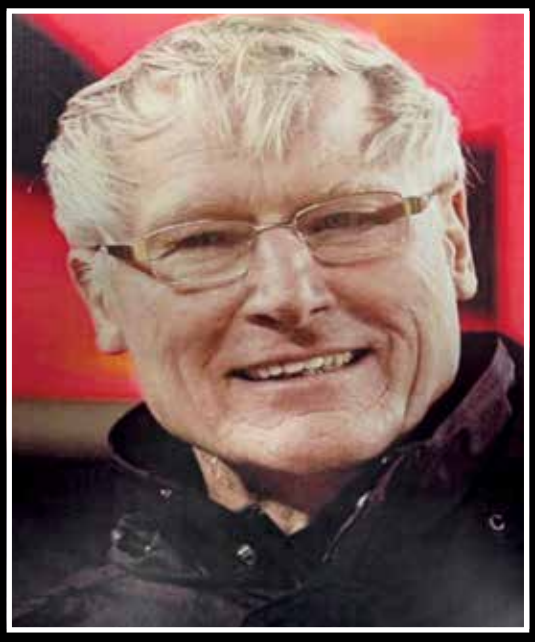
Temple University Journal of Orthopaedic Surgery & Sports Medicine



Ray Moyer, MD

Volume 9 Spring 2014

A John Lachman Society Publication

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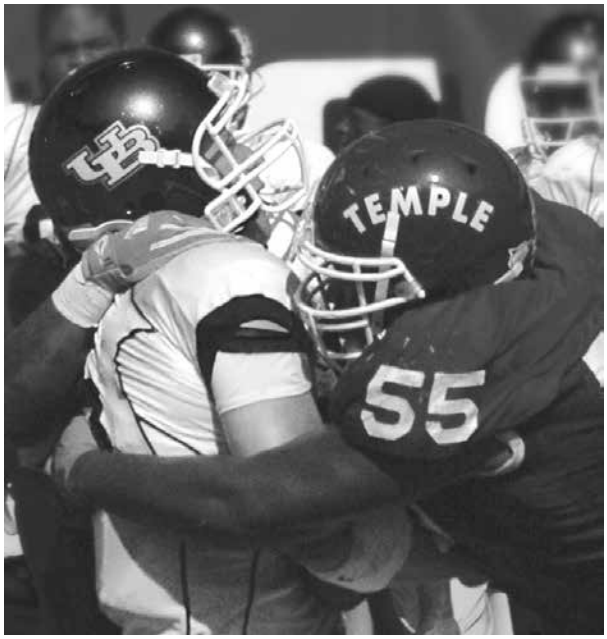
The Temple University Concussion and Athletic Neurotrauma Program

Cerebral concussion, traumatic brain injury, transient spinal cord paralysis and brachial plexus injuries are potentially serious insults to the nervous system that are associated with contact athletic injuries. In accord with the principle that the management and return-to-play decisions should only be made by a qualified professional, Temple University has established its **Concussion and Athletic Neurotrauma Program.**

Temple's experienced, multidisciplinary faculty is well-suited to evaluate and manage athletic-induced neurotrauma, utilizing the latest imaging capabilities, neurocognitive **ImPACT™** testing and clinically established **return-to-play** protocols.

Utilizing the facilities of Temple University Hospital, Temple Orthopaedics & Sports Medicine satellite offices, Temple Medical School faculty and in concert with the Shriners Hospitals for Children in Philadelphia, this program is designed to provide the necessary experience to meet the needs of team and family physicians, athletic trainers, athletic administrators, coaches, parents and, most importantly — the athletes.



Proper tackling technique protects both head and cervical spine.

Research Goals

Current understanding of cerebral concussion and athletic-induced traumatic brain injury is limited to a variety of descriptive classifications and epidemiologic patterns. Lacking is an application of the known underlying pathophysiology to clinical management practice with particular regard to injury prevention. Clearly, much is not known and there are many questions to be answered regarding athletically-induced neurotrauma. The goal of this program is to bring this issue to the same meaningful conclusion that Temple physicians achieved with paralytic spinal cord injuries 35 years ago.

Temple University Hospital

Clinical Program

Athletes sustaining impact injuries and experiencing any of the following signs or symptoms should be evaluated and, if indicated, managed by a physician experienced with athletic injuries to the head, spine and brachial plexus:

Central Nervous System

- Loss of consciousness
- Confusion
- Dazed appearance
- Forgetfulness
- Unsteady movements
- Slow cognition
- Personality changes
- Retrograde/antegrade amnesia
- Headache
- Dizziness
- Nausea or vomiting
- Altered sense of well-being

Spinal Cord

- Four extremity paresthesias (numbness)
- Four extremity weakness
- Four extremity transient paralysis

Brachial Plexus

- "Stinger" lasting more than 20 minutes
- "Stinger" with persistent weakness
- Recurrent "stingers"

The neurotrauma team consists of orthopaedic sports medicine specialists, neurologists, neurosurgeons, neurophysiologists, physiatrists and biostatisticians.

ATHLETES REQUIRING EVALUATION AND/OR MANAGEMENT CAN BE SEEN AT TWO OF TEMPLE'S CLINICAL SITES:

Temple University Hospital

3509 N. Broad Street
5th Floor Boyer Pavilion
Philadelphia, PA 19140
215-707-2111

Temple Orthopaedics & Sports Medicine Satellite Office

414 Commerce Drive
Fort Washington, PA 19034
215-641-0700

E-mail us at: concussion@tuhs.temple.edu
Website: www.templeconcussion.com

Temple Orthopaedics & Sports Medicine

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Letter from the Editor-in-Chief

Welcome! It is with great enthusiasm that I introduce this year's edition of the *Temple University Journal of Orthopaedic Surgery & Sports Medicine,* Volume 9. The goal of the Editorial Staff was to compile a representative collection of our Department's academic prowess; we believe the commentaries, review articles, and original research will provide you with a diverse and contemporary window of academic Orthopaedic Surgery at Temple University.

Temple University had the privilege of the podium and the poster board at several major national meetings including the American Academy of Orthopaedic Surgeons, American Society for Surgery of the Hand, Orthopaedic Trauma Association, American Association for Hand Surgery, and the Orthopaedic Research Society. Furthermore, we were honored with two national awards this year: the "Julian M. Bruner Award for Best Poster at the ASSH" and a "Top Poster" recognition at the AAOS meeting, which was highlighted at a special guided tour session.

In addition, we have striven to rise as stewards of our body of knowledge and drivers of the research field, as we have been featured in several peer reviewed publications such as the *Journal of the American Academy of Orthopaedic Surgeons, Journal of Hand Surgery, American Journal of Medicine, Journal of Pediatric Orthopaedics, Orthopedic Clinics of North America, Orthopedics, Canadian Association of Radiologists Journal, American Journal of Orthopedics, Spine, Neurosurgery Clinics of North America, European Spine Journal, Surgical Technology International,* and *Knee Surgery, Sports Traumatology, and Arthroscopy.*

I am excited to dedicate this issue to one of the most iconic figures in Temple Ortho history, Ray Moyer. I would also like to extend a heartfelt thank you to the John Lachman Society, who have funded many (if not all) of the endeavors herein. I would also thank my associate editors, Scott Barbash, Colin Mansfield, Arianna Trionfo, Will Smith, and John Jennings, and my faculty advisors, Joe Torg and Saqib Rehman, for their hard work in making this issue come to fruition. Personally, I thank my mentor, Joseph Thoder, for fostering a strong and balanced educational environment that has allowed me and countless surgeon trainees to grow beyond our imaginations; your enduring commitment to Temple's surgeon education shines as the consummate example of integrity, loyalty, perspicacity, and technical giftedness.

Rick Tosti, MD
Editor-in-Chief
Class of 2015

Letter from the Chairman and Residency Director

Joseph J. Thoder, MD
John W. Lachman Professor
Chairman, Department of Orthopaedic Surgery and Sports Medicine

J. Milo Sewards, MD
Assistant Professor
Residency Director

This journal carries on as a source of significant pride within our department, as it has effectively shown the substantial improvements in our research endeavor over the last several years. We would like to recognize and thank this year's editor-in-chief, Rick Tosti, as well as our resident editors, Scott Barbash, Colin Mansfield, Arianna Trionfo, Will Smith, and John Jennings, and our faculty editors, Joe Torg and Saqib Rehman. Pekka Mooar and Joanne Donnelly also deserve recognition for their stewardship of the summer research program, which has produced several articles in this and previous journals.

As reported each year, interest in the Residency Program grows. This past year, we received over 750 applications for our four PGY-1 positions. This year, we introduced a simulation curriculum to the intern's education. As in many other departments around the country, this is a work in progress, and we expect to continue to add learning modules over the next several years. All of your contributions to the Lachman Society are very much appreciated, as we expect to be requesting grants from the society to support these teaching efforts.

Thanks to all of our colleagues on the faculty at Temple, as well as our affiliate institutions and the supporting members of the John Lachman Society. We continue to have the privilege of leading a strong residency program that improves each year. It remains a distinctive honor for all of us to have graduated from or to have been affiliated in some way with the Temple Orthopaedic Surgery residency program.

Message from the John Lachman Society

The John Lachman Society was founded in 2004 to honor Dr. Lachman and propagate his principles of integrity, teaching, and excellent patient care. The Society also provides discretionary funds for the Chairman to promote and support the academic mission of the Department including student and resident research. The mechanism to accomplish these goals is through the Society's support of the John Lachman Orthopedic Research Fund (JLORF), incorporated in Pennsylvania as a non-profit corporation. The Internal Revenue Service has determined that the John Lachman Orthopedic Research Fund is exempt from federal income tax under 501 (C) (3) of the Internal Revenue Code and that contributions to the fund are tax deductible.

Those interested in membership in the John Lachman Society should contact the Chairman of the Membership Committee, Philip Alburger, MD or Milo Sewards, MD, c/o The John Lachman Society, P.O. Box 7283, Wayne, PA 19087.

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In keeping with the request of the Director at the annual meeting of the board of directors of the John Lachman Orthopedic Research Fund, the following officers were re-elected for a one-year term:

President: J. Milo Sewards, MD
First Vice President: Phil Alburger, MD
Second Vice President: Eric Lebby, MD
Treasurer: Albie Weiss, MD
Secretary: Joe Torg, MD

The summer medical school intern program continues to be a most successful program. This past summer, 12 sophomore medical students participated in the program. In addition to a number of the students producing manuscripts suitable for publication in the *Journal,* it became evident that the major value of this program is that in view of the curriculum changes no longer requiring students to rotate through orthopedics, those students interested have an opportunity to interface with our department. Clearly, this has become a major avenue of acquainting students to the residency program.

Once again, the John Lachman Society published and distributed the *Temple University Journal of Orthopaedic Surgery & Sports Medicine,* Volume 8. Eighteen hundred copies of the *Journal* have been distributed as follows: a) active faculty of the Temple University School of Medicine, b) orthopedic surgeons who are alumni of Temple University School of Medicine, c) members of the John Lachman Society, d) department chairman and residency directors of all orthopedic programs throughout the United States, and e) fellowship directors to all orthopedic programs throughout the United States.

Academic support for resident travel to meetings by the John Lachman Orthopedic Research Fund during the period January 1, 2013 through December 31, 2013, involved 10 residents who have attended either formal courses or national meetings.

The Ninth Annual John Lachman Lecture was presented by Vasilios (Bill) Kalogredis, Esq. at the annual meeting of the Pennsylvania Orthopaedic Society this past fall which was held at State College. Speaking on "The Orthopedic Survival Guide for Obamacare," the talk was riveting, relevant, and engaging, giving all a good opportunity to anticipate what the future holds for orthopedic surgeons.

The John Lachman Society web page can be entered at www.johnlachmansociety.org.

In keeping with the request of the director of the residency program, the John Lachman Orthopedic Research Fund is committed to a $2,500 year expenditure for texts and other educational materials.

The John Lachman Society, through the John Lachman Orthopedic Research Fund and working in close cooperation with the Temple-Shriners' Alumni group, continues its mission to support and enhance both the academic program of the department and the orthopedic residency program.

Joe Torg, MD
Secretary

Letter from the Office of Clinical Trials

The Office of Clinical Trials and Research Support was established in 2004, under the direction of Pekka A. Mooar, MD and supported by the School of Medicine's Office of Clinical Research Administration, with Ms. Joanne Donnelly as the full-time research and program coordinator.

The research journey continues into its 10th year and is going strong, continuing the mission set forth to maintain a variety of industry-sponsored clinical trials for any attending interested in clinical research as well as individual projects.

The summer research program continues to be a hit with Temple medical students taking part in an eight-week summer course designed to provide the basic foundation of clinical research. This program is mentored by Dr. Torg and me, and we look forward to another good year of research projects. Students are provided with a morning orientation session consisting of instruction from the Temple Research Library staff, who teach the best ways to search and store topics. The students also learn to use a cloud application that puts the citations in AP format. Also, the students are given a presentation on the basic statistical applications to be used for data analysis on their respective project. Group meetings occur each Tuesday and Wednesday mornings where progress is assessed and weekly assignments are turned in. Each student has the opportunity to attend cases in the operating room, see patients at office hours, and work closely with their project mentor and resident. This close-up introduction to Orthopaedics is an excellent way to see the many aspects of the field.

I am delighted to report that we have 12 Temple Medical Students who have signed up to participate this summer. *(At the time of this report, not all of the projects have been assigned.*)*

2013 Summer Medical Student Research Projects:

See Journal under "Medical Student Research Projects"

2014 Summer Medical Student Research Projects*:

- Predictors of Re-Admission after Total Joint Surgery
- Comparison of Physician Attire and How It Equates with Patient Perception of Physician
- What Is the Fate of Below Knee DVT in Trauma and Total Joints? To Treat or Not Treat and Does a Risk Stratification Tool Guide the Treatment Decision?
- Incidence of Symptomatic DVT and PE in Lower Extremity Fractures Below the Knee: Comparing Lovenox, Aspirin or Nothing
- Use of Tranexamic Acid in the Trauma Patient
- Cost of Orthopaedic Surgical Equipment: Does the Orthopaedic Surgeon Know the Cost of the Implants He/She Uses?
- Does CAM Morphology Predict Hip Pain After Antegrade IM Nailing of Femoral Shaft and Peritrochanteric Hip Fractures?
- TDP-43 Proteinopathy and Motor Neuron Disease in Chronic Traumatic Encephalopathy
- Division I Intercollegiate Football Program Success as Predicted by Geographic Locations and NFL Competition
- Financing Orthopaedic Graduate Medical Education: The Role of Non-Profits in the Development of Extramural Funding
- Parameters for Baseline Testing of Ocular and Vestibular Function: The Effects of Post-Concussion Test Randomization in Dynamic Visual Acuity Results: A Final Report
- Performance Enhancing Drugs and Morality

Current Industry-Sponsored Clinical Trials Drug or Device:

Stryker
(INSITE) Intramedullary Nail Versus Sliding Hip Screw Intertrochanteric Evaluation: A Multi-Center Randomized Controlled Trial of Intramedullary Nail Versus Sliding Hip Screw in the Management of Intertrochanteric Fractures of the Hip
Saqib Rehman, MD, Principal Investigator; Bruce Vanett, MD, Sub-Investigator; Christopher Haydel, MD, Sub-Investigator, Phase IV Device. Ongoing enrollment — 16 subjects.

EMSI
The Electrostim Medical Services, Inc. (EMSI) Bone Growth Stimulator (BGS) Clinical Study for the Treatment of Long Bone Fractures Acquired Secondary to Trauma Where Serial Radiographs Taken at Least 90 Days Apart Have Shown No Visible Progressive Signs of Healing
Pekka Mooar, MD, Principal Investigator, Phase IV Device. Enrollment beginning April 2014.

Department of Defense
Assessment of Severe Extremity Wound Bioburden at the Time of Definitive Wound Closure or Coverage: Correlation with Subsequent Post-Closure Deep Wound Infection (Bioburden Study)
Saqib Rehman, MD, Principal Investigator; Christopher Haydel, MD, Sub-Investigator. Prospective cohort observational study. Ongoing enrollment — 3 subjects.

AESCULAP
A Phase 3, Prospective, Randomized, Partially Blinded Multi-Center Study to Measure the Safety and Efficacy of Novocart® 3D, Compared to Microfracture in the Treatment of Articular Cartilage Defects
J. Milo Sewards, MD, Principal Investigator; Pekka A. Mooar, Sub-Investigator; Eric Kropf, MD, Sub-Investigator. Enrollment to begin April 2014.

Current Investigator and Resident Initiated Studies Coordinated by the Office:

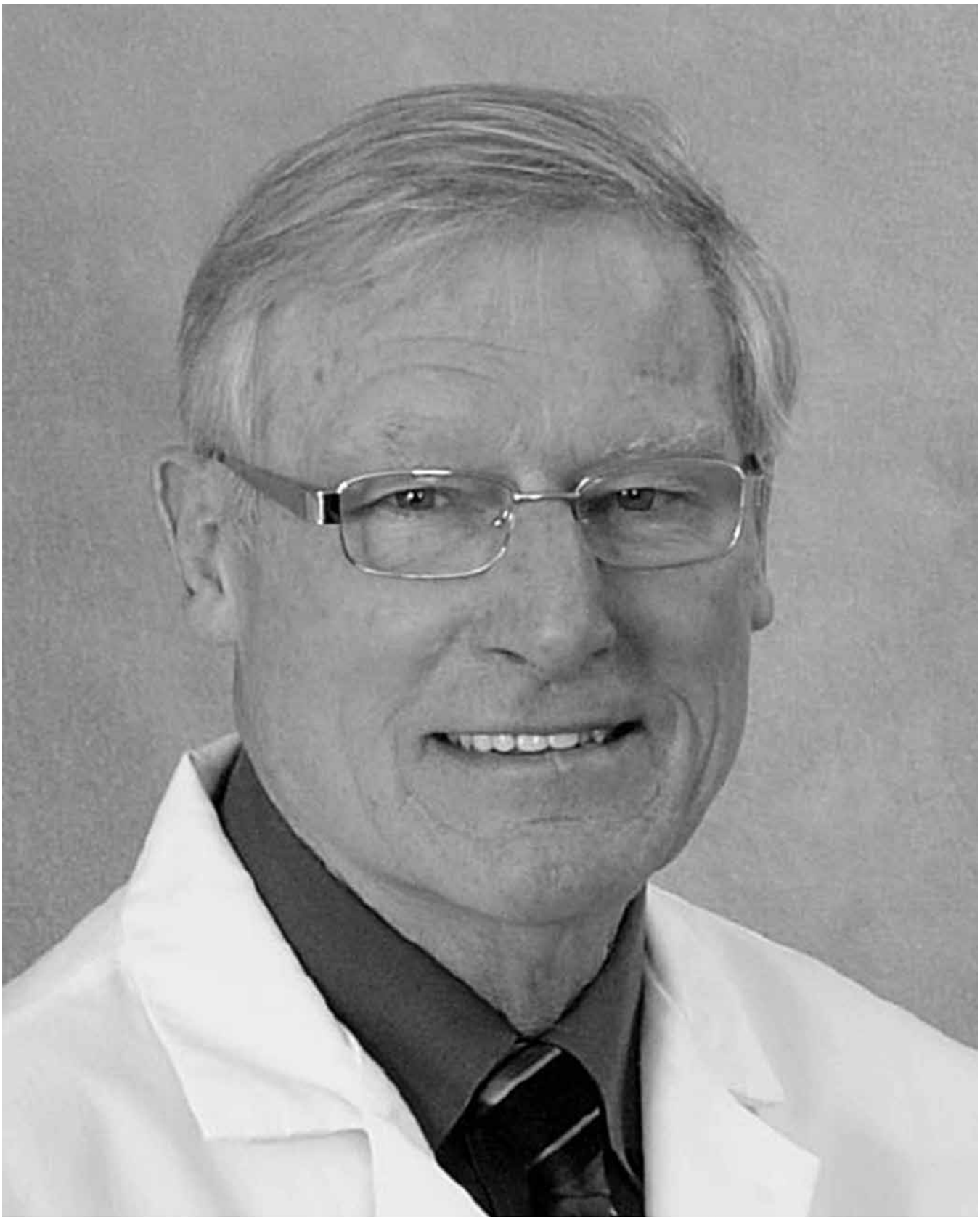
Does CAM Morphology Predict Hip Pain After Antegrade IM Nailing of Femoral Shaft and Peritrochanteric Hip Fractures
Eric Kropf, MD, Principal Investigator (IRB Approval #21651 Expedited Category)

Immediate Functional Bracing Versus Coaptation Splinting for Closed Diaphyseal Fractures of the Humerus. *In Process.*
Christopher Haydel, MD, Principal Investigator; John Jennings, MD, PGY-1

Septic Arthritis of the Wrist
Alyssa Schaffer, MD, Principal Investigator; John Jennings, MD, PGY-1

Comparing How the Attire of the Physician Equates to the Perception of the Physician by the Patient
Christopher Haydel, MD, Principal Investigator; Kasey Komperda, MD, PGY-3

Joanne Donnelly



Ray Moyer, MD
Director of Sports Medicine and Team Physician, 1978–2013

Dedication

Ray Moyer, MD

JOSEPH TORG, MD

Team physician par excellence, role model for the ages, and possessed with an impeccable integrity and an unassuming demeanor, clearly Ray Moyer is an exceptional human being. And, regarding a major personality trait, decisiveness is not one of his short comings.

A graduate of Lafayette College and the University of Pennsylvania School of Medicine, he interned at the University of Vermont Medical Center prior to serving three years in the United States Navy as a combat flight surgeon. He then completed an orthopedic residency at Temple University Hospital and subsequently joined the faculty at Temple in 1978. Of note, he was named the Howard Steel Professor of Orthopedic Surgery in 1996.

J. Milo Sewards, Joe Paterno, and Ray Moyer at the Temple vs Penn State game.

Having served in the capacity of the Director of Sports Medicine and Team Physician from 1978–2013 where he managed a vast variety of athletic-related health problems, he is without a doubt today the most experienced sports medicine practitioner in the United States if not the planet! And when the game is on the line, it is his experience that counts and carries the day. Classic example: Prior to a recent game, an offensive starting running back developed signs and symptoms of an acute abdomen. Rather than getting a second opinion and an elaborate diagnostic workup that would have precluded the player from participating in the game, Moyer simply infused two liters of saline IV. The cramps are gone, the player plays, and Temple wins. Thus, he advocates and supports the "captain of the ship" and "too many chiefs spoil the broth" concepts which are at odds with the medical management by committee concept that is prevalent today. Moyer also relates an interface with the University of Alabama medical support staff prior to a game at Franklin Field several years ago that consisted of seven individuals, two orthopaedic surgeons, a general surgeon, an internist, a dentist and a podiatrist. Representing Temple was simply Ray Moyer and his wife Page, an experienced registered nurse and side line activist. Unfortunately, however, Temple lost the game but not to the Alabama medical overload.

Ray Moyer has served as Temple University's team physician since 1978, a 35-year tenure during which the only games he missed were those played on his wedding day and when his son was varsity quarterback in college. Clearly, he represents the longest tenure of any division I team physician in the country and I submit, on the basis of firsthand knowledge, his diagnostic acumen and management capabilities are unequaled. Impeccably honest, extraordinarily dedicated, he is clearly a giant among his peers. And to be noted, Ray Moyer is revered by former temple coaches Wayne Harden, Bruce Arians, Al Golden, John Chaney, Steve Adizzio and Fred Turoff, to mention a few. And it was John Chaney who recommended and insisted that Ray be included in the Temple University Athletic Hall of Fame.

In keeping with the phenomena that "no good deeds go unpunished," this past fall Ray was confronted by the newly appointed athletic director who subscribed to the concept of full-time training room physician coverage; that is, an orthopedic surgeon in the morning and general sports medicine practitioner in the afternoon, in addition to game and practice coverage. Accordingly, this is the way it is done at the University of Indiana, a school noticeably void of a successful football program. And the implementation of this coverage would increase the cost to the athletic department from $65,000 to $400,000 a year. In the face of the current decision by the University to cancel several varsity sports including baseball, gymnastics, etc., this clearly demonstrated to Moyer how out of touch this thinking is with regard to the current realities of life at Broad and Berks Streets.

Acting decisively and most appropriately he concluded, in his words, that "this train is moving in a new direction and I'm getting off the train." Today, Ray Moyer is held in the highest esteem by players, former coaches, colleagues, patients and all who know him. It is my view that after the good Lord created Ray Moyer, He threw the mold away!

Commentary

Will the New Milestone Requirements Improve Residency Training?

RICK TOSTI, MD

Temple University Department of Orthopaedic Surgery and Sports Medicine, Philadelphia, PA

Education in orthopaedic surgery is evolving. Recently, the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Orthopaedic Surgery (ABOS) have implemented a set of clinical "milestones" which training programs will use as progressive benchmarks to evaluate each resident's acquisition of medical knowledge and patient care skills.[1] The milestones are a step toward standardizing resident education based on a progression model, which is already being used by European and Asian countries. The evaluations are disease-specific and graded from Level I (incoming resident) to Level V (career specialist). Contrary to many resident's first impressions, the milestone levels do not correspond to post-graduate year; the recommended target for graduates is actually Level IV. Although these milestones are not intended to supersede the program's decision to graduate an individual, program directors are now encouraged to complete these evaluations, with co-faculty, at the semi-annual review in order to identify possible weaknesses in the either the resident or in the institution's teaching methods. Several pros and cons have been identified with the current paradigm shift in orthopaedic education, and the following article will discuss those controversies from one resident's perspective.

Pros

Residents will now have a tangible set of goals for each rotation, and the acquisition of medical knowledge and clinical skills can be directed toward them. During the mid-year review, residents will be provided with unambiguous feedback that either confirms their progress and/or identifies their weaknesses. Faculty will have an opportunity to reflect on their own teaching methods and adjust them according to their goals for the block. On a national scale, the ACGME and ABOS will have a large bank of normative data to compare programs.

Cons

Inherent biases of the rating scales and the raters are the major limitation of this initiative. Although a well-respected group of orthopaedic surgeons developed the milestone levels, the rating scales are nonetheless only one small group's interpretation of a resident's proper educational growth. Additionally, a few surgeons are less than enthusiastic about the increase in paperwork and may not give close consideration to the evaluation. Last, these scales are not validated and inter-observer variability limits the comparison of residents within and among programs.

My View

John Dewey, one of the fathers of modern education, is quoted in his book *Experience and Education* saying, "education should derive its material from present experience and should enable the learner to cope with problems of the present and the future."[2] Dewey criticized the traditional authoritative teaching model of the early 1900s; methods of that time emphasized a rigid classroom structure, unchallenged dogmas, and a master instructor who expected students to absorb facts in a classroom and apply them in the "real world." Does this sound familiar to anyone? It is surprising that with many of the advances in educational philosophy that many instructors still teach with rote memorization in a Socratic fashion. Fortunately, it appears that many training programs are striving to improve the quality assurance of their product and, like Dewey, are advocating for gradual freedom of independent thought and progressive, step-wise, learning through guided experience. I think the milestones are a step toward Dewey's progressive pedagogical philosophy for several reasons:

1) The milestones provide an opportunity for the residents to assess their own growth and potential for independence. I think often residents feel a progressive sense of entitlement as they rise in post-graduate year. I have heard the phrase "he doesn't let me do anything in the case" many times. Perhaps in this new model, residents can see why some surgeons do not think they are ready to operate. For example, many of the trauma modules require pre-operative planning skills before the resident is advanced to placing implants. Many residents may feel like they enjoy the case more if the surgeon lets them handle the equipment, but in reality, even medical students can implant hardware if someone is thinking for them and telling them every step. The milestone for hip fracture asks that the resident first shows a thought process behind the choice of implants, the approach, and postoperative management (Level II) before they repair a simple or complex hip fracture (Level III and IV).

2) The milestones provide an opportunity for the educators to reflect on the effectiveness of their teaching methods. How many of us have held a leg for hours in an arthroscopy

case only for the attending to point to the popliteus tendon and ask the name? How many of us have done this as a chief resident? I think milestones will now ask the faculty to think about the resident's skill level and adjust the surgical experience appropriately. In the future, perhaps that same experience might now expand to a guided interpretation of x-rays and MRI findings (Levels II and III) or discussing controversies of meniscal repair techniques and supervising a resident through one (Level IV).

3) The milestones provide an opportunity for programs to evolve. Overall, I think it will be challenging to compare programs nationally because evaluators/residents will not equally value this system. However, I think the best implementation lies in studying trends within individual programs. If taken seriously, program directors can have another tool to monitor the progress of trainees and make adjustments; some residents may need to work harder and recognize their deficiencies, and some faculty members may need to reflect on their relationship with the residents.

At my program, the residents and instructors complete the evaluations and compare; at least in the short term, I think this exercise has generated healthy discussion for quality improvements on both ends, which has the potential to improve training. As medicine is becoming increasingly judged on the quality of care, the quality of the surgeon must rise as well, and we should continue to seek new ways to meet that demand.

Acknowledgements: Special thanks to J. Milo Sewards, MD, Orthopaedic Surgery Residency Director, Temple University School of Medicine.

References

1. Stern P. *Orthopaedic Surgery Milestones*. Available at http://www.acgme-nas.org/milestones.html. Accessed November 11, 2013.
2. Dewey J. *Experience and Education*. New York, NY: Kappa Delta Pi; 1938.

Commentary

An Overview of Robotics in Joint Replacement Surgery

MATTHEW LOREI, MD

Introduction

Recently, "robotic surgery" has gained headlines across the nation as a way of performing complicated, intricate surgeries more safely and less invasively. Notable examples include the DaVinci device for performing radical prostatectomies, hysterectomies and cardiac valve replacements. Orthopaedic surgery, particularly hip and knee replacement, has not been a stranger to robotic surgery. Attempts have been made to automate hip and knee replacement, at least experimentally, since the mid 1980s. Recently, newer FDA-approved robotic systems have come to the marketplace. This article will attempt to review various applications of robotics in hip and knee replacement surgery.

A robot is defined as a machine that carries out a variety of tasks automatically or with a minimum of external impulse. Strictly speaking, most robotic surgery is not robotic at all in that the machine is not carrying out the surgery, but instead the machine enhances the surgeon's ability to perform the operation. A better term might be computer assisted surgery or machine enhanced surgery.

Categories of Robotic Surgery

There are two main types of "robotic" surgery currently available: telesurgical and navigational controlled. Telesurgical devices allow the surgeon to remotely control surgical instruments to perform an operation. The advantage of telesurgical instruments is that they allow the surgeon to effectively get closer to the operative site than human vision will allow. They also give access to the surgeon to work at a smaller scale than conventional surgery permits, allowing the surgeon to perform intricate surgery deep in a body cavity more easily, more safely and typically less invasively. The DaVinci Device from Intuitive is the most widely know telesurgical device. Currently, there are no applications for telesurgical devices in Orthopaedic surgery.

Navigational controlled devices use registration and mapping of the relevant anatomy to help carry out a preplanned procedure. These devices work best on rigid structures where the anatomical relationships are consistent. They are especially useful in bony procedures or in soft tissue procedures carried out in a bony cavity (e.g., intra-cranial surgery). Navigational controlled devices fall under three categories: Passive, Active or Semi active. All three are available for use in Orthopaedic surgery.

Passive computer assisted surgery systems are designed to give the surgeon feedback as to whether a particular tool, preparation or implant is in the appropriate position. They cannot and do not prevent the surgeon from doing something at odds with the planned procedure. They simply provide guidance as to how things should be done to generate the preplanned, desired result. The most well known example of a passive system is computerized navigation for joint replacement. Various systems have been made by Brainlab, Aesculap, Stryker and DePuy among others. All of these systems use pins rigidly fixed to bony structures upon which are mounted arrays which communicate via a radiofrequency to a computer to give real time data on positioning. These systems all require bony surface mapping and joint registration to let the computer know where the relevant structures are in space. Some systems are based on a preop CT scan, some use intraop fluoroscopy and some are completely imageless. All systems guide placement of various cutting jigs to ensure more accurate bony resection to meet the preop goal or plan. The actual use of the cutting instrument is purely manual as is the placement of components.

Active computer assisted surgery systems (also known as Autonomous systems) are truly automated or robotic systems that once properly programmed and set up, complete a portion of the procedure without any assistance from the surgeon. An example of this in orthopedic surgery is the ROBODOC device. Similar to Navigation systems, the ROBODOC requires a preop CT scan which is used to plan the procedure. Intraoperatively, again pins and arrays are placed and the relevant landmarks and alignment are determined by registration and mapping. The skin and soft tissues are exposed and protected by the surgeon and then the ROBODOC system is mounted to a frame rigidly fixed to the skeleton. The machine then performs the bony portions of the procedure to the exact specifications. The surgeon has no control of the robot once the work is initiated except for a "kill switch" which allows him to stop or abort the procedure at any time. The surgeon is not, however, able to change the parameters of the procedure at any time. ROBODOC is used only for bone preparation and not implantation of components. It has applications for Total Hip Arthroplasty as well as Total Knee Arthroplasty although only the former is available in the U.S.

Semi active computer assisted surgery systems allow the surgeon to use or "drive" the robot to perform the operation.

These systems are also variously known as Haptic, Shared control or Active constraint systems. Unlike active systems, the procedure is not automated and needs constant input from the surgeon to proceed. Examples of Semi active systems in joint replacement surgery include the Robotic Arm Interactive Orthopaedic System (RIO) from MAKO Surgical Corp., the Stanmore Sculptor RGA (previously known as the Acrobat System), and the Navio System from Blue Belt Technologies. All three systems utilize a preop CT scan which is used to plan the procedure. Similar to other navigated procedures, pins and arrays are placed and registration and mapping are performed. After skin and soft tissue exposure, a burr mounted on a robotic arm is used to resect the bone according to the preprogrammed plan in preparation for the implants. The robotic arm limits the tip of the burr to remove bone only within the confines of the predefined cutting zone. A real time virtual model of the bony structures is visualized on a monitor allowing the surgeon to see what bone has been removed and what remains to be removed. The arm does not drive the procedure in any way. It simply prevents the surgeon from over-resecting and gives the operator visual feedback on the work to be done. The burr will automatically stop if the surgeon attempts to go outside the predetermined zone. Except for the Rio THA which guides acetabular component insertion, these systems only guide bony preparation and not implantation. The Navio System and the Stanmore Sculptor are available only for Partial Knee Replacement. The RIO system is available for Total Hip Replacement and for Partial Knee Arthroplasty. There is no commercially available Semi active device for Total Knee arthroplasty.

Impetus for Robotic Surgery

The most important question is not whether we can use robotics or a computer to help perform our surgery, but rather can a robot or computer input bring real value to the procedure in terms of limiting invasiveness, increasing the speed of the operation, decreasing costs, improving accuracy of component placement and joint alignment, improving the functional results or improving the long-term results. The impetus for applying robotic technology to hip and knee replacement has largely been along the line of improving our accuracy which in theory should lead to better satisfaction with the procedure and decrease the risk of mechanical complications, improving longevity of the prosthetic construct.

With survivorships >90% at 10 years for most TKA and UKA, durability of knee replacements is not the concern it once was. However, patient satisfaction rates for both UKA and TKA have hovered in the 80–85% range for decades. Newer designs and better instruments have improved polyethylene wear rates, loosening and patellofemoral complications, but patient satisfaction with the procedure remains largely unchanged. There is clearly some relationship between implant malalignment and accelerated wear and loosening with time. It has also been postulated that patient dissatisfaction could be due to improper fit. The argument then is perhaps a device that helps us achieve better fit, alignment and soft tissue balancing could decrease the risk of wear and loosening, improve implant survival and potentially also increase patient satisfaction. Despite fairly sophisticated manual instrumentation, the risk of malalignment in standard TKA is still 10–30%. Computer navigated surgery held the promise of eliminating malaligned TKAs and there has been little doubt that navigated TKA surgery improves positioning and has virtually eliminated the potential for malaligned knees. However, there are limitations to a passive navigation system. There is still potential for error. Subtle movement of a guide or human error with saw cuts have been shown to create up to a 1.1 degree error in the coronal plane and up to a 1.8 degree sagittal plane error in passive navigated surgery. Computer navigation was primarily designed to improve coronal plane (and to a lesser extent sagittal plane) alignment of knee arthroplasties. It has historically not been very good with rotational alignment, sizing and soft tissue balancing. In addition, computerized navigation has not been shown to improve patient satisfaction, or improve long-term durability of knee replacement. Computer navigated surgery also adds significant time and expense to the procedure. Because of the added costs as well as lack of documented efficacy, it has largely fallen out of favor with the orthopaedic community.

Active or Semi Active Robotic knee surgery holds the promise of eliminating or at least markedly decreasing human error. It can not only accurately prepare the bone for ideal placement of the component in the sagittal and coronal planes but can also accurately size a component, accurately determine rotation and can help to guide soft tissue balancing. It is hoped that better positioning, sizing and soft tissue balancing will not only improve alignment but also improve patient satisfaction with the procedure and increase the longevity of the implants. Furthermore, robotic surgery once mastered could potentially decrease the time of the procedure as it eliminates guesswork and streamlines bony preparation.

Unlike knee replacement, total hip replacement is a procedure with high rates of satisfaction — in most series >95%. It has also proven quite durable with survivorship >95% at 10 years. Positioning of implants remains a concern. There is a subset of patients with pain that is thought to be due to impingement of the prosthesis on bone or of soft tissue impingement on overhanging implant. Both of these conditions are thought to be due to malaligned acetabular components. Dislocation rates vary from 1–10% and are also commonly attributable to cup position. Leg length and offset problems are also common and are usually functions of femoral component positioning. Leg length inequality is a common cause of dissatisfaction. If the hip is too short, it might be predisposed to weakness and instability. Alterna-

tively, if it is too long, the patient is often unhappy — especially if it requires the use of a lift. Femoral offset inequality can also be a source of dissatisfaction. If the femoral offset is increased substantially, the patient may complain of tightness and loss of ROM (particularly external rotation) as well as lateral hip pain. If the offset is decreased substantially, it may lead to weakness and instability. Computer assisted surgery held the promise of improving accuracy of socket positioning; unfortunately, there were no good applications to guide femoral component preparation or positioning. Also, there was large potential for human error in acetabular preparation — the acetabulum was commonly over reamed, under reamed or malpositioned despite the guidance. Passive navigation systems did not display the high degree of accuracy and precision in hip replacements that they demonstrated in knee surgery and were truly only useful for the acetabular portion of the operation. Computer assisted surgery was not able to consistently show any added benefit over standard total hip arthroplasty. Navigated surgery significantly increased the time and expense of hip replacement. Because of the lack of proven benefit and the added costs, passive navigated hip surgery, like navigated knee surgery, has largely fallen out of favor with orthopaedic surgeons.

The potential benefit of Autonomous or haptic Robotic hip surgery is that it has the ability to precisely control preparation and insertion of both the femur and acetabulum, allowing for perfect or near perfect positioning of the implants. It guides placement of the acetabular component such that position, sizing, inclination and version are all ideal — it eliminates the potential for over-reaming or under-reaming. It sizes, prepares and guides femoral implant positioning so that there is an excellent press fit and leg length and offset are perfectly restored. Ideally, this accurate placement should help to eliminate impingement and pain due to malposition, eliminate limb length inequality, and markedly reduce the risk of dislocation. In addition, like robotic knee surgery, robotic hip surgery potentially holds the promise of decreasing OR time due to minimized guesswork and streamlined bony preparation.

Experience with Autonomous (Active) Robotic Systems

The ROBODOC system was initially developed for hip replacement and early studies showed significant improvements in fit, fill and alignment. The system had some degree of popularity in Germany in the 1990s but experienced a decline in use due to safety concerns. In one study, 9% of the operations had to be converted to manual surgery due to safety or technical issues. There are very few published results on the ROBODOC hip. The ROBOBDOC knee has been in use in Europe since 2000. Numerous comparative studies versus manual techniques have documented superior overall alignment with very few mechanical outliers. In general, however, the time of surgery was substantially longer and the early clinical results were no better than the manual technique. Long-term studies are lacking. There are safety concerns as well. Several studies have emphasized the potential of damage to the patellar tendon. Technical problems are still a concern and have led to the abandonment of the procedure in 5–22% of cases. The operation typically requires a wide exposure and meticulous soft tissue protection. Minimal incision surgery is not conducive to use of the ROBODOC. To date, only the hip module is available in the U.S.

Newer experimental TKR systems are being developed that hold the promise of decreasing the cost and increasing the safety and efficiency compared to the larger ROBODOC system. These include the MBARS robot developed at Carnegie Mellon University and the Praxiteles developed in Grenoble, France.

Experience with Semiactive (Haptic) Robotic Systems

Results of the Acrobat assisted UKA have generally shown improvement in overall alignment when compared to manual techniques as well as elimination of outliers. In addition, short-term functional and pain relief scores seem to be better. Average additional operative time varied from 10 to 20 minutes. Similarly, published results of the RIO UKA system have shown superior alignment compared to manual techniques and virtual elimination of outliers. However, clinical data to support improved pain or function scores are lacking. Additional time of surgery varied from 10 to 25 minutes after the learning curve was completed. As both systems have only recently come to the marketplace, long-term data is absent. There are no current published studies documenting the results of the RIO hip replacement system or the Navio partial knee system.

Invasiveness

Unlike Autonomous systems, the RIO, Acrobat and Navio are all compatible with minimal incision surgery. Although they do not decrease the exposure needed for a typical mini-invasive hip or partial knee procedure, the incision does not need to be lengthened to accommodate the device. However, all devices currently require placement of at least two pins in each of the bones on either side of the joint — typically through separate small incisions. There have been reports of pin site infection or fracture about the pin sites but these have been largely anecdotal.

Costs

Robotic or computer guided systems are not inexpensive. Passive surgery systems typically have a start up cost of $150,000 to $300,000, yearly maintenance and a cost of disposables at up to $1,000/case. The Mako/RIO system

retails for roughly $1,000,000 and disposables add $1,100 to the cost of each case. Other Active and Semiactive systems are priced comparable with the RIO.

Closed Platform Versus Open Platform

The Stanmore Sculptor RGA (Acrobat), Navio and ROBODOC are all open platform systems, that is they can be adapted to any commercially available implant from any manufacturer. The RIO is a closed platform design; that is, it is only compatible with their own proprietary designs. These implants are new to the marketplace and do not have a published track record as of yet. Mako has recently been purchased by Stryker Corporation and time will tell if they are eventually converted to an open platform system or at least a Stryker specific platform.

Conclusions

Passive, computerized navigational systems clearly increase the accuracy of knee replacement although the same cannot necessarily be said of hip replacement. Unfortunately, this accuracy has not translated into better short-term or long-term results. Active or Autonomous hip and knee replacement surgery also significantly increases the precision of the operations and improves three-dimensional position and alignment but has not gained acceptance in the U.S. due to safety concerns. Haptic or semiactive systems are an exciting new technology that is gaining wider acceptance in the U.S. This technology is performed through a small incision, ensures precision not only in coronal plane alignment but in three-dimensional positioning as well. Its chief advantage over Autonomous systems is direct surgeon control which may minimize soft tissue injury. It also holds the possibility of soft tissue balancing and guiding implant placement, not just bony preparation. The question now is whether this technology will improve short-term outcomes or long-term durability and whether the results will justify the added costs of the process.

Distinguished Alumni Paper

Clinical Diagnosis of Anterior Cruciate Ligament Instability in the Athlete

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The anterior crucial ligament in the face of trauma has remained an enigma. Diversity of opinion exists regarding mechanism of injury, efficacy of diagnostic techniques, as well as appropriate methods of management. We believe that an understanding of the majority of traumatic knee problems that occur in the athlete begins with the knowledge of the status of the anterior crucial ligament.

The purpose of this paper is to deal with the problem of the clinical diagnosis of anterior cruciate ligament instability. A new diagnostic test will be described. The frequency of injury to the anterior cruciate ligament as well as injury to several other structures of the knee will be determined. Also, correlation of these lesions with several clinical diagnostic tests will be made.

Literature Review

Helfet[1] has observed that "occasionally, when operating for a torn medial cartilage, one finds that the anterior cruciate ligament has been torn from its insertions in the tibia . . . but this knee does not demonstrate anterior-posterior instability preoperatively or postoperatively, and removal of the cartilage cures all symptoms. It is not possible to diagnose the coincidental rupture of the cruciate ligament before operations." Of interest is that Helfet also stated that "isolated ruptures of the cruciate ligament are rare and of little clinical significance."

Smillie[2] has observed that "the drawer sign is 'minimal' in isolated ruptures of the anterior cruciate ligament." He further notes that "if the sign is 'maximal,'" it is almost certain that "the medial ligament has been involved." Also, in the face of an acute injury, the drawer sign is "not easy to establish and may be masked by pain, muscle spasm, and haemarthrosis." With regard to treatment, Smillie states that, in the case of isolated rupture, "the anterior cruciate ligament alone is not the factor controlling instability, and a repair does not necessarily improve function. When rupture is associated with a tear of the medial meniscus, treatment is meniscectomy, the ruptured ligament being ignored."

O'Donoghue,[3] reporting on end results of his series of major injuries to the ligaments of the knee, observed that, of 69 patients with disruptions of the medial joint structure, 50, or 72 percent, had tears of the anterior cruciate ligament. On the basis of analysis of these cases, he concludes that crucial ligament instability causes definite disability and recommends repair of the ligament as being surgically feasible.

More recently, Kennedy et al.[4] studied 50 patients with anterior cruciate ligament tears. He concluded that isolated tears of this ligament do occur and that there is a high incidence of associated medial meniscal injuries (19 of 50, or 40%). Most interesting was his observation that an acceptable result following an anterior cruciate tear may be anticipated in a high percentage of patients with or without repair!

Feagin et al.[5] have reported 64 isolated tears of the anterior cruciate ligament diagnosed at surgery at the United States Military Academy between 1965 and 1971. Re-exploration of 16 knees in which the ligament had been repaired revealed eight, or 50 percent, to be intact. Of interest is that the medial meniscus was torn in 12, or 75 percent, of these re-explored knees.

Allman[6] has also observed that "complete tear of the anterior cruciate ligament may occur as an isolated injury and that in such cases, there is no demonstrable laxity of the knee, thus making the diagnosis extremely difficult."

Anterior Drawer Test

Classically, the orthopedist has been taught that a clinical diagnosis of anterior cruciate instability is contingent upon demonstration of a positive anterior drawer sign, that is, anterior translation of the tibia in its relationship with the femur when the knee is flexed to 90 degrees and anterior stress is applied. The origin of this maneuver is obscure, but for most, its validity has remained unquestioned. As noted, however, the unreliability of the drawer sign has been pointed out by several authorities. On the basis of our experience with 172 knees with anterior cruciate ligament disruption diagnosed at surgery, we agree with those who reject the reliability of this diagnostic test. Analysis of the factors involved reveals three causes for a "false negative" drawer test in instances of an isolated tear of the anterior cruciate ligament. First, in the face of acute injury, isolated anterior cruciate tears are often, but not always, accompanied by a tense haemarthrosis and reaction synovitis that precludes flexion of the knee to 90 degrees. Second, protective spasm of the hamstring muscles secondary to joint pain can, in the well-

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muscled, well-conditioned athlete, generate considerable force. Simple vector analysis dictates that to effect translation of the tibia in the direction opposite to such a force requires an effort on the part of the examiner that would tax the capabilities of most of us. Third, and perhaps most important, a consideration of the anatomy of the medial joint compartment with knee flexed to 90 degrees explains the main cause for difficulty in effecting anterior translation of the tibia on attempting the drawer test. The posterior surface of the medial femoral condyle is acutely convex in configuration. This convex femoral articulating surface lies in relationship with the concavity formed by the articulating surface of the medial tibial plateau and attached medial meniscus. The spatial relationship is almost like that of a ball-and-socket joint. Specifically, it is the posterior horn of the medial meniscus buttressed against the posteriormost margin of the medial femoral condyle that precludes forward translation of the tibia (Fig. 1A). Our observations indicate that significant "anterior drawing" occurs only after peripheral separation of the posterior horn of the medial meniscus or disruption of the medial capsular and/or posterior oblique ligaments.

Lachman's Test

John W. Lachman, MD, Chairman and Professor of Orthopedic Surgery at Temple University, has for many years taught a simple, reliable, and reproducible clinical test to demonstrate anterior cruciate ligament instability.[7] The examination is performed with the patient lying supine on the table with the involved extremity on the side of the examiner (Fig. 2). With the patient's knee held between full extension and 15 degree flexion, the femur is stabilized with one hand while firm pressure is applied to the posterior aspect of the proximal tibia in an attempt to translate it anteriorly. A positive test indicating disruption of the anterior cruciate ligament is one in which there is proprioceptive and/or visual anterior translation of the tibia in relation to the femur with a characteristic "mushy" or "soft" end point. This is in contrast to a definite "hard" end point elicited when the anterior cruciate ligament is intact. When the anterior horizon of the knee is viewed from the lateral aspect, the normal slope of the infrapatellar tendon becomes obliterated (Figs. 3A and 3B). A corollary to interpreting the test is that if question remains in the examiner's mind as to whether the test is positive or negative, the ligament is torn.

The Lachman test for anterior cruciate instability obviates those problems mentioned as inherent in the classical "drawer sign." First, the position of comfort of the acutely injured and distended knee joint is one of slight flexion, the position described for performing this test. Second, the force produced by hamstring spasm is negated by testing for anterior translation of the tibia with the knee extended. The physics of static friction resolves the force necessary to translate the tibia in a direction 90 degrees to the opposing force of the hamstring muscles to simply that force necessary to overcome the friction of the two surfaces plus the weight of the leg. By extending the knee, the force of the hamstring is negated, and that force necessary to overcome the friction of articular surfaces is negligible. Third, with the knee extended, that area in contact with the tibial plateau and attached medial meniscus is the slightly convex weight-hearing surface of the femur. The relatively flat configuration of this surface does not obstruct forward motion of the tibia as previously described when the joint is flexed to 90 degrees (Fig. 1B).

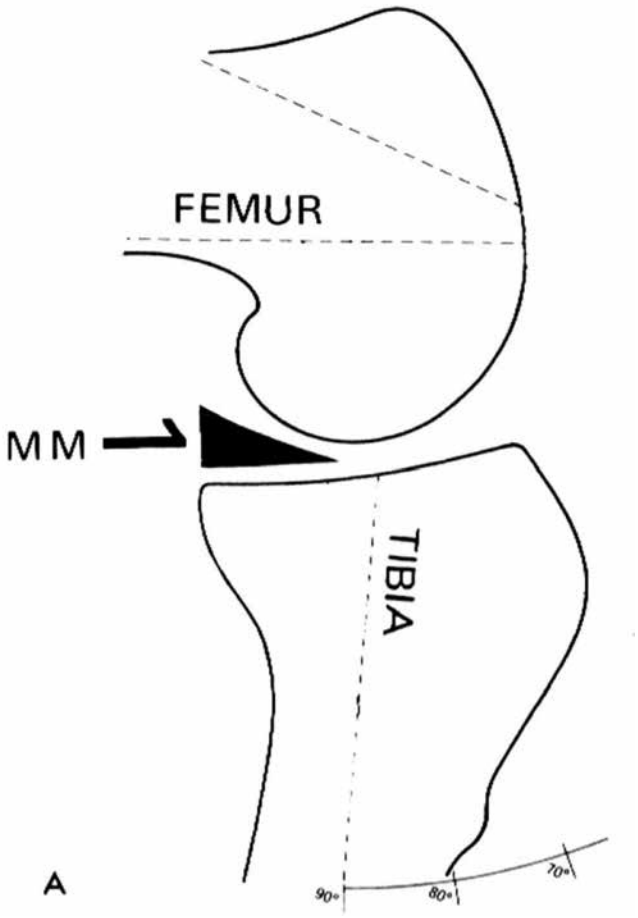

Figure 1A. Diagrammatic representation of the relationship of the medial femoral condyle, medial meniscus (MM), and tibia in the sagittal plane with the knee flexed to 90°, the position in which the classical anterior drawer sign is performed. The medial meniscus, being attached to the tibia, abuts against the acutely convex surface of the medial femoral condyle, having a "door stopper" effect, and prevents anterior translation of the tibia and precludes a "positive drawer sign." Disruption of the medial capsular ligament and/or posterior peripheral separation of the medial meniscus, however, will permit a positive drawer sign when the anterior cruciate ligament is torn.

Material and Methods

In order to evaluate the several clinical methods for diagnosing traumatic disruption of the anterior cruciate ligament as well as to determine the relative frequency of this lesion as related to injury of other structures, we have reviewed the clinical and operative findings of 250 knees in athletes that

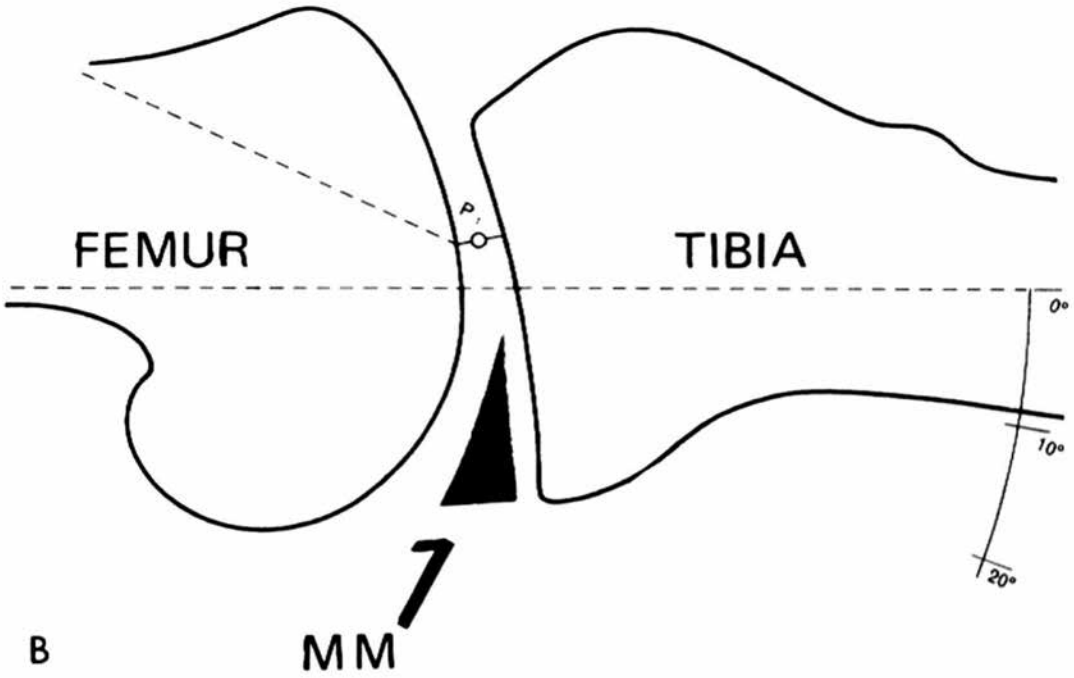

Figure 1B. With the knee extended, the relationship of the femur, medial meniscus, and tibia is significantly changed. The comparatively flat weight-hearing surface of the femur does not obstruct forward motion of the meniscus and tibia when anterior stress is applied. Thus, in instances where there is an isolated tear of the anterior cruciate ligament, anterior stress of the tibia with the knee extended will demonstrate clinically cruciate instability.

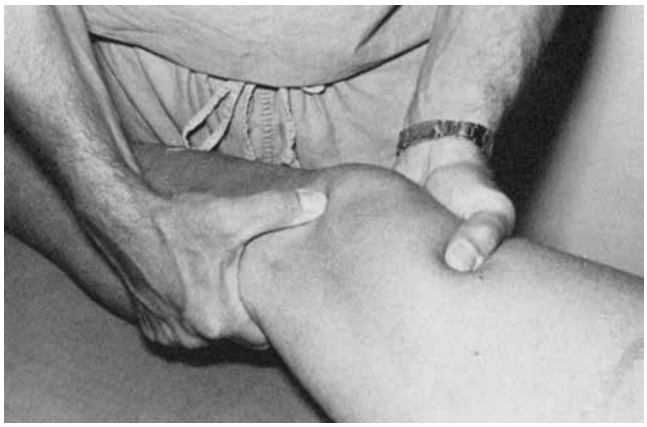

Figure 2. Lachman's test for anterior cruciate ligament instability is performed with the patient lying supine on the examining table with the involved extremity to the side of the examiner. With the involved extremity in slight external rotation and the knee held between full extension and 15° flexion, the femur is stabilized with one hand and firm pressure is applied to the posterior aspect of the proximal tibia, lifting it forward in an attempt to translate it anteriorly. Position of the examiners hands is important in performing the test properly. One hand should firmly stabilize the femur, while the other grips the proximal tibia in such a manner that the thumb lies on the anteromedial joint margin. When an anteriorly directed lifting force is applied by the palm and four fingers, anterior translation of the tibia in relationship to the femur can he palpated by the thumb. Anterior translation of the tibia associated with a soft or a mushy endpoint indicates a positive test.

came to surgery for several forms of "internal derangement." Included in this retrospective study were a series of consecutive knees operated on for injuries that resulted from participation in recreational and competitive athletics and where operative findings confirmed the diagnosis of injury to one or more of the following structures: anterior cruciate ligament, medial meniscus, lateral meniscus, medial capsular ligament, and tibial collateral ligament.

