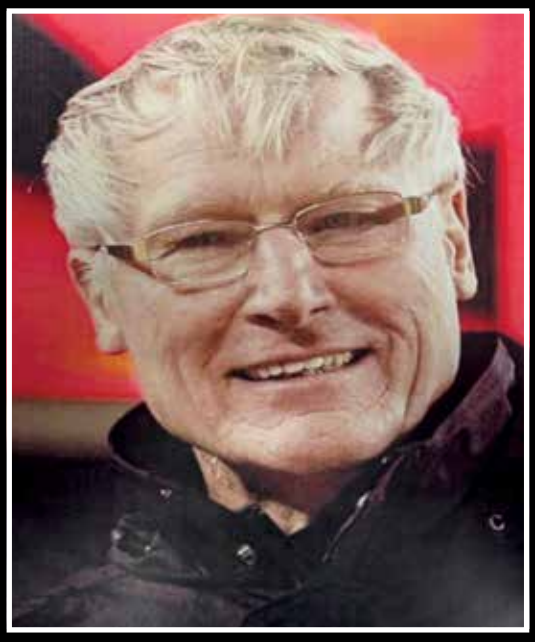
Temple University Journal of Orthopaedic Surgery & Sports Medicine



Ray Moyer, MD

Volume 9 Spring 2014

A John Lachman Society Publication

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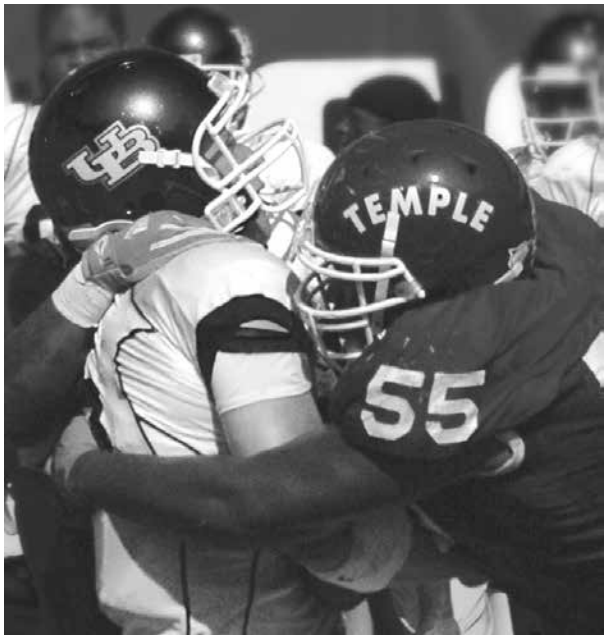
The Temple University Concussion and Athletic Neurotrauma Program

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:

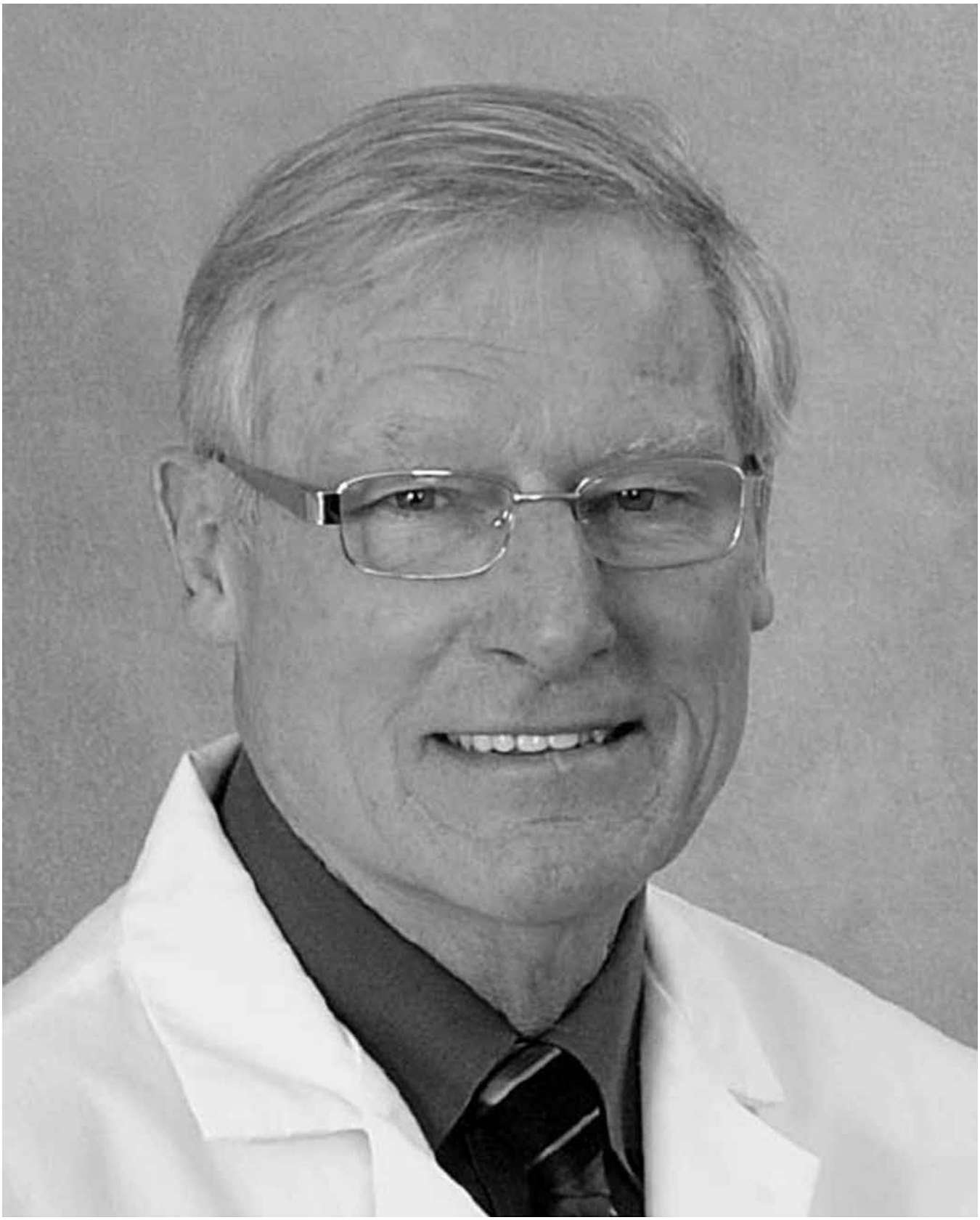
Does CAM Morphology Predict Hip Pain After Antegrade IM Nailing of Femoral Shaft and Peritrochanteric Hip Fractures
Eric Kropf, MD, Principal Investigator (IRB Approval #21651 Expedited Category)

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).

