2014 • Volume 34

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INSTRUCTIONS FOR AUTHORS, 2015 EDITION


We will consider any original article relevant to orthopaedic surgery, orthopaedic science or the teaching of either for publication in *The Iowa Orthopaedic Journal*. Articles will be enthusiastically received from alumni, visitors to the department, members of the Iowa Orthopaedic Society, residents, and friends of The University of Iowa Department of Orthopaedics and Rehabilitation. The journal is published every June. **The deadline to receive articles for the June 2015 edition is Monday, January 5, 2015.**

Published articles and illustrations become the property of *The Iowa Orthopaedic Journal*. The journal is peer reviewed and referenced in *Index Medicus* and MEDLINE. Articles previously published will not be accepted unless their content has been significantly changed. The IOJ receives approximately 57,000 downloads per month.

When submitting an article, send the following:

1. The original manuscript with illustrations and **ABSTRACT**.
2. The **corresponding author** must be clearly identified with mailing address, telephone/fax numbers and e-mail address. Manuscripts will not be returned unless requested.
3. The bibliography must list references **in the order of their appearance**, and be double-spaced. References must be presented in the text by superscript numbers.
4. **Legends** for all illustrations should be listed in order of appearance and single spaced.
5. **Illustrations/Images:**
   a. Color illustrations may not be used unless it is the opinion of the journal that they convey information not available in black and white.
   b. Each image should be sent to renae-thompson@uiowa.edu as an individual .tif or .jpg file. All images must have resolution of 600 pixels per inch (ppi). Web page images are to be avoided. Set digital cameras to their highest quality (ppi) setting for photographs.
   c. When submitting an illustration that has appeared elsewhere, give full information about previous publication and credit to be given, and state whether or not permission to reproduce it has been obtained.

6. Send electronic copies of all items to renae-thompson@uiowa.edu. Special illustrations and photographs may be exempted from this electronic requirement and should be mailed to the address below.

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**Preparation of manuscripts:** Manuscripts must be typewritten and double spaced. Write out numbers under 10 except percentages, degrees or numbers expressed as decimals. Direct quotations should include the exact page number on which they appeared in the book or article. All measurements should be given in SI metric units. In reporting results of surgery, only in rare instances can cases with less than two years of follow-up be accepted.

Additional copies of these instructions may be obtained at http://www.uiortho.com/index.php/education/iowa-orthopaedic-journal.html or by writing to Renae Thompson, University of Iowa Hospitals and Clinics, Department of Orthopaedics and Rehabilitation, 200 Hawkins Drive – 01020 J.P.P., Iowa City, Iowa, 52242-1088 or by emailing renae-thompson@uiowa.edu.
2014 IOJ EDITORS’ NOTE

It is with great honor and pleasure that we present the 34th edition of the Iowa Orthopaedic Journal (IOJ) in 2014. As in previous years, this edition represents work and contributions from countless faculty, support staff and residents from within our department as well as from across the nation and globe. The impact of the IOJ continues to increase, as the articles are freely available via Pub Med. A recent analysis demonstrated that more than 57,000 articles from the IOJ are downloaded from Pub Med each month. We are hopeful that the Pub Med exposure will continue to increase the IOJ readership and result in continued growth.

As per tradition, we would like to recognize the graduating senior residents, Drs. Kho, Willey, Schick, Dawson, Warth, and Yehyawi. They have led by example and inspired younger resident classes to high achievement. We thank them for all they have provided for the department and wish them well as they begin fellowships and the start of what will undoubtedly be remarkable careers.

Unlike past editions where recipients of the IOJ dedications have been single individuals, this year we would like to dedicate the edition to the 100th anniversary celebration, the department’s major achievements in orthopedic education, research, and practice as well as our alumni and friends whose unending support of the department have made the achievements possible. We included in the dedication stories and pictures shared by participants. We hope the celebration will always remind our alumni of the department and the Iowa Orthopaedic roots.

The IOJ would not be possible without the help of several people. The faculty and residents have worked diligently on various projects that will certainly add to the orthopaedic literature. Nicole Schick, John Phung, and Renae Thompson deserve recognition for their work in organizing the articles, designing the front cover, and helping with the journal production. We would like to thank our corporate sponsors for their generous support that made this publication possible. We would also like to thank our faculty advisor, Dr. Jose Morcuende, whose guidance continues to make the IOJ possible. We are indebted to him for his input, leadership, and service.

It has been an honor to serve as the editors for the IOJ for 2014. We hope you find that this year’s edition of the IOJ continues in the same high standard as previous editions. We are thankful for the premier training we have received from our faculty and we look forward to being connected throughout our careers.

Mai P. Nguyen, M.D.
Andrew J. Pugely, M.D.
Co-Editors
Iowa Orthopaedic Journal
Department of Orthopaedics and Rehabilitation
University of Iowa Hospitals and Clinics
IOWA ORTHOPAEDIC JOURNAL
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INTRODUCTION

Traditionally, each edition of the Iowa Orthopaedic Journal is dedicated to a single individual for their accomplishments in pursuit to uphold the mission of the department. As many may know, October 2014 marked the 100th year anniversary celebration of the University of Iowa Department of Orthopaedics. Given the magnitude and tremendous success of this event, the 2014 Iowa Orthopaedic Journal will be dedicated to the 100th anniversary event. A brief reflection on this remarkable weekend follows.

HISTORY OF THE IOWA ORTHOPAEDIC DEPARTMENT

Our department has a history worthy of celebration. Since 1913 when John Bowman, the ninth President of the University of Iowa appointed Arthur Steindler as Instructor in Orthopaedic Surgery, the University of Iowa Department of Orthopaedics and Rehabilitation has become an internationally recognized preeminent clinical, educational and research program. This success is due to the education and talent of generations of faculty, residents, staff and alumni of the residency program and the medical school.

Over the last 100 years, Iowa Orthopaedics has helped advance the entire specialty of orthopaedics. The Department’s studies of the cell, molecular and matrix biology of bone, cartilage, growth plate, tendon and ligament and intervertebral disc and the injuries and diseases that affect these tissues have led to many of the most important developments in musculoskeletal research. This work continues in the Ponseti Biology Laboratory and the Spine and Bone Healing Laboratory. The University of Iowa Orthopaedic Biomechanics Laboratory has been a world leader in advancing understanding of the mechanics of the musculoskeletal system, the invention of new joint replacements and methods of fracture fixation and innovative approaches to measuring the wear of joint replacements and the mechanical forces that cause osteoarthritis. Clinical research based in the Department has helped guide improvements in the treatment of patients with fractures and joint injuries, severe arthritis that requires joint replacements and skeletal deformities including congenital hand deformities, clubfoot, scoliosis and hip dysplasia. The Department’s teaching programs have educated generations of medical students and Orthopaedic residents, and many former Iowa Orthopaedic residents have become leaders in Orthopaedic surgery. The Department’s nationally recognized residency program attracts the best medical students from schools throughout the United States. Faculty have earned national and international recognition for their clinical expertise, research, and regional, national and international leadership positions, and participation in groups dedicated to improving national health policy. Four faculty have served as president of the world’s largest Orthopaedic society, the American Academy of Orthopaedic Surgeons, four faculty have served as president of the world’s oldest Orthopaedic society, the American Orthopaedic Association, five faculty have served as president of the Orthopaedic Research Society and six faculty have served as directors of the American Board of Orthopaedic Surgery – an exceptional record of leadership and accomplishment. A 100 year timeline of the Department history has been included (Table 1).

Table 1: Iowa Orthopaedics and Rehabilitation 100 Year Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1912</td>
<td>Arthur Steindler begins holding Orthopaedic Clinics in Iowa City at the first University of Iowa Hospital on the East side of the Iowa River. The building is now known as Seashore Hall.</td>
</tr>
<tr>
<td>1913</td>
<td>Arthur Steindler is appointed as Instructor in Orthopaedic Surgery by University of Iowa President John Bowman. Steindler receives a stipend of $800 per year and moves his orthopaedic practice to the University of Iowa Hospital from the Drake Medical School.</td>
</tr>
<tr>
<td>1915</td>
<td>The Iowa State Legislature passes the Perkins Act which supports transport of children with musculoskeletal deformities and diseases to the University of Iowa for treatment.</td>
</tr>
<tr>
<td>1915</td>
<td>Arthur Steindler is appointed Professor of Orthopaedic Surgery.</td>
</tr>
<tr>
<td>1917</td>
<td>Construction is completed on the University of Iowa Children’s Hospital on the West side of the Iowa River. The new hospital houses the Orthopaedic Clinics, operating rooms, offices, operating rooms, laboratories, library and rehabilitation facilities.</td>
</tr>
<tr>
<td>1927</td>
<td>The Iowa Orthopaedic clinical and academic programs are recognized as an independent department by the Iowa Board of Regents.</td>
</tr>
<tr>
<td>1929</td>
<td>Ruth Jackson joins the Iowa Orthopaedic Residency. After working with Dr. Steindler, she decides to pursue a career in Orthopaedic Surgery. She is now recognized as the first woman Orthopaedic Surgeon in the United States.</td>
</tr>
<tr>
<td>1948</td>
<td>Arthur Steindler leaves the University of Iowa to found the Steindler Clinic at Mercy Hospital.</td>
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<tr>
<td>1950</td>
<td>Carroll Larson becomes the Chair of Orthopaedic Surgery.</td>
</tr>
<tr>
<td>1972</td>
<td>Reginald Cooper becomes Chair of Orthopaedic Surgery.</td>
</tr>
<tr>
<td>1999</td>
<td>Joseph Buckwalter becomes Chair of Orthopaedic Surgery.</td>
</tr>
<tr>
<td>2000</td>
<td>Joseph Chen joins the faculty and starts the Physical Medicine and Rehabilitation clinical and academic programs.</td>
</tr>
<tr>
<td>2013</td>
<td>Recognition of 100 Years of Iowa Orthopaedics.</td>
</tr>
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### Table 2: 100 Year Celebration Schedule of Events

**Thursday, October 10th, 2014**

**Evening**
- Open House Welcome Reception  
  Location: Hotel Vetro Lehman Ballroom

**Friday, October 11th, 2014**

**Morning**  
Academic Program: The Orthopaedic World: Changes Since You Left Iowa  
Location: University of Iowa, College of Public Health Building
- The Healthcare Environment Overview  
  Stuart L. Weinstein  
  Ignacio V. Ponseti Chair and Professor
- Healthcare Delivery System Reform  
  James N. Weinstein  
  President and CEO Dartmouth Hitchcock Healthcare
- Department of Orthopaedic Surgery in the New Academic Medical Center  
  Charlie Saltzman  
  Professor and Chairman Department of Orthopaedic Surgery: University of Utah
- The Quality of Movement in Orthopaedic Surgery  
  Kristy Weber  
  Professor of Orthopaedic Surgery; University of Pennsylvania
- Residency Training in the 21st Century  
  J. Lawrence Marsh  
  Carroll B. Larson Professor
- ABOS in the 21st Century  
  Ned Amendola  
  John and Kim Callaghan Chair and Professor
- Research Funding in Orthopaedic Surgery  
  John Callaghan  
  Lawrence and Marilyn Dorr Chair and Professor
- Pediatric Orthopaedics; The Iowa Legacy  
  Dennis Wenger  
  Professor of Orthopaedics UCSD
- The Adult Hip  
  Tom Brown, PhD  
  Richard and Jan Johnston Professor and Chair
- Osteoarthritis Cort Grant (OR) Translational Research  
  Don Anderson PhD  
  Associate Professor
- Rehabilitation Service  
  Joseph Chen  
  Associate Professor
- The Women of Iowa: A Dynasty of Diversity  
  Andrea Saterbak  
  St. Croix Orthopaedics
- Operation Walk  
  Larry Dorr  
  Clinical Professor of Orthopaedics  
  University of Southern California Keck Medical School

**Evening**
- Black Tie Reception and Dinner  
  Location: Marriott Hotel and Conference Center

**Saturday, October 12th, 2014**

**Morning**  
Iowa Orthopaedic Department Day  
Location: University of Iowa, College of Public Health Building
- The Steindler Era  
  Joseph A. Buckwalter  
  Arthur Steindler Chair and Professor; Department Head
- The Larson Years  
  Reginald Cooper  
  Professor Emeritus
- The Cooper Years  
  Stuart L. Weinstein  
  Ignacio V. Ponseti Chair and Professor
- The Buckwalter Years  
  Brian Wolf  
  Ralph and Marilyn Congdon Professor
- Iowa Orthopaedic Society and Their History with the Department  
  President of the IOS
- Department Video  
  Joseph Smucker  
  Associate Professor
- The Future of the Department  
  Joseph A. Buckwalter

**Afternoon**
- Golf and Tennis Tournament  
  Location: Brown Deer Golf Course and UI Hawkeye Tennis and Recreation Complex

**Evening**
- Cocktail Party and Hor D’Oeuvres Reception, with “special” auction  
  126 Restaurant

**Sunday, October 13th, 2014**
- Ponseti Races  
  UI Sports Medicine Center
**SUMMARY OF 100 YEAR ANNIVERSARY EVENTS**

This past October, alumni, friends and families from around the world gathered in Iowa City to commemorate the Department’s 100th anniversary. In total, 96 alumni with hundreds of other friends and family, participated in the event. Over the course of four days, from October 10th -13th, 2014, we celebrated the rich history of Iowa Orthopaedics (Table 2). We took a look back at our major achievements including Ponseti’s revolutionary treatment for clubfoot, advancements in joint replacement surgery, multidisciplinary research to prevent post-traumatic osteoarthritis, and bracing for adolescents with scoliosis. Through the eyes of leaders in the field and world renowned faculty and alumni we reflected on current and future issues in US Healthcare, residency education, certification, philanthropy, research and diversity in orthopaedic surgery. A separate session, entitled “Department Day” celebrated the last 100 years through the eras of each of Iowa’s four chairmen: Steindler, Larson, Cooper, and Buckwalter (Figures 1 and 2). The fact that there have been only four chairmen is unique among academic orthopaedic departments with a history that extends back for a century. The academic session concluded with a discussion of the future of Iowa Orthopaedics, specifically reflecting on current and future initiatives to ensure that the future will be better than the past.

In addition to the rich academic sessions, multiple social events allowed alumni from near and far to reunite and celebrate the past, present, and future. For the last century, Iowa Orthopaedics has been a big family and our anniversary celebration was also our family reunion. Although the weather in Iowa City was perfect, many of our alumni traveled through hazardous wintry conditions, even from as far away as New Zealand (Figure 3).
Visionary $1,000,000+
John J. and Kim L. Callaghan
Roy D. and Linda Crownshield
Lawrence D. and Marilyn A. Dorr
Richard C. and Janice C. Johnston
Marvin A. and Rose Lee Pomerantz
Vera Patricia Siman-Creebo Estate

Benefactor $500,000-999,999
Leeta M. Berry Estate
Ron D. and Judith K. Carter
DePuy Spine, Inc.
Mark A. and Mary Ann Kaufman
Arthur D. Stetfree

Leader $250,000-499,999
Joseph A. Buckwalter IV and Kathleen C. Buckwalter
Roy J. Carver Charitable Trust
Ralph H. and Marcia A. Congdon
Beszie M. Millhine
Helena Percas-Ponseti and Ignacio v. Ponseti
Theodore A. Willis

Founder $100,000-249,999
Benjamin E. and Annabelle Bierbaum
Michael and Ruth M. Bonfiglio
Byran D. and Nancy K. Den Hartog
DePuy Orthopaedics, Inc.
Sutherland C. Dows and Frances M. Dows Charitable Trusts
Richard J. and Margaret C. Ling
Evelyn A. Magown Estate
James V. and Catherine M. Nepola
Pluinit and Kantima Phisitkul
Smith & Nephew, Inc.
Martin J. and Joan L. Steindler
Herbert L. and Nancy M. Townsend
Peter D. and Susan K. Wirtz

Table 3: Iowa Orthopaedics 100 Year Donation List

<table>
<thead>
<tr>
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<th>Partner $50,000-99,999</th>
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<td>Annunziato and Alison L. Amendola</td>
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<td>Donald W. Blair Estate</td>
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<td>The Robert Campeau Family Foundation (U.S.)</td>
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<td>Charles Richard and Barbara S. Clark</td>
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<td>Grand Chaper of Iowa-Order of the Eastern Star</td>
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<td>Daniel C. and Denise F. Fitzpatrick</td>
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<td>Iowa Orthopaedic Society, Inc.</td>
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<td>Maude-Alice Junk</td>
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<td>Ralph P. Katz and Dottie S. Gill-Katz</td>
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<td>Thomas L. Lambert and Mary Ann Bramhall-Lambert</td>
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cluded with a speech from Dr. Marilynne Robinson, a well-established Iowa Writers’ Workshop Professor. The social program concluded Saturday night with hor d’oeuvres and cocktails (Figures 7, 8). Here, Iowa faculty held a special “auction” where department relics were sold-off for high dollars (Figures 9, 10). Some lucky alumni were able to snatch up items ranging from scrub caps to scoliosis braces (Figure 11). Other social events including the tennis and golf tournaments and Ponseti’s race were also alumni favorites (Figures 12-14). Not surprisingly, most brought their best, as Orthopaedic surgeons seem to rarely miss an opportunity for a little friendly competition.
FUTURE DIRECTIONS

Since 1913, the Department of Orthopaedics and Rehabilitation at the University of Iowa has worked tirelessly to improve the lives of people suffering from diseases, deformities and injuries of the spine and limbs. Our department has proven to be one of the best in the world in patient care, research and education. As we move into our second century, we will continue to pursue excellence and improve upon our traditions. The 2nd Century Campaign has been started to ensure continuation of philanthropy and support of the Department. By October, we were able to raise millions of dollars. This number continues to increase through private support. In line with our vision of continuing to be a leader in Orthopaedic Surgery, we expect the addition a new free standing Orthopaedic Department Building at the Iowa River Landing Site in the next 5 years to further our ability to care for patients. This building will include clinic, office, and operating room space.

Department leadership has also transitioned. Shortly after the 100 year celebration Dr. Joseph Buckwalter announced his resignation of the Chairmanship. As the University finalizes the nation-wide chairman search, Dr. John Lawrence Marsh has taken the intern chair position. J. Lawrence Marsh MD is a tenured professor in the Department of Orthopedic Surgery at the University of Iowa Hospitals and Clinics. He is the Carroll B. Larson Chair and serves as the Program Director of the Orthopedic Residency Training Program. He received his BA from Colgate University, his medical degree from Upstate Medical Center in Syracuse, New York and trained in orthopedic surgery at Boston University. After the completion of his training he served for two years as University Lecturer in orthopedic surgery at Oxford University in Oxford, England.

Dr. Marsh’s clinical practice is devoted to orthopedic trauma and adult reconstruction and he has developed techniques of minimally invasive articular fracture surgery. His research has focused on articular fractures and techniques of image analysis to assess the mechanical factors leading to post traumatic osteoarthritis. He has also been instrumental in initiatives that have led to new requirements for laboratory-based surgical skills training for orthopedic residents and his research in this area has led to new skills assessments and validated skills training techniques. His research has been funded by the NIH, OTA, Arthritis Foundation, AO and by NBME. He and his co-authors were recipients of the 2011 OREF clinical research award for their work on Post Traumatic Osteoarthritis. He is the author of more than 140 peer-reviewed publications on various topics in orthopaedics and trauma.
Dr. Marsh currently serves as the Chair of the Residency Review Committee for Orthopedic Surgery and is a member of the ACGME’s Council of Review Committee Chairs. He is a Director for the American Board of Orthopedic Surgery and Chair of the Oral Examination Committee. He is a member of the National Board of Medical Examiners and is the incoming President of the Mid-American Orthopedic Association and American Orthopaedic Association. He has served the AOA as an ASG travelling fellow and has been Chairman of the Fellowship Coordinating Committee, the ASG committee and the CORD Assessment Tools committee and as a member of the Academic Leadership Committee and is currently the incoming President.

**CONCLUSION**

Alumnus Dr. William Robb III summed the department vision well, “The next 100 years will be even better than the first.” Our department has many great strengths and rich heritage. We have seen the University of Iowa Hospitals and Clinics thrive as a premier medical center with a tradition of excellence in academic orthopaedics; outstanding, world-renowned faculty; and one of the strongest orthopaedic residency programs in the United States, with an enviable basic translational and clinical research program. Now, more than ever, with the evolving landscape of the healthcare in this country, we are embracing the new challenges for the opportunity to lead advances in the care of patients with musculoskeletal disorders.

**THE FUTURE OF IOWA ORTHOPAEDICS AND REHABILITATION: A VISION FROM DEPARTING CHAIRMAN, JOSEPH A BUCKWALTER**

The University of Iowa Department of Orthopaedics and Rehabilitation is a unique institutional resource as well as an international leader in providing superlative care, unsurpassed education and scholarship and leadership of regional, national and international professional and scientific organizations. The department has many great strengths including a heritage of over 100 years of excellence in academic orthopaedics, an outstanding faculty, one of the premier orthopaedic residencies in the United States and enviable basic translational and clinical research programs. Changes taking place in the healthcare environment are creating opportunities for the department to build on its strengths and have an even larger role in advancing the care of patients with musculoskeletal disorders and the position of the UIHC as a premier medical center. To accomplish this goal the Department needs to pursue a series of new initiatives while maintaining its fundamental values.

