrum and ligaments to the glenoid rim. We hope to reestablish the normal stabilizing mechanisms without sacrificing the normal glenohumeral laxity or range of motion. This approach is designed to protect neurovascular structure, articular surface, cuff tendons, or other tissues.

Methods

To evaluate the initial strength of this repair method, we attached a six-degree-of-freedom position sensor and force and torque transducer to the humerus and scapula of eight normal cadaveric shoulders. Bankart lesions were created arthroscopically and were deemed adequate when complete antero-inferior joint dislocation occurred on crank test (Figure 1). Dislocation required sectioning the inferior sling as well as the anterior glenohumeral ligaments.

The severed capsulo-labral complex was reattached to the glenoid rim with sutures placed arthroscopically. We measured the normal, released, and repaired preparations sequentially using the Orthokine system developed by a member of our team (JAS). Using manual manipulation, we assessed eight motion ranges and six laxity tests.

Performing the Arthroscopic Repair:

Posterior, anterior-inferior, and antero-superior portals are used for access to the glenohumeral joint. The detached labrum and capsular ligaments of the Bankart lesion are prepared by smoothing the fibrillated edge of the soft tissue with a motorized blade placed through the antero-inferior portal. An elevator rasp and burr abrader are used to decorticate the anterior nonarticular aspect of the glenoid rim and neck until a bleeding surface is obtained (Figure 2).

The arthroscopic glenoid drill guide is placed through the postero-superior portal. The drill guide is positioned over the margin of the glenoid at the inferior aspect of the Bankart lesion. A K-wire is placed in the guide and drilled through the glenoid rim. The guide is stabilized while the K-wire is removed and exchanged for the suture passer (Figure 3).

The capsular position and tension is adjusted by grasping the labrum, pulling it superiorly, and allowing the sharp suture passer tip to perforate the capsulo-labral junction in the appropriate location. A#0-PDS (Ethicon Co.) suture is inserted through the passer. The suture in the joint is grasped through the posterior cannula and paired with the other strand. A slip knot is advanced to secure the tissue to the glenoid rim. Alternating half hitches are pushed down to secure the tissue with locking knots.

The technique is repeated by placing additional sutures along the glenoid rim for repair of the entire Bankart lesion. If necessary, slack in the capsule can be removed by forcing the needle through the tissue further away from the labrum. Four to five sutures usually are needed to repair a Bankart Lesion (Figure 4).

Results

Releasing the capsular ligaments to create the dislocation increased the passive range of motion, especially, with the arm elevated 60 degrees. It also caused significant increases in translation on anterior and posterior drawer and crank tests. Repair times ranged between one and three hours (mean 1.5) and decreased with practice.

After repair, laxity was restored to normal levels. Glenohumeral motion was never decreased after repair relative to the normal joint. Loads of greater than 3,500 newton-millimeters of torque and 40 N of force were applied manually to the repair without causing failure.

In each specimen, close inspection of the repair at dissection confirmed that the labrum was reattached to the glenoid directly adjacent to the rim in its anatomic position. The knots did not untie or loosen when subjected to loading. All neurovascular structures were uninjured and safely away from the repair.

Discussion

The advantages of arthroscopic Bankart repair include avoidance of an incision in the subscapularis, less postoperative pain, lower morbidity, early recovery of strength, and minimal to no loss of motion (even throwing athletes can return to their pre-injury level of competition). Other advantages are a shorter hospitalization and rehabilitation resulting in a lower cost per surgical treatment.

At subsequent open surgery, most arthroscopic failures demonstrate a detached inferior glenohumeral ligament at the antero-inferior labrum. Secure repair at this region of the glenoid rim has been difficult or limited by anterior arthroscopic approaches.

Our posterior approach to the Bankart repair using the arthroscopic glenoid suture guide permits secure restoration of the labrum and capsular ligaments to the low antero-inferior rim of the glenoid. Our tool enables the surgeon to place sutures through the glenoid rim precisely in the location where tissue avulsion occurred, and we hope to reduce the high failure rate associated with some arthroscopic methods.

This arthroscopic repair provides anatomic reattachment and deepens the glenoid concavity comparable to that achieved with open Bankart repair. Unlike other methods, it does not rely on transosseous sutures adjacent to neurovascular structures, and there is no potential for malposition, migration, or impingement of implanted metallic or absorbable devices against tendons or articular surfaces. This new method restores normal joint stability, preserves full motion, and can withstand forceful loads without failure. Ongoing clinical trials will substantiate whether the technique is as safe and reliable as suggested by this in vitro study.

Supported by the University of Washington Department of Orthopaedics

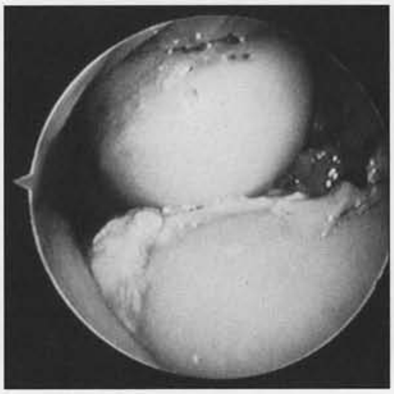

FIGURE 1: Note that the entire anterior and inferior labrum has been released from the glenoid to achieve complete antero-inferior dislocation of the glenohumeral joint with the limb in the crank test position.

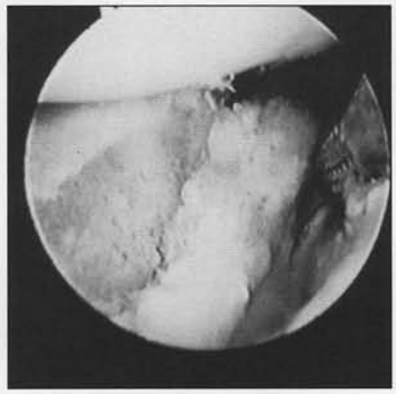

FIGURE 2: Arthroscopic view through the antero-superior portal after preparation of the glenoid rim and scapular neck. The labrum is retracted medially against the decorticated bone, which is now ready for placement of suture holes.

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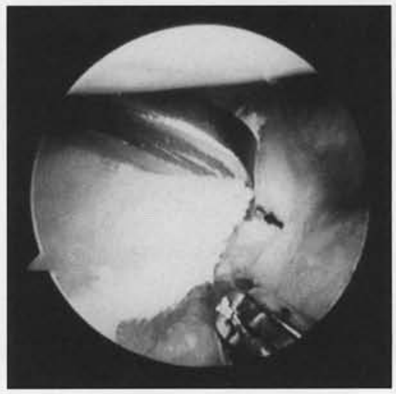

FIGURE 3: The arthroscopic drill guide is positioned inferiorly for the first suture hole. A 0.062-in diameter K-wire is drilled through the articular rim 3.5 mm away from the articular edge forming a 2.5-mm thick bone bridge. The suture passer is in place (suture extending from hole). The capsulo-labral junction is grasped and positioned over the tip of the suture passer.

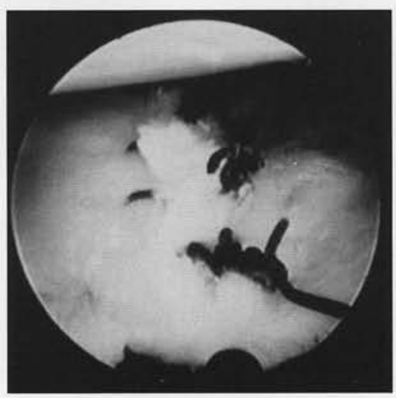

FIGURE 4: Arthroscopic view of the repaired labrum and capsular ligaments to the articular rim of the glenoid. Notice how the glenoid concavity has been deepened by the repair.

Robotic Assistance in Orthopaedic Surgery:

A Proof of Principle Using Distal Femoral Arthroplasty

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We have been exploring the application of robotic assistance in situations where accuracy and precision are required in orthopaedic surgery. Our initial investigation concerned the planning, positioning, and orientation of the bony cuts and holes required for the femoral component of a total knee arthroplasty.

The clinical outcome of total knee arthroplasty depends on many factors such as patient selection, prosthesis design, soft-tissue balancing, and postoperative care. The prostheses are manufactured so that the geometry of their joint surfaces meet very high tolerance standards. Yet, the precision and accuracy of the technique by which a surgeon implants these components are much less rigorous.

Two aspects of the surgical procedure involve precise geometrical relationships. One is the positioning of the prosthetic joint surfaces so that optimal kinematics can be achieved. The second is the location and orientation of the bony cuts and holes to fit the back of the component exactly, providing a durable bone-prosthesis interface.