Results

Incidence of various derangements in 250 knees was as follows: (1) isolated tear of the lateral meniscus — 43, or 17 percent; (2) combined tears involving the lateral meniscus and anterior cruciate ligament — seven, or 3 percent; (3) combined tears involving the lateral meniscus, medial meniscus, and anterior cruciate ligament — 12, or 5 percent; (4) isolated tear of the medial meniscus — 35, or 14 percent; (5) combined tears of the medial meniscus and anterior cruciate ligament — 93, or 37 percent; (6) combined tears of medial meniscus, anterior cruciate ligament, and medial capsular ligament — 43, or 17 percent; and (7) triads — 17, or 7 percent (Table 1).

The incidence of specific anatomic lesions in 250 knees was as follows: (1) lateral meniscus — 62, or 25 percent; (2) medial meniscus — 200, or 80 percent; (3) anterior cruciate ligament — 172, or 69 percent; and (4) medial capsular and/or tibial collateral ligament — 60, or 24 percent (Table 2).

In 171 knees, arthrotomy and meniscectomy was performed because of primary derangement of the medial meniscus. At surgery, meticulous examination documented that 136, or 79 percent, had associated tears of the anterior cruciate ligament (Table 3).

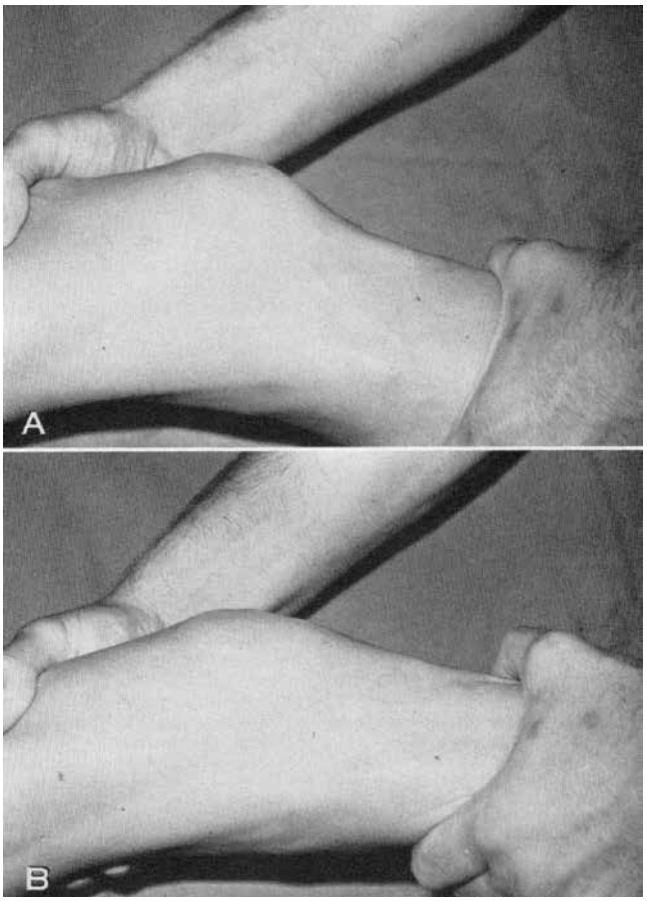

Figure 3. (A) When viewed from the lateral aspect, the silhouette of the inferior pole of patella, infrapatellar tendon, and proximal tibia is one of a slight concavity. **(B)** With disruption of the anterior cruciate ligament, anterior translation of the tibia obliterates the infrapatellar tendon slope.

Table 1. Incidence of Various Derangements Observed in 250 Knees

1) LM	43 (17%)
2) LM, ACL	7 (3%)
3) LM, ACL, MM	12 (5%)
4) MM	35 (14%)
5) MM, ACL	93 (37%)
6) MM, ACL, MCL	43 (17%)
7) MM, ACL, MCL, TCL	17 (7%)

LM = lateral meniscus; ACL = anterior cuciate ligament; MM = medial meniscus; MCL = medial capsular ligament; and TCL = tibial collateral ligament.

Table 2. Incidence of Specific Anatomic Lesions Observed in 250 Knees

1) LM	62 (25%)
2) MM	200 (80%)
3) ACL	172 (69%)
4) MCL +/or TCL	60 (24%)

LM = lateral meniscus; MM = medial meniscus; ACL = anterior cuciate ligament; MCL = medial capsular ligament; and TCL = tibial collateral ligament.

Table 3

Medial Meniscectomies	171
Associated Tears of Ant. Cruc. Ligament	136 (79%)

Operative findings were correlated with the classic anterior drawer sign; rotatory instability test as described by Slocum, and Lachman's test.

Of the 43 knees diagnosed at surgery as having isolated tears of the lateral meniscus, all three tests were negative pre- and postoperatively.

Of the 35 knees diagnosed at surgery as having an isolated tear of the medial meniscus, all three tests were negative pre- and postoperatively.

Of the 93 knees with combined tears of the medial meniscus and anterior cruciate ligament without valgus laxity, preoperative anterior drawer test was negative in 42, equivocal in 14, and positive in 37. All except five with bucket-handle tears demonstrated positive Lachman's sign, and none had rotatory instability. Postsurgery, all 93 demonstrated both positive Lachman's sign and anterior drawing. Six had rotatory instability.

Of the 43 knees with combined tears of the medial meniscus and anterior cruciate ligament with valgus laxity, preoperative anterior drawer test was negative in four, equivocal in five, and positive in 34. All 43 demonstrated positive Lachman's test. Rotatory instability was negative in 30, equivocal in one, and positive in 12. Postoperatively, all 43 had both positive Lachman's and anterior drawer tests. Most significant was that all but 10 which had static stabilizing procedures demonstrated rotatory instability post operatively.

Discussion

An analysis of 250 knees operated on for injuries sustained in recreational and competitive athletics has demonstrated to our satisfaction the value of testing for anterior cruciate ligament instability with the knee held in 0 to 15° flexion. In none of the 35 isolated tears of the medial meniscus was the test positive prior to or following meniscectomy. Likewise, the 43 isolated tears of the lateral meniscus demonstrated negative Lachman tests both before and following lateral meniscectomy. It should he noted that in some instances following meniscectomy, there is slight increase in anterior-posterior translation of the tibia in relationship to the femur when stressed in extension, but in all instances there is an abrupt end point with an intact anterior ligament.

An additional 17 knees, examined under anesthesia, but not operated upon, were diagnosed as having "incomplete tears of the medial collateral ligament," or, more specifically, of the medial capsular ligament. In no instance of isolated tears of the medial capsular ligament was anterior translation of the tibia in relation to the femur discernible when the knee was stressed in extension.

In 88 of the 93 combined lesions involving the anterior cruciate ligament and medial meniscus, the test was positive

both pre- and post-operatively. The false negative tests were attributed to incarcerated bucket-handle tears blocking forward translation of the tibia. On the basis of our observations, we believe that testing for the instability of the anterior cruciate ligament by stressing the knee between 0 and 15° of flexion is a reliable and readily discernible diagnostic procedure. The test can be positive only in the presence of partial or complete disruption of the anterior cruciate ligament.

Analysis of the data reveals that, of the 250 knees in this study, operative diagnosis demonstrated tear of the lateral meniscus in 25 percent, tear of the medial meniscus in 80 percent, tear of the anterior cruciate ligament in 69 percent, and tears of one or more components of the medial collateral ligament in 24 percent. Noteworthy is the extraordinary high incidence of partial and complete tears of the anterior cruciate ligament in the knees of these patients. We believe that injury to the anterior cruciate ligament is common in the athlete and that this structure is the second most frequently injured in those knees that come to surgery. Furthermore, in those 171 knees in which meniscectomies were performed because of injury to the medial meniscus, 136, or 79 percent, demonstrated associated disruption of the integrity of the anterior cruciate ligament.

The value of the above observations is not limited to the demonstration of a previously undescribed and reliable clinical test for anterior cruciate ligament instability or the demonstration of the high frequency of this lesion, particularly associated with tears of the medial meniscus in athletes. Rather, the data indicate the value of interpreting several clinical signs with regard to specifically delineating the various combinations of common structural defects occurring and affecting anterior and medial knee joint stability.

Table 4 summarizes the correlation of operative findings with the several clinical tests for anterior and medial instability. The clinical findings include evaluation of valgus laxity, Lachman's test, anterior drawer test, and rotators instability test.

In instances of tears of the medial or lateral meniscus, all these clinical tests and signs are negative both pre- and post-meniscectomy.

In instances of an isolated tear of the medial capsular ligament, valgus laxity is present; all others are negative.

In instances of a combined lesion involving the anterior cruciate ligament and medial meniscus without valgus laxity, Lachman's test is positive. However, 50 percent have negative anterior drawer sign prior to meniscectomy. Following meniscectomy, all have positive drawer sign. Valgus strain and rotatory instability tests are negative.

In instances of a combined lesion involving the anterior cruciate ligament and medial meniscus with medial capsular ligament laxity prior to meniscectomy, all tests except that for rotatory instability are positive. In 75% of these knees, the test for rotators instability is prevented from being positive by the presence of the medial meniscus. Following meniscectomy, all tests, including that for rotatory instability, are positive.

Table 4. Correlation of Operative Findings with Clinical Test for Anterior and Medial Knee Instability

Lesion	Valgus Laxity	Lachman's Test	Anterior Drawer Test	Rotatory Instability Test
Isolated Tear				
Medial Meniscus				
Pre-Meniscectomy	Neg	Neg	Neg	Neg
Post-Meniscectomy	Neg	Neg	Neg	Neg
Lateral Meniscus				
Pre-Meniscectomy	Neg	Neg	Neg	Neg
Post-Meniscectomy	Neg	Neg	Neg	Neg
Medial Capsular Ligament	Pos	Neg	Neg	Neg
Anterior Cruciate Ligament	Neg	Pos	Neg	Neg
Combined Lesion				
Anterior Cruciate Ligament				
Medial Meniscus			½ Neg	
Pre-Meniscectomy	Neg	Pos	½ Pos	Neg
Post-Meniscectomy	Neg	Pos	Pos	Neg
Medial Capsular Ligament				¾ Neg
Pre-Meniscectomy	Pos	Pos	Pos	¼ Pos
Post-Meniscectomy	Pos	Pos	Pos	Pos

Conclusions

1. Lachman's test is a simple, reliable, and reproducible method for demonstrating anterior cruciate ligament instability. In our experience, this is the only test specific for this lesion.

2. Injury to the anterior cruciate ligament is extremely common in the athlete and occurs in 69 percent of those knees that came to surgery for the various forms of internal derangement.

3. Partial or complete disruption of the anterior cruciate ligament was observed in 79 percent of the knees with tears of the medial meniscus.

4. Clinical evaluation of the status of the anterior cruciate ligament in the face of injury must include consideration of the status of all joint structures, particularly the medial meniscus and the medial capsular ligament. This necessitates the utilization of the various clinical tests evaluated in this study. It is intended that the clinical-pathologic correlation presented will assist the clinician's understanding of the majority of traumatic knee problems which occur in the athlete and involve the anterior cruciate ligament.

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Editorial Comment

Dr. H. Rover Collins, Cleveland Ohio: It is a pleasure to discuss Doctor Torg's paper. Doctor Torg has stressed the importance of the anterior cruciate ligament in providing stability of the knee in the pivoting and cutting athlete in contrast to previously held views which stated that this ligament was of no clinical significance. He has discussed the incidence of isolated anterior cruciate tears as well as those associated with other lesions in the knee, particularly meniscus tears. He has stressed the importance of multiple diagnoses in the knee of which the orthopaedist must be aware. Doctor Torg has stated that there is a high incidence of anterior cruciate damage, i.e., ligamentous tear associated with medial meniscus tears and that this must be looked for. He has also emphasized the importance of examining the knee after the meniscus has been removed in order to determine whether instability, which was not felt to be present prior to meniscectomy, may now he present when the stabilizing structure has been removed.

The main emphasis of Doctor Torg's paper lies in his discussion of a new test to determine instability or laxity of the anterior cruciate ligament. He has stressed the point that the usual anterior drawer test is often falsely negative due to tenseness of the knee as a result of hemarthrosis, protective muscle spasm, and posterior horn tear of the medial meniscus which may prevent forward movement of the tibia on the femur, and often will cause the improper positioning of the tibia. He described a test and sign which are new to me, that being Lachman's test.

I have several questions that I would like to ask Doctor Torg:

1. What does Doctor Torg do when he finds an anterior tear of the cruciate ligament?

2. What does he do when there is rotatory instability after meniscectomy?

3. What static stabilizing procedure was he referring to in his paper?

4. What is the natural history of anterior cruciate ligament tears in the athlete?

In conclusion, I would like to state that the anterior cruciate ligament is an extremely important structure in the athlete, and I appreciate the fact that Doctor Torg sent his paper to me in plenty of time to prepare a discussion.

Authors' Reply

I would like to thank Dr. Collins for his kind comments and encouraging evaluation of our paper. We have attempted to present a relatively simple, reliable, inexpensive, and noninvasive clinical test to determine the status of the anterior cruciate ligament. We have found Lachman's test most helpful in evaluating the relatively large number of knee problems that we see in our clinic.

With regard to his question as to what we do in instances of an isolated tear of the anterior cruciate ligament, suffice it to say that the initial management is nonsurgical. The joint is aspirated, and the individual is immediately placed on an intensive isotonic exercise program for both quadriceps and hamstrings. Early return to activity is encouraged. For individuals involved in vigorous activity, bracing and/or taping is recommended. It is our opinion that attempts to surgically repair an isolated tear of the anterior cruciate ligament, regardless of the location of the disruption, are a fruitless surgical exercise. I am not aware of any evidence in the current literature that would lead me to believe otherwise.

As Dr. Collins has noted, mentioned in this paper was a reference to an extra-articular static stabilizing procedure for anteromedial joint instability — a situation that we believe necessarily requires disruption of the anterior cruciate ligament. Although the initial results of this procedure have been quite encouraging, our series is too small and follow-up too short to share the details with this audience today.

The natural history of the athlete with an isolated tear of his anterior cruciate ligament has been aptly described by Dr. Fred Allman as "the beginning of the end." Disruption of the anterior cruciate ligament, as an isolated phenomenon, results in functional anterior instability of the tibia in relation to the femur, similar to that demonstrated by the Lachman test. When this occurs and a valgus and/or rotatory stress results in forceful incarceration of the medial meniscus between the tibia and femoral condyle, posterior peripheral separation and/or longitudinal tears in the substance of the posterior horn of the medial meniscus occur. It is this event that is responsible for the "knee-going-out" sensation described by the patient. With the meniscus is impinged between the tibial surface and femoral condyle and a force of significant magnitude applied, there can also result tearing and/or stretching of the posteromedial supporting ligamentous structures. Repeated episodes result in increasing ligamentous laxity. When this situation is associated with a lax medial capsular ligament, anteromedial rotatory instability results.

Temple Pearls

My Technique for Suprapatellar Tibial Nailing

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Introduction

The use of intramedullary nails is a widely accepted method of treatment for tibia shaft fractures including those that extend into the proximal and distal thirds. Challenges arise especially when treating fractures in the proximal third with resultant procurvatum and valgus deformities. Ideally leaving the limb in the semi-extended position will help alleviate the procurvatum deformity by relaxing the pull of the quadriceps. Also, the limb can be left in the same position to better maintain reduction, to obtain orthogonal fluoroscopic views during the procedure, and to minimize further soft tissue insult secondary to repetitive manipulation when placing a guide wire in the appropriate starting point. All of these advantages are available with the use of a suprapatellar portal for placing a tibia intramedullary nail.

Instrumentation and Special Equipment

Typical instrumentation for suprapatellar systems include a soft tissue sleeve assembly that serves as protection for the articular cartilage of the patella-femoral joint. These instruments are composed of peek and/or stainless steel. Some systems have a flexible, disposable outer sleeve that will conform to the instruments as they are passed through the patella-femoral joint (Fig. 1). The centering sleeve frequently has two portals for guide wire passage (Figs. 2–3). The offset portal allows for minute adjustments in guide wire placement without changing the position of the entire soft tissue sleeve assembly.

In addition to the instrumentation, an extended reamer shaft is also necessary (Fig. 4). Because the portal is superior to the patella, standard reamer shafts will be inadequate to

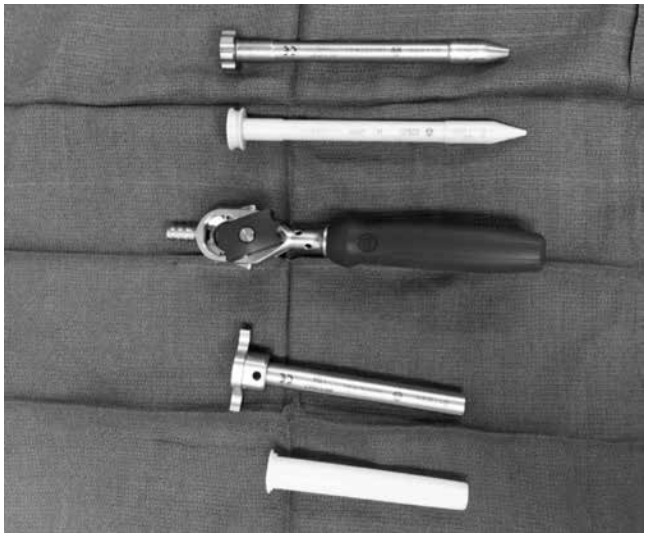

Figure 1. Suprapatellar instrumentation. Pictured from top to bottom: centering sleeve, PEEK trocar, handle for protection sleeve, protection sleeve, outer protection sleeve.

Figure 2. Centering Sleeve. Notice that there are center and offset portals. The offset portal allows for small adjustments without changing the position of the soft tissue sleeve assembly.

Figure 3. Soft tissue assembly. The centering sleeve is in place. The PEEK trocar (left) should be used when passing the assembly through the patella-femoral joint.

Figure 4. Standard reaming shaft (top) and long reaming shaft (bottom). The long reaming shaft measures 620 mm and is recommended for tibial nails that will measure 320 mm or greater in length.

reach the physeal scar. This is especially important when placing intramedullary nails for fractures in the distal one-third of the tibia.

Positioning

The patient is placed supine on a radiolucent table. The upper extremities are placed on well-padded arm boards and secured. The well leg is placed in a gel roll trough and a compression device is placed on the leg to aid in deep vein thrombosis prevention during the procedure. A radiolucent bolster or ramp should be firmly secured to the operating table with tape. The fractured limb is then placed on the bolster or ramp with the knee in the semi-extended position (Fig. 5a). The limb should then be prepped and draped in a standard sterile fashion. A sterile tourniquet can placed on the thigh to aid in hemostasis during the initial approach, but must be deflated during the reaming process to avoid the risk of thermal necrosis. The C-Arm should have a sterile drape and there should be a drape to protect the surgical field when obtaining lateral x-rays (Fig. 5b).

Approach and Surgical Technique

The incision is marked approximately one to two finger breaths proximal to the superior pole of the patella (Fig. 6a). Dissection is taken down to the patellar tendon (Fig. 6b). Once the patellar tendon is identified, it is incised in line with the skin incision to gain access to the patella-femoral joint. Using a clamp to widen the arthrotomy portal may help facilitate passage of the soft tissue sleeve assembly.

After making the arthrotomy, the soft tissue assembly is passed gently through the patella-femoral joint (Fig. 7). If resistance is encountered, a clamp can be used to gently expand the entry portal within the joint. The trocar is exchanged for the cannulated centering sleeve that has the central and peripheral guide wire portals. The trochlea of the

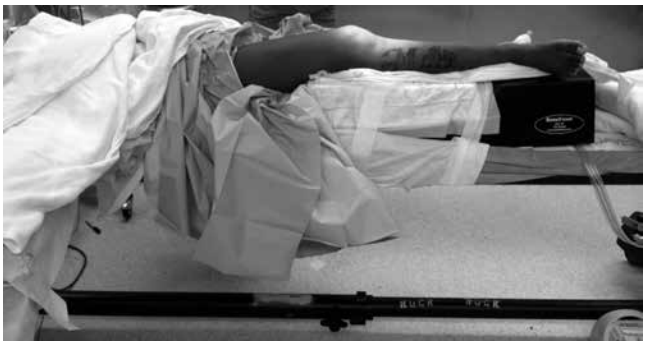

Figure 5a. Patient Positioning. The patient is supine on a radiolucent table. A radiolucent bump or platform should be used. This will allow the limb to remain stationary and simplify fluoroscopic imaging. The bump should also allow some knee flexion to help achieve the appropriate guide wire entry angle.

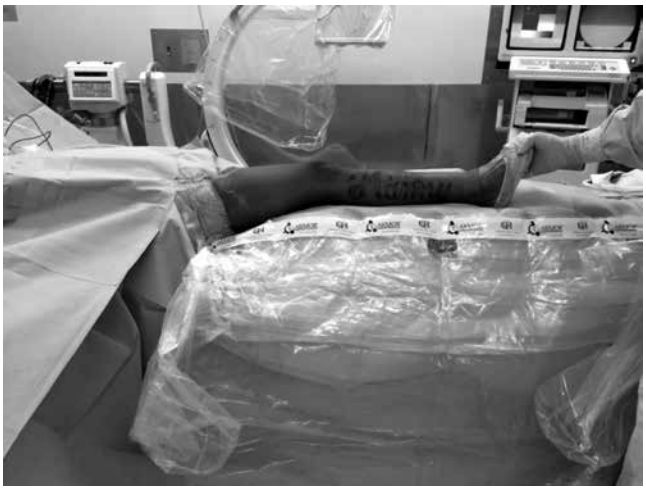

Figure 5b. Patient positioning. After prepping and draping of the operative lower extremity, a sterile sheet or C-Arm drape should be secured in place to obtain lateral images of the entire tibia.

femur will help guide the soft tissue assembly in to the proper position with small adjustments made to locate the starting point. A small bump can be placed posterior to the knee in order to achieve a guide wire insertion angle that is near parallel to the intramedullary canal on the lateral fluoroscopy view (Fig. 8a). The short threaded guide wire is inserted through the centering sleeve and driven into the proximal tibia at the appropriate starting point located on the medial edge of the lateral tibial eminence on the AP film and just anterior to the articular surface of the tibia on the lateral film (Figs. 8b–c). Once the threaded guide wire is placed, the centering sleeve is removed and the entry reamer is placed over the guide wire down to the starting point on the proximal tibia. It is imperative to make sure the soft tissue assembly is seated on the proximal tibia to ensure the articular surfaces of the patella and femur are protected from the entry reamer. Once the entry portal has been created in the proximal tibia, the reamer is removed and the threaded guide wire is exchanged for a long ball-tipped guide wire with a slight bend in the distal end.

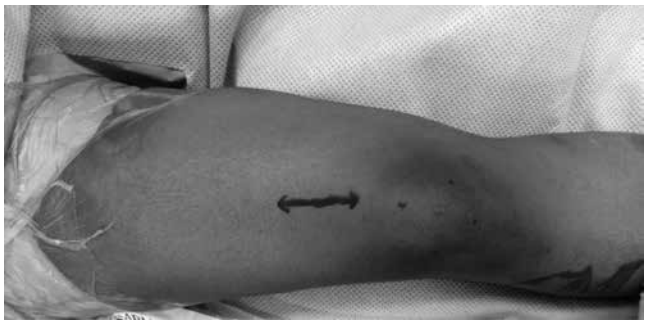

Figure 6a. Approach. A 3–4 cm incision is made approximately 2–3 finger breaths proximal to the superior pole of the patella.

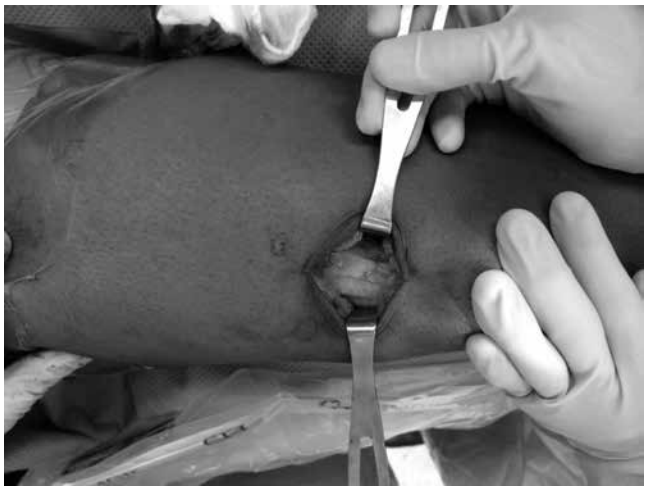

Figure 6b. Approach. The quadriceps tendon is identified and incised in line with the skin incision. The entry portal to the patella-femoral joint can be widened by gently spreading the tissues with a clamp.

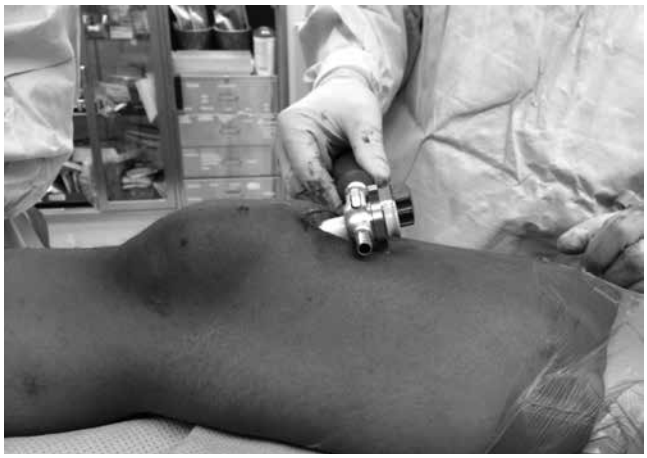

Figure 7. Soft tissue assembly with PEEK trocar placed within the patella-femoral joint. Passage of the assembly through the joint should be smooth. If there is resistance, widen the entry portal with a clamp. Placing the knee in extension will relax the surrounding structures. The patella will usually translate medially when the assembly is passed.

Measurements for length are taken and reaming is performed in a standard fashion. Again, make sure that the soft tissue assembly is seated on the proximal end of the tibia. In addition, the reamers can be placed just inside the bone

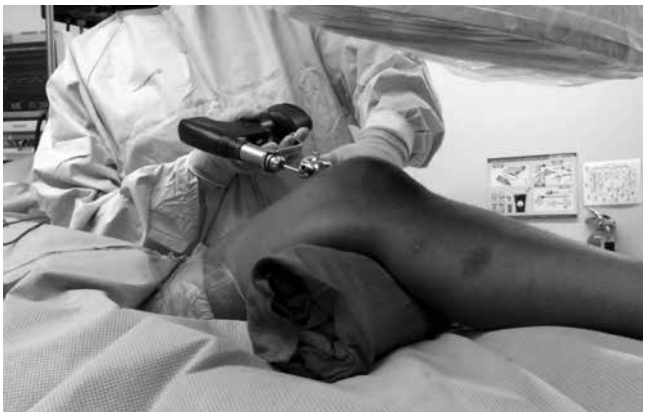

Figure 8a. Guide wire insertion. A small bump placed behind the knee will position the knee in more flexion allowing the guide wire to be placed in line with the tibia intramedullary canal on the lateral fluoroscopic view.

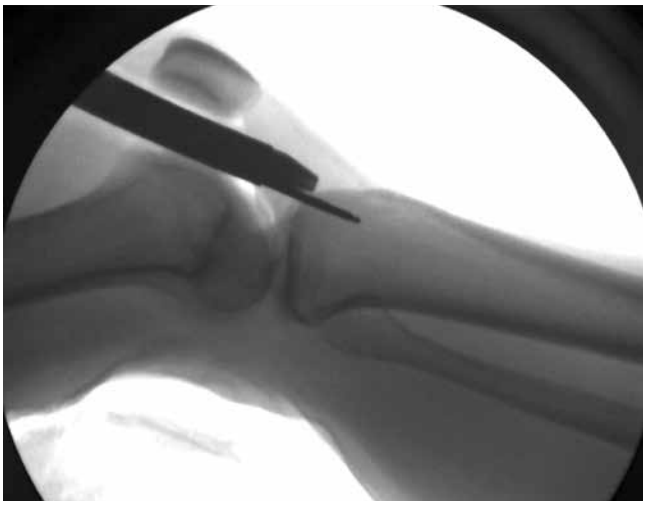

Figure 8b. Guide wire insertion lateral fluoroscopic view. The ideal starting point on this view is just anterior to the articular surface of the proximal tibia. The offset portal of the centering sleeve is being used. The guide wire is placed in line with the intramedullary canal of the tibia.

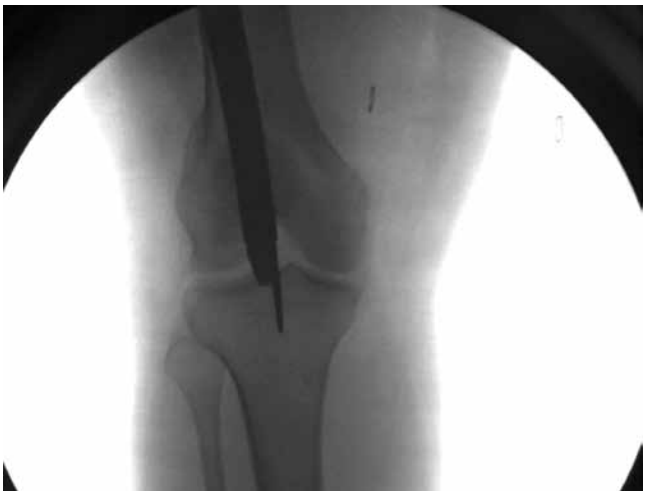

Figure 8c. Guide wire insertion Anteroposterior fluoroscopic view. The ideal starting point on this view is in line with the medial boarder of the lateral tibial spine. The offset portal in the centering sleeve can aid in small adjustments to the guide wire starting point.

before reaming is initiated as long as the reamer diameter is smaller than the diameter of the entry portal (Fig. 9). After reaming is complete, the inner protection sleeve must be removed before nail insertion because it is not large enough to accommodate the diameter of the nail (Fig. 10a). The nail is then placed into the tibia using a twisting motion or short controlled strikes with a mallet (Fig. 10b–d).

Once the nail is seated, the arming arm is attached to the insertion handle (Fig. 11). Proximal and distal locking bolts are then inserted routinely. Once the insertion handle is removed from the proximal end of the nail, the soft tissue assembly can be used to irrigate the knee to remove and debride from reaming. The quadriceps tendon is then closed with an interrupted or running suture.

Summary of Tips

1) Be familiar with the instrumentation. There are many different systems with subtle steps involved.

2) A longer reamer shaft is needed when placing nails that are greater than 330 mm in length.

3) Use a radiolucent table and bumps that will allow the knee to be in a stationary, slightly flexed position.

4) If the soft tissue assembly does not pass through the patella-femoral joint easily, do not force it. The portal through the superior capsule must be widened with a clamp.

5) Placing an additional small bump behind the knee will help gain the flexion to achieve the proper guide wire insertion angle on the lateral fluoroscopic x-ray.

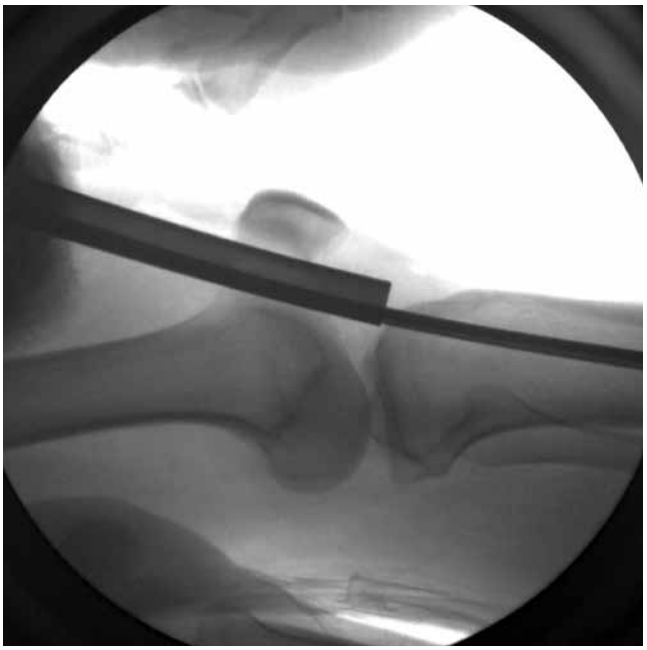

Figure 9. Reaming. The centering sleeve and short threaded guide wire are removed and a ball-tipped guide wire is placed. The protection sleeve is seated on the cortex of the tibia so that the reamer does not damage any intra-articular structures. As the reamer is removed, it may get caught on the posterior aspect of the protection sleeve. Lifting up on the reamer shaft will center the reamer and allow it to pass through the protection sleeve.

6) The offset portal in the centering sleeve can help make small adjustments to starting point position without moving the entire soft tissue assembly.

7) Make sure the protection sleeve is abutting the proximal tibia to protect the intra-articular structures from the reamers.

8) Center the reamer shaft when removing the reamer from the protection sleeve. If the reamer is off center, it will get stuck on the edge of the protection sleeve.

9) Remove the inner protection sleeve before placing the nail.

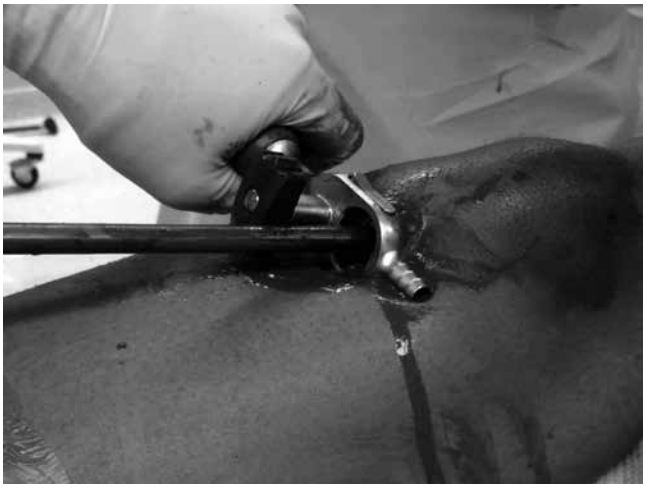

Figure 10a. Nail placement. The protection sleeve is removed from the soft tissue assembly leaving the protection sleeve handle and the outer protection sleeve. The nail is advanced using a twisting motion or controlled taps with a mallet.

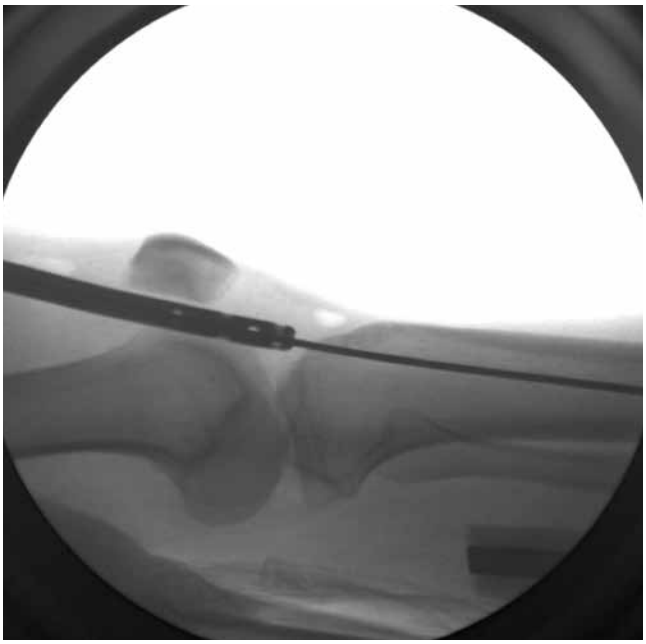

Figure 10b. Nail insertion. The nail is passed through the outer protection sleeve through the patella-femoral joint. Note that the outer protection sleeve is radiolucent.

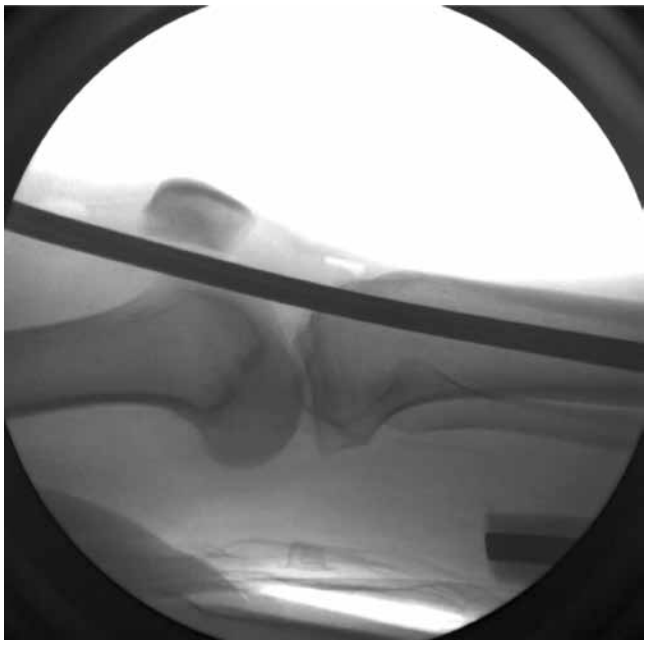

Figure 10c. Nail insertion continued.

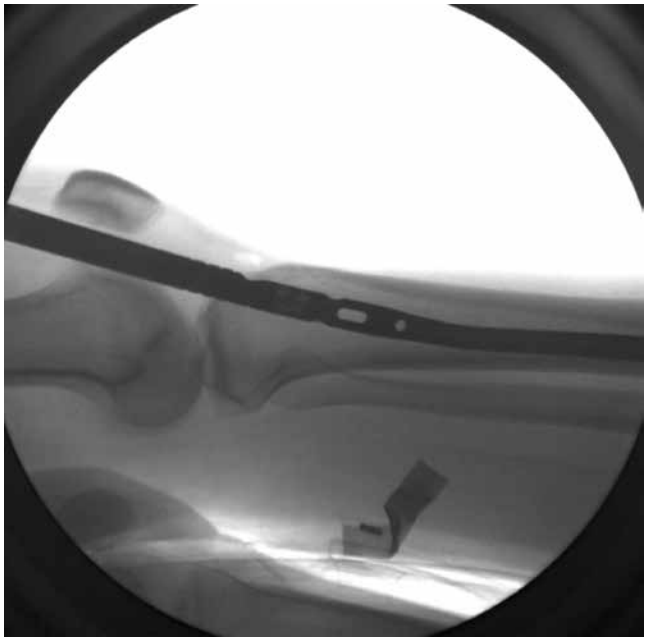

Figure 10d. Nail insertion continued.

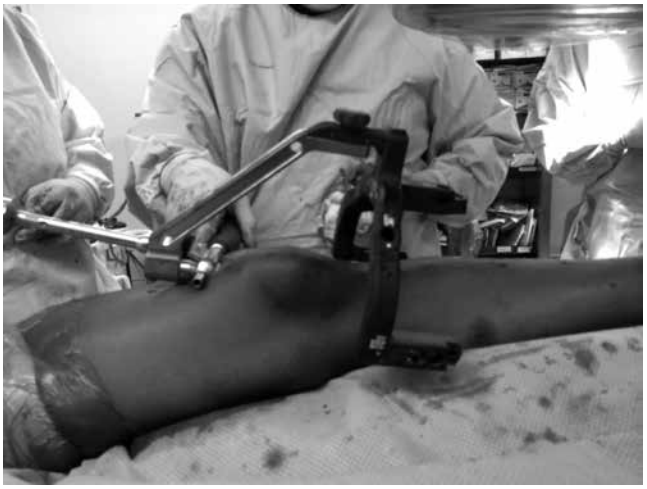

Figure 11. Proximal and distal locking. The aiming arm is placed onto the insertion handle and proximal locking is performed as in infrapatellar nail systems. Distal interlocking bolts are placed using fluoroscopy or computer assistive devices depending on what system is used.

Temple Pearls

Physical Examination of the Foot and Ankle

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The history is certainly the most important beginning for a good foot and ankle examination. The most important question is: "What is the problem and where?" After that, how long has it been affecting the person, how did it start and what was the cause. What makes it worse or makes it better? Also, what treatment has the person had so far? History should include other problems including different arthritic conditions such as rheumatoid arthritis, diabetes, and old, related injuries or conditions.

Examination of the foot follows the pattern of inspection, palpation and manipulation and is made effective because of the (easily accessible) anatomic makeup of the foot and ankle. Further, the exam breaks down the region of the foot and ankle into four sections: the ankle, hindfoot, midfoot, and the forefoot. Of course, thorough knowledge of the anatomy is important as well as an awareness of the common "foot and ankle" problems.

Review of anatomy shows: 26 bones, 28 joints, nine extrinsic muscles and tendons, 20 intrinsic muscles and tendons, three arteries, five nerves and countless ligaments as well as skin and fascial layers. These components are all fairly accessible for examination.

Differential Diagnosis

First, I think a personal list of common problems involving the foot and ankle is helpful in an examination. Here are the most frequent I encounter:

Forefoot

Differential diagnosis includes bunion, hammertoe, bunionette, sesamoiditis, corns and calluses, stress fractures, hallux rigidus, ingrown toenail, Morton's neuroma, fractures of the toes and metatarsals, and metatarsalgia. For problems associated with the cavus foot, I further consider synovitis of the MP joints, cellulitis, ulcers, osteomyelitis. And don't forget rheumatoid arthritis, diabetes, and gout.

Midfoot

Look out for stress fractures of the metatarsals (Jones Fracture), acute fractures of the metatarsals, Lisfranc joint injury, cuneiform fractures, plantar fibromatosis, anterior tarsal tunnel, as well as conditions involving arthritis such as Charcot midfoot and gout.

Hindfoot

Commonly, I see posterior tibial tendon insufficiency, proximal plantar fasciitis, arthritis of the subtalar joint or Chopart's joints, fractures of the talus, calcaneus, cuboid, and navicular (including calcaneal beak and lateral talar process fractures), stress fractures of the navicular and the calcaneus, Charcot foot, infectious processes, ulceration over bony prominences, tarsal coalitions, and Lyme disease.

Ankle

I suspect ankle arthritis, osteochondral lesions of the talus, fractures, Charcot ankle, posterior tibial tendon insufficiency, peroneal tendinitis, tears, or dislocation, achilles tendinitis either mid substance or at the insertion, Achilles tendon rupture, anterior tibial tendon rupture, flexor hallucis longus tendonitis, anterior impingement, retrocalcaneal bursitis, os trigonum syndrome, sprains of the medial, lateral or syndesmotic ligaments.

Physical Exam

A good examination will include an inspection, palpation, and manipulation. It should include an exam during sitting, standing, and gait. Certainly, one should focus on the area of complaint, but I still recommend a complete systematic exam.

Standing Exam

Visualization of the posture on standing from all vantage points should demonstrate the overall alignment of the foot and limb alignment. As the patient is standing, ask yourself the following: is there a high arch (pes cavus), a low arch (pes planus), an average arch (pes rectus)? Is the heel in valgus or varus? Are there other obvious deformities such as bunions or a bunionette or hammertoes; are there any prominences indicating masses or bony protrusions? Are there corns or calluses, any ulceration or notable toenail problems? Is any swelling indicating edema, any ecchymosis or erythema present?

In the midfoot, look for any masses or prominence indicating a cyst or tumors. On the plantar surface, note if swelling is present on the plantar fascia, as seen with plantar fibromatosis. Does the midfoot look normal without gross swelling and in good alignment?

Observe the hindfoot alignment on standing. Is there any swelling of the tendons of the hindfoot (i.e., the peroneals, posterior tibialis or the achilles tendon)? Is there any deformity of the heel? A characteristic of a cavo-varus foot is that when the feet are viewed from the front while standing, you can see the medial aspect of the heel; this is a "peek-a-boo heel." In adult-onset flatfoot (posterior tibial tendon insufficiency), a "too many toes sign" is present; it is seen as the feet are viewed from behind. On the involved side, you can see more toes lateral to the ankle because of the eversion and pronation of the affected foot. You should check for a standing single leg toe raise which is present when there is an intact posterior tibial tendon; this is absent in posterior tibial tendon insufficiency Stage II.

In observing the ankle, look for diffuse swelling in the joint indicating arthritis. Localized swelling anteriorly or laterally may indicate anterior impingement or lateral ankle sprains, respectively. Also note the alignment of the ankle.

Gait Exam

Observe a barefoot gait down a long corridor. Watch one foot through a cycle then the other, noting the stage during which a deficiency occurs. Common problems I encounter are the drop foot gait or an antalgic gait. Observe the heel strike, flat foot and toe off phases. Toe off may be painful in patients with hallux rigidus, and they may push off the lesser toes instead of the great toe.

Sitting Exam

Now examine the foot with the patient seated. As you palpate during this exam, you should continue the inspection of the structures. Again, ask yourself a few questions: is the skin normal looking in color? Is there normal moisture as you feel the skin? Is it dry, cracked, or ulcerated? Do you see calluses or corns (look between toes for soft corns). Is pitting edema or swelling/induration present? Check the dorsalis pedis and posterior tibial pulses. Palpate the foot, noting the specific anatomic structures. Perform a light touch exam noting hypersensitivity and pinprick using a large safety pin. Augment the exam with 5.06 filament for the Semmes Weinstein testing for protective sensation in people with peripheral neuropathies such as diabetes.

Examine the toes for swelling and stiffness and deformity. Is the forefoot tender at the joints or, as in Morton's neuroma, in the interspaces either 3/4 most commonly (85%) or the 2/3 interspace (15%)? The Mulder's test is used for the diagnosis of Morton's neuroma. With pressure on the plantar surface of the foot in the questionable intermetatarsal space, the forefoot is squeezed from medial to lateral at the level of the metatarsal heads. A positive finding will elicit a click and often the pain and numbness at the area from the irritation of the Morton's neuroma. Note the alignment of the toes: are there hammertoe deformities and are they fixed or flexible? Is there a hallux valgus and is it correctable or stiff? Is the great toe MP joint swollen with tenderness and stiffness with often painful, limited motion seen in hallux rigidus? Active dorsiflexion of the great toe MP joint should be 50° of dorsiflexion and 20° of plantarflexion. Are the medial and/or lateral sesamoids tender as seen in arthritis, sesamoiditis or stress fracture?

In the midfoot, is the Lisfranc joint swollen and tender; does it hurt on medial/lateral stress holding the foot proximal to the Lisfranc joint and stressing the joint by manipulating the forefoot? Is there dorsal bossing in the midfoot or prominent tenderness of the navicular tuberosity? The sinus tarsi is tender with arthritis or with fractures of the calcaneal beak, the lateral talar process, and in stage III posterior tibial tendon insufficiency. Are the anterior tendon tibial and the extensor hallucis longus tendons palpably and visibly intact? To examine for subtalar joint motion, check by rocking the heel medially and laterally while securing the ankle. This motion should be between 10 and 15° with inversion to eversion. Are there any firm, hard, subcutaneous, fixed "lumps" on the medial border of the plantar fascia — such as in plantar fibromatosis? A significant occult injury (a stress fracture) to the tarsal navicular not seen by initial x-rays often can be diagnosed (suspected and confirmed by MRI) by direct palpation on the body of the navicular.

Examining the hindfoot, note the posterior tibial tendon and the presence of swelling and tenderness along with a valgus heel. Note the peroneal tendons for the presence of swelling and tenderness behind the lateral malleolus, as seen with tendinitis or tearing. Do the tendons subluxate with active motion, especially plantarflexion with inversion and eversion? There also can be tenderness and swelling of the peroneals along the calcaneus — especially involving the p. longus ("POPS" syndrome). Is the Achilles swollen at the insertion with a "pump bump" (insertional Achilles tendinosis) or is the swelling and tenderness at the midsubstance? In the midsubstance Achilles tendinosis, the prominence migrates proximal and distal with plantar flexion and dorsiflexion. If it's a tendonitis, seen usually in younger individuals, the process involves only the tenosynovium, not the tendon, so plantar flexion and dorsiflexion does not move this "mass." Squeezing the calcaneus medial/lateral will also elicit significant pain in someone with a stress fracture of the calcaneus which is not rare especially in active runners. Is there swelling of the Achilles tendon with a palpable gap in the middle indicating a rupture? If this is the case, the Thompson test will be positive. This exam is done with the patient prone with the knee flexed and the patient as relaxed as possible; the test is simply squeezing the calf muscle. When the tendon is intact, the ankle passively plantarflexes. A positive test is noted when no motion is observed by squeezing. In addition, after a tear, the rest position of the foot usually does not assume the normal 20° plantarflexion, but is more at a 90° or neutral position since the Achilles tension has been disrupted. Last, note tenderness posteriorly at the ankle indicating a retrocalcaneal bursitis or possibly an FHL tendinitis or os trigonum.

Is the ankle joint swollen and deformed; is there an effusion? Is there local tenderness at the anterior lateral aspect indicating an ankle sprain or a fibular fracture? Check for medial malleolar tenderness. Anterior ankle tenderness indicating some ankle impingement is accompanied with pain on dorsiflexion anteriorly as well. Some tenderness anteromedial or anterolateral on forced plantarflexion of the ankle with direct palpation at the ankle joint can indicate a possible talar osteochondral lesion.

Specific stress testing of the ankle includes anterior drawer at neutral to 20° of plantarflexion for the anterior talofibular ligament; varus stress with the ankle in neutral for the calcaneal fibular ligament, and the external rotation or Kleiner's test for syndesmotic injury. Valgus stress for the deltoid can also be done with the ankle in dorsi, plantar, and neutral flexion to test the components of this ligament. Ankle motion should include 10–20° of dorsiflexion and up to 50° of plantar flexion. The Silverskiold test for discernment of Achilles versus gastrocnemius tightness compares ankle dorsiflexion with the knee flexed versus ankle dorsiflexion with the knee fully extended. If ankle dorsiflexion is good with the knee flexed but decreased with the knee extended, the tightness is in the gastrocnemius muscle not in the Achilles.

Muscle testing includes the anterior tibialis with resisted dorsi flexion and inversion; posterior tibialis plantarflexion and inversion; peroneus longus and brevis with plantarflexion and eversion. To differentiate the peroneus brevis from the p. longus, force the first ray into plantarflexion diminishing the pool the p. longus, EHL tested with the foot and ankle at neutral (L5), and the FHL of the ankle and foot in neutral (S1).

Sensation testing over the dorsum of the foot for the superficial peroneal nerve, between the first and second toes distally to test the deep peroneal nerve, the dorsal lateral foot for the sural nerve, and the medial and lateral plantarfoot respectively for the medial and lateral plantar nerves. Again, the 5.06 filament (Semmes-Weinstein) to test protective sensation in the neuropathic patient.

In summary, listen to the patient, look well and use your fingers to feel all the anatomy; the foot does hide much from a good examiner.

Original Research

Prospective Evaluation of Pronator Quadratus Repair Following Volar Plate Fixation of Distal Radius Fractures

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Abstract

Purpose: To evaluate the efficacy of PQ repair following volar plating of distal radius fractures.

Methods: All consecutive distal radius fractures treated operatively with a volar plate during a one-year period were assigned to receive a repair of the PQ versus no repair. Surgical exposure, reduction, and the postoperative rehabilitation were equivalent in both groups. Clinical outcomes with a minimum follow-up of 12 months were assessed via range of motion, grip strength, Disabilities of the Arm, Shoulder, and Hand scores, and visual analog scale scores.

Results: Sixty consecutive distal radius fractures were treated operatively with a locking volar plate. Full follow-up data were available for 33 patients in the PQ repair group and 24 patients in the control group. At 12 months, the mean Disabilities of the Arm, Shoulder, and Hand score was eight for the repair group and five for the control group. Range of motion at the wrist, grip strength, and visual analog scale scores were also not significantly different between groups. Additionally, no significant differences were found in any of the parameters at the two, six, or 12-week intervals except greater grip strength and wrist flexion was observed in the repair group at six weeks. Reoperation was required for four patients in the repair group and one patient in the control group.

Conclusion: PQ repair following volar plating of a distal radius fractures did not significantly improve postoperative range of motion, grip strength, or DASH and VAS scores at one year. The rates of reoperation between groups were not significantly different.

Introduction

Distal radius fractures are among the most common fractures of the skeleton and are estimated to account for 2.5% of all visits presenting to the emergency room.[1] As the treatment of this common injury has evolved, internal fixation with the volar locking plate has gained popularity as a method of contemporary surgical management.[2] Volar plate fixation has the advantages of obtaining articular fragment stability, a relatively low risk of tendon rupture, and early return to motion and functional strength.[3–9] However, in order to gain access to the fracture site through the volar approach, the pronator quadratus muscle (PQ) must be released and elevated. Controversy surrounds the merits of its subsequent repair, which theoretically augments postoperative clinical function, stability of the distal radioulnar joint, and soft tissue coverage over the hardware. Opponents of the PQ repair claim that the quality of the tissue often precludes a durable repair, and outcomes studies are universally good regardless. However, since PQ repair was first advocated by the early technical descriptions of volar plating, one retrospective study has formally challenged this assertion.[9]

The purpose of this prospective trial was to evaluate the outcomes following volar plate fixation for distal radius fractures as a function of pronator quadratus repair. We assessed outcomes primarily through range of motion, grip strength, Disabilities of the Arm, Shoulder, and Hand (DASH) scores, and visual analog scale (VAS) scores. We secondarily compared the incidence of reoperation and postoperative complications such as tendon rupture, tendonitis, neuritis, malunion, and nonunion.

Materials and Methods

A double-blinded prospective clinical trial was conducted from January 2011 to December 2011. Institutional review board permission was obtained, and all patients signed an informed consent. Sixty consecutive distal radius fractures treated operatively with a volar plate were assigned into one of two groups. Repair of the PQ was performed in the study group, and no repair of the PQ was performed in the control group. The patients were blinded to their respective study group. For ease of facilitation, patients born with an odd birth year were assigned to the repair group, while those born with an even birth year were assigned to the control group. Patient demographics such as age, hand dominance, co-morbidities, fracture severity, and presence of concurrent ulnar styloid fracture were recorded. The senior author (A.I.) classified all fractures in a blinded manner using the AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation) classification system. Surgical exposure, reduction, and the postoperative rehabilitation were similar in both groups. Two patients were

lost to follow-up before one-year and were excluded from the final analysis. One patient with an ipsilateral elbow fracture-dislocation was also excluded.

Surgical Technique

All surgical procedures were performed by a single orthopedic hand surgeon. Either regional or general anesthesia was used in all cases with tourniquet control. The volar distal radius was exposed through a flexor carpi radialis approach. The PQ was released along its distal and radial borders and elevated in a sub-periosteal fashion ulnarly with care being taken not to violate the muscle or compromise its neurovascular pedicle inserting on the ulnar side from the interosseous membrane. All fractures were repaired with one of two variable-angle volar locking plates: a Medartis APTUS plate (Kennett Square, PA) or a Synthes 2.4 Variable-Angle LCP two column plate (Paoli, PA). In the repair group, repair of the PQ was performed over the plate with 4–5 interrupted figure-of-eight 2-0 vicryl sutures to return the released edges of the PQ to the radial and distal borders of the radius. Repair of the muscle was achieved in all attempted cases, although varying degrees of muscle injury were observed. In the control group, the PQ was placed back to its anatomic position but was not repaired with sutures.

Post-Operative Management

Immediately following surgery, the patient was encouraged to elevate the hand and begin early and unrestricted finger motion. The postoperative soft dressing was maintained for 10–14 days until the first follow-up visit. At that visit, the dressings and sutures were removed, radiographs were taken, and therapy was started under the supervision of a certified hand therapist. A pre-fabricated orthosis was also applied for comfort and protection, but its use was optional. During weeks two through six, an aggressive anti-edema protocol was initiated along with tendon gliding and range of motion exercises. At six weeks postoperatively, the patients were re-evaluated and advanced to progressive strengthening and resistance exercises upon evidence of sufficient interval healing by radiographs and clinical exam. Additionally, use of the orthosis was discontinued. During re-evaluation at 12 weeks postoperatively, the patients were advanced to a work hardening program or discharged from therapy depending upon occupational needs, and orthosis use would be terminated. A final visit was performed 12 months postoperatively. An equivalent postoperative protocol was used for all patients irrespective of the study arm.