**CHANGES IN THE HEALTH CARE ENVIRONMENT THAT AFFECT ORTHOPAEDICS AND REHABILITATION**

The health care environment is changing at an increasing rate. Important drivers of change in the current environment are the growth of large integrated health systems and changes in the compensation for health care including ACOs and integrated health systems. There are demands to demonstrate the quality of care while decreasing costs. It is essential that institutions such as ours improve the access for patients and the convenience of patient care. We must excel on publicly available comparisons of hospitals and individual physicians. At the same time there is clearly going to be a continually increasing demand in North America for musculoskeletal care driven by raising patient expectations of life long pain free mobility, the aging of the population and new technology. For at least the next two decades demand for the spectrum of orthopaedic services, in particular; joint replacements, treatment of musculoskeletal injuries including fragility fractures and treatment of spinal disorders will increase as much as 50%. At the same time that the department adapts to these changes and identifies and takes advantages of opportunities created by transitions in the health care environment, the department must take new approaches to funding its essential missions in patient care, teaching and research.

**DEPARTMENTAL INITIATIVES TO INSURE THE FUTURE SUCCESS OF IOWA ORTHOPAEDICS AND REHABILITATION**

The most critical initiative for the immediate future is improving patient access and convenience while meeting the needs for increased musculoskeletal services and doing so in a cost efficient fashion. Specific strategies including efficient and appropriate use of mid-level providers and integration of comprehensive musculoskeletal care with primary care providers that excel in treating common musculoskeletal conditions that do not need surgical care including back pain, shoulder and knee pain. It is clear from the experience of other institutions and the experience in musculoskeletal oncology at Iowa that multidisciplinary teams can improve quality and efficiency of care. Such teams would include orthopaedists, internists and anesthesiologists who provide care for patients with fragility fractures and multiple serious musculoskeletal injuries as well as patients with musculoskeletal complications of diabetes and patients with pediatric disorders. Better integration of musculoskeletal care with critical ancillary services
including imaging, physical therapy, electrodiagnostics and sophisticated treatments of chronic pain will further enhance the quality of care and its efficiency.

There are great opportunities for Iowa Orthopaedics and Rehabilitation to help define and demonstrate the quality and cost efficiency of musculoskeletal care. Members of the department working with members of the hospital administration and investigators in other departments are making progress in using the electronic medical record to help define the true costs of care as well as the outcomes of care relative to cost. These strategies will yield many benefits for the department and the hospital. Efficient use of these records and other strategies will help the department excel on publicly distributed measures of quality including patient satisfaction and patient based outcomes. A critical component of the department’s initiatives to improve care is the support of new clinical initiatives and technologies. Orthopaedics has a wide range of such potential initiatives and technologies including new approaches to minimally invasive and image guided surgery, new biologic and surgical treatments of osteoarthritis, musculoskeletal injuries and deformities.

The department has a long and impressive heritage of basic and translational research, but in the future these research efforts will need to be more clearly focused on specific diseases that have significant impact on the population. Such disorders include osteoarthritis, musculoskeletal injuries and spinal disorders. The department basic and translational research program must emphasize translation of discoveries in biology and bioengineering and to advances of care and potentially new devices and products that will be of value to patients and the institution. Accomplishing these changes in basic and translational research will require a new approach, a virtual musculoskeletal research center. Such a center will facilitate collaboration with investigators in other departments and colleges at the University of Iowa, facilitate focused grant proposals that build on the University of Iowa strengths and lead to new and innovative departmental research directions. This new structure will require recruitment of scientific leaders to replace the senior faculty who have served well in this capacity in the past.

The department also has a long heritage of ground breaking clinical research, however, the field of clinical research is also changing rapidly. The department, to maintain its role in clinical research, will need to invest in department and institutionally support cost value and outcomes research expertise and capacity. The department has initiated with a series of faculty in participation in prospective national and international studies. These studies will shape clinical practice in the future. The department needs to ensure that our faculty continue to be leaders in these efforts such as the multi-center orthopaedic outcomes network, the high value of health care collaborative, the American College of Surgeons National Quality Improvement Program and others.

One of the critical functions and missions in the department is providing outstanding education for future generations of orthopaedic surgeons. Resident education needs to change to prepare residents to adapt to the changes in the healthcare delivery system and to understand and participate in efforts to demonstrate quality and improved efficiency while decreasing costs. The department is a leader in improving surgical skills education which helps accomplish all of the goals.

Central to the success of these aims is taking new approaches to funding departmental missions. The department has recently established a Finance Committee that is taking a very aggressive yet thoughtful approach to strengthening the department’s financial base. Among the initiatives the committee needs to pursue and is beginning to do so effectively are decreasing expenses within the department and decreasing hospital expenses to improve hospital revenue as well as departmental revenue. Among the specific strategies are adoption of voice recognition software and reassigning support staff to areas of the department where there is a need for improved efficiency. Perhaps the most important change needed for the department is a new facility for ambulatory orthopaedic and rehabilitation clinical services. As has been documented in an extensive study and site visits to other academic orthopaedic centers, the department’s clinic facilities are decades out of date in terms of patient convenience and provider efficiency. They also have problems with poor access and inefficient patient flow through the clinics, imaging and physical therapy. In every other academic orthopaedic department where a modern facility has been constructed the patient and provider satisfaction has dramatically improved, cost efficiency has improved and revenue generation has increased dramatically. In addition, the department needs to continue to refine the faculty practice plan to recognize and reward academic excellence, high quality efficient patient care and the development of new and productive clinical services.

During this time of change and department approach, the faculty, staff and residents must concentrate their energies and efforts on the enduring missions of the department while adapting to change and recognizing and taking advantages of important opportunities to strengthen the department and institution. Among the most critical elements in accomplishing the goals and initiatives outlined above, we will continue to attract talented students, residents, faculty and staff and give people an opportunity to develop their careers and make contributions to the advancement of the department and the institution. The department’s vision and commitment shared by faculty, residents, staff, nurses and alumni will ensure that the future of Iowa Orthopaedics and Rehabilitation will be better than the past.
2014-2015
DEPARTMENT OF ORTHOPAEDICS AND REHABILITATION
SCHEDULE OF LECTURESHIPS AND CONFERENCES

(Larson Conference Room, 01090 JPP, unless otherwise noted)

**Carroll B. Larson Shrine Memorial Lecture**
May 16-17, 2014
Paul D. Sponseller, MD, MBA
Sponseller Endowed Professor
of Pediatric Orthopaedics
Head, Division of Pediatric Orthopaedics
The Johns Hopkins Hospital
Baltimore, MD
Spring 2015 to be arranged. Contact Nancy Love @ (319) 356-1872

**2014 Senior Resident's Day**
June 13-14, 2014
Marybeth Exaki, MD
Professor of Orthopaedic Surgery
UT Southwestern Medical School
Director of Hand Surgery
Texas Scottish Rite Hospital for Children
222 Welborn Street
Dallas, Tx 75219

And

Mohit Bhandari, MD, PhD, FRCSC
Professor and Academic Chair,
Division of Orthopaedic Surgery,
Canada Research Chair in Surgical Outcomes,
Associate Chair-Research, Department of Surgery,
Executive Director,
Center for Evidence-Based Orthopaedics
McMaster University
Hamilton, ON
CANADA

**2015 Senior Residents Day**
June 12-13, 2015
Discussants to be arranged.

**30th Annual Hawkeye Sports Medicine Symposium**
December 11-12, 2014
Marriott Hotel and Conference Center
300 East 9th Street, Coralville
Guest speaker - to be arranged
Contact Kris Kriener @ (319) 353-7954

**Ponseti Races**
October 4, 2014
UI Sports Medicine Center
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2014 GRADUATING ORTHOPAEDIC RESIDENTS

**Jeremiah Dawson, MD**
Jeremiah was born in Willits, California (“Gateway to the Redwoods”, about 3 hours north of San Francisco) the youngest of six children. His father was and still is the local general surgeon serving Frank R. Howard Memorial Hospital in Willits. In order to provide character building exercises, they kept a hobby ranch with horses, 15-20 head of cattle, as many as 60 sheep and plenty of poultry. Jeremiah was active in 4-H since the age of 5 and thanks them for his lack of fear of public speaking and large animals. He was active in sports, wrestling since the 6th grade. He also ran cross country, swam and played football to stay in shape for wrestling and would like to thank Bob Colvig, his wrestling coach, for putting him through trials that make the rest of life tolerable.

He graduated valedictorian and wrestling league champion, a big fish in a small pond.

He then left small town life and went to the University of California, Santa Barbara to major in biological sciences. During this time he developed many close lasting friendships; including his future wife, Kristin Moreno, whom he met on a blind date in Los Angeles while visiting his eldest brother. This came just four months after his best and closest friend Randy Clark was murdered in an altercation in Chico, California. Kristin helped Jeremiah to grieve and stay on track.

He honed his Spanish and developed a love for orthopaedics. It was this love that brought him to Iowa.

Impossible to summarize their experience in Iowa in a few short sentences, they are changed for the better by exposure to MidWest culture. It was here that they brought their two children Violet and Clark into the world. The orthopaedic surgery that he learned here will now benefit Northern Californians as he returns full circle to practice general orthopaedics in Willits, California at the new Frank R. Howard Memorial Hospital that is under construction.

He would further like to thank his Mom and Dad, Carol and Tedd Dawson, his five brothers and sisters, and his wife and two kids who have been his readily available support system throughout.

**Jenniefer Kho, MD**
Jenniefer was born and raised in Glendale, California. Her mother and father emigrated from South Korea in their 20s with little in their pockets, but worked hard to support Jenniefer and her older brother. When Jenniefer was in grade school, her father accepted a job offer in Korea, where he worked until she graduated from college. Fortunately, she had a very caring grandmother who helped make sure Jenniefer stayed on track while her mother was at work.

She was accepted to UC Berkeley where she majored in biochemistry. Upon graduation, she worked at a research lab at UC San Francisco for one year.

Medical school was conducive to not only developing a great tan, but being exposed to the world of orthopaedics for the first time. Whether by chance or fate, she applied to University of Iowa for orthopaedic residency and was offered an interview. Although she nearly missed her interview due to a blisty Iowa snowstorm (“What?! A snowstorm?!”), she was so thankful she made it as she met wonderful people who would soon become her mentors.

Miraculously, this Cali girl survived five Iowa winters, and has so much to be thankful for. Not only has she received unparalleled training, but she has met great people, found the second love of her life (Penny the dog), and has gotten a taste of Hawkeye tailgating, cauliflower ears, Iowa corn, and fried Oreos. She will greatly miss her co-residents and will never forget the memories she shares with the 29 other amazing men and women, in particularly with Bullfrog, Dr. YumYum, Brooks Jr., Scheek, and Big Willey (in no particular order).

Philadelphia awaits Jenniefer, John, Penny, and George the cat, where she will further her training in hand surgery at Thomas Jefferson University.

She thanks her mother, father, brother, and grandmother for supporting her unexpected journey. Hopefully a warmer forecast is on the horizon.
Lucian (Luke) Warth was born and raised in Iowa City, and still considers himself a ‘townie’. He was the first of two children born to Ed and Melodie Warth. Melodie was an OR nurse at the University and later moved on to the Orthopaedic Spine Clinic. Early in life Luke thought he wanted to be an orthopaedic spine surgeon, but by the age of ten he thankfully realized that he was more interested in Dr. Found’s Magic tricks than the spine. Luke’s childhood was filled with summer baseball and fall Iowa football. His roots remain in Iowa and he will always be a Hawkeye. Luke grew up on the good side of the tracks, graduating from West High School, before moving on to college at Stanford University for his undergraduate education. Four years and several Rugby injuries later, he graduated with a major in Biological Sciences and a minor in Philosophy. After college graduation Luke returned home to Iowa City, where he worked as a research assistant for Dr. John Callaghan for a year prior to attending medical school at Northwestern University. A future in orthopaedics was never really in question, but it was during this time that Luke first came to enjoy research and love arthroplasty. He has been riding Dr. Callaghan’s coat-tails ever since. Luke attributes much of his success during this year to the friendship of Steve Liu, who taught him ‘the research shuffle,’ and has buffered him from several of Dr. Callaghan’s infamous ‘grasshopper enemas’.

On the first day of medical school orientation Luke had the good fortune to meet his future wife, Melissa. It was likely the pink shirt and aviators that sealed the deal. Melissa feigned indifference for nearly two years, but Luke’s charm eventually proved overwhelming. After a great 4 years in Chicago, Luke was thankful to match into orthopaedic residency at the University of Iowa and return home. He was even more thankful that he was able to convince Melissa to accompany him to Iowa City. Luke and Melissa were married during his 3rd year, and welcomed their son, James T. Warth, to the family during his 4th year of residency (both fruitful research rotations). Ed, Luke’s father, still lives in Iowa City and during residency has provided constant support, friendship, love and excessive amounts of food. He has nicknamed his grandson ‘Toad’. Ed, Luke’s Mother, passed away tragically in 1999. She is loved and remembered every day, and would be very proud of ‘Toad’.

After graduation Luke, Melissa, and James are moving to the Big Apple for a fellowship in joint arthroplasty at the Hospital for Special Surgery. Luke would like to thank his sister, Ali, who lives in Manhattan and has volunteered to babysit free of charge every Saturday for a year so that Luke and Melissa can get the most out of NYC.

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Cameron Schick, MD
Cameron was born and raised in Houston, Texas where he grew up with his younger sister, Katie, and parents, Robert and Shelley Schick. He studied Biology at the University of Iowa where he was a scholarship gymnast for the Hawkeyes from 1999-2003. During his recruiting trip in 1999, he experienced his first orthopaedic procedure. Dr. Albright, who was active in the recruiting process of student athletes interested in medicine, invited Cameron to scrub in for a case. It was this experience that piqued Cameron’s interest in orthopaedics.

After college, he attended medical school at the University of Texas Medical Branch in Galveston, Texas. He loved medical school, especially the intramural sports and fishing. He met his wife, Nicole, in anatomy lab during their first class of medical school. They were married in their last year, just five days before the Match. They were thrilled to both match at the University of Iowa after doing rotations here during medical school. During his last year of residency and while chief of the trauma service, Cameron and Nicole welcomed the arrival of their twin boys, Elliot and Brennan.

Cameron has loved his time in Iowa City. He appreciates the superior teaching and experiences provided within the department, as well as the camaraderie among the residents, and is grateful for the opportunity to be a resident here.

Upon graduation, Cameron will complete a Hand/Upper Extremity fellowship at the Indiana Hand to Shoulder Center in Indianapolis. After fellowship, he will join Bellevue Bone and Joint Physicians near Seattle, Washington.

Luke Warth, MD
Lucian (Luke) Warth was born and raised in Iowa City, and still considers himself a ‘townie’. He was the first of two children born to Ed and Melodie Warth. Melodie was an OR nurse at the University and later moved on to the Orthopaedic Spine Clinic. Early in life Luke thought he wanted to be an orthopaedic spine surgeon, but by the age of ten he thankfully realized that he was more interested in Dr. Found’s Magic tricks than the spine. Luke’s childhood was filled with summer baseball and fall Iowa football. His roots remain in Iowa and he will always be a Hawkeye. Luke grew up on the good side of the tracks, graduating from West High School, before moving on to college at Stanford University for his undergraduate education. Four years and several Rugby injuries later, he graduated with a major in Biological Sciences and a minor in Philosophy.

After college graduation Luke returned home to Iowa City, where he worked as a research assistant for Dr. John Callaghan for a year prior to attending medical school at Northwestern University. A future in orthopaedics was never really in question, but it was during this time that Luke first came to enjoy research and love arthroplasty. He has been riding Dr. Callaghan’s coat-tails ever since. Luke attributes much of his success during this year to the friendship of Steve Liu, who taught him ‘the research shuffle,’ and has buffered him from several of Dr. Callaghan’s infamous ‘grasshopper enemas’.

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Tameem Yehyawi, MD

Tameem was born and raised in the small town of Keokuk, Iowa. The love and support of his parents served to instill many values in their five children, including a strong work ethic and compassion for others. Growing up, Tameem enjoyed rough housing with his two older brothers who would occasionally beat up on him. They shared everything, including a love for sports and they remain his closest friends today. Having excelled in both wrestling and football throughout high school, Tameem earned a scholarship to play football at Truman State University in Kirksville, Missouri where he majored in biology. College football taught him many lessons about discipline and teamwork, but most importantly, it exposed him to the field of Orthopaedics.

After earning his bachelor’s degree, Tameem was accepted to the University of Iowa Carver College of Medicine. It was during medical school that he became active in Orthopaedic research and confirmed his desire to become an Orthopaedic surgeon. A few years later, he was honored to match at the University of Iowa’s Orthopaedic Residency program. As fate would have it, he developed a close friendship with another resident that became even more. Shannon has been the greatest blessing of his life and the couple is engaged to be married next May.

In August, Tameem will be entering the Sports Medicine Fellowship Program at Kaiser Permanente in San Diego, California. He is looking forward to advancing his surgical training, but will remain eager to return to the Midwest to start his practice and be reunited with Shannon and his family.

Tameem would like to thank the Iowa Orthopaedic faculty who have provided him tremendous mentorship and guidance throughout his residency. As for his fellow residents, they will be greatly missed and he is extremely grateful to have been surrounded by such intelligent, skilled, and compassionate individuals. Lastly, and most of all, Tameem would like to thank his brothers, Eyad and Nabeel, his sisters, Jackie and Gloria, his wonderful fiancé, Shannon, and his parents, Tahseen and Nancy, for their patience, unwavering support, and belief in him over the course of the past five years.

Michael Willey, MD

Michael Willey grew up in Onawa, IA. He attended West Monona High School with his future wife Lindsey Towne. They moved to Iowa City to attend the University of Iowa in 2001 and have not left since. After finishing his degree in Biomedical Engineering, he attended medical school at the University of Iowa Carver College of Medicine. He was fortunate to get the opportunity to be an orthopaedic resident at the University of Iowa. After residency he will complete a trauma fellowship at Iowa with Drs. Marsh and Karam.

Michael has many friends and family that he needs to thank for their support. His wife, Lindsey, has always provided endless love and support throughout their time together. She is a loving mother to his three children Audrey, Norah, and Owen. On top of all this, Lindsey is also a Physician Assistant in Tipton, IA. His parents, Greg and Rhonda, have always been dedicated to making sure that their children achieved their goals and knew the importance of hard work and honesty. His younger siblings Alisha, Steven, and Jacob were always entertaining growing up and kept him grounded throughout his training. As for the residents at the University of Iowa, he could not think of a more enjoyable and talented group of individuals to spend five years with in training.

After earning his bachelor’s degree, Tameem was accepted to the University of Iowa Carver College of Medicine. It was during medical school that he became active in Orthopaedic research and confirmed his desire to become an Orthopaedic surgeon. A few years later, he was honored to match at the University of Iowa’s Orthopaedic Residency program. As fate would have it, he developed a close friendship with another resident that became even more. Shannon has been the greatest blessing of his life and the couple is engaged to be married next May.

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Tom Ebinger, MD

Tom grew up in Cedar Rapids, Iowa. He received a bachelor’s degree in Molecular Biology from Yale University, he then returned home to Iowa for his medical training. He completed medical school and his residency in orthopaedic surgery at the University of Iowa and was fortunate to stay within the department for his fellowship in upper extremity surgery. Tom is extremely proud to be a part of the Iowa Orthopaedics family, he is also extremely thankful for all of the instruction he has received through his fellowship year. He would specifically like to thank his fellowship mentors, Dr. Brian Adams, Dr. Ericka Lawler, and Dr. Apurva Shah for their wisdom and guidance in hand surgery throughout his training. Most of all he would also like to thank his wife Laura, and his daughters Maggie and Molly, for their constant love and support.

Kevin D. Martin DO

Major, United States Army Medical Corps

Kevin is the University of Iowa Foot and Ankle fellow for 2013-2014. He was raised in rural Michigan on a dairy farm, after high school he enlisted in the United States Army as a Combat Medic and has continued his service as an Active Duty Physician. Kevin attended Western Michigan University with a BA in Biomedical Sciences, and completed medical school at Lake Erie College of Osteopathic Medicine. His orthopaedic residency was completed at William Beaumont Army Medical Center in El Paso Texas.

Kevin has been supported by his loving bride Emily Martin for the past 14 years and has been blessed with three children Luke, Blake and Vivian.

Upon completion of fellowship, Kevin will be stationed at Fort Carson Colorado to continue his serve in the Army.

Kevin would like to send his thanks to the entire University of Iowa Orthopaedic Department and his deepest appreciation to Drs. Amendola, Femino and Phisitkul for their commitment to education and excellence.
David P Patterson, MD

David is the University of Iowa Sports Medicine Fellow for 2012-13. He was born and raised in Northern California, attended the University of California at Berkeley and graduated with honors with a degree in Molecular and Cellular Biology. He then attended medical school at the Keck School of Medicine at the University of Southern California in Los Angeles. He was a Howard Hughes Medical Institute fellow during medical school before his training at the University of Washington and Harborview Medical Center.

After fellowship, David will join his wife as she pursues her own career in surgery as a plastic surgery resident. David would like to thank Drs. Amendola, Bollier, Hettrich, Nepola, Smoot and Wolf, as well as the numerous athletic trainers with whom he worked this year and the staff at both the Sports Medicine Institute and the Ambulatory Surgery Center. They have made it a truly educational and enjoyable experience.

Saran Tantavisut, MD

Saran is the current University of Iowa Orthopaedic Trauma and Adult Reconstruction Fellow for 2012-2014. He was born and raised in Bangkok, Thailand. He earned his medical degree and completed his orthopaedic residency training at Chulalongkorn University, Bangkok, Thailand. He then attended the arthroplasty fellowship program at the same university from 2009-2011. After fellowship at the University of Iowa, Saran will return to Bangkok this summer to join orthopaedic and adult reconstruction specialists of Chulalongkorn University.