The optimal execution of such a geometrical procedure is non-trivial: the relationship of each component to the bone has six degrees of freedom. These include three directions of translation (proximal-distal, medial-lateral, anterior-posterior) and three directions of rotation (flexion-extension, internal-external rotation, varus-valgus). Furthermore, the implantation of each component requires several bone cuts and holes. Each cut plane has two rotational and one translational degree of freedom. Each hole has two rotational and two translational degrees of freedom. Each degree of freedom represents a possible surgical error that can compromise the kinematics of the joint or the durability of component fixation.

Conventionally, procedures such as knee arthroplasty are planned using two-dimensional templates superimposed on two-dimensional radiographs. Such planning cannot specify all the necessary variables for a three-dimensional arthroplasty. Even if a three-dimensional plan was established, for example using computerized tomograms or scaled physical models, the surgeon cannot ensure that the planned relationships would be achieved at the actual operation.

Robotic assistance offers the surgeon a unique opportunity to establish a complete three-dimensional geometrical plan and then to execute that plan on the bone with precision, accuracy, and efficiency. The robot can only be an assistant, however. A robot cannot approach the ability of an orthopaedic surgeon to make the surgical approach to the knee, to carry out the appropriate soft-tissue releases, or to judge the depth of a bony cut so that it does not injure the popliteal neurovascular structures.

Method

In our procedure, we used a three-dimensional digitizing template connected to the robot to specify the desired position and orientation of the component's articular surfaces in relation to the distal femur. The guiding system software employed this spatial relationship along with its knowledge of the geometry of the selected arthroplasty component to plan the precise location of the required bone cuts and holes.

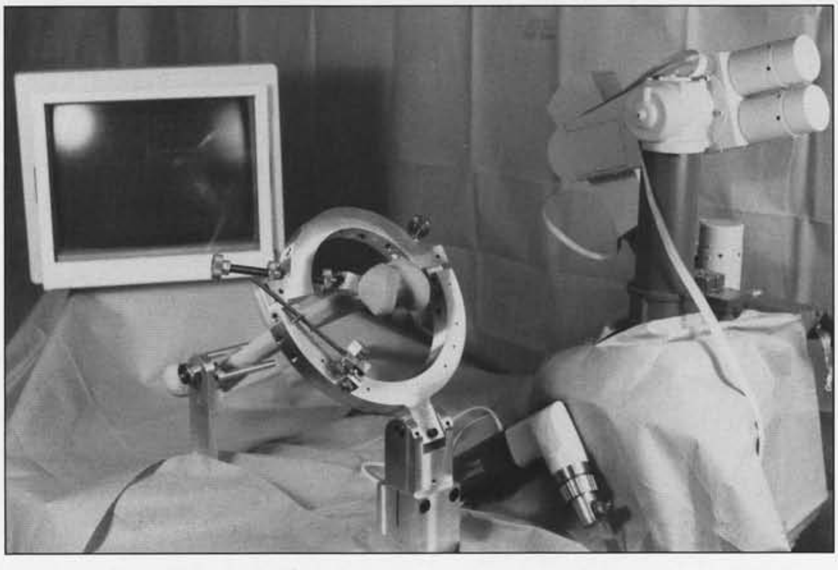

FIGURE 1: The robot assistant (at right) is mounted to the operating table in close proximity to the femur. The femur is attached to the table by the immobilization halo (center). The robot assistant is controlled using a touch screen menu on the computer display (back left). The surgeon makes the cuts using a standard surgical saw (below right center).

Finally, the small (16-kg) robotic assistant sequentially positioned saw and drill guides with respect to the distal femur, allowing us to make these cuts and holes in the locations necessary for optimal component fit, position, and orientation (Figure 1). The robotic assistant functioned easily in the operating room environment, increased the accuracy, and decreased the time, equipment, and personnel required to conduct the geometrical part of this surgical procedure.

To test the ease of learning the system as well as its accuracy and efficiency, we asked five surgeons to perform arthroplasties on plastic femora using both conventional and the robotic-assisted technique. The surgeons had no difficulty in learning the robotic procedure. The total average times for these surgeons to perform a conventional distal femoral preparation and the robot-assisted preparation were virtually identical (22.6 +/- 5.3 minutes and 21.1 +/- 1.8 minutes, respectively).

The fit of the component was characterized by the relationship of the three major cuts: anterior, distal, and posterior. Three sets of data were collected to measure accuracy: (1) the angle between the anterior and distal cut; (2) the angle between the posterior lateral cut and the distal cut; and (3) the angle between the posterior medial cut and the distal cut.

Lump analyses of all three sets of data yielded a two-degree RMS error for the robot and five-degree RMS error for the conventional system (Figure 2). The distribution of these errors was such that for the conventional system only 16 of 30 angles were within two degrees of the intended angle. By contrast, 24 of 30 angles for the robotics system were within two degrees of the desired value. Of particular importance is the observation that the extreme errors allowed by the conventional system were not allowed by the robotic system.

Finally, a demonstration of the technique was performed on a full cadaver in the operating room under surgical conditions including standard draping. The distal femoral replacement was performed with the knee exposed through the standard paramedian incision, without alteration of the menisci or tibia, and without sacrifice of the anterior or posterior cruciate ligaments. No additional dissection was required beyond that normally used for total knee arthroplasty. After the patella had been reflected laterally, the distal femur was mounted in the immobilization jig. The jig provided excellent fixation of the bone in a position where the femoral condyles and proximal tibia were well exposed.

After the bone preparation, the robot was dismissed and the surgeon drove the distal femoral component into position. An excellent press fit was attained with the prosthesis in excellent alignment, and the knee was removed from the halo. It showed a range of motion from 0-135 degrees and excellent stability in the anterior-posterior and varus-valgus directions.

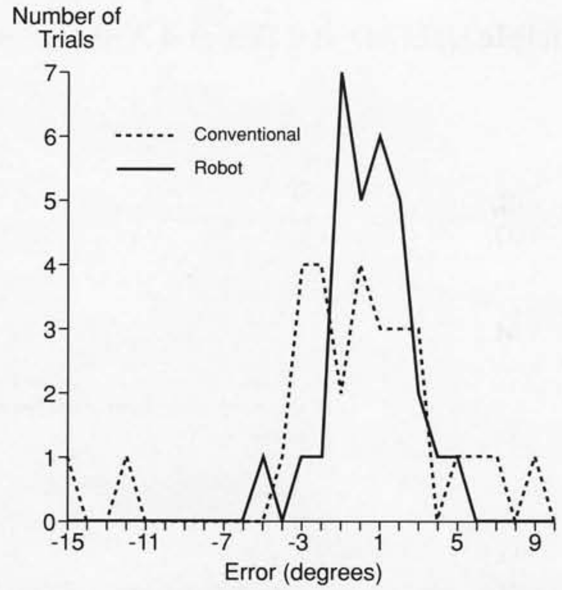

FIGURE 2: Comparison between the conventional and robotic-assisted distal femoral preparation. RMS errors are shown for five surgeons each doing two arthroplasties using the conventional system (broken line) and two using the robotic assisted system (solid line).

Summary

Industry uses robotics for tasks that require accuracy and precision. Despite the widely recognized need for geometrical accuracy and precision in orthopaedics, there has been minimal exploration of the possible role of robots. A robotic assistant offers potential benefit to the surgeon and patient by ensuring that the preoperative plan is formulated and executed with accuracy and precision. The effect of these improvements on the functional outcome and durability of total knee arthroplasty and other orthopaedic procedures must be determined by future investigation.

Supported by the University of Washington Departments of Orthopaedics and Mechanical Engineering

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Development of a Sustained-Release System to Deliver Growth Factors to Bone

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The recent identification of factors involved in bone growth and repair has led to great interest in developing systems to permit effective, site-specific delivery of these substances in therapeutic doses over time. Sustained-release growth factor preparations might be particularly useful for patients with bone defects or delayed fracture healing, or for promoting fixation to prosthetic components.

One example is in the delivery of platelet-derived growth factor (PDGF) to bone. PDGF is a naturally occurring polypeptide that acts by both mitogenic and chemotactic mechanisms. Normal delivery of PDGF to the fracture site by platelets and monocytes results in enhanced DNA and collagen synthesis. PDGF stimulates the proliferation of normal osteoblastic cells, and is most pronounced during the first part of fracture repair. PDGF also inhibits cell alkaline phosphatase, a marker of osteoblastic differentiation. Inhibiting differentiation would be most beneficial at the very beginning of fracture healing to maintain a population of osteoblasts.

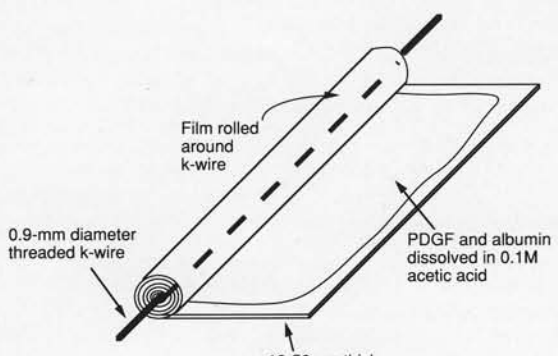

FIGURE 1: Schematic of PLA/PGA intramedullary implant loaded with PDGF.