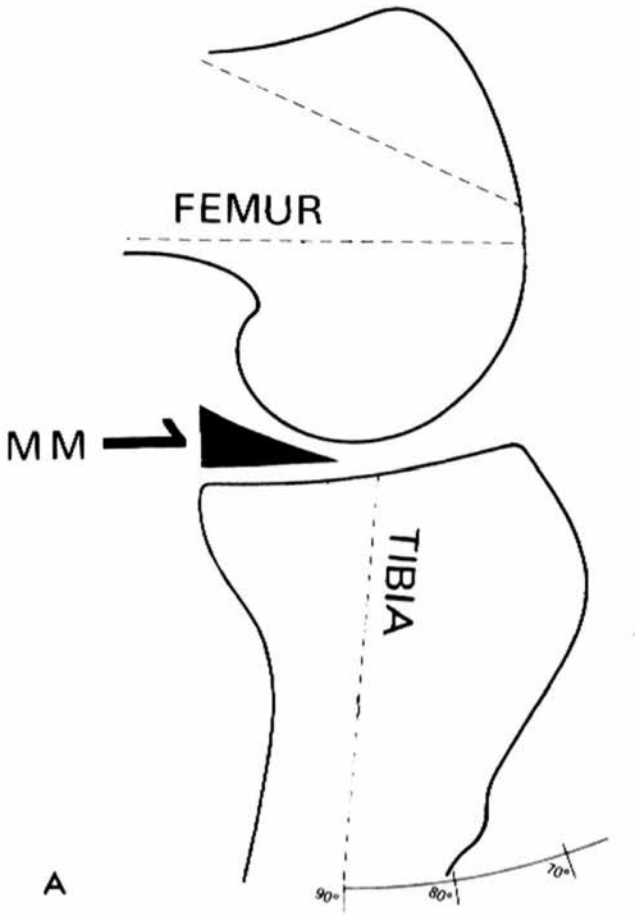

Figure 1A. Diagrammatic representation of the relationship of the medial femoral condyle, medial meniscus (MM), and tibia in the sagittal plane with the knee flexed to 90°, the position in which the classical anterior drawer sign is performed. The medial meniscus, being attached to the tibia, abuts against 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

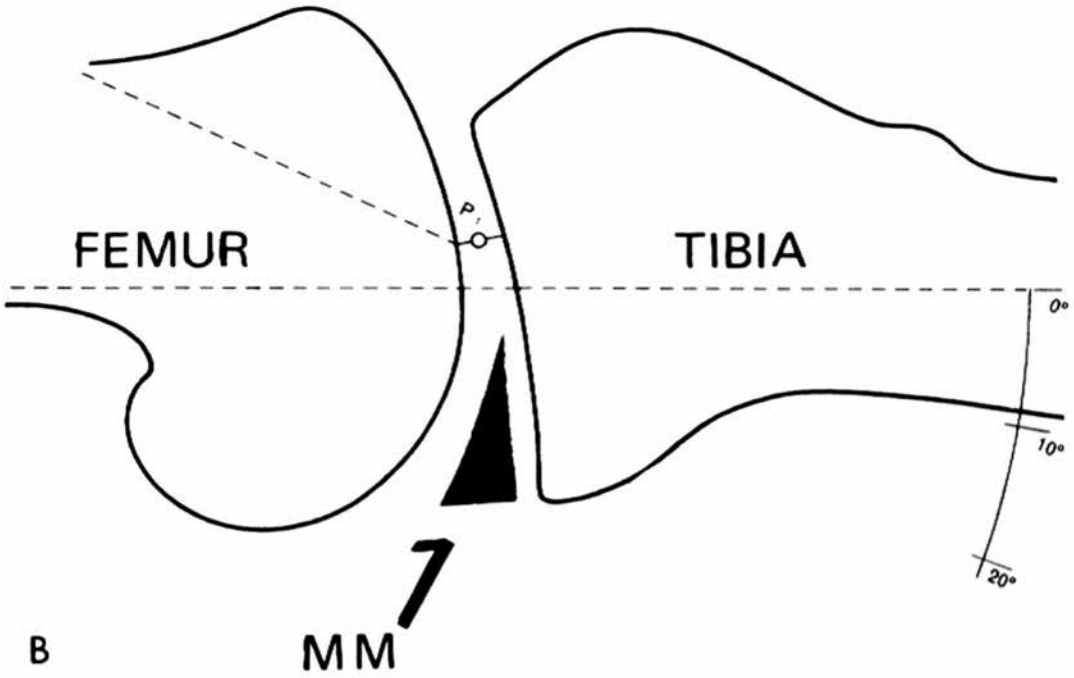

Figure 1B. With the knee extended, the relationship of the femur, medial meniscus, and tibia is significantly changed. The comparatively flat weight-hearing surface of the femur does not obstruct forward motion of the meniscus and tibia when anterior stress is applied. Thus, in instances where there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

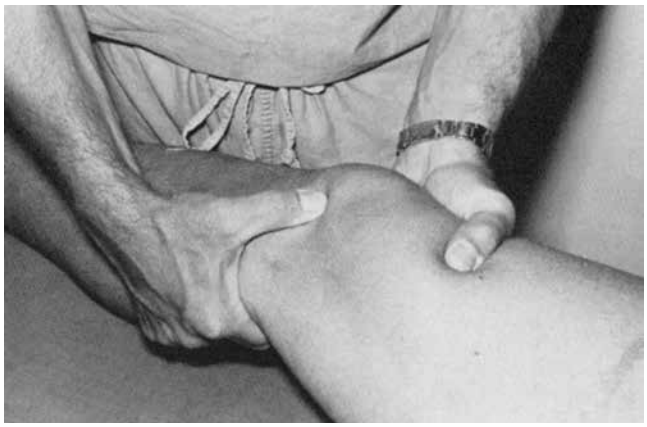

Figure 2. Lachman's test for anterior cruciate ligament instability is performed with the patient lying supine on the examining table with the involved extremity to the side of the examiner. With the involved extremity in slight external rotation and the knee held between full extension and 15° flexion, 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).