Assessment of Outcomes

The primary outcome measure was the DASH score. Secondary outcome assessments included measurements of the VAS score, range of motion, and grip strength. A blinded orthopedic nurse obtained all of the outcome measurements during the follow-up visits. Wrist flexion, extension, radial-ulnar deviation, and forearm rotation measurements were recorded with a goniometer. Grip strength was measured with a dynamometer (Jamar; Therapeutic Equipment, Clifton, New Jersey) with the elbow at 90 degrees and the wrist in neutral rotation. These measurements were compared to the uninjured side and expressed as a percentage. All patients were assessed at two, six, 12, and 52 weeks after surgery. The senior surgeon also analyzed radiographs at the same intervals for evidence of fracture healing and maintenance of reduction.

Statistical Analysis

Hypothesis testing was performed using the Fisher exact test for categorical values and a student t-test for continuous variables. Probability *(P)* values for the outcomes measures were generated with an analysis of variance. Statistical significance was defined as a *P*-value less than 0.05.

Source of Funding

No external source of funding was used for this study.

Results

A total of 57 patients were reviewed; PQ repair was performed in 33 subjects, and no repair was performed in 24 subjects. Basic demographics are summarized in Table 1. Concurrent procedures were performed in four patients in the control group and in three patients in the repair group. Ulnar fracture was identified in 17 patients of the control group and in 20 patients of the repair group. Concurrent pinning of the ulna was indicated in two cases in the control group and one case in the repair group. Concurrent carpal tunnel release at the time of plating was indicated in two cases for each group. The groups were also compared with respect to fracture severity by the AO/ASIF classification system. The differences in fracture severity between the groups were not found to be significant. Range of motion measurements at each time interval are shown in Table 2.

Table 1. Basic Demographic Information

	No Repair	PQ Repair	*P*
Demographics			
Patients (n)	24	33	
Median Age (years)	62 (range 30–89)	55 (range 16–83)	
Mean Age (years)	60 (sd 13.7)	51 (sd 18.9)	0.04
Male (%)	25	27	1.00
Concurrent Ulnar Pin (n)	2	1	0.57
Concurrent CTR (n)	2	2	1.00
Dominant Hand Injury (n)	10	23	0.06
Reoperations (n)	1	4	0.39
Associated Ulna Fracture			
No ulnar fracture (n)	7	13	0.26
Ulnar styloid fracture (n)	13	18	
Ulnar neck fracture (n)	4	1	
Ulnar base fracture (n)	0	1	
AO Classification			
A	2	8	0.26
B	1	1	
C	21	24	

Table 2. Range of Motion Measurements at Follow Up Intervals

	2 Weeks		6 Weeks		3 Months		12 Months	
	PQ Repair	No Repair	PQ Repair	No Repair	PQ Repair	No Repair	PQ Repair	No Repair
Extension	29°	29°	59°	52°	74°	71°	83°	80°
Flexion	33°	39°	58°*	47°*	74°	69°	84°	81°
Pronation	77°	75°	83°	81°	86°	84°	84°	84°
Supination	67°	56°	78°	71°	85°	84°	88°	86°
Ulnar deviation	31°	14°	31°	26°	34°	38°	36°	35°
Radial deviation	7°	8°	16°	11°	18°	18°	19°	20°

*Statistically significant difference

Outcomes assessed at two weeks did not demonstrate any significant differences in mean DASH score, VAS score, grip strength, or range of motion. At six weeks, grip strength and flexion in the repair group were significantly greater than that of the control group, but all other variables were not significantly different. Significant differences were similarly not observed in any of the variables at three months or one year. At final follow-up, the mean DASH score was eight for the repair group and five for the control group. In both groups, grip strength was 95% of the uninjured side, and VAS scores averaged below 0.5. The mean values of all variables demonstrated a stepwise improvement over the year, as range of motion and grip strength consistently increased, and DASH and VAS scores consistently decreased (Figures 1–3).

In the repair group, one patient developed extensor pollicis longus tenosynovitis, and three patients presented with late symptoms of carpal tunnel syndrome; all four of these cases required a reoperation for hardware removal or carpal tunnel release. In the control group, one case of extensor carpi radialis longus and brevis tenosynovitis required reoperation and plate removal. No cases of flexor tendonopathy, nonunion, hardware failure, infection, or acute carpal tunnel syndrome were observed.

Discussion

The frequency of volar plating as a treatment for unstable distal radius fractures has increased in recent years.[2] Numerous studies have reported outcomes in the good to excellent range on patient-rated scoring systems and with a relatively low rate of complications.[4–9] For example, Gruber et al. described their prospective case series on 54 distal radius fractures treated with volar plating and noted an average DASH score of five at two years and 13 at six years with no patients experiencing flexor tendonopathy.[5] Similarly, Arora et al. prospectively compared operative and nonoperative management of unstable distal radius fractures in the elderly, and in the 36 cases treated with open reduction internal fixation, the average DASH score at 12 months was six, and four patients experienced flexor tendonopathy from prominent hardware.[6] Our overall results were consistent with previous reports. We did not experience any cases of nonunion, and all subjects healed in a radiographically acceptable position.

Whether or not repair of the PQ is necessary after volar plating has been a topic of debate. Our study did not detect any significant differences between the PQ repair group versus control in mean grip strength, range of motion, DASH, or VAS scores for any of the study intervals within the first year. A study by Hershman et al. has also examined outcomes of volar plating as a function of the PQ repair. In their retrospective review of 112 patients, 62 patients underwent repair of the PQ, and no significant differences were found in mean grip strength, range of motion, DASH, or VAS scores when compared to the control group at one year. Four cases required reoperation: two for extensor pollicis longus rupture, one for intra-articular screw penetration, and one for flexor tendon irritation, which occurred in the repair group.[9]

A recent survey of 608 hand surgeons reported that 83% routinely attempted a repair of the PQ after fixation.[17] This trend likely stems from the first technical descriptions of

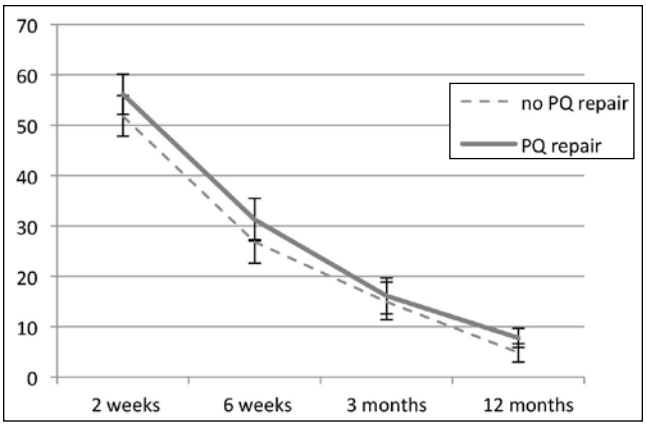

Figure 1. One-year trend of mean Disabilities of the Arm, Shoulder, and Hand scores following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

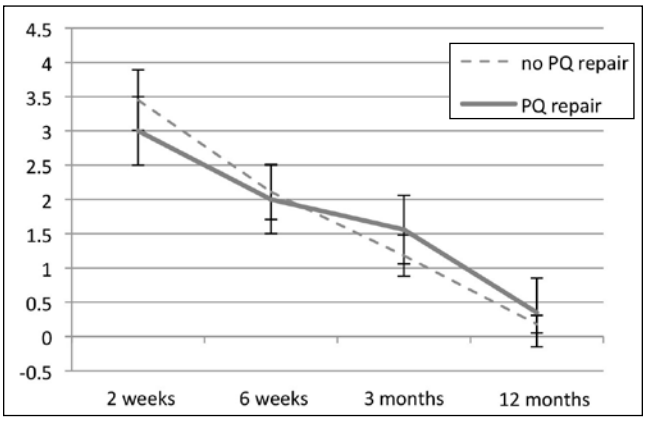

Figure 2. One-year trend of mean visual analog scale scores following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

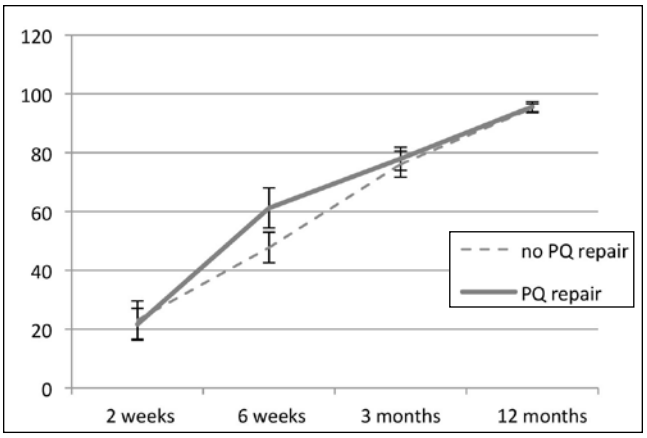

Figure 3. One-year trend of mean grip strength following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

volar plating in which PQ repair was thought to augment wrist strength, DRUJ stability, and soft tissue coverage over the plate.[3] Subsequently, several authors have suggested that interposing the PQ between plate and flexor tendons may provide additional protection to the flexor tendons by reducing friction and attritional injury during tendon gliding.[3, 18, 19]

Conversely, opponents of the PQ repair raise several questions with respect to its proposed advantages. First, no evidence exists that supports any of the proposed benefits of PQ repair, and theoretical disadvantages such as over-tight repair, PQ space compartment syndrome, or iatrogenic radial artery injury have alternatively been proposed.[18, 19] Second, some of the purported advantages of PQ repair can be explained, at least in part, by other factors. Placement of the locking plate proximal to the watershed line has been suggested as the key technical feature that reduces flexor tendon complications after plating.[10–16] White et al. reviewed their experience with 999 distal radius fractures treated via volar locking plates and found that six cases were complicated by nine flexor tendon ruptures, and a prominent volar plate was observed in all cases.[16] Additionally, Soong et al. reported that flexor tendon rupture occurred in three of their 73 cases, while Arora et al. described nine cases of flexor tenosynovitis in 141 cases; in both of these studies, volar prominence of the plate was suggested as the causative factor despite the fact that the PQ was routinely repaired.[12, 14] Brown and Lifchez found that even though the PQ was repaired, the flexor pollicis longus tendon had eroded through muscle and was partially lacerated on a prominent plate at the time of revision surgery.[20] A cadaveric study by Tanaka et al. similarly provided evidence to suggest that an improperly placed plate distal to the watershed line increases contact pressures at the plate-tendon interface and thus negates the anatomic advantages of the concave volar distal radius regardless of the interposed soft tissue.[21]

Other purported benefits such as increased distal radioulnar joint stability and greater wrist strength are also less convincing arguments in that the PQ is a relatively minor contributor to both of these functions.[22–25] Chirpaz-Cerbat et al. and Armangil et al. had shown that 12–19% of pronation strength may be lost when compared to the unaffected side after volar plating of the distal radius.[26, 27] However, a similar study by Huh et al. had shown no differences at one year.[28] In all the above studies, the PQ was released for exposure and subsequently repaired if possible. Alternatively, submuscular elevation of the PQ has been proposed to spare the dissection from the radial edge, but currently no biomechanical studies of post-surgical strength testing have been documented for this technique.[29]

The present study has limitations. One-year follow-up may not identify all of the potential complications such as tendon rupture, the need for hardware removal, or symptomatic post-traumatic arthritis. Although patients may present with late symptoms of flexor tendonopathy, many case studies have shown that tendon rupture and symptoms of impending rupture typically occur within 12 months after surgery.[6–9, 11, 13, 15, 16] Furthermore, we do not know whether or not the repairs were durable. However, a prospective trial by Swigart et al. assessed the durability of the PQ repair after volar plating and found it intact in 96% of cases at 3-months.[17] Additionally, in the present study, patients were not formally randomized, but rather assigned to groups via their birth year. The average age of the repair group was significantly less than the control group, which may introduce bias, as a younger patient may be more critical of the outcome. Finally, pronation and supination strength testing was not performed.

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Original Research

Posterior Spinal Fusion for Adolescent Idiopathic Scoliosis: Does Rod Material Make a Difference?

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Abstract

Study Design: Retrospective study.

Objective: To determine if there is a difference in initial correction and loss of correction (LOC) at two years after surgery in adolescent idiopathic scoliosis (AIS) patients with main thoracic (Lenke 1) curves undergoing posterior spinal fusion (PSF) and instrumentation with stainless steel (SS) rods, cobalt chromium (CC), and titanium (Ti).

Summary of Background Data: The standard surgical treatment of AIS is PSF and instrumentation with pedicle screws and SS, CC, or Ti rods. Currently, there is no gold standard rod material and studies have supported the efficacy of different rod metals in patients undergoing PSF. Long-term maintenance of spinal correction and fusion is another important goal of surgery. Biomechanical studies have evaluated responses of different rod materials to loading in bench top spinal models. *In vivo* comparison of initial deformity correction and maintenance of correction in patients with SS, CC, or Ti rods for surgical treatment of AIS has not been studied.

Methods: A prospectively collected, multicenter database was retrospectively queried to identify a consecutive series of patients with AIS Lenke type 1 curves who underwent PSF with a two-year minimum follow-up. Two hundred and sixty-five patients met the following inclusion criteria: diagnosis of AIS, Lenke type 1 (main thoracic) curve, Risser stage 2 or greater, age at surgery of 11–18 years, 5.5 mm dual rods of a single metal type (SS, CC, or Ti), and PSF with greater than 80% pedicle screws. Patients were divided into three groups based on whether they underwent PSF with SS (n = 195), CC (n = 34), or Ti (n = 36) constructs. The following radiographic parameters were evaluated preoperatively, at first postoperative (1-PO) visit, and/or at two years postoperatively (2-YP): thoracic Cobb angle, curve flexibility, percent correction, loss of correction, kyphosis, and lordosis. Complications of all three groups were reviewed.

Results: There were no differences in age, gender, thoracic curve flexibility, or Risser stage between groups. Preoperative thoracic curve magnitude was significantly greater in the SS group (51.2 ± 7.3°) compared to the CC (46.0 ± 5.8°) and Ti (47.2 ± 7.3°) groups. The SS group achieved greater coronal deformity correction on first erect radiographs than the Ti group (p = 0.01). No other differences in coronal correction were observed between groups on first postoperative x-rays. Average thoracic percent correction was significantly greater in the SS (71.1%) group compared to both Ti (62.9%) and CC (66.4%). At 2-YP, mean thoracic LOC from first postoperative visit was greater in the SS (3.6°) than CC (2.9°) and Ti (1.6°) groups. A difference in LOC was only significant between SS and Ti (p = 0.02). There were no differences in mean thoracic Cobb angle between groups at 2-YP (CC: 18.4°, SS: 18.4°, Ti 18.9°). However, there was a difference in kyphosis between CC (24°) and Ti (18.8°) at 2-YP without any difference between preoperative and 1-PO between all groups. Postoperative infection rates were 3.1% in SS, 5.9% in CC, and 0% in the Ti group.

Conclusion: In patients with Lenke 1 AIS, Risser stage 2 or greater, and similarly flexible curves undergoing PSF and instrumentation, SS may provide greater initial deformity correction than Ti rods. However, radiographic differences at 1-PO and 2-YP are small and unlikely to be associated with clinical significance. At two years follow-up, all three rod materials appear to provide similar coronal plane deformity correction. CC may impart more anatomic kyphosis than dual Ti rods although clinical differences were not determined. For patients in which infection is a concern, Ti may reduce the risk of infection compared to SS and CC. The decision to implant a given rod material should be based on surgeon preference and comfort.

Introduction

Adolescent idiopathic scoliosis (AIS) involves a complex three-dimensional spinal deformity often with hypokyphosis of the thoracic vertebrae and axial rotation of the ribs and apical spinal segment.[32, 46] Currently, posterior spinal fusion (PSF) with dual rods and segmental spinal instrumentation (SSI) using pedicle screws is the standard of care.[2] Pedicle

screws provide three-column fixation and allow the surgeon to perform transverse plane correction and derotation of the spine with good results.[12, 21, 23, 28, 29] However, to maximize fusion rates and prevent postoperative loss of correction, the construct must be stable with sufficient rod stiffness.[46, 56]

Initial spinal correction during surgery is an important goal and is obtained by reducing the spine to contoured rods.[6, 46] The stiffness of the construct, defined by resistance of an object to deformation under an applied load, is important in not only obtaining the initial correction but maintaining it. A wide variety of rod materials are available including stainless steel (SS), cobalt chromium (CC), titanium (Ti) of varying degrees of strength. However, there is no gold standard rod material and several studies have supported the efficacy of different rod metals despite varying material properties.[34, 46, 54, 56] Choice of rod material for implantation is largely determined by surgeon preference and deformity characteristics, such as curve flexibility and magnitude.

Another important goal of PSF for scoliosis surgery is long-term maintenance of correction and fusion. Rohlmann et al. reported that constructs continue to load share after the fusion mass has solidified which emphasizes the importance of implanting rods with adequate properties to support long-term stability.[44] Loss of coronal plane correction in AIS patients undergoing scoliosis surgery has been well-studied.[9, 27, 39, 41, 43, 50, 55] Risk factors include skeletal immaturity, pseudarthroses, premenarche, implant removal after PSF, and adding-on (worsening of the index curve beyond the level of fusion).[9, 27, 37, 39, 43, 55]

Cyclic loading of rod constructs and surface defects created by rod contouring and notching result in fatigue fracture of rod instrumentation.[13, 14, 30, 36] Optimal rod stiffness has not been defined in the literature although biomechanical studies have shown a relationship between rod stiffness and rod diameter, material type, and manufacturing process.[46, 54] To date, no studies have analyzed the effect of rod material on both initial spinal correction and loss of correction (LOC) over time. The purpose of this study is to determine if there is a difference in initial correction and loss of correction at two years after surgery in AIS patients undergoing PSF and SSI with SS, CC, and Ti rods.

Methods

A prospectively collected, multicenter database of patients with AIS was retrospectively queried to identify a consecutive series of patients with AIS Lenke type 1 curves who underwent posterior spinal fusion with a two-year minimum follow-up. IRB approval for the study was obtained locally from each contributing institution's review board, and consent was obtained from each patient prior to data collection.

The inclusion criteria were diagnosis of AIS, Lenke type 1 (main thoracic) curve, Risser stage 2 or greater, age at surgery of 11–18 years, 5.5 mm dual rods of a single metal type (SS, CC, or Ti), and PSF with greater than 80% pedicle screws. Patients with diagnoses other than AIS, outside the range of 11–18 years old, those who underwent anterior release or thoracoplasty, and treatment with less than 80% pedicle screws were excluded.

Patients were divided into three groups based on whether they underwent PSF with SS, CC, or Ti constructs. In all three groups, demographic data including age at surgery, gender, lumbar modifier (A, B, or C), Risser stage, and thoracic curve flexibility were analyzed to ensure homogeneity between patients. Thoracic curve flexibility was measured on lateral bending films. Additional parameters including thoracic Cobb angle; loss of coronal correction; coronal balance; Kyphosis (T5–T12); and lordosis (T12–sacrum) were compared between groups at three time points (preoperative [preop], first erect postoperative [1-PO], and two-year postoperative [2-YP]). Radiographic changes in coronal and sagittal plane correction from 1-PO to 2-YP were analyzed to identify loss of correction within each group over time.

Statistical Analysis

A one-way analysis of variance (ANOVA) was performed to compare all three groups (SS, CC, or Ti) in regards to demographic and radiographic parameters. Statistical analysis was performed using SPSS 12.0.2 statistical package (SPSS Inc., Chicago, IL). A p-value less than 0.05 was used to denote statistical significance.

Results

Patient Demographics [Table 1]

Two hundred and sixty-five patients with Lenke type 1 AIS were included in our study. Eighty-one percent (215/265) were female and 18.9% (50/265) were male with an average age at time of surgery of 15.2 ± 2.1 years. The mean preoperative main thoracic Cobb angle measured 51.2 ± 7.3°, 46.0 ± 5.8°, and 47.2 ± 7.3° in the SS, CC, and Ti groups, respectively.

Table 1. Patient Demographics

	Cobalt Chrome	Stainless Steel	Titanium	Total	p-value
Patients (n)	34	195	36	265	
Age ± SD (years)	15.1 ± 2.1	15.2 ± 2.1	15.4 ± 2.2	15.2 ± 2.1	0.74
Gender (%)					0.10
Females	91.2	78.0	88.9	81.1	
Males	8.8	22.0	11.1	18.9	
Lumbar Modifier (%)					0.58
1A	61.8	58.0	50.0	57.4	
1B	23.5	18.4	19.4	19.2	
1C	14.7	23.6	30.6	23.4	
Risser Stage (%)					0.79
2	11.8	15.5	5.7	13.7	
3	23.5	18.0	20.0	19.0	
4	50.0	47.4	54.3	48.7	
5	14.7	19.1	20.0	18.6	

Patients are Lenke 1, Risser 2 or higher, 80% PS, 5.5mm rods, no thoracoplasty's or anterior releases. SD = Standard Deviation.

Comparison of Patients with Cobalt Chromium, Stainless Steel, and Titanium Rods [Table 2]

Thirty-four patients underwent PSF with dual rods made of CC, 195 patients were treated with SS rods, and 36 were treated with Ti rods. There were no significant differences between the groups in regards to gender (p = 0.10), lumbar modifier (p = 0.58), Risser stage (p = 0.79), or thoracic curve flexibility.

There were significant differences in preoperative thoracic Cobb angle between SS and Ti (p = 0.02), and between SS and CC (p = 0.01) with the SS group demonstrating greater curvatures. Preoperative thoracic curve magnitude was not different between CC and Ti (p = 0.54). Preoperative radiographic parameters were not significantly different between any of the groups in regards to coronal balance (C7–CSVL), kyphosis (T5–T12), or lordosis (T12–sacrum).

Patients treated with SS rod constructs exhibited the greatest degree of correction despite having significantly larger thoracic curvatures preoperatively as shown by SS's superiority in thoracic curve percent correction (71.1 ± 11.5%) versus CC and Ti (66.4 ± 11.1% and 62.9 ± 10.3%, respectively) (Figure 1). At 1-PO the average thoracic Cobb angle in the SS group measured 14.8 ± 6.3°, Ti measured 17.3 ± 4.7°, and CC measured 15.5 ± 5.5°. The difference between SS and Ti at 1-PO was significant (p = 0.01) with no differences between any other group comparisons. No differences in coronal balance, kyphosis, or lordosis between groups were found at 1-PO.

At 2-YP, there were no differences in thoracic Cobb angle, thoracic curve percent correction, coronal balance, or lordosis between any groups. Despite differences in preoperative and 1-PO thoracic Cobb angle, average curve magnitude for all 3 groups were approximately 18° at 2-YP. However, a difference in kyphosis was found between CC (24.0 ± 8.1°) and Ti (18.8 ± 6.5°) at 2-YP (p = 0.02) although both groups exhibited similar kyphosis at 1-PO.

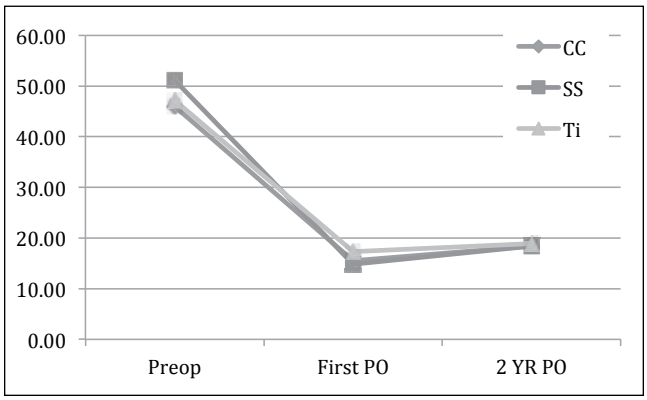
Loss of correction from 1-PO to 2-YP was found for certain radiographic parameters (Figure 2). Ti was the only

Table 2. Radiographic Measurements

	SS	CC	Ti	SS vs Ti p-value	CC vs SS p-value	CC vs Ti p-value
Thoracic Per. Flex. ± SD (%)	47.5 ± 19.4	43.9 ± 21.3	40.9 ± 17.4	0.33	0.06	0.53
Thoracic ± SD (°)						
Pre-op	51.2 ± 7.3	46.0 ± 5.8	47.2 ± 7.3	**0.02**	**0.01**	0.54
First Post-op	14.8 ± 6.3	15.5 ± 5.5	17.3 ± 4.7	**0.01**	0.28	0.12
2 Year Post-op	18.4 ± 7.1	18.4 ± 5.7	18.9 ± 6.5	0.50	0.60	0.91
p-value First Post-op to 2 Years	**0.01**	**0.01**	0.45			
Thoracic Per. Corr. ± SD (%)						
First Post-op	71.1 ± 11.5	66.4 ± 11.1	62.9 ± 10.3	**0.01**	**0.03**	0.17
2 Year Post-op	63.9 ± 13.2	60.3 ± 10.9	59.2 ± 15.3	0.06	0.14	0.74
p-value First Post-op to 2 Years	**0.01**	**0.02**	0.24			
Thoracic Loss of Corr. First Post-op to 2 Years						
Abs. val. ± SD (°)	3.6 ± 5.0	2.9 ± 3.1	1.6 ± 4.9	**0.02**	0.51	0.20
Percent ± SD (%)	16.8 ± 28.8	15.3 ± 18.3	3.8 ± 26.4	**0.01**	0.52	0.12
Coronal Balance (C7-CSVL) ± SD (cm)						
Pre-op	–0.1 ± 2.0	–0.1 ± 1.9	-0.6 ± 1.7	0.11	0.89	0.27
First Post-op	–1.0 ± 1.8	–0.7 ± 1.7	-0.6 ± 2.0	0.21	0.39	0.79
2 Year Post-op	–0.6 ± 1.3	–0.4 ± 1.5	-0.4 ± 1.6	0.44	0.51	0.95
p-value First Post-op to 2 Years	**0.01**	0.28	0.41			
Kyphosis (T5-T12) ± SD (°)						
Pre-op	19.9 ± 13.4	20.3 ± 11.6	20.6 ± 10.7	0.52	0.74	0.82
First Post-op	19.8 ± 7.3	20.7 ± 7.4	17.2 ± 7.2	0.13	0.55	0.11
2 Year Post-op	21.9 ± 8.2	24.0 ± 8.1	18.8 ± 6.5	0.08	0.20	**0.02**
p-value First Post-op to 2 Years	**0.01**	0.05	0.32			
Lordosis (T12-Sacrum) ± SD (°)						
Pre-op	–57.1 ± 11.0	–56.3 ± 13.0	–58.8 ± 11.9	0.41	0.64	0.33
First Post-op	–52.4 ± 10.9	–51.8 ± 12.5	–50.8 ± 12.5	0.49	0.70	0.82
2 Year Post-op	–58.1 ± 12.1	–61.7 ± 12.3	–57.0 ± 12.2	0.67	0.11	0.11
p-value First Post-op to 2 Years	**0.01**	**0.01**	**0.01**			
Complications n (%)						
Infection	6 (3.1)	2 (5.9)	0 (0)			
Pseudarthrosis	0 (0)	0 (0)	0 (0)			
Revision surgery	0 (0)	0 (0)	0 (0)			

CC = Cobalt Chrome, SS = Stainless Steel, Ti = Titanium, SD = Standard Deviation. Negative values denotes a left-sided curve in the coronal plane and lordosis in the sagittal plane.

Figure 1. Change in Thoracic Cobb Angle from Preoperative to Two-Year Follow-Up in Patients with CC, SS, and Ti Rods



CC = Cobalt Chrome, SS = Stainless Steel, Ti = Titanium, PO = Postoperative

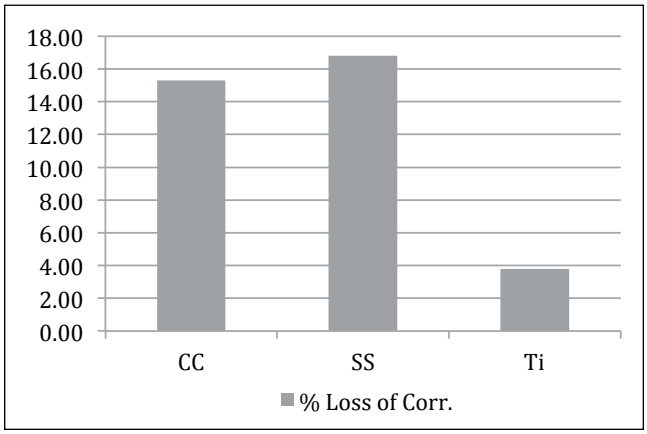
metal to maintain thoracic curve correction while SS and CC lost a mean of 3.6 ± 5° (16.8 ± 28.8%) and 2.9 ± 3.1° (15.3 ± 18.3%), respectively (p = 0.01). Analysis revealed significant loss of correction for SS compared to Ti (p = 0.02), and no difference between either CC and Ti, or CC and SS. Change in coronal balance from 1-PO to 2-YP was significant only for the SS group; however, mean coronal balance changed from only 1° to 0.6°. Similarly, SS was the only group to have a significant loss of kyphosis (p = 0.01) despite a relatively small change in average kyphosis from 19.8 ± 7.3° to 21.9 ± 8.2°. All groups had a significant change in average lordosis from 1-PO to 2-YP (CC: 9.9°, SS: 5.7°, Ti: 6.2°, p = 0.01).

Complications

The SS group had six infections (3.1%): two superficial and four deep. The superficial infections resolved with oral antibiotics and all deep infections resolved after incision and drainage (I&D) and intravenous (IV) antibiotics. Two of the 34 patients (5.9%) in the CC group developed infections: one superficial infection that resolved with oral antibiotics and one deep infection that resolved after I&D and IV antibiotics. There were no infections in the Ti group.

No patients developed pseudarthrosis or required revision surgery by two-years follow-up.

Figure 2. Loss of Correction Between Groups from First Postoperative Visit to Two-Year Follow-Up



CC = Cobalt Chrome, SS = Stainless Steel, Ti = Titanium, PO = Postoperative

Discussion

Scoliosis surgery for the treatment of AIS has seen many developments over the years from the Harrington rod construct to Cotrel-Dubousset instrumentation and, later, segmental fixation and derotation via pedicle screws.[15, 22, 31, 53] Currently, PSF and instrumentation with pedicle screws is the gold standard for correction of spine deformity in patients with AIS due to their superior pullout strength and three-column fixation compared with other fixation constructs such as hooks and sublaminar wires.[8, 21, 23, 24] PSF with pedicle screws is also safe with a low rate of complications such as infection, pseudarthrosis, neurologic deficits, and revision surgery.[18, 31, 51, 52]

Initial intraoperative correction and long-term maintenance of correction are important objectives of PSF. Various components of AIS surgery include sagittal and coronal plane deformity correction, derotation of vertebrae, and achieving optimal sagittal and coronal balance. Surgical techniques performed to obtain maximal correction include osteotomies, adjusting the extent of fusion, specific derotation maneuvers, and selecting a rod implant material that is best suitable for the curve characteristics. Maintaining the initial surgical correction is another important component of surgical management. Traditionally, a stiffer rod material such as SS or CC is selected for stiffer, more rigid curves with the goal of maintaining the coronal and sagittal profile of the spine. Loss of correction after PSF varies in the literature with rates between 12–54%.[1, 25, 43, 50] Causes of LOC include skeletal immaturity, pseudarthrosis, loss of fixation, removal of instrumentation, and crankshaft.[16, 25, 39, 43] In order to preclude the effect of skeletal immaturity on curve progression, our study only included patients of Risser stage 2 or greater.

Posterior spinal fusion for AIS can be performed with Ti, CC, or SS metals of varying grades. Titanium rods have the advantage of MRI-compatibility, corrosion resistance, and greater resistance to infection than SS and CC-based spinal constructs.[26, 30, 48, 49] An additional advantage of Ti is greater resistance to plastic deformation than SS and CC.[46, 54] SS rods are similar in stiffness to CC and produce greater correctional forces compared to Ti due to their greater elastic modulus.[46] SS is less likely than Ti to form stress risers during plate bending, which can shorten fatigue life.[3] However, SS is susceptible to fretting and crevice corrosion especially when rigid interconnections between rods are used.[26] Advan-

tages of CC include long-term corrosion resistance, biocompatibility with Ti screws, high tensile strength, and less MRI artifact production than SS rods.[3, 45]

Few studies have investigated the differences between rod materials in PSF for scoliosis patients. Upasani et al. studied plastic deformation of 5.5 mm Ti and SS rods by implanting rods of varying degrees of kyphosis into an 11-level, rigid, spinal model.[54] Ti rods maintained a 20° pre-contoured shape better than SS; however, all rods plastically deformed when pre-contoured to 30° and 40°. Serhan et al. used a synthetic spine model to compare the effect of rod curvature and material properties on rod flattening and correctional forces, and found that Ti was superior to SS and CC at maintaining its original shape in 20° and 30° pre-contoured rods.[46] We report similar findings with Ti demonstrating less plastic deformation than CC and SS in the sagittal and coronal plane despite greater stiffness of the latter two metals. In our study, Ti rods lost a mean of 1.6° of coronal thoracic curvature, and SS and CC rods deformed a mean of 3.6° and 2.9°, respectively. SS and CC's greater susceptibility to plastic deformation compared to Ti can be explained by different yield strengths. A material's yield point is the stress at which a material ceases to behave elastically or, similarly, plastically deforms. Titanium alloys, despite lesser stiffness, exhibit a greater yield point than standard 316L SS and CC alloys and are therefore better able to resist plastic deformation.[3]

In the sagittal plane, patients with SS rods underwent a significant radiographic change in kyphosis from 1-PO to 2-YP, and the CC group's loss of kyphosis approached, but did not reach, significance ($p = 0.05$). At 2-YP, only the difference in kyphosis between CC and Ti was significant with the former group averaging more kyphosis ($24.0 \pm 8.1°$ vs. $18.8 \pm 6.5°$, respectively). Ti better resisted sagittal plane plastic deformation at final follow-up although this may not be desirable in AIS patients. AIS is associated with hypokyphosis and, often, imparting greater kyphosis is a goal of surgery.[8] Our findings could be interpreted as Ti being inferior to CC in its ability to produce kyphosis. However, differences in kyphosis may reflect changes in instrumentation technique over time, such as over-bending rods. There were no differences in preoperative, 1-PO, or 2-YP lordosis between groups and no patients had a diagnosis of spondylolisthesis, hamstring contractures, or neuromuscular disease that would affect lumbar lordosis. Lastly, there were no differences in coronal balance between groups and no significant change from 1-PO to 2-YP in patients with CC and Ti rods. Patients with SS rods demonstrated a significant loss of coronal balance but the overall mean LOC was small (0.4°). The clinical relevance of these findings is unclear but likely insignificant.

Serhan et al. also measured correctional force differences between different rods, and found that CC and ultrahigh-strength SS produce greater correctional forces than Ti-based rods.[46] We found significantly greater thoracic correction in the SS group compared to Ti and CC, which may reflect SS's properties as a stiffer metal. Thoracic curve percent correction was most notable between SS ($71.1 \pm 11.5\%$) and Ti ($62.9 \pm 10.3\%$). No difference was found between CC and Ti. Our findings suggest that SS may be preferable for obtaining correction in larger, main thoracic curves. Apart from rod material, the surgeon must also consider that corrective forces produced during spinal surgery are correlated with the distance between the spine and rod, pedicle screw fixation and configuration, and use of monoaxial versus polyaxial screws.[10, 35, 38, 46] Although we report differences in magnitude of initial correction and LOC, we are reluctant to draw conclusions regarding the superiority of any one rod material because no differences were found in thoracic Cobb angle at 2-YP with all groups exhibiting 18° of coronal curvature. Our study also included patients with similarly flexible, Lenke type 1 curves and this could explain the comparable amount of correction obtained between groups. Additionally, Cobb angle measurement error varies approximately 4–8° and may account for significant differences between groups.[4, 20]

Titanium is not without its disadvantages. Purported drawbacks of the metal include susceptibility to notching and lower fatigue resistance compared to stiffer metals. In general, rod failure is secondary to repetitive loading well below the yield point of the metal.[30] Lindsey et al. studied differences in fatigue resistance of Ti and SS rods and reported significantly lower fatigue life of contoured Ti compared to SS rods and straight Ti rods.[30] The authors concluded that bending of Ti rods creates surface irregularities responsible for decreased fatigue resistance. Another concern regarding Ti is its greater flexibility and greater deformation under an equivalent stress than a stiffer metal, such as SS.[56] Our study focused on patients with relatively short-term follow-up which may be one reason we did not have patients requiring revision surgery due to instrumentation failure.

Infection after PSF for AIS is reported to be between 2.7% and 6.9%.[11, 40, 42] An association between fretting corrosion, subsequent inflammation, and delayed infection has been postulated.[17, 40] Dubousset et al. reported that micromotion producing metal debris and a granulomatous reaction was a risk factor for postoperative infection.[17] Kirkpatrick et al. used surface analysis stereomicroscopy to study fretting and corrosion in modular spine implants and found that Ti-based implants did not demonstrate corrosion but SS implants with rigid interconnections were most susceptible to corrosion.[26] Only one CC construct was included and did not show any evidence of corrosion. Studies have supported a lower incidence of infection and bacterial adherence with Ti-based constructs compared to other metals.[11, 47, 48] DiSilvestre et al. performed a retrospective case series of 540 patients with AIS who underwent PSF and found a significantly lower incidence of infection in patients with Ti rods (4/15) than in

patients with SS rods (11/15) and concluded that Ti implants were less susceptible to postoperative infection.[11] Bacterial glycocalyx has been implicated in adherence of bacteria to metals and antibiotic resistance.[19] Our findings also support a lower rate of infection with Ti-based constructs (0%) compared to SS (3.1%) and CC (5.9%). However, it is possible that our results are affected by the large difference in number of SS patients (n = 135), CC (n = 34), and Ti (n = 36). Regardless, we found a similar infection rate with that reported in the literature and our findings appear to support the results of DiSilvestre et al.[11] and Soultanis et al.[49]

Stainless steel has been used as an orthopedic implant since the 1920s and its use preceded that of all other metals in orthopedic surgery.[7] Advantages of SS are good corrosion and fatigue resistance, greater stiffness than Ti, and less expensive cost.[3, 56] Rod stiffness is important in PSF because construct stiffness correlates with fusion rates.[1, 5, 56, 57] In our study, the patients with SS constructs had significantly greater mean preoperative thoracic curves than both the CC and Ti patients, and achieved a greater mean amount of correction than patients with Ti rods. However, the difference between groups in regards to preoperative curvature was only 4–5° and the average amount of correction obtained was 36.4° for SS, 30.5° for CC, and 29.9° for Ti. Significant differences in our results despite similar degrees of curvature may reflect our large sample size and likely do not reflect clinical significance. No nonunions were observed in our patients but this may be due to lack of long-term follow-up.

In addition to type of rod metal selected for fusion, construct stiffness is dependent upon rod diameter, manufacturing process, and number of pedicle screws.[6, 46, 54, 56] Rod diameter affects construct stiffness because it is proportional to the fourth power of the radius. Adequate stiffness is necessary to limit motion during bony healing and reduce the risk of pseudarthrosis. Wedemeyer et al. investigated rod stiffness, rod diameter, material yield stress, and predictors of rod failure between SS and Ti rods in immature bovine spines.[56] Their results supported superior rod stiffness in 5.0 mm SS rods compared to 4.0 mm SS in torsion and flexion, and compared to 4.75 mm Ti alloy in torsion and flexion. However, percentage of yield stress was lower for Ti constructs in all testing and the authors concluded that Ti can withstand greater strains and has a lower risk for fatigue failure than SS which is more brittle. Dual rod constructs with greater stiffness result in less strain at the rod-screw junction.[33] All of the patients in our study had 5.5 mm rods and no revisions due to implantation failure or pseudarthrosis occurred.

A major strength of our study is the analysis of a uniform population of patients with Lenke type 1 (main thoracic) AIS who underwent PSF with greater than 80% pedicle screws from a prospectively-collected, multi-center database. To our knowledge, no other studies have evaluated LOC in this demographic population undergoing PSF with SS, CC, or Ti rods. Prior studies have reported results from bench-top spinal models and we believe our study provides additional information to the topic of initial and loss of correction between different rod materials. A second strength of our study is the analysis of patients with similar curve flexibilities. This is an important finding because it precludes curve flexibility (or stiffness) as a variable affecting initial correction and LOC at 2-YP. Another strength is our inclusion of patients who underwent PSF with uniform rod diameter (5.5 mm). As previously described, including variable rod diameters would change the PSF construct and affect the results of our study.

There are a few limitations in our study. First, there is a large discrepancy between the number of patients in our SS group compared to the number of patients in the CC and Ti groups. Regardless of the numbers of patients between groups, we were able to identify significant differences in certain radiographic parameters. Secondly, the patients who underwent PSF with SS rods had greater preoperative main thoracic curves. This finding may reflect surgeon's preference for stiffer rod material like SS in more severe curves. A study comparing initial spine correction and long-term LOC between rod materials in larger, stiffer curves may be a topic for research in the future. A third limitation is our relatively short-term follow-up of two years. It is possible that changes in spinal deformity will occur at longer than 2-YP. A fourth limitation is our general categorizing of SS, CC, and Ti-based rods. Metals are available in a variety of grades and their properties vary with processing methods.[3] It is possible that a subanalysis of rods with different yield strengths would reveal different results. Lastly, being a multi-center study, PSF was performed due to each surgeon's technical preference and the number of levels of instrumented fusion was unable to be controlled. However, this was necessary to include the maximum number of subjects in the study.

Our results suggest that 5.5 mm SS rods impart greater initial coronal plane correction than 5.5 mm Ti rods in patients with Lenke type 1 AIS, Risser stage 2 or greater, undergoing PSF with modern technique. Dual CC rods provide adequate coronal plane correction with results similar to SS. Although SS demonstrated the greatest thoracic percent correction at 1-PO, average Cobb angles for all groups were between 14.8° and 17.3°, which is unlikely to be associated with clinical significance. Also, there appears to be no difference in thoracic Cobb angle at two-year follow-up in patients with similarly flexible curves. From 1-PO to 2-YP, degree of mean LOC was small (1–4°) for all rod types in the coronal plane. The only 2-YP difference between groups was achievement of more anatomic kyphosis in patients with CC versus Ti rods. In patients where infection is a concern, implanting Ti-based rods may reduce the risk of infection compared to SS and CC.

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Original Research

Most Femoral Implants Used for Hip Arthroplasty Lack Supporting Clinical Data

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Abstract

Background: Numerous femoral implants used for hip arthroplasty are available, many of which lack peer-reviewed outcome data. This study catalogues a large sample of stems and reports the numbers that have peer-reviewed literature investigating postoperative clinical outcomes and a disclosed conflict of interest statement.

Methods: PubMed was searched using the database keyword search function with the following terms: *(manufacturer/stem name) + femoral implant, component, stem, primary hip stem, hip implant,* and *hip* and studies reporting clinical outcomes were identified. Manufacturers were contacted in order to cross-reference the studies we identified and to determine if additional peer-reviewed studies were available. Articles were read to determine if the authors' conclusions were favorable or unfavorable for continued use of the stem and if conflicts of interest were disclosed.

Results: A total of 161 femoral stems from 12 manufacturers were included in the literature search, which identified 201 studies. The overall percentage of stems with a minimum of one peer-reviewed study investigating postoperative outcomes was 35 percent. Ninety-three percent of the studies identified reported favorable results. Less than 45 percent of studies had a disclosed conflict of interest.

Conclusions: The low overall percentage of stems with a minimum of one peer-reviewed study reporting outcomes demonstrates a paucity of clinical follow up for the majority of femoral implants. The ability to predict the ultimate clinical performance of a stem may be influenced by bias introduced by a propensity to publish studies with positive outcomes and non-disclosed conflicts of interest. Although some studies have proven valuable in their ability to guide clinical practices by identifying implants demonstrating unacceptable early failure rates, the current system is imperfect at best. Much of the best evidence for implants is derived from registry data collected outside the United States, highlighting the critical importance of establishing a United States arthroplasty registry and standardized reporting of clinical outcome data in the United States.

Introduction

In orthopedics, there has been a movement towards the practice of evidence-based medicine, with an emphasis on the evaluation of safety, efficacy, and the cost-effectiveness of care. Evidence-based medicine seeks to inform clinical decision making based on data from peer reviewed literature in the fields of clinical medicine, epidemiology, and economics, rather than expert opinion, tradition, and personal experiences.[72] Health policy makers have emphasized evidence-based practices and compliance with such practices is likely to become a criterion used for grading physician performance. Steps that have been taken towards developing such criterion include the Physician Quality Reporting Initiative from the Centers for Medicare & Medicaid Services (CMS) and the possibility of mandatory evidence-based pay-for-performance initiatives instituted by third party payers.[74]

According to the Agency for Healthcare Research and Quality, more than 285,000 total hip replacements are performed each year in the United States, with the number estimated to grow to 572,000 by 2030.[80] A wide range of femoral implants are available to surgeons from multiple manufacturing companies. Although some stems have undergone significant pre-clinical testing and full evaluation by the United States Food and Drug Administration (FDA), many stems have been brought to market with less rigorous testing and less stringent FDA evaluation. The 510(k) approval process allows implant approval by the FDA without going through the full evaluation trials required of a new product when the implant is considered to be a modification of a pre-existing, previously approved design. Once the FDA approves a stem, industry incentive to report on implant clinical performance may be diminished. Furthermore, in the United States, there is no national arthroplasty registry to serve as a surveillance system for implants with higher than expected rates of failure. Taken together, these factors have led to a situation in which clinical performance of some stems has not been well established.

Our study aims to catalogue a large sample of femoral stems currently approved for clinical use from 12 different manufactures and to identify all peer-reviewed studies investigating their postoperative clinical outcomes. Additional goals include determining the percentage of studies in which

the authors report favorable versus unfavorable outcomes and to determine the percentage of studies disclosing conflicts of interest.

Materials and Methods

Twelve manufactures of femoral stems were chosen for a literature search to determine the number of peer-reviewed articles available investigating clinical outcomes related to stem survivorship, defined by time to failure or revision. Femoral stems were identified for each manufacturer using the published list of available stems on the manufacturer's website. We performed a thorough literature search for each stem in the PubMed, using the database keyword search function and including the following search terms: *(manufacturer/stem name) + femoral implant, femoral component, femoral stem, primary hip stem, hip implant,* and *hip.* Manufacturer representatives were then contacted to determine if any industry database or clinical data files were available for review. Studies provided directly from manufacturers were used to cross-reference those from the PubMed search. Not all manufacturers provided lists for cross-reference and attempts for contact were stopped after three failed requests via phone call or email. Manufacturers providing data included Zimmer, Biomet, Stryker, DePuy, Exactech, Biopro, Whiteside, Kinamed, Ortho Development, and Whiteside. Case reports, *in vitro* or cadaveric studies, or those comparing surgical technique were excluded.

The combined investigator and manufacturer search identified 201 published articles, which were organized by manufacture and stem. Articles were read to determine if clinical data presented was favorable or unfavorable. Studies were considered to present a favorable result if the authors concluded a stem had adequate survivorship or supported continued clinical use. For stems with a minimum of one study, the best and worst survivorship, defined as the percentage of patients without femoral component loosening or mechanical failure, were noted.

Author or industry conflicts of interest were also evaluated. A conflict of interest was defined as author affiliation (consultants) or royalty payments (including charitable donations to author selected groups) and article sponsorships paid by the manufacturer of the stem being studied. Disclosure statements within or following the article identified conflicts. Articles lacking a disclosure statement were assumed to have no conflicts.

Results

A total of 161 femoral stems from 12 different manufacturers were identified and included in the literature search for studies investigating postoperative clinical outcomes. Two hundred and one studies were identified. The number of stems and clinical studies determined for each manufacturer are listed in Table 1. Wright Medical had the largest number of femoral stems identified (28), while Kinamed and Biopro had the least (three each). Zimmer had the largest number of clinical studies identified (53) with 14 of their 25 stems having reported clinical outcomes. Both Kinamed and Ortho Development had zero clinical studies identified for their stems. Whiteside and Stryker had the highest percentage of stems with at least one study investigating outcomes with 67%, (2/3), and 63%, or (12/19) respectively. In addition, Table 1 lists the range of post operative follow up, the number and percentage of studies with a favorable outcome as concluded by the author, and the number of studies with disclosed author or industry conflicts of interest.

Post operative follow up periods across all manufacturers and stems ranged from one to 20 years, with DePuy, Stryker, Biomet and Zimmer publishing 20-year follow up on some of their stems. Stelkast, on the other hand, had the shortest range of follow up, reaching a maximum of two years. Considering all manufacturers with at least one clinical study, the percentage of studies reporting or concluding favorable outcomes ranged from 81% (Stryker), with 39 of 48 total studies being favorable, to 100% for DePuy (29 of 29), Exactech (one of one), Biopro (two of two), Stelkast (one of one), and Whiteside (two of two). With respect to disclosed author or industry conflicts of interest from manufacturers with a minimum of 10 studies, Zimmer had the lowest percentage of studies with disclosed author or industry conflicts of interest (19%, or 10 out of 53 studies). Exactech, Biopro, and Whiteside had the highest percentage of studies with disclosed author or industry conflicts of interest across all manufacturers (100% or one out of one, two out of two, and two out of two, respectively).

Detailed findings for each individual stem with respect to their number of studies, post operative follow up range, disclosed conflicts of interest, and survivorship extremes are organized by manufacturer into supplemental Tables 2–8. For DePuy (Table 2), the AML Total Hip System stem had the largest number of studies (nine), and all studies for DePuy stems had favorable outcomes (29/29). With respect to the detailed Stryker data (Table 3), the ABG stems had the largest number of studies (23), with 17 reporting or concluding favorable results (74%) and seven disclosing conflicts of interest (29%). Styker had the largest range of stem survivorship, defined as patients without component loosening or mechanical failure, ranging from 58% to 100%. For Biomet (Table 4), the Taperloc stem had the largest number of studies (17), all reporting or concluding favorable results (100%, 17/17). For Zimmer (Table 5), the Alloclassic stem had the largest number of studies, with all 11 studies reporting or concluding favorable results. Only two studies (APR/Harris Galante Porous stems) from the total of 53 reported have unfavorable result (4%). For Smith and Nephew (Table 6), the BHR stem had the largest number of studies (seven), with four studies reporting or concluding favorable results and three reporting a mixture of favorable and unfavorable results depending on patient population variables. Only one study (Spectron EF stem) reported an unfavorable result

Table 1. Manufacturers, Available Stems, and the Total Number of Published Studies

Manufacturer	Total Number of Stems	Total Number of Published Studies	Percentage of Stems with Minimum of One Outcome Study	Range of Follow Up (Years)	Percent with Disclosed Conflict of Interest	Percent Favorable Outcome
Biomet	17	42	53% (9/17)	2 to 20	24% (10/42)	95% (40/42)
BioPro	3	2	33% (1/3)	4 to 10	100% (2/2)	100% (2/2)
DePuy	24	29	29% (7/24)	4 to 20	38% (11/29)	100% (29/29)
Exactech	10	1	10% (1/10)	2.50	100% (1/1)	100% (1/1)
Kinamed	3	0	0% (0/3)	N/A	N/A	N/A
Ortho Development	4	0	0% (0/4)	N/A	N/A	N/A
Smith and Nephew	17	14	29% (5/17)	2 to 18	43% (6/14)	93% (13/14)
Stelkast	8	1	13% (1/8)	2.00	0% (0/1)	100% (1/1)
Stryker	19	48	63% (12/19)	1 to 20	42% (20/48)	81% (39/48)
Whiteside	3	2	67% (2/3)	3.00	100% (2/2)	100% (2/2)
Wright	28	9	14% (4/28)	1 to 14	22% (2/9)	100% (9/9)
Zimmer	25	53	56% (14/25)	1 to 20	19% (10/53)	96% (51/53)
Total	**161**	**201**	**35% (56/161)**	**1 to 20**	**32% (64/201)**	**92% (186/201)**

Table 2. DePuy Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
Corail® Total Hip System	3[1–3]	1	3	8 to 20	100%/11.5 years	96.8/20 years
Tri-Lock BPS	4[4–7]	0	4	1 to 15	99.8%/8.9 years	88%/15 years
S-ROM	2[8–9]	1	2	5 to 11	99.6%/11 years	99.4%/5.3 years
AML® Total Hip System	9[10–18]	1	9	4 to 15	100%/15 years	98%/11.3 years
C-Stem™ AMT Total Hip System	2[19–20]	2	2	9.5 to 11.5	100%/11.5 years	N/A
Luster	1[21]	1	1	5	100%/4.8 years	N/A
Prodigy	8[22–29]	5	8	5 to 15	100%/11.4 years	97.9%/15 years
Stems Without Publications	Summit Press-fit, Summit Cemented, HPS II, Excel® Cemented, Excel® Fracture System, LPS™ Limb preservation system, P.F.R. Total Hip System, Replica, Bantam, Endurance, Elite Plus, Ultima PFC Cement, Ultima calcar, Unirom, Summit Tapered, G2					

Twenty-four stems were considered in the literature search, with a total of 29 studies identified. Clinical studies investigating outcomes were found for seven out of their 24 stems (29%). The AML Total Hip System stem had the largest number of studies (nine), while 17 stems had no studies. All studies had favorable results. The range of post-operative follow up was one to 20 years, with the Corail stem reporting outcomes at 20 years. Considering stems with at least one study, the Luster stem had the shortest follow up period of five years. The C Stem AMT and Prodigy stems had the highest percentage of studies with a disclosed conflict of interest (2/2 and 5/8, respectively), while the Tri-Lock BPS had no conflicts of interests disclosed in its four studies.

(7%). For Wright Medical (Table 7), the Profemur R stem had the largest number of studies (four), with all reporting or concluding favorable results (100%). All other studies reported favorable results (100%) and 24 stems had no studies identified. The detailed data from BioPro, Ortho Development, Exactech, Kinamed, Whiteside, and Stelkast are combined into supplemental Table 8. These manufacturers combined for 31 stems evaluated in the literature search, with a total of six studies identified. Clinical studies investigating outcomes were found for five of 31 stems (16%).

Discussion

There have been some notable hip implants receiving media and legal attention due to design features that have resulted in elevated rates of early failure. One such example is the Stryker ABG II modular stem recently recalled by the manufacturer following documentation of high rates of metallosis, resulting in failure rates as high as 3.1% within 3–5 years after implantation.[83] High failure rates have also observed with the modular ABG I implant, with Gallo and colleagues reporting a 23.5% rate of revision for osteolysis and aseptic loosening at and average of 9.8 years in 127 patients. Problems have also been observed with the Profemur Z implant (Wright Medical), with a documented failure rate of 11.2% at three years after implantation due largely to fracture of the implant's femoral neck, which has been attributed to its modular design.[87] Both the ABG II and Profemur Z are examples of implants which bypassed formal FDA

Table 3. Stryker Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
Accolade C	1[30]	1 (100%)	1 (100%)	2 to 5	98%/5 years	N/A
Accoloade TMZF	2[31, 53]	1 (50%)	2 (100%)	2 to 9	100%/2 years	97%/7.6 years
Secur-Fit HA	1[33]	1 (100%)	1 (100%)	5 to 10	100%/6.7 years	N/A
Secur-Fit Plus HA Stems	1[34]	0 (0.00%)	1 (100%)	2 to 5	100%/3.2 years	N/A
Citation TMZF	1[35]	1 (100%)	1 (100%)	1	100%/1 year	N/A
ABG (I/II)	24[32, 36–52, 202–207]	7 (29%)	18 (75%)	2 to 15	100%/15 years	58%/11 years
Definition PM	1[54]	1 (100%)	1 (100%)	5	98.4%/5 years	N/A
Meridian TMZF	1[55]	0 (0.00%)	1 (100%)	2	100%/2 years	N/A
Omnifit EON	10[56–65]	8 (80.00%)	10 (100%)	8 to 15	100%/15 years	88%/10.4 years
Omniflex	3[66–68]	0 (0.00%)	3 (100%)	3 to 9	100%/5.4 years	81%/8.6 years
PCA Hip	2[69–70]	0 (0.00%)	0 (0.00%)	12 to 20	90%/14 years	81%/20.2 years
Reliance	1[71]	0 (0.00%)	1 (100%)	5	100%/5 years	N/A
Stems Without Publications	Rejuvenate, Exeter V40, Osteolock, Precision, Precision Strata, Premise, Sentry					

Nineteen stems were evaluated in the literature search and 48 studies were identified. Clinical studies investigating outcomes were found for 12 of their 19 stems (63%). The ABG stems had the largest number of studies (23), with 17 reporting or concluding favorable results (74%) and seven disclosing conflicts of interest (29%). The PCA stem had the lowest percentage of reported favorable outcomes (0%, 0/2). Seven stems had no studies identified. The best and worst survivorship, defined as patients without component loosening or mechanical failure, is reported for each stem, ranging from 58% to 100%. The range of postoperative follow up was one to 20 years, with the PCA Hip stem reporting outcomes at 20 years. Considering stems with at least one study, the Citation TMZF stem had the shortest follow up period of one year. Seven stems had studies with a disclosed conflict of interest, while five stems had no conflicts of interests disclosed.