Saran thanks his family for their love and support. He also wishes to give special thanks to Drs. Marsh, Karam, Callaghan and Nepola for all they have taught him. Thank you to all the residents and friends for their help, friendship and being a great team to such a successful outcome. It has been a great two years and he feels blessed to have been here.
The University of Iowa Department of Orthopaedics and Rehabilitation, along with the Iowa Orthopaedic Society, sponsors this research award involving medical students.

The *Michael Bonfiglio Award* originated in 1988 and is named in honor of Dr. Bonfiglio who had an avid interest in students, teaching, and research. The award is given annually at the medical convocation and consists of a plaque and a stipend. It is awarded to a senior medical student in the Carver College of Medicine who has done outstanding orthopaedic research during his or her tenure as a medical student. The student has an advisor in the Orthopaedic Department. However, the student must have played a major role in the design, implementation and analysis of the project. He or she must be able to defend the manuscript in a public forum. The research project may have been either a clinical or basic science project, and each study is judged on the basis of originality and scientific merit. The winner presents their work at the spring meeting of the Iowa Orthopaedic Society as well as at a conference in the Department of Orthopaedics and Rehabilitation.

This year the selection committee consisted of Dr. Brent Overton, President of the Iowa Orthopaedic Society, and Drs. Charles R. Clark, Jose Morcuende, and John Femino, all members of the Department of Orthopaedics and Rehabilitation. They recommended that T.J. Ridley, M4, receive the 2014 Michael Bonfiglio Student Research Award. T.J.’s award was based on his project, “Effect of BMI on Patients with Multiligament Knee Injuries”. His advisor is Dr. Matthew Bollier.

The Michael Bonfiglio Award is very prestigious, recognizing student research on the musculoskeletal system. This award has indeed attained the goal of stimulating such research and has produced many fine projects over the years.

The Department of Orthopaedics and Rehabilitation is very grateful for the Iowa Orthopaedic Society and our president, Dr. Brent Overton, for the generous support of this award.

Charles R. Clark, M.D.
The Michael Bonfiglio Professor of Orthopaedic Surgery
From left to right: Charles R. Clark, M.D., Michael Bonfiglio Professor of Orthopaedic Surgery; T. J. Ridley, M4, winner of the 2014 Michael Bonfiglio Student Research Award; Matthew Bollier, M.D.; and J. Lawrence Marsh, M.D., Interim DEO.
ABSTRACT

In contemporary total hip arthroplasty, instability has been a complication in approximately 2% to 5% of primary surgeries and 5% to 10% of revisions. Due to the reduction in the incidence of wear-induced osteolysis that has been achieved over the last decade, instability now stands as the single most common reason for revision surgery. Moreover, even without frank dislocation, impingement and subluxation are implicated in a set of new concerns arising with advanced bearings, associated with the relatively unforgiving nature of many of those designs. Against that backdrop, the biomechanical factors responsible for impingement, subluxation, and dislocation remain under-investigated relative to their burden of morbidity.

This manuscript outlines a 15-year program of laboratory and clinical research undertaken to improve the scientific basis for understanding total hip impingement and dislocation. The broad theme has been to systematically evaluate the role of surgical factors, implant design factors, and patient factors in predisposing total hip constructs to impinge, sublux, and/or dislocate. Because this class of adverse biomechanical events had not lent itself well to study with existing approaches, it was necessary to develop (and validate) a series of new research methodologies, relying heavily on advanced finite element formulations. Specific areas of focus have included identifying the biomechanical challenges posed by dislocation-prone patient activities, quantifying design parameter effects and component surgical positioning effects for conventional metal-on-polyethylene implant constructs, and the impingement/dislocation behavior of non-conventional constructs, quantifying the stabilizing role of the hip capsule (and of surgical repairs of capsule defects), and systematically studying impingement and edge loading of hard-on-hard bearings, fracture of ceramic liners, confounding effects of patient obesity, and subluxation-mediated worsening of third body particle challenge.

INTRODUCTION

In total hip arthroplasty (THA), the inroads to particle-induced osteolysis that have accompanied low-wear advanced bearings have left instability as now the single most common cause for revision surgery. Dislocation - usually due to impingement and lever-out (Figure 1) - has always been high on the list of reasons for clinical failures, despite THA as a whole being among the greatest successes of modern medicine. Increased research attention to instability is therefore justified even on grounds of its increased relative burden of morbidity. Additionally, due to the less-forgiving nature of various design features of contemporary advanced bearings, it has become increasingly evident that even without occurrence of frank dislocation, prelude impingement and subluxation events can cause serious problems in their own right. Some of these “new” concerns are particle and ion loads from edge loading of metal-on-metal bearings; stripe wear, squeaking, chipping, and liner fracture in ceramics; and impingement rim damage of thin liners in large diameter metal-on-polyethylene bearings.

Although dislocation is an unmistakable event at the clinical level, its unpredictability and its abruptness of occurrence have posed major hurdles to drawing direct causative conclusions from clinical experience. Rather, it has been possible only to infer general associations with plausible predisposing factors. Those associations have often been of only low or modest statistical power, even when working with patient cohorts that are unusually large by orthopaedic standards. Moreover, using large patient cohorts for associative studies has usually required trading-off against heterogeneity of potentially confounding factors (surgeon variables, implant variables, patient variables.) One exception has been our
group’s opportunity for long-term follow-up of single-surgeon dislocation experience under conditions where relatively few changes of implant or surgical technique took place\textsuperscript{6, 7}. This has been advantageous in terms of statistical power for documenting the effects of those few factors which varied (e.g., head size, usage of skirts), although there has been the obvious trade-off that many factors of potential interest unfortunately could not be studied since they did not vary. Despite the substantial challenges of clinical research in this area, reducing the incidence of problems in patients is of course the gold standard by which any presumed improvements for THA stability must be judged. However, clinical experience does not lend itself well to efficiently identifying direct cause-and-effect relationships in this area. Rather, impingement/dislocation research needs to take place in controlled settings that are reasonably representative of clinical circumstances, where individual influence factors can be systematically studied.

Historically, dislocation and impingement/subluxation events have been an under-developed area of laboratory orthopaedic investigation, owing in large part to the complexity of the phenomena involved and the logistical difficulty of implementing appropriate models. Up until the mid-1990s, only a handful of investigations had even been attempted in this area, largely restricted to geometric range-of-motion samplings either with bench surrogates or in simplified cadaver preparations\textsuperscript{8}. Recognizing the un-met clinical need and the scientific opportunity in this area, in 1996 our group began developing platform technology to enable systematic study of surgical factors, implant design factors, and patient activity factors bearing upon THA dislocation propensity. A key consideration in that work from the very beginning - continuing up into the present - has been that dislocations and impingement/subluxation events need to be addressed fundamentally as kinetic phenomena, i.e., that forces and moments, and local stresses in the tissues and materials involved, are what matter clinically. While inter-related with traditional kinematic (geometric) factors such as range-of-motion, it is these kinetic factors that govern whether a given impinging implant will or will not dislocate, and whether tissues and/or implant components will or will not be harmed during a given impingement event. Necessarily, however, including kinetic considerations greatly increases the complexity and difficulty of quantifying impingement/dislocation events.

The present paper summarizes our group’s now 15-year research effort in investigating of THA instability kinetics, results from which have been reported in 31 original full length articles and 4 graduate theses. The problem of instability has been addressed from four inter-related perspectives (Figure 2): implant dislocation studies, soft tissue involvement, impingement models, and clinical studies. The principal laboratory research methodology adopted has been finite element analysis (FEA). Contemporary capabilities in the field of computational modeling have reached a level of sophistication such that the role of physical experimentation has withered in many areas within the broad field of mechanics. An FEA approach to THA impingement/dislocation held the attraction that once appropriate investments were made in model development and validation, individual variables or combinations of variables could be investigated systematically and efficiently, in virtually unlimited depth and detail. Of course, to enable applying FEA in this area, it has been necessary to design and conduct a number of novel experimental studies to collect input data that previously had been unavailable. And, even more importantly, physical experimentation has been indispensable for model validation. Specific questions appropriate for laboratory study have been informed by clinical experience, both of the THA community as a whole, and within our own group.
Impingement and Dislocation in Total Hip Arthroplasty: Mechanisms and Consequences

**Dislocation FE Model Development and Validation:**

A necessary first step was to develop capability to simulate dislocations computationally, in three dimensions. While 3D stress analyses of THA components with well-prescribed external loadings had become relatively routine even as of the late 1980s, dealing with stresses due to internal interface contact was problematic, especially in situations where the respective contacting surfaces were undergoing large relative sliding motions due to bearing surface articulation. Building on some then-recent success with performing sliding contact FEA simulations of walking in the context of THA wear, numerical trials were undertaken in which the femoral head was driven to rotate further within the acetabular component, until the neck made contact with the liner rim. Head rotation through the normal range of motion involves only a small amount of resistance, from bearing surface frictional torque. Making head rotation continue after the onset of impingement, however, required overcoming the much larger resisting moment developing due to (head-center-eccentric) contact force buildup at the impingement site. This resisting moment proved crucially important, for two reasons. First, its maximum achievable value was useful as an **overall dislocation resistance metric** for given set of THA construct parametric conditions (i.e., specific implant design, component surgical positioning, and patient activity challenge.) Second, resisting moment was a discrete entity also lending itself to direct physical measurement at any instant of an impingement/subluxation event, thus providing a basis for **validation of the computational results** (Figure 3).

After developing numerical techniques to allow computation of the sudden high stress concentrations at the site of **de-novo** impingement contact, the numerical model was then extended to address lift-out head subluxation associated with pivoting about the impingement fulcrum. Onset of subluxation involved progressive diminution of the initially hemispherical (bearing) contact surface, with progressive build-up of contact stress at the site of head egress (Figure 4), diametrically opposite from the neck impingement site. Often, peak stress magnitudes computed for small contact cusp at the head egress site even exceeded stress magnitudes at the neck impingement site. (This phenomenon of subluxation-associated cusp stress concentration at the acetabular rim, initially encountered in 1996, has nowadays come to be familiarly known as edge-loading.)

A final step in first-generation model development was to generalize from single-axis to multi-axial head rotations, toward being able to simulate dislocation-prone physiologic patient maneuvers. This proved challenging computationally because the impingement site became then no longer a statically-located fulcrum, but rather a patch of extreme stress concentration, traveling along a substantial swath on the liner rim. In some instances of relatively glancing neck-liner contact, there could be up to between 10 to 20 degrees of additional head rotation between initial impingement and frank dislocation, reinforcing that conventional geometric range of motion is only a very loose surrogate for the true angular range of THA kinetic stability.

**Kinetics and Kinematics of Dislocation-Prone Maneuvers:**

While successful computational execution of the dislocation FEA formulation was a necessary step, deriving clinically meaningful information from that model depended also on physiologically realistic input data. At the time, unfortunately, there had been very little precedent for dislocation as a laboratory research topic, so data were lacking as to kinetics and kinematics of patient motions typically associated with dislocation. For that reason, studies were undertaken of THA age-matched individuals executing a battery of dislocation-prone maneuvers (leg-crossing, rising from a low seat, bending to tie a shoe, and four others), using an Optotrak® motion analysis system to record segmental kinematics of the pelvis and lower extremities, along with inverse Newtonian equilibrium analysis and optimization to determine muscle forces and articular contact force at the hip. Several dislocation-prone maneuvers involved hip
joint contact forces that were dramatically (sometimes even > 2x) higher than those conventionally reported for locomotion activities, owing to the upper body’s center of gravity being shifted well anterior of the hip centers, thus requiring high force outputs from the hip extensor muscles to maintain sagittal plane equilibrium, in turn therefore elevating hip joint contact force.

**Parametric Effects in Conventional Constructs:**

Having a physically validated three-dimensional FE model driven by physiologically grounded inputs opened the way for parametric studies of implant design factors, component surgical positioning factors, and patient motion challenge factors bearing upon THA dislocation. Variables parametrically considered included head size, liner lip chamfer angle, liner lip breadth, cup inset depth, cup backing diameter, cup liner offset, femoral stem offset, femoral component head/neck diameter ratio, presence/absence of a skirt, liner material characterization (UHMWPE elastic modulus and several variants of elasto-plastic behavior), component surgical orientation (cup abduction, cup anteversion, femoral component anteversion), and patient dislocation challenge (five posterior and two anterior risk maneuvers). The FE model was extended to also include peri-implant osseous structures, for purposes of quantifying dislocation propensity due to component-on-bone and bone-on-bone impingement (a consideration especially for larger head sizes.) Concurrently, work also was undertaken to extend the breadth of model validation by linking in with ongoing cadaveric testing at Baylor University.

From among the body of results for the many individual parameters considered, two broader-level sets of relationships became evident. First, regarding implant design factors, while both the peak moment developing to resist dislocation and the range of kinetic stability (i.e., the range of motion prior to frank dislocation) were sensitive to many individual attributes of implant design, there was nearly always a very direct trade-off between those two considerations. That is, individual design parameter changes that achieved improvements in peak resisting moment involved reduction in kinetic range of stability, whereas improved range of stability came at the expense of lower peak resisting moment. The second broader-level set of relationships involved surgical positioning. While it was always possible to identify a zone of component orientations that protected very well against dislocation for any given patient challenge maneuver, those orientations’ level of protection against certain other challenge maneuvers was much less. For example, cups that were ideally well positioned to avoid posterior dislocation from activities such as shoe tying or rising from a low seat were highly vulnerable to anterior dislocation from activities such as exorotation pivot or roll-over in bed, and vice-versa.

**Studies of Non-Conventional Constructs:**

Besides quantifying dislocation propensity and trade-offs for conventional unconstrained THA designs, the FE model lent itself also to exploring unconventional design concepts. One of these (Figure 5) was bi-curvilinear impingement surfaces; convex meridional curvature of the acetabular lip, and concave meridional curvature of the femoral neck, such that any neck-on-lip impingement would have the tendency to cause the neck contact site to “roll” radially outward on the lip (and radially downward on the neck), thus progressively building up more resisting moment than would occur for a conventional (non-rolling) impingement fulcrum. This indeed turned out to be the case: depending on the specific dislocation challenge considered, there was up to a 29% improvement in peak resisting moment, and (i.e., without trade-off) up to a 14° improvement in kinetic stability range. Also, because the mating radial curvatures between neck and liner led to line-like contact rather than point-like contact at the impingement site, there was up to 50% reduction in peak polyethylene contact stress. Another study of alternative design concepts involved constrained liners. This class of specialty devices had been conceived for last-resort attempts to maintain stability in patients with recurrent dislocations, and had been the subject of a number of clinical studies at our institution. Experiences had been highly variable both at our center and elsewhere, with some patients tending to re-dislocate even despite positive head capture (i.e., cup rim extending past 180° of arc), and with some implants undergoing dissociation due to hoop-stress-induced fracture of the equatorial metal restraining ring. A competing consideration was that intra-operative assembly - or in select circumstances, even closed reduction after an initial constrained liner dislocation - requires that the surgeon forcefully push the head into the cup.
in order to achieve the interference fit necessitated by the “undersize” cup opening. The FE model allowed systematically addressing these issues (Figure 6), to identify amount of cup opening undersizing that afforded a balance between difficulty of interference fit assembly versus resistance to head lever-out, and corresponding retaining ring dimensions. Physical validations were provided both by lever-out testing of resisting moments, and by “push-in” measurements of interference fit resistance in a series of implants with parametrically varied cup openings, custom-fabricated for this study by one of the collaborating manufacturers.

An alternative approach to recurrent dislocation lies in increasing the implant’s kinetic range of motion, rather than increasing its peak resisting moment. In concert with a clinical series at our institution\(^4\), laboratory studies of ranges of motion of tri-polar implant were undertaken, which showed than these devices indeed functioned very closely as intended\(^4\). (Those laboratory assessments needed to be done experimentally rather than computationally, because the FEA model’s capabilities at that time (1997-1998) were limited to dealing with just a single surface of articulation, whereas tri-polar implants involve two concentric “in series” surfaces of articulation.) This favorable short-term experience with tri-polar constrained implants for patients with recurrent dislocations has continued into the intermediate term\(^3\).

We also have found that in cases where the (dislocated) primary implant’s acetabular shell remains well fixed and undamaged, very good performance can be achieved by cementing in a tri-polar liner\(^3\), similarly to what is often done for worn conventional liners\(^2\).

**Capsule Contributions to Construct Stability:**

Another set of considerations bearing upon THA impingement/subluxation and dislocation involves the hip capsule. It has long been recognized that patients with capsular biomechanical deficit are at elevated risk of dislocation\(^4\), prior hip surgery being one major cause for capsule compromise. This is widely felt to be a principal reason why dislocation rates are consistently higher for revision THAs than for primaries\(^2\), especially for surgeons using extensive or even full\(^2\) capsule resection. Despite the intuitive attraction of implant designs and surgical component positioning that provide intrinsically maximum dislocation resistance, these intrinsic factors need to be viewed within the context of the overall THA construct, of which the capsule is an important part.

Capsule abnormality can take various forms, including thickness anomaly, stiffening/scarring, substance tears, detachments from bony insertions, and surgical incisions. Dealing with these different forms of capsule mechanical deficit involves different technical considerations intraoperatively. Ideally definitive repairs almost always involve trade-offs, especially the need for additional surgical exposure. Intraoperative decision-making would benefit from better information linking site and severity of capsule defect(s) to the corresponding dislocation propensity. Unfortunately for FEA purposes, however, this was another area for which there was almost no precedent knowledge base, so work was undertaken to biomechanically characterize the hip capsule, to enable its representation within the THA impingement/dislocation model. This involved systematic dissection of fresh-frozen normal cadaver hips, with mappings of anatomic attachments around the acetabula and femora, of capsule thickness, and of visually apparent fiber directions. Tensile testing of capsule sub-sections allowed compiling a database of mechanical properties as a function of anatomic location\(^2\).

The recorded loci of capsule attachment locations were registered to the bony surfaces of the existing FE model, so that the (three-dimensional) space encompassed by capsule tissue could be zoned into elements, and the corresponding distribution of mechanical properties assigned. Since the inner (i.e., synovial) surface of the capsule could sometimes wrap around portions of the enclosed implant and/or bony surfaces during various hip angulation maneuvers, and since the capsule could sometimes locally infold upon itself and/or be externally pinched, it was necessary to make provision computationally for an extensive set of surface-to-surface contact contingencies. Mainly because of these new complexities of contact, the computational run times for the FE dislocation models lengthened considerably - to days, or sometimes even weeks - when the capsule was included. However, despite this (initial) unwieldiness computationally, it was very clear from even the earliest capsule-inclusive FEA models that the capsule’s mechanical status was the single most important determinant of THA construct stability\(^3\). This provided motivation for investing additional developmental effort to further refine the sophistication of capsule representation in the model, and to streamline computational execution. The current capsule embodiment (Figure 7) involves 27 distinct material regions, each with fiber direction-based anisotropic local mechanical properties derived.
from additional cadaver dissections, along with CT and MR imaging. Building on the earlier work with tensile testing of strips of excised capsule tissue, the present capsule mechanical property values are grounded also in optimization-based matches with intact-joint load/deformation data. The computational runs now typically execute in 10 to 20 hours of clock time.

Given this identified importance of capsule integrity to THA stability, the need for capsule-focused physical validation of the overall construct FE model became paramount. This posed a unique challenge experimentally, in that baseline physical data ideally needed to be available that would reflect the full degree of THA stabilization provided by an intact capsule, for purposes of comparison with the corresponding baseline situation computationally. Conventional THA implantation in cadaver hip specimens was an unattractive option, since this would necessarily have required a capsule incision, which in a cadaver preparation could only be passively re-approximated with sutures, a very different situation than the full active healing that normally would occur clinically.

To address this challenge, specialty implant hardware was designed and built which replicated the intra-capsular geometry of conventional THA implants, but which could be implanted entirely without need for capsule incision. Briefly, there was a large metal collar which could be screw-anchored to the inner pelvic wall (Figure 8a), and whose underside had a recess which had been machined for purposes of subsequently seating a conventional THA acetabular component in a surgically appropriate position. After screw attachment to the inner pelvic wall, the collar served as a cutting guide for a circular hole to be sawed retrograde through the acetabulum. This exposed the native femoral head, which then was piecemeal-ablated and removed, working through the sawn acetabular portal. Next, from an entry point on the greater trochanter, a hole was bored approximately along the femoral neck axis, through which a metal rod was inserted. This rod, whose distal end was then screw-anchored in the proximal femur, had a proximal end that replicated the intra-capsular geometry of the THA femoral component neck and trunnion, and onto which a femoral component head could be seated through the acetabular access portal. The pelvic wall collar was then unscrewed, the THA acetabular component seated and screw-anchored into the collar’s underside recess, and the collar was then re-affixed to the pelvic wall. This resulted in replication of the intra-capsular aspects of conventional THA, while preserving full capsule integrity (Figure 8b). Thus-implanted hemipelvis specimens were in turn mounted within a purpose-built four degree-of-freedom servo-hydraulic hip simulator (Figure 8c), which had been programmed to replicate the (previously measured) kinematics and kinetics of various dislocation-prone maneuvers. A six degree-of-freedom load cell installed in the hip simulator allowed measurement of resisting moment during impingement/dislocation, directly corresponding to the resisting moment determined computationally. The agreement achieved between the computational and FE simulations was gratifying (Figure 8d.)