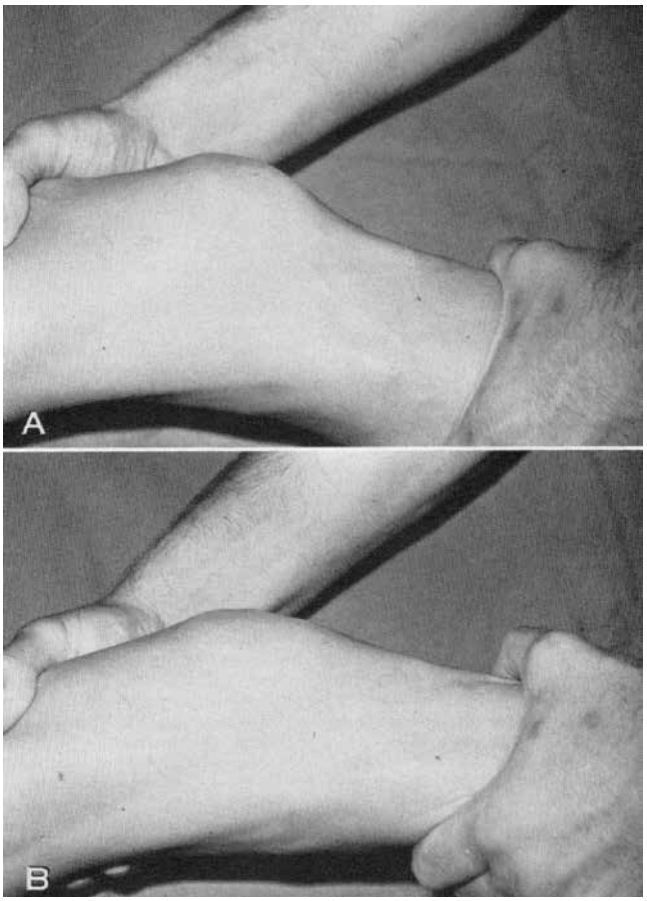

Figure 3. (A) When viewed from the lateral aspect, the silhouette of the inferior pole of patella, infrapatellar tendon, and proximal tibia is one of a slight concavity. **(B)** With disruption of the anterior cruciate ligament, anterior translation of the tibia obliterates the infrapatellar tendon slope.

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

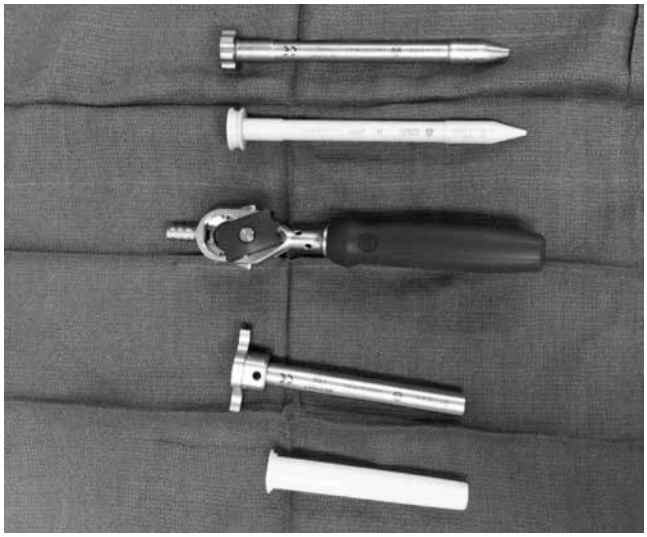

Figure 1. Suprapatellar instrumentation. Pictured from top to bottom: centering sleeve, PEEK trocar, handle for protection sleeve, protection sleeve, outer protection sleeve.

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

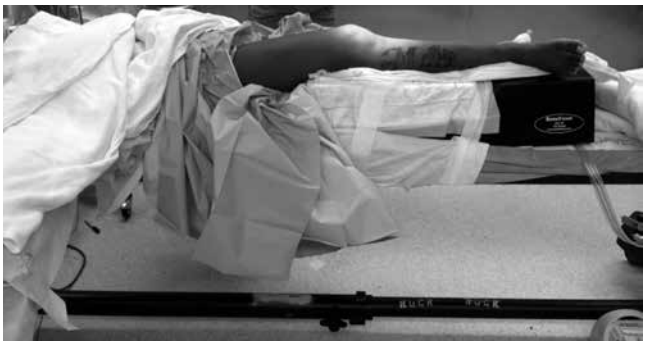

Figure 5a. Patient Positioning. The patient is supine on a radiolucent table. A radiolucent bump or platform should be used. This will allow the limb to remain stationary and simplify fluoroscopic imaging. The bump should also allow some knee flexion to help achieve the appropriate guide wire entry angle.

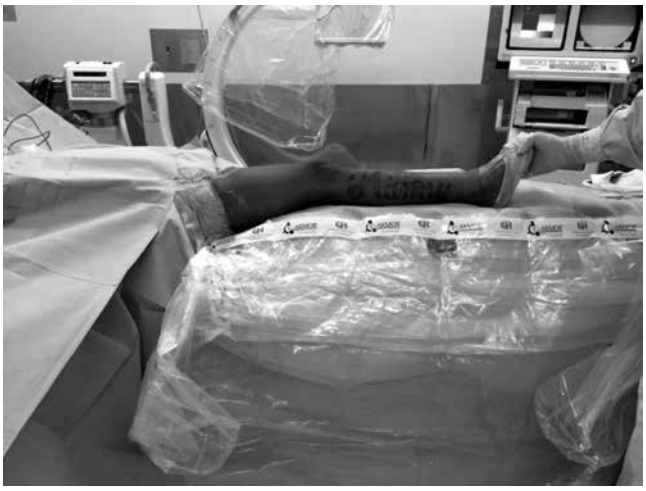

Figure 5b. Patient positioning. After prepping and draping of the operative lower extremity, a sterile sheet or C-Arm drape should be secured in place to obtain lateral images of the entire tibia.