The advantages of using a controlled-release system to deliver growth factors such as PDGF to bone are numerous: localized site-specific targeting, continuous therapeutic doses released over time, and independence of patient compliance. A biodegradable system appears to be a practical, efficient, and therapeutic method to accommodate the specific needs of both PDGF and the physiological situation. Ideally, the implant would degrade, releasing a large quantity of its active agent and simultaneously eliminating the need for implant removal.

We chose polylactic acid (PLA) and polyglycolic acid (PGA) copolymers as the basis for our system for several reasons. First, both the release rate and mechanical strength of the implant can be altered by changing the ratio of PLA to PGA. Second, both PLA and PGA are extremely biocompatible and their degradation products are metabolized. These polymers have already been approved for implantation by the FDA and are used as the base material for degradable sutures. The major challenge is developing procedures for maintaining the viability and mitogenic potential of the factor during fabrication and implantation of practical implant preparations.

Development of the Implant

Films ranging from 10 to 50 microns thick were made by solvent-casting PLA/PGA copolymers of choice in chloroform. PDGF and albumin were either dispersed in powdered form or dissolved into a solution and then spread across the surface of the film. Figure 1 shows a schematic diagram of an implant fabricated in the form of an intramedullary pin.

A polymer degradation study indicated that ratios of 85:15 PLA/PGA and 50:50 PLA/PGA copolymers may be useful in obtaining the desired release of PDGF. Implants of these copolymers were loaded with 100 μg of PDGF in powdered form. Copolymer ratio, film thickness, and the amount of albumin were varied. These implants were immersed in sterile saline at 37°C and 1-ml samples were taken over 40 days. The amount of PDGF in each sample was determined by an enzyme-linked immunosorbant assay (ELISA) developed by ZymoGenetics, Inc. (Seattle, WA).

The release characteristics of some of the implants are shown in Figure 2. The rabbit albumin powder was used as a material both to enhance degradation and to reduce the amount of PDGF binding to the implant. As expected, faster initial and overall greater PDGF release was obtained from the specimens with albumin.

The less crystalline nature of 50:50 PLA/PGA also enhances degradation, and thus greater PDGF release was observed from rods E and I. The greatest release was observed from rod I, a 50:50 PLA/PGA implant loaded with PDGF and albumin and constructed with a thinner film. These in vitro results provided reason to believe that upon further refinement this type of biodegradable polymeric implant would be able to provide sustained release and deliver significant levels of active PDGF.

Reproducibility of Release Characteristics

Results of the early experiments led to the use of 50:50 PLA/PGA, thinner films, and PDGF incorporation into the implant by solution rather than in powder form. Using this method we performed an in vitro repeatability study. Group I implants were loaded with 10 μg of PDGF per implant, while 100 μg of

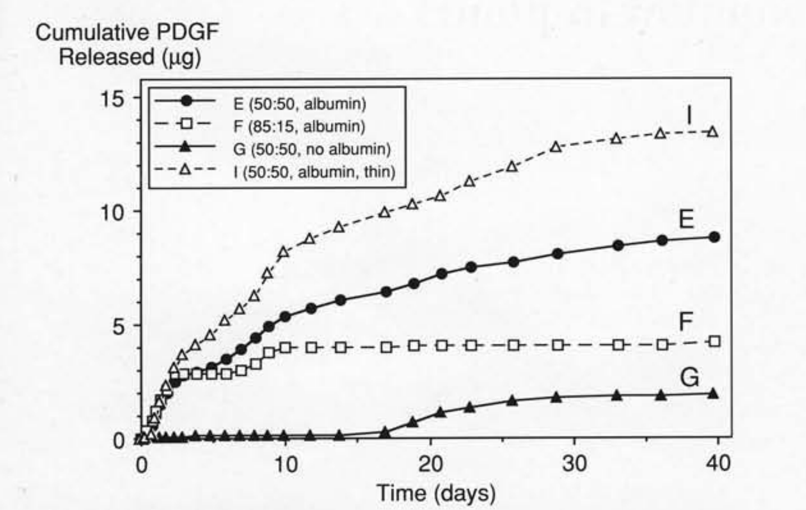

FIGURE 2: PDGF released from 50:50 and 85:15 PLA/PGA rods, quantified by ELISA. The use of thinner films and the presence of albumin resulted in faster initial release and greater overall release.

PDGF was incorporated into each of the Group II rods. Samples were analyzed as before.

The release curves from both groups are shown in Figure 3. Complete release of PDGF was observed in Group I, which contained 10 µg of PDGF. The cumulative amount released from Group II averaged 42 µg, or 42% of the amount loaded into the implant. In both groups, the amount of PDGF observed in solution was repeatable ($p<0.05$) within the group.

Conclusions

The best polymer for implant fabrication of those examined is 50:50 PLA/PGA. The incorporation of albumin leads to a faster initial release rate and greater total observed PDGF release. As seen by the incomplete release from specimens loaded with 100 µg PDGF, the total possible release remains undetermined. Nonetheless, these studies demonstrate that a viable method has been developed for the release of growth factor to bone.

We are considering several applications for this system. An initial study of fracture healing in the rat femur showed no differences between fractures fixed with polymer IM pins containing albumin only and those with sustained release of PDGF. More challenging models under consideration include healing across a gap and improvement of ingrowth into porous surfaces.

Supported by Harborview Medical Center, the University of Washington Department of Orthopaedics, and a grant from ZymoGenetics, Inc., a subsidiary of NovoNordisk

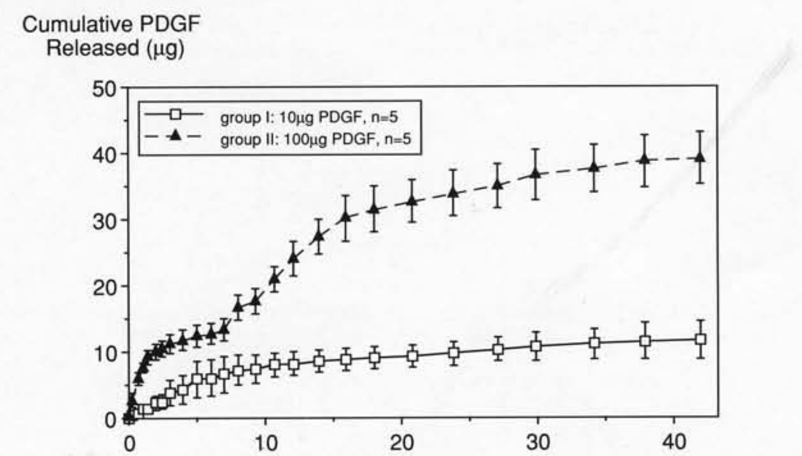

FIGURE 3: PDGF released from solution-loaded rods during in vitro repeatability study. Greater percentage release was obtained than in previous studies, but still not 100% for implants with 100 µg PDGF.

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Biochemical Markers of Postmenopausal Bone Loss

David R. Eyre, Ph.D.

Osteoporosis presents a major threat to the well-being of the human population as life expectancies continue to increase. The cost of medical care to treat fractures that result from osteoporotic bone loss puts a vast and growing burden on the U.S. national economy. At present, there are no accurate methods for predicting who will suffer from osteoporosis before extensive loss of bone has already occurred.

Type I osteoporosis, which strikes women after menopause, is generally more prevalent in small-framed, thin, white women of northern European extraction, and is exacerbated by smoking, alcohol consumption, and a sedentary lifestyle. Specific diagnostic tests are needed to identify women at risk before significant bone loss has occurred. Sophisticated bone scanning methods (e.g., dual x-ray absorptiometry, DXA) are evolving that can accurately measure the density of bone in the spine, hip, or wrist. By serial measurements over time, they can also measure how rapidly a person is losing bone.

However, densitometric measurements are of relatively limited value as predictors of the risk of future fracture except when bone density is already dangerously low or when serial measurements over several years show a rapid rate of bone loss. There is an urgent need, therefore, for simple, non-invasive biochemical tests that can assess the rate of bone loss and hence the risk for osteoporosis at a stage when preventive therapy can be effective.

Current expert opinion on the cause of osteoporosis points to an accelerated rate of resorption at menopause and particularly in the ensuing years when estrogen levels fall precipitously, leading to a rapid net loss of bone. There is also evidence that women who resorb bone most rapidly at menopause are at the highest risk of early-onset osteoporosis and fracture in later years. If these "high resorbers" could be reliably identified by a biochemical test, preventive therapy (for example hormone replacement or bisphosphonates) could begin early enough to prevent bone loss and osteoporosis in later years.