**Impingement of Hard-on-Hard Bearings:**

Following cadaver validations, parametric computational series were undertaken to determine the degree to which resistance to dislocation depended on capsule thickness, on the locations and extent of capsule detachment from bony insertions, and on (surgical) longitudinal incisions at various sites. Simulations were also run to assess stability improvements accompanying alternative suture repairs, and to assess the risk of failure of those repairs. Computationally, suture repairs could be conveniently simulated by numerically equivalencing (effectively, pinning together) pairs of finite element nodes on either side of the two tissue edges being attached. Nodal equivalencing also provided a direct basis for assessing suture failure risk, by means of querying the FEA algorithm’s internally-maintained datafile of resultant forces on all individual nodes. In the case of a pair of equivalenced nodes, these resultants were the forces necessary to keep the nodal pair held together, i.e., the local pull-apart force being resisted by the suture.
Posterior and postero-lateral capsule detachments, either from the acetabulum or the femur, involved pronounced decreases of construct stability. A useful single numerical metric for case-to-case stability comparisons is the mechanical energy required to cause dislocation, a parameter whose value could be readily calculated from the area under the curve of resisting moment versus imposed hip rotation angle. For flexion-dominated motion challenges, even relatively small (~1/8 circumference) posterior or postero-lateral detachments typically involved dislocation energy being reduced by 50% or more below levels for the intact capsule (Figure 9a). Repairs of such defects typically returned peak resisting moment values to within 10-20% of baseline levels. Unrepaired full-length longitudinal capsule incisions likewise were found to substantially compromise construct stability, also in a very site-dependent manner (Figure 9b).

Computed pull-out forces for individual sutures for various repair alternatives for various capsule defects are shown in Figure 10. It can be appreciated (shaded band in Figure 10d) that many repair arrangements that ideally would restore near-normal construct stability for severe defects unfortunately involved the suture sites being at substantial risk of failure. These often dramatic decreases of hip stability occurring for adversely located capsule deficits serve to underscore that capsule compromise may be the predominant predisposing factor for THA instability. Also, the substantial stress concentrations developed adjacent to local detachment sites, and the high tensile stresses at some of the suture repair sites, are consistent with the high incidence of early failures often seen in posterior structure repairs. Since most THA dislocations occur for flexion-dominated motion challenges, the model’s results help explain the lower dislocation rates documented in clinical series where the posterior capsular structures either have not been violated or have been robustly repaired.

For hard-on-hard (HoH) implants, the extremely localized nature of contact at neck impingement and head egress sites suggests stress magnitudes and stress gradients far more severe than those for comparable impingement events in metal-on-polyethylene implants. A difficulty in quantifying HoH impingement, however, is that whole-implant finite element zonings with enough spatial resolution to accurately capture stresses at impingement/egress sites are logistically prohibitive from a computational resource viewpoint. To overcome this difficulty, a novel multi-stage finite element strategy was devised. Regional results output from conventional-zoning-resolution FEA of the global THA construct were used as input for high-zoning-resolution FEA at impingement and egress sites. This formulation (Figure 11) allowed ascertaining the extent to which local stress concentrations from impingement/subluxation would challenge the bulk failure strengths of the HoH constituent materials. Independent validation of the computations was possible by comparison with mathematically idealized contact of a sphere (i.e., the femoral head) on a torus (i.e., a circularly radiused acetabular lip), a special case of the well-established family of canonical Hertzian engineering contact analyses for bi-curvilinear elastic surfaces.

Additionally, a new metric was introduced to enable assessing the relative propensity for debris to be generated from the localized scraping occurring at impingement and egress sites. The basis for this new metric was the...
Influence of Cup Design on Edge-Loading:

Given the current level of concern with edge loading of HoH bearings, another utility of FEA lies in investigating how changes of implant design might serve to moderate the effect. One important design parameter in that regard is the meridional curvature radius of the liner lip. The larger this radius, the broader the width of the cusp-shaped edge loading rim contact patch, other factors being equal. However, increasing the lip’s meridional curvature radius also has the effect of reducing the liner’s articular coverage area on the femoral component head, thus reducing construct stability, and therefore making it easier for an edge-loading situation to develop in the first place. A study was undertaken to parametrically explore this interplay for MoM bearings, as a function of surgical positioning of the cup69. Dependent variables of primary interest were kinetic range of motion, resistance to dislocation, contact stress on the cup lip, and propensity for debris generation due to scraping.

Seven different cup lip radii were considered, from 0 mm (i.e., a sharp lip edge) up to 6 mm, for a range of cup orientations involving univariate combinations of eleven different angles of abduction and ten different angles of anteversion. The data showed that increasing the liner lip radius affected both the kinetic range of motion and the energy necessary to cause dislocation, more strongly than did changes of cup orientation (Figure 12). More
than half of the permutations of cup orientation and lip radius that were considered were found to cause peak (von Mises) edge-loading stresses in excess of the yield strength of wrought CoCr alloy. Computed scraping wear tended to exhibit similar dependency upon lip radius and cup inclination as was observed for peak stresses.

**Significance of Femoral Head Size:**

Besides cup design, femoral component geometry is also important to construct performance. By increasing the kinematic range of motion prior to impingement, large femoral heads in principle provide improved stability. However, surgical compromises exist, since concomitantly increasing cup size requires increased acetabular bone stock removal, making accurate cup placement more technically challenging. Historical guidelines for the “safe zone” of implant orientation are based on much smaller head geometries, and consider only implant stability. These concerns have been addressed by multivariate analysis of cup orientation and head size (Figure 13a). Larger head sizes, while providing improved stability and decreased bearing surface stress (Figure 13b), demonstrate similar sensitivity to cup placement as smaller head sizes, especially in terms of requiring high accuracy of anteversion (Figure 13c).

**Fracture of Ceramic Liners:**

Another concern regarding HoH impingement/subluxation is the possibility of liner fracture, in the case of ceramics. This is a very different issue than the now-historical problem with taper-seating/impaction fractures of first generation ceramic femoral heads\(^4\), which material and design improvements have reduced to a marginal concern (0.004% prevalence\(^5\)). Fracture of contemporary ceramic liners, however, occurs on the order of a thousand times more frequently (3.5%\(^6\), 1.12%\(^7\), 0.22%\(^8\)), typically in high-flexion postures or maneuvers plausibly involving impingement. Because of the ongoing particle/ion problems with MoM and the expanding need for joint replacements in younger and more active patients, further improving the performance of ceramic liners is an important goal. This consideration motivated development work to add formal fracture prediction analysis to the existing capabilities of the impingement FEA model\(^9\). (To the authors’ knowledge, this has been the first application of engineering fracture mechanics to THA acetabular components.) As with earlier aspects of the FEA effort, the rationale was to lay groundwork to understand how specific design factors, surgical factors, and patient factors interact to influence implant performance.

In brittle materials such as ceramics, mechanical stress levels in the near vicinity of a crack tip exhibit what is known as a singularity, effectively an unbounded increase toward infinity. In a given brittle material object subjected to a given load, whether or not cracks will nucleate, whether or not they will propagate once nucleated, and whether or not such propagation will be stable (as in fatigue situations, for example stress fracture of bone) as opposed to unstable/catastrophic, can be quantified in terms of a family of mechanical parameters known as stress intensity factors. Calculating stress intensity factors in FEA requires a specialized meshing structure in the local region of interest. This makes fracture analysis a difficult proposition in complex structures such as orthopaedic constructs, because it requires a priori knowledge of the fracture site, and it requires successive rezonings of the mesh for cracks undergoing propagation.

Determining the extent to which fracture vulnerability of ceramic liners depends upon component malpositioning, and identifying which specific patient challenge maneuvers pose the greatest fracture risks, were two research questions lending themselves to answer by means of a novel meshing approach devised to bypass these traditional difficulties in FEA fracture mechanics\(^9\). The essential idea was to automatically zone local FEA meshes for incipient cracks at a large number of provisional locations serially in the liner, allowing the respective stress intensity factors to be compared in order to identify the site(s) most vulnerable to crack nucleation and propagation for any given liner orientation and impingement challenge.

Interestingly, during flexion-dominated impingement challenges such as low-seat-to-stand, the location of greatest fracture vulnerability consistently turned
Depending on the specific circumstance recently been identified as a risk factor for ceramic liner normal-weight versus obese patients, since obesity has designs and optimal cup orientations might differ for morbidly obese (BMI=50) patients. (The study’s clinical motivation was to determine whether optimal cup advancements with a new computational formulation constituted actual simulation of a fracture event. Recent advancements with a new computational formulation termed eXtended Finite Element Modeling (XFEM) have enabled that next key step. Working collaboratively with a group of industry-based (Abaqus®) software developers, we now have succeeded in computationally achieving impingement-induced crack propagation to change from stable to unstable/critical. The causality is not well understood. One possible mechanism is that thigh-on-thigh soft tissue contact during flexion and adduction induces laterally directed “external” force on the hip, tending to push the head laterally outward from the cup. To study this phenomenon, the THA dislocation FE model was augmented to include thigh-on-thigh soft tissue contact (Figure 16a). The model then was used to assess the extent to which BMI and cup position tended to increase instability due to this mechanism. Parameters investigated were head size, neck offset, and cup inclination, for eight graded levels of BMI (Figure 16b), four of which were in the morbidly obese range. Physical validation performed using a Tekscan pressure mat showed a 16% average discrepancy of computed versus measured thigh-on-thigh.
was inviting to test whether there might be an association between severity of impingement rim damage and presence of embedded particles. An examination was therefore performed of the walking-only group. Taken together with the retrieval analysis. The specimens that had had the interspersed acetabular liners were then counted using digital image analysis. The specimens that had had the interspersed acetabular liners were then counted using digital image analysis.

**Impingement Convection of Third Body Debris:**

Besides relatively immediate and direct problems in terms of implant damage, impingement is deleterious also because of its indirect linkage with bearing surface wear acceleration, via third-body debris. It is well recognized that the presence of third-body particles within the bearing space can substantially increase wear rates, even by order-of-magnitude. However, large sub-populations of the third bodies typically found embedded in weight-bearing regions of polyethylene bearing surfaces are grossly too large to have migrated through the extremely thin clearance zone between the head and cup surfaces. One possible explanation is that large third body particles might be actively transported into the bearing space by obligate fluid convection during impingement/subluxation events. Since impingement-induced indentation rim damage of UHMWPE cups is a commonplace finding in acetabular components retrieved for revision or at autopsy, it was inviting to test whether there might be an association between presence/severity of rim indentation damage and the presence/number of embedded third-body particles. An examination was therefore performed of 194 consecutively retrieved cups, which revealed statistically significant association (p<0.01) between presence of impingement rim damage and presence of particles embedded in the bearing, and highly statistically significant correlation (p<0.0001) between severity of impingement rim damage and presence of embedded particles.

This finding provided encouragement that it might be possible to identify the mechanism. Toward that end, a computational fluid dynamics finite element model was developed of the obligate fluid motions accompanying THA impingement/subluxation. The computational results were validated by comparison with laser velocimetry of fluid velocity distributions in a directly corresponding physical model. The FE results showed vigorous obligate indraw of peri-articular joint fluid into the bearing region during impingement/subluxation (initially at more than a hundred-fold multiple of the subluxation velocity of the femoral head). The computed fluid pathlines showed that third body particles initially freely suspended just outside the bearing space could reach locations within 11° of the pole of the cup. As a final step to directly demonstrate causality, new metal-on-polyethylene THA head-liner pairs (n=10) were mounted in the servohydraulic joint motion simulator, with the implants immersed in a synovial fluid analog bath within which CoCrMo particles were suspended. All THA component pairs were subjected to 7200 cycles of simulated normal level walking. Half of the pairs were also subjected to 20 intermittent impingement/subluxation events, one per 360 walking cycles. At termination of testing, the number and location of particles embedded on the bearing surface of each of the acetabular liners were then counted using digital image analysis. The specimens that had had the interspersed impingement/subluxation events had 15.7 times as many embedded particles (p=0.017) as the specimens with walking cycles alone. The femoral heads from the walking+impingement group also had dramatically more severe scratching damage than those in the walking-only group. Taken together with the retrieval...
results associating impingement rim damage with third body embedment, and with the finite element results documenting vigorous obligate fluid in-draw accompanying impingement/subluxation, these motion simulator results convincingly indicate that impingement/subluxation events potently facilitate third body debris gaining access to wear-critical regions of the bearing surface.

Directions forward:
This summarized body of research hopefully has contributed to reducing an important set of clinical problems. However, it remains a work in progress. Going forward, three broad areas of effort suggest themselves. The first of these is to continue developing and improving the current finite element model paradigm, by specific tangible steps such as validating the ceramic liner fracture analysis, by including passive constraint effects and active loadings of individual muscles at the hip, by refining (and validating) the scraping damage metric, etc., and by ongoing internal technical improvements algorithmically. The second broad direction forward, by contrast largely outside the scope of the present model paradigm, is that there needs to be a much better base of knowledge regarding the numbers and frequencies of impingement/dislocation challenge events in THA patients' habitual activity regimens. In a controlled laboratory setting, replicate captures of kinetic and kinetic data for well-prescribed challenge events are encouragingly reproducible\textsuperscript{13}, but this alone provides an unduly narrow window into the real-world of impingement and dislocation challenges that THA constructs encounter. The third broad direction forward is that the work needs to move beyond its present paradigm of delineating causality relationships for individual parameters. Basis needs to be developed for integrating multiple concurrent risk factors, in order to be able to make reasonable trade-offs between directly competing individual variables, and to have rationale for relative weighting of multiple independent variables.

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MINIMIZING ALTERATION OF POSTERIOR TIBIAL SLOPE DURING OPENING WEDGE HIGH TIBIAL OSTEOTOMY: A PROTOCOL WITH EXPERIMENTAL VALIDATION IN PAIRED CADAVERIC KNEES

Robert W. Westermann, MD1, Thomas DeBerardino, MD2, Annunziato Amendola, MD1

ABSTRACT

Introduction: The High Tibial Osteotomy (HTO) is a reliable procedure in addressing uni-compartmental arthritis with associated coronal deformities. With osteotomy of the proximal tibia, there is a risk of altering the tibial slope in the sagittal plane. Surgical techniques continue to evolve with trends towards procedure reproducibility and simplification. We evaluated a modification of the Arthrex iBalance technique in 18 paired cadaveric knees with the goals of maintaining sagittal slope, increasing procedure efficiency, and decreasing use of intraoperative fluoroscopy.

Methods: Nine paired cadaveric knees (18 legs) underwent iBalance medial opening wedge high tibial osteotomies. In each pair, the right knee underwent an HTO using the modified technique, while all left knees underwent the traditional technique. Independent observers evaluated postoperative factors including tibial slope, placement of hinge pin, and implant placement. Specimens were then dissected to evaluate for any gross muscle, nerve or vessel injury.

Results: Changes to posterior tibial slope were similar using each technique. The change in slope in traditional iBalance technique was -0.3º ±2.3º and change in tibial slope using the modified iBalance technique was -0.4º ±2.3º (p=0.29). Furthermore, we detected no differences in posterior tibial slope between preoperative and postoperative specimens (p=0.74 traditional, p=0.75 modified).

Discussion & Conclusions: Alterations in posterior tibial slope are associated with HTOs. Both traditional and modified iBalance techniques appear reliable in coronal plane corrections without changing posterior tibial slope. The present modification of the Arthrex iBalance technique may increase the efficiency of the operation and decrease radiation exposure to patients without compromising implant placement or global knee alignment.

INTRODUCTION

High tibial osteotomies (HTOs) have been used effectively for decades1-3. Coventry and Insall popularized HTOs in the 1970’s-1980’s4,5 and they continue to prove a reliable treatment for medial compartment osteoarthritis with associated varus deformity6,7. Today, medial opening wedge HTOs are most commonly indicated in younger patients (<60 years) who display medial compartment osteoarthritis with an associated varus limb alignment and have preserved knee motion8. There are several commercially available systems and described techniques to guide surgeons in performing HTOs. In general, most current techniques advocate similar principles including medial-sided opening wedge9 osteotomies, incomplete osteotomies (i.e. incomplete proximal tibial bone cut resulting in plastic deformation of the lateral cortex) and rigid medial fixation10. The Arthrex iBalance system incorporates these core principles and has demonstrated clinical efficacy and safety11,12.

Alterations in posterior slope may occur with HTOs, both with closing wedge and opening wedge techniques. Careful attention must be paid to posterior tibial slope as this is related to global knee stability and function13,14. In particular, opening wedge osteotomy is related to increasing the posterior tibial slope and creating a relative patella baja. These alterations in posterior tibial slope have been demonstrated in clinical series with the use of medial opening wedge HTOs15. The ability...
Minimizing Alteration of Posterior Tibial Slope During Opening Wedge High Tibial Osteotomy

of a given technique to accurately correct alignment while maintaining tibial slope is, therefore, an important consideration.

The iBalance technique utilizes several radiographs and has several intraoperative steps and is reliant on both AP and lateral fluoroscopic views\(^2\). The safety of patients as well as the operating surgeon are concerns that warrant merit in the setting of fluoroscopy-reliant procedures\(^3\).\(^4\). There are suggestions that thyroid cancer and cataracts are potential complications of prolonged radiation exposure to orthopaedic surgeons.\(^5\)\(^6\). Efficient use of operative time is also thought to decrease chances of complications and improve patient safety. Given this, an optimal technique would allow for ideal implant placement, decrease operative time and limit intraoperative radiation to both the patient and surgeon.

The purpose of this study is to validate a modified technique for the Arthrex iBalance HTO system. The goals of the technique modification are to increase efficiency and decrease use of intraoperative fluoroscopy. We assessed a modified operative HTO protocol and compared it to the standard technique using paired cadaveric knees. The principle outcome parameters assessed number of procedure steps, amount of fluoroscopy used, implant placement and maintenance of tibial slope. We hypothesize that this technical modification will increase efficiency and decrease fluoroscopy utilization without comprising implant placement or sagittal alignment.

MATERIALS AND METHODS

Nine paired cadaveric knees (18 legs) (ages 44-72, mean 57.3) were utilized. In each pair, the left knee underwent a HTO using the traditional iBalance technique\(^7\), while the contralateral knee underwent the modified technique. [Appendix] All HTOs were performed by two experienced orthopaedic surgeons (AA and TB).

Modifications to the iBalance Technique:

Standard preoperative planning and correction calculations were carried out in both groups. The aim of each correction was to direct the mechanical axis through a point representative of 62.5% of the tibial plateau (medial = 0% to lateral = 100%).

The surgical incision and approach including periosteal elevation, posterior dissection of the popliteus and identification of the retropatellar space in the modified technique was identical to the standard procedure. In the new modified technique, the next step is obtaining an optimal AP fluoroscopy view is obtained with the leg in 20-30° of flexion [Figure 1]. The view must be on-axis (i.e. looking down) the medial plateau’s posterior tibial slope, and have neutral rotation so that the lateral tibial cortex intersects the mid-portion of the fibular head at its widest point. With the optimized AP image, there was no need to switch between AP and Lateral views throughout the procedure using the modified technique and no lateral view was needed throughout the procedure. The neurovascular (NV) shield was then assembled and placed posteriorly 15° relative to the tibial plateau, and confirmed by AP fluoroscopy. Assembly of the adjustable base, keyhole guide and alignment guide was performed and the patellar tendon protector was placed. The medial aspect locator was positioned 2.5 cm distal to the joint line, and the AM tab was placed on the anteromedial surface of the tibia. Using the four circles in the adjustable base, the size of the implant and instrumentation was confirmed using a perfect AP view [Figure 1]. The new trocar fixation pin was then placed, and the hinge pin was inserted after assuring the distance from the pin to lateral plateau was at least 1.25x greater than the distance from the hinge pin to the nearest lateral cortex (x) to prevent propagation of the osteotomy to the joint surface. A second new trocar fixation pin was then inserted through the anteromedial hole in the base, and the alignment handle was removed. The remaining steps including drilling of keyholes, application of the cutting guide, osteotomy, installation of Opening Jack, grafting, seating the implant placement and anchors was performed identically in the traditional and modified iBalance groups.

Overall, the technique modification reduces the fluoroscopy images required. By obtaining a perfect AP view, two of the nine total steps were eliminated from the setup.
Hinge Pin Placement
Following the procedures, gross dissection was carried out to assess the placement of the hinge pin. Careful measurements were performed calculating the distances between the hinge pin and tibial plateau and hinge pin and lateral cortex. Measurements were performed by three independent observers. Traditional and modified techniques were directly compared using two-tailed student’s t-tests.

Implant Placement
The placement of the implant was assessed relative to the medial tibial cortex. Measurements quantifying implant overhang (or step-off) relative to the posteromedial tibial cortex were made in millimeters. Measurements were performed and compared in both standard and modified groups.

Assessment of Tibial Slope
The ability of the modified technique to maintain native posterior tibial slope was also assessed. Posterior tibial slope was measured on pre-operative lateral radiographs in all specimens. These measurements were compared to post-procedure lateral radiographs after final implant placement. All digitized fluoroscopic images were exported to JPEG files for independent observer measurements. Slope was assessed by first defining the proximal tibia’s anatomic axis (PTAA). [Figure 2] The PTAA was determined by identifying the anteroposterior diameter of the tibia at 5cm distal to the tibial tubercle and 15cm distal to the joint line, and dividing these distances by two. Next, a line connecting these two half-way reference points was extended proximally to the level of the tibial plateau, then posteriorly at a 90-degree angle. Secondly, a line connecting the highest-most points of the anterior medial plateau and posterior medial plateau was drawn. The posterior tibial slope was then measured, and represented by the “theta” in the above image.