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.

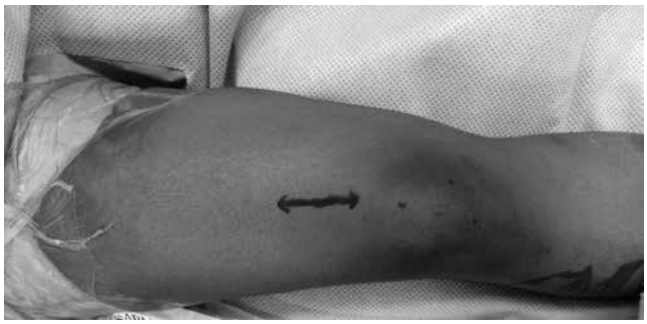

Figure 6a. Approach. A 3–4 cm incision is made approximately 2–3 finger breaths proximal to the superior pole of the patella.

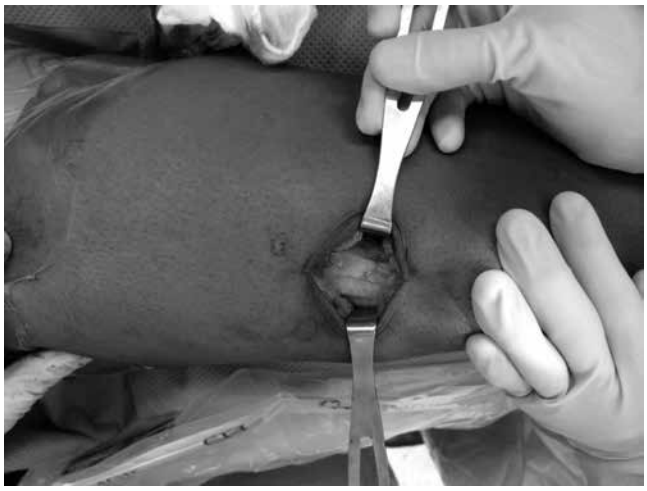

Figure 6b. Approach. The quadriceps tendon is identified and incised in line with the skin incision. The entry portal to the patella-femoral joint can be widened by gently spreading the tissues with a clamp.

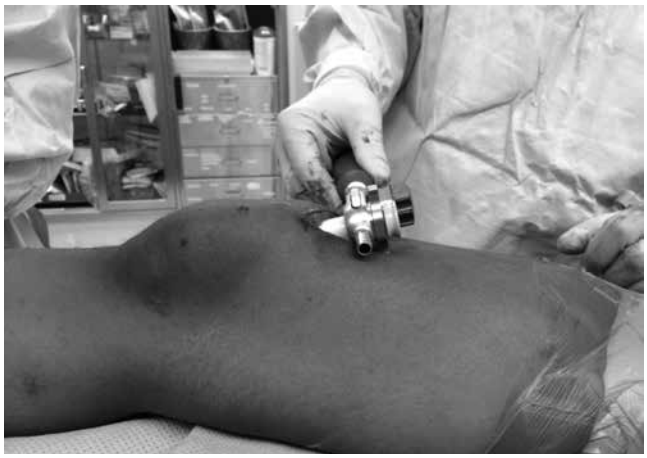

Figure 7. Soft tissue assembly with PEEK trocar placed within the patella-femoral joint. Passage of the assembly through the joint should be smooth. If there is resistance, widen the entry portal with a clamp. Placing the knee in extension will relax the surrounding structures. The patella will usually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

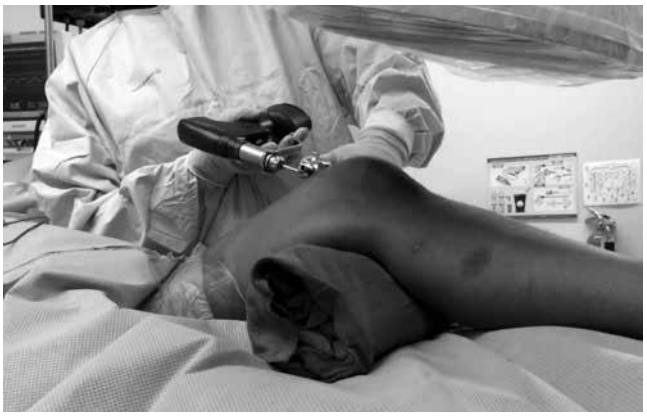

Figure 8a. Guide wire insertion. A small bump placed behind the knee will position the knee in more flexion allowing the guide wire to be placed in line with the tibia intramedullary canal on the lateral fluoroscopic view.

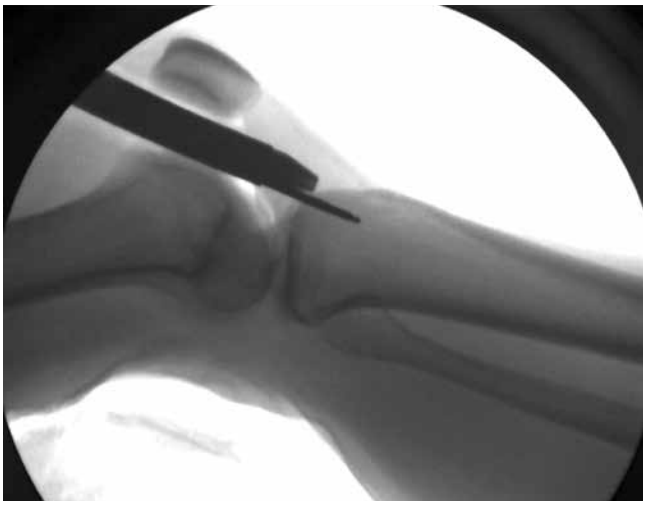

Figure 8b. Guide wire insertion lateral fluoroscopic view. The ideal starting point on this view is just anterior to the articular surface of the proximal tibia. The offset portal of the centering sleeve is being used. The guide wire is placed in line with the intramedullary canal of the tibia.