To this end, we have been pursuing the concept that specific peptide fragments found in the urine from the proteolysis of bone collagen by osteoclasts can provide an accurate index of bone degradation rates. When osteoclasts resorb bone, they dissolve not only the mineral but also the organic framework, which is 70% collagen. Collagen is the principal structural protein of connective tissues, including bone.

Osteoclasts not only remove mineral, but also dissolve bone collagen by secreting proteolytic enzymes. The resulting peptide fragments of bone collagen are degraded further (within the osteoclast and perhaps in the liver and kidney) to amino acids which re-enter the body's synthetic pathways. Certain amino acids, however, such as hydroxyproline, hydroxylysine, and cross-linking amino acids that are specific to collagen cannot be reused for protein synthesis and are either oxidized in the liver or excreted in the urine. Urinary hydroxyproline has long been used clinically as a measure of bone resorption; however, it has limited value except in conditions of highly accelerated bone turnover, such as Paget's disease and hyperparathyroidism.

Over the past few years, leaders in the field of metabolic bone disease have been paying increasing attention to the cross-linking amino acids of collagen, the so-called pyridinolines, which are secreted in urine. Each of these residues fastens three collagen molecules together in a polymeric fibril of collagen (Figure 1).

Two forms, hydroxy-lysyl pyridinoline (HP) and lysyl pyridinoline (LP), are most prominent in bone. These residues provide a more specific index of bone degradation and, unlike hydroxyproline, are not affected by diet. Assays for these residues in urine are time consuming, expensive, and unreliable.

In addition, our own work has shown that urinary levels of pyridinolines are influenced by the destruction of tissues other than bone and can be affected by degradation before analysis. Their measurement in individual patients is, therefore, neither convenient nor reliable as a routine clinical tool for screening bone resorption rates or as a monitor of response to therapy.

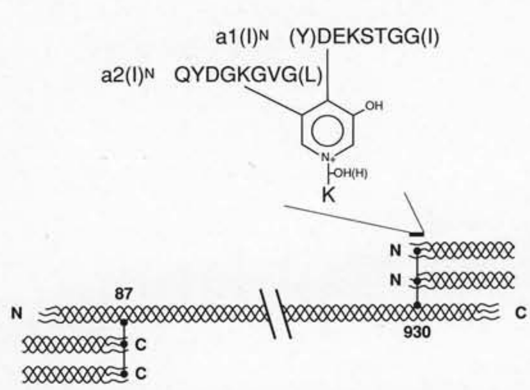

FIGURE 1: Structure of the core peptide from the N-telopeptide-to-helix cross-linking site in bone type I collagen that is recognized by monoclonal antibody 1H11. The hydroxypyridinium (pyridinoline) cross-link fastens three polypeptide chains together, at sequences shown in single letter code.

In recent years, we have been developing an alternative but related approach, which has proven to be much more specific and lends itself to a simple immunoassay that can be directly applied to urine with no preparation steps. The assay is based on a peptide fragment that is derived from one of the two trifunctional (pyridinoline) cross-linking sites in collagen type I of bone (Figure 1). This cross-linked N-telopeptide-to-helix protein domain resists further proteolysis in the body, by virtue of its compact structure and other chemical features. Its quantitation is proving to be a reliable index of the rate of bone resorption in the body.

We raised a mouse monoclonal antibody (Mab) to this peptide fragment and developed a simple enzyme-linked immunosorption assay (ELISA) on 96-well microtiter plate. The assay is highly specific for this cross-linked domain of bone type I collagen, and does not cross-react with any other molecular domains in type I collagen or in collagen types II, III, etc., of other tissues. Most importantly, the Mab 1H11 does not recognize the cross-linking pyridinoline residues, but rather the cross-links themselves, which accounts for the specificity of the assay.

Subjects in a clinical trial who were given a new bisphosphonate (alendronate) that is known to block bone resorption showed a much greater suppression and longitudinal reproducibility of cross-linked N-telopeptide excretion rates than was revealed through measurements of urinary pyridinolines (Figure 2). The data also showed a negative correlation between absolute bone density in the spine and resorption rate at trial entry (baseline) measured by cross-linked N-telopeptide concentrations normalized to creatinine.

A trend also emerged from results on the placebo group for a negative correlation between rate of bone loss (by spinal DXA) and baseline resorption rate. Resorption rate by the assay was threefold higher in early postmenopausal women than in premenopausal women. The upper end of the range was up to tenfold higher postmenopausally than premenopausally.

It will be important to follow up these studies in more extensive clinical trials to establish accurately the correlation index between bone resorption rate measured by the assay and rate of bone loss by densitometry, as well as with the risk of osteoporotic fracture. These studies are underway.

With the 1992 advent of the NIH Women's Health Initiative, as many as 150,000 women will be followed for risk of osteoporosis, heart disease, and breast cancer for a minimum of 10 years at 50 centers around the United States. These biochemical assays will be evaluated as measures of bone metabolic status and, most importantly, as a potential screen for predicting risk of osteoporosis.

Using similar basic concepts, we also are pursuing molecular markers with a view to developing immunoassays for detecting and quantifying the degradation rate of cartilage as a monitor and screen for arthritic disease, and similarly for other connective tissues in various inflammatory and degenerative disorders.

Supported by the Ernest M. Burgess Endowed Chair for Orthopaedic Research and the University of Washington Department of Orthopaedics, and grants from Ostex International, Inc., and the National Institutes of Health

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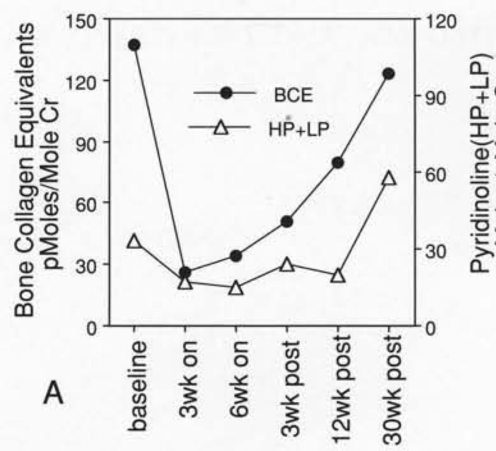
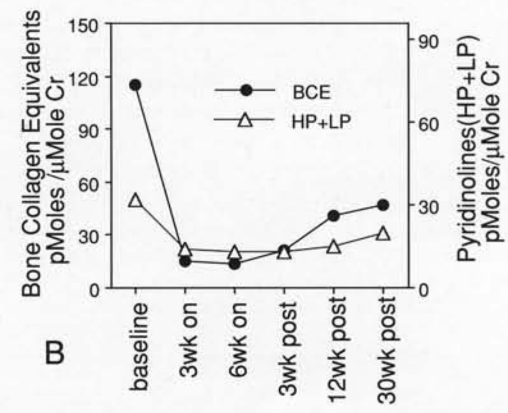


FIGURE 2A-B: Monitoring the suppression of bone collagen degradation by assay of serial urine samples in two subjects in early postmenopause on 6 weeks of bisphosphonate therapy. The immunoassay results (solid circles) are normalized to creatinine and monitor the marked suppression in bone resorption mediated by the drug. In comparison, the assay by HPLC of total cross-links does not have this degree of specificity and discriminating power for monitoring bone resorption. Similar results with estrogen have been observed in other studies. The baseline measurements for these two subjects are both in the upper end of the early postmenopausal range (c.f. mean at 0.5 - 3 years after menopause = 90 pMoles bone collagen/μMole creatinine; compared with a premenopausal mean of 40 pMoles bone collagen/μMole creatinine). **A** (above): Resorption rate of this subject returned to high levels by 30 weeks post-therapy. **B** (below): Resorption rate of this subject remained suppressed at 30 weeks post-therapy.



Similarities and Differences in the Lumbar MRI of Identical Twins

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Controversy surrounds the etiology of most morphologic anomalies and degenerative changes in the lumbar spine. Environmental factors such as trauma, heavy occupational loading, whole-body vibration, and smoking have been widely investigated as possible risk factors for back pain and structural changes. Yet, much of the variability in morphologic and degenerative variations remains unexplained.

Genotype also may play an important role. Genetic predispositions have been suggested for scoliosis, ankylosing spondylitis, spondylolisthesis, and adolescent disc herniations based on studies of their occurrence rates among family members. In addition, radiographic studies of identical twins have revealed similarities implicating genotype in the development of hyperostosis affecting the ligaments of the spine, juvenile lumbar disc herniation, and Schmorl's nodes.

FIGURE 1: The spines of a pair of 36-year-old twins show similarities in size and shape.

These few investigations of identical twins, however, used very small sample sizes, ranging from one to seven pairs. We conducted a larger systematic review of the magnetic resonance images of the lumbar spines of identical twins. The purpose of our study was to gain insight into the issue of environmental versus genetic effects of genotype and to guide the further study of etiologic factors.