RESULTS

Implant Placement
The mean distance from the hinge (perfect circle) to ridge in knees undergoing the traditional iBalance technique was 14.8 ± 3.52mm (range 10.9 mm to 18.6 mm). The mean distance from the hinge (perfect circle) to ridge in knees undergoing the modified iBalance technique was 15.1 ± 2.84 mm (range 10.2 mm to 19.2 mm). There were no significant differences observed between the two groups (p=0.85).

Tibial Slope
The preoperative posterior tibial slope values were similar in paired knees. Preoperatively, the mean posterior tibial slope in the traditional group was 7.9º ± 1.2º compared to 8.1º ± 1.6º in the modified group (p=0.8). There were no significant differences in postoperative tibial slope between the traditional (7.6º ± 2.3º) and modified (7.7º ± 3.2º) groups (p=0.9). The mean difference in pre-procedure and post-procedure posterior tibial slope observed using the traditional iBalance technique was -0.3º ±2.3º. The mean difference in pre-procedure and post-procedure posterior tibial slope observed using the modified iBalance technique was -0.4º ±2.3º. No significant differences were noted between the traditional and modified groups in terms of mean difference between slopes (p=0.9). Both the traditional and modified groups maintained native posterior tibial slope as there were no detected differences in posterior tibial slope between preoperative and postoperative specimens (p=0.74 traditional, p=0.75 modified). Interclass correlation coefficients were calculated to be 0.84 and 0.62 in the pooled preoperative and postoperative measurements, respectively.
Injuries to the popliteus muscle were identified in 3 specimens (2 traditional technique specimens and 1 modified technique specimen). There were no identified injuries to nerve, blood vessels and no identified peri-implant or lateral cortex fractures in either of the two groups.

**DISCUSSION**

In this study, we evaluated a novel technique modification for the Arthrex iBalance HTO system. The modified technique used nearly one-third less fluoroscopic views during setup, and eliminated two of the nine steps required to align instrumentation for the iBalance HTO. After performing HTOs with the modified technique, we critically analyzed hinge pin placement and maintenance of posterior tibial slope and compared this to traditional iBalance techniques. Modifications to HTO techniques continue to evolve. Current trends are leading to technique simplification. Principle objectives when modifying an operative technique should be to increase patient safety and procedure efficiency.

The technique modification lead to less fluoroscopy images necessary for completion of the iBalance HTO procedure. This is beneficial in two ways: efficiency of the operation and decreasing radiation exposure. Patient, surgeon, and surgical team safety should always be considered during fluoroscopy reliant procedures24. Techniques used to prevent excessive radiation exposure include wearing lead, keeping a safe distance and wearing protective eyewear. Improvements to techniques such as the modification presented provide an additional avenue to avoiding excessive radiation.

With decreased fluoroscopic views (specifically lateral views), the ability of the new technique to provide adequate and safe implant placement was a potential concern. We found no differences in hinge pin or final component placement between the traditional and modified groups. Hinge pin placement is important and when placed improperly the lateral cortex may be at risk for fracture. Intraoperative and postoperative fractures of the lateral cortex, when combined, have been reported in up to 8.6% of cases25. We observed no cases of intraoperative lateral cortex fracture in either the traditional or modified techniques in the present study. Given this technique modification, we aimed to assure safety in hinge pin placement and therefore avoiding iatrogenic

### Table 1: Mean measurements of the 3 independent observers in assessment of preoperative and postoperative posterior tibial slope measurements. Note, no significant changes in posterior tibial slope occurred with placement of iBalance HTOs using either traditional or modified techniques.

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### Table 2: Interclass Correlation Coefficients calculated by pooling all preoperative posterior tibial slopes, and comparing the three readers. The ICCs demonstrated indicate high observer agreement.

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![Table 1: Mean measurements of the 3 independent observers in assessment of preoperative and postoperative posterior tibial slope measurements. Note, no significant changes in posterior tibial slope occurred with placement of iBalance HTOs using either traditional or modified techniques.](image1)

![Table 2: Interclass Correlation Coefficients calculated by pooling all preoperative posterior tibial slopes, and comparing the three readers. The ICCs demonstrated indicate high observer agreement.](image2)
fracture to the lateral cortex. The modified technique compared well with the traditional technique in terms of hinge pin placement, final component placement, and absence of lateral cortex fracture. Maintenance of posterior tibial slope is an important consideration in tibial osteotomies as slope ties closely to knee stability. Careful attention should be paid to preoperative sagittal knee alignment, especially in the setting of cruciate injury and/or knee instability. Population norms for preoperative tibial slope ranges from 0° to 18°. This compares well with the present cohort who averaged 8.0° of posterior tibial slope. Posterior tibial slope has been demonstrated by Brouwer et al to differ by almost 2.4° after medial opening wedge osteotomies. Posterior tibial slope in our study decreased by an average of 0.4 degrees with the modified technique, and 0.3 degrees with the traditional technique; these differences in posterior tibial slope were not statistically significant. There were no significant differences in post-procedure posterior tibial slope between groups (p=0.9). Therefore, tibial slope was adequately maintained using this technique modification as changes to posterior tibial slope were insignificant in both groups.

The use of paired cadaveric knees, experienced orthopaedic surgeons and independent observers analyzing data were strengths of the present study. A weakness of the study is evaluated only one surgical technique. Findings may not be generalizable to all opening wedge HTO techniques.

CONCLUSIONS

Both traditional and modified iBalance techniques appear reliable and reproducible in coronal plane corrections without changing posterior tibial slope. The present modification of the Arthrex iBalance technique may increase the efficiency of the operation and decrease radiation exposure to patients without compromising implant placement or global knee alignment.

REFERENCES


APPENDIX

New Modified Arthrex iBalance HTO Surgical Technique

Objective- Validating the New Modified Surgical Technique

Preoperative Planning

Using the full-length, standing A/P radiograph, a line is drawn from the center of the femoral head to the center of the tibial-talar joint. This demonstrates the patient’s mechanical axis. Another line is drawn from the center of the femoral head to a point midway in the lateral knee joint. A final line is drawn from the center of the tibial-talar joint to the same point in the lateral knee joint. The angle formed by the intersection of these two lines determines the degree of correction required to return the patient’s mechanical axis to the point of intersection on the lateral side. Prior to final fixation, the alignment will be verified by external examination and fluoroscopy. This point is located at 62.5% of the width of the proximal tibia (i.e., 80 mm [width of proximal tibia] x .625 = 50 mm).

Surgical Approach

Step 1

Plan a longitudinal incision midway between the tibial tubercle and the posterior border of the tibia. Start the incision just distal to the joint line and extend distally 7-9 cm.

Step 2

Clear/dissect tissue to the level of the pes/Sartorius fascia. Plan an L-shaped, inverted L-shaped, or vertical incision through the periotenuse and upper aspect of the Sartorius attachment on the pes anserine bursa. If inverted L-shaped incision was chosen the inverted portion of the L-shaped incision should be at least 1cm distal to the joint line and parallel to the tibial slope to ensure avoidance of the joint space.

Step 3

Identify the retropatellar tendon space and expose with the Cobb Elevator. Partially elevate the proximal aspect of the pes anserine tendons from their distal insertion through the periotenuse incision. Sharply dissect deeply to the proximal and anterior fibers of the superficial MCL. The Cobb Elevator may be used to complete the dissection posterior and distal.
Step 4

Advance the Posterior Elevator along the medial aspect of the tibia to the posterior border. Slide the tip of the elevator deep to the popliteus musculature, fascia tissue and periosteum. From the posterior border, continue to advance the elevator deep to the popliteus musculature and toward the fibular head. When fully inserted, the elevator tip should rest under the popliteus muscle. Remove the elevator and palpate along the posterior margin of the tibia to ensure adequate elevation of the popliteus musculature, fascia and periosteum.

Step 5

Assemble the NV Shield and Handle. Insert the NV Shield through the elevated sleeve. Ensure that the tip of the NV Shield remains in contact with the bone surface during the entire insertion in the same manner as used with the Posterior Elevator. When fully inserted, the NV Shield tip should rest deep to the popliteus muscle. Confirm the NV Shield position is oriented approximately 15˚ from the tibial plateau with the AP fluoroscopic view described above. Important to use the right size NV shield in order to ensure adequate soft tissue elevation posteriorly throughout the desired length of the osteotomy. Remove the NV Shield and Handle.

Setup the Fluoroscope as Follows

Large C-arm must approach the patient from the lateral side of the operative knee for optimal maneuverability and viewing. Support the leg in a fixed position 20-30 degrees of flexion.

Position fluoroscopes monitor such that it can be viewed from the operative field.

Adjust the rotation and alignment of the image on the fluoroscope monitor such that the image corresponds to the actual positions of the femur, tibia, anterior and posterior knee.

Establish the tibial AP view focusing on aligning and maintaining two key points:

Medial Tibial Plateau: Align the posterior medial tibial plateau with the anterior medial tibial plateau until they appear as a single line.

Lateral Tibial Cortex: Align the lateral tibial cortex rotationally until it crosses the widest point of the fibular head at approximately 30-50%.
With the fluoroscopic AP view described above, the size of the iBalance HTO implant and instrumentation is confirmed. The 4 holes/circles on the Adjustable Base illustrate the 4 potential (SM, MD, LG, XL) end/hinge points of the osteotomy. Once the sizing is confirmed, assemble the Hinge Pin Aimer, Biplanar Alignment Mount, and Hinge Pin Aimer Collet Nut onto the Adjustable Base and set to the determined size (SM, MD, LG, XL).

Step 7
Place the New Trocar tipped Fixation Pin into the anterior fixation pin hole on the Adjustable Base. Do not fixate into bone.
Maintaining the AP fluoroscopic view described above. Check to ensure the following conditions are met:

- The Medial Aspect Locator is directly against the medial aspect of the tibia approximately 2.5cm distal to the joint line.
- The AM Tab is against the anteromedial surface of the tibia.
- Maintaining the Medial Aspect Locator and AM Tab against the cortices, the instrumentation is aligned to the specific AP fluoroscopic view described above until the Hinge Pin Hole appears as a complete/perfect circle. Confirm that the distance from the Hinge Pin to the lateral plateau is at least 1.25 times greater than the distance from the Hinge Pin to the nearest lateral cortex.

Insert already placed New Trocar Fixation Pin into bone via Mallet until the flange on the Fixation Pin seats against the base.

If the Hinge Pin hole is too close to the lateral plateau, adjust the position by rotating it around the frontal Fixation Pin, keeping the Medial Post and the AM Tab in contact with bone. This will lower the Hinge Pin hole away from the tibial plateau. If the Hinge Pin hole remains too close to the intra-articular surface, reevaluate the initial position of the instrumentation and return to the beginning of Step 7.

Insert a second New Trocar Fixation Pin through the anteromedial hole in the Base. Remove the Alignment Handle.

***Refer to the iBalance HTO Surgical Technique for the rest of the procedure***
ABSTRACT

Background: A laterally tracking patella is commonly seen in patients with chronic recurrent lateral patellar dislocations. Clinical appearance of the J-sign occurs when the patella is congruent with the trochlear groove in flexion and moves over the lateral border of the femoral condyle as the lower leg reaches complete extension. A Fulkerson osteotomy procedure corrects this maltracking of the patella by medially transferring the tibial tubercle. There are many radiographic patellofemoral indices that can be used to describe this incongruence about the patellofemoral joint. The current literature supports the use of the tibial tubercle-trochlear groove (TT-TG) index in determining the appropriate amount of medialization of the extensor mechanism. However, there is little agreement on how far to transfer the tibial tubercle to best achieve maximum patellofemoral congruency. It is the senior author’s belief that lateral patellar edge (LPE) measure on voluntary quadriceps active hyperextension MRI scan has the strongest correlation with final operative tibial tubercle transfer distance needed to achieve maximum patellofemoral congruency.

Purpose: The purpose of this study was to show that the voluntary quadriceps active hyperextension MRI measurement of lateral patellar edge (LPE) has the strongest correlation with final operative tibial tubercle transfer distance needed to achieve maximum patellofemoral congruency compared to all other patellofemoral indices measured on axial MRI scans with the knee in passive extension, voluntary active knee flexion to 30 degrees, and voluntary quadriceps active hyperextension.

Methods: Forty-three Fulkerson osteotomy patient charts were reviewed retrospectively. Three pre-operative axial MRI views were then examined and measured for Tibial Tubercle- Trochlear Groove (TT-TG), lateral patellar edge (LPE), bisect offset (BSO), and lateral patellar displacement (LPD). Each patient had three MRIs: one with the knee resting in extension, one in voluntary quadriceps active hyperextension, and one in voluntary quadriceps active 30 degree flexion. Statistics were then calculated using Statistical Package for the Social Sciences (SPSS) (IBM corp).

Results: Tibial tubercle transfer distances required to achieve congruency intraoperatively correlated moderately (0.500-0.300) and were statistically significant (alpha .050) for passive extension MRI measurement of TT-TG (Pearson 0.403, alpha 0.010) and LPD (Pearson .362, alpha 0.022); voluntary quadriceps active hyperextension TT-TG (Pearson 0.487, alpha , 0.001); voluntary quadriceps active flexion TT-TG (Pearson .548, alpha < 0.001), LPE (Pearson .332, alpha 0.029), and LPD (Pearson 0.446 alpha .003).

Conclusion: The hypothesis that voluntary quadriceps active hyperextension MRI LPE measurement best correlated with tibial tubercle transfer distance was incorrect. The data collected showed correlation and statistical significance for voluntary quadriceps active flexion LPE with required tibial tubercle transfer distance (Pearson 0.34, alpha 0.026). The MRI measurement that best correlated with tibial tubercle transfer distance was voluntary quadriceps active flexion measure of TT-TG (Pearson .556, alpha < 0.001).

Keywords: Patellar instability; lateral patellar subluxation; Fulkerson osteotomy; lateral patellar edge (LPE); lateral patella displacement (LPD); tibial tubercle- trochlear groove (TT-TG); bisect offset (BSO); anatomy; radiographic landmarks

INTRODUCTION

The decision for operative correction of lateral patella instability hinges largely on qualitative reports of instability, the J-sign, and the apprehension test. Quantitative measures do exist, however, that utilize MRI scans of passive knee extension, voluntary active quadriceps knee extension, and voluntary quadriceps active knee flexion to 30 degrees. These add objective data, which can help to supplement clinical decision-making in determination.
Correlation of Radiographic Patellofemoral Indices with Tibial Tubercle Transfer Distance

Correlation of how far to transfer the tibial tubercle. Currently the literature supports the use of tibial tubercle to the trochlear groove (TT-TG) distance in preoperative planning of the distance the tibial tubercle needs to be transferred to achieve correction of the extensor mechanism. The purpose of this case series is to show that the voluntary quadriceps active hyperextension MRI measurement of lateral patellar edge represents the terminal phase of the J-sign and has the strongest correlation with actual tibial tubercle transfer distance as determined intraoperatively by direct observation and palpation of the knee extensor mechanism congruency with concurrent femoral nerve stimulation.

**Goals of Analysis:**
1) Compare preoperative MRI measurements of tibial tubercle-trochlear groove (TT-TG), lateral patellar edge (LPE), bisect offset (BSO), and lateral patellar displacement (LPD) to actual tibial tubercle transfer distance to see which has the highest correlation.

**MATERIALS AND METHODS**

**Imaging:**
In total, 43 Fulkerson osteotomy patients were retrospectively reviewed. Each patient had received three knee MRI scans using a Siemens Tesla 3. Each patient had a scan with the knee voluntarily actively flexed to 30 degrees, in passive full extension, and in voluntary active quadriceps hyperextension as part of the standard MRI workup for patients undergoing a Fulkerson osteotomy. All the patients undergoing Fulkerson osteotomy had a history of recurrent lateral subluxations and obvious patellofemoral maltracking on both clinical exam and quadriceps active knee extension MRI.

**Clinical Information:**
All of the patients underwent a Fulkerson osteotomy between the years of 2006-2012.

**Measurements:**
Each of the following patellofemoral indices were measured before surgery at voluntary active 30 degrees of knee flexion, passive extension, and voluntary active hyperextension. All measurements were performed in the axial plane. In order to normalize for the size of the patella, a bisect offset (BSO) measurement was made. First, a line was drawn tangential to the posterior aspect of both the medial and lateral femoral condyles. A perpendicular line then was drawn through the deepest point of the sulcus. The BSO is the ratio of the patella lateral to the perpendicular line compared with the total width of the patella (Figure 1A)\(^3,8\) To measure lateral patellar displacement (LPD), a line was drawn tangential to the posterior aspect of both medial and lateral femoral condyles. A perpendicular line was then drawn through the apex of the medial femoral condyle. The distance from this line to the most medial part of the patella was then measured (Figure 1B)\(^3,6\). Lateral patellar edge (LPE) is identical to LPD, except the apex of the lateral condyle was used instead of the apex of the medial condyle (Figure 1C)\(^3,2\).

To measure TT-TG, a reference line was drawn posterior to both the medial and lateral condyles then horizontal lines drawn between the deepest point in trochlear groove and apex of the anterior tibial tubercle perpendicular to the reference line. The distance was then measured between the tibial tubercle and trochlear groove (Figure 2)\(^3,4,6\).
Statistics:
Data was then analyzed using the SPSS (IBM Corp). The statistical methods used included Pearson Correlation Coefficients and Chi Square Analysis. Statistical significance was set at p=.05.

RESULTS
Forty-three patients were included, with ages ranging from 13-51 years old with an average age of 24 (Table 1). Nineteen of the patients were male and 24 were female.

The MRI measurements for passive knee extension, active knee extension, and active knee flexion to 30 degrees are summarized on Tables 2-4 respectively. The average final operative tibial tubercle transfer distance was 21.6mm (4.53mm standard deviation, 30mm maximum, and 12mm minimum).

MRI scan of passive quadriceps knee extension had patellofemoral indices measures of TT-TG (22.6mm average, 4.18mm standard deviation, 12.7mm minimum, 31.1mm maximum), LPE (8.40mm average, 6.44mm standard deviation, -5.7mm minimum, 19.3mm maximum), LPD (18.5mm average, 8.53mm standard deviation, 2.70mm minimum, 38.2mm maximum), and BSO (4.97mm average, 4.29mm standard deviation, 1.21mm minimum, 19.8mm maximum).

MRI scan of active quadriceps knee hyperextension had patellofemoral indices measures of TT-TG (23.2mm average, 4.27mm standard deviation, 14.0mm minimum, 31.9mm maximum), LPE (15.5mm average, 6.03mm standard deviation, 1.8mm minimum, 28.2mm maximum), LPD (25.8mm average, 8.15mm standard deviation, 5.80mm minimum, 41.1mm maximum), and BSO (10.7mm average, 10.5mm standard deviation, 1.6mm minimum, 39mm maximum).

MRI scan of quadriceps active knee flexion to 30 degrees had patellofemoral indices measures of TT-TG (18.0mm average, 5.58mm standard deviation, 9.20mm minimum, 34.0mm maximum), LPE (8.63mm average, 6.35mm standard deviation, -5.80mm minimum, 24.0mm maximum), LPD (15.1mm average, 10.3mm standard deviation, 2.60mm minimum, 42.9mm maximum), and BSO (3.71mm average, 3.42mm standard deviation, 0.450mm minimum, 18.6mm maximum).

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Table 3: MRI measurements active knee extension

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In the analysis of actual tibial tubercle transfer distances with the measures made on the three different preoperative MRI scans actual tibial tubercle transfer distances correlated moderately (0.5-0.3) and were statistically significant (alpha .05) for passive extension MRI measurement of TT-TG (Pearson 0.403, alpha 0.012), LPE (Pearson 0.155, alpha 0.338), LPD (Pearson 0.363, alpha 0.021), BSO (Pearson -0.149, alpha 0.359). MRI measurements compared with actual transfer distance are summarized on Table 5.

### DISCUSSION

The purpose of this study was to show that LPE measurement on a voluntary quadriceps active MRI scan has the highest correlation with final operative tibial tubercle transfer distance. Our hypothesis that voluntary quadriceps active hyperextension MRI LPE measurement best correlated with actual tibial tubercle transfer distance (determined by intra-operative end point of visualization and palpation of the extensor mechanism showing no overlap of the patella on the lateral femoral condyle with femoral nerve stimulation) was incorrect (Pearson 0.155, alpha 0.338).

The measurement with the highest correlation of all measures with actual tibial tubercle transfer distance was voluntary quadriceps active 30 degrees of knee flexion measure of TT-TG (Pearson 0.548, alpha < 0.001). This is in contrast to the universally accepted TT-TG measurement which is done in passive full knee extension as described Dejour et al.² While we did include these measures in our calculations, quadriceps active knee flexion had the highest correlation in achieving maximum congruency at the patellofemoral joint as determined intraoperatively.

Among all of the MRI scans when the leg was held in mid-air with the quadriceps contracted (quad active flexion) and the knee in 30 degrees of voluntary flexion, LPE had the highest correlation with final tibial tubercle transfer distance of any LPE measurement (Pearson 0.332, alpha 0.029). However, all LPE measurements correlated less than TT-TG measurement in quad active flexion with final tibial tubercle transfer distance.

These findings where the measurement of TT-TG is more reliable when the patella in the trochlear groove in flexion is consistent with finding of McDermott et al. that demonstrated that TT-TG should be used in at least a 1:1 transfer distance ratio when the goal for preoperative planning is to achieve maximum congruency at the patellofemoral joint.

### CONCLUSIONS

In conclusion our hypothesis was incorrect that quadriceps active measure of LPE is the best predictor of how far the tibial tubercle needs to be transferred to in order to eliminate the J-sign and achieve maximum patellofemoral congruency of the extensor mechanism with femoral nerve stimulation at the time of surgery. The findings of this study are consistent with the recommendation in the current literature of the use of TT-TG in at least a 1:1 transfer distance ratio when the goal for preoperative planning is to achieve maximum congruency at the patellofemoral joint.