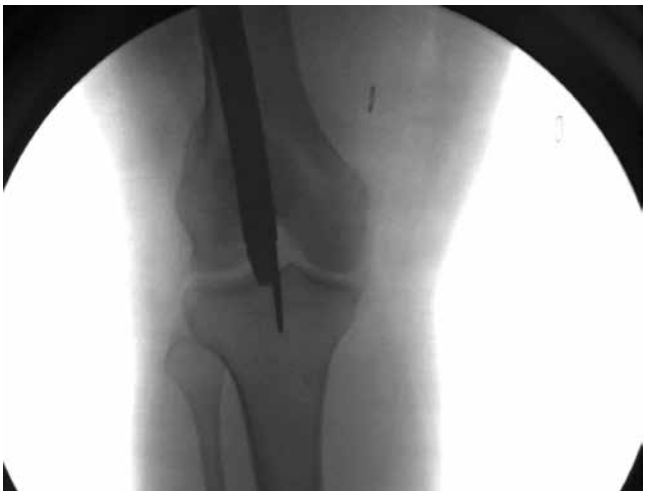

Figure 8c. Guide wire insertion Anteroposterior fluoroscopic view. The ideal starting point on this view is in line with the medial boarder of the lateral tibial spine. The offset portal in the centering sleeve can aid in small adjustments to the guide wire starting point.

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.

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.

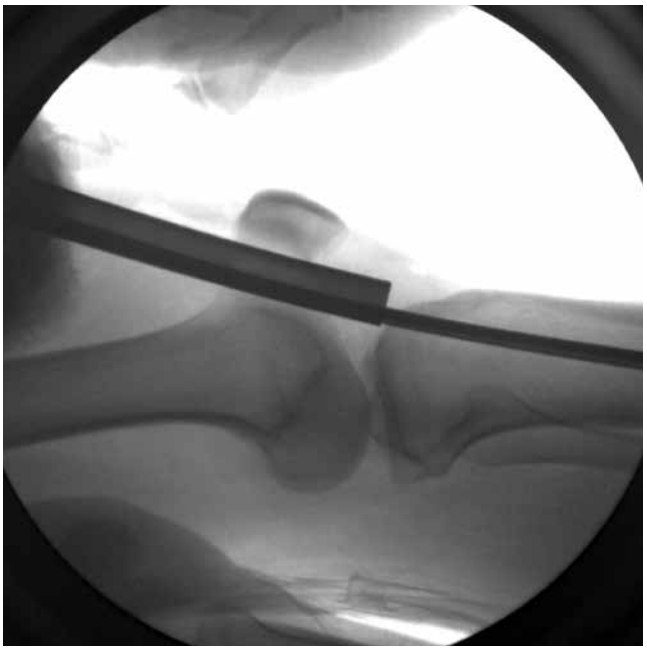

Figure 9. Reaming. The centering sleeve and short threaded guide wire are removed and a ball-tipped guide wire is placed. The protection sleeve is seated on the cortex of the tibia so that the reamer does not damage any intra-articular structures. As the reamer is removed, it may get caught on the posterior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

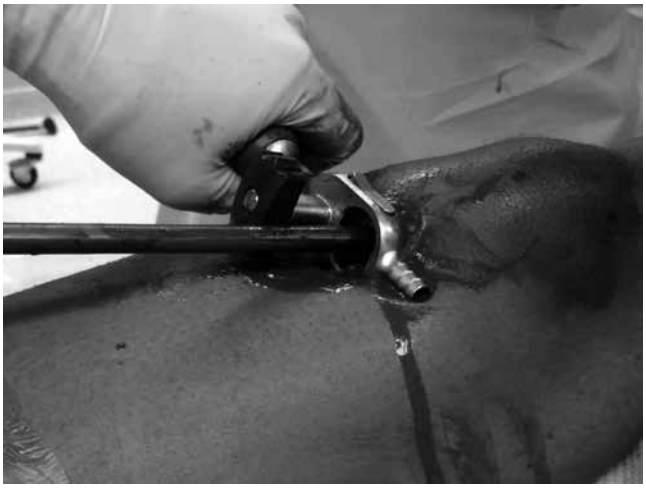

Figure 10a. Nail placement. The protection sleeve is removed from the soft tissue assembly leaving the protection sleeve handle and the outer protection sleeve. The nail is advanced using a twisting motion or controlled taps with a mallet.

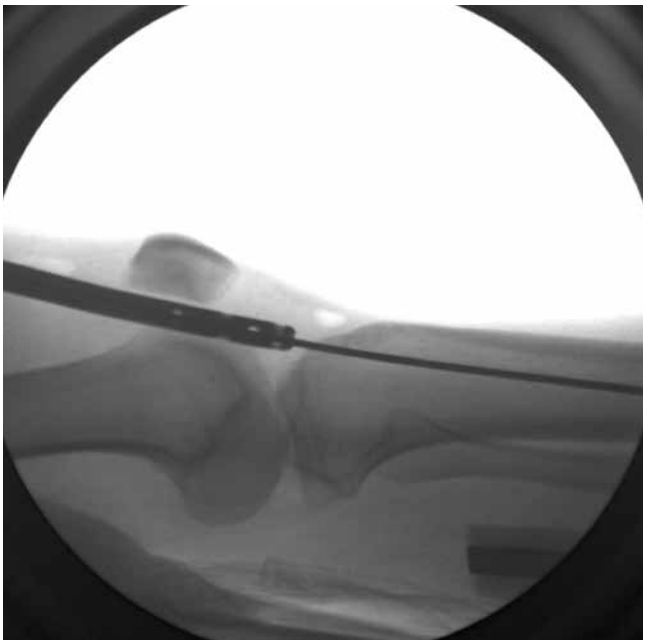

Figure 10b. Nail insertion. The nail is passed through the outer protection sleeve through the patella-femoral joint. Note that the outer protection sleeve is radiolucent.