Table 4. Biomet Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
BiMetric	6[73, 75–79]	0	4	3 to 15	100%/10 years	84%/10.2 years
Bi-Metric Interlok	1[81]	0	1	3	99%/3 years	N/A
TaperLoc® 12/14 Taper Femoral Components	1[82]	1	1	5 years	100%/5.7 years	N/A
Mallory Head	6[84–86, 88–90]	2	6	6 to 15	100%/12.7 years	97.1%/15 years
Muller Stem CoCr	3[91–93]	0	3	5 to 10	98.2%/10 years	97.3%/10.2 years
Muller Stem Titanium	4[94–97]	0	4	5 to 10	98.4%/9 years	65.8%/10 years
Integral	2[98–99]	1	2	6 to 11.5	100%/5.8 years	98.4%/11.6 years
Stanmore stem	2[100–101]	0	2	5 to 10	99.5%/10 years	97%/5 years
Taperloc	17[102–118]	6	17	2 to 20	100%/16 years	79.3%/5 years
Stems Without Publications	Magnum tM System, Osteocap RS, Bio-Moore II, Balance, Rx90, Progressive, Generation 4, Answer					

Seventeen stems were considered in the literature search, with a total of 47 studies identified. Clinical studies investigating outcomes were found for nine out of 17 stems (53%). The Taperloc stem had the largest number of studies (17), all reporting or concluding favorable results (100%, 17/17) and six disclosing conflicts of interest (35%). The Bio-Metric stem had the lowest percentage of reported favorable outcomes (67%, 6/9). The range of post operative follow up was three months to 20 years, with the Taperloc stem reporting outcomes at 20 years. Considering stems with at least one study, the BioMetric Interlock stem had the shortest follow up period of 3.5 years. The Mallory Head and Integral stems had the highest percentage of studies with a disclosed conflict of interest (4/8 and 1/2 (50%), respectively), while the Muller (CoCr and Titanium), Stanmore, and Bi-Metric Interlock stems had no conflicts of interests disclosed in seven, two, and one identified studies, respectively.

trials through the 510(K) approval process. Perhaps the most well publicized implant to be recalled is the ASR (DePuy) cup for metal on metal THA and hip resurfacing, which was designed as a monoblock cup with low clearance and less than full hemispheric coverage. Although the clinical performance of the ASR was predicted to be superior to other existing cups based on simulator studies, the Finnish Arthroplasty registry documented failure rates of 5% at four years and 8% at six years. Further studies have show revision rates ranging from 21% at four years to 49% at six years for the ASR XL device.[210] These implants illustrate the risk to surgeons and their patients in using an implant without a long

Table 5. Zimmer Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
M/L Taper with Kinectiv	1[119]	1	1	2	100%/2 years	N/A
ZMR	3[120–122]	0	3	4 to 7	97.4%/3.5 years	92.7%/3.8 years
APR	3[123–125]	1	2	4 to 10	100%/10 years	89%/6.7 years
Alloclassic	11[126–136]	3	11	1 to 20	100%/20 years	98%/11 years
Anatomic	2[137–138]	1	2	7 to 9.5	100%/9.7 years	N/A
CLS Spotorno	3[139–141]	0	3	2.5 to 17	100%/17 years	97.9%/13 years
Natural Hip	1[142]	0	1	2	100%/2 years	N/A
VerSys	6[143–148]	3	6	1 to 10	100%/10.1 years	99.5%/8.5 years
Wagner Cone	3[149–151]	0	3	11.5 to 12	100%/12 years	94.7%/11.5 years
Wagner SL	9[152–160]	0	9	1.5 to 14	100%/2 years	90.9%/7.1 years
Metasul	5[161–165]	0	5	3.5 to 13	100%/7.3 years	94.4%/12.3 years
Fibre Metal Taper (FMT)	2[166–167]	0	2	7 to 9.5	100%/6.8 years	98.9%/9.5 years
Durom (CPT Stem)	2[168–169]	0	2	6 to 6.5	100%/6 years	98.8%/6.5 years
Harris-Galante Porous	2[170–171]	1	1	5.5 to 8	98%/6 years	95.9%/5.5
Stems Without Publications	Fitmore, M/L Taper, TM Primary, Allofit, TMARS, Converge, Trilogy, ZCA, CLS Brevius, Durasul, Longevity					

Twenty-five stems were considered in the literature search, with a total of 53 studies identified. Clinical studies investigating outcomes were found for 14 of 25 stems (56%). The Alloclassic stem had the largest number of studies (11), with all 11 studies reporting or concluding favorable results (100%) and three disclosing conflicts of interest (27%). Only two studies (APR and Harris Galante Porous stems) from the total of 53 reported an unfavorable result (4%, or 2/53). Eleven stems had no studies identified. The range of postoperative follow up was one to 20 years, with the Alloclassic stem reporting outcomes at 20 years. Considering stems with at least one study, the M/L Taper with Kinectiv and Natural Hip stems had the shortest follow up period of two years. Six stems had at least one study with a disclosed conflict of interest, while eight stems had no conflicts of interests disclosed.

Table 6. Smith and Nephew Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
BHR™ Birmingham Hip Resurfacing	7[172–178]	1	4 (3 mixed)	2 to 10	100%/4 years	84.5%/8 years
Spectron EF	2[179–180]	1	1	2 to 18	100%/2 years	91.6%/18 years
Synergy	3[181–183]	2	3	6 to 6.5	100%/5.8 years	99.5%/6 years
Echelon	1[184]	1	1	8	99.3%/8 years	N/A
SL Plus	1[185]	1	1	2	99.7%/4 years	N/A
Stems Without Publication	Echelon cemented, Conquest, CPCS, Image, Platform, STS, Emperion, SL Plus MIA, Synergy cemented, Cobra, SMF Short Modular Femoral Hip System, ANTHOLOGY™ Hip System					

Seventeen stems were considered in the literature search, with a total of 14 studies identified. Clinical studies investigating outcomes were found for five of their 17 stems (29%). The BHR stem had the largest number of studies (seven), with four studies reporting or concluding favorable results and three reporting a mixture of favorable and unfavorable results depending on the patient population variables (gender). Only one study (Spectron EF stem) reported an unfavorable result (7%, or 1/14). Twelve stems had no studies identified. The range of postoperative follow up was two to 18 years, with the Spectron EF stem reporting outcomes at 18 years. Considering stems with at least one study the SL Plus stem had the shortest follow up period of two years. All six stems had at least one study with a disclosed conflict of interest.

standing, well established track record. For the ABG II modular stem and ASR cup, greater than expected early failure rates that have been observed have prompted a recall, and it is anticipated that over time, an increasing number of implants will go on to premature failure. In order to monitor for the failure of these implants, increased clinical surveillance, testing, and expense will be required, resulting in anxiety for both the surgeon and patient; for cases that go on to fail, the costs will be even greater. In the United States, additional medical legal ramifications may exist. Such failures raise questions about how hip implants are studied, the effectiveness of the FDA approval process, the appropriateness of clinical follow up and monitoring, and whether an evidence-based approach to selection of hip implants could decrease similar future complications.

Clinical outcome studies have highlighted the value of prospectively collecting clinical data to monitor the performance of orthopedic implants and their ability to shape clini-

Table 7. Wright Medical Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
PERFECTA® Plasma Spray Stems	1[186]	0	1	14	99%/14 years	N/A
PROFEMUR® R Revision	4[188–191]	0	4	1 to 6	100%/1 year	94%/5.2 years
CONSERVE® Total Hip System with BFH® Technology	2[192–193]	1	2	5.5 to 12	97%/5.6 years	90.3%/11.7 years
LINK® MP™ Reconstruction Hip Stem	2[194–195]	1	2	3.5 to 4	97.2%/3.5 years	96.9%/4 years
Stems Without Publications	PERFECTA® PDA Stems, PERFECTA HA, PERFECTA® Total Hip System, PERFECTA® IMC Stems, PERFECTA® RS Stems, PROFEMUR® E Hip Stems, PROFEMUR® FC Stem, PROFEMUR® LX 5/8 Stem, PROFEMUR® PLASMA Z Hip Stems, PROFEMUR® RENAISSANCE® Stem, Profemur R, PROFEMUR® TL Total Hip System, PROFEMUR® Total Hip System, PROFEMUR® Z Hip Stems, PROFEMUR® S, PROFEMUR® T, PROFEMUR X, PROFEMUR® RAZ, EXTEND POROUS, EXTEND CEMENTED, PROFEMUR® LX 5/8 Revision Stem, RESOLUTION, PERFECTA RA, NEXUS II					

Twenty-eight stems were considered in the literature search, with a total of 10 studies identified. Clinical studies investigating outcomes were found for four of 28 stems (14%). The Profemur R stem had the largest number of studies (five), with four studies reporting or concluding favorable results (80%) and none with a disclosed conflict of interest (0%). All other studies reported favorable results (90%, or 9/10). Twenty-four stems had no studies identified. The range of postoperative follow up was one to 14 years, with the Perfecta Plasma Spray stem reporting outcomes at 14 years. Considering stems with at least one study, the Link MP stem had the shortest follow up period of four years. Two stems had at least one study with a disclosed conflict of interest, while two stems had no conflicts of interests disclosed.

Table 8. Clinical Studies, Outcomes, Conflict Disclosures and Follow Up

Manufacturer	Stem	Clinical Studies (#)	Number with Disclosed Conflict of Interest (%)	Number with Favorable Outcomes (%)	Range Follow Up (Years)	Best Results (% Survivors at X Years)	Worst Results (% Survivors at X Years)
Biopro	BioPro® PSL	2[196–197]	2	2	4 to 10	100%/3 years	97%/10 years
	Stems Without Publications	BioPro Living Hip, Optima					
Exactech	AcuMatch™ M-Series Modular	1[198]	1	1	2.5	98%/2.5 years	N/A
	Stems Without Publication	Novation™ tapered Comprehensive Hip System, Novation™ splined, Novation™ Cemented Plus, Novation™ Element's® tapered-wedge, AcuMatch™ C-Series, AcuMatch™ P-Series Press-Fit, AcuMatch™ L-Series cemented, AcuMatch™ L-Series Press-Fit, Aura™ cemented hip system					
Kinamed	None	0	0	0	0	N/A	N/A
	Stems Without Publication	Exact-Fit, CTN Cemented stem, Reality cemented stem					
Ortho Development	None	0	0	0	0	N/A	N/A
	Stems Without Publications	Encompass® Hip Stem Plasma Spray, PRIMALOC, Encompass® CEMENTED, OVATION					
Stelkast	ProClass™ hip stem	1[201]	0	1	2	100%/2 years	N/A
	Stems Without Publications	Progeny™ Hip Stem, Protract™ Hip Stem, Provident™ hip stem, EXp Polyethylene Technology, Proform cemented, DTW, SRRS					
Whiteside	Quatroloc primary	1[199]	1	1	3	100%/3 years	N/A
	Quatroloc revision	1[200]	1	1	3	97.7%/3 years	N/A
	Stems Without Publications	QUATRO M					

These manufacturers combined for 31 stems considered in the literature search, with a total of six studies identified. Clinical studies investigating outcomes were found for five of 31 stems (16%). The BioPro PSL stem had the largest number of studies (two), with both studies reporting or concluding favorable results (100%) and disclosing a conflict of interest (100%). The AcuMatch M (Exactech), Quatroloc Primary and Revision (Whiteside), and Pro Class (Stelkast) stems each had one study investigating outcomes, and all reported favorable results (100%, or 5/5). Stems from Kinamed and Ortho Development had no studies identified. The range of postoperative follow up was two to 10 years, with the BioPro PSL stem reporting outcomes at 10 years. Considering stems with at least one study, the ProClass hip stem had the shortest follow up period of two years. All but one study had a disclosed conflict of interest (4/5), with only the ProClass study having no disclosed conflict.

cal practice.[125] Kadar and colleagues reported a comparison of the short-term (two year) clinical outcome of the Spectron EF and Charnley stems in 150 patients. Favorable outcomes were reported, with the Spectron EF demonstrating less subsidence (0.20 mm) compared to the Charnley (0.26 mm) at two years. However, five-year data from a Norwegian arthro-

plasty registry found the Spectron EF stem had a higher revision rate due to aseptic loosening beyond five years. This led authors to stress the importance of prospective long-term follow-up of prosthetic implants in clinical trials and national registries to support a stepwise introduction of implants to the clinical market.[187]

Dorr and colleagues reported the results of 100 consecutive primary total hip arthroplasties performed with the APR-I (Zimmer) stem at an average of 6.7 years follow up. Data demonstrated an unacceptable revision rate of 16% and a mechanical failure rate of 11% over that time period, quoting polyethylene wear, osteolysis, and progressive loosening as causes for early failure. These results led the authors to discontinue use of the stem in their practice. However, despite these reported unfavorable results by Dorr, our review identified two additional studies for the APR stem, both with favorable results, and to this point no manufacturer recall of the implant has ever been issued.

Similarly, clinical outcome studies available for the Birmingham Hip Resurfacing (BHR) femoral component (Smith and Nephew) have also demonstrated their ability to shape clinical practice. Coulter and colleagues reported the clinical results of 213 Birmingham hip resurfacings at an average of 10.4 years follow up. Data demonstrated a significant difference in failure rate between men and women, with 2.1% (3/140) and 11% (8/73) failure rates, respectively.[175] The majority of failures in women were thought to be due to metal wear which may be increased in women due to a greater range of motion at the hip. Increased motion coupled with smaller diameter implants may predispose the metal liner to increased edge loading, resulting in increased production of wear debris and osteolysis.[208] These results led authors to discontinue offering resurfacing arthroplasty with the BHR implant to their female patients.

Our review of the femoral stems available for THA from 12 different orthopedic device manufacturers demonstrated that a large number of implants are available to orthopedic surgeons in today's market. This presents a unique challenge of choice between using an older stem design with an established track record, or using a newer stem, which may have been aggressively marketed by the manufacturer, but is lacking significant published evidence to support its use. Our review of the literature demonstrated the overall percentage of stems with a minimum of one published clinical study investigating postoperative outcomes was only 35%, with 105 of the 161 stems included in our sample having no published clinical outcome data. There was a wide spectrum in the reporting of clinical outcomes between individual manufacturers, ranging from 0% to 67%. When considering only the larger manufactures (over 15 stems available), a wide range of data reporting was still observed, with Stryker having the highest percentage of stems with published data (63%) and Wright Medical having the lowest (14%).

The ABG modular stem highlights that even a stem with ample clinical data may still fail to predict clinical failure of an implant. The ABG stems overall had a significantly higher number of clinical studies investigating outcomes compared to many of the other stems in our review. Of the 23 studies investigating clinical outcomes for the ABG stems (I/II), 17 (74%) reported favorable results. Only four of the 23 studies (17%) provided data specifically for the modular version of the stem recently recalled, with 100% (4/4) reporting favorable results for a follow up range of three to 11 years. Despite several studies reporting on the performance of the ABG stem, premature failure of the modular stem was not predicted. This situation raises questions about the ability of these studies to demonstrate true implant performance, either due to limits in their methods of data collection and analysis, a lack of reliability of the study conclusions, or potentially author conflicts of interest.

Overall, 93% of the studies that were identified in our review of the literature demonstrated favorable results. The high percentage of studies with favorable results may indicate a propensity to publish studies supporting use of a stem, rather than those that discourage it. One possible explanation for this trend may be that authors are conflicted due to personal financial interests and other ties to the manufacturer; therefore, we also sought to determine the percentage of studies with a disclosed conflict of interest. For the 12 implant companies we evaluated, the range of studies with a disclosed author or manufacturer conflict of interest ranged from 0% to 100% of published studies. When considering only larger manufacturers (over 15 stems available), this range was from 19% to 43%. Overall, less than 45% of the studies reviewed disclosed an author conflict of interest, suggesting that the majority of the studies lacked this form of bias. Yet greater than 90% of studies reviewed reported favorable outcomes, leading one to question whether author conflicts may have been under reported, possibly suggesting a lack of transparency. In a study from 2010, Chimonas and colleagues evaluated the current journal disclosure system by examining physician payment information from five orthopedic device manufacturers, including Biomet, DePuy, Smith and Nephew, Stryker, and Zimmer. It was concluded that disclosure of company payments varied considerably, with nondisclosure rates as high as 46% among first-, sole-, and senior-authored articles and 50% among articles directly or indirectly related to payments.[209] Further, accuracy of disclosures did not vary with the strength of journals' disclosure policies, indicating current practices do not yield complete or consistent information regarding authors' industry ties.[209] These values are similar to the rate of disclosure found in our study, supporting the idea that there may be bias in published outcome reporting for orthopedic implants. The Patient Protection and Affordable Care Act set to take effect in 2013 will require pharmaceutical and device companies to disclose payments to physicians, providing a resource to determine conflicts in future outcome studies.

Although this study highlights the fact that most stems lacked any published outcome data, and many of the studies

that we identified were only of short-term duration, we did identify some stems with good support in the literature. The AML Total Hip system that was originally introduced in 1983 by DePuy has nine studies with follow-up as long as 15 years, demonstrating a 3% (7/227) rate of unstable fixation at short term (four year average),[18] a 0% (0/74) failure rate at medium term follow up (6.1 year average),[12] and a 16% (17/105) overall failure rate at long-term follow up (12.9 year average).[13] Of note, all 17 cases requiring revision at long-term follow up were due to acetabular component failure, with no femoral stem components requiring revision.[13] The Taperloc stem that was originally introduced in 1983 by BioMet has 17 studies with follow-up as long as 20 years, demonstrating a 0% (0/98) failure rate at short term (3.8 year average),[112] a 0% (0/105) failure rate of the femoral component at medium term follow up (6.1 years average),[117] and a 0% (0/132) failure rate at long-term follow up (20 years average), with no femoral component undergoing revision for aseptic loosening.[104] The Alloclassic stem that was originally introduced in 1987 by Zimmer has 11 studies with follow-up as long as 20 years, demonstrating a 0.7% (1/129) failure rate at the earliest documented follow up (5.9 year average),[134] a 0.7% (1/200) failure rate at medium term follow up (10 year average),[132] and a 0% (0/74) femoral component failure rate at long-term follow up (20 year average). There was a 6.8% (5/74) reoperation rate at 20 years for exchange of inlay and head; however, the femoral implants were found to be stable at the time of reoperation.[127] Lastly, the Omnifit EON stem that was introduced by Stryker has 10 studies with follow-up as long as 15 years, demonstrating a 1.2% (4/328) femoral component failure rate at the earliest documented follow up (five year average),[63] a 2% (1/52) failure rate for aseptic loosening at medium term follow up (10.4 year average),[65] and a 0.6% (1/166) femoral component failure rate due to component loosening at long-term follow up (15 year minimum).[62]

In conclusion, the low overall percentage of stems with a minimum of one study investigating outcomes (35%) included in this review demonstrates a paucity of clinical follow up in the form of peer-reviewed articles for the majority of femoral hip implants available. Furthermore, the ability of some published studies to predict the ultimate clinical performance of a stem may potentially be influenced by bias introduced through disclosed or non-disclosed conflicts of interest. Although some studies have proven valuable in their ability to guide clinical practices by preventing continued use of products demonstrating unacceptable early failure rates, or documenting good long-term clinical performance of others, the current system is imperfect at best. Much of the best evidence for or against use of orthopaedic implants is derived from registry data collected outside the United States, highlighting the critical importance of establishing a United States arthroplasty registry. Although the drive for innovation and improvement may lure surgeons and their patients to consider the use of new but untested implants, the conservative approach may be to choose an implant with a long, well-tested track record.

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Original Research

Prospective Comparison of Vitamin D Levels in Young Adults With and Without Distal Radius Fractures

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Abstract

We sought to compare serum levels of 25-hydroxyvitamin D in young adults who sustained a low energy distal radius fracture to healthy individuals without a history of fracture and to define any correlation between fracture severity and vitamin D levels.

A single-center, prospective study was performed. Study subjects were aged 18–45 years and sustained a low energy distal radius fracture. Control subjects were age-gender matched. Vitamin-D deficiency was classified by the Institute of Medicine guidelines. Fracture severity was classified with the AO/ASIF system and correlated to vitamin-D level via Spearman coefficients.

Fifteen distal radius fractures and 67 healthy controls met inclusion criteria. The overall range of 25-hydroxyvitamin-D level was 7.0–50.2 ng/mL, and the average measurement was 22.4 ng/mL in the control group and 21.4 ng/mL in the study group ($p = 0.97$). In patients who sustained a distal radius fracture, vitamin-D levels were categorized as: deficient in 13.3%, insufficient in 46.6%, and adequate in 40.0%. No significant correlations were found between fracture severity and vitamin-D level.

Vitamin-D levels in both study arms were in the low-normal range, but not significantly different. Additional supplementation in an otherwise healthy, young population appears unlikely to affect the occurrence of these fractures.

Introduction

Vitamin D and its metabolites are important in maintaining calcium homeostasis and regulating bone metabolism.[1, 2] Supplementation of calcium and vitamin D has been shown to reduce the risk of fragility fractures in the hips and vertebral columns of elderly patients, and more recently the role of vitamin D deficiency has been more closely studied for an association with low energy distal radius fractures.[3–8] Awareness of vitamin D deficiency is increasing in both the elderly and pediatric populations insofar as it pertains to bone mass accrual and fracture risk, and as a result, controversy exists with regard to the indications for vitamin D supplementation in asymptomatic individuals.[3–13]

Furthermore, the indications for vitamin D supplementation in asymptomatic young adults are not defined but may be suggested if a demonstrable risk of fracture is observed in deficient patients.

The purpose of this study was to measure the serum levels of 25-hydroxyvitamin D in young adults who sustained a low energy fractures using the distal radius as an experimental model and compare those values to that of healthy age-gender matched individuals without a history of fracture. We hypothesized that the mean vitamin D levels in those who sustained a fracture would be lower than that of the control subjects. Secondary goals aimed to determine the prevalence of vitamin D deficiency, as defined by the Institute of Medicine, in the Northeastern United States population and to define possible correlations between fracture severity and Vitamin D level.

Methods

A prospective clinical trial was conducted from January 1, 2011 to December 31, 2011 at an urban, level I trauma center in the northeastern region of the United States. Full institutional review board permission was obtained, and all patients signed an informed consent prior to investigation. All consecutive low energy distal radius fractures that presented to the outpatient office or the emergency room for evaluation of a distal radius fracture were identified. Inclusion criteria included age 18–45 years and a low energy mechanism, which was defined as one involving a fall from ground level or from less than eight feet. We excluded any patients with a history of menopause, renal disease, and hyperparathyroidism. Fractures sustained from high energy mechanisms including gunshots and motor vehicle collisions were additionally excluded. Demographic information was recorded and included: age, sex, ethnicity, mechanism of injury, hand dominance, co-morbidities, and body mass index (BMI). Vitamin D 25-OH levels were obtained either at the time of presentation in the emergency room, outpatient clinic, or prior to surgical intervention. All blood draws were performed within 30 days from the time of injury. Patient

records were followed for six weeks in order to record the frequency of operative management. Comparisons of the study group were made to a control group of healthy age and gender matched individuals retrospectively from a prospectively gathered database recorded from 2010 to 2011 by the internal medicine service. Approximately 4–5 controls were matched to each study subject. Control subjects were not included in the matching if any history of comorbidity or fracture existed. Age, gender, body mass index, and 25-hydroxyvitamin D levels were obtained, but race and ethnic data were not available.

Blinded radiographs from each of the subjects were classified by the senior author in accordance to the AO/ASIF (Association for Osteosynthesis/Association for the Study of Internal Fixation) classification system as type A (extra-articular), type B (partial articular) or type C (complete articular). Correlations between vitamin D level and fracture severity were then performed.

Statistical Analysis

A biostatistician performed all statistical analyses. A fisher exact test was used for categorical variables, and a student t-test was used for continuous variables. Statistical significance was determined by probability (p) values <0.05. A sample size calculation based on 80% power was estimated to be at least 15 subjects per group in order to detect a difference of 8 ng/ml of 25-hydroxy-vitamin D. This estimate was chosen in reference to the levels defined by the Institute of Medicine, which define the low end of normal as 20 ng/ml and the high end of deficient as 12 ng/ml.[11] We initially hypothesized that the mean vitamin D level of those who sustained low energy fractures would be in the deficient range, while the mean level for the controls would be in the adequate range. Correlations between fracture severity and vitamin D levels were calculated via Spearman correlation coefficients. The range of coefficients is from –1 to +1. A positive correlation coefficient indicated that the two variables were directly proportional. A negative correlation indicated that the two variables were inversely proportional. The statistical significance of a correlation coefficient was defined as a p value <0.05.

Results

A total of 15 subjects over the one year period met inclusion criteria, and 67 controls were able to be age and gender matched. The overall results are summarized in Table 1. The average age was 32.3 years with 44.7% male subjects for the control group, and 32.1 years with 46.6% male subjects for the fracture group; these differences were not statistically significant (p = 0.86 and p = 1.00 respectively). Body mass indices were also compared between the two groups, which averaged 27.5 kg/m^2 for the controls and 28.6 kg/m^2 for the fracture group; these differences were also not statistically significant (p = 0.87). The fracture group had three patients with comorbidities known to affect vitamin D levels; two of these patients were pregnant in the first trimester (vitamin D levels 24 and 31 ng/ml) and one patient was on anti-seizure medication (vitamin D level 16 ng/ml).

Table 1. Demographic Information for Patients With and Without Fracture

	No Fracture (n = 67)	Fracture (n = 15)	p value
Age (years)	32.3	32.1	0.8661
Male	44.7% (n = 30)	46.6% (n = 7)	1.0000
BMI (kg/m2)	27.5	28.6	0.8758
Race			
African Am		13.3% (n = 2)	
Caucasian		46.6% (n = 7)	
Hispanic		33.3% (n = 5)	
Other		6.6%% (n = 1)	
Comorbidities*	0	3	0.0051
Vitamin D level (ng/mL)	22.4	21.4	0.9761

*Comorbidities known to affect Vitamin D level (pregnancy n = 2, seizure medication n = 1)

The control group had no comorbidities.

When comparing the mean vitamin D levels of fracture subjects to controls, no significant differences were found (p = 0.97). The control group averaged 22.4 ng/ml (range 7.3–50.2 ng/ml) and the fracture group averaged 21.4 ng/ml (range 7.0–43.0 ng/ml). The proportions of all subjects with distal radius fractures were also stratified based on the Institute of Medicine categories. Sufficiency was diagnosed in 40.0%, insufficiency was diagnosed in 46.6%, and deficiency was diagnosed in 14.3%. The distribution of these proportions was also compared to that of the controls and was not dissimilar (Table 2).

Table 2. Vitamin D Deficiency in Patients With and Without Fracture

Vitamin D Classification*	Vitamin D Level (ng/mL)	No Fracture (n = 67)	Fracture (n = 15)	p value
Deficiency	<12	25.3% (n = 17)	13.3% (n = 2)	0.5011
Insufficiency	12–20	22.3% (n = 15)	46.6% (n = 7)	0.1027
Adequate	>20	52.2% (n = 35)	40.0% (n = 6)	0.5690

*Based on the recommended values provided by the Institute of Medicine

Fracture severity classified by the AO/ASIF classification had the following distribution: five type A fractures, two type B fractures, and eight type C fractures. Spearman correlation coefficients were calculated for fracture severity in relation to vitamin D level and age (Table 3). Both calculations yielded non-significant negative correlations; vitamin D level had a coefficient of –0.33 (p = 0.24) and age had a coefficient of –0.42 (p = 0.12).

Discussion

Hypovitaminosis D is a well-known risk factor for osteomalacia, secondary hyperparathyroidism, and fragility fractures in the elderly, and several studies have noted defi-

Table 3. Spearman Correlation Coefficients Related to Fracture Severity

	Vitamin D Level (ng/mL)	p Value	Age (Years)	p Value
AO Fracture Classification	–0.33	0.24	–0.42	0.12

ciencies in various populations on a global scale.[14, 15] Supplementation has been suggested as a possible strategy for reducing the risk of fragility fractures, and in fact, a recent Cochrane review noted a risk reduction (RR 0.84) in hip fractures for elderly patients who supplemented with both calcium and vitamin D but not with vitamin D alone.[4] Low energy fractures of the distal radius are being study with more frequency, as they may represent a sentinel event heralding a hip fracture in the elderly.[16] Oyen et al. studied 575 women and 72 men (ages 50–90 years) with distal radius fractures and noted significantly lower vitamin D levels in the fracture group when compared to controls.[6] Similarly, Jang et al. studied low energy distal radius fractures compared to aged matched controls in post menopausal women and not only found significantly lower vitamin D levels in the fracture group but also found a lower average bone mineral density.[5] Both reports by Jang et al. and Oyen et al. suggested that vitamin D supplementation may reduce the risk of fracture and would warrant further study.[5, 6]

We proposed a similar preliminary evaluation in order to review the levels of vitamin D in patients with and without fractures in the young adult population and found a mean vitamin D level of 22.4 ng/ml and 21.4 ng/ml for the control and fracture groups respectively, which were not significantly different. The vitamin D levels are comparable to a similar study by Bee et al. in which vitamin D levels were sampled from all orthopaedic trauma patients (age range 4–95); the average vitamin D levels in wrist fractures were 23 ng/ml and 21.6 ng/ml for the winter and summer respectively.[17] They concluded that the average orthopaedic trauma patient was "deficient" but did not compare their values to that of normal controls.

The optimal level of vitamin D is not known and presently controversial. Recently, the Institute of Medicine released its recommendations of vitamin D level based on an extensive review of the current literature and defined sufficiency as a level greater than 20 ng/ml. Insufficiency was defined as a level between 12–20 ng/ml, and deficiency was a level below 12 ng/ml.[13] Other investigators have defined vitamin D sufficiency to be above 32 ng/ml and deficiency below 20 ng/ml.[2, 5, 17] Supporters of the latter recommendation contend that parathyroid hormone regulation reaches a nadir around 30–40 ng/ml, calcium absorption from the gut is optimized above this level, and that histological bone changes have been observed below these levels.[1, 18, 19] These ill-defined benchmarks have created considerable variability in defining vitamin D insufficiency worldwide, as 30% of the population fall under the 20 ng/ml mark, while 70% of the population fall below 30 ng/ml.[15]

We believe that without direct comparisons to controls, making recommendations for supplementation in a young adult based on one guideline or another is difficult. Not only does marked variation in mean vitamin level exist with respect to region, race, and season, but it also appears to vary with age. Several investigations in adolescents have found no correlation between bone mineral density and vitamin D levels provided the patients have maintained normal calcium and phosphate levels. One possible explanation for this observation is that hormones such as growth hormone or sex hormones may have a greater influence on calcium homeostasis in the young person.[20–22] Our study showed that the mean levels of vitamin D in patients with and without fracture were not different, which may suggest other factors were involved in contributing to a fracture under low energy conditions.

Several limitations to the present study exist. Foremost, the control group, although age and gender matched, was not matched in experiencing a low energy fall. Second, serum calcium and phosphate levels were not drawn in the present study, so the serum effect of vitamin D was not known. Additionally, ethnic data was not available, which could have biased the control group if they were exclusively African or Hispanic American. Low energy fractures in this age group were relatively uncommon; although 15 subjects were required for the comparison of mean vitamin D levels, more subjects would have enhanced the strength of the correlation calculations. Last, firm conclusions about the long-term effects or extra-skeletal effects vitamin D levels cannot be drawn from the present study, and these results should not be used to judge the appropriateness of calcium and vitamin D supplementation in the elderly population.

Conclusion

Depending on the criteria, vitamin D levels in the Northeastern region of the United States are generally low or low-normal in young adults. Insufficiency or deficiency was diagnosed in 60% of patients with a distal radius fracture using the guidelines recommended by the Institute of Medicine. Young adults sustaining low energy distal radius fractures did not have significantly different levels from that of age and gender matched controls, and no correlation was found between fracture severity and vitamin D level. Although further studies are warranted, these data may suggest that other factors are responsible for low energy fractures in young adults and vitamin D supplementation in an otherwise healthy, young population is unlikely to be protective in the short term.

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Medical Student Research Project

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Parameters for Baseline Testing of Ocular and Vestibular Function: The Effects of Post-Concussion Test Randomization in Dynamic Visual Acuity Results; A Preliminary Report

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Abstract[1]

Neurocognitive testing, such as the ImPACT test, has vastly improved the diagnosis of concussion and has helped physicians and trainers in the management of the post-concussion athlete and the return-to-play decisions.[2] However, it has been shown that neurocognitive tests can misdiagnose concussions and should not be used as stand-alone test, but rather as an adjunct to clinical judgment to in clinical management. Clinical ocular testing has been done on post-concussion subjects, particularly using the Dynamic Visual Acuity (DVA) test.[3] However, these tests are have been conducted in isolated formats with high degrees of repetition and it can be argued that the manner in which they are conducted can confound values and create inaccurate baseline results because of the "learning effect," particularly in the vision testing. This study will attempt to correct for this hypothesized learning mechanism in the DVA test by randomizing the order of the frequencies of the test and integrating the entire set of frequencies and directions (horizontal and vertical) with other known clinical post-concussion tests that examine balance and other ocular function. The randomization of the tests for visual acuity, convergence, balance seems to have a significant effect on the outcome of DVA scores in healthy subjects. A stricter evaluation of recovery in the post-concussion athlete, taking into account vestibular and ocular fatigue that may occur during test randomization, may lead to the prevention of concussion recurrence and sequella.

Introduction

Much has been achieved recently to better understand and evaluate athletic-induced concussions. Clinical findings, such as loss of consciousness, are often not sufficient for diagnosis and can lead to underreporting. It is estimated that 1.6 million sports-related concussions occur annually, of which only 300,000 result in loss of consciousness.[4] Neurocognitive testing, such as the ImPACT test, has vastly improved the diagnosis of concussion and has helped physicians and trainers in the management of the post-concussion athlete and the return-to-play decisions.[5] However, it has been shown that neurocognitive tests can misdiagnose concussions and should not be used as stand-alone test, but rather as an adjunct to clinical judgment to in clinical management. Almasi et al., in a recent survey, found that a significant portion of athletic trainers and coaches would allow a player to return with lower than baseline levels of ImPACT test findings, and that a number of athletes returned to play before currently accepted guidelines would allow.[6] This evidence stresses the need for additional testing in diagnosis of sports-related concussions and eventual return to play.

Mihalik et al. have demonstrated that in many cases the concussed athlete will demonstrates ocular and vestibular abnormalities.[7] Therefore, it appears that baseline parameters for ocular and vestibular function be established, as these can be used comparatively in post-concussion analysis. There does exist clinical tests for both ocular and vestibular function, focusing on tasks that examine the patient's balance and vision with simultaneous head movement.[8] However, these tests are have been conducted in isolated formats with high degrees of repetition and it can be argued that the manner in which they are conducted can confound values and create inaccurate baseline results because of the "learning effect," particularly in the vision testing.

Clinical ocular testing has been done on post-concussion subjects, particularly using the Dynamic Visual Acuity (DVA) test. This test has also been shown as a reliable technique for setting ocular baseline values in normal subjects. Prior literature, Dannenbaum et al., discuss DVA testing in which the test was conducted in an isolated format, using horizontal or vertical head movements at frequencies of 1.0 Hz, 1.5 Hz, and 2.0 Hz in succession.[9] It can be hypothesized that this format of testing leads to inflated baseline values based on a learning mechanism in the testing subjects, simi-

lar to the way in which having a patient perform the same task multiple times in succession will lead to improvement. Our study will attempt to correct for this hypothesized learning mechanism in the DVA test by randomizing the order of the frequencies of the test and integrating the entire set of frequencies and directions (horizontal and vertical) with other known clinical post-concussion tests that examine balance and other ocular function. These post-concussion tests include the Balance Error Scoring System (BESS), convergence test, and King-Devick Test. By using this technique of randomization in the testing format, this study will aim to achieve a truer measure of vestibular and ocular function in normal subjects and correct for any type of learning mechanism that may occur with an isolated DVA test.

Materials and Methods

Using a control of 10 healthy, non-concussed second-year medical students, a randomized set of four different tests were administered to obtain parameters of vestibular and ocular function in each subject, each consisting of tasks that isolate certain mechanisms. For vestibulo-ocular function, the DVA test will be used. For comparability, the test will be conducted under the same guidelines as that of Dannenbaum et al.[10] Each subject was be placed sitting upright at a distance of 10 feet from a standard vision chart. For reference, the subject read the chart initially without head motion. Using a metronome at three different frequencies of 1.0 Hz, 1.5 Hz, and 2.0 Hz, the subject was instructed to read the vision chart at a rate of one letter per beat. The smallest line that is visible to the subject at each frequency will be recorded. Reading was done from left to right and top to bottom, as would a normal American textbook. Subjects were then shown the range of motion for head rotation using a goniometer, which is 20 degrees to both left and right. The examiner held a goniometer fixated to 40 degrees above the subject's head during testing to ensure proper amount of head rotation. Using a metronome, the subject rotated his/her head to one side at each beat while reading the vision chart. The subject was instructed to read the chart at the rate of one letter per beat in the same manner that was used for the reference line. All three frequencies were tested (1.0 Hz, 1.5 Hz, 2.0 Hz), and the lowest visible line was recorded for each test. If the subject corrected an error during the test, it was counted as a correct reading.

The vision chart selected for this study was the E-chart, which displayed lines of the letter "E" oriented up, down, left and right. This type of chart was selected based on the previous research that demonstrated a higher accuracy of the DVA measurements with the E-chart than with the other alternatives.[11] Other vision charts, displaying lines with different letters, created confusion between certain letters that have similarities, i.e., "F" and "E." The E-chart also has the same amount of letters per line, making the pacing of the test easier for the subject. The frequencies at which the test was conducted, 1.0 Hz, 1.5 Hz, and 2.0 Hz, were based on previous studies done to determine the ideal frequencies to be used.

For vestibular function, the Balance Error Scoring System (BESS) was used. This test examined the subject's ability to remain in balance in multiple positions on both floor and foam pad.[12] Prior literature suggested high reliability in this test as an indicator of diminished vestibular function.[13] The foam pad was used to create an unstable surface and more challenging balance task. Twenty-second trials were conducted in which the subject had their eyes closed and attempted to maintain balance in an assigned position. Three assigned positions were used, double leg stance, single leg stance, and tandem stance. Hands of the subjects were placed on the iliac crest and were required to remain there for the entirely of the trial. For the single leg stance, the non-dominant leg was used. During the 20-second trial for each position, both on floor and foam pad, the examiner counted errors made by the subject. Errors were credited to the subject for stumbles, falls, abduction or flexion of the hip beyond 30 degrees, lifting the forefoot or heel from testing surface, removing hands from the iliac crest or remaining out of position for greater than five seconds. The maximum total number of errors for any single condition was 10. If a subject committed multiple errors simultaneously, only one error was recorded. Subjects that were unable to maintain the testing procedure for a minimum of five seconds were assigned the highest possible score, 10, for that testing condition.

To test ocular function, the King-Devick test was used. Subjects were seated in a well-lit area and read a test card at a normal reading distance. If necessary, glasses or contact lenses were worn in order to obtain optimal scores. The tester explained to the subject that the arrows connecting the numbers on the test card should be followed and when the test begins, the subject will read the numbers from left to right and top to bottom, the way a normal American textbook is read. It was emphasized that the subject should read the numbers as fast as possible without errors and without using hands or fingers to track the pattern. The test was administered twice and the baseline score recorded as the fastest time without errors. If the subject made an error and promptly corrects it, no error was recorded. A demonstration card was used initially to explain the test to the subjects in order to prevent memorization of the numbers prior to testing.

Examining the subject's convergence ability also tested ocular function. Convergence was tested using text written on a tongue depressor. The subject held the tongue depressor in their hand and move it closer to their face gradually. The subject was instructed to say when the text on the tongue depressor becomes blurry or unreadable, and the distance of the tongue depressor from the bridge of the subject's nose will be recorded. This test was conducted twice and the measurements was averaged.

In order to test the hypothesis put forth in this study, each of these isolated tasks were assigned a number, which was

chosen at random by the testing subjects selecting cards from a container. Each task within the DVA test, such horizontal head motion at 1.0 Hz or vertical head motion at 1.5 Hz were given its own individual number. In this way, subjects integrated and randomize all forms of ocular, vestibular, and vestibulo-ocular testing to prevent a learning mechanism that may arise from an isolated DVA test. Certain subjects may end up conducting multiple DVA tasks in succession based on randomness; however, the order in which the tasks are conducted were monitored and recorded for later evaluation. The main set of data analyzed was the results of the DVA testing, as this study aims to remove any learning mechanism that would occur when multiple DVA tests are conducted consecutively. The other tests administered were done in attempt to simulate a scenario in which all elements of the post-concussion test are integrated so as to prevent learning mechanisms as well as adding the element of vestibulo-ocular fatigue.

Results

The results of the DVA test in this randomized trial were compared to that of Dannenbaum et al., in which the DVA was the sole test being conducted. Dannenbaum et al. used 31 healthy subjects and 10 patients with complete absence of vestibular function on one side owing to surgical resection of an acoustic neuroma that was preformed four to 62 months before the study.[14] Of the 31 healthy subjects, none or only one of the 31 healthy subjects had an abnormal DVA score at head movement frequencies of 1.5 of slower.[15] This provided a stark contrast to the results of this trial, in which the percentage of healthy individuals with abnormal DVA scores ranged from 70% to 90% depending on different frequencies of head movement. Percentages in this trial are noted here, as the number of healthy subjects in this study was 10, compared to the 31 of the Dannenbaum trial. Figure 1 displays the raw number of subjects with abnormal recorded DVA scores, as results of this randomized trial (A) are shown in comparison to the results of the Dannembaum study (D) at each frequency. It should be noted that the Dannenbaum study did not examine subjects at a vertical frequency of 2.0 Hz. Despite a lesser number of subjects, this study demonstrated a significant increase in the number of abnormal DVA scores in comparison to Dannenbaum. In the Dannenbaum study, healthy subjects were administered the test three times consecutively, indicating that a learning mechanism may have contributed to the markedly better DVA scores.[16] In comparison, the randomization of this trial with integrated balance, convergence, and visual testing likely accounted for the significant drop in DVA test results. The removal of any possible learning mechanism indicates a more baseline evaluation of the vestibular and ocular capabilities of the subject, particularly under conditions of vestibulo-ocular fatigue from the BESS, convergence, and King-Devick tests.

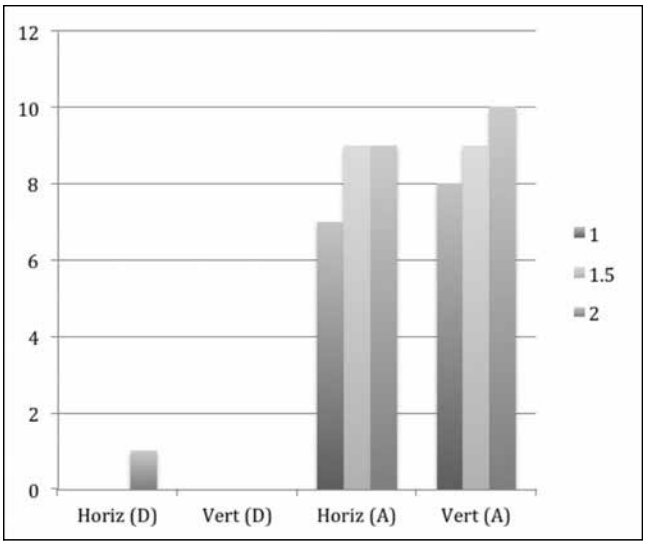

Figure 1. Abnormal DVA Scores of both Agarwala (A) and Dannenbaum (D) studies

The Dannenbaum study also recorded the DVA results for the 10 abnormal subjects, those lacking vestibular function in one side, which were found to be quite comparable to the results obtained in this randomized trial of the 10 healthy subjects. In fact, the abnormal DVA scores of the healthy subjects in this trial outnumbered the abnormal DVA scores of the impaired subjects of the Dannenbaum study.[17] Figure 2 and Figure 3 demonstrate the near mirroring of abnormal DVA scores between the two studies, despite abnormal subjects in the Dannenbaum study and healthy subjects in this study with randomized testing. Vertical testing of 2.0 Hz was not recorded in the Dannenbaum study and thus was not compared.

Discussion

These results indicate that the various DVA tests being interspersed with tests for balance and convergence can actually yield results comparable to that of subjects that lack vestibular function in one side. This analysis further underlines the significance of the learning mechanism that takes place with multiple trials in healthy subjects, as only the first DVA test of impaired patients in the Dannenbaum study were used for evaluation as opposed to the best of three tests given to the healthy subjects in the Dannenbaum study.

Conclusions

The randomization of the tests for visual acuity, convergence, balance seems to have a significant effect on the outcome of DVA scores in healthy subjects. In prior studies such as Dannenbaum et al., the learning mechanism of repeating testing appears to be evident in the improvement of DVA scores. By integrating the DVA test into a randomized set of tests for balance and visual acuity such as the BESS test and convergence, a better, more accurate measure

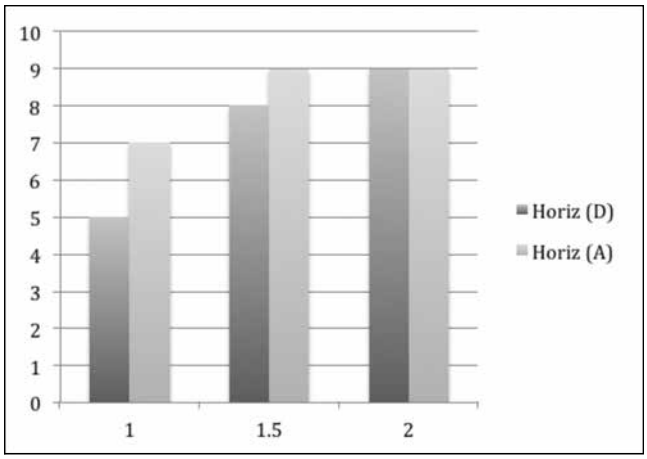

Figure 2. Abnormal DVA Scores Recorded in Horizontal DVA Testing, Dannenbaum Subjects (D) with One-Sided Lack of Vestibular Function vs. Healthy Subjects (A) of Randomized Study

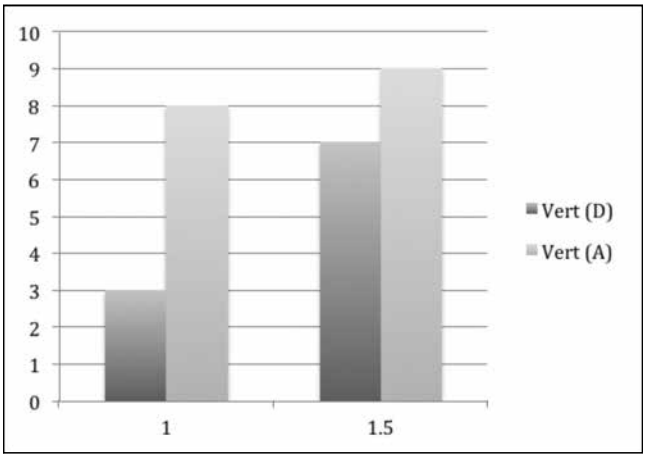

Figure 3. Abnormal DVA Scores Recorded in Vertical DVA Testing, Dannenbaum Subjects (D) with One-Sided Lack of Vestibular Function vs. Healthy Subjects (A) of Randomized Study

of baseline vestibular and ocular function can be obtained. By removing the element of learning through randomization of testing for balance, convergence, and vision during head movement, the examiner can better determine how a concussion has affected the vestibular and ocular function of the athlete in question during the recovery phase. Further testing is required for more accurate depictions on the true effects of post-concussion test randomization; however, it is likely that a more accurate baseline evaluation should help in improving the management of the post-concussion athlete, particularly in the decision for return to play. A stricter evaluation of recovery in the post-concussion athlete, taking into account vestibular and ocular fatigue that may occur during test randomization, may lead to the prevention of concussion recurrence in the future.

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Medical Student Research Project

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Reliability and Limitations of Neurocognitive Testing in the Management of Athletic Induced Concussions: The Sandbagging Effect

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Abstract

The purpose of this paper to provide a status-report on the current concerns with neurocognitive testing, specifically pertaining to the ImPACT test and a possible "learning effect" and the under diagnosis of sports-related concussions. Also addressed is the practice of "sandbagging" the action in which athletes score purposely low on their baseline assessments so that following a concussion, their scores will return to baseline levels faster, enabling them to return to play earlier. No significant increase in test scores, which would indicate the presence of a practice or learning effect, was observed over the course of this study, validating the claim that the ImPACT test eliminates the practice effect. Within the ImPACT test are certain validity indicators which aim to identify test takers who are performing poorly due to a lack of effort rather than poor cognition. For example, a score of 30 or greater on the Impulse Control module, which was only found in five percent or less of healthy high school, collegiate, and professional athletes, will automatically flag the test as invalid.[23] Since an invalid score is only marked by placing a ‡ below the test score in the desktop version or ++ in the online version, it is important that the test interpreter is attentive to the possibility of an invalid baseline test performance.

Introduction

The assessment and management of sports-related concussions have recently received growing attention in the fields of neuropsychology and sports-medicine. Specific studies have focused on concussion diagnosis, recovery rates, return-to-play guidelines, and the long-term health implications of repeated concussions. Continued research has led to the development and evolution of various neurocognitive tests which are used to assess an athlete's level of cognition before and after sustaining a suspected concussion. These tests have provided team physicians and athletic trainers with a useful standardized and efficient tool to help them manage a concussed athlete and make proper return-to-play decisions. Nevertheless, concerns surrounding the clinical management of concussions persist and the fact that many concussions go undiagnosed brings into question the reliability and specificity of neurocognitive testing. Additionally, new research addresses the practice of 'sandbagging,' the action in which athletes score purposely low on their baseline assessments so that following a concussion, their scores will return to baseline levels faster, enabling them to return to play earlier. It is the intention of this paper to provide a status-report on the current concerns with neurocognitive testing, specifically pertaining to the ImPACT test, and the under diagnosis of sports-related concussions.

Definition and Prevalence of Sports-Related Concussions

While there is no universally accepted definition of concussion, the American Medical Society for Sports Medicine provides this concise and versatile statement: "Concussion is defined as a traumatically induced transient disturbance of brain function and involves a complex pathophysiological process. Concussion is a subset of mild traumatic brain injury (MTBI), which is generally self-limited and at the less severe end of the brain injury spectrum."[10] It is currently estimated that as many as 3.8 million concussions occur in the United States during competitive sports and recreational activities each year and that up to 50 percent of concussions are undiagnosed. Further, at least 5.3 million people, about two percent of the American population, are living with long-term disability associated with TBI from all causes.[10, 13] While concussions can be sustained in nearly all sports, the most incidences occur in football followed by hockey, rugby, soccer, and basketball. In football, the positions with the highest incidence of concussions per exposure are linebackers, offensive linemen, defensive backs, and quarterbacks.[9] It should also be noted that previous concussions and the female gender are risk factors for sustaining a sports-related concussion.[18]

Relevance: Pathophysiology and Health Implications of Recurrent Concussions

Recent discoveries regarding the pathophysiology and long-term health implications of recurrent concussions have elevated the importance of concussion research. The pathophysiology of a concussive blow involves cellular metabolic dysfunction that results from the cells' exposure to immediate changes in both their intracellular and extracellular environments. It is suggested that these changes are due to the excitatory amino acid (EAA)-induced ionic shifts with increased Na/KATP-ase activation and resultant hyperglycolysis. The overall result is a "metabolic mismatch" where there is a high energy demand within the brain shortly after the concussive injury with a simultaneous decrease in cerebral blood flow.[14] Although not yet implemented in the clinical setting, much of the current pathophysiology research examines the use of fMRI as a diagnostic tool.

The long-term health implications of TBI show that repeated concussions can be severely debilitating, and the field is receiving much research attention. Results from a population-based study indicate that a person diagnosed with any form of TBI is 1.8 times as likely to report binge drinking, 1.5 times increased risk for depression, 11 times as likely to develop epilepsy, 2.3–4.5 times increased risk of Alzheimer's, and annually are overall 7.5 times as likely to die.[13] The onset of Chronic Traumatic Encephalopathy (CTE) has been specifically linked with repetitive concussions.[19] CTE is a neurological degenerative disease which can only be definitively diagnosed postmortem by the presence of tau protein deposition. Common clinical manifestations of CTE include symptoms of dementia such as memory loss, aggression, confusion, and depression. The onset of these symptoms can range from years to decades after the initial injury.

In addition to linking repetitive concussions with CTE, a study by McKee et al., 2009, reported four cases of former and active football players who committed suicide whose brains demonstrated tau protein deposition on autopsy.[19] They include former professionals Dave Duerson of the Chicago Bears and Andre Waters of the Philadelphia Eagles. Nonprofessional football players are Owen Thomas, co-captain of the Univeristy of Pennsylvania team, who did not have a documented history on concussions, and Austin Trenum, a high school student from Nokesville, Virginia.[19] More recently and receiving the attention of the entire nation is the case of 10-time All-Pro NFL linebacker Junior Seau who shot himself in the chest in 2012. Upon autopsy, the National Institutes of Health concluded that Seau also suffered from CTE.

The recent discoveries of the long-term health risks posed by repeated concussions combined with the many tragic cases including former athletes have made it clear that proper assessment and management of a concussed athlete is paramount to the athletes' long-term health. In support of this claim, several animal and human studies demonstrate that athletes who experience a second blow to the head before the brain has fully recovered from a concussion experience worsening metabolic changes within the brain cells. Further, experimental evidence suggests that the concussed brain may be susceptible to prolonged dysfunction if it is prematurely exposed to cognitive and physical activity before a full recovery has taken place (Harmon et al., 2013).

Brief History of Neurocognitive Testing

The use of Neurocognitive testing as a diagnostic and management tool for sports-related concussions emerged in the mid-1980s at the University of Virginia.[1] Their classic study examined the utility of neurocognitive testing as a means of recording cognitive recovery in the first weeks following a sports-related concussion. Further studies and practices led to the widespread implementation of a baseline (pre-concussion) assessment at the professional level in the NFL and NHL in the mid-early 1990s. This baseline assessment can be analytically compared with an athlete's test scores post-injury, thus providing objective data to aid in making return-to-play decisions (Lovell, 2009). However, while the use and rapid expansion of traditional neurocognitive testing (e.g., paper and pencil tests) greatly enhanced our understanding of the effects of concussions, its expansion to the amateur, college, and high school ranks was limited. Paper and pencil testing was deemed too costly and time consuming, and many of these organizations were limited by a shortage of neuropsychologists who are required to interpret the test results.[14]

One of the major factors which led to the outdating of paper and pencil neurocognitive tests were studies which demonstrated a significant "practice effect" associated with traditional neurocognitive tests. A practice effect takes place when one's performance improves significantly from one test to the next due to one's prior test taking experience. A study by Crawford and colleagues in 1989 found that upon re-administration of the Rey Auditory Verbal Learning Test 27 days after initial testing, subjects performed significantly better. Supporting these results is a study by Benedict and Zgaljardic in 1998 which demonstrated that subjects repeatedly taking the same form of both verbal and non-verbal memory tests improved significantly, with the largest improvement seen between the first and second testing sessions. Also, the study demonstrated that subjects taking an alternate form of the nonverbal memory test involving drawing designs produced similar practice gains. The implications of the Benedict and Zgaljardic study are that retesting with repeated questions, both verbal and non-verbal, and unrepeated questions involving drawing leads to a practice effect; however, retesting with alternate questions which do not involve drawing, such as in the verbal memory test, produced stable results. Thus, due to the many limitations of traditional testing, research began in developing improved computer-based neurocognitive assessments (Lovell, 2009).

Cumputer-based neurocognitive testing led to the ImPACT test, which has several advantages over traditional testing. First, the ImPACT test allows for the evaluation of a large number of athletes in a relatively short amount of time while requiring little professional oversight. Second, testing data is easily and efficiently stored. Third, computers provide a more accurate recording of reaction times; computers are accurate to 1/100 of a second whereas traditional testing is accurate to one to two seconds. Fourth, the ImPACT test aims to eliminate the practice effect by presenting different questions in a randomized order.[14] Supporting the last assertion is a study by Lovell and colleagues in 2003 which compared baseline scores with retested scores in both normal and concussed high school athletes. The study revealed that concussed athletes scored significantly lower composite scores following a concussion when compared with their baseline scores, while healthy subjects displayed no significant increase or decrease on their retested scores. Thus, no practice effect was observed in both healthy patients and concussed patients.