### REFERENCES


ABSTRACT

Osteochondral lesions of the talus are being recognized as an increasingly common injury. They are most commonly located postero-medially or antero-laterally, while centrally located lesions are uncommon. Large osteochondral lesions have significant biomechanical consequences and often require resurfacing with osteochondral autograft transfer, mosaicplasty, autologous chondrocyte implantation (or similar methods) or osteochondral allograft transplantation. Allograft procedures have become popular due to inherent advantages over other resurfacing techniques. Cartilage viability is one of the most important factors for successful clinical outcomes after transplantation of osteochondral allografts and is related to storage length and intra-operative factors. While there is abundant literature about osteochondral allograft transplantation in the knee, there are few papers about this procedure in the talus. Failure of non-operative management, initial debridement, curettage or microfractures are an indication for resurfacing. Patients should have a functional ankle motion, closed growth plates, absence of cartilage lesions on the tibial side. This paper reviews the published literature about osteochondral allograft transplantation of the talus focusing on indications, pre-operative planning, surgical approaches, post-operative management, results and complications of this procedure.

INTRODUCTION

Osteochondral lesions of the talus are being recognized as an increasingly common injury, and may occur in up to 50% of acute ankle sprains and fractures, particularly in association with sports injuries. They are most commonly located postero-medially (57%) or antero-laterally (43%), while centrally located lesions are uncommon. There is a consensus regarding non-operative management of an asymptomatic osteochondral lesion of the talus, but in symptomatic patients, non-operative treatment has been reported to be successful in only 45% of the cases. Surgery is often indicated in these cases and multiple techniques have been proposed. Smaller lesions can be treated with arthroscopic debridement and drilling/microfracture, with satisfactory results in more than 80% of the patients. On the other hand, large osteochondral lesions have more significant biomechanical consequences and often require resurfacing. The three most common treatments are: osteochondral autograft transfer (OATS)/mosaicplasty from the knee, autologous chondrocyte implantation (ACI), or similar methods such as micronized cartilage matrix (BioCartilage, Arthrex, Naples, Florida) or juvenile cartilage fragments (DeNovo, Zimmer, Warsaw, Indiana); and osteochondral allograft transplantation. OATS and ACI have both been reported to have successful results in up to 90% of the patients with large lesions. Allograft transplantation procedures have become popular due to inherent advantages over other techniques. When compared to OATS/mosaicplasty, allograft has no donor site morbidity, no curvature mismatch, no fibrocartilage growth between plugs, and can be used in cases with irregularly-shaped defects. In addition, there is scant evidence to support the assumption that cartilage from the knee can withstand the tremendous forces sustained by the talar dome. Compared to ACI, and other cartilage scaffolds, allograft is a single stage procedure that also replaces the subchondral bone, and can be applicable to the shoulder of the talus, therefore may be biomechanically more suitable.

While there is an abundant literature about osteochondral allograft transplantation in the knee, there are few papers about this procedure in the talus. Cartilage viability is one of the most important factors for successful clinical outcomes after transplantation.
of osteochondral allografts. Donor chondrocytes can be damaged during storage and/or preparation of the graft, but also recipient cartilage can be damaged during surgery. Osteochondral allograft can be stored frozen or fresh, with the latter system having better results in terms of cellular viability, stiffness and matrix content both at the time of implantation than on the long term. Storage length can modify the features of fresh allograft. Williams et al. reported that chondrocyte viability and viable cell density remained unchanged after storage up to 14 days and then declined at 28 days, proteoglycan synthesis declined at 14 days and no significant differences were detected in glycosaminoglycan content and in biomechanical properties after storage for 28 days. During surgery, osteochondral grafts require multiple physical manipulations that are prone to cause iatrogenic injury and apoptotic cell death. Harvesting of the donor osteochondral graft from a larger piece of osteochondral tissue may subject the articular cartilage to mechanical damage and subsequent cell death. Motorized coring devices are likely to cause even greater damage and cell death than manual trephines. The subsequent surgical step involves creating an osteochondral defect in the recipient bone with a motorized coring instrument. Drill injuries to articular cartilage can cause extensive apoptosis in the surrounding cartilage that extends outwards from the initial injury site over time. As a result, a rim of relatively acellular matrix surrounds the recipient site. This apoptotic response has been hypothesized to impede effective cartilage integration in cartilage repair procedures. Finally, repetitive impacts necessary to insert donor grafts can cause an extensive cell death. Currently, fresh osteochondral allograft are used in clinical practice, but the recommendation for storage length vary widely between authors, ranging from 24-48 hours to 42 days.

**Indications and contraindications**

Acute lesions are usually treated by excision particularly if the fragment is small, displaced, or comminuted. Indications for repair are controversial, but if the fragment is large (> 35% talar dome surface area) with a cartilage surface intact, repair may be attempted, particularly with an anterolateral approach. In chronic lesions, although conservative treatment has fair success rate, most authors consider a three to six month nonoperative management the standard first-line approach for non-displaced lesions. An initial period of immobilization in a cast or controlled ankle motion brace followed by protected weight-bearing, pain medication, physical therapy for range of motion (ROM) and strengthening, and orthotic shoe-wear modification have been utilized.

Indications for surgery varied significantly among studies, and in some cases were not reported at all. In general, failure of non-operative management is an indication for surgical intervention. Initial surgical treatment should likely be some form of debridement, curettage or microfracture so there is a stable bleeding base. Failed initial debridement is an indication for resurfacing, with OATS/mosaicplasty or ACI performed first. Generally, osteochondral allograft transplantation is considered as a rescue procedure if they fail, but can be done as a first resurfacing treatment in high-demand patients, or in large lesions that cannot be treated successfully with other resurfacing techniques. Patients should have functional ankle ROM, closed growth plates and absence of cartilage lesions on the tibial side. Contraindications for surgery include degenerative joint disease, reflex sympathetic dystrophy, uncorrectable malalignment, ligamentous instability, active infections and malignancy. Generally, a calcaneal osteotomy or a supramalleolar osteotomy and correction of instability may be of value. Allografts are particularly suitable for large defects with bone loss, where some flexibility is necessary to fill the defect.

Allograft can be either a circular plug, press-fit, or block-shaped to address different locations and different lesion sizes. Plug-shaped allograft are indicated for contained lesions but in some cases larger defects may require the use of multiple plugs in the so-called snowman technique, which consists of placing and fixing the first plug, then drilling a second recipient site next to or partially over the first one. On the other hand, block-shaped allograft are indicated for irregularly shaped lesions, uncontained lesions involving the shoulder of the talus, and lesion that cannot be reached perpendicularly with the plug technique.
Planning

Pre-operative planning includes X-rays, CT scan, bone scan, and MRI to define the location, size, cartilage surface, and joint condition. Plain X-rays include weightbearing antero-posterior (AP), lateral, and mortise views (Fig 1). A plantar-flexed mortise view may better visualize posteromedial lesions; conversely, dorsiflexed radiographs are indicated to detect an anteromedial or anterolateral lesion. A Canale view (15 degrees pronation of the foot and the tube angled 75 degrees cephalad) is useful to assess the talar profile^2^5. The sensitivity of routine radiography is 50% to 75%, whereas pickup on bone scan is 99% sensitiv^2^. MRI is indicated if radiographic results are normal and allows a good evaluation of the cartilage surface, underlying stability of the fragment, surrounding bony edema, and other soft tissue injuries^2,26,27^ (Fig 2). There are controversies on the ability of MRI to accurately assess the dimensions of the lesion, due to overestimation related to bone edema. Some authors prefer to associate a CT scan for a more accurate planning^2,10^. Plain radiographs and MRI are sent to the tissue bank in order to obtain a whole talus of a matching size, but the final measurement is up to the surgeon. An allograft differing up to 2 mm from the native talus is considered acceptable^28^.

Surgical approaches

Most areas of the talar dome can be accessed perpendicularly without the necessity for a malleolar osteotomy. In fact, Muir et al. demonstrated that, on average, only 17% of the medial talar dome and 20% of the lateral talar dome could not be accessed without an osteotomy. After an anterolateral osteotomy, they reported an increase of 22% in sagittal exposure, while malleolar osteotomies provided access to the entire medial and lateral talar dome areas with a residual central 15% of the talar dome remaining inaccessible perpendicularly. Critical to all methods of osteotomy is a precise reduction and fixation to avoid fibrous nonunion or malunion. For centrally located lesions an anterior approach to the ankle joint should be performed.

Medial approach

A 10 cm medial incision is carried out from 3 cm above the joint line to the tip of the malleolus and then curved anteriorly toward the tubercle of the navicular. The saphenous vein must be retracted anteriorly. The capsule is incised at the anteromedial corner allowing visualization of the joint and lesion. The tibialis posterior tendon is protected with a small Homan retractor. The medial...
malleolus is predrilled and a step cut\textsuperscript{20} or an oblique osteotomy\textsuperscript{22} is performed, and the fragment is retracted posteriorly. Fluoroscopy can be used if necessary to direct this cut (Fig. 3). The amount of talar dome exposed can be modified by making the osteotomy exit slightly more laterally, but this amount still does not give complete access to the talus. The most posterior capsular attachment can be released to allow retraction of the malleolus on the deltoid ligament. Two Steinmann pins with a Hintermann distractor can be used to improve exposure\textsuperscript{8,12,28} (Fig. 4).

**Lateral approach**

A 4 to 6 cm longitudinal incision is made medial to the fibula and centered on the ankle joint line. The branches of the superficial peroneal nerve should be protected. The extensor retinaculum is incised and the extensor digitorum longus is retracted medially. The joint capsule is incised in line with the incision. Slight plantar flexion of the ankle will further facilitate exposure. For large lesions extending posteriorly, an anterior fibular periosteal flap can be created including the origin of the anterior talofibular ligament and, if necessary, the calcaneofibular ligament. The talus can then be drawn forward and rotated downward with the help of a Kirschner wire “joy stick” that is driven through the body of the talus. When a fibular osteotomy is needed, a 6 cm incision is made laterally over the distal fibula, starting from the tip of the lateral malleolus and extending proximally. A microsagittal saw is used to perform a transverse fibular osteotomy 1 cm proximal to the joint line. The distal syndesmotic ligaments are incised, and the distal fibula retracted inferiorly. Two Steinmann pins with a Hintermann distractor can be used to improve exposure\textsuperscript{28}. To improve reduction, some authors suggested placing a semitubular plate and a lag screw and then removing them before the osteotomy\textsuperscript{16}.

**Anterior approach**

A longitudinal incision is made on the anterior aspect of the leg starting 7.5 cm proximally and extending to about 5 cm distal to the joint. The deep fascia is divided in line with the skin incision. The interval between the anterior tibialis and extensor hallucis longus tendons is developed and the neurovascular bundle is retracted laterally with the long extensor tendons of the toes, and the anterior tibial tendon is retracted medially. The periosteum, capsule, and synovium are incised in line with the skin, and the full width of the ankle joint is exposed anteriorly by subcapsular and subperiosteal dissection\textsuperscript{32}. To increase exposure, temporary joint distraction can be applied with a unipolar external fixator\textsuperscript{10}.

**Surgical techniques**

**Plug-shaped allograft**

The osteochondral defect is visualized and measured in a medial-lateral direction. Debridement of the chondral surface is carried out with curettes, in order to expose the damaged area and assess its real dimensions. A guide pin is drilled perpendicular to the articular surface and it is used to select the adequate cannulated allograft sizer, that is then replaced with an appropriately sized OATS graduated reamer. The cartilage and the subchondral bone
are reamed out at about 7-8 mm deep until a bleeding surface. Care should be taken not to injure the cartilage of the tibial side. The reamer and the guide pin are then removed (Fig. 5). The allograft talus is affixed on the OATS holder and carefully examined as well. The donor talus is marked on the medial (or lateral) side using the sizer. The OATS workstation bushing of corresponding size is placed into the top housing over the graft, and set to the exact angle necessary to match the recipient’s contour perpendicularly. Once the correct inclination has been determined, the housing is securely fastened. The graduated donor harvester is drilled through the allograft talus, and the graft is carefully extracted. A graduated OATS dilator is inserted in the reamed portion of the recipient talus to reach 0.5 mm dilatation. The medio-lateral dimension of the recipient site is measured again with a ruler. The allograft core is secured in the specifically designed forceps and trimmed by a saw free hand to achieve the appropriate shape and medio-lateral length. Then the allograft is inserted in the native talus with a gentle impaction (Fig. 6). If necessary, additional fixation can be provided to an unstable graft with chondral darts or pins or screws.

**Block-shaped allograft**

The talus lesion is identified and debrided to stable articular cartilage margins and bleeding cancellous bone. The edges are cut square with a fine saw to allow for correct geometric fitting of the allograft. The dimensions of the lesion are marked onto the corresponding location of the fresh allograft talus. The graft is then cut with an oscillating saw, and it is stabilized with one or two countersunk titanium mini-fragment (2.0 mm) headed cancellous screws.

At the end of the surgery malleolar osteotomies are fixed with screws or plates and the syndesmosis should be repaired and fixed with a syndesmotic screw through the plate (if necessary). Intraoperative fluoroscopy should be performed to confirm the placement and fit of the graft and the alignment of the malleolar osteotomy (Fig. 7) and the ankle should be axially loaded and put through ROM to mold the graft.

**Post-operative protocol**

Different protocols have been reported after surgery. In general, patients are immobilized in a splint or a short leg cast and non-weightbearing after surgery. Subsequently, a below-knee fracture boot or a splint is applied and active, assisted ROM of the ankle is permitted outside of the boot. Weightbearing as tolerated is started at 6-8 weeks postoperatively, and patients are fully weightbearing by 12 weeks. A physical therapy program focusing on joint mobilizations, strength, and balance is initiated at eight weeks. The authors performing both plug- and block-shaped allograft used the same protocol for all the patients. Imaging to follow healing includes X-rays, but an MRI or CT scan may be utilized to ensure there is bony union of the graft.

**RESULTS**

There are few papers about osteochondral allograft of the talus, and most of them have low level of evidence and small sample size. Improvement of function, reduction of pain and good patient satisfaction are reported in all these studies. Different outcome scores were used, so a direct comparison between studies is not possible. Additional surgery after the index procedure is common, with ankle arthroscopy, hardware removal, non-union or malunion of malleolar osteotomy, supramalleolar or calcaneal osteotomy been described. Success rates of osteochondral allograft of the talus are reported to range between 73% and 100%. Failures can be treated with a revision allograft transplantation (bipolar or not), ankle fusion or total ankle arthroplasty.
Gross et al.\(^8\) retrospectively reviewed nine patients with stage IV lesions of the talus treated with a block-shaped allograft. At a mean follow-up of 12 years (range, 4–20), ankle arthrodesis was performed in three cases because of resorption and fragmentation of the graft, rather than arthritic deterioration. The average overall survival of the nine grafts was nine years (range, 3–19). Two grafts appeared to be raised 1 mm above the host articular surface. One graft was 50% resorbed, with no evidence of osteoarthritis, whereas the other exhibited an area of fragmentation that involved less than one-third of the graft. No evidence of gross or microscopic rejection was found.

Raikin\(^8\) reviewed 15 cases of fresh block-shaped allograft of the talus. At a mean follow-up of 44 months (range, 26-88), some evidence of collapse or resorption of the graft was observed in 10 patients. Additionally, nine ankles demonstrated some narrowing of the joint space overlying the graft area. Two patients underwent ankle fusion.

Görtz et al.\(^10\) followed up prospectively, using a clinical database, 11 patients (12 ankles) treated with a block-shaped allograft. At a mean follow-up of 38 months (range, 24-107), two failures were reported (one underwent arthrodesis and one revision allograft), 90% of the patients were satisfied, 80% reported less pain and 60% reported improved function.

Hahn et al.\(^11\) retrospectively reviewed 13 patients with a block-shaped allograft at a mean follow-up of 48 months. All the patients were all satisfied with the results, all but one had osteophytes and other mild arthritic changes were seen in two patients. Five patients had complications related to the allograft and needed additional surgery (four had hardware removal and one had debridement of an impingement spur). All 13 allografts healed, but in two cases it took longer.

Janis et al.\(^12\) in their retrospective study on 15 block-shaped allografts of the talus, evaluated at a mean follow-up of 1.6 years (range, 0.9-2.1), reported no graft-related complications, no subsequent surgical procedures and no delamination. Six grafts revealed mild lucency but no resorption, four lesions had a step-off of less than 1 mm and two had step-off of 1 mm or greater. Arthrosis was mild in four patients and severe in two.

Adams et al.\(^13\) in a retrospective study reported the results of eight patients treated with a block-shaped allograft. At a mean follow-up of 48 months (range, 25-91), three grafts had partial lucency at the interface with the host bone, but they were asymptomatic. In one case lucency and graft resorption were suspected at X-rays, but CT scan showed only lucency on the anterior graft-host interface. In one case a non-union of the graft was suspected.

Berlet et al.\(^14\) retrospectively reported the results of 12 patients at a mean follow-up of 3.3 years (range, 2.0-4.6). A plug-shaped allograft was used in six cases and a block-shaped allograft in the remaining cases. No graft-related complications were noted. Eight patients had MRI at the last follow-up showing graft incorporation in seven cases, radiolucencies were observed in three cases. The authors also reported on a patient that did not meet the inclusion criteria of the study, but showed graft collapse after 2.7 years, which required revision. The authors reported that their sample size was underpowered to determine a statistical difference in SF-12, but not in AOFAS outcomes.

El-Rashidy et al.\(^15\) in their retrospective study reported 4 failures in 38 patients with a plug-shaped allograft at a mean follow-up of 37.7 months (range, 6-22). Three MRI scans showed moderate arthritis while one showed advanced joint space collapse. In five cases at least one sign of graft instability was found, and one case showed graft collapse. Four cases showed slight articular irregularity ad one showed complete discontinuity.

Haene et al.\(^16\) reported prospectively the results of 17 block-shaped allografts for treatment of osteochondral lesions of the talus. At a mean follow-up of 4.1 years (range, 2-7), five ankles were considered failures, two had poor results, six good and four excellent.

**COMPLICATIONS**

Allograft-associated infection is rare but may potentially be fatal. Clostridium contamination risk increases with the length of time between donor death and procurement\(^13-14\). Safety guidelines established by the American Association of Tissue Banks (AATB) advocate donor screening, extensive serologic, bacterial, and viral testing; procurement and storage requirements; and graft quarantine until negative testing results are ensured\(^35\). Deep infection following allograft transplantation should be considered for surgical debridement and graft removal. To improve the safety of allograft use, tissue banks and surgeons must keep tracking information and report any allograft-related infection\(^36\).

Failure in the osseous portion of the allograft is most common, where subchondral collapse, delayed union or nonunion may occur. Larger and bulkier grafts are associated with higher risks of these complications. Graft fragmentation and collapse are among the main failure mechanisms usually presenting as new onset of pain, joint effusion, and mechanical symptoms. As a milder complication, allograft subsidence may occur\(^37\). Whenever mechanisms usually presenting as new onset of pain, joint effusion, and mechanical symptoms. As a milder complication, allograft subsidence may occur\(^37\). Whenever
CONCLUSIONS

Fresh osteochondral allograft transplantation can improve function of the patients with talar dome lesions. Risk factors for a poor outcome are large lesions, multiple previous surgeries and bipolar defects. The high rates of secondary arthroscopic debridement and clinical failure suggest that the current indications for this surgery should be carefully evaluated and the patient should be properly selected and educated before surgery.

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FUNCTIONAL OUTCOMES OF MPFL RECONSTRUCTION
VS. GRAFT TISSUE PLACEMENT

Evan Larson, BS, Alan Edwards, BS, ATC-LAT, John Albright, MD

ABSTRACT

Background: The medial patellofemoral ligament (MPFL) is essential for the maintenance of correct biomechanical function of the knee. Reconstruction of the MPFL is commonly used in the restoration of patellofemoral stability after traumatic lateral subluxation of the patella. Although a method to accurately determine the MPFL's insertion point has been described, it remains unclear if anatomic placement of MPFL graft tissue is essential for preservation of knee function after MPFL reconstruction. Thus, the purpose of this study was to determine the importance of anatomic placement of MPFL graft tissue for the preservation of knee function following MPFL reconstruction operations.

Methods: Twenty-seven subjects who underwent MPFL reconstruction operations were retrospectively analyzed. Postoperative radiographs were reviewed. Measurements were taken, and the placement of each patient's MPFL graft tissue was determined to be anatomic or non-anatomic based on radiographic methods previously described in the literature. Each subject's electronic medical record was then reviewed, and clinical data was recorded. Finally, the clinical outcomes of each patient were compared to placement location of the MPFL graft tissue in their procedure.

Results: Thirteen patients were found to have anatomic MPFL graft tissue placement, and 14 non-anatomic. A significant post-operative difference was found between groups in the following parameters: WOMAC pain (anatomic mean = 85.71 ± 11.34, non-anatomic mean = 75.00 ± 26.35, p = 0.018), function (anatomic mean = 85.85 ± 9.96, non-anatomic mean = 79.09 ± 24.45, p = 0.017) and in KOOS symptom (anatomic mean = 75.63 ± 11.79, non-anatomic mean = 67.83 ± 22.40, p = 0.024), pain (anatomic mean = 77.54 ± 8.61, non-anatomic mean = 71.39 ± 25.18, p = 0.01), ADL (anatomic mean = 85.85 ± 9.97, non-anatomic mean = 79.09 ± 24.45, p = 0.017) and overall (anatomic mean = 74.61 ± 10.33, non-anatomic mean = 69.41 ± 24.25, p = 0.01) scores. No significant difference was observed for post-op instability (p = 0.290) or apprehension (p = 0.496), improvement in WOMAC or KOOS, 2-week, 6-week, or final 1-year range of motion, WOMAC stiffness, or KOOS sport/recreation or QOL.