Methods

Forty male identical twins (20 pairs) participated in this investigation. The twins ranged in age from 36 to 60 years, and had been selected based solely on smoking discordance. The incidence of back pain reported was similar among smoking and non-smoking co-twins, and none of the twins had a history of spinal fractures or surgery.

Magnetic resonance imaging provided mid-sagittal views of the lumbar spines of the subjects. Two experienced observers blinded as to twinship independently reviewed the images for each subject. Each intervertebral disc from T12-L1 through L5-S1 and its adjacent endplates were classified according to their appearance on midline sagittal images. The structures were evaluated specifically with respect to Schmorl's nodes, other endplate changes, disc desiccation, disc bulging/herniation, and disc height.

Schmorl's nodes were noted as being either absent or present, and other endplate changes were classified according to the system described by Modic. Disc desiccation was classified on a 0-3 scale, with the anterior, middle, and posterior thirds of the disc rated separately. The anterior and posterior thirds correspond roughly to the annulus fibrosus, while the middle third represents the nucleus pulposus.

A rating of 0 on this scale corresponds to no detectable signs of disc degeneration, and a rating of 3 represents a complete or near-complete loss of disc space signal. The presence of a disc bulge or herniation was graded on a 0-3 scale (0=normal, 1=minimal bulge, 2=diffuse bulge, 3=focal bulge/herniation) and classified according to location (anterior or posterior). Loss of disc space height also was classified on a 0-3 scale. Observers were asked to record any other notable findings when reviewing the films. Disc height and width measurements were obtained using a micrometer.

For Schmorl's nodes, other endplate changes, disc height narrowing, disc bulging/herniation, and disc degeneration scores, we compared co-twins for matching in excess of that expected by chance. The 0-3 scales were simplified to binary scales (0-1=normal, 2-3=abnormal) to score the number of matches between co-twins for each variable and level. We used Monte Carlo simulations to compare these matches with the degree of agreement expected by chance.

The scores for all twins were randomly redistributed among the twins and the degree of similarity was computed for the simulated findings. A total of 1,000 redistributions were performed for each finding, and the degree of similarity actually found was compared to the empirical distribution of scores from the simulations. The P-value represents the probability of getting as many or more matches randomly as the number actually observed among the twins.

Partial correlation coefficients were computed for the disc height measurements of the co-twins, adjusting for the effects of age. The disc height measurements were further examined by an analysis of variance model that controlled for the effects of spinal level, age, and smoking status, and examined the remaining variability in disc height explained by "twinship."

Results

Similarities can be readily appreciated in the lumbar MRIs of identical twins. For example, there are apparent similarities in the overall size and shape of the spines (Figure 1), as well as in some degeneration patterns and endplate irregularities (Figures 2-3). However, visual inspection showed clear differences in the MRIs of some twin pairs. Yet, as in the case of one pair, despite differences in the extent of degenerative changes, there were marked similarities in vertebral body marrow changes.

Evaluation of the lumbar MRI revealed only five Schmorl's nodes among the subjects, and none appeared at the same level in a co-twin. Thus, there were no matches. Although it was more common not to have matching assessments between co-twins, in the case of other endplate changes such as disc desiccation scores, disc bulging and herniation, and disc height narrowing, we found excessive number of matches beyond that expected by chance ($P<0.03$ in all cases). For example, in 33 instances the disc desiccation scores found in one twin were not present in his co-twin. In 30 instances similar scores were found in both twins. The probability of getting 30 or more matches randomly is $P=0.0001$.

Co-twins were highly correlated with respect to disc width (age adjusted $r=0.84$-0.92), whereas simple disc height measurements correlated to a lesser degree (age adjusted, $r=0.53$-0.67). Even after controlling for the effects of age, spinal level, and smoking status, a high degree of similarity in disc height measurements between co-twins remained ($P<0.0001$). The amount of variability explained by twinship was of a similar magnitude as that explained by spinal level.

Discussion

The pathogenesis of degenerative changes and other anomalies of the spine is probably rarely purely genetic or environmental, but rather the effect of environmental forces acting on structures whose strength is partially genetically predetermined.

When viewing images of the lumbar spines of identical twins, one is struck by the high degree of similarities in size and configuration of the structures. However, a systematic review suggests that many degenerative changes or structural failures detected on MRI are primarily influenced by environmental factors.

There was no indication from the study findings that Schmorl's nodes (occurring in the same location), at least in the absence of Scheurman's kyphosis, are genetically predetermined. The incidence of these findings, however, was quite low and results need to be regarded cautiously. Environmental factors would appear to be the major determinants of other endplate changes, disc desiccation, and notable disc bulging and narrowing as assessed from MRI, as well. However, similarities in the occurrence of these findings between the co-twins went well beyond what would have been expected by chance occurrence alone.

Because identical twins are commonly concordant for many environmental factors, similarities in spinal morphology and degenerative changes cannot be attributed purely to genetic make-up. Thus, this study cannot rule out the possibility that the similarities revealed are due to similar environmental exposures of twins and the effects of age. Instead, a comparison of identical twins may provide an upper limit for the effects of genetic factors (or a lower limit for the effects of environmental factors).

In summary, degenerative changes appear to be primarily influenced by environmental factors, but the study findings suggest that genetic factors also may have a significant effect. In a larger ongoing study of identical twins we are investigating the influence of environmental exposures and "twinship" on determining degenerative changes of the lumbar spine.

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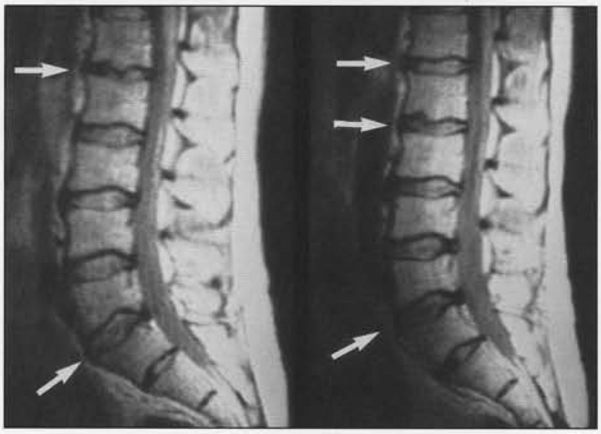

FIGURE 2: Arrows point to similar degenerative patterns and endplate irregularities in a pair of 44-year-old twins.

FIGURE 3: The spines of a pair of 40-year-old twins also have similar degenerative patterns.

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The Ageless Athlete

Carol C. Teitz, M.D.
Nancy A. Felix, M.S.

Photo by Geoff Manasse

As the population of the United States ages, interest increases in improving functional abilities and quality of life of older adults and lowering health care costs. Activity levels generally decline with age, but how much of this change is due to lifestyle and how much to the reduction of physiological capacity or the effects of disease is not well understood.

The effects of aging, disuse, and disease are not easily separated. However, taking into account changes in muscle and bone, proprioception, reaction time, and mental status, age appears to explain only about 25% of the noted declines in performance, while inactivity is responsible for the majority of functional loss.

Various population studies have shown a decrease in lean body mass, muscle strength, and aerobic capacity with age. More recent data suggest that VO_2 max can increase with training at any age, that there is no decrease in the metabolic potential of the muscle, and that continued aerobic exercise can prevent a loss of strength between ages 30 to 70. Age-related changes are not progressive, uniform, or irreversible and can be modified by exercise, nutrition, and hormonal therapy.

Because exercise is correlated with numerous health benefits and is often prescribed in the treatment of diseases, we need to understand factors limiting participation in exercise by older persons. Understanding motivation of older adults also is important for promoting physical activities in this population.

Along with the benefits of exercise comes the risk of related injuries. Few studies have described injuries in an active elderly population. This study was designed to answer three questions. First, what limits the amount of physical activity by older adults? Second, which factors are important in motivating older adults to be physically active? Third, what types of injuries do active older adults incur?

Subjects were drawn from members of the Seattle Jewish Community Center, including those who use the center for exercise activities and less active persons who use it mainly for social activities. A letter describing the study was sent to all members aged 55 or older (531), and 144 persons (27%) agreed to participate. Demographic information and body mass index (kg/m2) was collected from each participant. A questionnaire designed to assess activity levels, limiting and motivational factors, and history of injuries was administered by personal interview.

Subjects ranged in age from 55 to 93 with the majority aged 60 to 79. Sixty-seven were men and 77 were women. Sixty-nine percent were married, 22% widowed, and 9% divorced. Fifteen percent were employed full time, 24% part time, and 60% were not working.

Ninety percent participated in at least one light activity, with walking and calisthenics reported most frequently. Moderate activities such as swimming and water aerobics were reported by 56%. Only 19% of the study group reported participating in heavy activities such as aerobic dance or handball (Table).

Fifty percent of subjects reported decreased activity over the past 10 years. Musculoskeletal disorders were the most frequently reported reason for decreased activity. When subjects were asked what currently limited their amount of exercise, lack of time was cited most often. Musculoskeletal disorders and decreased stamina also were listed frequently. Chronic back pain and osteoarthritis, as well as previous back and knee injuries, were the most frequently reported and most limiting musculoskeletal problems.