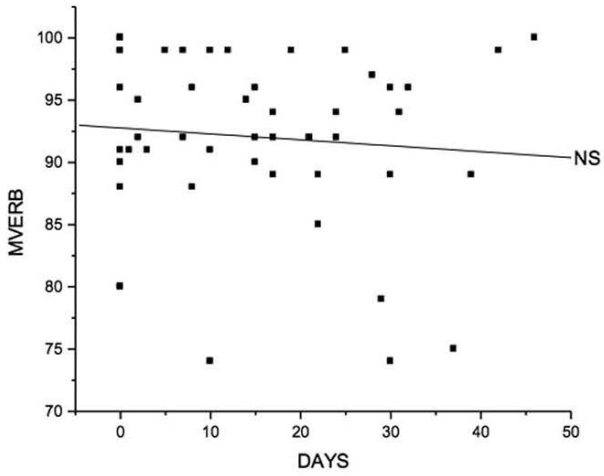
Supporting the claim that the ImPACT test eliminates the practice effect observed in traditional paper and pencil testing is a study performed by Torg et al. in 2012. At Temple University Hospital, 10 healthy non-concussed medical students were evaluated using the ImPACT test on five different occasions. Subjects were instructed to perform to the best of their ability on each test. The repeated evaluations were carried out weekly and all tests were completed within 46 days of the first assessment. The ImPACT test consists of six testing modules: word discrimination, design memory, Xs and Os memory location, symbol matching, color matching, and three letter memory; each testing a different aspect of cognition. The results from specific parts of each of the modules were sorted into four composite scores: verbal memory, visual memory, visual motor speed, and reaction time. These results for each student were scored and plotted over time (Figure 1). Analysis was completed using a linear regression for each score vs. time which was fitted to the data. The results demonstrate that verbal memory, visual memory, and visual motor speed composites show no significant change with repeated assessments. The reaction time composite showed a decrease in scores over time. On average, the reaction time decreased .0011 units per day. In sum, no significant increase in test scores, which would indicate the presence of a practice or learning effect, was observed over the course of this study, validating the claim that the ImPACT test eliminates the practice effect.

Impact Verification Studies: Validity, Sensitivity, and Specificity

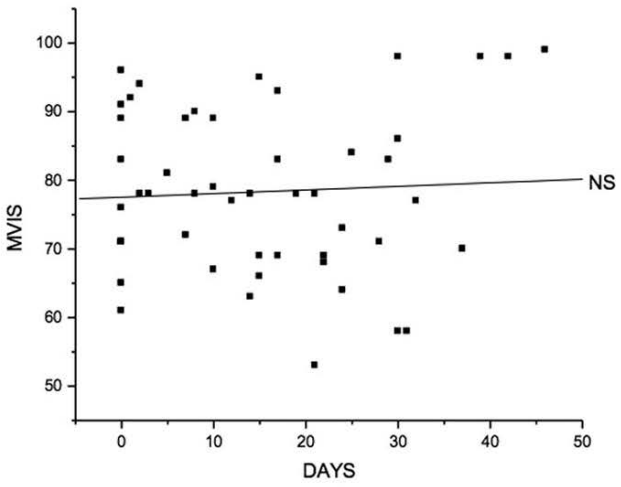
In addition to the elimination of a practice effect, many studies have documented the ImPACT test's high degree of validity, sensitivity, and specificity. The validity of the ImPACT test, the test's ability to measure a decrease in cognitive function following a concussion, was examined in 2003 by Iverson, Lovell, and Collins. In their study, the test and retest scores of healthy young adults were compared with those of concussed amateur athletes. The study demonstrated that the concussed athletes were 47 times more likely to display a significant decrease in two or more ImPACT scores than non-concussed subjects. In a follow-up article, the validity of ImPACT was demonstrated by comparing it to the SDMT (Symbol Digit Modalities Test), a traditional neurocognitive measure. The article found a high correlation between SDMT and ImPACT composite scores, the highest seen with the Processing Speed and Reaction Time ImPACT sections.[11] The sensitivity and specificity of ImPACT's original desktop version was measured to 81.9 percent and 89.4 percent using healthy and recently concussed high school athletes, respectively.[23] In a recent study by Schatz et al., however, the sensitivity and specificity of ImPACT's online version was measured, using both healthy and recently concussed high school and collegiate athletes, to 91.4 percent and 69.1 percent respectively.[23] As the authors from this study note, the sensitivity and specificity may be higher than reported because included in the study were asymptomatic athletes that the researchers suspected of hiding their concussion symptoms.

Current Concerns with Neurocognitive Assessments and Under Diagnosis of Concussions

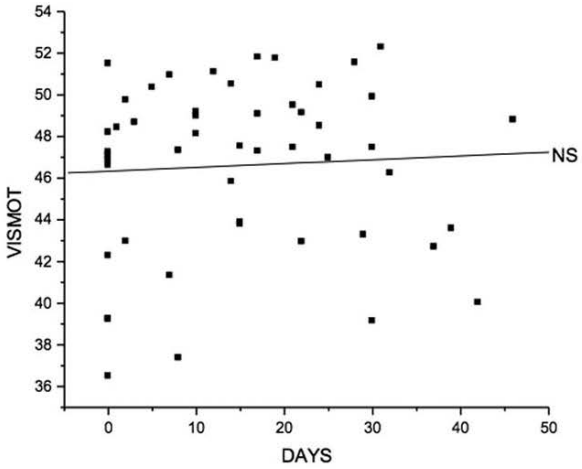
While protocols for the on-field diagnosis of concussions have improved, many concussions continue to go undiagnosed. Despire the many studies which support the validity, sensitivity, and specificity of the ImPACT test, specific cases and player surveys question the ImPACT test's susceptibility to deception.[23] In 2010, Owen Thomas, captain of the University of Pennsylvania football team and a student whom his coach described as 'the most popular kid on our team,' committed suicide by hanging. An autopsy of Thomas' brain revealed tau protein deposits and mild stages of CTE. Pointing to the shortcomings of concussion management is the fact that Owen Thomas was never actually diagnosed with a concussion.[21] In a recent survey of 103 NFL players from 27 different teams, 56 percent of the players said that they would hide concussion symptoms to keep playing (staff report, 2012). Similarly, in a high school football survey, nearly 53 percent of players reported that they intentionally did not report having sustained a concussion.[23] When asked to list the reasons they did not report their concussion, 66.4 percent did not think their concussion was serious enough to warrant medical attention, 41 percent said they did not want to be removed from competition, and 22 percent listed that they did not want to let down their teammates.[23] It should also be noted that the general attitude among highly competitive athletes is to minimize concussive symptoms because of the belief that they must "play hurt" in order to be successful.[15]



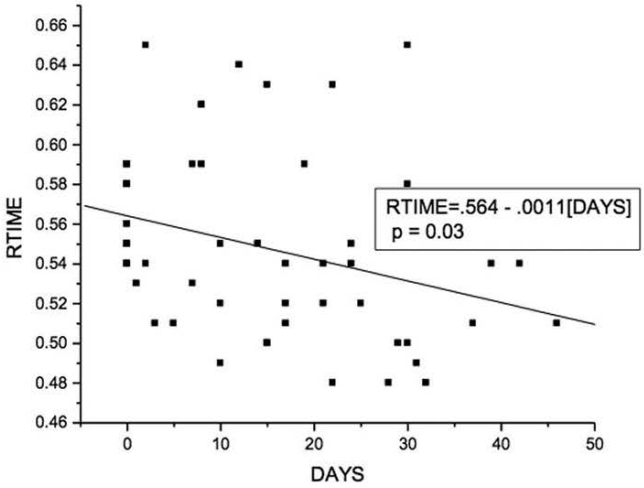
a) Verbal Memory



b) Visual Memory



c) Visual Motor



d) Reaction Time

Figure 1. Graph showing ImPACT composite scores over time for test subjects. A linear regression for each score vs. time was fitted to the data. Graphs **(a), (b),** and **(c)** demonstrate that subjects' Verbal Memory, Visual Memory, and Visual Motor scores remained stable and did not significantly change over time. Graph **(d)** displays a significant decrease in subjects' reaction time scores over time.

Although the ImPACT test is not used as an in-game diagnostic tool, the general attitude of hiding symptoms and tricking concussion tests in order to return to play calls into question whether or not the ImPACT test is vulnerable to deception. Supporting this concern is the case of former Penn State quarterback Michael Robinson who suffered a concussive blow in a game against Wisconsin in 2004 which was serious enough for him to be removed from the field on a body board and hospitalized overnight. Interestingly, when Robinson took the ImPACT test a few days later, he scored surprisingly better than his baseline examine on several sections.[6]

Sandbagging, the Present Issue with Neurocognitive Testing

Whereas the original paper and pencil neurocognitive tests suffered from a practice effect, one of the main problems with the current computerized neurocognitive tests is players attempting to sandbag the baseline exam. Researchers commonly use the terms 'sandbagging' and 'sandbaggers' to describe athletes who purposely produce a low score on their baseline test. Their thinking is that following a concussion, their scores will reach baseline sooner mimicking a fast recovery thereby allowing them to return to play. In

relation to the case of Michael Robinson, it is possible that he simply recovered very quickly, but a more plausible explanation might be that he 'sandbagged' his baseline exam.

The benefits of establishing a baseline level of performance on neurocognitive assessments with regard to return to play decisions are logical and have been examined experimentally. Formal preseason baseline assessments have been recommended to provide a basis for comparison in the event of a sports-related concussion during the season. Baselines have been emphasized namely because cognitive performance levels vary greatly between individuals, and without the advantage of knowing the players' pre-concussion performance, it is difficult to detect deficits or to establish when an athlete is fully recovered (Lovell and Collins, 1998). A study by Gardener et al. in 2012 demonstrates that without a baseline exam, the use of the ImPACT and CogSport neurocognitive tests post-concussion do not improve diagnostic and concussion classification better than what would be predicted using only the traditional demographic variables (e.g., age and number of previous concussions).[8] Supporting the validity of comparing preseason baseline ImPACT scores with post-concussion scores, a study by Schatz in 2010 reported that ImPACT baseline levels do not significantly change over a two-year period for collegiate varsity athletes. Further, a study by Elbin et al. in 2011 reports that ImPACT baseline levels do not significantly change over a one-year period for high school athletes.[5]

Most athletes are not aware that sandbagging the baseline exam without detection is not as simple as they might think. Within the ImPACT test are certain validity indicators which aim to identify test takers who are performing poorly due to a lack of effort rather than poor cognition. For example, a score of 30 or greater on the Impulse Control module, which was only found in five percent or less of healthy high school, collegiate, and professional athletes, will automatically flag the test as invalid.[23] Since an invalid score is only marked by placing a ‡ below the test score in the desktop version or ++ in the online version, it is important that the test interpreter is attentive to the possibility of an invalid baseline test performance.[23]

Despite the internal validity detection system of the ImPACT test, researchers have described studies in which athletes were able to sandbag the baseline assessment while avoiding detection. In a study by Erdal in 2012,[7] collegiate athletes who performed valid baseline exams were retested on ImPACT and instructed to perform worse than their baseline but without reaching the threshold of detection. Of the 75 athletes, eight (10.7 percent) were able to successfully avoid detection. The author notes that all of the successful sandbaggers did not perform significantly worse on the Reaction Time and Visual Motor Speed composites and thus deem these sections as the least sensitive in detecting sandbaggers. In contrast, the Verbal Memory and Visual Memory Composites identified the most sandbaggers and were thus considered the best sandbagging identifiers.[7] In a follow-up study by Schatz and Glatts in 2013, collegiate athletes completed a baseline assessment on ImPACT and MSVT (Medical Symptom Validity Test). They were then divided into three groups — best performance, naïve, and coached — and retested. The best performance group was instructed to perform their best, the naïve group was simply asked to perform poorly, and the coached group was asked to perform poorly but they were instructed to do so without making obvious errors in order to avoid detection. When tested on ImPACT alone, 40 percent of the naïve group and 25 percent of the coached group, respectively, were successfully able to avoid detection. However, when the data from both the MSVT and ImPACT are used together, five percent and zero percent of the naïve and coached sandbaggers, respectively, were able to avoid detection.[23] These results display that when assessed on ImPACT alone, a higher percentage of sandbaggers might go undetected than was previously believed.

Current Practices of Athletic Departments and the Implications

Continual new discoveries of severe long-term health risks resulting from repeated concussions have given the field of sports-related concussions a great deal of national attention. Now more than ever, proper use of neurocognitive testing is paramount for the correct diagnosis and management of concussed athletes. Athletic trainers and other sports medicine professionals at the pro, collegiate, and high school level play the primary role in assessing injuries and managing their athletes' health, including making important return-to-play decisions. A quantitative online survey of sports medicine professionals at the collegiate and high school level administered by Covassin et al., 2009, examines the current practices of neurocognitive testing and use of baseline testing and its role in making return-to-play decisions. Study participants were 399 athletic trainers (ATs) with an equal number from the high school and collegiate ranks. Of the 399 ATs, 94.7 percent reported that they administer baseline assessments; however, only 51.9 percent of these ATs reported examining the baseline tests for validity. The fact that just over half of the responding ATs examine baseline tests for validity is concerning with relation to the current sandbagging problem. As previously described, the ImPACT test has built-in validity indicators which have been reported in two studies to detect 89, 75 and 60 percent of sandbaggers; yet, if the baseline results are not examined, then ImPACT's sandbagging detecting ability has no effect.[7, 23] Further, the study reports that only 45.8 percent of high school ATs and even worse only 12 percent of collegiate ATs readminister baseline testing every two years. This is a potential major problem as the current research only validates the stability of baseline scores for two and one year in collegiate and high school athletes, respectively.[5, 23]

The survey also describes two scenarios regarding return-to-play decisions: first, would you return an athlete to competition despite a return to baseline performance on ImPACT if the athlete were still experiencing symptoms? Second, would you return an athlete to competition who is symptom free but who scores below ImPACT baseline scores? In response to the first scenario, 95.5 percent of ATs would not return the athlete to competition; whereas in the second scenario, 86.5 percent of ATs would not return the athlete to competition, 9.8 percent would, and 3.8 percent specified that it 'depended on the importance of the competition.'[3] Overall, the responses from these two scenarios indicate that most ATs (in this study) rely more on symptoms than on neurocognitive test scores when making return-to-play decisions. The decrease in the percent of ATs who would not allow an athlete return to play in the second scenario is problematic because cognitive impairment after a concussion may last longer than the subjective symptoms.[10]

Recommendations and Conclusions

The fourth international consensus statement on concussions in Zurich addresses the importance of neurocognitive concussion testing and provides specific recommendations for its use as a diagnostic and concussion management tool. The statement describes neurocognitive testing as a 'cornerstone' of concussion management, and that brief computerized cognitive evaluation tools, such as the ImPACT test, are the mainstay of these assessments.[18] The consensus statement further highlights the value of neurocognitive testing by stating that 'these tests provide important data on symptoms and functional impairments that clinicians can incorporate into their diagnostic formulation.' The conference recommended the use of neurocognitive testing to aid in the diagnosis and to assist with return-to-play decisions following a concussion. It should also be noted that the authors strongly believe that computerized testing should not be the sole basis of diagnostic and concussion management decisions.[18] With regard to baseline testing, in contrast with many previous recommendations, the consensus statement did not feel that there was sufficient evidence to mandate its widespread routine usage. The authors do, however, believe that baselines may be helpful or add useful information to the overall test evaluation; additionally, baseline testing provides an extra educational opportunity to discuss the significance of a concussion with the athlete.[18]

This review article has focused its attention on the evolution, usage, limitations, and current practices of neurocognitive testing, specifically pertaining to the ImPACT test in the diagnosis and management of sports-related concussions. The long-term health concerns associated with repeated concussions are severe. Increasingly more research is aimed at investigating the pathophysiology and clinical course of sports-related concussions. This in turn places more importance on the proper utilization of neurocognitive testing as a key tool in the proper diagnosis and management of a concussed athlete. The transition from the original paper and pencil assessments to online computerized tests has eliminated the previously demonstrated practice effect and greatly increased the overall accuracy and efficiency of assessing cognition. The preponderance of studies demonstrates the importance of the use of baseline testing while remaining vigilant to the onset of sandbagging. This article aims to bring awareness to the current benefits, practices, and concerns surrounding neurocognitive testing in the hope that it will encourage proper usage and direct research towards maximizing the potential benefits of these assessments.

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Medical Student Research Project

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Acute Management of Open Long Bone Fractures: Clinical Practice Guidelines

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Abstract

Introduction: The acute management of an open fracture aims to promote bone and wound healing through a series of key steps; however, lack of standardization in these steps prior to definitive treatment may contribute to complications.

Methods: A literature review was conducted to determine the best practice in the acute management of open long bone fractures to be implemented at Temple University Hospital, with a primary focus on prophylactic antibiotic administration, local antibiotic delivery, time to debridement and irrigation techniques.

Results: A computerized search yielded 2,037 results, of which a total of 21 articles were isolated and reviewed based on the study criteria. The final total was then subdivided into the topics focused on in this review: duration of prophylactic antibiotics (n = 2), local antibiotic delivery (n = 7), time to debridement (n = 10), and irrigation techniques (n = 2).

Conclusion: Recommendations were developed based on a review of clinical studies on open fracture management. Prophylactic antibiotic recommendations, including coverage of choice and duration of administration, were adapted from the guidelines proposed by the Eastern Association for the Surgery of Trauma workgroup. In addition, the use of local antibiotic delivery techniques may prove beneficial as an adjunct to systemic prophylactic antibiotic therapy in the management of severe open fractures and in patient populations where prolonged antibiotic therapy is otherwise indicated. Debridement and irrigation should occur emergently, but only if resources are available. A low-pressure (6–10 pounds per square inch) lavage system using either detergent or saline, with increased volumes for more severe fractures, is recommended prior to fracture fixation to reduce the bacterial load.

Introduction

Current complications of an open fracture include infection, nonunion of the fracture, and missed compartment syndrome,[1, 2] often resulting in loss of function of the limb. Infection rates can range from 0–50% depending on fracture severity and location[2–5] and nonunion rates are reported at an incidence of 18–29%.[6, 7] Historically, amputation of the fractured limb and mortality were commonly associated with open fractures.[8, 9] However, due to developments in its management, outcomes for open fractures have generally improved, as limbs are often salvaged and patients can retain function of the injured extremity. Despite generalized standards for open fracture treatment, there remains variation and controversy over the initial management of open fractures, which may contribute to complications following treatment.

Open fractures occur when the fractured bone penetrates through the skin, involving damage to the bone and soft tissue. Complications following an open fracture relate to the severity of soft tissue injury,[3] which became the basis of the open fracture classification system as described by Gustilo and Anderson. Despite recent reports of interobserver variability in fracture classification,[10] the Gustilo-Anderson classification of open fractures has been used for many years. In 1976, open fractures were divided into three categories (Table 1). Type I fractures were described as open fractures that resulted in a laceration length of less than one centimeter, were moderately clean and had minimal soft tissue injury. Type II fractures were wounds greater than one centimeter in length with moderate soft tissue damage. Type III fractures had extensive soft tissue damage and a high degree of contamination.[3] Several years later, Type III fractures were further divided: Type IIIa fractures had adequate soft tissue for bone coverage; Type IIIb involve loss of soft tissue, including periosteal stripping; and Type IIIc involve arterial injury requiring repair.[11] These fracture classifications are currently used in practice to determine the appropriate steps in the treatment of an open fracture.

The management of open fractures includes adherence to Advanced Trauma Life Support (ATLS) guidelines, assessment of neurovascular injury, prophylactic antibiotic and tetanus toxoid administration within three hours of injury,[1, 12–14] temporary coverage of the wound with sterile saline soaked gauze, emergent meticulous debridement and irrigation,

temporary or definitive fixation, and wound closure and coverage,[1, 7, 15–17] with the latter operative steps commonly left to the discretion of the surgeon. Goals of treatment focus on bone and wound healing, with the prevention of infection.[8, 18] The lack of agreement over key steps in the initial management of open fractures may contribute to common complications such as infection or nonunion of the fracture.

Recent guidelines have described prophylactic antibiotic use in the management of open fractures based on fracture classification (Table 1, Appendix 1a and 1b).[9, 13, 14] Nonetheless, noncompliance with these recommendations occurs, such as antibiotic use exceeding the recommended duration, which can lead to further complications.[19] Additional concerns with prolonged antibiotics use are the development of antibiotic resistance, allergic reactions, host toxicity and increased costs.[9, 17] Several studies evaluate the benefits of local antibiotic delivery as adjunctive prophylactic therapy in the management of open fractures in an effort to decrease systemic levels of antibiotic.[16, 20–27]

Another area of current debate is the urgency of surgical intervention, from the time of injury to initial debridement. The "six-hour" window for operative treatment, which has been the standard practice in the management of open fractures for several decades, is being reevaluated to assess the scientific validity of such a timeframe and whether operative treatment within this time period is advantageous to the patient. Recent studies have suggested that the experience and preparedness of the surgical team may be a more important determinant in treatment outcome[28] and that a delay in operative treatment until the appropriate resources are available may reduce the risk of poor outcomes.[6, 29]

Irrigation is another critical step in the initial management of an open fracture, as it serves to reduce the bacterial load in the wound.[30, 31] However, there remains great variation in the techniques used for irrigation of the wound,[32] some of which may result in complications, including poor wound healing, delay in fracture healing, host toxicity and the increased risk of infection.[30, 33–37]

The purpose of this study is to conduct a literature review to develop current recommendations for the initial management of open fractures in long bones to be implemented at Temple University Hospital (TUH), with a primary focus on prophylactic antibiotic administration, local antibiotic delivery, time to debridement, and irrigation techniques, and assess how these influence the development of complications seen commonly after the treatment of an open fracture.

Methods

A literature review was conducted by a computerized search using the MEDLINE database with the following medical subject headings (MeSH) terms: *Fractures, Open* [Mesh] AND *Fractures, Open/classification* [Mesh] AND *Fractures, Open/therapy* [Mesh]; *Fractures, Open* [Mesh] AND *Antibiotic Prophylaxis* [Mesh] AND *Antibiotic Prophylaxis/adverse effects* [Mesh]; *Fractures, Open* [Mesh] AND *Therapeutic Irrigation* [Mesh]; *Fractures, Open* [Mesh] AND *Surgical Wound Infection* [Mesh]; *Fractures, Open* [Mesh] AND *Debridement* [Mesh]; (*Arm Bones* [Mesh] OR *Leg Bones* [Mesh]) AND *Fractures, Open* [Mesh]; *Antibiotic Prophylaxis* [Mesh] AND *Drug Resistance, Bacterial* [Mesh] AND *Surgical Wound Infection* [Mesh]; *Fractures, Open* [Mesh] AND *Fractures, Open/complications* [Mesh] AND *Therapeutic Irrigation* [Mesh] AND *Surgical Wound Infection; Fractures, Open/complications* [Mesh] AND (*Fractures, Open/surgery* [Mesh] OR *Fractures, Open/therapy* [Mesh]); *Fractures, Open* [Mesh] AND *Anti-Bacterial Agents/administration and dosage* [Mesh]; *Fractures, Open/surgery* [Mesh] AND *Polymethyl Methacrylate* [Mesh]; (*Fractures, Open* [Mesh]) AND *Polymethyl Methacrylate* [Mesh]) AND *Anti-Bacterial Agents* [Mesh]. Additional key words used in the search included *local antibiotic* and *antibiotic bead pouch.*

Through a title and keyword review of the initial search results, studies were considered if they included open fractures of long bones, such as the tibia, femur, humerus, and forearm, in an adult population. Studies were excluded from the review if they did not meet the inclusion criteria, were not published in English, were not performed on human subjects, used a patient population that was younger than 19,

Table 1. Fracture Classifications and Prophylactic Antibiotic Recommendations

Classification	Description	Antibiotic Recommendations
Type I	<1 cm wound, minimal soft tissue damage, moderately clean	First generation cephalosporin (gram-positive coverage), continued for 24 hours after wound closure.
Type II	>1 cm wound, moderate soft tissue damage	First generation cephalosporin (gram-positive coverage), continued for 24 hours after wound closure. The addition of a once-daily aminoglycoside is safe and effective.
Type III	Extensive soft tissue damage, high degree of contamination	First generation cephalosporin (gram-positive coverage) and aminoglycoside (gram-negative coverage) continued for 72 hours after injury, but no more than 24 hours after soft tissue coverage of the wound. Penicillin is recommended for farm-related injuries, with soil or fecal matter contamination. Fluroquinolones offer no advantage over cephalosporins and aminoglycosides and have been found to have a negative impact on open fracture outcome.
Type IIIa	Adequate soft tissue coverage of bone	
Type IIIb	Loss of soft tissue, periosteal stripping	
Type IIIc	Vascular injury needing repair	

Fracture classification as described by Gustilo and Anderson and by Gustilo et al.[3, 11]
Antibiotic recommendations as per the Eastern Association for the Surgery of Trauma (EAST) guidelines proposed in 1998 and 2011.[13, 14]

classified gun shot wounds as open fractures, or contained pelvic bones or long bones of the hand or foot. Papers fit for the study were further isolated through an abstract and article review, excluding studies that did not fit the topic of the current review. In addition, references of relevant review articles were reviewed for citations missed by the initial computerized search, and were subjected to the same review process as described above.

Articles that met the inclusion and exclusion criteria were later subdivided into the topics focused on in this review: prophylactic antibiotic administration, local antibiotic delivery, time to debridement, and irrigation techniques.

Results

Search Results

The initial search yielded 2,037 results, 485 of which were duplicates, resulting in 1,552 articles (Figure 1). Filters were then applied to remove studies that were not published in English, were not performed on human subjects and used a patient population that was younger than 19. Reviews were also removed from consideration, resulting in 640 articles for title review. Four hundred and ninety-one articles were excluded through a title review based on exclusion and inclusion criteria. The resulting articles were subjected to abstract and article reviews resulting in 18 papers. Three articles were added through a review of references of relevant reviews. The final total (n = 21) was then subdivided into the topics focused on in this review: duration of prophylactic antibiotics (n = 2), local antibiotic delivery (n = 7), time to debridement (n = 10), and irrigation techniques (n = 2).

Prophylactic Antibiotic Duration

The database search resulted in one article that met the criteria for the study of prophylactic antibiotic duration in the management of open fractures, and a review of the references of relevant reviews produced an additional study. A total of two articles were reviewed for the study of prophylactic antibiotic duration in the management of open fractures (Table 2).

In an earlier work from 1988, Dellinger and colleagues[38] conducted a double blind randomized prospective study comparing the efficacy of a one-day versus a five-day prophylactic antibiotic regimen for the management of open fractures in the arm and leg. This study found no statistical difference in infection rates between patients that received the short duration antibiotic regimen compared to those that received the five-day regimen (27% vs 23%), demonstrating that a short duration of antibiotics is as effective as a longer duration.

More recently, Dunkel et al.[39] assessed the risk of infection following varying durations of prophylactic antibiotic treatment in 1,492 open fractures using a retrospective case control model. The odds ratio (OR) for infection based on antibiotic duration using a multivariable regression analysis was

Figure 1. Method of Article Selection for Literature Review

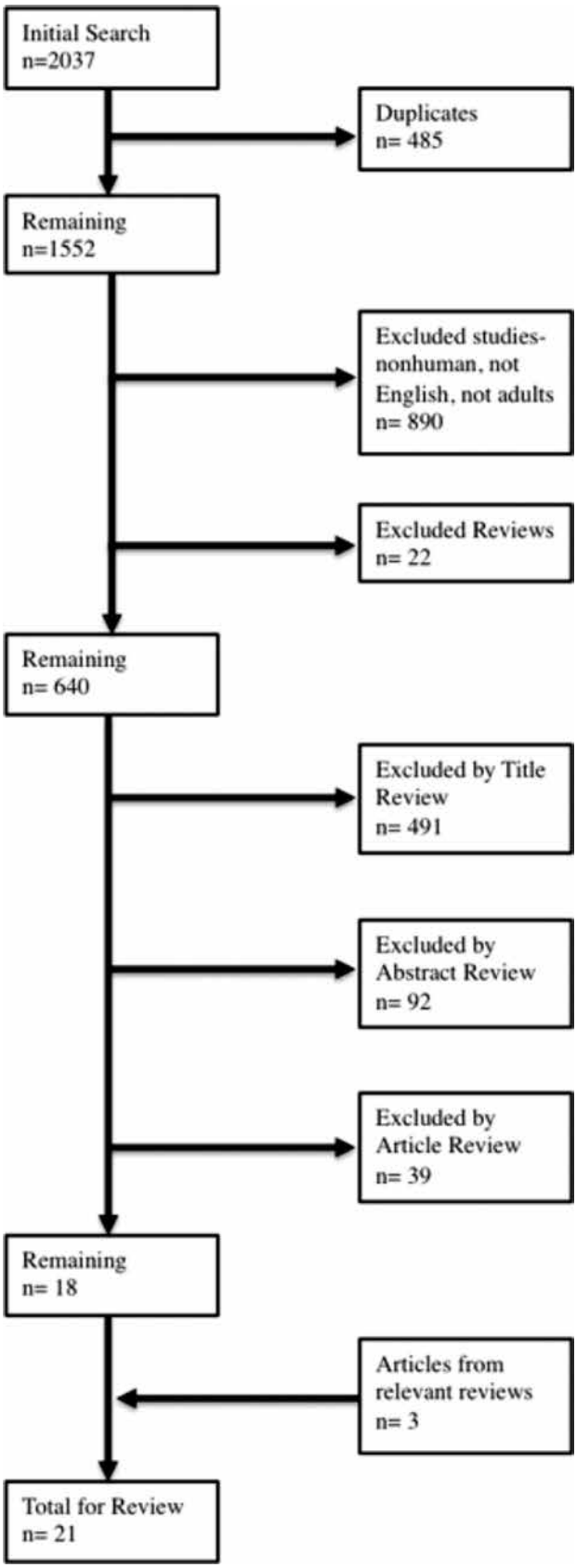

Table 2. Prophylactic Antibiotic Duration — Study Details

Author	Year	Study Design	Results	Conclusions
Dunkel[39]	2013	Retrospective case control study; n = 1492; compared varying durations of antibiotic treatment using univariate and multivariable regression analyses	Antibiotic duration groups of 1 day, 2–3 days, 4–5 days, and >5 days were compared. Multivariate OR were reported as follows: 1 day: reference 2–3 days: 0.6 (0.2–2.0) 4–5 days: 1.2 (0.3–4.9) >5 days: 1.4 (0.4–4.4) None were significant. A significant difference ($p < 0.001$) was found in a univariate analysis in the OR for 4–5 days (8.9) and for >5 days (9.8)	Increased duration of antibiotics is not related to infection
Dellinger[38]	1988	Double blind randomized prospective study; 248 patients with open long bone fractures were divided into three treatment groups: (1) 2 g cefonicid sodium IV x 1 day (n = 79) (2) 2 g cefonicid sodium IV, followed by 1 g/24 hours x 5 days (n = 85) (3) 2 g cefamandole nafate IV, followed by 1 g/6 hours x 5 days (n = 84)	Infection rates between the groups had no statistical significance: (1) 27% (2) 23% (3) 27% Fracture site infections were compared between 1-day groups (1) vs 5-day groups (2, 3): 1 day: 13% 5 day: 12%	Short duration of antibiotics is as effective as a longer duration

OR = odds ratio; IV = intravenous

reported: one day, reference; 2–3 days, 0.6 (confidence interval (CI 0.2–2.0); 4–5 days, 1.2 (CI 0.3–4.9); and >5 days, 1.4 (CI 0.4–4.4), all failing to reach statistical significance. These results show that there was no association between infection and duration of prophylactic antibiotic administration.

Local Antibiotic Delivery

The database search resulted in a total of six studies that met the criteria for the study of local antibiotic delivery in the management of open fractures in adults. An additional study was found through a reference review of relevant review articles resulting in a total of seven articles for consideration in this study (Table 3).

A group from the University of Louisville, Ostermann, Henry and Seligson, conducted a series of five retrospective reviews that contributed greatly to the study of local antibiotic delivery in the management open fractures.[20, 21, 24-26] In the most recent study, 1,085 consecutive open fractures in 914 patients were analyzed to assess the effects of local antibiotic administration on the incidence of infection. The adjuvant use of local antibiotics using tobramycin-impregnated polymethylmethacrylate (PMMA) beads resulted in a significant decrease in infection rates compared to patients that were administered only intravenous antibiotics prophylactically (3.7% vs 12%). Furthermore, Type IIIb fractures demonstrated a statistically significant decrease in overall infection rates with the adjuvant use of local antibiotics (6.5% vs 20.6%), whereas other fracture grades showed a trend of decreased infection rates, failing to reach statistical significance.[25] Earlier studies conducted by the same group had similar outcomes.[20, 21, 24] Seligson et al.[26] reviewed 72 Type IIIc fractures that required vascular repair from the study population described above, 40 of which were treated with tobramycin-impregnated PMMA beads as an adjunct to systemic prophylactic antibiotic therapy. Wound infection rates significantly decreased with the use of supplemental local antibiotic delivery compared to systemic antibiotic administration alone in the management of severe open fractures (5% vs 25%, respectively).

In 1996, Keating et al.[22] treated 81 open Type II and III tibia fractures with reamed intramedullary nailing comparing the effectiveness of a combination of systemic antibiotic administration with a local antibiotic pouch to the use of only systemic antibiotic use in preventing infection. The addition of the antibiotic bead pouch reduced deep infection rates from 16% to 4%. Though decreases were found in infection rates in each fracture classification, none of these were statistically significant.

The most recent clinical study compared the use of local antibiotic delivery to intravenous administration of antibiotics in a pilot randomized prospective study. Moehring et al.[23] randomly divided patients of Type II, IIIa and IIIb open long bone fractures to receive either local antibiotics or systemic antibiotics following surgical intervention. A third cohort was nonrandomly assigned to be co-administered local antibiotic-impregnated beads and intravenous antibiotics. Patients in this third group, however, were treated for either nonorthopaedic reasons or sustained a limb threatening injury. Infection rates of the three groups reported were 8.3%, 5.3% and 15.4%, respectively.

Time to Debridement

The database search resulted in nine citations that met the criteria for the relationship between time to debridement and infection rates in the management of open fractures. The references of recent review articles were searched to find publications missed by the database search resulting in a total of 10 articles for review (Table 4).

In 1989, Patzakis and colleagues[4] evaluated 1,104 open fractures retrospectively to determine predisposing factors to

Table 3. Local Antibiotic Delivery — Study Details

Author	Year	Study Design	Results	Conclusions
Moehring[23]	2000	Randomized prospective pilot study and a nonrandomized prospective study. n = 75 open long bone fractures. Study groups: Local Antibiotic beads (n = 24) Systemic Antibiotics (n = 38) Systemic and Local, nonrandomized (n = 13)	Infection Rates: Local Antibiotics: 8.3% Systemic Antibiotics: 5.3% Systemic + Local: 15.4% Not statistically significant	Suggests that local antibiotic delivery can be used as an adjunct to systemic antibiotic administration to prevent infection in open fractures
Keating[22]	1996	Retrospective review of 81 Type II and III open tibia fractures treated by reamed intramedullary nailing. Study groups: Systemic Antibiotics (n = 26) Systemic and Local Antibiotics (n = 55)	Deep Infection Rates: Systemic Antibiotics: 16% Systemic + Local: 4% No statistical significance was found neither between the two study groups overall nor within fracture classifications in these two groups	Addition of an antibiotic bead pouch reduced deep infection rates
Ostermann[25]	1995	Retrospective review of 1,085 open limb fractures over nine years. Study groups: Systemic Antibiotics (n = 240) Systemic and Local Antibiotics (n = 845)	Infection Rates: Systemic Antibiotics: 12% Systemic + Local: 3.7% ($p < 0.001$) Type III fractures displayed a significant decrease in infection rates: Systemic Antibiotics: 20.6% Systemic + Local: 6.5% ($p < 0.001$)	
Seligson[26]	1994	Retrospective review of 72 Type IIIc open fractures. Study groups: Systemic Antibiotics (n = 32) Systemic and Local Antibiotics (n = 40)	Wound Infection Rates: Systemic Antibiotics: 25% Systemic + Local: 5% ($p < 0.05$)	Administration of aminoglycoside-impregnated PMMA beads is of significant benefit in preventing infectious complications in severe injuries
Ostermann[24]	1993	Retrospective review of 704 open limb fractures over seven years. Study groups: Systemic Antibiotics (n = 157) Systemic and Local Antibiotics (n = 547)	Infection Rates: Systemic Antibiotics: 17% Systemic + Local: 4.2% ($p < 0.001$) Type III fractures displayed a significant decrease in acute wound infection rates: Systemic Antibiotics: 29% Systemic + Local: 6% ($p < 0.001$)	Antibiotic impregnated PMMA beads used prophylactically with systemic antibiotics prevented infectious complications in open fractures, especially in the use with Type IIIb fractures
Henry[21]	1993	Retrospective review of 227 open limb fractures managed using an antibiotic bead pouch technique	Infection rates based on fracture classifications: Type I: 0% Type II: 3.6% Type III: 10.9%	The bead pouch technique decreases the incidence of infection. This technique is most useful in Type III fractures
Henry[20]	1990	Retrospective review of 404 open fractures over six years. Study groups: Systemic Antibiotics (n = 70) Systemic and Local Antibiotics (n = 334)	Infection Rates: Systemic Antibiotics: 21.4% Systemic + Local: 4.2% ($p < 0.001$) Type III fractures displayed a significant decrease in infection rates: Systemic Antibiotics: 43.9% Systemic + Local: 8.7% ($p < 0.001$)	

PMMA = polymethylmethacrylate

infection. One factor analyzed by Patzakis was time to debridement. Similar rates of infection were reported between early, defined as debridement within 12 hours, and delayed debridement, defined as debridement after 12 hours (6.8% and 7.1%, respectively). Although time to debridement was not an important predictor of infection rates in this study, early debridement was still recommended.

Bednar and Parikh[40] had similar findings in the association between time to primary management and subsequent infection rates. In a retrospective review of 82 open fractures of the lower extremity, the early debridement group (debridement within six hours) had an infection incidence of 9%, whereas the late debridement group (debridement after six hours) had an infection rate of 3.4%.

Table 4. Time to Debridement — Study Details

Author	Year	Study Design	Results	Conclusions
Enninghorst[6]	2011	Retrospective, open tibia shaft fractures; n = 89 Debridement times: Early: <6 h Delayed: >6 h	No significant difference found in early vs delayed groups (no data shown) Time to operative treatment: Infected (n = 15): 7.87 h ± 4.7 Non-infected (n = 74): 7.95 h ± 4.5	Time to debridement was a not a predictor of poor outcome
Pollak[46]	2010	Retrospective review of LEAP participants, n = 307 Debridement times: Early: <5 h Delayed: 5–10 h Late: 10–24 h	Incidence of infection, major infection: Early: 28%, 15.1% Delayed: 29%, 14% Late: 25.8%, 18.8%	Time to debridement did not affect incidence of infection. Infection related better to fracture grade
Sungaran[45]	2007	Retrospective review (n = 161) of open tibia fractures Debridement times: Early: <6 h Delayed: 6–12 h Late: 12–24 h	Total infection rate: 3.7% Incidence of infection: Early: 7.8% Delayed: 1.3% Late: 0% Of the infections that presented, 83% were from the early group	Infection rate was not associated with time to debridement
Charalambous[44]	2005	Retrospective review (n = 383) of open tibia fractures, mostly Type III fractures Debridement times: Early: <6 h Delayed: >6 h	No significant difference in incidence of infection was found between early and delayed groups Incidence of infection: Early: 28.8% Delayed: 25.6%	No difference was found in infection rates between early and delayed debridement patients
Spencer[29]	2004	Prospective audit of 115 open long bone fractures Debridement times: Early: <6h Delayed: >6h	Incidence of infection: Early: 10.1% Delayed: 10.8%	No difference found between delayed and early debridement in relation to infection
Khatod[43]	2003	Retrospective review of open tibia fractures (n = 106) Debridement times: Early: <6h Delayed: >6h	Infection rates (estimated): Early: 19% Delayed: 18% Average time to debridement (h): Infected vs not infected Type I: 9 vs 6.5 Type II: 5 vs 10 Type IIIa: 6.2 vs 10.4 Type IIIb: 4.7 vs 5.5 Type IIIc: 3.5 vs 3.8	Infection rates did not increase between early and delayed debridement groups
Harley[42]	2002	Retrospective review of open fractures using a multivariate and univariate regression analysis (n = 241) Debridement time: Early: <8 h Delayed: >8 h	Infection rates: Early: 9% Delayed: 10% Nonunion rates: Early: 21% Delayed: 16%	Time was not a significant factor in determining poor outcomes such as infection and nonunion
Kindsfater[41]	1995	Retrospective review of Type II and III open tibia fractures (n = 47) Debridement time: Early: <5 h Delayed: >5 h	Infection rates: Early: 7% Delayed: 38% ($p < 0.03$)	A difference in infection rates between early and delayed debridement lends support to the standard 6 hour window
Bednar[40]	1993	Retrospective review of open long bone fractures (n = 82) Debridement time: Early: <6 h Delayed: >6 h	Infection rates: Early: 9% Delayed: 3.4%	Early debridement does not hold a benefit over delayed debridement in relation to incidence of infection
Patzakis[4]	1989	Retrospective review of open fractures (n = 1104) Debridement time: Early: <8 h Delayed: >8 h	Infection rates: Early: 6.8% Delayed: 7.1%	Time to debridement is not an important factor in determining risk of infection, however authors support early debridement

LEAP = lower extremity assessment project

In 1995, however, Kindsfater and Jonassen[41] were able to support the standard "six hour" rule for operative treatment in a retrospective review that analyzed the development of osteomyelitis in Type II and III open fractures following either early (<5 hours) or delayed (>5 hours) debridement. In Type II open fractures, 10% of the early group and 33% of the delayed group developed osteomyelitis. In Type III open fractures, no one in the early group developed osteomyelitis, whereas osteomyelitis developed in 41% of the delayed group.

Almost a decade later, Harley et al.[42] conducted a retrospective review comparing open fractures treated within eight hours and those treated after eight hours. Time to debridement had no relationship to open fracture complications such as deep infection and fracture nonunion. Deep infection rates reported from a univariate analysis were 9% in the early group compared to 10% in the late group. Nonunion analyses were also similar between early and late debridement, reported at 21% and 16%, respectively.

Khatod and colleagues[43] studied 106 open fractures to determine the relationship between time to operative treatment and infection and found no difference in infection rates between open fractures subjected to debridement within six hours compared to those after six hours.

A five-year prospective audit of 115 open fractures was conducted by Spencer et al.[29] which supported previous studies. Infection rates in early and late debridement groups were comparable. There was a 10.1% infection rate in fractures debrided within six hours, whereas there was a 10.8% infection rate in those debrided after six hours.

In reviewing 383 open tibial fractures, Charalambous et al.[44] found no significant difference in the incidence of infection between patients debrided within six hours and those debrided after six hours (28.8% vs 25.6%, respectively).

Similarly, Sungaran and colleagues 45 found no association between time to debridement and infection rates in a retrospective review of 161 patients with open tibia fractures sorted into three groups: debridement from 0–6 hours, 6–12 hours and 12–24 hours. A total infection rate of 3.7% was reported, most of which occurred in the 0–6 hour debridement group.

In 2010, a sub-study of the lower extremity assessment project (LEAP) reviewed 315 Type III open fractures of the lower extremity to evaluate the relationship between time to operative treatment and infection rates. Pollak et al.[46] found that time to debridement did not influence infection rates. There was a 15.1% incidence of major infection, such as osteomyelitis, in groups debrided within five hours; 14% incidence of infection in the group with a 5–10 hour delay to debridement; and 18.8% incidence in groups debrided between 10–24 hours. Similar to previous studies, Pollak et al. did not find an association between infection and the timing of debridement following injury.

In the most recent study, Enninghorst and colleagues[6] explored predictors of poor outcomes in open tibia fractures using a retrospective study of 89 patients. Both univariate and multivariate analyses failed to detect a statistically significant difference in infection rates with early and late debridement times. Similar to previous studies, although no relationship was found between time to debridement and infection rates, the author recommends early debridement when possible.

Irrigation — Solutions and Delivery

The database search resulted in a total of two studies that met the criteria for irrigation techniques in the management of open fractures in adults (Table 5).

Anglen[47] conducted a prospective randomized clinical control study assessing the effectiveness of different irrigation solutions, specifically focusing on antimicrobial additives compared to a non-sterile soap. A total of 458 open fractures of the lower extremity were used in the study. No significant differences were found between groups receiving an antimicrobial additive compared to those receiving a detergent in infection rates (18% vs 13%) and bone healing (25% vs 23%). Although, patients that received irrigation with the antimicrobial solution had a wound healing problem incidence of 9.5%, whereas those that received a detergent for irrigation had a 4% incidence. Therefore, Anglen concludes that there is no advantage to the use of antibiotic irrigation solutions as there is an increased risk of wound healing complications.

In 2011, a multicenter pilot study comparing alternative irrigation solutions and pressures was tested. As part of the fluid lavage in patients with open fracture wounds (FLOW) study, investigators 48 conducted a blinded randomized 2 x 2 factorial pilot in which 111 patients were treated with either detergent or normal saline and either high- or low-pressure lavage. Rates of primary outcome, including infection, wound healing problems or nonunion, were similar between groups that received a detergent versus those that received saline as the irrigation solution (23% vs 24%). When comparing pressure settings for irrigation, 28% in the high-pressure irrigation group had a primary outcome, whereas 19% of low-pressure group had an outcome.

Discussion

Prophylactic Antibiotic Duration

Despite an association between prolonged antibiotic use and poor outcomes such as the development of antibiotic resistant infections and host toxicity,[9,17] there have been a limited number of studies that examine the relationship between prophylactic antibiotic duration in the early management of open fractures and subsequent complications. In the two studies found by the search described above, only one was a randomized control study comparing the efficacy of a short duration and long duration prophylactic antibiotic therapy; the other retrospectively analyzed the duration of prophylactic antibiotics in 1,492 open fractures. Both of

Table 5. Irrigation Techniques — Study Details

Author	Year	Study Design	Results	Conclusions
Bhandari[48]	2011	A randomized multicenter pilot developed by FLOW comparing irrigation solutions and techniques; n = 111 Patients divided into four groups: SL = saline, low-pressure SH = saline, high-pressure CL = castile, low-pressure CH = castile, high-pressure	Primary outcome (infection, wound healing, nonunion) rates: S: 24% C: 23% H: 28% L: 19%	The castile soap group had a 23% hazard risk reduction compared to saline. Favor use of castile soap and low-pressure (6–10 psi) lavage.
Anglen[47]	2005	Prospective randomized study comparing the detergent and antibiotic solutions for irrigation of open wounds; n = 458 Groups: B: bacitracin (antibiotic) C: nonsterile castile soup (detergent)	Infection rates: B: 18% C: 13% Bone Healing Delays: B: 25% C: 23% Wound Healing Problem Rates: B: 9.5% C: 4%	No difference was found between infection rates and bone healing after either antimicrobial or detergent irrigation solutions. However, the antibiotic group had an increased risk of wound healing problems. Therefore, an antimicrobial irrigation solution has no advantage over a detergent and may result in complications.

FLOW = fluid lavage in patients with open fracture wounds; psi = pounds per square inch

these studies concluded that a shorter duration of prophylaxis is just as effective in preventing infection as longer duration therapies.[38, 39] However, each study had limitations. Many uncontrollable factors were present in both studies as the preferences and techniques of the surgeon, often determined by the standard practice at the trauma center, influenced the surgical treatment. Additionally, neither study assessed the risks of prolonged prophylactic antibiotic therapy. Dellinger et al.[38] briefly mention risks, such as increased antibiotic-resistant infections and increased costs, occurring in about 5–17% of patients, in their discussion and use this as support of shorter duration therapies, but neglect to measure these outcomes in their study population. Dunkel and colleagues[39] excluded infections that occurred after two months or were considered nosocomial from their study, even though other clinical studies look beyond four months to assess wound infection and osteomyelitis. Furthermore, *S. aureus,* the leading pathogenic cause of nosocomial infections,[17, 49] has been found to be the predominant microbe isolated from open fracture wounds.[3, 4, 43, 50] Restriction to infections within two months and exclusion of nosocomial infections may overlook the effects of antibiotic resistant microbes, which can put a patient at greater risk for infection.[50]

In 1998, the Eastern Association for the Surgery of Trauma (EAST) proposed guidelines,[14] updated recently in 2011,[13] for prophylactic antibiotic use in the management of open fractures that describe recommended classes and durations of antibiotics based on fracture grade (Table 1, Appendix 1a). The Surgical Infection Society (SIS) released similar recommendations in 2006 using a systematic review of the literature from 1985–1997 (Appendix 1b).[9] According to recent reports, however, these guidelines are not always followed in practice. Barton et al.[19] performed a retrospective review of patients from 2004–2008 assessing the adherence to the guidelines set forth in 1998 by the EAST workgroup. The study reported that 28.5% of patients received compliant therapy. Noncompliance to the guidelines was typically due to prolonged duration of the correct coverage antibiotic, thus exceeding the recommendations. This was associated with increased hospital and intensive care unit length of stay and the number of surgeries performed. Unfortunately, the duration of antibiotics was not measured after it was determined to be noncompliant to the recommendations, and therefore, the length of antibiotic therapy could not be related to the complications reported. Lavelle et al.[51] similarly showed inconsistency with prophylactic antibiotic use in practice, with greater variability in more severe fracture classifications, following a survey of orthopaedic residency programs. This study, however, did not assess outcomes as a result of this variation.

Environmental factors can also influence wound healing, development of postoperative infections and union of the fracture. Diabetes, smoking, obesity, immunosuppression and malnutrition, commonly seen in the patient population at TUH, are several risk factors for infectious complications and poor wound healing.[17, 52–56] The appropriate duration of prophylactic antibiotic administration, however, has yet to be elucidated in these population groups. Surgeons have reported making exceptions to current recommendations when they judged that an extended antibiotic regimen was needed for these patients.[19] As previously mentioned, prolonged antibiotic use does not decrease the risk of surgical site infections and has been associated with complications such as antibiotic resistant infection, toxicity and allergic reactions, which may put this population at a greater risk for poor outcomes following open fracture management. More clinical research is needed to determine the recommended prophylactic antibiotic therapy for populations at an increased risk for infection and impaired wound healing.

After review of the studies supporting a shorter duration of prophylactic antibiotic use and comparing current stan-

dards of practice with the recommendations proposed by EAST and SIS workgroups, guidelines were created for prophylactic antibiotic administration in the management of open fractures that modeled those proposed the EAST workgroup.

Local Antibiotic Delivery

Local antibiotic therapy is an effective method for delivering a high concentration of antibiotic to the wound site while maintaining low systemic levels.[16, 21, 22, 27] Impaired vascularity and devitalized bone, common characteristics of severe open fractures, can result in increased growth of organisms[11] and poor delivery of intravenous antibiotics.[23] The use of local antibiotics as an adjunct to prophylactic systemic antibiotics in severe open fractures nonetheless remains a debate, despite the advantages such therapy may provide. Benefits of adjunct local antibiotic delivery in reducing the incidence of infections are supported by several retrospective studies[20–22, 24–26] and a pilot prospective study;[23] however, limitations of these studies prevent the standardization of local antibiotic delivery in the management of open fractures.[9] A difference in soft tissue wound management between study groups has been noted as a great limitation of these studies.[20, 21, 23–26] For effectively high concentrations of antibiotic, antibiotic beads should be placed in a closed wound environment,[27] often packed into the dead space of the wound and sealed with a porous plastic film,[21, 22] although other techniques have been described. Variations in wound closure techniques between the study groups may influence infection rate outcomes; however, more recent studies have demonstrated that wound closure remains an independent predictor of infection.[57, 58] Another weakness of the studies includes nonrandomization of antibiotic treatment, as the implantation of antibiotic-impregnated beads was determined by the surgeon and bead availability,[20, 21, 24–26] creating a selection bias. Nonetheless, these studies support the supplemental use of local prophylactic antibiotic administration in severe open fracture management.

Despite the limited number of clinical studies evaluating the benefits of co-administration of local antibiotics with prophylactic systemic antibiotics in the management of open fractures, antibiotic-loaded beads appear promising through a decreased risk of the complications associated with prolonged antibiotic therapy. These beads can achieve high local levels while maintaining low systemic levels of antibiotics.[16, 21, 22, 27] Therefore, concerns of systemic toxicity, allergic reactions to antibiotics and the development of antibiotic-resistant nosocomial infections, which have been reported to occur rarely with this local administration technique,[17, 22, 27] can be minimized. Use of local antibiotics when an extended duration of antibiotics would otherwise be indicated,[9] such as in cases of severe open fractures or in patients with factors affecting wound healing, may thus prove beneficial.

Time to Debridement

Recent clinical studies sought to reevaluate the evidence behind the standard "six-hour" window between the time of injury and time of initial debridement. This urgency has been based on bacterial culture and reproductive data in animal wound models, which describe a relationship between the levels of bacterial contamination, time and infection.[59–61] At six hours, bacterial levels that reach greater than 105 organisms per gram of tissue can result in infection whereas lower levels are below the infection-causing threshold.[60] Clinical studies, however, have not been able to provide evidence for the standard six-hour window of time to debridement.

All but one of the papers reviewed failed to find an association between infection and time to debridement as animal studies previously described.[4, 6, 29, 40, 42, 44, 46] Although studies varied slightly in outcome measures of infection and the times considered as early versus delayed debridement, infection rates between early and delayed debridement study group were not significantly different. Furthermore, several studies reviewed only open fractures of the lower limb,[6, 40, 43–46] whereas others included open fractures of both lower and upper extremities.[4, 29, 42] Despite these differences, infection rates reported were similar to those previously reported.[2, 3] An additional limitation of these papers includes variation in surgical techniques and treatment used between study groups, resulting in uncontrollable confounding factors.

Unlike other clinical studies, Kindsfater and Jonassen[41] found a significant difference in infection rates between early (≤5 hours) and late (>5 hours) debridement groups, lending support to earlier animal studies that describe an association between time to debridement and the development of infection. However, this study only reviewed open tibia fractures of Gustilo-Anderson classification II and III and used a more limited definition of infection, measuring only the incidence of osteomyelitis development. Therefore, this study cannot be generalized to all open fractures.

However, in further support of early debridement, a recent study using an open femur fracture model in rats was conducted by Penn-Barwell et al.[62] which sought to control for confounding factors such as surgical techniques, as criticized in clinical studies. A significant increase in positive cultures was found in animal groups that received surgical debridement between 2–6 hours compared to those that received surgical debridement within two hours. This experimental model was not without its limitations, however. The open fracture and associated wound were created surgically, minimizing the extent of soft tissue damage and thus preventing its applicability to more severe open fractures. Furthermore, infections rates reported ranged from 50–100% which is very high compared to those reported in clinical studies.[2–4] Additionally, sample sizes were small, with a total of 10 animals per experimental group. Though this experimental design attempted to demonstrate the significance of

urgent debridement on the prevention of infection, it failed to mimic other elements of an open fracture seen clinically.

Despite a lack of clinical evidence for the six-hour rule, many clinical studies continue to suggest early debridement when possible. In 2009, Ricci and colleagues[28] demonstrated an association between after-hours surgeries and a higher incidence of complications. Thus, to prevent complications following the management of open fractures, early debridement and operative treatment are recommended for all open fracture classifications when adequate resources are available.

Irrigation: Solutions and Delivery

Copious irrigation is one of the most important steps in the management of open fractures;[16, 30, 31, 36] however, there is great variation in the techniques used. In an international survey of orthopaedic surgeons in 2008, no standard practice was found amongst surgeons with respect to irrigation techniques. Differences were found in irrigation volume, solution and delivery for each open fracture classification.[32]

A limited number of clinical studies assess the efficacy of the various irrigation techniques. The search described above yielded two clinical studies that met the inclusion criteria, which included a randomized control study comparing irrigation solutions[47] and a randomized pilot study comparing irrigation delivery and solutions.[48]

The delivery of irrigation solution remains a debate. The 2008 FLOW survey reports that a majority of surgeons use low-pressure lavage, although definitions of "low" remain unclear.[32, 33] When comparing pressure settings for irrigation, the FLOW pilot study demonstrated a greater incidence of infection, wound healing or nonunion in the high-pressure (25–30 pounds per square inch (psi)) irrigation group when compared to the low-pressure (6–10 psi) group.[48]

High- and low-pressure lavage were also compared in *in vitro* studies using human and canine tibia sections. High-pressure lavage resulted in more fissures and defects in the bone than low-pressure lavage; however, when compared to controls that did not receive pressure lavage, low-pressure lavage also showed increases. The number and size of defects were proportional to the pressure; however, it is unclear whether this relationship is direct. This study also illustrated that both high- and low-pressure lavage were equally effective at removing bacteria for up to three hours. After six hours, however, low-pressure lavage decreased in effectiveness, and a higher pressure was recommended.[33] In 2002, Adili and colleagues[35] analyzed the biochemical effects of high-pressure irrigation on fracture healing *in vivo* and found decreased mechanical strength of bone when compared to bulb syringe irrigation. Therefore, although high-pressure lavage is effective at removing bacteria, it can be harmful and thus low-pressure lavage (6–10 psi) is recommended for the irrigation of open fracture wounds.