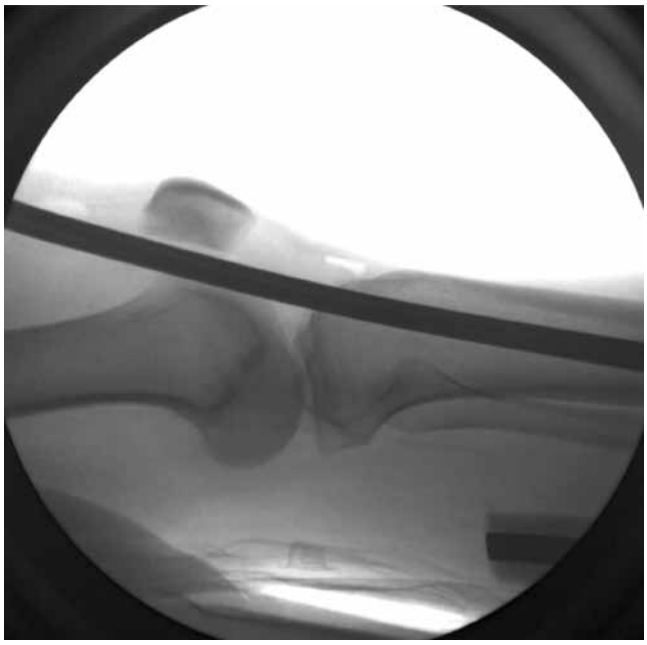

Figure 10c. Nail insertion continued.

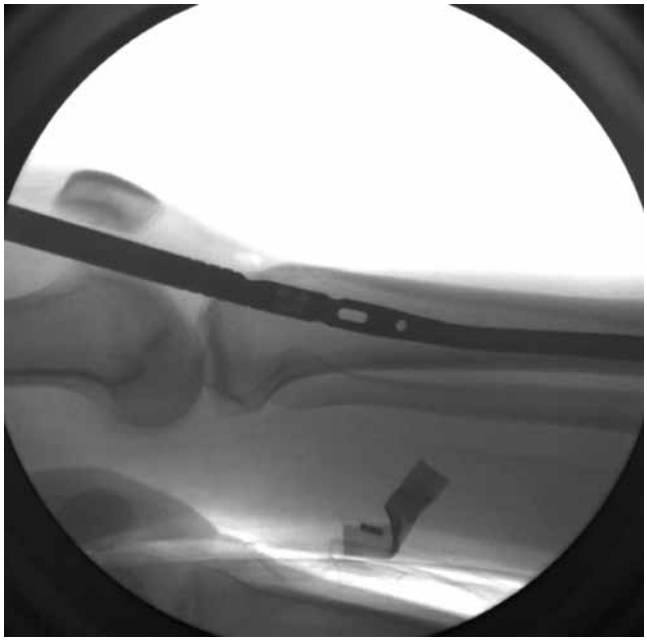

Figure 10d. Nail insertion continued.

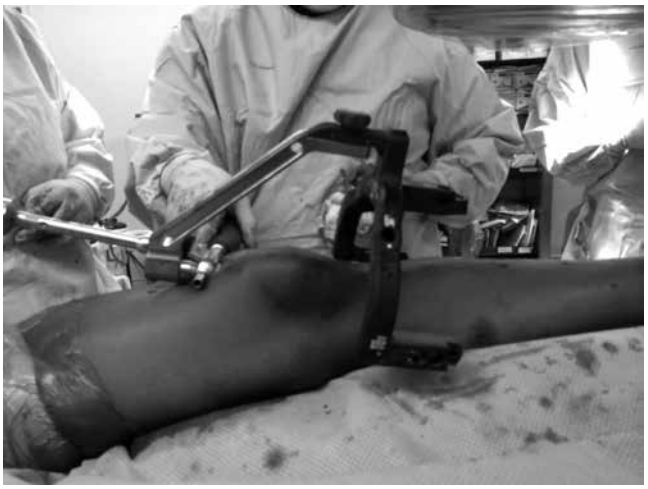

Figure 11. Proximal and distal locking. The aiming arm is placed onto the insertion handle and proximal locking is performed as in infrapatellar nail systems. Distal interlocking bolts are placed using fluoroscopy or computer assistive devices depending on what system is used.

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

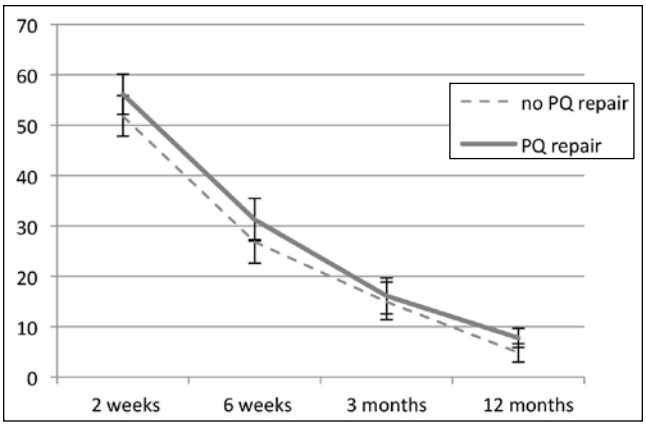

Figure 1. One-year trend of mean Disabilities of the Arm, Shoulder, and Hand scores following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

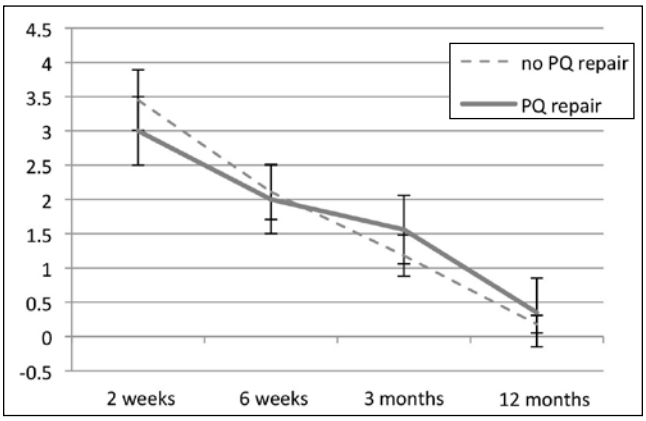

Figure 2. One-year trend of mean visual analog scale scores following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