Fifty participants reported a total of 67 injuries suffered prior to the previous year that affected current activity. Trauma caused the majority of injuries; 30% were fractures. The lower back and knee were the most common sites of injury. Seventy-nine percent reported medical diseases, which 15% ranked as important limiting factors. Seventy-one percent reported musculoskeletal disorders, and 26% ranked these as important limiting factors.

Twenty-five percent of subjects reported increased physical activities over the past 10 years. Increased time and health consciousness were the most common reasons for increased activity levels. When study participants were asked what currently motivated them to exercise, the responses most frequently cited were fitness, health maintenance, and enjoyment; the first two ranked as significantly more important than all other motivating factors. There were no significant differences in these factors as a function of sex, age, or activity level.

Nineteen percent of subjects sustained injuries during the previous year. The majority occurred during activities of daily living. Most were traumatic, with falls the primary cause. Eight percent had exercise-related injuries equally divided between traumatic and overuse injuries. Lower back and knee injuries were the most common.

Despite our attempt to study both inactive and active persons, a bias resulted in the self-selected study population in that most of the respondents were active. While we cannot generalize our findings to the inactive population, our study suggests that activity levels of most adults decrease with age.

Health care providers should remind older persons that exercise not only has a beneficial effect on various medical problems such as coronary heart disease, hypertension, adult-onset diabetes mellitus, colon cancer, and depression, but also decreases the incidence of falls, slows the progression of osteoporosis, and maintains mental status. In sum, exercise as one ages allows the maintenance of functional independence. Moreover, our study did not suggest an increased risk of injury from exercise in the population studied.

There are few data to indicate the incidence of risks to those who exercise regularly. Our data indicate that most of the injuries of independently living older adults occur during activities of daily living. Thus, we should remind older adults to be wary of environmental hazards and reassure them of the relative safety of exercise, especially light-intensity activities that might be expected to have low injury rates.

Knowing that musculoskeletal problems are one of two key factors limiting activity in this independently living population, we must examine etiologic factors for potential prevention strategies, and seek better ways of treatment including the role of rehabilitation in avoiding long-term disability. In the meantime, we need to design exercise programs that allow safe, pain-free activity despite extant musculoskeletal problems.

What is the ideal exercise prescription for the older adult? Any program must be tailored to the participant's age, fitness level, and overall health. Evaluation should take into account cardiopulmonary status, strength and flexibility, neuropathy and equilibrium, joint disease, and medications. Aerobic exercise involving large muscle groups is best.

For someone who has been sedentary, the exercise potential of daily activities such as walking to the store, gardening, and painting, should be used initially. Later the person can begin formal exercise sessions at 50% of maximal aerobic capacity, and strive for exercise at 60% of maximal oxygen uptake for 30 minutes/session.

Cardiorespiratory fitness will require four to five such sessions per week. Exercising below 50% of maximal aerobic capacity less than two days per week is inadequate for either developing or maintaining fitness. Many persons experience problems in the initial six weeks of an exercise program, so close supervision is recommended so that the person does not become discouraged and quit the program. Exercise prescriptions can be adapted for patients with physical limitations.

The challenge for the future is to better assess what factors prevent patients who are not currently active from initiating activity, and to assess the risks involved in initiating exercise programs in this population.

Supported by the University of Washington Department of Orthopaedics

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TABLE: Mean Activity Profile During a Two-Week Period

Activities	Percent Participating	Sessions	Minutes/ Session
Light	90		
Walk	70	7	38
Yardwork	35	4	82
Dance	12	1	78
Calisthenics/weights	49	9	22
Golf	8	4	213
Bowling	1	1	60
Other	3	3	133
Moderate	56		
Hike	10	4	112
Tennis	3	5	84
Bicycle	17	7	35
Swim/water aerobics	40	5	34
Heavy	19		
Run	6	6	18
Aerobic dance	12	3	44
Handball	1	6	60
Other	1	4	68
No activities	6		

Two Decades of Clinical Research at CHMC:

Improved Care for Children and Reduced Cost for Society

Lynn T. Staheli, M.D.

Flat feet, rotational deformity, bow-legs, and knock-knees are common developmental problems that occur in normal infants and children. Traditionally, these problems were thought to be permanent and to cause disability during adult life. They were commonly "treated" with shoe modifications, braces, and exercises during childhood.

The arch developed in the foot, intoeing and bowing resolved, and the "treatment" was credited with a "cure." The physician and parent were pleased, and shoe modifications became known as "corrective shoes." The need for corrective shoes, braces, and exercises became widely accepted as a necessary burden of childhood. Millions of children were treated without any proof that the "treatment" was responsible for the resolution.

This treatment was not without cost. The devices and physicians' visits were expensive and the interference in the child's life was significant. Stiff shoes were uncomfortable, embarrassing, and made running difficult for the child. Braces limited daytime play, and night splints disturbed the child's sleep.

One category of clinical research at CHMC during the past two decades has focused on developmental problems. This research has contributed to the reduction in unnecessary and ineffective interference in the child's life. These studies also have provided a basis for scientifically based, rational management plans for the common developmental problems of the lower extremities. This report summarizes the major studies performed at CHMC.

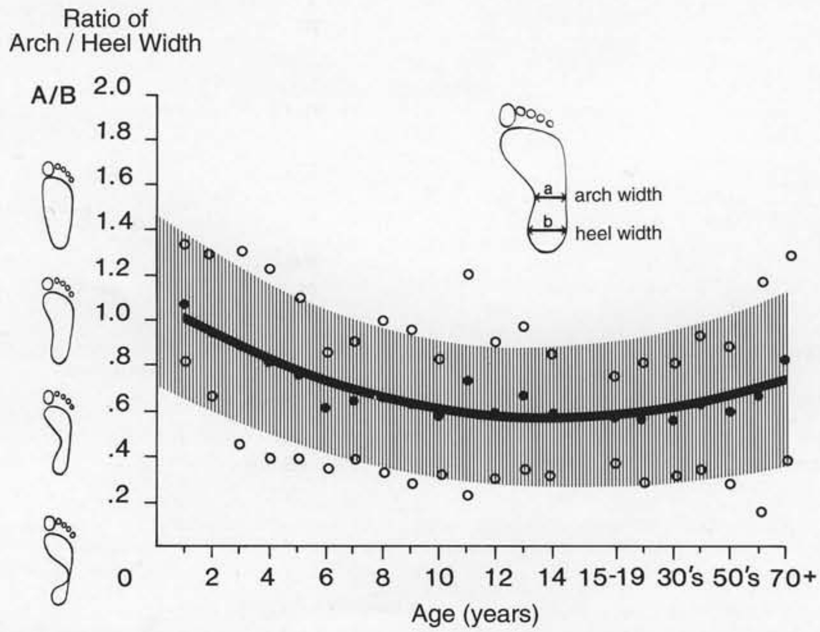

FIGURE 1: The longitudinal arch develops with growth in childhood. Note the wide range of normal. Flat feet fall within the normal range (shaded area ± 2 SD). (From Staheli, et al, 1987.)

Flat Feet

Traditionally, the height of the longitudinal arch concerned parents and physicians. Parents feared that their child would be flatfooted or have "fallen arches." To promote arch development, physicians prescribed stiff shoes, various arch supports, and shoe wedges or special heels.

The CHMC study (Figure 1) demonstrated that flat feet are simply a developmental stage, and that the longitudinal arch develops spontaneously in most children. The range of normal is very broad. Our studies demonstrated that nearly all infants, many children, and some adults are flatfooted. These clinical findings were confirmed by our radiographic study of the feet of normal children. This study showed that radiographic measures, often considered as diagnostic for flat feet, fell within the normal range. The development of the arch as previously attributed to "corrective shoes" was simply due to normal development.

Rotational Problems

Intoeing and outtoeing still concern parents and are a common reason to consult a physician. Formerly, these children were usually "treated" with a variety of shoe modifications, braces, or even by surgery. Normal value studies at CHMC showed that wide variability exists in the way infants and chil-dren walk (Figure 2), and that mild intoeing falls within the range of normal. These studies also showed that intoeing resolved spontaneously by lateral rotation of the tibia and femur. Millions of children were "treated" with various wedges applied to the sole of the shoes. We studied the effect of shoe wedges and found the degree of intoeing was un-affected by such treatment (Figure 3).

Intoeing due to medial femoral torsion often was corrected by rota-tional osteotomy. The indication for correction was based on the assump-tion that this torsional deformity would cause an inefficient gait in adulthood and eventual degenerative arthritis of the hip.

Our studies demonstrated that adults with medial femoral torsion functioned well, and that degenera-tive arthritis of the hip was not asso-ciated with medial femoral torsion. Furthermore, complications occurred in 15% of children undergoing opera-tive correction. We concluded that not only was the procedure usually unnecessary but also carried consid-erable risk.