Current irrigation solutions include saline, antimicrobial and antiseptic additives and detergent. In a comparison of castile soap, a detergent, and an antimicrobial irrigation solution in a clinical prospective randomized study of open fractures, the detergent proved to be as efficacious in preventing infection, and did not result in wound healing delays as the antimicrobial agent did.[47] Similarly, the FLOW pilot study demonstrated a decreased relative risk in the development of infection with the use of castile soap compared to saline.[48]

Several animal studies also support the use of detergent over antibiotic, antiseptic and saline irrigation solutions.[33, 36, 63] Bhandari and colleagues assessed the effect of different irrigation solutions on bone structure and their effectiveness in removing bacteria using an *in vitro* model. The use of detergent with low-pressure lavage proved more effective at removing adherent bacteria up to six hours over saline. Additionally, the detergent solution had less of an impact on bone healing, measured by the number and function of osteoblasts and osteoclasts.[34] Similarly, Burd et al. showed that detergents decrease the bacterial load and number of infections in an animal wound model when compared to saline.[63]

Despite evidence of the superiority of detergent over saline and the potential for harm associated with antimicrobial and antiseptic agents, the FLOW survey reports that saline remains the solution preference of most surgeons, followed by antimicrobial agents and then antiseptic; detergents remain the least commonly used.[32] The limited use of detergents in practice is likely due to its difficulty in accessibility. Therefore, in circumstances where detergent is unavailable, saline can be used as an alternative. More importantly, antibiotic and antiseptic additives should not be used in irrigation solutions due to their potential risks.

The volume of irrigation solution has been least studied clinically. In 2001, Anglen reported volumes used for each Gustilo fracture classification based on convenience of a three liter (L) irrigation bag size: Type I 3L; Type II 6L and Type III 9L.[30] The FLOW survey reported that 63.9% of surgeons preferred to use 3L or less for Type I fractures, 50.1% used 3–6L for Type II fractures and 41.3% preferred to use 3–6L also for Type III fractures.[32] Clinical study methods illustrate a range from 3–9L when irrigation volumes were reported,[29, 39–43, 47] one of which used a minimum of 9L saline per wound.[39] Animal studies have demonstrated that increased volumes of irrigation solution aid in the removal of bacteria and dirt,[30] and thus more effectively decrease the bacterial load in the wound. However, no clinical data can provide evidence to support these ranges.

Thus low-pressure lavage (6–10 psi) using either saline or detergent (i.e., castile soap) with increased volumes for more severe injuries proves to be the favored irrigation technique for effectively removing bacteria from a contaminated wound, and thus preventing infection and other complications.

Summary

Recommendations provided (Table 6) are based on a review of the above clinical and animal studies, with the data from clinical study considered with more weight over animal models.

Prophylactic antibiotics should be administered as soon as possible after injury, preferably within three hours. The drug class and duration of antibiotic given is determined by the severity of the open fracture, as described by Gustilo and Anderson. Antibiotic recommendations have been adapted from the updated EAST guidelines after review of the information provided and consideration of current practice standards. Type I and Type II fractures should be given gram-positive coverage, such as a first generation cephalosporin, for no more than 24 hours after wound closure. Gram-negative coverage, such as an aminoglycoside, should be added for Type II fractures. Type III fractures should be administered both gram-positive and gram-negative coverage, such as a cephalosporin and an aminoglycoside, which should be continued for 72 hours after injury and no more than 24 hours after wound closure. Fluroquinolones should not be used, as they offer no advantage over cephalosporins and aminoglycosides and may have a negative impact open fracture outcome. Local antibiotic delivery may prove beneficial in Type III open fractures and in patient populations where prolonged antibiotic therapy is otherwise indicated. Emergent surgical intervention should occur if resources and an experienced surgical team are available. A low-pressure (6–10 psi) pulsatile lavage system with either saline or detergent (i.e., castile soap) using increased volumes of solution for more severe fractures should be used to irrigate the wound prior to fixation. If irrigation occurs after six hours, a higher pressure may be necessary to adequately reduce the bacterial load.

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Table 6. Summary Guidelines and Recommendations

Fracture Classification	Type I	Type II	Type IIIa-c
Prophylaxis Antibiotic	First generation cephalosporin (gram-positive coverage), continued for 24 hours after wound closure.	First generation cephalosporin (gram-positive coverage), continued for 24 hours after wound closure. The addition of a once-daily aminoglycoside (gram negative coverage) is safe and effective.	First generation cephalosporin (gram-positive coverage) and aminoglycoside (gram-negative coverage) continued for 72 hours after injury, but no more than 24 hours after soft tissue coverage of the wound. Penicillin is recommended for farm related injuries, with soil or fecal matter contamination.
	Fluroquinolones should not be used as they offer no advantage over cephalosporins and aminoglycosides and may have a negative impact open fracture outcome.		
	Local antibiotic delivery may prove beneficial in Type III open fractures and in patient populations where prolonged antibiotic therapy is otherwise indicated.		
Time to Debridement	Debridement should occur in an emergent fashion if the resources and a prepared surgical team are available. Early debridement, before six hours, is recommended but not supported by current evidence.		
Irrigation Volume	<3L	3–6L	>6L
Irrigation Solution	Low-pressure (6–10 pounds per square inch) lavage with saline or detergent (i.e., castile soap) is recommended if debridement occurs within six hours after injury. After six hours, a higher pressure system may be necessary to adequately reduce the bacterial load. Antibiotic and antiseptic additives should not be used due to potential risks.		

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Appendix

1a. Eastern Association for the Surgery of Trauma (EAST) Guidelines

Luchette et al., 2000[14]:

Type I: Pre-operative dosing with prophylactic antibiotics as soon as possible after injury for coverage of gram-positive organisms (Level 1). Antibiotics should be discontinued 24 hours after wound closure (Level 2).

Type II: Pre-operative dosing with prophylactic antibiotics as soon as possible after injury for coverage of gram-positive organisms (Level 1). Antibiotics should be discontinued 24 hours after wound closure (Level 2).

Type III: Pre-operative dosing with prophylactic antibiotics as soon as possible after injury for coverage of gram-positive organisms (Level 1). Additional coverage for gram-negative organisms should be given. High dose penicillin should be added to the antibiotic regimen when there is a concern for fecal/clostridial contamination, such as in farm related injuries (Level 1). Antibiotics should be continued for only 72 hours after the time of injury or not more than 24 hours after soft tissue coverage of the wound is achieved, whichever occurs first (Level 2).

Update — Hoff et al., 2011[13]:

Type I: Systemic antibiotic with gram-positive coverage initiated as soon as possible after injury (Level 1).

Type II: Systemic antibiotic with gram-positive coverage initiated as soon as possible after injury (Level 1). Once-daily aminoglycoside dosing is safe and effective (Level 2).

Type III: Systemic antibiotic with gram-positive coverage initiated as soon as possible after injury. Gram-negative coverage should be added. High-dose penicillin added in the presence of fecal/clostridial contamination (Level 1). Antibiotics should be continued for 72 hours after injury or not >24 hours after soft tissue coverage has been achieved (Level 2). Once-daily aminoglycoside dosing is safe and effective (Level 2).

In addition, fluoroquinolones offer no advantage over cephalosporin and aminoglycoside agents but may have detrimental effects on fracture healing and result in high infection rates in Type III open fractures (Level 1).

1b. SIS (Surgical Infection Society) Recommendations

Hauser et al., 2006[9]:

Type I: Administration of a first generation cephalosporin (or similar gram-positive coverage) for 24–48 hours perioperatively is a safe and effective prophylactic choice (Level 1).

Type II: Administration of a first generation cephalosporin (or similar gram-positive coverage) for 48 hours perioperatively is a safe and effective prophylactic choice (Level 2). A single broad-spectrum agent given pre-operatively and extended for 48 hours post-operatively is a safe and effective prophylactic choice (Level 3).

Type III: Administration of a first generation cephalosporin (or similar gram-positive coverage) for 48 hours perioperatively is a safe and effective prophylactic choice (Level 2). A single broad-spectrum agent given pre-operatively and extended for 48 hours post-operatively is a safe and effective prophylactic choice (Level 3).

Insufficient data to support the use of gram-negative antibiotics against bacilli as prophylaxis in open fractures, prolongation of prophylactic antibiotic use past the initial perioperative period, administration of prophylactic penicillin in *Clostridium*-prone injuries, use of antibiotic beads in the management of open fractures, and antibiotic therapy based on wound cultures.

2. Recommendation Levels of Evidence (from the EAST and SIS Guidelines)

Level 1:

EAST Recommendations: based on Class I data (prospective, randomized, controlled study) or a preponderance of Class II data (prospective, randomized, non-blinded trials); based on the available scientific evidence alone

SIS Recommendations: based on sufficient Class I and Class II data (any prospective or randomized-trial data)

Level 2:

EAST Recommendations: supported by Class II data or a preponderance of Class III evidence (retrospectively collected data, database and registry reviews, and meta-analysis); justified by the available scientific evidence and strongly supported by expert critical care opinion

SIS Recommendations: based on sufficient Class I and Class II data

Level 3:

EAST Recommendations: supported by Class III data; supported by available data, but inadequate scientific data are available

SIS Recommendations: based on sufficient Class I, Class II, and Class III data (Class III data are purely observational or retrospective studies)

Medical Student Research Project

Supported by The John Lachman Orthopedic Research Fund and Supervised by the Orthopedic Department's Office of Clinical Trials

Initial Management of Femoral Shaft Fractures in the Multiply Injured Patient: Clinical Practice Guidelines

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Abstract

Background: The optimal management of femoral shaft fractures in multiply injured patients remains controversial. The purpose of this research is to create a clinical guideline for the initial treatment of femoral shaft fractures at Temple University Hospital that helps identify the "borderline" patient and outlines the best management for borderline patients, patients with concomitant chest injuries, and patients with concomitant head injuries.

Methods: A systematic review of published English-language studies using MEDLINE (1946–2013) was done using medical subject headings: *femoral fractures, multiple traumas, respiratory distress syndrome, adult, fracture fixation, traction, external fixator, thoracic injuries,* and *craniocerebral trauma.* Studies pertaining to the borderline patient, provisional stabilization of femoral shaft fractures, or the timing and/or method of definitive fixation of femoral shaft fractures in multiply injured patients were selected for review.

Results: Twenty reviews met inclusion criteria and were grouped into borderline patient (six studies), provisional stabilization (five studies), timing of definitive fixation in borderline (three studies), concomitant chest-injured (eight studies), and concomitant head-injured patients (seven studies), and physiological indicator of patient stability (one study) with some overlap.

Conclusion: Borderline patient characteristics were added to previously published descriptions. External fixation (EF) and skeletal traction (ST) were identified as provisional stabilization methods for borderline and severely injured patients that are not resuscitated quickly. Reported time to conversion from provisional stabilization to definitive intramedullary nailing (IMN) in borderline patients were less than one week. The optimal timing for IMN in both chest and head-injured patients with femoral shaft fractures remains controversial. However, as long as the patient is adequately resuscitated before surgery, the evidence showed early IMN within 24 hours of injury was associated with fewer complications than delayed procedures in patients with either concomitant chest or head injuries. Multiply injured patients with preoperative lactate level <2.5 mmol/L demonstrated fewer complications after an IMN procedure than those with lactate level >2.5 mmol/L. The collective evidence was used to create practice guidelines to be implemented at Temple University Hospital.

Introduction

Femoral shaft fractures are serious injuries usually caused by high-energy trauma, and early medical attention helps prevent subsequent morbidity or mortality. The standard of treatment for this type of fracture is definitive fixation with an intramedullary nail (IMN).[1] However, differences in clinical outcomes between subgroups of patients with femoral shaft fractures have been observed. Historically, it was shown that patients with femoral shaft fractures and concurrent head trauma were at increased risk of mortality compared to patients with isolated femoral shaft fractures.[2] A recent study has shown that femoral fractures and associated injuries continue to predict increased risk of morbidity and mortality.[3] Today, there is debate over the best initial management and optimal timing of definitive fixation in multiply injured patients who have femoral shaft fractures associated with other traumatic injuries.

For the past few decades, discussion regarding the management of these multiply injured patients has mainly focused on the timing of definitive fixation of the fracture. Bone et al.[4] conducted a prospective study in the late 1980s which showed multiply injured patients with femoral shaft fractures treated with IMN within 24 hours after injury trended to a lower incidence of Adult Respiratory Distress Syndrome (ARDS) and pulmonary dysfunction compared to delayed IMN. This finding contributed to a movement toward early IMN procedures for all femoral shaft fractures, even in the multiply injured patient, called "Early Total Care" (ETC). This approach was questioned by Pape[5] in the early 1990s after he observed that multiply injured patients with a femoral shaft fracture and associated chest injury had an increased incidence of ARDS after early reamed IMN compared to delayed treatment. In the study, "borderline patients" were introduced as the subpopulation of femoral

shaft fracture patients with associated injuries that predispose them to developing major complications.

It was thought that early reamed IMN produced a "second hit" of trauma too soon after the initial trauma, which could then overwhelm the patient and lead to complications such as ARDS.[6, 7] Another treatment methodology called "Damage Control Orthopedics" (DCO) was coined by Scalea[8] to describe the method of using external fixation (EF) as a means of temporarily stabilizing a femoral fracture before converting to definitive IMN. This approach was thought to protect the borderline patient by reducing the initial operative burden and lowering the systemic inflammatory response compared to an IMN procedure.[9]

As orthopaedics treatment of this injury pattern has evolved, subgroups of patient populations have demonstrated that one treatment paradigm or method does not fit all in the case of multiply injured patients with femoral fractures. The injury patterns that receive attention in the literature are borderline patients and patients with concomitant chest and/or head injuries. These multiply injured femoral shaft fracture patients are a diverse population, and optimal treatment of the femoral shaft fractures may require an individualized approach. The purpose of this research was to create a clinical guideline that can help identify the "borderline" patient and outline the best provisional treatment methods for borderline patients, patients with concomitant chest injuries, and patients with concomitant head injuries.

Methods

Literature searches were conducted using MEDLINE (1946 to July 12, 2013) and the Cochrane Library databases (July 12, 2013). The following medical subject headings and search strategies were used: *femoral fractures* [MeSH:NoExp] AND *multiple traumas* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *multiple traumas* [MeSH] AND *respiratory distress syndrome, adult* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *multiple traumas* [MeSH] AND *fracture fixation* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *multiple traumas* [MeSH] AND *traction* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *multiple traumas* [MeSH] AND *external fixator* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *fracture fixation* [MeSH] AND *thoracic injuries* [MeSH]; *femoral fractures* [MeSH:NoExp] AND *fracture fixation* [MeSH] AND *craniocerebral trauma* [MeSH].

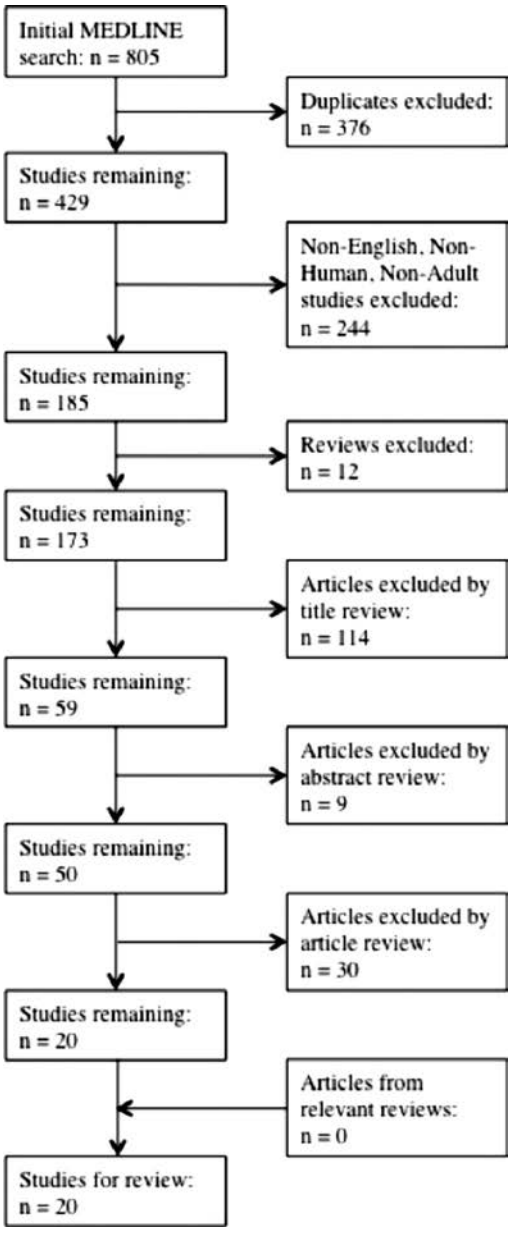
Searches were restricted to articles that were written in English and analyzed adult human patients. Reviews were excluded from analysis. Searches were not restricted by geography or date. Title, abstract, and article reviews were done in succession to select relevant articles that pertained to the borderline patient, provisional stabilization of femoral shaft fractures, or the timing and/or method of definitive fixation of femoral shaft fractures in multiply injured patients. Additionally, bibliographies of relevant review articles were surveyed to find studies not found though the computerized search.

Results

Search Results

Twenty articles met selection criteria (Figure 1) for this review and were then divided into the following topics: identifying the borderline patient, provisional management of femoral shaft fracture, and timing of definitive fixation. When appropriate, studies were used in multiple topics. Unless otherwise noted, studies described below were retrospective analyses of patients selected from single or multicenter trauma databases.

Figure 1. Literature Search Process and Results



The Borderline Patient

Borderline patient characteristics were selected from patients that were associated with a greater risk of complications after early IMN or were non-randomly treated with DCO. Patients with increased risk of complications after early IMN had an associated thoracic injury (Abbreviated injury scale (AIS) thorax ≥2)[5] or a severe abdominal injury (AIS ≥3).[10, 11] A prospective observational study of trauma patients with femoral shaft fractures found multiple IM nailing procedures and associated thoracic injury as independent risk factors for respiratory failure.[12] Patients treated with EF at a trauma center in Baltimore, MD had lower mean admission Glasgow Coma Score (GCS) (11), higher Injury Severity Scale (ISS) (26.8) scores, were more likely to have been in shock, had an AIS Head ≥3,[8] and presented with higher lactate levels at admission[13] than their early definitive IMN treated counterparts. These characteristics are presented along with previously published descriptions from a review by Pape[14] (Table 1).

Table 1. Patient Description to Identify the "Borderline" Patient (modified from Pape et al.)[14]

Polytrauma + ISS >20 and additional thoracic trauma (AIS >2)
Polytrauma with abdominal/pelvic trauma (> Moore 3, AIS ≥3*) and hemodynamic shock (initial BP <90 mmHg)
ISS 40 or above in the absence of additional thoracic injury
Radiographic finding of bilateral lung contusion
Initial mean pulmonary arterial pressure >24 mmHg
High presenting lactate level*
Multiple IMN procedures at one time*

*Author added

ISS = Injury Severity Scale score; AIS = abbreviated injury scale; BP = blood pressure; IMN = Intramedullary Nailing

Provisional Stabilization of Femoral Shaft Fractures

Two methods of provisional stabilization before conversion to IMN were described in the reviewed studies: EF and skeletal traction (ST) (Table 2). Studies that compared EF (as part of a DCO protocol) with early IMN found worse[8] or comparable[15, 16] outcomes after EF. However, subgroup analysis in one of these studies revealed lower incidence of acute lung injury (ALI) after EF in borderline patients.[15] The EF (or DCO) group was significantly more seriously injured upon admission in each of these studies. Comparison of provisional ST and early IMN showed that ST patients were more seriously injured than their IMN treated counterparts.[17] In this study, patient outcomes were worse in the ST group than early IMN group, but comparable with the Damage Control-External Fixation (DC-EF) group.

Patients with femoral shaft fractures and concomitant chest injuries (thoracic AIS >2) treated with DCO had significantly higher rates of death and longer Intensive Care Unit (ICU) length of stay (LOS) compared to those treated with IMN, but the DCO group was significantly more severely injured upon admission.[13]

The literature search did not yield any studies that addressed provisional stabilization of femoral fractures in patients with concomitant femoral shaft fractures and head injuries.

Timing to Definitive Stabilization of Femoral Shaft Fractures — Borderline Patient

Three studies that reported times to conversion from provisional stabilization to definitive IMN in borderline patients were reviewed (Table 3). One study reported conversion from EF to IMN in a median of four days[8] with normalized lactate (value not stated) and mean cardiac index 5.9 L/min per m^2, while another study reported conversion from EF in a mean of 5.04 days[17] and from ST in a mean of 4.08 days (no physiologic criteria were stated). One study compared infection rates in DCO patients and found significantly more pin-site contaminations without clinical consequence on patients converted to definitive IM nailing after 14 days compared to before 14 days.[18] Patients were converted from external fixation at the senior surgeon's discretion based on hemodynamic stability, local soft-tissue status, presence of systemic complications, and logistic availability of staff and operating rooms.

Timing to Definitive Stabilization of Femoral Shaft Fractures — Concomitant Chest Injury (Non-borderline)

Eight studies analyzed the timing of IMN in chest-injured patients by comparing presence or absence of femoral shaft fracture and treatment, early vs. delayed treatment, or early IMN vs. DCO (Table 4). Three studies showed that chest-injured patients with femoral shaft fractures treated with early IMN did not suffer worse outcomes compared to chest-injured patients without femoral shaft fractures.[19–21] Two studies found either an increased risk of ARDS[7] or a trend to higher mortality[22] after early IMN (<24 hours of injury) compared to delayed IMN. In contrast, two other studies found no difference in mortality rates between early and delayed IMN treated patients[23] as well as lower rates of pulmonary complications after early IMN compared to delayed treatment.[11, 23] O'Toole et al.[13] found that early IMN (mean 14.0 hours from admission) treated chest-injured patients had better outcomes compared to DCO treated patients. Three of these studies described physiologic criteria that were met before definitive IMN including normalized lactate levels (<2.5 mmol/L), hemodynamic stability, and respiratory stability.[11, 13, 21]

Timing to Definitive Stabilization of Femoral Shaft Fractures — Concomitant Head Injury

Seven studies analyzed the timing of IMN in chest-injured patients by comparing early vs. delayed treatment or presence or absence of femoral shaft fracture and treatment (Table 5). Two studies were unable to find any adverse effects on mortality or ICU LOS between head-injured patients with or without femoral shaft fractures treated by

Table 2. Provisional Stabilization of Femoral Shaft Fractures

Author, Year	Comparison	Relevant Results	Conclusions & Notes
Borderline Patient			
Scalea et al., 2000[8]	• External Fixation **(EF)** n = 43 • Intramedullary nailing **(IMN)** n = 281	**EF vs. IMN:** • EF group significantly more severely injured (higher ISS, lower GCS, higher % in shock, higher AIS-Head score) ($p < 0.01$) • EF group had significantly higher rate of ICU stay, longer hospital LOS ($p = 0.001$), and trend to more deaths (not 2º to fracture management)	• External fixation is reserved for more seriously injured patients (Damage Control Orthopaedics) • Serious injuries may require more resuscitation and result in higher mortalities
Pape et al., 2007[15]	• Initial temporary external fixation **(EF)** n = 71 • Early Intramedullary Nailing **(IMN)** n = 94 **Subgroups:** • Stable n = 121 • Borderline n = 44	**EF vs. IMN:** • EF group significantly more severely injured (RTS, ISS, head trauma score) ($p < 0.01$) • No difference in post-operative complications (Controlling for different initial injury severity) **Subgroup analysis:** • *Stable:* IMN group had shorter duration on ventilator than EF group ($p < 0.05$) • *Borderline:* IMN group had higher incidence of ALI than EF (odds ratio 6.69) ($p < 0.05$)	• In stable patients, IMN produced better outcomes • In borderline patients, temporary initial external fixation has better pulmonary outcomes
Tuttle et al., 2009[16]	• Early Total Care **(ETC)** n = 42 • Damage Control Orthopedics **(DCO)** n = 55	**ETC vs. DCO:** • No statistically significant differences in outcomes: ARDS, MOF, ICU & hospital LOS • Initial EF had significantly shorter operative time and less blood loss than primary IMN ($p < 0.005$)	• Method of fracture fixation does not have major impact on incidence of systemic complications • DCO has benefit of fracture stabilization with decreased operative burden (time, blood loss)
Scannell et al., 2010[17]	• Primary Intramedullary Nailing (<24 hours) **(IMN)** n = 126 • External Fixation converted to IM nail **(DC-EF)** n = 19 • Skeletal Traction converted to IM nail **(ST)** n = 60	**ST vs. IMN:** • ST group significantly higher mean AIS-head/neck, ISS, lower RTS, greater BD, and lower mean GCS score ($p < 0.01$) • ST group had significantly worse outcomes: MOF, Pneumonia, LOS, ICU LOS, MV days, and death ($p < 0.0002$) **ST vs. DC-EF:** • No difference in outcomes: ARDS, MOF, PE, DVT, Pneumonia, ICU LOS, MV days, Death • DC-EF group had significantly higher incidence of sepsis and longer LOS ($p < 0.05$) • In borderline: no differences in outcomes.	• Worse outcomes between ST and IMN due to differences in severity of injuries between groups • ST traction has lower incidence of sepsis and shorter LOS compared to DC-EF, but no difference in outcomes • If patient is not already under general anesthesia for another procedure, ST is a safe option
Femoral Shaft Fracture & Associated Chest Injury			
O'Toole et al., 2009[13]	• Primary reamed intramedullary nailing **(IMN)** n = 199 • External fixation converted to IMN **(DCO)** n = 28 **Subgroups:** (n = IMN/DCO) • ISS >17 n = 199/28 • ISS >17 and thoracic AIS score >2 n = 151/24 • ISS >28 and thoracic AIS score >2 n = 60/18	**DCO vs. IMN** • DCO group significantly more injured ($p < 0.05$) • DCO group had higher lactate levels at all time points than IMN ($p < 0.05$) • IMN group had 1.5–3.3% ARDS rate compared to 0% in DCO (n.s.) **Subgroup Analysis:** • *ISS >17:* DCO group had significantly higher rate of death and longer ICU LOS than IMN ($p < 0.05$) • *ISS >17 and thoracic AIS >2:* DCO group had significantly higher death rate and longer ICU LOS than IMN ($p < 0.05$) • *ISS >28 and thoracic AIS >2:* DCO group had significantly higher death rate and longer ICU LOS than IMN ($p < 0.05$)	• DCO reserved for patients who do not respond well to aggressive resuscitation • IMN method had a relatively low rate of ARDS and death as long as patients adequately resuscitated

ISS = Injury Severity Scale; GCS = Glasgow Coma Score; AIS = Abbreviated Injury Scale; ICU = Intensive Care Unit; LOS = Length Of Stay; RTS = Revised Trauma Score; ARDS = Adult Respiratory Distress Syndrome; MOF= Multiple Organ Failure; BD = Base Deficit; MV = Mechanical Ventilation; DVT = Deep Vein Thrombosis; n.s. = not statistically significant

IMN within 24 hours of injury.[24, 25] Two studies did not find a statistically significant difference between early or delayed IMN in terms of days on ventilation, ICU LOS, hospital LOS,[26] or discharge GCS,[23] but Starr et al.[26] did notice that a delay in femur stabilization was a statistically significant predictor of pulmonary complications. One study showed that patients treated with IMN between 2–4 days of admission had lower rates of mortality and shorter hospital LOS compared to those treated within 24 hours or after four days of admission,[22] but these results were not statistically significant. Another study, however, observed a statistically significant increase in complications and incidence of sepsis after

Table 3. Timing to Definitive Fixation in the Borderline Patient

Author, Year	Comparison	Criteria Met Before Conversion	Time to Definitive Fixation	Relevant Results	Conclusions
Scalea et al., 2000[8]	• External Fixation **(EF)** n = 43 • Intramedullary nailing **(IMN)** n = 281	• "normalized" lactate (median time to normalization: 28 hours) *normal value not stated • Mean cardiac index: 5.9 L/min per m^2 • opening ICP: 22 mmHg	4 days (median)	• ICU-LOS: 11.0 days (median) for EF group, 8.0 days for IMN group • Hospital LOS: 17.5 days (median) for EF group, 5.7 days for IMN group ($p = 0.001$) • Deaths: 9% of EF group	• Patients treated with EF tended to be more seriously injured • Deaths in the EF group were not secondary to fracture management selected (due to serious irreversible brain injury, or organ failure)
Harwood et al.,2006[9]	• Initial External Fixation **(DCO)** n = 98 • Intramedullary nailing **(IMN)** n = 75	Senior surgeon's discretion based on: • hemodynamic stability • local soft-tissue status • presence of systemic complications • logistic availability of staff and operating rooms	**Subgroups of DCO:** <7 days (n = 31) 7–14 days (n = 28) >14 days (n = 52)	• Significantly more pin-site contamination after 14 days compared to before 14 days	• Pin-site contamination did not have clinical consequence • Earlier conversion to IMN can reduce chance of contamination, but not worth risking patient stability
Scannell et al., 2010[17]	• Primary Intramedullary Nailing (<24 hours) **(IMN)** n = 126 • External Fixation converted to IM nail **(DC-EF)** n = 19 • Skeletal Traction converted to IM nail **(ST)** n = 60	Not stated	**DC-EF group:** 5.04 days (mean) **ST group:** 4.08 days (mean)	• No significant difference in mean time to definitive fixation b/n ST and DC-EF groups • No difference in outcomes: ARDS, MOF, PE, DVT, Pneumonia, ICU LOS, MV days, Death • DC-EF group had significantly higher incidence of sepsis and longer LOS	• Both DC-EF and ST treated patients were converted to definitive fixation within a similar time period of 4–5 days • However, the criteria for conversion were not stated

ICP = Intracranial Pressure; ICU = Intensive Care Unit; LOS = Length of Stay; ARDS = Acute Respiratory Distress Syndrome; MOF = Multiple Organ Failure; PE = Pulmonary Embolism; DVT = Deep Vein Thrombosis; MV = Mechanical Ventilator

delayed IMN compared to IMN.[11] One study observed occurrence of intraoperative hypotension based on time to operative fixation and found a statistically significant eight-fold increase in risk of hypotension if the fixation procedure happened within two hours of admission compared to after 24 hours.[27] However, no statistically significant difference in mortality was observed between patients who did or did not experience intraoperative hypotension. In these studies, definitive fixation proceeded based on criteria similar to those mentioned above[11, 25] or at the neurosurgeon's discretion.[26, 27]

Physiological Indicator of Patient Stability

There was one study that compared outcomes based on early (<24 hours of injury) definitive fixation in resuscitated and incompletely resuscitated multiply injured patients. Crowl et al.[28] observed that patients with femoral shaft fractures treated with early definitive fixation without adequate resuscitation had a significantly higher rate of complications (50%) compared to patients who were treated after complete resuscitation (20%) ($p < 0.01$). The incompletely resuscitated patients also suffered from significantly more infections and incurred significantly higher hospital costs compared to their adequately resuscitated counterparts.

Discussion

Identifying the Borderline Patient

Several studies have picked out patient profiles that tend to have complications after early IMN. Pape et al.[5] was one of the first authors to challenge the ETC approach when he noticed that patients with a femoral shaft fracture and thoracic injury had a significantly higher incidence of ARDS after early IMN compared to a similarly treated group without thoracic injuries. Within the group with associated thoracic injuries, the incidence of ARDS was higher after early IMN compared to delayed IMN, but the difference did not reach significance. Zalavras et al.[12] also identified thoracic injuries as a risk factor for respiratory failure. Both Morshed et al.[10] and Nahm et al.[11] found an increased risk of complications in patients with severe abdominal injuries, which further diversified the borderline patient profile. The authors from the shock trauma center in Baltimore stated that their DCO patients represented a small percentage of the femoral shaft fractures that they treat, and that these patients tended to be more severely injured and unstable.[8, 13]

It is important to identify borderline patients, because they are a group of patients that tend to have poorer outcomes

Table 4. Timing to Definitive Fixation for Femoral Shaft Fracture and Concomitant Chest Injury

Author, Year	Comparison	Criteria Met Before Definitive Fixation	Time to Definitive Fixation	Relevant Results	Conclusions
Pape et al., 1993[5]	• Thoracic trauma (AIS thorax ≥2) + IMN <24 hours **(TI)** n = 24 • Thoracic trauma (AIS thorax ≥2) + IMN >24 hours **(TII)** n = 26 • No thoracic trauma (AIS thorax <2) + IMN <24 hours **(NI)** n = 33 • No thoracic trauma (AIS thorax <2) + IMN >24 hours **(NII)** n = 23	Not stated	• TI & NI = <24 hours after trauma • TII & NII = >24 hours after trauma	• Duration CMV: NII longer than NI ($p < 0.05$) • Total duration of ventilation: NII longer than NI ($p < 0.05$) • ICU stay: NII longer than NI ($p < 0.05$) • Incidence of ARDS: TI had greater incidence than NI ($p < 0.05$) and TII (n.s.) • Mortality: TI had highest incidence (n.s.)	• If AIS thorax <2, IMN within 24 hours reduces duration of ventilation, CMV, and length of ICU stay compared to IMN after 24 hours • If AIS thorax ≥2, IMN within 24 hours has greater risk of ARDS compared to AIS thorax <2 treated in same time frame • AIS thorax ≥2, IMN within 24 hours has higher incidence of ARDS and mortality than IMN after 24 hours, but not statistically significant
Fakhry et al., 1994[22]	Management of femoral fracture (n = ISS <15/ ISS ≥15): • Group I: non-surgical n = 665/200 • Group II: surgery within one day of admission n = 965/212 • Group III: surgery 2–4 days after admission n = 387/55 • Group IV: surgery >4 days after admission n = 256/65 Subanalysis: • severe head injury (AIS ≥3) • severe chest injury (AIS ≥3)	Not stated	<u>ISS ≥15 and chest injury (AIS ≥3)</u>: • Group I: non-surgical n = 71 • Group II: within one day of admission n = 69 • Group III: 2–4 days of admission n = 19 • Group IV: >4 days after admission n = 27	<u>For ISS ≥15 and severe chest injury (AIS ≥3)</u>: Mortality: • Group I had significantly higher mortality compared to operative groups ($p < 0.001$) • Group II had highest mortality compared to delayed surgery (n.s.) • Hospital LOS increased with delay in surgery (n.s.)	• Femoral fractures treated within one day of admission has higher mortality rate than delayed, but this did not reach statistical significance • However, increasingly delayed surgery was associated with longer hospital LOS
Boulanger et al., 1997[19]	• Thoracic injury (AIS thorax ≥2) + early IMN ≤24 hours **(TE)** n = 68 • Thoracic injury (AIS thorax ≥2) + late IMN >24 hours **(TL)** n = 15 • No thoracic trauma (AIS thorax < 2) + early IMN ≤24 hours **(NE)** n = 57 • No thoracic trauma (AIS thorax < 2) + IMN >24 hours **(NL)** n = 9 • Case control group with AIS thorax ≥2 and ISS >16 without a femur fracture **(T)** n = 68	Not stated	• TE & NE = <24 hours after injury • TE & NE = >24 hours after injury	• No difference in % survival, total hospital stay, total critical care days, % admitted to ICU, or duration of ventilation between TE, NE, and T • No difference in incidence in ARDS, reported fat embolism, pneumonia, pulmonary embolism, or MOD between TE, NE, and T groups	• Early IMN within 24 hours of injury presence of blunt thoracic injury (AIS ≥2) is not additionally detrimental to patient outcomes compared to either non-thoracic injury patients (AIS <2) with femur fractures or thoracic injury patients (AIS ≥2) without femur fractures • Study could not compare TE vs. TL because TL group was too small
Brundage et al., 2002[23]	Severely injured patients with coexistent chest (Chest AIS ≥2) or head (Head AIS ≥2) injuries with IM fixation occurring: • <24 hours **(I)** n = 867 • 24–48 hours **(II)** n = 155 • 48–120 hours **(III)** n = 37 • >120 hours **(IV)** n = 22 • Nonoperative fixation **(V)** n = 281	Not stated	<u>Chest AIS ≥2</u>: • I: <24 hours n = 186 • II: 24–48 hours n = 43 • III: 48–120 hours n = 14 • IV: >120 hours n = 8 • V: Nonoperative n =77	<u>For patients with chest trauma (Chest AIS ≥2)</u>: • Mortality: Groups I–IV no statistical difference, Group V had highest mortality rate (40%) • ARDS: Significantly higher incidence in Group III (64%) compared to Group I (12%) ($p < 0.0001$) • Mean hospital and ICU LOS: longer times in Group III vs Group I (p value not reported)	• No statistically different rates of mortality as function of time to operative management • ARDS incidence was significantly lower in patients with chest trauma treated <24 hours compared to 48–120 hours

Table 4. Timing to Definitive Fixation for Femoral Shaft Fracture and Concomitant Chest Injury *(Continued)*

Author, Year	Comparison	Criteria Met Before Definitive Fixation	Time to Definitive Fixation	Relevant Results	Conclusions
Handolin et al., 2004[20]	Chest injured patients (Thoracic AIS ≥3) with: • Fracture + IMN n = 27 • No fracture n = 34	Not stated	Within 24 hours of injury	• Length of ventilator treatment: no difference between groups • ARDS, pneumonia, and MOF: no correlation to IMN shown	• No observed immediate harmful effects of femoral fracture treated with IMN within 24 hours of injury in patients with associated chest injury • Included femoral and tibial shaft fractures, so isolating effect of femoral IM nailing is not possible
Weninger et al., 2007[21]	• Severe thoracic trauma (Thoracic AIS ≥3) and early unreamed IMN **(Study)** n = 45 • Severe thoracic injury (Thoracic AIS ≥3) without lower extremity fracture **(Control)** n = 107	Upon arrival or within one hour after admission: Stable hemodynamic condition (systolic BP >90 mmHg) Stable respiratory condition	Within six hours after admission	No statistically significant differences between groups for: • duration of ventilation • duration of ICU stay • rate of pneumonia • rate of organ insufficiencies • rate of MOFS • rate of morbidity	• Unreamed IM nailing within six hours after admission did not produce worse outcomes than thoracic injury patients without femoral fractures
O'Toole et al., 2009[13]	• Primary reamed intramedullary nailing **(IMN)** n = 199 • External fixation converted to IMN **(DCO)** n = 28 **Subgroups:** (n = IMN/DCO) • ISS >17 n = 199/28 • ISS >17 and thoracic AIS score >2 n = 151/24 • ISS >28 and thoracic AIS score > 2 n = 60/18	• Lactate trending toward 2.5 mmol/L or less • optimized ventilatory and hemodynamic parameters	IMN: 14.0 hours (mean time from admission) DCO: time to conversion to IM not reported	**DCO vs. IMN** • DCO group significantly more injured ($p < 0.05$) • DCO group had higher lactate levels at all time points than IMN ($p < 0.05$) • IMN group had 1.5–3.3% ARDS rate compared to 0% in DCO (n.s.) **Subgroup Analysis:** • ISS >17: DCO group had significantly higher rate of death and longer ICU LOS than IMN ($p < 0.05$) • ISS >17 and thoracic AIS >2: DCO group had significantly higher death rate and longer ICU LOS than IMN ($p < 0.05$) • ISS >28 and thoracic AIS >2: DCO group had significantly higher death rate and longer ICU LOS than IMN ($p < 0.05$)	• Definitive fixation within 24 hours in resuscitated patients has better outcomes than DCO approach • IMN was not performed in emergent manner since mean time was 14.0 hours from admission
Nahm et al., 2011[11]	For patients with associated injuries to chest (minor chest AIS <3; severe chest AIS ≥3) or head (minor GCS >8; severe ≤8) receiving either: • Definitive treatment <24 hours of injury **(Early)** • Definitive treatment >24 hours of injury **(Delayed)**	No formal protocol Resuscitation gauged by: • pH • Base deficit • lactate • ICP monitor for severe head injuries	<u>Patients with minor chest injury (AIS <3)</u>: • Early: <24 hours of injury n = 37 • Delayed: >24 hours of injury n = 12 <u>Patients with severe chest injury (AIS ≥3)</u>: • Early: <24 hours of injury n = 122 • Delayed: >24 hours of injury n = 49	<u>For patients with chest injury</u>: • more complications observed for delayed group vs. early group ($p < 0.0001$) • odds ratio for developing pulmonary complications: surgical delay = 1.9 compared to early treatment ($p = 0.04$) <u>For patients with severe chest injuries</u>: • Sepsis: Early group (2.5%) had lower incidence than delayed (10.2%) ($p = 0.044$) • odds ratio for developing complications: surgical delay = 2.4 compared to early treatment ($p = 0.009$)	• Delayed definitive treatment beyond 24 hours doubles chance of developing pulmonary complications in patients with chest injuries • Delayed definitive treatment beyond 24 hours showed greater incidence of sepsis in patients with severe chest injuries

AIS = Abbreviated Injury Scale; CMV = Controlled Mechanical Ventilation; ICU = Intensive Care Unit; ARDS = Acute Respiratory Distress Syndrome; ISS = Injury Severity Score; MOD = Multiple Organ Dysfunction; LOS = Length of Stay; MOF = Multiple Organ Failure; BP = Blood Pressure; MOFS = Multiple Organ Failure Syndrome; ICP = Intracranial Pressure; n.s. = not statistically significant

with the standard of treatment for femoral shaft fractures. It is also important to not include everyone as a borderline patient, as several authors have pointed out that DCO was not intended to be generalized for every patient with femoral shaft fractures and multiple injuries, but rather a subset of patients who may be physiologically overwhelmed by

Table 5. Timing to Definitive Fixation for Femoral Shaft Fracture and Concomitant Head Injury

Author, Year	Comparison	Criteria Met Before Definitive Fixation	Time to Definitive Fixation	Relevant Results	Conclusions
Fakhry et al., 1994[22]	Management of femoral fracture (n = ISS <15/ ISS ≥15): • Group I: non-surgical n = 665/200 • Group II: surgery within one day of admission n = 965/212 • Group III: surgery 2–4 days after admission n = 387/55 • Group IV: surgery >4 days after admission n = 256/65 Subanalysis: • severe head injury (AIS ≥3) • severe chest injury (AIS ≥3)	Not stated	ISS ≥15 and head injury AIS ≥3: • Group I: non-surgical n = 82 • Group II: within one day of admission n = 59 • Group III: 2–4 days of admission n = 14 • Group IV: >4 days after admission n = 14	For ISS ≥15 and severe head injury (AIS ≥3): Mortality: • Group I had significantly higher mortality compared to operative groups ($p < 0.02$) • Groups II and IV showed higher mortality than Group III (n.s.) • Hospital LOS lowest for patients operated on between 2–4 days (n.s.)	• Femoral fractures treated between 2–4 days suffered less mortality and shorter LOS, but not statistically significant
McKee et al., 1997[24]	Femur Fracture with concomitant severe head injury (AIS head ≥3) **(Study)** n = 46 Matched severe head injury patients without femur fractures **(Control)** n = 99	During operative procedure: • adequate CPP (minimum 70–80 mmHg) • adequate oxygenation (minimum PaO_2 80 mmHg) • Patients with admitting GCS ≤7: ICP at or below 20–25 mmHg	<24 hours (for 83% of study group)	• Mortality: no difference between groups • Hospital or ICU LOS: no difference between groups • Neuropsychological testing: no difference between groups	• No demonstration of adverse effect of femoral fracture with early definitive fixation for patients with severe head injuries
Townsend et al., 1998[27]	In patients with coexistent severe head injury (GCS ≤8), timing to operative fixation: • 0–2 hours n = 22 • 2.01–12 hours n = 24 • 12.01–24 hours n = 3 • 24.01–244.0 hours n = 12	Clearance by trauma surgeon and neurosurgeon	Intraoperative hypotension: • eight-fold increase in risk if fixation occurs <2 hours of admission compared to after 24 hours ($p < 0.007$) • four-fold increase in risk if fixation occurs within 2–24 hours compared to after 24 hours ($p < 0.007$) • No statistically significant difference in mortality between patients with intraoperative hypotension and patients without intraoperative hypotension	• Risk of intraoperative hypotension can be 8x higher for patients with femoral fixation within two hours and 4x higher for patients with femoral fixation within 2–24 hours compared to patients with femoral fixation after 24 hours • Intraoperative hypotension not associated with increased mortality	• No statistically different rates of mortality as function of time to operative management • ARDS incidence was significantly lower in patients with chest trauma treated <24 hours compared to 48–120 hours
Starr et al., 1998[26]	• Severe head injuries (GCS ≤8) + fixation <24 hours **(I)** n = 9 • Severe head injury (GCS ≤8) + fixation >24 hours **(III)** n = 5 • Minor head injury (GCS >8) + fixation <24 hours **(II)** n = 6 • Minor head injury (GCS >8) + fixation >24 hours **(IV)** n = 12	On call neurosurgeon's discretion	I: 1 day II: 1 day III: 6 days IV: 7.44 days	No statistically significant differences between early and delayed fixation for neither severe nor minor head injuries: • Days on ventilation • Days in ICU • Days in hospital Predictors of pulmonary complications: • delay in femur stabilization >24 hours ($p = 0.0042$) • severity of chest AIS ($p = 0.0057$) • severity of head AIS ($p = 0.0133$)	• Delay in femur stabilization is a strong predictor of pulmonary complications • No significant difference in length of stay found between groups • Small sample size limits the study

Table 5. Timing to Definitive Fixation for Femoral Shaft Fracture and Concomitant Head Injury *(Continued)*

Author, Year	Comparison	Criteria Met Before Definitive Fixation	Time to Definitive Fixation	Relevant Results	Conclusions
Brundage et al. 2002[23]	Severely injured patients with coexistent chest (Chest AIS ≥2) or head (Head AIS ≥2) injuries with IM fixation occurring: • <24 hours **(I)** n = 867 • 24–48 hours **(II)** n = 155 • 48–120 hours **(III)** n = 37 • >120 hours **(IV)** n = 22 • Nonoperative fixation **(V)** n = 281	Not stated	Head AIS ≥2: • I: <24 hours n = 283 • II: 24–48 hours n = 65 • III: 48–120 hours n = 17 • IV: >120 hours n = 13 • V: Nonoperative n = 133	For patients with head trauma (Head AIS ≥2): • Discharge GCS: no statistically significant difference between Groups I–IV, but group V had significantly lower score than other groups ($p < 0.05$)	• No statistically significant difference in neurological outcome based on time of definitive fixation
Nau et al., 2003[25]	Multiple-injury patients with coexistent combined head and chest injury (head and chest AIS ≥2): • with femoral shaft fracture **(study)** n = 28 • without femoral shaft fracture **(control)** n = 120	• Hemodynamic stability • Respiratory stability Both achieved within one hour of admission and remaining stable for following three hours after admission	Study group: within 24 hours of injury	No statistically significant difference between groups: • Mortality • Length of ICU stay • Ventilation time • GOS	• No statistically significant difference in outcome between patients treated with IM nail within 24 hours of injury after hemodynamic and respiratory stability achieved compared to patients with chest and head injury without femoral fracture
Nahm et al., 2011[11]	For patients with associated injuries to chest (minor chest AIS <3; severe chest AIS ≥3) or head (minor GCS >8; severe ≤8) receiving either: • Definitive treatment <24 hours of injury **(Early)** • Definitive treatment >24 hours of injury **(Delayed)**	No formal protocol Resuscitation gauged by: • pH • Base deficit • lactate • ICP monitor for severe head injuries	Patients with minor head injury (GCS >8): • Early: <24 hours of injury n = 155 • Delayed: >24 hours of injury n = 27 Patients with severe head injury (GCS ≤8): • Early: < 24 hours of injury n = 44 • Delayed: >24 hours of injury n = 22	For patients with head injury: • more complications observed for delayed group vs. early group ($p < 0.001$) For patients with minor head injury: • more complications observed for delayed group vs. early group ($p = 0.002$) For patients with severe head injuries: • Sepsis: Early group (4.5%) had lower incidence than delayed (22.7%) ($p = 0.037$)	• More complications observed for delayed definitive treatment beyond 24 hours in both minor and severe head injured patients • Delayed definitive treatment beyond 24 hours showed greater incidence of sepsis in patients with severe head injuries

ISS = Injury Severity Scale; AIS = Abbreviated Injury Scale; LOS = Length of Stay; CPP = Cerebral Perfusion Pressure; GCS = Glasgow Coma Score; ICP = Intracranial Pressure; ICU = Intensive Care Unit; GOS = Glasgow Outcome Score

another stimulus.[1, 8, 13] To our knowledge there has not been a sensitivity or specificity analysis of the characteristics presented here to determine the likelihood of a borderline patient suffering pulmonary complications if treated with early IMN. However, they are included in our practice guidelines (Table 7) to help trauma and orthopaedic teams identify potential borderline patients.

Provisional Stabilization of Femoral Shaft Fracture

Patient outcome after provisional stabilization followed by conversion to definitive IMN relative to early IMN varies. In all of the studies comparing provisional stabilization and early IMN, the patients who were treated with provisional stabilization, whether by EF or ST, were significantly more severely injured than the early IMN patients.[8, 13, 15–17] This difference may have contributed to the longer LOS and higher incidence of mortality found in the Scalea et al.,[8] Scannell et al.,[17] and O'Toole et al.[13] studies. Scalea[8] also mentioned that the deaths in their study were not secondary to the fracture management selected, but rather the initial injuries sustained. The prospective randomized intervention trial by Pape et al.[15] showed a 6.69 fold increase in odds of developing ALI for borderline patients treated with early IMN instead of provisional EF, which gives strong evidence in favor of initial temporary EF in the borderline patient population. Provisional EF has a significantly shorter operative time and blood loss in the initial procedure compared to IMN, which reduces the operative burden for the vulnerable borderline patient.[16] This is also supported by evidence that the DCO method induces a significantly lower systemic immune response compared to early IMN.[9] There were no statistically significant differences in incidence of complications between the DCO and IMN groups in the Tuttle et al.[16] study, but the groups represented two different time periods.

Table 6. Physiological Indicators for Definitive Fixation in Multiply Injured Patients

Author, Year	Comparison	Criteria Met Before Definitive Fixation	Time to Definitive Fixation	Relevant Results	Conclusions
Crowl et al., 2000[28]	IM fixation within 24 hours of injury with: • Complete resuscitation (lactate <2.5 mmol/L) **(Group I)** n = 27 • Incomplete resuscitation (lactate >2.5 mmol/L) **(Group II)** n = 20	• Lactate <2.5 mmol/L • Systolic BP >100 mmHg • Heart rate <120 bpm • urine output ≥1 ml/kg per hour	Group I and II: within 24 hours of injuries	• Lactate at admission: Group II had higher levels than Group I ($p < 0.01$) • Lactate before surgery: Group II had higher levels than Group I ($p < 0.01$) • Time to correct lactate levels: Group II took significantly longer (16.8 hours) than Group I (8 hours) ($p < 0.05$) • Complications: Group II had significantly higher rate of complications (50%) than Group I (20%) ($p < 0.01$) • ISS >18: Group II had significantly more complications than Group I ($p < 0.05$) • Infectious complications: Group II had significantly more infections (72%) than Group I (28%) ($p < 0.01$) • Days on ventilator: no significant difference between groups • Hospital cost: Group II had significantly higher costs ($53,540) compared with Group I ($30,553) ($p < 0.001$)	• Patients with uncorrected occult hypoperfusion before early IM fixation have increased incidence of postoperative complications, took longer to correct lactate levels, and had higher hospital costs

BP = Blood Pressure; ISS = Injury Severity Score

There is a possibility that the DCO era also benefited from advances in other resuscitation techniques that could have affected the results. This kind of effect was seen in Pape et al.'s[29] study that analyzed outcomes over time as their trauma center changed practice patterns from predominantly ETC to DCO over a period of 20 years. Incidence of post-operative complications decreased in all treatment methods over time, although incidence of ARDS was still higher in primary IMN treated patients than DCO treated patients in the most recent time period analyzed.

Only one study addressed provisional stabilization of femoral shaft fractures in patients with concomitant severe chest injury. The results suggested that DCO was reserved for the patients that did not respond to aggressive resuscitation, while the patients that were resuscitated quickly were treated with early IM nailing and went on to have better outcomes.[13] The difference in patient ability to recover from initial trauma may have contributed to worse outcomes in the DCO group. It is also difficult to predict how these more severely injured patients would have fared with early definitive IM nailing.

Scannell et al.[17] presented skeletal traction as an alternative or complement to external fixation. When compared to the early IMN treated group, the ST group was more seriously injured and suffered significantly worse outcomes, similar to DCO outcomes in the other studies. Relative to the DC-EF group, there were no differences in several outcome measures. However, the ST group had significantly lower incidence of sepsis and shorter overall LOS compared to the DC-EF group overall, though not in borderline patients. ST is easier to apply compared to EF, and there is no need for general anesthesia, unlike EF. However, the logistics of implementing ST such as patient portability and patient mobility may be a concern in other settings.

Provisional stabilization is an important step in the initial management of multiply injured patients with femoral shaft fractures. In borderline patients, initial temporary external fixation may reduce the operative burden early on until they are physiologically stable enough for an IMN procedure. In patients with concomitant chest injuries, the DCO method may best serve the patients that have trouble being resuscitated quickly, since there is evidence that early IMN may yield better outcomes. There is no evidence in the literature that addresses provisional stabilization in patients with concomitant head injuries. Skeletal traction could be an alternative method to external fixation if the patient is not already under general anesthesia for another procedure. In any situation where provisional stabilization is utilized, the patient is most likely severely injured and susceptible to complications independent of the treatment modality used.

Timing of Definitive Fixation — Borderline Patient

After provisional stabilization of the femoral shaft fracture in a borderline patient, the next step is determining when the patient is ready for conversion to definitive fixation. Studies have reported times to conversion that were within one week of the initial procedure.[8, 17] Only Scalea et al.[8] reported physiologic criteria that were also met before conversion, which included a normalized lactate level that was not specified and a cardiac index value. Harwood et al.[18] stated that conversion to IMN from EF proceeded at the senior surgeon's discretion. Although, these authors found an increase in pin-site contaminations on patients who were converted to IMN after 14 days, they reported that these

Table 7. Practice Guidelines for Femoral Shaft Fractures in the Multiply Injured Patient

Borderline Patient	Concomitant Chest Injury	Concomitant Head Injury
I. Identification of Patient Subgroups		
Description (modified from Pape et al.[14]): • Polytrauma + ISS >20 and additional thoracic trauma (AIS >2) • Polytrauma with abdominal/pelvic trauma (> Moore 3, AIS ≥3*) and hemodynamic shock (initial BP <90 mmHg) • ISS 40 or above in the absence of additional thoracic injury • Radiographic finding of bilateral lung contusion • Initial mean pulmonary arterial pressure >24 mmHg • High presenting lactate level(~6.5 mmol/L)* • Multiple IMN procedures at one time*	***Description:*** • AIS chest/thorax ≥2	***Description:*** • AIS head ≥2 • GCS ≤8
II. Provisional Stabilization		
Evidence: • Evidence of lower risk of acute lung injury with provisional EF compared to early IMN[15] and decreased operative burden[16] • Evidence of comparable outcomes between provisional ST and EF, but lower risk of sepsis and no need for general anesthesia[17] • Evidence of greater injury severity and worse outcomes in patients treated with EF or ST compared to early IMN candidates[8, 15–17]	***Evidence:*** • Evidence of greater injury severity and worse outcomes in patients treated with provisional EF compared to adequately resuscitated patients treated with early IMN[13]	***Evidence:*** • No literature supported evidence found
Recommendation: • Skeletal traction pin placed upon admission • Consider external fixation if patient is under general anesthesia for another procedure	***Recommendation:*** • Skeletal traction pin placed upon admission • For patients who do not respond quickly to resuscitation, consider external fixation if patient is already under general anesthesia	***Recommendation:*** • Skeletal traction pin placed upon admission
III. Timing to Definitive Fixation		
Evidence: • Reported conversion times from temporary stabilization to definitive IM nail between 4–5 days in the presence of adequate cardiopulmonary resuscitation[8, 17] • Evidence of higher incidence of pin-site contamination without clinical consequence after conversion to definitive IMN past 14 days[9]	***Evidence:*** • No evidence of worse outcomes due to presence of femoral shaft fractures treated with IMN <24 hours of injury in chest-injured patients[19–21] • Evidence of worse outcomes with early compared to delayed definitive fixation, but may have analyzed borderline patient5 or failed to show statistical significance[22] • Evidence of comparable mortality rate[23] and lower rate of pulmonary complications[11, 23] with early IMN (<24 hours of injury) compared to delayed • EAST guidelines reported no difference in complications or hospital LOS between definitive treatment before and after 48 hours of injury based on Class II and III data[30]	***Evidence:*** • Evidence of comparable outcomes between head-injured patients with and without femoral shaft fracture[24, 25] • Evidence of comparable outcomes between early (<24 hours) and delayed fixation[23, 26] • Evidence of increased complications and rate of sepsis after definitive fixation >24 hours[11] • Evidence of eight-fold increased risk of intraoperative hypotension during IMN within two hours of injury[27] • Not statistically significant trend of lower mortality rate and shorter hospital LOS after definitive fixation between 2–4 days of admission compared to earlier or later treatment[22] • EAST guidelines reported no difference in complications or hospital length of stay between definitive treatment before and after 48 hours of injury in head-injured patients based on class II and III data[30]
Recommendation: • If patient is temporarily stabilized, conversion to definitive IM nail should occur within one week, if patient health permits • Adequate resuscitation required: lactate <2.5 mmol/L in presence of hemodynamic and respiratory stability**	***Recommendation:*** • Definitive fixation by IMN within 24 hours of injury, emergent treatment not required • Adequate resuscitation required: lactate <2.5 mmol/L, hemodynamic and respiratory stability**	***Recommendation:*** • Definitive fixation by IMN within 24 hours of injury, but emergent treatment within two hours of admission not recommended • Adequate resuscitation required: lactate <2.5 mmol/L, hemodynamic and respiratory stability** • Monitor ICP intraoperatively to maintain at or below 20–25 mmHg or as per neurosurgery

*Author added

**Resuscitation guidelines based on evidence of increased complications, infections, and hospital costs after early definitive fixation in incompletely resuscitated patients compared to completely resuscitated patients.[28]

ISS = Injury Severity Scale score; AIS = abbreviated injury scale; BP = blood pressure; GCS = Glasgow Coma Score; EAST = Eastern Association of the Surgery of Trauma; ICP = Intracranial Pressure

contaminations were of no clinical consequence and warned against premature conversion.