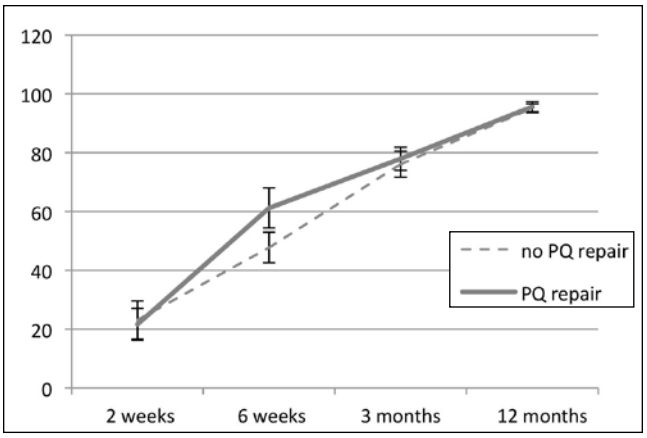

Figure 3. One-year trend of mean grip strength following volar plate application for distal radius fractures in patients with and without repair of the pronator quadratus.

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.

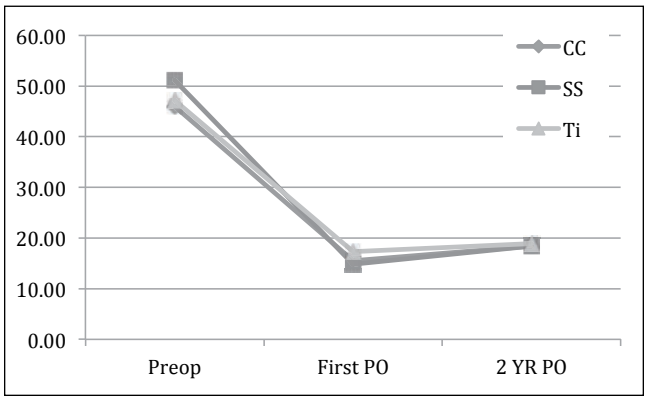
Loss of correction from 1-PO to 2-YP was found for certain radiographic parameters (Figure 2). Ti was the only

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

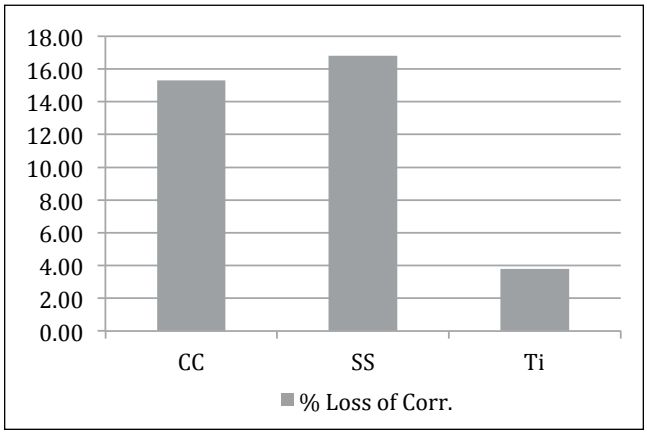
metal to maintain thoracic curve correction while SS and CC lost a mean of 3.6 ± 5° (16.8 ± 28.8%) and 2.9 ± 3.1° (15.3 ± 18.3%), respectively (p = 0.01). Analysis revealed significant loss of correction for SS compared to Ti (p = 0.02), and no difference between either CC and Ti, or CC and SS. Change 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.

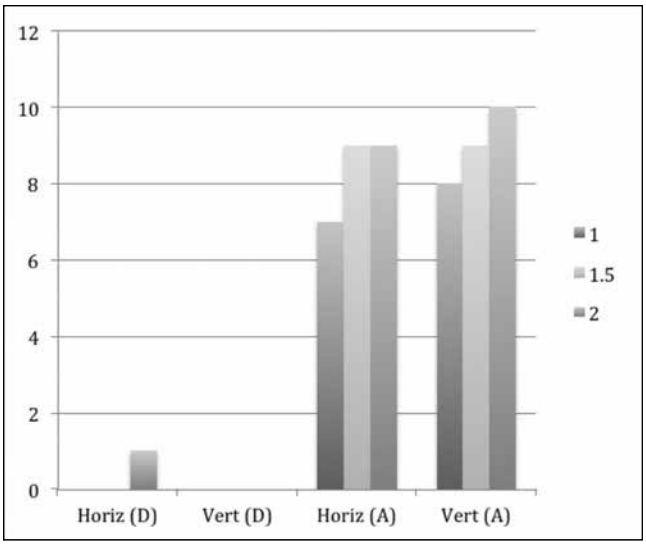

Figure 1. Abnormal DVA Scores of both Agarwala (A) and Dannenbaum (D) studies

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

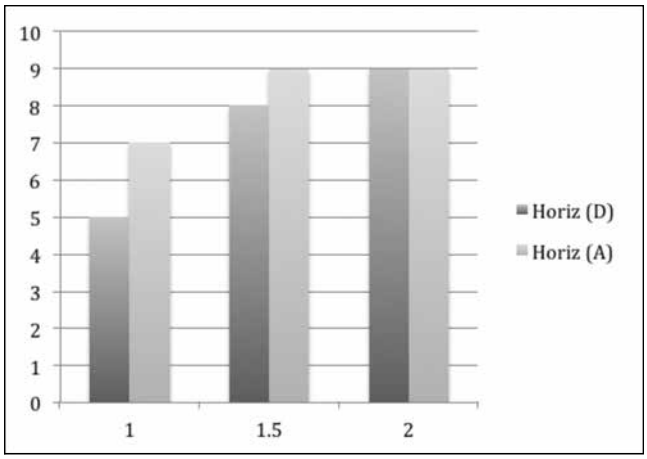

Figure 2. Abnormal DVA Scores Recorded in Horizontal DVA Testing, Dannenbaum Subjects (D) with One-Sided Lack of Vestibular Function vs. Healthy Subjects (A) of Randomized Study