Conclusion: Within the range of graft placement values considered by this study, while no reduction in range of motion was seen, non-anatomic placement of MPFL graft tissue in MPFL reconstruction operations caused increased pain and decreased function, evidenced by post-operative KOOS and WOMAC scores.

Clinical Relevance: It seems that the pivotal step in MPFL reconstruction operations is ensuring correct patellofemoral tracking via intraoperative electrical femoral nerve stimulation. If this step of the procedure is performed correctly, non-anatomic placement will not limit range of motion, lead to continued apprehension, or affect the overall biomechanical functioning of the knee.

Keywords: medial patellofemoral ligament (MPFL); patellar instability; lateral patellar subluxation; MPFL graft tissue placement; anatomy; radiographic landmarks; outcome scores; WOMAC; KOOS

INTRODUCTION:

The medial patellofemoral ligament (MPFL) guides the patella into the trochlear groove during the first 30 degrees of knee flexion. With bony anatomy, other ligamentous restraints, and the dynamic action of the quadriceps, it keeps the patella in correct alignment in the early stages of knee flexion when the bone has yet to engage the trochlear groove. It provides a connection between the patella and the femur, stabilizing and tethering the patella as it travels in the groove. It has been established that the MPFL inhibits lateral subluxation of the patella. It is not an isometric structure, and is tighter in extension than in flexion. Because of this discrepancy, the ligament allows the knee to enter full flexion without the structure being damaged.
The tethering function that is present at the initiation of flexion ensures that the patella enters the trochlear groove, avoiding pain, apprehension, and loss of function associated with subluxation\textsuperscript{10,22}. Population-wide lateral patellar subluxation is common\textsuperscript{12}. Certain anatomic variants, such as patella alta and vertical positioning of the patella, make lateral subluxation more likely\textsuperscript{14}. With lateral subluxation, the MPFL is often disrupted. Lateral patellar subluxation is most often traumatic, and commonly results from injuries sustained while engaging in sporting activities or other forms of vigorous exercise\textsuperscript{16}. Although their exact mechanism varies, these injuries involve lateral translocation of the patella beyond the lateral border of the trochlear groove, resulting in rupture of the MPFL and the medial capsule\textsuperscript{16}. They do, however, always involve valgus motion and external rotation of the extended knee, which cause the patella to miss entry to the trochlear groove leading to lateral translocation and patellar subluxation in flexion\textsuperscript{16}.

When this occurs, a partial or total tear of the MPFL can result. In many cases after this trauma, surgical correction of the MPFL is not necessary and gentle medial force can be applied to the patella as the knee is extended to reduce the structure back into the correct anatomic position\textsuperscript{16,22}. In some cases, however, surgical MPFL reconstruction is indicated\textsuperscript{16,18}. One of the most common scenarios necessitating surgical MPFL reconstruction is correction of chronic lateral patellar subluxation\textsuperscript{16,18}. Chronic lateral patellar subluxation can greatly hinder the performance of an athlete, and lead to loss of functionality of the knee joint and great suffering in the individual\textsuperscript{16,18}. If this ligamentous laxity is not corrected surgically, the function of the knee joint may be chronically compromised\textsuperscript{16,18}.

Palmer first recognized the importance of correct graft positioning for ligamentous reconstruction operations in 1938\textsuperscript{16}. In his research on anterior cruciate ligament (ACL) reconstruction, he found that placement of the graft tunnel in the correct anatomic position lead to improved clinical results\textsuperscript{12,22}. As a result of his work, the clinical outcome of anatomic vs. non-anatomic placement of ACL graft tissue is now well-known\textsuperscript{1,5,6}. It is hypothesized that the same parameter holds true with the placement of the MPFL graft tissue during surgical reconstruction of the MPFL\textsuperscript{16}.

MPFL reconstruction procedures generally yield excellent results, even in the presence of degenerative conditions such as trochlear dysplasia\textsuperscript{15,16,18}. In patients with recurrent lateral subluxation, however, a significantly higher failure rate has been demonstrated\textsuperscript{10}. Patellofemoral joint hypermobility has been linked to below-average functional improvements after the procedure\textsuperscript{19}. Case series and other previous work have suggested that incorrect graft placement may cause continued patellar apprehension, subluxation, and dislocation, as well as pain, limited motion, and arthritis\textsuperscript{5,13}. Incorrect graft placement has also been shown to lead to lengthening of the graft post-operatively, and cause application of increased force to the medial patellofemoral cartilage\textsuperscript{23,24}. Anatomic graft placement is technically difficult to achieve\textsuperscript{20}. Nonetheless, redislocation after surgery is uncommon and patient satisfaction is high\textsuperscript{21}.

In determination of the importance of correct anatomic placement of MPFL graft tissue during MPFL reconstruction operations, location of this anatomic connection of the MPFL to the medial aspect of the femur is paramount\textsuperscript{16}. Other authors have described a method to determine graft placement based on post-operative radiographs\textsuperscript{6}. Bollier et al. published a case series that demonstrated the frequency by which the anatomic ideal point of femoral insertion is hit during MPFL reconstruction operations\textsuperscript{7}. The purpose of our study is to further explore this issue, investigating the effect of non-anatomic graft placement on range of motion, pain in the knee, and functional outcome scores. We hypothesized that patients with MPFL placement closest to anatomic have the lowest incidence of patellar instability and apprehension, greatest improvement in [Western Ontario and McMaster Universities Arthritis Index (WOMAC)] and [Knee injury and Osteoarthritis Outcome Score (KOOS)] scores, and best achievement of early range of motion.
During MPFL reconstruction operations, including the Fulkerson Osteotomy and MPFL reconstruction, using the senior author’s technique, femoral nerve stimulation is used to both determine correct tracking of the patella and MPFL isometry. This step ensures that, during entry into knee flexion, the patella is centered on the lateral trochlear edge and is congruent. After correct patellar tracking is verified, reconstruction of the MPFL is performed to provide a check-reign and eliminate the apprehension sign. Thus, the function of the MPFL is not to force the patella to track correctly, but rather to tether the patella (much like a dog on a leash) while it tracks in the trochlear groove. This function cannot be sufficiently performed if underlying patellofemoral biomechanics are disrupted.

**METHODS**

Patients who underwent Fulkerson Osteotomy procedures involving MPFL reconstruction performed by the senior author between the years of 2006 and 2012 were considered for the study. Before being included in the study population, patients had to meet a series of criteria. These criteria included the following:

1) Patient had adequate post-operative radiographs that clearly displayed MPFL tunnel and surgical placement of MPFL graft tissue in the femur.

2) Patient’s electronic medical record contained both pre-operative and post-operative functional scores (WOMAC and KOOS) as well as range of motion at two weeks, six weeks and final 1 year follow-up.

Twenty-seven subjects were ultimately considered as the study population. These 27 subjects who underwent MPFL reconstruction were retrospectively analyzed for MPFL graft tissue placement relative to the anatomic ideal. The total distance from anatomic ideal was determined trigonometrically by first measuring the two distances (anterior or posterior, and proximal or distal to ideal), then determining the actual geographic distance from anatomic ideal using the Pythagorean theorem (Figure 2). The Pythagorean theorem states that for any right triangle, the length of the side opposite the right angle is equal to the square root of the square of one side plus the square of the other side, or $c = \sqrt{a^2 + b^2}$.

Using this method, ‘c,’ or the actual geographic distance between point of MPFL graft placement and anatomic ideal, was calculated.

A guide pin is placed intraoperatively to mark the desired location of the MPFL tunnel, then a cannulated drill bit (7 mm in diameter) is placed over the pin. Since the drill bit is 7 mm in diameter (used for radiographic location of the intended tunnel), the distance from the center of the drill bit to the edge (its radius, 3.5 mm) plus a one-drill-bit-diameter (7 mm) margin of error was found to equal 10.5 mm. Clinical exam by intraoperative femoral nerve stimulation of the quadriceps muscle is used in each case to determine isometry of the graft and maximum patellofemoral congruency.

Anatomic placement was determined using the method described by Schottle et al. Placement of the MPFL tunnel center less than 10.5 mm from the anatomic ideal was designated to be anatomic, and placement greater than 10.5 mm was designated to be non-anatomic. This determination was calculated using a 7 mm margin of error from the edge of Schottle’s ideal femoral tunnel point, and based on intra-operative practices during MPFL reconstruction operations.

Functional scores including WOMAC (pain, stiffness, and function) and KOOS (symptom, pain, function in daily living (ADL), sport/recreation, knee related quality of life (QOL), and overall scale) were then recorded and analyzed at two weeks, six weeks and final 1 year follow-up. Range of motion at two weeks, six weeks and final 1 year follow-up was recorded, and patient-reported
problems with knee flexion were recorded. Inter- and intra-rater reliability were pursued by performance of all measurements twice each by two investigators.

In the final step of the data analysis, the clinical data that was gathered was compared with the placement of the MPFL graft tissue tunnel on the lateral radiographs. SPSS Statistical software (IBM Corp) was used to perform statistical comparison and analysis of the data gathered. Chi square and independent samples t-tests were performed.

**RESULTS**

The study population was comprised of 10 males and 17 females, with a mean age of 23.48 ± 8.31, an average height of 171.5 cm ± 11.15, and an average weight of 79.83 kg ± 19.5 (Table 1). Thirteen patients had their surgery on the right knee, and 14 on the left. All patients had both Fulkerson Osteotomy procedures involving MPFL reconstruction with intraoperative femoral nerve stimulation.

Inter- and intra-rater reliability values were found to be very strong. Intraclass correlation values for intra-rater reliability of investigator 1 were 0.998 (95% CI 0.996-0.999, p < 0.05) for single measures and 0.999 (95% CI 0.998-1.000, p < 0.05) for average measures. Intraclass correlation values for intra-rater reliability of investigator 2 were 0.995 (95% CI 0.988-0.998, p < 0.05) for single measures and 0.997 (95% CI 0.994-0.999, p < 0.05) for average measures. Intraclass correlation values for inter-rater reliability were 0.993 (95% CI 0.987-0.996, p < 0.05) for single measures and 0.998 (95% CI 0.997-0.999, p < 0.05) for average measures (Tables 2-4).

A significant post-operative difference was found between groups in the following parameters: WOMAC pain (anatomic mean = 85.71 ± 11.34, non-anatomic mean = 75.00 ± 26.35, p = 0.018), function (anatomic mean = 85.85 ± 9.96, non-anatomic mean = 79.09 ± 24.45, p = 0.017) and in KOOS symptom (anatomic mean = 75.63 ± 11.79, non-anatomic mean = 71.39 ± 25.18, p = 0.017) and KOOS pain (anatomic mean = 77.54 ± 8.61, non-anatomic mean = 71.39 ± 25.18, p = 0.01) scores. No significant difference was observed for post-op instability (p = 0.290) or apprehension (p = 0.496), improvement in WOMAC or KOOS, 2-week, 6-week, or final 1-year range of motion, WOMAC stiffness, or KOOS sport/recreation or QOL (Table 5).

Non-anatomic graft placement did not predispose patients to reported flexion problems (p = 0.163), post-op chondromalacia (p = 0.148), or continued post-op patellofemoral articulation pain (p = 0.586), as there was no statistically significant difference noted between the anatomic and non-anatomic groups in these parameters.

**DISCUSSION**

The medial patellofemoral ligament (MPFL) is essential for the maintenance of correct biomechanical function of the knee. Reconstruction of the MPFL is commonly used in the restoration of patellofemoral problems.
stability after traumatic lateral subluxation of the patella. Although a method to accurately determine the MPFL's insertion point has been described, it remains unclear if anatomic placement of MPFL graft tissue is essential for preservation of knee function after MPFL reconstruction. Thus, the purpose of this study was to determine the importance of anatomic placement of medial patellofemoral ligament (MPFL) graft tissue for the preservation of knee function following MPFL reconstruction operations.

Intra- and inter-rater reliability were likely strong due to measurement simplicity and investigator agreement regarding key parameters prior to their performance. The measurements were relatively easy to perform, and the investigators agreed on placement of the line perpendicular to the posterior femoral cortex, the line tangential to the posterior condyle, and the line tangential to the posterior aspect of the Blumensaat line. Within the range of graft placement values considered by this study, nonanatomic placement of the femoral MPFL tunnel appears to cause increased pain and decreased function as evidenced by post-operative KOOS and WOMAC scores. However, no significant difference was noted in apprehension, range of motion, quality of life, sport and recreation, patellofemoral pain, or incidence of chondromalacia. These parameters commonly serve as clinical benchmarks, and are generally considered to be the most important indicators of early success of the MPFL reconstruction operation.

This study had a number of limitations. It was a small retrospective review of cases that were performed at a single institution (University of Iowa Hospitals and Clinics). It was a case series. Follow-up length only extended to one year, as dictated by the information available in the electronic medical record. Also, one surgeon performed all operations in the cases considered by the study.

It is recommended that particular attention be paid during surgery to the tightness of the graft during active extension and passive flexion to 90 degrees. Clinical exam is performed intra-operatively using femoral nerve stimulation to determine the isometry of the graft. If it were felt that there was tightening of the ligament in flexion, then loosening of the graft would be allowed without compromising its check-reign function in the extended position. If this pivotal portion of the MPFL reconstruction procedure is performed correctly, it seems that the patella tracks correctly into the trochlear groove post-operatively regardless of graft tissue placement site. Also, the graft tissue will not be damaged by the normal flexion and extension of the knee joint, and no limits to range of motion or apprehension should occur if correct isometry is achieved intra-operatively.

REFERENCES


CLINICAL OUTCOMES OF PATELLAR CHONDRAL LESIONS TREATED WITH JUVENILE PARTICULATED CARTILAGE ALLOGRAFTS

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ABSTRACT

Background: Juvenile particulated cartilage allograft (DeNovo NT®, Zimmer, Warsaw, IN) transplantation is a relatively new technology for the treatment of high-grade cartilage lesions. To date there is limited literature demonstrating its effectiveness and safety. The present study specifically looks at the short-term efficacy of DeNovo NT® allograft for symptomatic high-grade cartilage lesions of the patella. Clinical outcomes and complications are reported.

Methods: Seventeen cases of DeNovo NT® allograft transplantation at our institution were retrospectively reviewed from 2010 to 2013. Thirteen patients had the procedure performed for patellar lesions and are included in the present study. A chart review was performed to record demographic data, surgical technique, and complications. In addition, we analyzed preoperative and postoperative KOOS outcome scores.

Results: The mean age was 22.5 years (range, 14 - 34), with 3 males and 10 females. Mean follow-up was 8.2 months (range, 0.67 – 32.7). Six of the patients had concomitant anteromedialization of the tibial tubercle. DeNovo NT® allograft transplantation resulted in improvement for each outcome measure used. Overall KOOS score significantly improved from a mean of 58.4±15.7 to 69.2±18.6 (P = 0.04). Improvement in KOOS subscales of pain, ADL, and symptoms all approached but did not reach statistical significance (P values between 0.05 and 0.10). There were no infections or hardware complications.

Conclusions: This series demonstrates that DeNovo NT® allograft transplantation for symptomatic high-grade cartilage lesions of the patella results in pain relief and improved outcomes in the short term.

Further studies are needed to better evaluate this new technology.

Level of Evidence: Level IV, therapeutic case series

INTRODUCTION

Cartilage lesions of the patella are a difficult problem that can cause significant pain and functional limitation in patients. These lesions have demonstrated poor capacity to heal spontaneously and frequently require surgical treatment. There are multiple surgical options for these lesions, including microfracture, osteochondral autograft transfer, osteochondral allograft transplantation, and autologous chondrocyte implantation (ACI). Microfracture and ACI have been less successful in treating patellar lesions than femoral condylar lesions, thought to be secondary to the insufficient quality of the repair tissue. Osteochondral transplant is not feasible for many patellar lesions given the patellar contour, hard subchondral bone, and limited bone depth. Tibial tubercle osteotomies with anteriorization can also be used alone or in conjunction with the above procedures in an attempt to unload the lesion and improve outcomes. More recently, juvenile particulated cartilage transplantation (DeNovo NT®, Zimmer, Warsaw, IN) has been used for patellar lesions with success. Multiple studies have demonstrated that chondrocytes from particulated cartilage can migrate to form new hyaline-like repair tissue that integrates with surrounding tissue. This procedure is relatively new and there is limited literature supporting its effectiveness for patellar lesions. The present study represents a retrospective analysis of clinical outcomes for patients undergoing juvenile particulated cartilage transplantation for patellar lesions at our institution.

MATERIALS AND METHODS

Patients

Between 2010 and 2013, 17 patients at our institution underwent juvenile particulated cartilage transplantation.
for full-thickness cartilage lesions of the knee by one of three senior authors (JPA, BRW, and MB). After institutional review board approval, we retrospectively reviewed their charts for demographic information, operative reports, clinic notes, complications, and preoperative and postoperative (Knee injury and Osteoarthritis Outcome Score) KOOS scores. Four of these patients had lesions of the femoral condyle or tibial plateau and were excluded from the present analysis. An additional four patients did not have pre-operative KOOS scores. Thus, 13 patients were analyzed for complications and a total of nine patients were analyzed for functional outcomes measures. The final analysis included 13 patients, ranging in age from 14 - 54 (mean 22.5), with three males and 10 females. Mean follow-up was 8.2 months (range, 0.67 – 32.7). All participants had full-thickness patellar defects identified on preoperative MRI. The indication for surgery was persistent anterior knee pain refractory to nonoperative treatment. The indication for concomitant tibial tubercle osteotomy was patellar malalignment and patellofemoral pain. This was performed in six total patients (TABLE 1).

**Tibial Tubercle Osteotomy Procedure**

Six of 13 patients underwent a concomitant tibial tubercle osteotomy at the time of the patellar procedure to address patellar alignment. Prior to surgery, the Tibial Tuberosity-Trochlear Groove (TT-TG) distance, as calculated by measuring the distance from the tibial tuberosity to the deepest portion on the trochlear groove on parallel, superimposed axial CT images was calculated. In six cases the TT-TG distance, the TT-TG distance was greater than 10mm and thus patients were indicated for tibial tubercle osteotomy.

The osteotomy was carried out in the standard dovetail fashion, then the patellar lesion as addressed using
Rehabilitation

Post-operatively, patients without a concomitant Fulkerson osteotomy were placed in hinged knee brace with weight bearing as tolerated with knee locked in extension when ambulatory. Patients then began the standard microfracture post-operative physical therapy, focused on quadriceps strengthening at approximately 2 weeks post-operatively. Patients with Fulkerson osteotomy were non-weight bearing for 6 weeks with seated range of motions and brace locked in extension at all other times. Then, patients began a standard post-operative lower extremity strengthening rehabilitation protocol. Patients were then followed with regular follow up visits at 2 weeks, 6 weeks, 3 months and 6 months.

Second-Look Arthroscopy

A second-look arthroscopy was performed in one patient. The arthroscopy was performed in the standard fashion with establishment of anteromedial, anterolateral and superolateral outflow portals. A standard diagnostic arthroscopy was performed and no additional surgical procedures were performed at time of arthroscopy.

Statistical Analysis

Patient data was compiled in a spreadsheet database, and statistical calculations were performed utilizing the spreadsheet software (Microsoft Excel, Redmond, Washington). A two-tailed t-test was performed comparing preoperative and postoperative scores for overall KOOS as well as each of the KOOS subscales.

RESULTS

Clinical Outcomes

Juvenile articular cartilage transplantation resulted in improvement in all outcomes measured (CHART 1). The overall KOOS score improved from a mean of 58.4±15.7 to 69.2±18.6 (P = 0.04), which achieved significance (TABLE 2). Improvement in KOOS subscales of pain, Activities of Daily Living (ADL), symptom and WOMAC function all approached but did not reach statistical significance (P values between 0.05 and 0.10).

Table 2. Results of KOOS subscales: paired two-sample t-test for means.
Complications

Of the 13 patients that met criteria for inclusion in the study, two had post-operative lumbar plexopathies manifested by lower extremity weakness and likely associated with the pre-operative femoral nerve block given the distribution of weakness. One patient responded well to physical therapy and the plexopathy and weakness resolved. The other patient had continued weakness at last follow up. Two other patients developed post-operative quadriceps weakness, not associated with a lumbar plexopathy. One patient weakness resolved with physical therapy and the other patient had continued weakness at last follow-up. Both of these patients had a concomitant Fulkerson procedure performed at the time of cartilage transplantation. Another patient developed pes anserine bursitis and painless crepitus with range of motion of the knee. This was resolving with physical therapy at last follow-up. This patient also had a concomitant Fulkerson procedure (TABLE 1).

DISCUSSION

There are multiple surgical options for treatment of cartilage lesions of the patella, including microfracture, osteochondral autograft transfer, osteochondral allograft transplantation, autologous chondrocyte implantation, and, more recently, transplantation of juvenile particulated cartilage. The successful restoration of hyaline-like cartilage in animal models, and the ability of this cartilage to potentially restore adult damaged articular cartilage has been reported. The conceptual use of juvenile particulated cartilage for chondral defects has been theorized for some time, but its clinical use in patellar chondral lesions is a relatively new concept. There is a paucity of literature supporting its effectiveness.