Timing of Definitive Fixation — Concomitant Chest Injury

The reviewed studies provided conflicting evidence for the best timing of definitive fixation in non-borderline patients with a concomitant femoral fracture and chest injury. Multiple studies showed that among patients with chest injuries, there were no additional incurred risks because of the presence of a femoral shaft fracture and subsequent treatment with early IMN.[19–21] Among these, Weninger et al.[21] reported that the unreamed IMN procedure occurred within six hours of admission given that the patient was in stable hemodynamic (systolic blood pressure >90 mmHg) and respiratory condition within one hour after admission. However, these studies could not make comparisons between early IMN and delayed IMN because of their study design or small group size.[19]

The four studies that were able to compare early versus delayed IMN were split on the outcomes. Pape et al.[14] found that patients with an AIS thorax score ≥2 and femoral shaft fracture treated with IMN within 24 hours of injury had a greater risk of ARDS compared to similarly injured patients treated with delayed IMN and compared to non-severe thoracic injured patients treated with IMN. However, only the difference between severe and non-severe thoracic injured patients was found to be statistically significant. Fakhry et al.[22] observed that patients with severe chest injuries treated with definitive fixation within one day of admission trended toward higher rates of mortality than patients treated after one day, but this finding was complicated by evidence that delayed surgical treatment was associated with longer hospital stays. Neither of these results reached statistical significance. In contrast to these findings, Brundage et al.[23] did not find a statistically significant difference in mortality rates based on timing of operative management. These authors did find a significantly lower incidence of ARDS in chest-injured patients treated within 24 hours compared to between 48–120 hours. These results were supported by Nahm et al.[11] who observed a statistically significant two-fold increased risk of developing pulmonary complications and a significantly higher incidence of sepsis after delayed (>24 hours of injury) IMN treatment in chest-injured patients with a femoral shaft fracture. In their study, the authors reported that there was no formal protocol in place to determine when to proceed with IMN, but that resuscitation was gauged by pH, base deficit, lactate, and ICP monitor.

O'Toole et al.[13] was the lone study that compared early IMN and DCO methods for chest-injured patients. Their findings support early, but not emergent, definitive fixation by IMN in this patient subpopulation unless they are not adequately resuscitated quickly, in which case they may be treated with DCO. The authors defined resuscitation by lactate levels trending to <2.5 mmol/L in the presence of optimized ventilatory and hemodynamic parameters, which were not stated. The EAST (Eastern Association of the Surgery of Trauma) guidelines for femoral shaft fractures in polytrauma patients reported no difference in mortality, ARDS, mechanical ventilation requirements, ICU LOS, and hospital LOS with definitive treatment before and after 48 hours of injury based on class II and class III data.[30]

The findings reported in this review generally echo those of the EAST guidelines, but add recent evidence supporting early IMN and provide physiological measures that can be used to help determine a patient's fitness for an IMN procedure.

Timing of Definitive Fixation — Concomitant Head Injury

Evidence for the best timing of definitive fixation in patients with a concomitant femoral fracture and head injury seems to favor early, but not emergent treatment. McKee et al.[24] observed that patients with head injuries (AIS ≥3) and concomitant femoral shaft fracture treated with reamed IM nailing within 24 hours of injury showed no difference in early mortality, LOS, or long-term neurological function compared to matched head injured patients without femoral fractures. Nau et al.[25] observed no statistically significant difference in mortality, length of ICU stay, ventilation time, nor Glasgow Outcome Score (GOS) between multiply injured patients with concomitant head and chest injuries with and without femoral shaft fractures, given respiratory and hemodynamic stability before the IMN procedure. These results suggest that the addition of a femoral shaft fracture with early treatment did not yield worse outcomes for patients with head injuries.

Fakhry et al.[22] observed that patients with severe head injuries (AIS ≥3) who had their femoral shaft fracture definitively treated between 2–4 days trended towards lower mortality and shorter hospital LOS compared to those treated within one day or after four days, but differences did not reach statistical significance. Nahm et al.,[11] however, found a statistically significant difference in outcomes that favored early definitive fixation to delayed treatment in head-injured patients. Starr et al.[26] found no statistically significant differences between early and delayed fixation for neither minor (GCS >8) nor severe (GCS ≤8) head injuries, though their sample sizes were small. However, a delay in femur stabilization beyond 24 hours was found to be a strong predictor of pulmonary complications. Townsend et al.[27] found that definitive fixation of femoral shaft fractures in patients with severe head injuries (GCS ≤8) within two hours of admission was associated with an eight-fold increased risk of intraoperative hypotension compared to after 24 hours. Furthermore, operation between 2–24 hours was associated with a four-fold increased risk of hypotension compared to after 24 hours. This study was unique in that it analyzed

smaller time periods than 24-hour increments. However, the authors did not find an association between intraoperative hypotension and mortality.

The reviewed findings are mostly in line with the EAST guidelines, which report no difference in outcomes based on timing of definitive fixation.[30] However, the recent articles reviewed here may add evidence suggesting early definitive fixation may have clinical benefits over delayed fixation, as long as the patient is stabilized.

Physiological Indicator of Patient Stability

Although almost half of the studies stated some sort of criteria met before the surgeons proceeded with definitive fixation of femoral shaft fractures, few reported specific values. Crowl et al.,[28] however, were able to show that completely resuscitated patients with femoral shaft fractures treated with an IM nail within 24 hours of injury had fewer complications and lower hospital costs than those who were treated without adequate resuscitation. The study reported threshold values for lactate (<2.5 mmol/L), systolic BP (>100 mmHg), heart rate (<120 bpm), and urine output (>1 ml/kg per hour) to differentiate completely resuscitated patients from incompletely resuscitated ones. O'Toole et al.[13] reported using a similar lactate threshold for patients undergoing a primary reamed IM nailing procedure, while Scalea et al.[8] mentioned a "normalized" lactate criterion for their patients without giving a specific value. In further support of Crowl's study, a recent study by Grey et al.[31] observed an increased requirement for inotropic support for patients who underwent femoral fracture fixation with preoperative lactate >2.5 and otherwise normal vital signs compared to those with preoperative lactate <2.5. Another potential marker for hypoperfusion is serum bicarbonate. Morshed et al.[32] showed an association between IMN procedures performed in the setting of serum bicarbonate-defined hypoperfusion and pulmonary organ dysfunction in multiply-injured patients. Although the use of serum bicarbonate as a diagnostic of hypoperfusion has yet to be validated by another study, this study does provide further evidence that physiologic markers can help guide clinicians determine when to proceed with IMN in multiply injured patients.

Conclusion

Much of the literature has been concerned about the timing of definitive fixation of femoral shaft fractures in multiply injured patients. The debate over the ideal time to IMN continues, but few studies have analyzed results based on smaller time intervals than 24 hours. This time period could span from emergent treatment to treatment the next morning. There may be a smaller time interval than 24 hours when patient outcomes can begin to diverge. Recently, an increasing number of studies have reported physiological parameters used to determine patient stability for an IMN procedure. These parameters, such as lactate level, can be complementary guiding factors in addition to concerns about time in the management of femoral shaft fractures in multiply injured patients.

Results of the reviewed studies were weighed with respective study designs and sample sizes to create practice guidelines for the initial treatment of femoral shaft fractures in the multiply injured patient intended for use at Temple University Hospital (Table 7). Although there was only one prospective randomized trial reviewed, the collective sample size of the studies gives a substantial amount of evidence for the approach we describe. Our guidelines generally agree with those put forth by EAST, but also serve as an update to their guidelines, which are now more than 10 years old. However, it should be noted that only articles written in English were included in this review, which excluded a large number of German studies that have contributed to the topic. We believe that there was enough evidence with North American patients to create a set of practice guidelines that could be implemented at our trauma center in Philadelphia.

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Original Research

Training and Prolonged Performance of a Low Force Repetitive Task by Mature Rats Induced Detrimental Bone Remodeling, Cortical Porosity and Inflammation

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Abstract

We have shown that repetitive reaching and grasping leads to trabecular bone adaptation in young adult rats at moderate force loads. Our goal here was to assess forearm bone microarchitecture in mature rats performing a moderate level reaching and grasping task, with the hypothesis that bone quality would decrease. We examined radii of three groups of mature rats (14 months of age at onset of experiment): 1) rats that trained for 10 minutes/day for four weeks to perform a high repetition low force task, and then performed this task for two hours/day for 12 weeks (HRLF Mature); 2) age-matched rats that trained only and then rested for 12 weeks (TRLF + Rest); and 3) age-matched normal controls (NC Mature). TNFalpha and IL-1beta increased in distal and diaphyseal regions of TRLF + Rest and HRLF Mature bones, IL-6 increased in diaphyseal region of HRLF Mature bones, while IL-10 decreased in diaphyseal HRLF Mature bones. Micro-computed tomography analysis of TRLF + Rest and HRLF Mature bones showed that despite no loss in bone volume, significant anisotropic and structure model index changes were present in distal trabeculae. Their mid-cortical diaphyses also showed endosteal resorption, cortical thinning and increased porosity, indicative of reduced cortical bone quality, compared to NC Mature rats. Thus, repetitive reaching and grasping at constant moderate loading levels, leads to increased bone inflammatory cytokines, reduced trabecular bone quality without loss of bone volume, and decreased cortical bone quality, changes associated with increased fracture risk.

Introduction

According to the Bureau of Labor Statistics report titled "Nonfatal Occupational Injuries and Illnesses Requiring Days Away from Work, 2012," work-related musculoskeletal disorders (WMSDs) account for 33% of lost workday injuries and illnesses in the US, and are estimated to cost over $61.2 billion annually.[1] However, the mechanisms leading to pathophysiological tissue changes associated with WMSDs are incompletely understood. The 2010 National Manufacturing Agenda of the National Institute of Occupational Safety and Health cites the need for etiologic research in determining the contribution of biomechanical and biochemical mechanisms towards the development of tissue injury and musculoskeletal disorders.[2, 3] Recent government show increased risk of WMSDs of the upper extremities in people above 35 years of age.[1, 2] As the average age of the American workforce rapidly increases,[4] due to economic realities in the United States (as well as world-wide), more WMSD cases are predicted, enhancing the need for understanding the effect of WMSD long-term on aging musculoskeletal tissues.

Hand and wrist injuries are prevalent in occupations requiring upper extremity repetitive tasks, and can be further aggravated by advancing age.[5, 6] Both acute and cyclical over-load of tissues can affect bone quality and morphology.[7, 8] Prolonged performance of repetitive tasks, dependent on the force load, repetition rate and duration of task, can either lead to bone adaptation or pathological bone changes.[9] Prior work from our lab using our innovative rat model of WMSDs in which rats voluntarily perform an upper extremity repetitive reaching and grasping task, showed that forelimb bones undergo exposure-dependent increases in pro-inflammatory cytokines (e.g., IL-1beta and TNF-alpha), and greater bone resorptive changes and cartilage damage with higher force loads.[9–11] We have also observed enhanced inflammatory cytokine production in serum and tendons of mature rats performing a high repetition low force (HRLF) task,[12] compared to young adult rats performing the same task, as well as in serum of mature control rats compared to young adult control rats.[13] In these studies, the mature rats were 14–18 months of age during the course of the experiment, while the young adults rats were 2.5–6.5 months of age). These serum changes were concomitant with enhanced task-induced degenerative changes in forelimb tendons in mature HRLF rats.[12] These results are consistent with other studies showing that aging mammals typically have increased IL-1beta and TNF-alpha in tissues and systemically, compared to young adult mammals, even in the absence of detectable tissue injury.[14, 15] These cytokines are known to stimulate osteoclast formation and to impair osteoblast differentiation.[16–20] We have already reported qualitative bone changes in young adults performing a high repetition low

force (HRLF) task for 12 weeks, but we have yet to examine bones of aging mature rats in our WMSD animal model.[9]

Aging is not only associated with decreased bone quality and mass,[8, 21–25] but also with normal structural parameter changes[26] triggered by age-related hormonal and inflammatory changes.[15, 27] The loading threshold required to initiate an osteogenic response is higher in aging bones than in younger bones.[8, 25] Therefore, the effect of performing repetitive tasks on bone architecture needs further evaluation to assess if aging combined with performance of repetitive task for 12 weeks enhances bone inflammation, remodeling or degradation.

Thus, our aim here was to investigate the impact of WMSD on bones in aging (mature) non-menopausal female rats, as very little is known about WMSDs in an aging population. We favored a female rat model based on the higher prevalence of these disorders in women,[28] and for comparison to data from our past studies on young adult female rats, using this model. We hypothesized that low grade loading occurring during the initial training period of 10 minutes/day, five days/week, for four weeks (TRLF + Rest rats), would encourage bone formation and indicate potential adaptation or reduced resorption. We further hypothesized that performance of a high repetition low force (HRLF) task for two hours/day, three days/week for 12 weeks (HRLF Mature rats) would lead to bone changes indicative of degradation.

Materials and Methods

Overview

Using our innovative operant animal model of a repetitive upper limb reaching and handle-pulling task, we examined radii of three groups of mature female rats (14 months of age at onset of experiment): 1) rats that trained for 10 minutes/day for four weeks to perform a low force task, and then performed a high repetition low force task for two hours/day for 12 weeks (HRLF Mature); 2) age-matched rats that trained only and then rested for 12 weeks (TRLF + Rest); and 3) age-matched normal controls (NC Mature). We performed the following analyses: investigated pro-inflammatory-cytokines in forelimb bones, and bone morphometric using micro-computerized tomography (microCT).

Animals

All experiments were approved by the Temple University Institutional Animal Care and Use Committee and were in compliance with NIH guidelines for humane care and use of laboratory animals. A total of 48 mature aging adult female Sprague-Dawley rats were used (14 months of age at onset of experiments; 18 months at completion). The rats were housed in a central animal facility in separate cages with a 12 hour light-dark cycle with free access to water and environmental enrichment toys. After the first week of acclimation, animals were randomly selected to NC Mature (n = 18), TRLF + Rest (n = 12), or HRLF Mature (n = 14) groups; rats were yoked and age-matched throughout the experiment. There were also four food-restricted control rats used to confirm the validity of using free access to food rats (NC rats) as controls. TRLF + Rest and HRLF Mature rats were weight-matched as well. In addition to 45 mg food pellet rewards provided during training and task performance (a 1:1 mix of purified grain and banana flavored pellets, both from Bioserve, NJ, USA), all rats received Purina rat chow daily. Results were compared to age-matched NC Mature rats that received similar amounts of food reward pellets daily as TRLF + Rest and HRLF Mature rats, in addition to free access to Purina rat chow. Three additional rats had to be excluded, as one was euthanized before the completion of the experiment due to renal failure, another due to presence of palpable tumors, and one that died unexpectedly. To further reduce illness-related confounders, additional sentinel rats were examined for presence of viral infections as part of the regular veterinary care (no viruses or infections were detected).

Behavioral Task Apparatuses, Training and Task Performance

The behavioral apparatuses used were 16 custom-designed force apparatuses (Custom Medical Research Equipment, Glendora, NJ) that were integrated into an operant behavioral training system (Med Associates, Georgia, VT), as previously described and depicted.[29] Training and task performance were as described previously.[9]

Analysis of Bone Cytokines Using ELISA

To study bone inflammation, cohorts of animals were deeply anesthetized with 5% isofluorane in oxygen, blood collected by cardiac puncture using a 23-gauge needle, and euthanized using cardiac exsanguination. Forelimb bones were collected from subcohorts of animals: NC Mature (n = 14), TRLF + Rest (n = 8), HRLF Mature (n = 8), and four food-restricted only control rats. Soft tissue were removed from the bones, and then distal (carpal bones, epiphysis and metaphysis of the radius and ulna) and proximal (diaphysis of radius and ulna) bones were separated, flash-frozen, and homogenized separately to assess interleukin (IL)-1β and tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6) and anti-inflammatory cytokine interleukin-10 (IL-10) using commercially available ELISA kits (BioSourceTM, Invitrogen Life Sciences, CA), as described previously.[30] Each sample was run in duplicate. ELISA data (pg cytokine protein) were normalized to total protein, determined using a bicinchoninic acid (BCA) protein assay kit (Thermo Scientific Pierce BCA Protein Assay).

MicroCT Imaging and Analysis

Rats were deeply anesthetized and blood collected as described above. They were perfused transcardially with 0.9% saline and then with 4% paraformaldehyde in 0.1 M PO_4 buffer (pH 7.4). Forelimb bones were collected and

cleaned of soft tissues from the dominant reach limbs of: NC Mature (n = 5), TRLF + Rest (n = 4) HRLF Mature (n = 6). The microarchitecture of radial trabecular bone at the distal metaphysis and the diaphysis cortical bone were investigated using a SkyScan 1172-12mPix high resolution cone-beam microCT scanner (Skyscan, Ltd, Antwerp, Belgium). First, collected forelimb bones were stored in 4% paraformaldehyde in 0.1 M PO_4 buffer. Twenty-four hours prior to micro-CT analysis, the bones were rinsed and immersed in phosphate buffered saline. Forelimb bones of food-restricted only rats (n = 4) were also analyzed in a separate study and used to confirm the validity of using free access to food rats (NC rats) as controls. The bones were scanned from the metacarpal bones of the wrist to mid-shaft using the following settings: air media wrapped in parafilm, x-ray source spot size of 300 nm, pixel size of 5.89 μm, Al 0.5 mm filter, voltage of 59 kV, current of 167 μA, rotation step of 0.40°, frame averaging of five. Each scan approximately took 45 minutes per bone. During reconstruction of the images (Skyscan NRecon), a ring artifact correction of 10, and a beam hardening correction of 60% were applied to all samples. The image slices were reconstructed using cone-beam reconstruction software based on the Feldkamp algorithm.

Using the Skyscan CT Analyzer (CTAn) software, two regions of interest (ROI) of the radius were delineated using a region of interest tool, and then binarized separately. The metaphyseal trabecular bone ROI was defined from 1.5 mm below the center of the distal growth plate and extending proximally for 1 mm (170 slices). The volume of interest (VOI) for the trabecular microarchitecture variables was defined by a consistent circle shape within a few pixels inside the endocortical margin. The cortical diaphyseal ROI was delineated from 5 mm below the distal growth plate and extending proximally from that side for 0.5 mm. The cortical VOI was defined by circling the outside of the cortical bone surface. The registered data sets were segmented into binary images. Because of a low noise and the relative good resolution of the data sets, we used simple global thresholding methods. For trabecular bone, an upper threshold of 255 (the maximum) and a lower threshold of 95 were used. For the cortical analysis, the upper threshold remained 255, but the lower threshold was increased to 125 to delineate each pixel as "bone" or non-bone. Despeckling was performed at a two-dimensional setting of 50 pixels, prior to two-dimensional (2D) and three-dimensional (3D) analyses of both ROIs. We also utilized the shrink-wrap option of the CTAn software to cover holes of more than 50 pixels for the cortical analysis, in order to eliminate larger arterial profiles from the analysis.

Trabecular morphometric traits were computed from binarized images using direct 3D techniques that do not rely on prior assumptions from the underlying structures. Trabecular bone volume per total volume (BV/TV), bone surface per bone volume (BS/BV), bone surface density (BS/TV), mean trabecular thickness (Tb.Th.), mean trabecular number (Tb.N.), and mean trabecular separation (Tb.Sp.) were measured in 3D, along with degree of anisotropy (DA — indicator of mechanical strength) and structure model index (SMI — rods or plates architecture). Cortical morphometry was analyzed from obtained binarized images using 2D techniques. Total cross-sectional area inside the periosteal envelope (Tt.Ar.), cortical bone area (Ct.Ar.), Cortical area fraction (Ct.Ar./Tt.Ar.) and average cortical thickness (Ct.Th) were reported based on the Journal of Bone and Mineral Research guidelines.[31] Additionally, we gathered data about cortical porosity (Ct.Po.) pore volume (Po.V.) and pore density volume (Po.Dn.), which can be indicators of microdamage and Haversian system remodeling. The person carrying out the microCT analyses was blinded to treatment.

Statistical Analyses

To determine differences between and among groups, one-way ANOVAs were performed for ELISA for cytokines and microCT data. To determine the effect of the dependent variables, for each ANOVA, the Bonferroni post-hoc method for multiple comparisons was used. Adjusted p-values are reported, and after adjustment, a p-value of <0.05 was considered statistically significant. A two-tailed Pearson's correlation test was used to compare cortical area (Ct.Ar.), bone volume (BV/TV) and cortical thickness (Ct.Th.) with the animal weights and estrogen level at euthanasia. Data are expressed as mean ± standard error of the mean (SEM). One-way ANOVA p-values are listed with the individual graphs.

Results

Inflammatory Cytokines Increased with Training and Task in Forelimb Bones

Significant changes in cytokines were observed in both distal and proximal forelimb bone regions. IL-1beta and TNF-alpha increased in distal forelimb bones of TRLF + Rest and HRLF Mature rats, compared to NC Mature rats (Fig. 1A, C), while IL-10 was reduced in HRLF Mature rats only (Fig. 1G). TNF-alpha, IL-1beta and IL-6 increased in proximal diaphysis of forelimbs bones of TRLF + Rest and HRLF Mature rats (Fig. 1B, D, F), while IL-10 increased only in TRLF + Rest animals proximally (Fig. 1H).

MicroCT Showed No Loss of Radial Trabecular Bone Volume, But Increased Anisotropy and Plate Like Structure

Morphological features of trabeculae in the radial metaphyses, analyzed by microCT, did not show significant changes across the groups in bone volume density (BV/TV), BS/BV, BS/TV, trabecular number, thickness or separation (Tb.N., Tb.Th. or Tb.Sp.; Fig. 2A–F). However, trabecular architecture changes were noticeable in 3D reconstructed images (Fig. 2G–I). Therefore, we examined the degree of anisotropy (DA) and structural model index (SMI). We observed that training and task performance lead to uneven trabeculae redistribution (i.e., increased DA), making the trabeculae

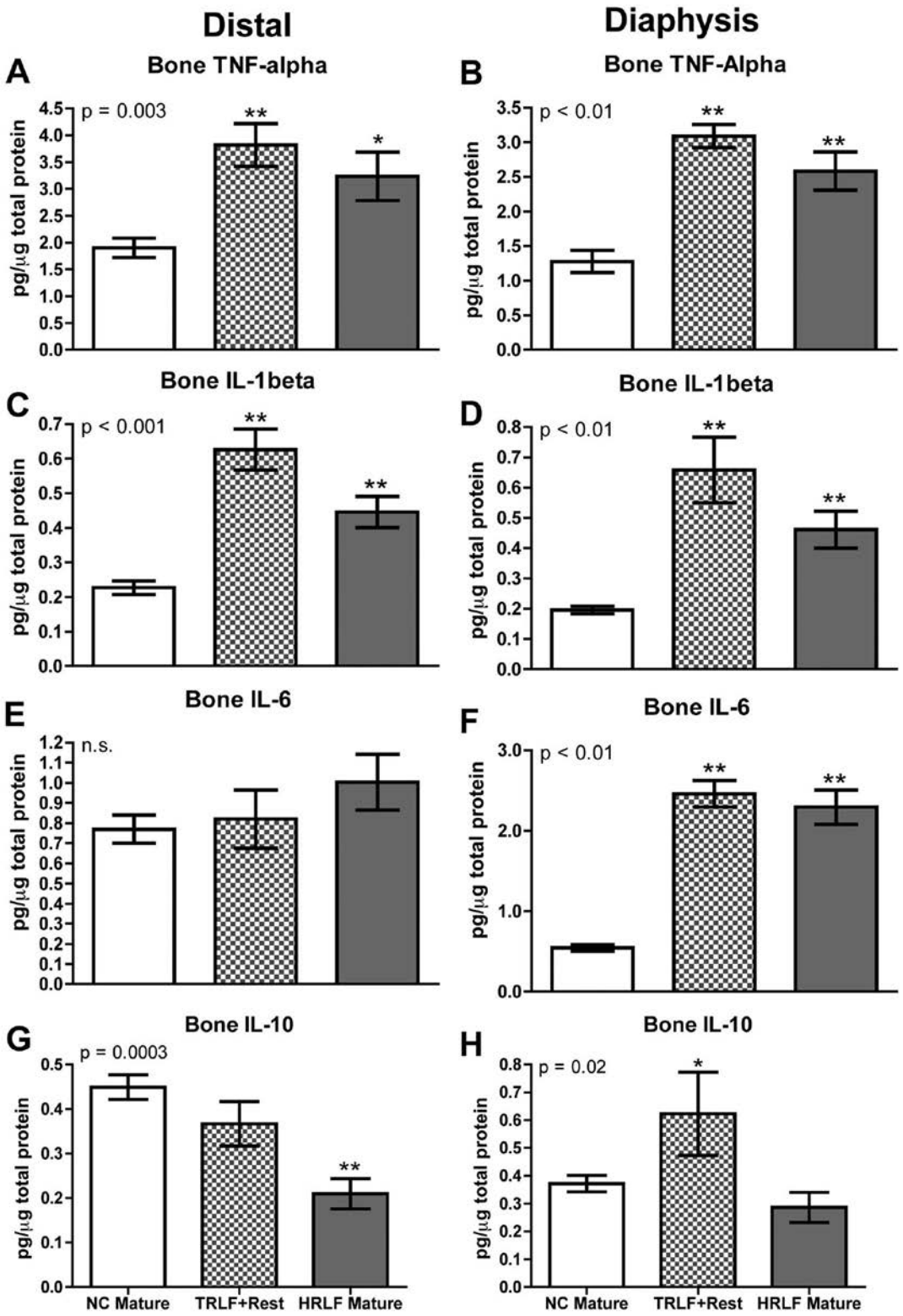

Figure 1. Bone cytokines, assayed using ELISA. After homogenization, forelimb bone supernatant was analyzed separately for the distal (radial and ulnar metaphysis, epiphysis and carpal bones) and proximal diaphysis (radial and ulnar diaphysis) regions in NC Mature, TRLF + Rest and HRLF Mature rats. **A-B)** TNF-Alpha levels in distal and diaphyseal bone. **C-D)** IL-1 beta levels in distal and diaphyseal bone. **E-F)** IL-6 levels in distal and diaphyseal bone. **G-H)** IL-10 levels in distal and diaphyseal bone. ANOVA p-values are reported on individual graphs.

* and **$p < 0.05$ and $p < 0.01$, compared to NC Mature rats.

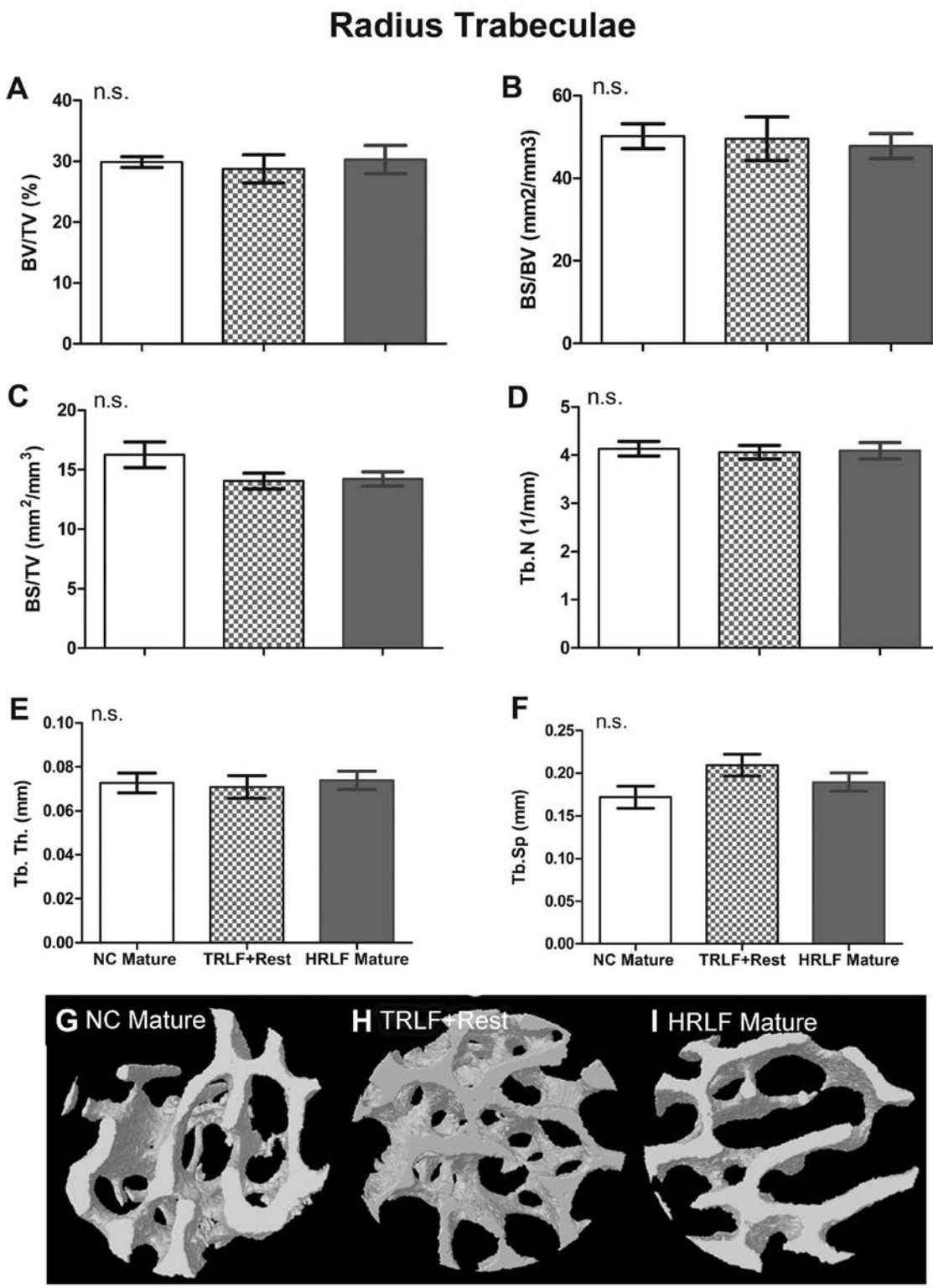

Figure 2. Micro-computed tomography (microCT) analysis of trabeculae in the distal radial metaphysis. **A)** Bone volume over tissue volume (BV/TV), **B)** bone surface over bone volume (BS/BV), **C)** bone surface over tissue volume (BS/TV), **D)** trabecular number (Tb.N.), **E)** trabecular thickness (Tb.Th.) and **F)** trabecular separation (Tb.Sp.) did not significantly vary in TRLF + Rest or HRLF Mature rats, compared to NC Mature rats. **G-I)** Reconstructed three-dimensional (3D) microCT transaxial images of the ROI of trabeculae in the distal radial metaphysis. n.s. = ANOVE was not significantly different.

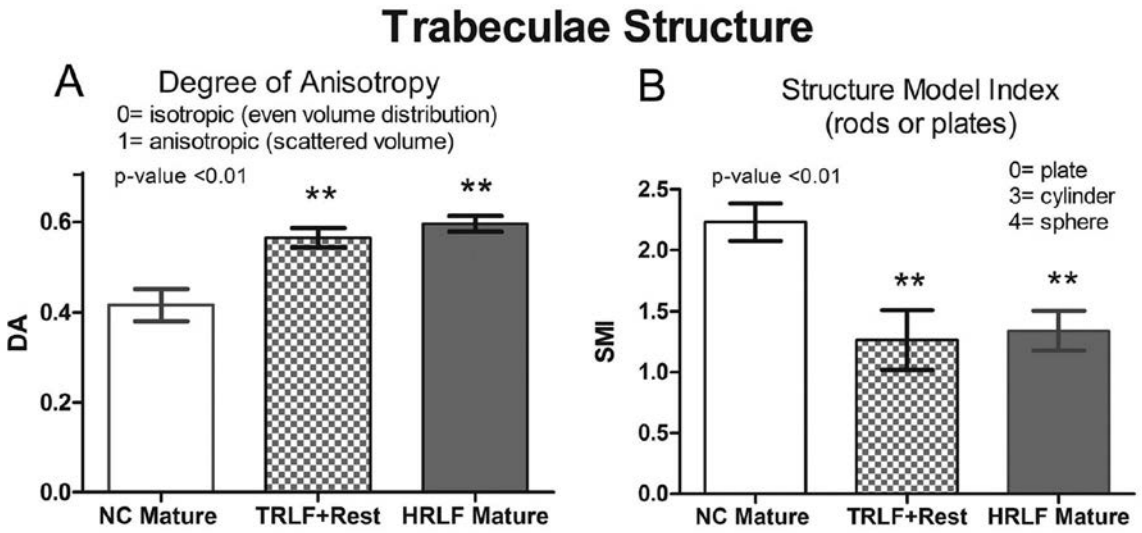

Figure 3. Trabecular microstructure analysis. **A)** Degree of anisotropy (DA) shows an increase with TRLF + Rest and HRLF12W Mature in disorganization of the trabeculae volume. Zero (0) is more isotropic (even distribution of volume) and one is indicative of anisotropy (scattered distribution). **B)** Structure model index indicates a slight increase towards the beneficial plate-shape with TRLF + Rest and HRLF task. ANOVA p-values are reported on individual graphs.
**p < 0.01, compared to NC Mature rats.

more scattered (Fig. 3A). Training and task performance also lead to conversion of a rod-like trabeculae structure, seen in NC Mature, to a more plate-like configuration in TRLF + Rest and HRLF Mature rats (Fig. 3B).

MicroCT Showed Loss of Radial Cortical Bone Quality

Interestingly, the radial diaphysis showed significant of cortical bone remodeling and degradation. The total cortical area (Ct.Ar., Fig. 4C) and total area (Tt.Ar., Fig. 4B) remained unchanged. In contrast, the marrow area (Ma.Ar.) was increased in TRLF + Rest and HRLF Mature animals (Fig. 4D), leading to a reduction in cortical thickness (Fig. 5E). More detrimental changes were observed as increased total porosity volume (Po.V., Fig. 4F), percentage of cortical porosity (Ct.Po., Fig. 4G) and pore density (Po.Dn., Fig. 4H) in TRLF + Rest and HRLF Mature rats, compared to NC Mature rats. Representative 3D images showing the visual differences are shown for NC Mature (Fig. 4I), TRLF + Rest (Fig. 4J) and HRLF Mature (Fig. 4K).

Discussion

We observed that inflammatory cytokines increased in distal and diaphyseal regions of TRLF + Rest and HRLF Mature bones, compared to NC mature rats, while a key anti-inflammatory cytokine decreased in the HRF + Mature rats. Micro-computed tomography analysis of TRLF + Rest and HRLF Mature bones showed that despite the increase in pro-inflammatory cytokines, that there was no significant loss in trabecular bone volume in the distal metaphysis of the radius. However, there were significant anisotropic and structure model index changes in the distal trabeculae. The mid-cortical diaphyses of these same groups also showed endosteal resorption, cortical thinning and increased porosity, indicative of reduced cortical bone quality, compared to NC Mature rats. Thus, repetitive reaching and grasping at constant moderate loading levels, leads to increased bone inflammatory cytokines, reduced trabecular bone quality without loss of bone volume, and decreased cortical bone quality. Both of the latter bone changes are associated with increased fracture risk.

We have recently shown using ELISA that both the training period and performance of this same HRLF task for 12 weeks by young adult rats lead to no significant increases in pro-inflammatory cytokines in the distal forelimb bones,[9] which is in contrast to the increases in IL-1beta, TNF-alpha and IL-6 observed in the mature trained and HRLF task rats in this study. The young adult rats used in that past study were 2.5 months of age at onset of the training, while the mature rats used in this study were 15 months of age. These findings of increased inflammatory cytokine production in mature rat tissues are consistent with our past findings of increased inflammatory cytokine production in serum and tendons of mature rats performing a HRLF task,[12, 13] compared to young adult rats performing the same task. These serum changes were concomitant with enhanced task-induced degenerative changes in forelimb tendons in aged HRLF rats.[12] These results are consistent with other studies showing that aging mammals typically have increases in the same cytokines (IL-1beta, TNF-alpha and IL-6), in tissues and systemically, compared to young adult mammals, even in the absence of detectable tissue injury.[14, 15] These cytokines are known to stimulate bone resorbing osteoclast formation and impair bone forming osteoblast differentiation,

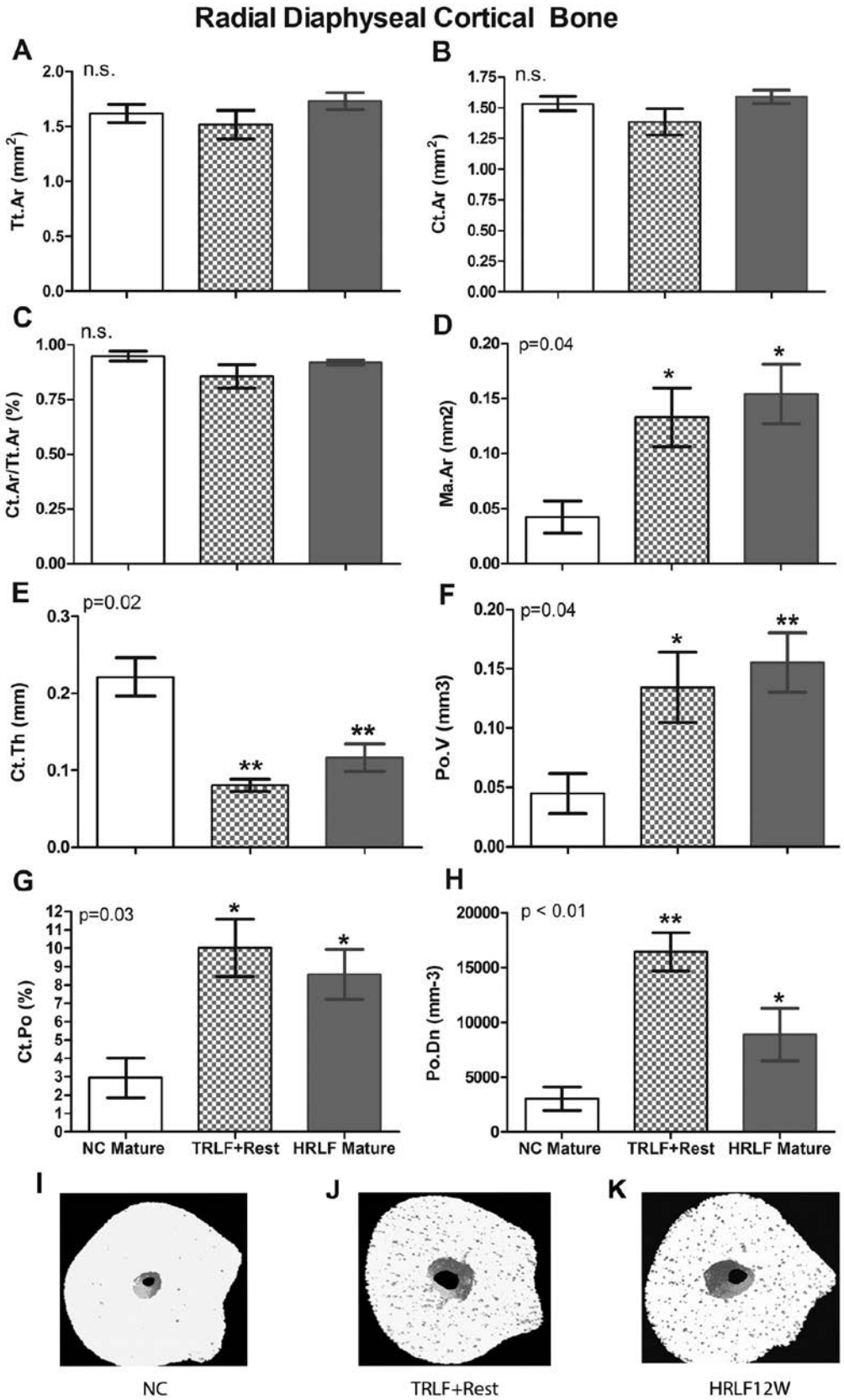

Figure 4. MicroCT diaphyseal cortical differences. **(A)** Total cross-sectional area inside the periosteal envelope (Tt.Ar), **(B)** cortical bone area (Ct.Ar), **(C)** cortical area fraction (Ct.Ar/Tt.Ar), **(D)** marrow area (Ma.Ar), **(E)** average cortical thickness (Ct.Th), **(F)** pore volume (Po.V). **(G)** percent cortical porosity (Ct. Po), and **(H)** pore density volume (Po.Dn). **(I-K)** Transaxial views of selected of diaphyseal cortical volumes of interest. ANOVA p-values are reported on individual graphs. * and **$p < 0.05$ and $p < 0.01$, compared to NC Mature rats. n.s. = ANOVE was not significantly different.

which could lead to a net bone loss.[16–20] Thus, the increase in cytokines in Trained + Rest and HFLF Mature rat forelimb bones could be contributing to the reduced quality in these bones.

Aging is associated with decreased bone quality and mass.[8, 21–25] Although we did not see a reduction in bone volume in distal trabecular region of the radius, we observed altered trabecular structure (increased degree of anisotropy and a decrease in the structural model index), cortical thinning and increased porosity in the TRLF + Rest mature and HRLF Mature rats. The degree of anisotropy (DA) in trabecular bone is one of the most important determinants of mechanical bone strength;[32, 33] its increase in the radius is suggestive of a decrease in strength in this region. We also observed a decrease in the structural model index (SMI) in the distal radial trabeculae. SMI is an architectural description of the rods versus plate shape of the trabeculae in 3D. Osteoporotic bone is characterized by a change from plate-like trabeculae to rod-like trabeculae.[34] The cortical thinning was due to endosteal resorption that was not matched by periosteal apposition after training and task performance. More detrimental changes were obvious as increased bone porosity, which is indicative of active Halverson system remodeling[22] or increased resorption spaces,[35, 36] changes implicated in skeletal fragility and stress fractures.[8, 37] These results differ dramatically from our previous results in young adult rats, in which performance of the same HRLF task for 12 weeks induced anabolic changes in the distal trabecular region of the radius, including increased bone volume and increased trabecular thickness.[9] Thus, we observed several changes in bone structure and quality in these mature rats that are also linked to increased fracture risk and perhaps even osteoporosis.

In conclusion, the combination of aging with prolonged performance of occupational repetitive tasks lead to decreased bone quality that has been associated with increased risk of fractures.

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Review Article

Conflict of Interest: Current Concepts and the Recommendations for the Practicing Physicians

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Introduction

Awareness and understanding of what constitutes a conflict of interest (COI) in healthcare is vital to ensure proper patient care, uphold the high ethical standards of the profession, and to comply with regulatory statutes. The recent implementation of the Patient Portability and Accountable Care Act (PPACA or ACA),[1] and specifically the "Sunshine" provision contained therein constitutes a major effort at the federal level to increase transparency for transfers of value from pharmaceutical, device, and medical supply companies to physicians. Under this act, all gifts to physicians of a $10.00 value or more will be posted on a public website. This has increased the scrutiny of physician benefits and sources of income.[2] Another federal statute, the Stark Law prohibits physicians from directing health care referrals or "business" to any entity in which they hold a financial interest or from which they receive something of value. Violations of the Federal Anti-Kickback and Stark Laws may result in substantial monetary penalties, exclusion from participation in health care programs, and imprisonment.[3] In the current climate of increased regulatory burden resulting in increased administrative expense and declining reimbursement, the transition from a fee-for-service to a value-based model has caused the physician to experience a virtual or real decline in income. As such, secondary issues, such as financial gain[4] may become a more central concern to the health care provider. This, in turn, may result in an unconscious, instinctive, psychological motivation for the physician to engage in relationships or transactions that constitute a COI.[5] It is therefore imperative that physicians, particularly physicians in training, understand and recognize these concepts proactively.[6–9]

In this brief review, the relevant behavioral data will be examined, the necessity and purpose of disclosure discussed, and the pertinent legislation summarized.

Behavior

A COI in medicine exists when physicians' secondary interests influence their decision-making in patient care, administrative issues or scientific research. Specifically, the influence from relationships between physicians and industry are of importance because they elicit two kinds of behavior: the tendency to default to one's own self-interest and the need to reciprocate.[5] Both have strong subconscious foundations.

Self-interest refers to anything that could be considered desirable to the physician, such as monetary benefit or praise from peers. Its impact on physician decision-making may not be intuitively obvious. The literature is, however, clear. One study showed that when faced with two fairly equal choices, individuals will choose the one that is even slightly more self-beneficial; this effect can potentially subvert consciousness.[10, 11] In another study, Roth and Murnighan (1982) showed that people conflate their own interests with what is ethical. They designed an experiment where two subjects bargained over the distribution of 100 lottery tickets. A winning ticket paid $20 to one subject and $5 to the other. The results showed that the $5 earners advocated for an equal monetary split and the $20 earners advocated for an equal ticket number split,[12] suggesting an inability to consider the opposing view. Additionally, self-entitlement appears to positively correlate with personal struggles. Sah et al. (2010) showed that physicians reminded of personal sacrifices such as long work hours and incurred debt were more likely to condone the acceptance of gifts as compared with others who were not reminded.[13]

When individuals have unconscious desires or motivations for situational outcomes where they stand to benefit, they may rationalize their views by selective interpretation and explanation.[14] Ditto and Lopez (1992) showed that people tend to look hardest for what they want to see. They conducted an experiment where subjects were told they were being tested for a dangerous enzyme deficiency. The subjects provided a saliva sample that was placed on a placebo test strip. Some were told if the strip turned green, they had the deficiency, while others were told if it turned green, they did not. Those subjects hoping for the strip to turn green waited much longer than those who hoped it did not.[15] For physicians, this might mean justifying a COI based only on criteria that the physician wants to see — i.e., criteria that dismiss it as an actual COI. There may also be a tendency to ignore facts that support the opposing viewpoint. An experiment by Karlsson et al. (2006) showed people tend to look up the value of their stocks less often when the market is down than when it was up,[16] suggesting they were less interested in bad news than good.

The desire to maintain an honest self-image and avoid a negative one[14] does somewhat limit the degree to which individuals accept COI. In an experiment by Mazar et al. (2006) that evaluated whether decreasing the probability of being caught cheating affected the magnitude of deception, it was shown that individuals allowed themselves to cheat a little, but no more, suggesting they either feared being caught or felt guilty about what they did, or both.[17] This suggests physicians might be more likely to engage in CsOI they can justify or that will not raise suspicion, such as accepting pens or pencils from a drug company representative, as opposed to an all-inclusive paid vacation.

Physicians might also be more likely to engage in CsOI if there are degrees of freedom between relationship and reward, as in the case of accrued credits that can be redeemed for a gift at a later date. As a follow up to their study in 2006, Mazar et al. (2007) showed the amount of cheating doubled when subjects received tokens for correct answers that could be exchanged for money, rather than money directly. The effect was attributed to the subconscious perception that the personal sense of guilt subjects experiences was reduced by being less-directly rewarded.[18]

Similar to self-interest, *reciprocity* has deep-seated evolutionary roots that can predictably influence the way a physician behaves. Such effects are measurable through Functional Magnetic Resonance Imaging (fMRI), which correlates the degree of blood flow in specific regions of the brain with decision making. King-Cases et al. (2005) looked at the relationship between behavior and trust through fMRI. "Investor" subjects decided how much money they would give to "trustee" subjects, and trustee subjects then determined how much they would return. Brain fMRIs were obtained periodically over many rounds. The researchers found activity in the head of the caudate nucleus correlated with whether trustees were going to increase or decrease repayment to investors, where the amount repaid represented the magnitude of trust between the parties. In early rounds, signal intensity correlated with the trustees' reactions to the immediate amount invested, but in later rounds correlated with its anticipation.[19] The study suggests that the need to reciprocate, e.g., a tendency to prescribe a specific drug or use a specific device, is based on the degree of trust in a relationship, which in many cases reflects the "friendship" between physicians and industry representatives. This friendship, however, is not always genuine, and despite the best intentions, drug and device companies know that "friendship sells":[5, 22] pharmaceutical companies spend $12 billion to $18 billion annually marketing to physicians,[21] much of this through direct face-to-face contact with industry representatives.

Another important mechanism that makes physicians susceptible to COI is the belief that they will not be swayed by biased information. This is certainly a factor in explaining why physicians will frequently meet with industry representatives despite an awareness of the potential COI implications. Chimonas et al. (2007) demonstrated this effect and showed a positive correlation between drug company-physician interaction and prescribing behavior of a marketed drug.[23, 24] Such effects were also found to be present in medical students.[14]

Disclosure

Disclosure is important in the management of COI, as it empowers the patient or reader to be the final arbiter of whether or not a conflict may exist. While disclosing a COI may appear to give an unbiased interpretative context to a physician's advice, two effects — strategic exaggeration and moral licensing — can often result in the opposite effect.[10, 26] *Strategic exaggeration* is the tendency to impart more biased information in order to offset what is being disclosed, essentially nullifying the intent of the disclosure. An example might include a physician disclosing his financial benefit to a patient he is trying to recruit for a clinical trial and then following the disclosure with information about how beneficial the new treatment has been. This, in effect, distracts the patient from considering the physician's advice in the context of his COI and may even deter the patient from seeking a second opinion.[14]

Moral licensing is the unconscious judgment that biased advice is acceptable because COI has been disclosed. It provides physicians with a false sense of security to impart advice regardless of how biased it may be.[26] Loewenstein et al. (2005) demonstrated the effect by designing an experiment where advisers would make recommendations to estimators to help determine how many coins were contained in a jar. The advisers were permitted to observe these jars close up and for extended periods of time, whereas the estimator could only observe for a short time and from a distance. Both the estimators and advisors were compensated based on the accuracy of their estimates, but the advisers were additionally compensated based on how high the estimates were. The results showed the advisers tended to overestimate the amount when their competing interests were disclosed, likely in an effort to compensate for lack of trust.[27]

This does not nullify the importance of disclosure, since CsOI are ubiquitous in medicine and disclosure still remains the most feasible common pathway for an individual to determine credibility on their own. It suggests, however, that the advisee must be knowledgeable on how to detect bias and discount it if disclosure is to be effective.[28] Forced disclosure may deter involvement with avoidable CsOI because of reputational concerns. For example, accepting a calendar from a pharmaceutical company is not likely to alter public perception about a physician's ethical choices, but accepting an invitation to a weekend golf retreat might. Physicians may therefore be more apt to engage in CsOI that on the surface appear benign but are CsOI nonetheless.[28, 29, 30]

The Current Environment

The physician-hospital relationship is changing dramatically. With the number of doctors employed by hospitals increasing in recent years (32%, from 2000 to 2010[31]), physicians must understand aims or goals of the hospital may not be identical to theirs. Specifically, two policies merit scrutiny: COI credentialing and economic loyalty policies. Both represent efforts by hospitals to avoid competition and protect their interest by leveraging the financial position of physicians.

COI credentialing is a form of exclusivity: physicians are forbidden to seek medical staff appointments at other hospitals or to admit patients at unaffiliated health care facilities. Economic loyalty policies limit the ability of physicians to participate in activities that compete against the economic interests of the hospital. Both are effective because many physicians depend on treating hospitalized patients and having access to managed care provider panels for income. Consequently, they cannot afford to jeopardize their source of income by failing to comply with a COI credential policy.[32] While both practices are not explicitly illegal, they affect patient health care by limiting access. In a given community, physicians are prohibited from developing or participating in a competing facility that could possibly offer greater benefit to the patient. Insurance plans also limit where a patient can seek treatment because reimbursement is frequently dependent on physician referrals, and physicians are only able to refer within their hospital network.[32]

As governmental funding sources have declined, the influence of the industry has increased. Physicians represent a large target market, as 80% of all health care expenditures depend on their advice and recommendations to patients.[33] Understanding these mechanisms can help physicians consider the impact they may have on patient care.

Industry utilizes two broad strategies to promote their products: push and pull. *Push strategies* rely on marketing products to physicians with the hope that they are utilized for patient care. The marketing occurs in the form of gifting promotional items such as pens, pencils, mugs, and calendars, all of which include the company name or logo, favors, meals or any initiative that directly or indirectly benefits the physician.[34] While the Pharmaceutical Research and Manufacturers of America[35] have discouraged such gifts unless they have educational purpose and do not exceed $100 in value, compliance is voluntary.[36, 37] For those in compliance, representatives will often provide "reminder" items at carefully selected time intervals, which include anatomic models, stethoscopes, and textbooks.[38] It costs five to 10 times as much to gain a new customer-physician than it does to retain an established one;[39] hence, persistence pays.

Pull strategies rely on advertising and sales promotion to patients. Companies then expect patients to bring the product to the attention their physician. Direct-to-consumer marketing has become increasing popular over the last few decades, with industry spending approximately $40 million in 1989, $350 million in 1995,[40] and $2.3 billion in 2000.[41] The trend reflects its effectiveness. In a study by Huang et al. (2000), 33% of those who saw an advertisement for a specific pharmaceutical product asked their physician for that product. Of those, 75% were prescribed the drug requested.[42] This appears consistent with the finding by Paul et al. (2002), which showed 63% of primary care physicians felt pressured to prescribe drugs that patients brought up.[43]

Taken in the context of the behavioral data noted above, and the increased regulatory burden to be discussed below, it is clear that a prudent and transparent relationship with industry is the order of the day. While industry is a valuable partner in patient care, education and research, neither the practitioner nor the scientist must realize that the ultimate goals of industry and medicine are divergent. As noted above, disclosure is a major step in transparency and appropriate management of real or perceived COI; federal legislation codifies and requires it.

Relevant Legislation

Historically, government regulation has targeted manufacturers regarding inappropriate relationships with physicians. The physician is now the subject of similar regulation.[44] The increased monitoring and public disclosure of payments from companies to physicians has made targeting physicians easier;[46] aside from ethical considerations, it is, thus, important from a practical and legal standpoint that physicians understand what constitutes *legally reprehensible behavior.* Four major articles of legislation are directly relevant: the Stark Law, the Sunshine Act, the Anti-Kickback Statute, and the False Claims Act.

The Stark Law (Figure 1) is intended to govern physician self-referral of Medicaid and Medicare patients. It prohibits a physician from referring those patients to any entity with which the physician, or a member of the physician's immediate family, has a financial relationship. For the Stark Law to apply, the referral must be for designated health services (DHS, for a complete list: http://www.cms.gov/physicianreferral/40_list_of_codes.asp) reimbursed by Medicare, and the receiving party must meet the defining "entity" criteria.[47] The law was written under the premise that physician self-referral constitutes an inherent conflict of interest which excessively increases the use of health care services.[48, 49, 50–52, 53]

Under Stark, an entity is a solo or group practice, corporation or partnership that renders DHS services. It may or may not bill Medicare directly for those services.[54] Immediate family members include husband, wife, mother, father, sibling, or child, stepparent, stepsibling, or stepchild, father-in-law, mother-in-law, brother-in-law, sister-in-law, grandparent or grandchild, spouse of a grandparent or grandchild.