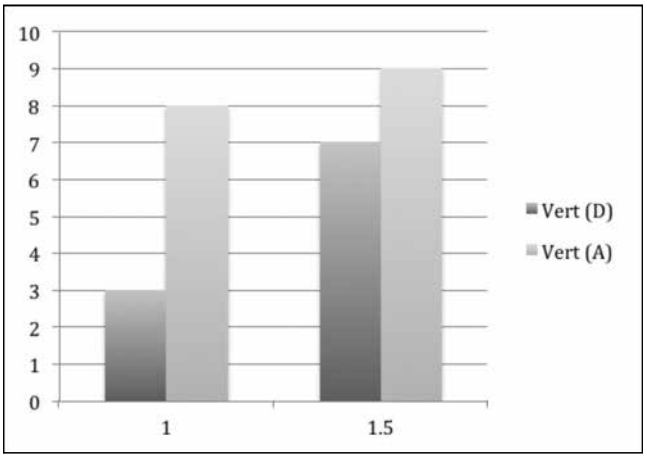

Figure 3. Abnormal DVA Scores Recorded in Vertical DVA Testing, Dannenbaum Subjects (D) with One-Sided Lack of Vestibular Function vs. Healthy Subjects (A) of Randomized Study

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.

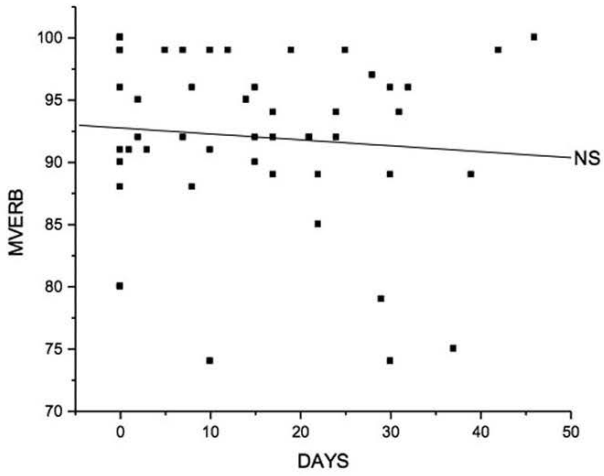
Supporting the claim that the ImPACT test eliminates the practice effect observed in traditional paper and pencil testing is a study performed by Torg et al. in 2012. At Temple University Hospital, 10 healthy non-concussed medical students were evaluated using the ImPACT test on five different occasions. 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

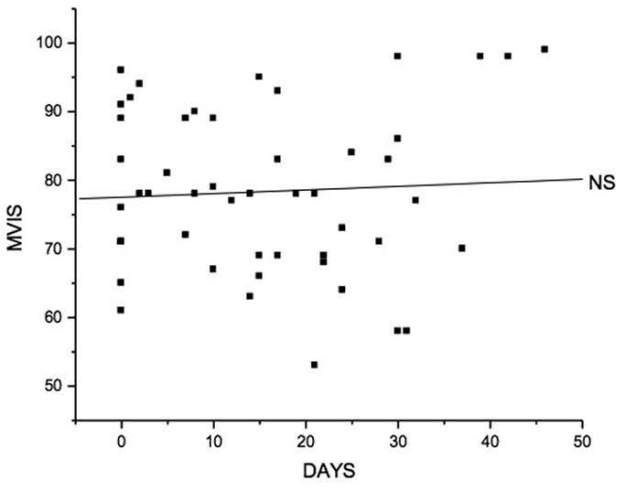
In addition to the elimination of a practice effect, many studies have documented the ImPACT test's high degree of validity, sensitivity, and specificity. The validity of the ImPACT test, the test's ability to measure a decrease in cognitive function following a concussion, was examined in 2003 by Iverson, 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

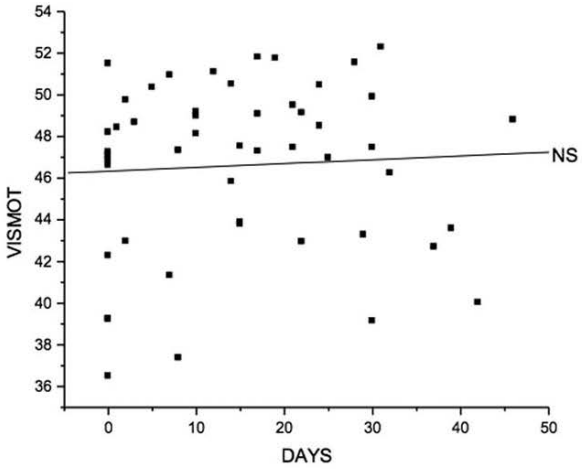
While protocols for the on-field diagnosis of concussions have improved, many concussions continue to go undiagnosed. Despire the many studies which support the validity, sensitivity, and specificity of the ImPACT test, specific cases and player surveys question the ImPACT test's susceptibility to deception.[23] 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]



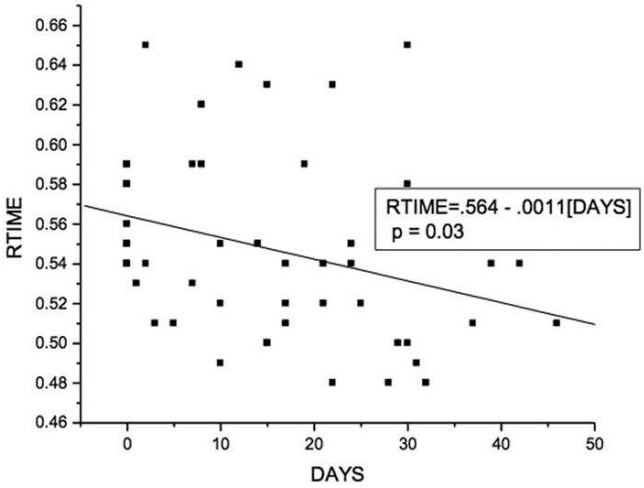
a) Verbal Memory



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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