These studies have dramatically reduced the number of operations performed for this problem. We have found that the vast majority of children who formerly would have had an osteotomy for correction show spontaneous resolution. Our indica-tions are very strict, and we perform the procedure only for the rare child with a persisting severe deformity that causes functional problems that show little improvement with time.

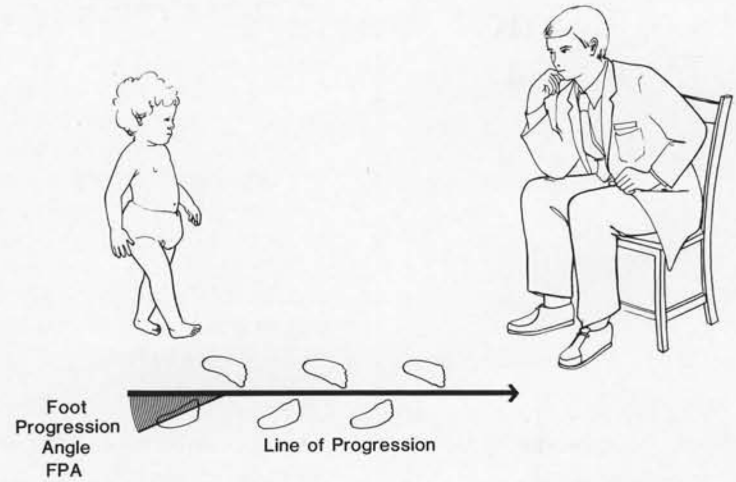

FIGURE 2A: The foot progression angle. The foot progression angle (FPA) is the average of the angles formed by the axis of the foot and the line of progression. (From Staheli, et al, 1987.)

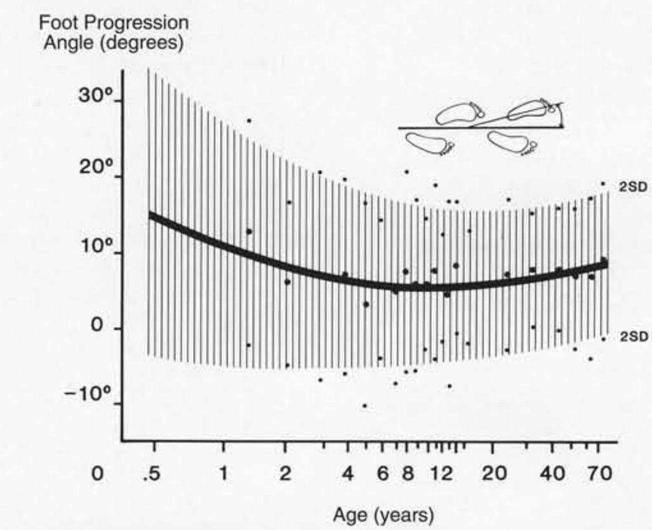

FIGURE 2B: Lower-extremity rotational problems in children. Normal values to guide management. (From Staheli, et al, 1985.)

Bow-Legs and Knock-Knees

Bow-legs often occur during late infancy and knock-knees during early childhood. This type of bowing is "physiologic" and usually resolves spontaneously. Bowing may be a family or a racial characteristic. The CHMC investigations included one of the earliest studies to show that bowing is a common development pattern in many children. The most recent CHMC study provided data to establish the extent of normal range (Figure 4). These data allow an assessment of the severity of the deformity and are useful in establish-ing a prognosis for resolution.

Shoe Design

Possibly the most important outcome of the clinical research at CHMC is its influence on shoe design for children. These studies and publications have contributed substantially to the improvement in children's shoe designs that have occurred during the last decade. Formerly, stiff shoes were consid-ered desirable based on the assump-tion that the child's foot needed "support" to develop optimally. Our study on arch development, and our review articles contributed to this change. It is now well estab-lished that the child's foot fares best when allowed to move freely, with-out shoes or in flexible shoeware that simulates the unshod state. This work is important as it affects nearly every child. Freeing the child from the stiff shoe makes childhood a more pleasant time. Furthermore, flexible shoes are usually less expensive for the family.

Summary

The clinical research and publi-cations from CHMC over the past two decades have improved the quality of life for children. These studies have provided a scientific

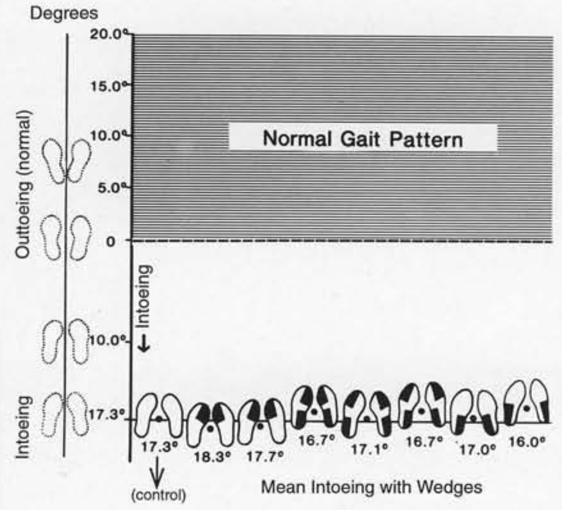

FIGURE 3: This study demonstrates the ineffectiveness of shoe wedges in changing the foot-progression angle. Various wedges were placed. Mean values for intoeing for each wedge are shown compared with the unwedged controls (100 measures in 10 children). (From Knittel and Staheli, 1976.)

basis for managing flat feet, intoeing, and lower limb bowing. These conditions are generally only variations of normal and in the vast majority, resolve spontaneously. Our studies found that traditional treatment for these conditions was both unnecessary and ineffective.

These studies have challenged the myth of the "corrective shoe." The CHMC research prompted the shoe industry to change shoe designs from stiff "supportive" shoes to flexible "physiologic" shoes. These flexible shoes have become the standard for children's shoe construction. The "barefoot" model that guides shoe construction and selection is now accepted.

The clinical research at CHMC has contributed to reduced costs in managing positional variations. These changes have probably saved millions of dollars in medical costs by reducing the use of special shoes, braces, office visits, and operative procedures for millions of children. This inexpensive clinical research has been extraordinarily "cost-effective" and has benefited society both medically and financially.

Supported by Children's Hospital and Medical Center and the University of Washington Department of Orthopaedics

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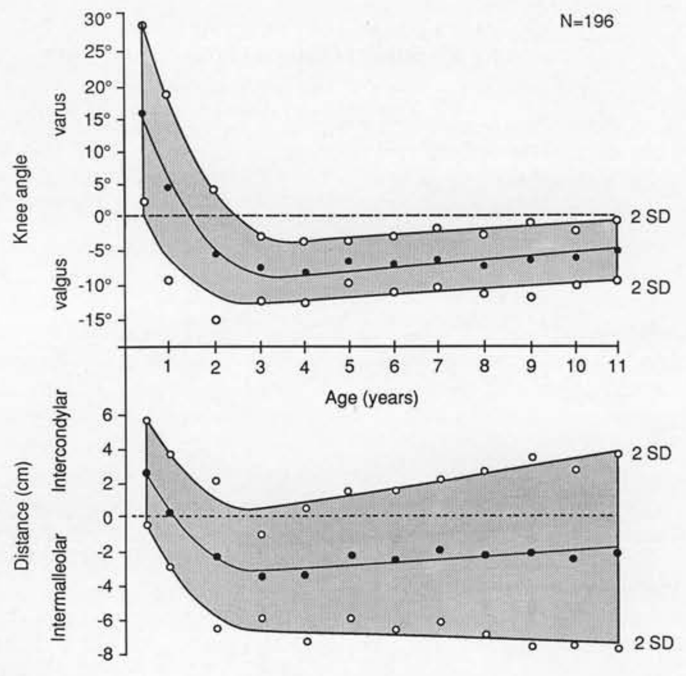

FIGURE 4: Normal values for knee angle. The normal values for the knee angle are shown both in degrees (upper) and intracondylar or intramalleolar distances (lower). (From Heath and Staheli, 2993.)

Chief Resident Abstracts

Displaced Intra-Articular Fractures of the Distal Radius

Susan R. Schmitt, M.D.
Thomas E. Trumble, M.D.
Nicholas B. Vedder, M.D.

Open reduction and internal fixation are often required in comminuted, displaced intra-articular fractures of the distal radius when closed manipulation has failed to restore articular congruity. Our retrospective study of 49 patients reviewed results of surgical stabilization and articular reconstruction of 52 displaced, intra-articular distal radius fractures.