Two categories of prohibited financial relationships exist: those associated with ownership and investment interests and those associated with compensation arrangements. Each

may be either a direct or indirect relationship.[55] Ownership and investment interests include equity, debt, stock, loans, and bonds.[56] Compensation arrangements involve money.[57] Indirect relationships link a physician with an entity through at least one intermediary, whereas direct relationships do not.[58] A direct interest, for example, could involve a physician holding partial stock in a physical therapy practice to which he/she refers. If the stepson of a physician owns a nursing home and the nursing home owns partial stock in the physical therapy practice, the physician would be considered to have a vested interest in the profitability of the physical therapy practice as well;[49] this is an indirect interest.

Penalties for violation of the Stark Law are significant, and the may include denial or refund of payment for services rendered as a consequence of the improper referral, exclusion from federal health care programs, and civil monetary penalties. Civil monetary penalties are substantially higher (up to $100,000 vs. $15,000) if the physician knowingly engages a circumvention scheme or cross-referral arrangement. For example, consider a scenario where Physician A and Physician B have ownership interests in Treatment Facility A and B, respectively. Both physicians cannot refer patients to their respective treatment center because it constitutes an obvious COI, but they also cannot refer patients to the other physician's treatment facility if a referral agreement exists. Such an agreement would involve Physician A sending all his patients to Treatment Facility B and Physician B sending all his patients to Treatment Facility A.[49, 59–62]

The Sunshine Act is a provision of the *Patient Protection and Affordable Care Act (PPACA)* that is intended to increase the transparency of physician-industry relationships by requiring pharmaceutical, device, biological, and medical supply companies to disclose payments and other transfers of value associated with products covered by Medicare, Medicaid, or Children Health Insurance Program (CHIP) to physicians and teaching hospitals.[1] The act also requires companies to disclose ownership and investment interests held by physicians or their immediate family members.[63] The information will be available online and searchable by manufacturer, physician, and teaching hospital name.[2] All of the following are considered payments and will be posted: cash or a cash equivalent, items or provided services, stock, stock options, or any other ownership interest, dividend, profit, or return on investment, consulting fees or compensation for services, honoraria, and gifts, or charitable contributions, food, entertainment, or travel, education or research, including grants and compensation for speaking at medical education programs, current or prospective ownership or investment interest.[64]

Payments are reported annually to the Centers for Medicare and Medicaid Services (CMS), a federal agency with the United States Department of Health and Human Services (HHS).[65] Manufacturers and Group Purchasing Organizations (GPOs) issuing payment are responsible for reporting; recipient physicians are not. Among other criteria, the reports will include:[66] the name of the manufacturer or GPO issuing payment, the recipient physician's name, specialty, business street address, and national provider identifier (NPI), the amount, date, form, and nature of the payment, the name of the associated covered drug, device, biological, or medical supply, and whether or not the payment was to a physician holding ownership or investment in the applicable manufacturer. Payments and transfers of value do not have to be reported if they meet any of the following criteria:[64, 67] are individually less than $10 and do not aggregate above $100, consist of educational materials that direct benefit patients or are intended for patient use, and are received from a third party where the manufacturer is unaware of the physician's identity

The disclosure of payment does *not* indicate or imply the presence of a conflict of interest. Its presence on the CMS website merely serves the purpose of providing objective information on the types of relationships between manufacturers and group purchasing organizations (GPOs), and physicians. However, this does not preclude its use in prosecuting physicians for violations of the Anti-Kickback Statute, False Claims Act (FCA), or Stark Law. The website will also contain information about enforcement action taken the previous year.[2, 68, 69]

It is thus imperative that physicians monitor this information for accuracy. Physicians registered on the CMS website are notified by CMS 45 days prior to public disclosure and can contest inaccurate information during this time. If a dispute arises, a 15-day resolution period is granted that allows the manufacturer or GPO to correct the information. The information may be repeatedly contested if it is not correct. Data that becomes publically available but still remains contested is marked as "disputed."[70]

The Anti-Kickback Statute (Figure 1) is a criminal statute that forbids a physician from knowingly receiving remuneration in exchange for referrals and services.[71] The statute necessitates intent. Per the Office of the Inspector General (OIG), intent is met if a purpose of remuneration is to induce referrals for, or purchases of, an item or service covered under a federal health program. The amount of remuneration is irrelevant,[72] as are any additional good intentions that may exist with regard to such an arrangement.[73]

Fee-splitting is also illegal under this statute. Fee-splitting is considered to be means by which physicians increase profits by charging clients substantially more for tests that they themselves pay less for. Consider the example whereby a physician contracts with a local pathology lab to read slides. The physician pays a volume based a discounted price to the lab and does not pass such discounts on to the patient and charges a substantially increased price. This constitutes fee-splitting and sets a precedent for not only overbilling federal health care programs but for potentially exposing the patient to unnecessary tests at the expense of increased profits.[74]

Violations of the Anti-Kickback statute can result in both criminal and civil penalties, up to $25,000 in fines and five

Figure 1. How Does the Anti-Kickback Statute Differ from the Stark Law[82]?

- Prohibition: The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving *anything* of value to induce or reward referrals, whereas the Stark Law prohibits a physician from referring Medicare patients for *designated health services* to an entity with which the physician has a financial relationship.
- Referrals: The Anti-Kickback Statute includes referrals from anyone, whereas the Stark Law includes referrals only from a physician.
- Intent: Intent must be proven under the Anti-Kickback Statute, whereas no intent standard for overpayment is necessary under the Stark Law. However, intent is required for civil monetary penalties for knowing violations under the Stark Law.
- Penalties: Violations of the Anti-Kickback Statute may result in criminal penalties, which include fines up for $25,000 per violation and up to a five-year prison term per violation, or civil penalties, which include up to $50,000 per violation. Violations of the Stark Law only result in civil penalties, which may include overpayment/refund obligations and up to $15,000 per violation. Both laws may also civilly result in False Claim Act liability, program exclusion for violations, and civil assessments of up to three times the amount claimed/received.
- Exceptions: Meeting requirements for exceptions under the Anti-Kickback Statute are voluntary, whereas meeting requirements for exceptions under the Stark Law are mandatory. In other words, if an arrangement does not comply with a safe harbor, it may not necessarily violate the Anti-Kickback Statute, but if an arrangement does not comply with a Stark Law exception, it constitutes a violation.
- Federal Health Care Programs: The Anti-Kickback Statute applies to all federal health care programs, whereas the Stark Law applies only to Medicare and Medicaid.

years in prison per violation, and from Medicare and Medicaid participation and fines up to $50,000 per violation plus triple the amount in question, respectively.[72]

Physicians are, however, protected from prosecution under the Anti-Kickback statute if their activities or arrangements are considered "safe harbors." Safe harbors were exceptions instituted by congress in response to the potential breadth of improper application of the Anti-Kickback Statute.[75] Of particular importance are those that deal with investment interests, referral services, and discounts.

Investment interests are protected providing the physician is not individually receiving remuneration in exchange for referrals to an unfair degree. This is particularly relevant for a financial interest in hospitals and departments. A physician is permitted to have a stake in an entire hospital because financial benefit from referrals to that hospital is considered insignificant. The COI is not considered insignificant if the physician has complete ownership of a subdivision or department because of internal referrals, thereby benefiting individually and completely.[72]

Physician investment is also permitted to invest in an ambulatory surgery center (ASC) providing that he/she owns no more than 40% of the ASC, and completely discloses the ownership interest to patients. This is permitted due to the rationale that ASCs can often deliver services at lower costs than hospitals for similar procedures.[77, 78] However, physicians are urged to utilize caution. It has been shown that physicians are more likely to refer well-insured patients to these facilities than they are Medicaid patients, which reimburse less, a clear COI. Additionally, physicians are still prohibited from referring patients to facilities that they own in numerous other categories.[79]

Referral services include professional societies and other consumer-oriented groups that refer patients. Physicians who pay fees to these organizations to be listed on their referral lists are protected providing the fees only reflect operational costs. Fees cannot be based on the volume or value of any referrals.[79, 80] Cross-referrals, however, are permissible. A cross-referral permits one physician to refer a patient to another physician, who later refers the patient back to the original referring physician. This safe harbor exists to permit what otherwise constitutes a normal everyday referral. No payment, however, is permitted for the re-referral.[79, 80, 81]

The False Claims Act (FCA) is a statute that protects the federal government from being overcharged.[83] It imposes liability on any person who submits a claim to the federal government that they know (or should know) is false. The law also forbids the creation or use of false records in order to justify payment from the federal government.[84] "Should know" means that the physician does not have to have actual knowledge that the claim is false. If he acts in reckless disregard or in deliberate ignorance of the truth, he is liable.[84, 85]

Violations of the FCA may result in fines of $5,500 to $11,000 per claim, plus three times the government's damages.[85] Most physicians generate a bill for each set of services rendered per patient. While the billed amount may be relatively inexpensive, many thousands of bills are usually submitted per year. Each bill is susceptible to its own fine. In comparison, treble damages represent a relatively small component.[84]

Public and internal monitoring has been encouraged and rewarded by *qui tam.* A qui tam action allows private persons to file suit for violations of the FCA on behalf of the federal government. They are entitled to a percentage of the amount recovered by the federal government. A private person includes anyone aware of the illegal claiming actions, such as office and billing staff. The qui tam creates a precedent these individuals to come forward by rewarding them.[84]

Conclusions and Suggestions

The climate in which healthcare is delivered is changing rapidly. Increased regulation, declining reimbursement, public and governmental suspicion have resulted in increased critical scrutiny of medical science and practice. Only by understanding the substance and implications of COI, managing COI with robust disclosure and complying scrupulously with governmental regulation do we, as physicians, have a chance to serve our patients and profession properly. In an effort to do so, the authors suggest the following questions be considered as a beginning for self examination.

1) Are there professional issues that might be constituted as a conflict of interest?

Conflict of interest issues include professional and business interests of the physician as well as institutional and

organizational relationships that might alter or affect the clinical treatment of patients. As discussed previously, such conflicts can subconsciously affect the physician's ability to make an unbiased decision, even if the physician feels it plays no role. For clear CsOI, the recommendation is divesture or termination of the contract or relationship in question.

2) Are there legal, public health, or safety consequences that might affect clinical decision making?

Legal rules may, effectively, impose limits on the ethical options of physicians, as in the case of violating physician-patient confidentiality or the prescription of regulated medication. Public health and safety concerns may also necessitate breaches in confidentiality and as well as preventative measures to ensure public well being. If such dilemmas occur, consultation with a regulatory expert or ethicist is recommended.

3) Are there parties other than clinicians and patients who have an interest in clinical decisions?

Other parties include the patient's family, hospital and managed care administrations, public health authorities, third-party payers, employers, police officers, lawyers etc. The legitimacy of such claims raises various ethical issues for the physician that may impede the delivery of care, and have clear legal ramifications. For these reasons, any professional or business relationship with a close relative, as defined above, should be approached with extreme caution.

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Senior Abstract

Optimal Differentiation of Tissue Types Using Combined Mid and Near Infrared Spectroscopy

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Introduction: Despite the number of anterior cruciate ligament reconstructions performed every year, the process of ligamentization, transformation of a tendon graft to a healthy functional ligament is poorly understood. Fourier transform infrared (FT-IR) spectroscopy is a technique sensitive to molecular structure and composition changes in tissues. FT-IR fiber optic probes combined with arthroscopy could prove to be an important tool where nondestructive tissue assessment is required, such as assessment of graft composition during the ligamentization process. The mid-IR spectral absorbances from connective tissues are well understood, but mid-IR radiation has limited penetration, through only ~10 microns of the tissue. In contrast, near infrared (NIR) has deeper penetration depth (mm to cm), but the spectral absorbances are much weaker and not as well understood. Combining these two spectral regions may provide valuable information about the sample composition. Previous studies in the food industry have shown that combining NIR and MIR spectroscopy resulted in optimal differentiation of composition. Mid-IR fiber optic probes have previously been used to differentiate between normal and pathologic connective tissues, and a recent study by our group has shown that the fiber optic probe spectral parameters correlate with cartilage histological grading. NIR fiber optic probes have been used during arthroscopy to evaluate the degree of degeneration of cartilage. The aim of this study was to combine and compare the use of MIR and NIR to differentiate regions within the ACL, and to differentiate ACL versus patellar tendon, as a preliminary study towards better understanding the ligamentization process *in vivo*. We hypothesize that the combination of NIR and MIR spectra will result in better differentiation compared to NIR or MIR spectroscopy alone.

Methods: Bovine ACLs (n = 3) and patellar tendons (n = 3) were dissected from freshly slaughtered 2–14 days old calves (Green Village, NJ). NIR spectra were collected in diffuse reflectance mode using a 3 mm diameter NIR fiber optic probe (Art Photonics, Berlin, Germany) coupled to a Matrix-F infrared spectrometer (Bruker, MA). Spectra were collected from two points at the midsubstance, the femoral and tibial insertion sites of each ACL and patellar tendon (4000 to 11,000 cm^{-1} at 32 cm^{-1} spectral resolution with 128 co-added scans). At each data point three spectra were collected thus resulted in a total of 72 spectra. MIR spectra were collected from the same location as NIR data using a Thermo Scientific Nicolet iS5 FT-IR spectrometer fitted with a fiber optic coupler (Harrick Scientific Products, Inc., Pleasantville, New York) and a silver halide attenuated total reflectance (ATR)-loop mid-infrared fiber optic probe (Art Photonics, Berlin, Germany) at 8 cm^{-1} spectral resolution, with 32 co-added scans in the frequency range of 600-2000 cm^{-1}.

Data Processing: The spectra were processed using Unscrambler 10.1 (CAMO, NJ). The spectra were pretreated with a multiplicative scatter correction (MSC) followed by second derivative (savitzky golay, 3rd polynomial order, 11 point smoothing for MIR and 21 point smoothing for NIR data). A concatenated matrix was formed with NIR and MIR spectra where rows were comprised of NIR and MIR spectral absorbances from same sample as well as same location. MIR and NIR spectra were pretreated separately. Combined spectra were normalized by the standard deviation at each wavelength in the entire spectral collection. Separate partial least square discriminant analysis (PLS-DA) models with random cross validation were performed to differentiate ACL versus patellar tendon (11 segment with six samples) and insertion site versus midsubstance within the ACL (seven segments and four samples) using NIR spectra, MIR spectra and NIR and MIR combined together.

Results and Discussion: MIR spectra from ACL and patellar tendon were dominated by collagen peaks at 1650 (amide I), 1550 (amide II), 1338 (side chains) and 1240 cm^{-1} (amide III) which result from vibrations of the peptide bonds (also present to lesser amounts in proteoglycans, (PG)), and by PG sugar ring vibrations, 985–1140 cm^{-1}. NIR spectra of ACL and patellar tendon were dominated by water peaks at 5200 cm^{-1} and 6890 cm^{-1}. To discriminate ACL and tendon, the best PLS-DA classification was based on MIR spectra alone, which resulted in 97.2% accurate classification. However, to discriminate insertion sites and midsubstance regions within the ACL tissue, PLS-DA based on combined use of NIR and MIR resulted in the best classification (87.1%).

Discussion: The loadings (which reflect the spectral features that contribute to the model) for the MIR spectra PLS-DA model of ACL versus patellar tendon classification were dominated by the amide II absorbance at ~1550 cm^{-1}, likely reflecting differences in collagen and PG content in these two tissues at the surface. Ligament is a heterogeneous tissue, and its matrix composition varies throughout the length and depth. MIR alone did not perform well to classify different regions of ACL, likely due to the limited penetration of the MIR radiation which could not fully interrogate the ACL structure. However, addition of the NIR spectral region resulted in better discrimination between insertion sites and midsubstance within the ACL tissue. The loadings for PLS-DA model based on combined MIR and NIR spectral regions were dominated by water peaks at ~5200 cm^{-1} and 7000 cm^{-1}, and by matrix peaks at 1079 cm^{-1}, 1250 cm^{-1}, 1643 cm^{-1}, 4300 cm^{-1} and 4700 cm^{-1}. It should be noted that both spectral regions contributed towards differentiation of ACL regions, with the dominant frequencies arising from both water and matrix components.

Significance: The combination of NIR and MIR spectral regions could lead towards better understanding of healing of various orthopedic tissues, and effect of therapeutics and treatment modalities.

Senior Abstract

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Vascular Complications in Total Knee Arthroplasty: A Newly Recognized Complication and Lessons from Our Practice

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Introduction

Vascular injuries are a rare but potentially devastating complication of total knee arthroplasty (TKA). We report our vascular injuries from a high volume community-based practice, including a previously unreported type of injury in the orthopaedic literature.

Methods

We retrospectively reviewed morbidity and mortality data and associated records at our institution over a 12-year period from 2001 through 2012. We included all primary TKAs performed by 10 orthopedic surgeons (three accounted for over 80% of cases). The majority of these TKAs were performed using a minimally invasive approach.

Results

Over this period, seven vascular injuries were identified out of 5,166 TKAs (0.14%); three acute vascular injuries (laceration/puncture, 0.06%), two popliteal thromboses (0.04%) and one popliteal pseudoaneurym (0.02%). We also had a case of an arterial thromboembolic event secondary to discontinuation of anticoagulation in a patient with atrial fibrillation, a previously unreported event in orthopaedic literature. A minimally invasive approach was not associated with an increased risk of vascular complications. There were no amputations or mortalities due to these injuries in our group.

Conclusion

Vascular injury is a rare complication with a rate of 0.14% in our population. Although acute laceration/puncture was the most common injury seen in our patients, arterial thrombosis after discontinuation of anticoagulation is a potential complication of which the orthopaedic surgeon should also be aware. Early awareness and recognition is the key to avoiding long-term sequelae.

Senior Abstract

Effects of Shear Loading on Repaired and Unrepaired Longitudinal Vertical Meniscal Tears

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Introduction: Effects of shear loading on menisci on intact, *ex vivo* bovine knees is poorly understood. Many prior biomechanical studies have loaded excised, repaired menisci in tension and three studies have loaded excised menisci in shear. These studies hypothesized that shear force plays a more important role in stressing meniscal tear repairs. This study endeavored to describe the impact of shear loading on various commercially available meniscal repair systems on in situ menisci.

Methods: Four cm long longitudinal vertical tears were created in the posterior horn of the medial meniscus in 32 adult, fresh frozen, hind bovine knees. This group was subdivided into control (no repair), inside-out repair with a vertical mattress technique using No. 2 FiberWire, all-inside technique using No. 0 Orthocord with two PEEK anchors, and an all inside technique using No. 0 braided polyester suture with two flexible anchors (poly levo lactic acid or poly-acetal). The four groups of eight specimens were tested on an MTS Landmark 370.10 servo-hydraulic test system fitted with an Interface model 5200 multi axis load cell which enabled measurements of thrust and two separate moments. Each specimen underwent four rounds of 2,500 cycles at 2 Hz for a total of 10,000 cycles. In addition to data recorded by the multi-axis load cell, the cross-head displacement and total applied load were measured using machine transducers built in to the MTS. The machine design was capable of generating measurable shear loading on each sample. Primary outcomes measured between groups included stiffness, magnitude of shear stress, subsidence, amount of wear on repair device and amount of wear on menisci and the chondral surface. Statistical analysis was performed with JMP 8.0.1 software with two sided $p < 0.05$. An ANOVA test was used to compare the four study groups. A matched paired t-test was used to test for significant changes in mechanical characteristics between rounds of testing. A students t-test was used to compare the mechanical characteristics between groups of similarly scored repair devices and meniscal tissue samples.

Results: No statistically significant differences in geometric measurements (femoral length $p = 0.31$, tibial length $p = 0.41$, total length $p = 0.09$, flexion angle $p = 0.08$, max. valgus angle 0.75, area $p = 0.2$), compressive stress ($p = 0.77$, 0.63, 0.78, 0.86 respectively), subsidence ($p = 0.57$, 0.36, 0.36, 0.47 respectively), stiffness ($p = 0.11$, 0.43, 0.3, 0.22), or calculated shear force ($p = 0.09$, 0.09, 0.24, 0.62) were found between the four study groups (unrepaired, No. 0 Braided polyester suture, No. 0 Orthocord, Vertical Mattress). In the vertical mattress group, two samples demonstrated minimal knot slippage and only one of those two showed some mild meniscal fraying around the repair. In the same group, another sample with no measurable repair device failure demonstrated mild meniscal fraying around the repair. In the Orthocord with two PEEK anchor group, two samples had some minimal knot slippage and two other specimens had some mold meniscal fraying around the repair. In the braided polyestetr suture with two flexible anchor group, three samples demonstrated minimal knot slippage and one other sample showed mild meniscal fraying. The unrepaired group had four samples with significant fraying and lengthening of the tear and four other samples had significant chondral wear on the articular surfaces. The unrepaired group demonstrated significant differences in the compressive stress between samples exhibiting significant meniscal fraying and also those exhibiting condral wear ($p = 0.012$, 0.005, 0.036, 0.004) at each time point and significant difference in the magnitude of shear force at the same time points ($p = 0.035$).

Discussion: This is the first study to examine the effects of shear loading and fatigue on various repair techniques of vertical longitudinal meniscal tears in intact adult bovine knees. The study results support the efficacy of the machine design capable of simulating *in vivo* shear loading of menisci in intact bovine knees. The three repair groups demonstrated no statistically significant differences in any of the primary outcome measures. The statistically significant differences between repaired and unrepaired samples supports the importance of restoring normal anatomy after sustaining a meniscal tear.

Senior Abstract

Senior Bio Questionnaire

- Full Name: Samuel P. Popinchalk
- Birthdate: 12/19/1978
- Hometown: West Hartford, CT
- Undergraduate School: Worcester Polytechnic Institute
- Undergraduate Degree: BS Biotechnology
- Medical School: Tulane University School of Medicine
- Fellowship: Spine, University of Miami — Jackson Memorial Hospital
- Significant Other: Celine McGee — For all your support, my gratitude is immeasurable
- Children: None
- Hobbies: Golf, Reading
- Favorite Sports Team: New England Patriots
- Desired Practice Location: Philadelphia, PA
- Catch Phrase/Motto/Favorite Expression/Advice: Thoder's Five Fingers of life: 1. Work hard, play hard, 2. Don't ask someone to do something you won't, 3. Eat when you can, 4. Learn something new every day, 5. There are three sides to every story

Is Chemical Incompatibility Responsible for Chondrocyte Death Induced by Local Anesthetics?

M.T. Bogatch, D.G. Ferachi, B. Kyle, S. Popinchalk, M.H. Howell, D. Ge, Z. You, F.H. Savoie

Temple University Hospital, Department of Orthopaedics, Philadelphia, PA

Background

Chondrolysis associated with intra-articular administration of local anesthetics has been attributed to chondrocyte death induced by the local anesthetics. The mechanism of how the local anesthetics cause chondrocyte death is not clear.

Purpose

This study was conducted to determine whether and how the local anesthetics cause chondrocyte death.

Methods

Bovine articular chondrocytes in suspension culture were treated for one hour with phosphate-buffered saline or phosphate-buffered saline/medium mixture (as controls); 1% lidocaine alone; 0.25% to 0.5% bupivacaine alone; phosphate-buffered saline with pH values of 4.5, 3.8, 3.4, and 2.4; or mixtures of the local anesthetics and cell culture medium or human synovial fluid. Chondrocyte viability was analyzed by flow cytometry using the LIVE/DEAD Viability/Cytotoxicity Kit.

Results

In 1% lidocaine-alone or 0.25% to 0.5% bupivacaine-alone groups, the rate of cell death was 11.8% to 13.3% of bovine articular chondrocytes, whereas the phosphate-buffered saline control had 8.4% of cell death. Increased chondrocyte death was only found when the pH value of phosphate-buffered saline dropped to ≤3.4. In contrast, when bupivacaine was mixed with cell culture medium, needle-like crystals were formed, which was accompanied with 100% death of chondrocytes. Lidocaine did not form visible crystals when it was mixed with culture medium, but the mixtures caused death of over 96% of chondrocytes ($P < .001$).

Conclusion

Less than 5% of chondrocyte death was attributable to the anesthetics when applied to the cells alone or in phosphate-buffered saline-diluted solution. Acidity (as low as pH 3.8) or epinephrine in the anesthetic solutions could not account for chondrocyte death. However, chemical incompatibility between the local anesthetics and cell culture medium or human synovial fluid may be the cause of chondrocyte death.

Clinical Relevance

Intra-articular administration of lidocaine and bupivacaine is not an indicated usage of either anesthetic, although such a usage has become a common practice. Physicians should be aware of the potential incompatibility of the drug and synovial fluid.

Special Event

Touching Hands Project and the American Society for Surgery of the Hand (ASSH)

As the current President of the ASSH, Philadelphia Shiners Chief of Staff, Dr. Scott Kozin, has made it his goal for the Hand Society to become more involved in international outreach. Below is an excerpt from his mission statement and a link to the website for those interested in contributing their time or financial support. Personally, I have seen Dr. Kozin's presentation for the Touching Hands Project at both the ASSH and the AAHS meetings this year and felt particularly moved by his mission. Take a second to check out the mission and spread the word!

Rick Tosti, MD

http://www.assh.org/Professionals/AboutASSH/OurFoundation/AFSHFundedPrograms/Pages/Touching-Hands-Project.aspx

THE TOUCHING HANDS PROJECT

The mission of the American Foundation for Surgery of the Hand is to advance the care of hand and upper extremity disorders by supporting education, research and outreach through the efficient collection of donations and administration of grants.

The Touching Hands Project (THP) was initiated in 2013 as part of the American Foundation for Surgery of the Hand (AFSH) with the goal of extending the mission into outreach to contribute to the healthcare of underserved populations. In addition, adding outreach is a tangible way to engage ASSH members, providing an avenue for donations of both financial support and service.

The medical advisory board (MAB) and ASSH council has decided that the initial endeavor of THP requires collaboration with an established and experienced organization devoted to outreach. The American Society for Surgery of the Hand (ASSH) would provide the hand surgery resource and the established organization would provide the infrastructure and the "boots on the ground" to ensure safety and success for our members.

The MAB explored numerous potential organizations for collaboration. The field was narrowed to the Adventist Hospital and Partners in Health (PIH) in Haiti. Other future collaboration includes Guatemala Healing Hands (GHH) and Cure International. All of these organizations were enthusiastic about collaboration with the ASSH.

The MAB decided that the inaugural collaboration would be with Adventist Hospital in Haiti. The goal is to have the first mission in May 2014. Adventist Hospital is uniquely positioned for collaboration with ASSH and hand surgery. The hospital has an ongoing relationship with the Foundation for Orthopedic Trauma (a subsidiary of Orthopedic Trauma Association devoted to outreach). The hospital provides ample infrastructure and volumes of patients that need hand and upper extremity treatment. In addition, Christophe Mackenson serves as the volunteer coordinator and Francel Alexis, MD is the Chief of Orthopedics, both dedicated to improving the care of Haitians.

To accomplish this task, the THP is seeking financial support from ASSH members and corporate partners. The goal is to increase the outreach corpus, such that the monies to support THP will be generated by interest on the monies raised. The goal is to make the outreach portion of the THP self-sufficient.

We hope you consider this request in the spirit of outreach, a noble goal for the ASSH. This initiative represents an objective that would increase our impact around the world and within the global hand community. THP represents a potential legacy that would propel the ASSH into the future.

Scott H. Kozin, MD; Peter Weiss, MD; Jennifer Wolf, MD

Special Event

The Formation of the Temple Hand Society

On a dark and cool Thursday evening in the Alamo Square district of San Francisco, California, Temple Ortho Alumni Abtin Foroohar and Asif Ilyas were meeting to conjure the next great society of orthopaedic surgeons: The Temple Hand Society. Their mission: to encourage an annual get-together on the Thursday night of the American Society for Surgery of the Hand (ASSH) meeting.

As the first acting President, Abi Foroohar invited all Temple alumni who perform surgery on the hand to begin a new tradition of dinner, drinks, and good company to be had wherever the ASSH meeting takes place. Dr. Foroohar, elected to a three-year term as President, said "traditionally, surgeons will meet for a fellowship alumni reception on the Friday night of the meeting; it would be nice to stay in touch and discuss cases, meet at the annual ASSH meeting, and generally socialize." Member-at-large, Asif Ilyas, noted that "there are a growing number of hand surgeons who are also Temple Ortho alumni." The goals going forward are to expand the club into a list-serve that is available for networking and discussion of difficult cases.

The first meeting of the Temple Hand Society was a smashing success. The inaugural group hailed Temple hand surgeons from both the East and West coasts (see photo below). "Next year, we hope to expand, find more of our long lost alumni, and continue to have a great Thursday night!" said President Foroohar.

For more information about the Temple Hand Society, email Abi Foroohar at: aforoohar@gmail.com.

For more information on the ASSH Meeting 2014 in Boston, visit: http://asshannualmeeting.org/.

Rick Tosti, MD

Inaugural members: *(Front Row)* Allen Tham (and Mrs. Tham), Abi Foroohar, Wade Andrews, Irfan Ahmed, Brian George, John Fowler, Alyssa Schaffer, Asif Ilyas; *(Back Row)* Kate Criner and Rick Tosti

Special Event

The Howard H. Steel Lecture at the Philadelphia Orthopaedic Society

Presented by:

DR. ALVIN H. CRAWFORD
Professor Emeritus, University of Cincinnati

"Pediatric Orthopaedics — My Journey"

This last year saw another fantastic installment of the annual Howard H. Steel Pediatric Lecture. After a fitting introduction by Program Chair Dr. Lawrence Wells, Dr. Alvin Crawford recounted his unique and storied experiences through both his and the field of pediatric orthopedics, past to present. In the end, he offered humbling advice to all of the residents in attendance in pursuing a path to becoming a greater physician, surgeon, and caregiver while keeping the importance of family and friends close to heart. The Howard Steel Pediatric Lecture ended with a rousing round of applause and ovation for both the guest speaker and the great man for which the lecture was named.

Colin Mansfield

Temple residents and Dr. Steel enjoying post-lecture discussions: *(l-r)* Drs. Colin Mansfield, Rich Han, Howard Steel, James Bennett, Emeka Nwodim and Anastassia Persidsky

Special Event

A Summary of this Year's National Hand Meetings

American Society for Surgery of the Hand Meeting
October 2013 — San Francisco, California

American Association for Hand Surgery Meeting
January 2014 — Kauai, Hawaii

Temple had some great success at the two major hand surgery meetings this academic year. The American Society for Surgery of the Hand (ASSH) met in San Francisco this past October under the theme "Education Through Technology." The meeting highlighted several cutting edge techniques, instructional course lectures, and new technologies that are entering our field. Additionally, the symbolic torch was passed to Dr. Scott Kozin, of Shriners Hospital in Philadelphia, who was recently elected President for 2014. Dr. Kozin showcased his vision for the Hand Society during his presentation for the "Touching Hands Project," which is a new outreach program to improve health care and hand deformities in underserved regions such as Haiti.

Temple had a unique opportunity to shine, as Rick Tosti and Asif Ilyas won the Julian M. Bruner award for "Best Poster" entitled "Prospective Evaluation of Pronator Quadratus Repair Following Volar Plating of Distal Radius Fractures." The award came with a special display at the meeting, a monetary award, and a plaque. The ASSH also intends to share our poster at their exhibit at the 2014 American Academy of Orthopaedic Surgeons and the 2014 Orthopaedic Research Society Meetings in New Orleans, LA.

Temple also made its presence known at the American Association for Hand Surgery Meeting in Kauai, Hawaii. Rick Tosti and Temple Alumni John Fowler, Kris Matullo, and Asif Ilyas all took the podium for primary research presentations. Rick Tosti and Alyssa Schaffer had two poster presentations entitled "Prospective Evaluation of Vitamin D Levels in Young Adults With and Without Distal Radius Fractures" and "Emerging Multi-drug Resistance in MRSA Hand Infections."

Rick Tosti

Rick Tosti and Asif Ilyas at the American Association for Hand Surgery in Hawaii

Special Event

Resident Research Day

April 27, 2013

Presented in conjunction with Grand Rounds speaker

DR. VOLKER MUSAHL
Associate Professor, Orthopaedic Surgery Division of Sports Medicine, University of Pittsburgh

"How to Improve Outcome After ACL Reconstruction"

Once again, we had a successful and well-attended Resident Research Day. This year was prefaced with a Grand Rounds talk by Dr. Musahl and his work using motion tracking technology to follow ACL reconstruction outcomes. A lively discussion followed, rounded out by the presentations of a variety of this year's Temple resident research projects. An impressive amount of time, energy and commitment was evident throughout the morning after hearing the talks, for which the department can be proud. A brief intermission was allowed while the judging took place, and congratulations to all of those who participated were espoused.

The following is a list of our top three winners. Special recognition was also given to them at the Alumni Day Banquet, where again they were able to show their research pursuits to our many alumni in attendance.

1. Kate Criner:
   "Impact of statins on postoperative venous thromboembolic events following total knee and hip replacements"
2. Scott Barbash:
   "Near infrared spectroscopy differentiates tendon and ligament composition"
3. Justin Iorio:
   "Does Amicar affect blood loss in patients with adolescent idiopathic scoliosis treated with pedicle screws and Ponte osteotomies?"

Colin Mansfield

Special Event

Temple-Shriners Alumni Day

On a rainy Friday this past May 2013, the Temple University Hospital Department of Orthopaedics and Sports Medicine held its annual Temple-Shriners Alumni meeting at the Lulu Country Club. Although a little soggy, the day brought with it warm weather, great golf and a long line of Temple's best and brightest.

The event began with lectures given by distinguished Temple alumni. Topics included "Traumatic Instability of the Elbow" by Rob Kaufmann, MD, "Motion Preservation Options for Spondylolysis" by Paul Lin, MD and "Arthritis of the Ankle" by Chris Kestner, MD. These talks were followed by a point-counter point debate on the "Current Concepts in Surgical Treatment of Distal Radius Fractures" by Drs. Rob Kaufmann and his fellow (and Temple alumnus) at the University of Pittsburgh, John Fowler.

Next, the recipients of the Resident Research Award — Kate Criner (1st place), Scott Barbash (2nd place) and Justin Iorio (3rd place) — had the honor of re-presenting their works from Research Day.

The legendary Donald Ross designed golf course served as the perfect backdrop for several alumni and resident foursomes. These surgeons-turned-golfers competed for awards but mainly rekindled friendships beyond the walls of the operating room.

Arianna Trionfo

Special Event

Temple Ortho Tough Mudder

June 1, 2013
Jaindl Farms, Rural PA

A moment of inspiration came upon the Temple Orthopedics Department, an idea hatched in the depths of wintery flurries and pounding nor'easters: to sign up a team for the grueling and infamous Tough Mudder Run. A 10-mile bone and muscle crunching trek over, under and through a series of herculean obstacles made from mud, water, fire and glacier ice pits, and did I mention mud? If that wasn't enough to test the soul, several obstacles such as the one pictured above included electrical wires through which to navigate. The Temple Tough Mudder team met this challenge with vigor, and over a course of several months, trained for this event with the same tenacious and hard-working mentality that comes with being in the Temple Orthopedics family. Often in late night or early morning hours, each member sacrificed to prepare for this event, and it showed through the sweltering 80 degree day. And at the finish line, our team of eight made it through as one. When someone fell, there was a hand to pick them up. Whatever the trail had thrown at us, it was accomplished as a group. Staying true to 'Temple Tough,' we elected to finish the race as a linked unit: one-for-all through the live wires, and involuntary releases notwithstanding, we finished the day together as we started and for which we should be proud — as the Temple Orthopedics Team.

Colin Mansfield

Left to right: Drs. Sam Popinchalk, Matt Kleiner, Dustin Greenhill, Rupam Das, Colin Mansfield, J. Milo Sewards, Rick Tosti and Chris Haydel

Special Event

Fives Dominate Fours and Threes Earning Ponderosa Bowl Title 70-42

December 22, 2013

Sunday, December 22, 2014 marked the third annual Ponderosa Bowl. Formerly known as the "Shrine Bowl," this year marked another major improvement to the annual football tradition — the game was played on a Sunday.

Despite a sub-optimal turnout, this three-on-three matchup was high paced and high scoring. The Red Team was comprised of Sam Popinchalk, MD, Emeka Nwodim, MD, and Rich Han, MD from the fifth-year resident class. The White Team consisted of Rick Tosti, MD from the fourth-year class, and Rupam Das, MD and Colin Mansfield, MD from the third-year class. Chris Haydel, MD represented the attendings with an outstanding all-time-offensive performance. Dr. Thoder provided another impeccable performance as head referee.

The Fives wasted no time scoring on their first drive. In fact, they wasted no time and continued to score on every subsequent drive. Fans were overheard saying "they look like men amongst boys," and "a Ponderosa Bowl Hall of Fame should be created to remember this team," and "who knew that Sam would have such a deadly accurate cannon for an arm?" and "I think Rupam has thrown as many pick-sixes as Sam has thrown touchdown passes," and "Is that Colin coming in an hour late and why is he wearing a horse-head mask?"

The MVP award for this game was unanimous — Chris "Megatron" Haydel, MD. Chris was the prime target for quarterbacks on both sides in his all time-offensive standout performance. He ran more routes than anyone that day, demonstrating an athletic and cardiovascular capability that, quite frankly, surprised us all. Honorable mention goes to Rick Tosti, MD. Except for all of the plays that Emeka got by him for touchdowns, Rick was a "shut-down corner." Overall, it was a hard fought competition with moments of brilliance from all participants.

Fortunately, there were no injuries to report. Few escape ventures that far outside of their envelope of activity unscathed. I personally scheduled an anticipatory Achilles tendon repair with Dr. Eremus for the Monday following the game. I cancelled my surgery and my workers compensation claim.

As the game ended, the Red Zone began in the recently renovated basement of the Ponderosa. As we all know so well, Dr. Thoder knows how to throw a party. All enjoyed food, beer, cigars, NFL football, darts, pool, and an all around great time. Sunday game day will be a lasting part of the tradition.

Sam Popinchalk, MD

Departmental News

Faculty

Temple University Department of Orthopaedic Surgery and Sports Medicine

Chairman

Joseph Thoder, MD, *The John W. Lachman Professor*

Professors

William DeLong, MD
Pekka Mooar, MD
Ray Moyer, MD, *The Howard H. Steel Professor*
Joseph Torg, MD
F. Todd Wetzel, MD, *Vice Chairman*

Associate Professors

Easwaran Balasubramanian, MD
Saqib Rehman, MD
Bruce Vanett, MD
Albert Weiss, MD

Assistant Professors

Joseph Eremus, MD
Christopher Haydel, MD
Eric Kropf, MD
Matthew Lorei, MD
Stanley Michael, MD
Alyssa Schaffer, MD
J. Milo Sewards, MD

Adjunct Faculty — Philadelphia Shriners Hospital

Scott Kozin, MD, *Chief of Staff*
Randal Betz, MD, *Emeritus Chief of Staff*
Philip Alburger, MD
Patrick Cahill, MD
Richard Davidson, MD
Corinna Franklin, MD
Howard Steel, MD, *Emeritus Chief of Staff*
Joshua Pahys, MD
Amer Samdani, MD
William Schrantz, MD
Harold van Bosse, MD
Daniel Zlotolow, MD

Adjunct Faculty — Abington Memorial Hospital

Andrew Star, MD, *Chief of Orthopaedics*
Shyam Brahmabhatt, MD
David Craft, MD
Matthew Craig, MD
Greg Galant, MD
Michael Gratch, MD
Victor Hsu, MD
Moody Kwok, MD
Guy Lee, MD
Thomas Peff, MD
T. Robert Takei, MD
Jeffrey Vakil, MD

Adjunct Faculty — St. Christopher's Hospital for Children

Peter Pizzutillo, MD, *Chief of Orthopaedics*
Kiersten Arthur, MD
Alison Gattuso, DO
Martin Herman, MD
Michael Kwon, MD
Juan Realyvasquez, MD
Joseph Rosenblatt, DO
Shannon Safier, MD
Michael Wolf, MD

Temple University Hospital
Department of Orthopaedic Surgery and Sports Medicine
Faculty 2013–2014

Joseph Thoder, MD
John W. Lachman Professor
Chairman
Hand & Upper Extremity
General Orthopaedics

J. Milo Sewards, MD
Sports Medicine

Easwaran Balasubramanian, MD
Joint Reconstruction
General Orthopaedics

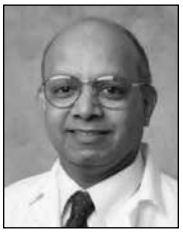
Joseph Eremus, MD
Foot and Ankle
General Orthopaedics

Christopher Haydel, MD
Orthopaedic Trauma
General Orthopaedics

Cory Keller, DO
Sports Medicine

Eric Kropf, MD
Sports Medicine
General Orthopaedics

Matthew Lorei, MD
Joint Reconstruction
General Orthopaedics



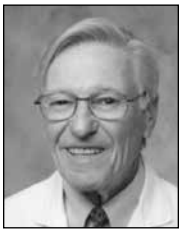
Stanley Michael, MD
Sports Medicine
Joint Reconstruction
General Orthopaedics

Pekka Mooar, MD
Sports Medicine
Joint Reconstruction
General Orthopaedics

Ray Moyer, MD
Howard Steel Professor
Sports Medicine

Saqib Rehman, MD
Orthopaedic Trauma
General Orthopaedics

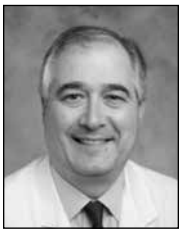
Alyssa Schaffer, MD
Hand Surgery



Joseph Torg, MD
Sports Medicine

Bruce Vanett, MD
General Orthopaedics

Albert Weiss, MD
Hand & Upper Extremity
General Orthopaedics



F. Todd Wetzel, MD
Vice-Chairman
Spine Surgery

Orthopaedic Surgery
& Sports Medicine
Temple University Health System

Temple University Hospital
Department of Orthopaedic Surgery and Sports Medicine
House Staff 2013–2014

Scott Barbash, MD
PGY-5

Richard Han, MD
PGY-5

Emeka Nwodim, MD
PGY-5

Samuel Popinchalk, MD
PGY-5

Stephen Refsland, MD
PGY-4

Craig Steiner, MD
PGY-4

Rick Tosti, MD
PGY-4

Justin Iorio, MD
PGY-4

Rupam Das, MD
PGY-3

Colin Mansfield, MD
PGY-3

Kaziemierz Komparda, MD
PGY-3

Mark Solarz, MD
PGY-3

Dustin Greenhill, MD
PGY-2

James Lachman, MD
PGY-2

Anastassia Persidsky, MD
PGY-2

Ariana Trionfo, MD
PGY-2

James Bennett, MD
PGY-1

Katharine Harper, MD
PGY-1

John Jennings, MD
PGY-1

William Smith, MD
PGY-1

Temple University Department of Orthopaedic Surgery and Sports Medicine: Research Update 2013–2014

Awards

"Highlighted Poster" for Hand and Wrist Guided Poster Tours at the American Academy of Orthopaedic Surgeons Annual Meeting 2014. Tosti R, Samuelsen B, Bender S, Gaughan J, Schaffer AA, Ilyas AM. Emerging multi-drug resistance of methicillin resistant staphylococcus aureus in hand infections.

"Julian M. Bruner Award for Best Poster of the ASSH" at the American Society for Surgery of the Hand Annual Meeting 2013. Tosti R, Ilyas AM. Prospective evaluation of pronator quadratus repair following volar plate fixation of distal radius fractures

"Best Poster" for Hand and Wrist section of American Academy of Orthopaedic Surgeons Annual Meeting 2013. Fowler JR, Maltenfort M, Ilyas AM. Ultrasound as a First Line Test in the Diagnosis of Carpal Tunnel Syndrome: A Cost-effectiveness analysis.

Podium Presentations

Tosti R, Samuelsen B, Bender S, Gaughan J, Schaffer AA, Ilyas AM. Emerging multi-drug resistance of methicillin resistant staphylococcus aureus in hand infections. Alternate paper presentation at *American Academy of Orthopaedic Surgeons Annual Meeting,* New Orleans, LA, March 2014

Tosti R, Ilyas AM. Prospective evaluation of pronator quadratus repair following volar plate fixation of distal radius fractures. Presented at the *American Association for Hand Surgery Annual Meeting,* Kauai, HI, January 2014.

Tosti R. Do povodone-iodine soaks reduce the number of operations needed to treat hand infections? Presented at the *American Association for Hand Surgery Annual Meeting,* Naples, FL, January 2013.

Dakwar E, Bennett JT, Samdani AF. Case Presentation: Treatment of Spinal Deformity and Diastematomyelia with Vertebral Column Resection. *48th Annual Scoliosis Research Society Meeting,* Lyon, France, September 18–21, 2013.

Singla A, Samdani AF, Flynn J, Bennett JT, Miyanji F, Pahys J, Marks M, Lonner B, Netwon P, Cahill P, Betz RR. What is Different About Surgically Treated AIS Patients Who Achieve a Minimal Clinically Important Difference (MCID) in Appearance at 5 Years Post Surgery? *48th Annual Scoliosis Research Society Meeting,* Lyon, France, September 18–21, 2013.

Singla A. Samdani AF. Sponseller P. Bennett JT, Pahys J, Marks M, Lonner B, Newton PO, Miyanji F, Betz RR, Cahill P. Selective Thoracic vs. Non-Selective Fusion in Lenke 3 Curves. *SRS 20th International Meeting on Advanced Spine Techniques,* Vancouver, British Columbia, July 10–13, 2013.

Feuer G, Bennett JT, Saha S, Mijares D. Shear Properties of Cancellous Bone from Osteoporotic Sheep Treated with Synthetic Bone Mineral. *39th Annual Northeast Bioengineering Conference,* Syracuse, NY, April 5–7, 2013:

Bennett JT, Samdani AF, Hoashi JS, Ames RJ, Kimball JS, Pahys JM. The Posterior Pedicle Screw Construct: 5 year results for thoracolumbar and lumbar curves. *AANS/CNS Disorders of the Spine and Peripheral Nerves 29th Annual Meeting,* Phoenix, AZ, March 6–9, 2013.

Bennett JT, Samdani AF, Belin E, Pahys J, Shah SA, Newton PO, Betz RR, Sponseller PD. Major Perioperative Complications after Surgery for Cerebral Palsy: Assessment of risk factors. *AANS/CNS Disorders of the Spine and Peripheral Nerves 29th Annual Meeting,* Phoenix, AZ, March 6–9, 2013.

Bennett JT, Samdani AF, Belin E, Pahys JM, Marks M, Miyanji F, Cahill P, Shufflebarger H, Lonner B, Newton PO, Betz RR. Unplanned Return to the Operating Room in Patients with AIS: Are we doing better with pedicle screws? *AANS/CNS Disorders of the Spine and Peripheral Nerves 29th Annual Meeting,* Phoenix, AZ, March 6–9, 2013.

Bennett JT, Ames RJ, Samdani AF, Garg H, Cahill PJ, Miyanji F, Lonner B, Marks MC, Betz RR, Newton PO. 5 Year Results for Lenke 1 and 2 Curves: Comparison of anterior, posterior hybrid, and posterior all pedicle screws. *AANS/CNS Disorders of the Spine and Peripheral Nerves 29th Annual Meeting,* Phoenix, AZ, March 6–9, 2013.

Poster Presentations

Tosti R, Samuelsen B, Bender S, Gaughan J, Schaffer AA, Ilyas AM. Emerging multi-drug resistance of methicillin resistant staphylococcus aureus in hand infections. *American Academy of Orthopaedic Surgeons Annual Meeting,* New Orleans, LA, March 2014.

Star A, Han R. Vascular Complications in Total Knee Arthroplasty: A Newly Recognized Complication and Lessons from our Practice. *American Academy of Orthopaedic Surgeons Annual Meeting,* New Orleans, LA, March 2014.

Criner K, Trionfo A. Impact of Statins on Postoperative Venous Thromboembolic Events Following Total Knee and Hip Replacements. *American Academy of Orthopaedic Surgeons Annual Meeting,* New Orleans, LA, March 2014.

Tosti R, Ilyas AM. Prospective evaluation of pronator quadratus repair following volar plate fixation of distal radius fractures. American Society for Surgery of the Hand: Julian M. Bruner Award Exhibit at the *American Academy of Orthopaedic Surgeons Annual Meeting,* New Orleans, LA, March 2014.

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Fowler JR, Maltenfort M, Ilyas AM. Ultrasound as a First Line Test in the Diagnosis of Carpal Tunnel Syndrome: A Cost-effectiveness analysis. *AAOS Annual Meeting,* Chicago, IL, March 19–23, 2013. (First place poster).

Padlakar M, McGoverin C, Barbash S, Kropf EJ, Pleshko N. Differentiation of ligament and tendon with near infrared spectroscopy. *ORS Annual Meeting,* San Antonio, Texas, January 26–29, 2013 (poster).

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Editorial Articles and Popular Media

Tosti R. "Will the new milestone requirements improve residency training?" *American Journal of Orthopedics.* December 2013.

Tosti R, Thoder JJ. "Intrinsic Contracture of the Hand." The Doctors Show. Sirius XM Satellite Radio. November 2013.

Grand Rounds 2013–2014

Wednesday, August 21, 2013
- 7:00–7:45 Pain Management in Orthopaedics — Gary Trehan, MD
- 7:55–8:15 Postoperative Disposition of the Opioid Dependent Patient — Samuel Popinchalk

Saturday, September 14, 2013
- 8:00–8:45 Current Concepts in ACL Injuries — Shyam Brahmabhatt
- 8:55–9:15 Evolution of Tommy John Surgery — Rick Tosti

Wednesday, September 25, 2013
- 7:00–7:45 Historical and Practical Notions About Osteomyelitis — Peter Axelrod
- 7:55–8:15 Local Antibiotic Treatment of Bone and Joint Infections: Current Evidence — Richard Han

Wednesday, October 16, 2013
- 7:00–7:45 The Subscapularis: Keystone of the Shoulder or Red-Headed Stepchild? — J. Milo Sewards
- 7:55–8:15 Long Head of the Biceps Tendon Pathology — Justin Iorio

Saturday, November 2, 2013
- 8:00–8:45 Osteoporosis: What Every Orthopaedic Surgeon Should Know(!) and Do(?) — Asif Ilyas
- 8:55–9:15 Acute Vascular Injury in the Hand and Forearm — Scott Barbash

Wednesday, November 13, 2013
- 7:00–7:45 Selected Topics in Pediatric Sports — Corinna Franklin
- 7:55–8:15 Shoulder Instability in Children — Emeka Nwodim

Wednesday, December 11, 2013
- 7:00–7:45 Pediatric Musculoskeletal Infection Update: MRSA and a New Paradigm for Treatment — Martin Herman, MD
- 7:55–8:15 Professionalism — Kazimierz Komperda

Saturday, January 4, 2014
- 8:00–8:45 What Do We Really Know About Picking a “Good” Orthopaedic Resident — Alyssa Schaffer
- 8:55–9:15 Is 80 Hours Enough? The Evolution of the Duty Hour Regulations — Rupam Das

Wednesday, January 15, 2014
- 7:00–7:45 Healthcare Changes in the Horizon — What the Orthopaedic Surgeon Needs to Know — Rob Purchase/John Cacciamani
- 7:55–8:15 Medical Student Debt and Its Effect on Career Choice — Mark Solarz

Wednesday, February 12, 2014
- 7:00–7:45 Non Arthritic Hip: Evaluation, Management, and Joint Preservation Surgery — Eric Kropf
- 7:55–8:15 Radiographic Evaluation of Hip Dysplasia Presenting in Adulthood — Stephen Refsland

Saturday, March 8, 2014
- 8:00–8:45 NATO Role 3 Kandahar, Afghanistan: My Orthopaedic Experience from a War Zone — Carlos Moreyra, MD
- 8:55–9:15 Management Update on Patellar Instability — Colin Mansfield

Snapshots from 2013–2014

The Orthopaedic "Soup and Bowl" hosted by Dr. Eremus and the Merion Cricket Club

Temple Ortho Tough Mudder Team (before the mud)

"Two attendings and six residents started; eight teammates finished!" — J. Milo Sewards

When doctors are ill they don't take sick days . . . they get IV fluids in between cases!

Dr. Lorei and Rick Tosti shop at the same store

Sideline docs at Heinz Field

Snapshots from 2013–2014

Dr. Thoder's classic carpal instability lecture

Cardiac Surgery Appreciation Day… they do have impeccable style!

Pulmonary and Critical Care Appreciation Day: function over fashion!

Trauma team dinner extravaganza

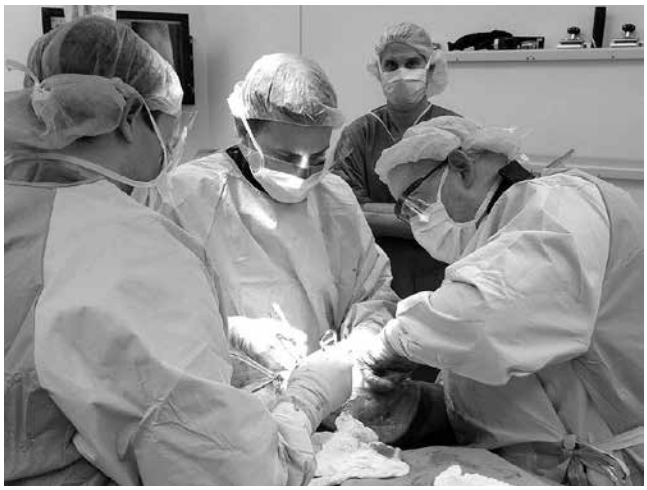
The chiefs after a long day of operating

Dr. Vanett rallying the team

Snapshots from 2013–2014

How does a Polish Orthopaedist read x-rays . . . ?

Dr. Sewards uses the dinnerware as a musculo-skeletal visual aid



Joe Dwyer and Chris Haydel say “there is a fracture, I need to fix it!”

Colin Mansfield and Kasey Komperda at the arthroscopy course in Rosemont, IL

Dr. Thoder and Colin Mansfield help Arianna Trionfo celebrate her first reduction of a dislocated hip

Ever wonder what goes on in the orthopaedics call room?

Snapshots from 2013–2014

Asif Ilyas, Alyssa Schaffer, and Rick Tosti enjoying a nice adventure after a day of presenting Temple research at the AAHS meeting in Naples, Florida

At the Arthroscopy course in Rosemont, IL: Steve Refsland, Rick Tosti and McLovin! (really, the actor happened to be in Rosemont)

Steve Refsland at the AANA course getting his scope on

Interns working hard (well . . . maybe one of them)

Dustin Greenhill and Scott Barbash watching the master at work

Monocles and handlebar mustaches: true men of style

Instructions to Authors

Editorial Philosophy

The purpose of the *Temple University Journal of Orthopaedic Surgery & Sports Medicine (TUJOSM)* is to publish clinical and basic science research performed by all departments of Temple University that relate to orthopaedic surgery and sports medicine. As such, *TUJOSM* will consider for publication any original clinical or basic science research, review article, case report, and technical or clinical tips. All clinical studies, including retrospective reviews, require IRB approval.

Editorial Review Process

All submissions will be sent to select members of our peer review board for formal review.

Manuscript Requirements

Manuscripts are not to exceed 15 double spaced type-written pages and/or 5,000 words (minus figures/tables/pictures). The manuscript should contain the following elements: Title page, Abstract, Body, References, and Tables/Legends. Pages should be numbered consecutively starting from the title page.

(1) Title Page — The first page, should contain the article's title, authors and degrees, institutional affiliations, conflict of interest statement, and contact information of the corresponding author (name, address, fax, and email address).

(2) Abstract — The second page, should be a one-paragraph abstract less than 200 words concisely stating the objective, methods, results, and conclusion of the article.

(3) Body — Should be divided into, if applicable, Introduction, Materials & Methods, Results, Discussion, and Acknowledgements. Tables and figures (in JPEG format) with their headings/captions should be listed consecutively on separate pages at the end of the body, not continuous within the text.

(4) References — Should be listed following the format utilized by *JBJS*. For example: Smith, JH, Doe, JD. Fixation of unstable intertrochanteric femur fractures. *J Bone Joint Surg Am*. 2002;84:3553–58.

Submissions

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  - > "The native radial head is variably offset from the axis of the neck of the radius"[7]
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- **Simple design** has no polyethylene, moving parts or set screws to wear out over time

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3. *Harrington; Journal of Trauma. 2001 50:46-52*
4. *King; J. Bone Joint Surg. 2008;90:271-80.*
5. *Grewal; J. Bone Joint Surg. 2006;88:2192-2200*
6. *Cloke, Ali, Stanley; Early Failure of a Press-fit, Anatomical Radial Head Prosthesis; Shoulder & Elbow 2010; 2 p223 (Abstracts from 21st Annual Scientific Meeting, BESS)*
7. *Graham King, MD et al, An Anthropometric Study of the Radial Head. J of Arthroplasty, 2001.*

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