Forty-three patients with a mean age of 37 years (range of 17-79 years) were available for evaluation. The mean follow-up time was 29 months (range 13-60 months). Acccording to the system proposed by the Association for the Study of Internal Fixation, 23 were rated ASIF type C2 and 21 were type C3. We devised an injury score system based on the initial injury radiographs to classify severely comminuted intra-articular fractures and to identify those associated with carpal injury (3 patients).

Fracture alignment, articular congruency, and radial length significantly improved following surgery (P<.01). Grip strength averaged 69% (± 22%) of the contralateral side and the range of motion averaged 75% (± 18%) of the contralateral side postoperatively. A combined outcome rating system that included grip strength, range of motion, and pain relief averaged 76% (± 19%) of the contralateral side. There was a statistically significant decrease in the combined rating with more severe fracture patterns as defined by the ASIF system (P<.01), Malone classification (P<.03), and the Injury Score System (P<.001). The latter system, in particular the number of fracture fragments, correlated most closely with outcome.

Operative reconstruction and correction of alignment of the articular surfaces of the distal radius with internal and/or external fixation, can significantly improve the radiographic alignment and functional outcome. Furthermore, the degree to which surgery improves articular step-off, gap between fragments, and radial shortening is strongly correlated with improved outcome. These results were corrected for severity of initial injury. Correction of radial or dorsal tilt did not correlate with improved outcome.

Autogenous Nerve Grafting for Lower Extremity Nerve Injuries

Eric Vanderhooft, M.D.
Thomas E. Trumble, M.D.

Fourteen consecutive patients who had sural nerve grafts to reconstruct the sciatic or peroneal nerves were evaluated retrospectively to assess functional reinnervation. All had at least two years of follow-up.

The patients ranged from 8 to 63 years old (mean age, 20 years). Eight patients had peroneal nerve injuries and six had sciatic nerve injuries. The mechanisms of injury included gunshot wounds, crush injuries, and lacerations. The average time from injury to grafting was 59 days (range 16-192 days) and the average length of the nerve grafts employed was 5.8 cm ± 2.5 cm.

We used a standardized functional evaluation to assess motor and sensory return of the injured compared to the contralateral side. Dorsiflexion and plantar flexion strength were measured to determine the recovery of muscle strength, which was recorded as a percentage of the strength of the contralateral extremity and by assigning a motor grade. Sensory recovery was monitored by evaluating the sensory grade, two-point discrimination, and response to Semmes-Weinstein monofilaments.

Thirteen of 14 patients regained protective sensation and five (36%) regained useful motor function, defined as M3 or M4 that corresponded to dorsiflexion strength 21% of the contralateral side. Four of the latter were pediatric patients.

Variables that may have affected functional recovery following nerve reconstruction were patient age, specific nerve injured, mechanism of injury, length of graft, and delay to grafting. Sensory function was essentially equivalent in all patients except the one with no protective sensation. This patient required the longest graft (11 cm) and had the longest delay to surgery (192 days).

Patients with peroneal nerve injuries had a better recovery of motor grade [2.4 ± 1.2 versus 1.0 ± 1.0 (p<0.05)] and percentage of strength return [14% versus 0.8% (p< 0.04)] than did patients with sciatic nerve injuries, which may reflect the longer distance necessary for nerve regeneration to reach target tissues. However, those with sciatic nerve injuries also required longer grafts [7.5 ± 2.9 cm versus 4.5 ± 1.3 cm (p< 0.02)] and had a greater time delay to grafting [85.7 ± 54 days versus 31.3 ± 16 days (p<0.02)] compared to those with peroneal nerve injuries. It is likely that length of graft used and delay to grafting contributed to the poorer results seen with the sciatic nerve injuries as both of these factors were inversely correlated with percentage of strength return. Age was not correlated with functional outcome.

The success rate of 36% compares favorably to reports of adults with similar injuries, but is lower than the results with upper extremity nerve grafting. However, the possibility that 44% of children may have a functional recovery and avoid permanent brace wear clearly suggests the value of nerve grafting. Furthermore, the patients regained protective sensation and none had causalgia that further decreased function.

We believe that these factors combined with the 36% possibility for a successful functional recovery indicates that sural nerve grafting for segmental loss of lower extremity nerves is a viable treatment option when end-to-end nerve repair is not possible.

Cartilage-Containing Osteosarcoma

Lyle S. Sorenson, M.D.
Ernest U. Conrad III, M.D.

Osteogenic sarcoma constitutes about 20% of all primary malignant bone tumors. The incidence of conventional osteosarcoma in the United States is approximately 1.7 cases per million per year — 600 to 900 new cases annually. With improved adjuvant and neoadjuvant chemotherapy, the overall five-year survival rate has improved from around 50% to 70-80%. Despite these advances, approximately 20-30% of patients have a worse clinical course with standard treatment.

Important variables related to aggressiveness of tumor behavior include location of primary lesion, size, local control of tumor, histologic grade, and histologic response to chemotherapy. Missing from this list are significant early biological markers such as histologic type, cell surface markers, and intracellular and extracellular matrix products, which might be important to modifying treatment in the early phase of tumor growth and diagnosis. There are few early predictors that can identify the significant proportion of osteosarcoma patients (20-30%) who respond poorly to current therapy.

Recent literature suggests a correlation between tumor histology and/or tumor protein products in patients who respond poorly to chemotherapy and have low survivability. These reports have not been substantiated and have not adequately defined the poor responder group. We hypothesized that patients with cartilage-containing or chondroblastic osteosarcoma have a poorer clinical course than other conventional types.

Preliminary retrospective data from patients' records show that eight of 31 patients (26%) treated at Children's Hospital in Seattle for stage IIB conventional osteosarcoma have significant cartilage-containing lesions. This group has responded poorly to chemotherapy.

According to pathology reports of the excised tumors, the noncartilage tumors (data available for 17 of 23 patients) showed a mean necrosis of 55% (range 10 to 100%). Data were available for six of the eight patients with cartilage-containing lesions, and showed a mean 44% necrosis (range 0 to 90%). These data show a trend, although it is not statistically significant. We will continue to follow this subset of tumors to evaulate the response to current therapy.

Oxygen Free Radicals in Fracture Healing

Philip J. Kregor, M.D.
Peter Simonian, M.D.
Steve Bain, Ph.D., et al.

Much research has focused on the mechanism of fracture healing and the roles of vascular ingrowth, growth factors, and mesenchymal cell differentiation in determining fracture callus quality and strength. A better understanding of these phenomena may lead to mechanical, electrical, or pharmacological techniques to improve fracture healing and decrease nonunions and delayed unions.

One of the most highly studied areas has been vascular reorganization during fracture healing. Avascular fragments and fracture ends are revitalized via creeping substitution. This neovascularization peaks in the first few weeks and may be regarded as reperfusion of a relatively ischemic area. Interestingly, it is becoming increasingly evident in other tissues that irreversible damage is not so extensive during the ischemic period itself, but occurs during reperfusion.

Reperfusion heralds the production of oxygen free radicals — highly reactive, unstable oxygen metabolites that damage cellular membranes, endothelium, and connective tissue matrix. Oxygen free radical scavengers, specifically superoxide dismutase (SOD), improve osteoblast/osteocyte survival in reperfused ischemic bone, and dramatically decrease bone resorption seen in association with free radical production.

We hypothesized that oxygen free radical scavengers can attenuate ischemia/reperfusion injury at a fracture site, which will, in turn, improve the rate and quality of healing. We tested this hypothesis in rats treated with saline or two different doses of superoxide dismutase-polyethylene glycol (SOD-PEG). Twenty-three rats survived anesthesia, retrograde intramedullary K-wire fixation, and production of a closed femoral midshaft fracture. They were divided into three groups: (1) saline, (2) 100 units SOD/cc plasma, (3) 300 units SOD/cc plasma. Solutions were injected intraperitoneally every three days.

Rats were sacrificed on day 33, and their femora explanted. Microradiographs were obtained and fractures were blindly graded for signs of healing. Femora were frozen and later thawed for blinded torsional tests on a servohydraulic machine.

No significant differences were seen between the two SOD groups. Results of biomechanical testing of femoral fracture stiffness showed that differences between the saline and SOD groups were not statistically significant when compared separately ($p=0.08$ and 0.14). If both SOD-PEG groups are combined ($n=15$) and compared with the saline group ($n=7$), the difference is statistically significant ($p=0.02$). Femoral torque exhibited similar trends. Radiographic grading yielded no differences among the three groups.

Treatment with free radical scavengers was associated with decreased femoral fracture strength. These results contradict our hypothesis that oxygen free radicals are detrimental to fracture healing and indirectly demonstrate that they may be beneficial. Furthermore, oxygen free radical scavengers may retard or decrease the quality of fracture healing. This finding is not entirely surprising, as high levels of oxygen free radicals are known to stunt the proliferation of fibroblasts in culture, while low levels enhance their proliferation.

A quantitative histologic analysis of these fracture calluses as well as biochemical analysis may provide more insight into the role of oxygen free radicals in fracture healing.

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