DeNovo NT® has been available for clinical use since 2007 and been used successfully for treatment of osteochondral dissecans (OCD) lesions of the talus. A recent case report by Bonner et al. reported improved International Knee Documentation Committee (IKDC) and KOOS subscale scores at 2 years with MRI evidence of resolution of chondral defect at 21 months. Similarly, another case report by Thompkins et al. found improved IKDC and KOOS subscale scores and MRI evidence of chondral defect resolution at a minimum of 18 months. Our study also indicates improvement in functional outcomes measures at short-term follow-up and augments the effectiveness of juvenile particulated cartilage in treatment of patellar chondral lesions. There were no infections or issues directly related to use of the DeNovo NT® graft in our series.

Traditionally, indications for a Fulkerson osteotomy include unloading of patella cartilage lesions for lateral patella overload or early degenerative changes as well as treating patellofemoral instability in the presence of a lateral tracking vector. Anteromedialization decreases total distal and lateral patellofemoral contact pressure and lateral trochlea compression. The addition of a tibia tubercle or Fulkerson osteotomy was used in 6/13 cases to unload the patella cartilage lesion. The tubercle osteotomy makes the patella cartilage resurfacing easier because the patella can be flipped over through the osteotomy improving access and exposure. The question remains whether the cartilage resurfacing procedure, the unloading osteotomy, or both are needed to decrease pain and improve function in patients with patella cartilage lesions. The key to surgical planning is to know the lesion location and the TT-TG distance, which is calculated by measuring the distance from the tibial tuberosity to the deepest portion on the trochlear groove on parallel, superimposed axial CT images.

We recommend an isolated anteromedialization (Fulkerson) osteotomy for lateral patella lesions. When the TT-TG distance is greater than 15 mm, it is important to move the tubercle fragment both anteriorly and medially. When the TT-TG is less than 10 mm, the tubercle should only be shifted anteriorly. For medial and central patella lesions, we recommend an osteotomy and cartilage resurfacing procedure. Similar to lateral lesions, the TT-TG distance determines the degree and amount of anterior or medial translation. If alignment is corrected (TT-TG less than 12 mm) and there is no instability, success rates of cell based cartilage resurfacing is around 70%.

The results of this study indicate that the use of DeNovo NT® cartilage in the treatment of patellar chondral defects is a viable option for patients with identified chondral defects. However, there are several disadvantages to the use of DeNovo NT®, including: risks with use of allograft, cost, inability to put the product back on the shelf once opened, and need for an arthroscopy. These disadvantages should be thoroughly considered prior to use of DeNovo NT®.

There is a potential risk of disease transmission with any allogenic transplantation and this hold true with the use of DeNovo NT®. However, several studies have indicated that the use of allogenic chondrocytes is safe and the risk of transmission is low given that native chondrocytes are adept at immune evasion as they do elicit an active response to allogenic chondrocytes and are capable of suppressing immune proliferation. The
risk of disease transmission or infection is possible with any allogenic transplantation. However, DeNovo NT® cartilage undergoes the same strict requirements for any transplantation, which include testing for known transmissible diseases for each donor as well as sterility testing for each set of DeNovo NT® that is ordered.

Prior to the use of DeNovo NT®, the treating physician must be aware of the cost of utilizing the chondrocytes. The current cost of 1 unit of DeNovo NT® graft costs approximately $4,000-$5,000. The nature of this procedure requires that the surgeon orders the correct amount of chondrocytes prior to in vivo evaluation of the lesion. Pre-operative MRI and plan films give some indication of the true character of the lesion; however, subtle aspects of the lesion may not be fully appreciated prior to full exposure. It is therefore possible to order too much DeNovo NT® graft, which is a significant monetary waste.

The use of DeNovo NT® requires an open arthrotomy, which, although a fairly common practice, is not without associated morbidity in comparison to arthroscopic procedures often performed in the knee. At this point there is no specific evidence to suggest that DeNovo NT® has superior outcomes to other arthroscopic procedures to address patellar cartilage defects. Thus, the surgeon must factor in the morbidity of the surgery itself in comparison to other known options when considering DeNovo NT®. Perhaps, similar to the evolution of the Use of DeNovo NT® in OCD lesions of the talus, techniques will develop that will allow the use of DeNovo NT® for patellar lesions arthroscopically, thus decreasing the morbidity associated with the open arthrotomy.

The current study indicates that use of DeNovo NT® is a potentially effective treatment for patellar cartilage defects. However, there are several limitations to this study. Firstly, this is a relatively small case series with retrospectively reviewed data. Thus, despite significant improvement in the overall KOOS score and improvements in all KOOS subscales, the study was underpowered and could not find a significant effect in the KOOS subscales. This is similar to the previous case series reported in the literature. However, a more powered study would likely indicate improvement of all KOOS subscales and other functional outcome measures. Also, the length of follow up is of short (average 8.2 months) and thus functional outcomes and potential complications cannot be fully determined. Although, a second look arthroscopy performed in one patient indicated full integration of the graft (FIGURE 2), we do not provide advanced imaging or histology in each patient that is suggestive of restoration of the articular surface.

The results of this study, similar to previous studies, indicate the potential advantages of DeNovo NT® for use in treatment of patellar cartilage defects. Further studies, with larger number of patient are required to fully address the effectiveness and safety of use of DeNovo NT® in patellar lesions. There is no clear superiority of one cartilage resurfacing procedure over another. We recommend Fulkerson osteotomy and cartilage resurfacing for central and medial patella lesions. Lateral patella lesions can be treated with osteotomy alone.

REFERENCES


ABSTRACT

Background: The OTA Fracture Classification is designed to provide a common language and facilitate effective communication among orthopaedic surgeons. We attempted to measure the degree to which this classification is currently being utilized in orthopaedic trauma literature.

Methods: We reviewed all of the articles in the JOT in 2011. We determined which of these articles could have appropriately utilized the 2007 OTA Classification. We calculated the percentage that mentioned and correctly cited this classification system as a reference.

Results: There were 145 articles in 2011. One hundred of these articles were appropriate for classifying a fracture. 38% of these articles utilized the OTA classification in the text. Only 42% of articles mentioning the OTA Classification cited a reference. 38% of these citations used the old (1996) OTA Classification reference, and only 8% overall correctly cited the 2007 OTA Classification reference. 51% of articles mentioned some other classification system; 21 in addition to OTA and 30 instead of the OTA classification.

Conclusions: The OTA Fracture Classification is being used more commonly (38%) but is not routinely used or correctly cited (8%) in articles currently being published in the Journal of Orthopaedic Trauma, despite the fact that it is “required” according to the instructions to authors. We conclude that future authors should utilize and correctly reference the 2007 OTA Classification so that the benefits of a common language can be realized. Routine and consistent utilization of the classification may ultimately lead to more consistency and improved interpretability of treatment outcomes in published orthopaedic trauma research.

Level of Evidence: Level-III case-control study, decision analysis

INTRODUCTION

Fracture classification systems are the means by which physicians communicate, characterize fracture patterns, make treatment decisions and determine prognoses. These systems are also useful for reporting and comparing treatment results. In general, fracture classification systems should be reliable and valid. The Orthopaedic Trauma Association (OTA) along with the AO Foundation developed a comprehensive fracture classification, which has gained worldwide acceptance. Its validity has been confirmed by various studies. The inter-observer and intra-observer reliability along with accuracy of this classification system has also been verified. The coding system associated with this classification provides a shorthand form and appears accurate and reliable in clinical practice. The classification is published in a readily available and electronically accessible form. It has been updated every ten years to incorporate new knowledge of fractures and classifications. The 2007 version reconciled any differences between the AO and the OTA Classification.

Although there are numerous fracture classification systems available for specific fracture locations, the OTA Fracture and Dislocation Classification Compendium is the most comprehensive. It applies consistent fracture classification principles to the entire axial and appendicular skeleton. It has incorporated the most useful concepts of individualized location classifications. Individualized location classifications are deficient at providing a common language for fracture classification, which can limit effective communication among orthopaedic surgeons.

Individualized classifications commonly have unknown or poor inter-observer reliability and poor intra-observer reproducibility. There are at least three ways in which a fracture classification can be incorporated into an article. One is to mention the classification and stratify the data and...
results based upon that classification. Another is to use the terminology of the classification to provide a standard and consistent form of communication that is amenable to computerized searching. A third way is to cite a reference to the classification so the reader can easily review an established, validated classification technique. This citation must be explicitly described and readily accessible in print and electronic form so the details do not have to be reproduced in each subsequent article.14,15.

To investigate the possibility that the OTA Classification was somehow deficient, we reviewed how frequently other classifications were utilized. The reason for utilizing other classifications instead of OTA could be that it has inherent deficiencies. If other classifications were utilized in addition to or instead of the OTA Classification, we then analyzed the text to determine whether there was some deficiency in the OTA Classification that the other classification solved. This information would be of value for future revisions of the OTA Classification in order to make it as clinically relevant as possible. We hypothesize that the OTA Classification is used, mentioned and cited some of the time but not always within the orthopaedic trauma literature.

METHODS

All of the articles in the Journal of Orthopaedic Trauma in 2011 were reviewed. We determined which of these articles could have appropriately utilized the OTA Fracture Classification by eliminating articles that did not directly deal with fractures or dislocations. We then calculated the percentage of those articles that mentioned the OTA Classification in the title or body of the article. We noted if another classification was used in addition to or instead of the OTA Classification and, if so, made a determination as to why another classification was mentioned. We then identified whether or not the OTA Classification was cited in the references and, if so, whether the 2007 reference was accurately cited or not. We also recorded whether or not another classification that was mentioned was cited in the references.

RESULTS

There were 10 volumes of JOT in 2011 containing 145 articles. One-hundred of 145 articles dealt with fractures or dislocations and the OTA Classification was appropriate for the subject matter of the article. These 100 “should” have mentioned the OTA Classification, as it pertained to the study design or methodology. However, the OTA Classification was mentioned in 38 of 100 (38%) articles. Thirty-one of 38 (82%) articles mentioned the “OTA Classification” specifically. Seven of 38 (18%) articles referred to it as a generic “Fracture Classification” or in another manner16 [Table 1].

Fifty-one of 100 (51%) articles mentioned another fracture classification system; 30 of 51 (59%) instead of the OTA Classification and 21 of 51 (41%) in addition to the OTA Classification [Table 2]. The reasons for using another classification were mentioned or deduced and reported as well [Table 3].

Overall, 16 of 100 (16%) articles cited an OTA Classification. Sixteen of the 38 (42%) articles that mentioned the OTA Classification cited some version of the OTA Classification as a reference. Six of 16 (38%) articles cited the older 1996 OTA Coding and Classification reference17 even though the newer classification had been published four years previously1. Ten of 16 (63%) articles cited the 2007 reference of the OTA Fracture Classification. Two of these 10 (20%) articles cited the 2007 reference with some error and eight of 10 (80%) or eight out of 100 (8%) articles correctly cited the 2007 OTA Fracture Classification reference [Table 4].

Fifty-seven of 100 (47%) articles cited another classification system as a reference. Forty-eight of 51 (92%) that mentioned another classification cited a reference. We did not investigate the accuracy of the citations.

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of other classification systems. In comparison, 38 of 100 (38%) articles mentioned the OTA Classification but only 16 of 38 (42%) cited a reference [Tables 4 and 5].

Forty-seven of 100 (47%) of articles cited another classification system as a reference. 11 of 47 cited the other classification in addition to citing OTA. Thirty-six of 47 cited another reference instead of the OTA Classification [Table 5].

Forty-eight of 100 (48%) articles did not cite either OTA or another classification system. Five of 100 (5%) articles cited only the OTA Classification. [Table 5]

**DISCUSSION**

The rate of utilization and citation of the OTA Fracture Classification in the Journal of Orthopedic Trauma (JOT) was reviewed for the year 2011. This was done in order to determine the degree to which this classification is being used amongst orthopedic traumatologists while communicating scholarly work.

We found that 38% of fracture articles utilized the OTA Classification and mentioned it in the body of the manuscript. This indicates that the classification is being used, but not in all or even most of the articles. The 45 articles that we excluded were anatomical and biomechanical studies related to fractures and fracture fixation where the OTA Classification was not “required” but might have been of some value to mention and cite as a reference. We also found that only 8% of fracture articles in the JOT in 2011 accurately referenced the correct citation for the OTA Fracture Classification. The recommended citation from the JOT is:

Marsh, J. L.; Slongo, Theddy F; Agel, Julie; Broderick, J. Scott; Creevey, William; DeCoster, Thomas A.; Prokushki, Laura; Sirkin, Michael S.; Ziran, Bruce; Henley, Brad; Audigé, Laurent: Fracture and Dislocation Classification Compendium -2007: Orthopaedic Trauma Association Classification, Database and Outcomes Committee. J Orthop Trauma. 2007;21(10 Suppl):S1-133.

The reasons that the classification is or is not used are not entirely apparent. We identified the rate at which other classifications were utilized instead of (30/51 or 59%) or in addition to (21/51 or 41%) the OTA Classification. There did not seem to be many cases where the other classification contained some clinically important parameter that was not captured by the OTA Classification. There did seem to be a sense, on the part of the authors, that the “other” classification was the expected standard for reporting their results. There is certainly a fair amount of consideration given to tradition and inertia when submitting articles for publication. Authors are likely following the standards set by existing published literature as well as their own previous publication experience.

It also appears that some authors may consider the OTA Classification common knowledge and do not see the need for a particular reference; just as one uses words without referencing the dictionary definition of every word. This consideration may be particularly true for articles that only use the bone segment aspect of the classification that emphasizes some other aspect of the intervention. That may, in part, explain why there is such a high rate of referencing a citation for other classifications (92%). Compare this to the 42% rate of referencing the OTA Classification even when it is already mentioned in the text.

An example is the report on regional versus general anesthesia for operative treatment of distal radius fractures. This article used OTA Classification terminology (distal radius), perhaps coincidentally. This article did not mention or cite the OTA Classification or any other fracture classification as the emphasis was on the treatment and not the inclusion criteria. Had the authors used the terms “Colles Fracture” instead of “Distal Radius” in the title, they likely would have felt it appropriate to cite a reference to “Colles fracture”. Since the authors used the more appropriate term “distal radius”, they may not have felt the need to reference any particular classification. If the results of the previous study are to be compared to another article describing conscious sedation versus general anesthesia for treatment of “forearm” fractures, then the importance of a precise scheme to distinguish between distal radius and radius shaft becomes more evident.

The choice of terminology such as “distal radius” and “radius and ulna shaft” that is built into the OTA Classification is of some importance. Authors may still choose “Colles fracture” instead of “distal radius fracture” or “both bone forearm fractures” instead of “radius and ulna shaft fractures”. One consequence of using non-standard terminology would be a lack of precision of the inclusion criteria. A “Colles fracture” is not specifically defined anywhere. Additionally, a computer search of all articles relating to “radius and ulna shaft” fractures will not capture all pertinent articles. For example, articles with titles including “both bone forearm, BBFA, forearm, Piedmont, fracture of necessity” or any other colloquial or eponym-derived fracture terminology may not come up when searching for “radius and ulna shaft”. This lack of consistency may lead to unawareness or under-appreciation of some potentially important articles. Furthermore, where would one go to distinguish between a “both bone forearm” fracture and “Colles fracture”? No clear distinction exists in the orthopedic literature, but, the OTA Classification clearly distinguishes “distal radius” from “radius shaft” fractures by the rule of squares.
The methods section of any article should enable subsequent researchers to reproduce the findings. If "forearm fracture" is the inclusion criteria it would be hard for a future researcher to determine whether or not to include distal radius metaphyseal fractures or not. This distinction would introduce an additional variable resulting in two studies of different, rather than the same, patient characteristics. If you want to avoid the problem of comparing apples and oranges then do not make “fruit” the inclusion criteria. Authors of the 2011 JOT articles who did cite a reference to the OTA Classification often utilized the 1996 version rather than the 2007 version. This is somewhat surprising and disappointing, but may be partially explained by the length of time a manuscript is in preparation and review prior to publication. Four years would seem to be a sufficient period of time to overcome this problem. It may also be explained by the historical tendency of authors to propagate previously cited references. This report highlights the current, correct reference for the OTA Classification and rationale for including it. It is helpful to publish this information to provide the orthopaedic community with objective data of its' current under-utilization as motivation to increase its' utilization in future publications.

The instructions to authors of JOT “require” utilization of the OTA Fracture Classification. It does appear that the presence of this requirement, accompanied by increasing clinical usage, has helped to increase the rate of utilization of the classification in the literature to some degree. Authors that submit a manuscript using another classification appear to have added the OTA Classification in some articles and that appears to be a satisfactory compromise. However, the requirement is not routinely enforced or accomplished. We believe that publication of this article will help remind authors and reviewers of the Journal of Orthopaedic Trauma that this requirement exists. We hope this will, in effect, enhance future compliance and will significantly improve the quality and relevance of orthopedic trauma literature. The more frequently the OTA Fracture Classification is utilized and cited, the more the level of expectation for future submissions will grow. This resulting increase in compliance will hopefully lead to an expansion of this practice to other journals that publish the results of orthopaedic trauma research.

In conclusion, OTA Fracture Classification is being used more commonly (38%) but is still not routinely used or correctly cited (8%) in articles currently being published in the Journal of Orthopaedic Trauma. This is so despite the fact that it is “required” according to the instructions to authors. We feel that authors should utilize and correctly reference the 2007 OTA Fracture Classification so that the benefits of a common language can be realized. Routine and consistent utilization of the classification may ultimately lead to more consistency and improved interpretability of treatment outcomes in published orthopaedic trauma research.

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ABSTRACT

Fat embolism syndrome (FES) is a multi-organ disorder with potentially serious sequelae that is commonly seen in the orthopaedic patient population after femur fractures. The major clinical features of FES include hypoxia, pulmonary dysfunction, mental status changes, petechiae, tachycardia, fever, thrombocytopenia, and anemia. Due to technological advances in supportive care and intramedullary reaming techniques, the incidence of FES has been reported as low as 0.5 percent. Here, we present a rare case of FES with cerebral manifestations. A previously healthy 24-year old nonsmoking male was admitted to our hospital after an unrestrained head-on motor vehicle collision. The patient’s injuries included a left olecranon fracture and closed bilateral comminuted midshaft femur fractures. The patient went on to develop cerebral fat embolism syndrome (CFES) twelve hours after immediate bilateral intramedullary nail fixation. His symptoms included unresponsiveness, disconjugate gaze, seizures, respiratory distress, fever, anemia, thrombocytopenia, and visual changes. Head computed tomography and brain magnetic resonance imaging showed pathognomonic white-matter punctate lesions and watershed involvement. With early recognition and supportive therapy and seizure therapy, the patient went on to have complete resolution of symptoms without cognitive sequelae.

INTRODUCTION

Fat embolism syndrome (FES), first described by Zenker in 1861, is associated with long bone fractures and often presents as a constellation of neurological, pulmonary, dermatological, and hematological symptoms. Zenker described the first autopsy case of fat embolism with the presence of pulmonary capillary fat deposition in a patient who suffered from a crush injury. In 1873, Bergmann described the first clinical case of FES in a patient who suffered a distal femur fracture. In 1875, Czerny explored cerebral symptoms associated with FES. The incidence of FES has been reported to occur in 0.5 to 11 percent of patients with long bone fractures. Although rare, it is more common at level I trauma centers where polytrauma patients are often transferred for specialized care. Mortality from FES has been reported to be as high as 20 percent. Early diagnosis, high-pressure PEEP, and supportive treatment have been the mainstays of treatment.

Multiple theories have been proposed to explain the pathophysiology of FES. In 1924, Gauss established the mechanical theory, which states that three conditions are necessary for the development of fat embolism: injury to adipose tissue, rupture of veins within the zone of injury, and a mechanism that causes the passage of free fat into the open ends of blood vessels. The biochemical theory proposed by Lehman in 1927 stated that plasma mediators mobilize fat from body stores and cause the coalescence of larger droplets. The presence of fat within various tissues such as the lungs and the brain initiates an inflammatory cascade causing injury.

Major and minor diagnostic criteria for FES were proposed by Gurd and Wilson. Using their system, a diagnosis of FES could be made if one major feature, four minor features, and fat macroglobulinemia were present. Schonfeld proposed the fat embolism index (FEI) to aid in diagnosing FES. A cumulative score of five or more over the first three days of hospitalization corresponds with a diagnosis of FES. Lindeque stated that FES could be diagnosed with respiratory changes alone. However, given the complex nature of polytrauma patients, it is often difficult to accurately diagnose FES as these patients have multiple injuries and are often intubated upon arrival.
C. C. Akoh, C. Schick, J. Otero, M. Karam

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Here, we present a case report of a 24-year old male who developed FES after intramedullary treatment of bilateral femoral shaft fractures with a drastic change in his mental status post-operatively.

**CASE REPORT**

A previously healthy 24-year old nonsmoking male was admitted to our hospital after an unrestrained head-on motor vehicle collision. The patient’s injuries included a left olecranon fracture and closed bilateral comminuted midshaft femur fractures. There were no thoracic, abdominal, or pelvic abnormalities upon initial imaging workup, and the head computed tomography (CT) scan was normal. Additionally, the patient had a normal neurologic examination without focal symptoms and an initial GCS of 15. Initial vitals were a heart rate of 115, respiratory rate of 24, and was saturating at 97 percent on 2L nasal cannula. In addition to mild tachypnea and tachycardia, he was noted to have an arterial blood gas (ABG) pH of 7.27, pCO₂ 56, pO₂ 53, -3 base deficit, and a lactate of 1.8 in the emergency department. The initial hemoglobin and hematocrit were 12.4 and 36, respectively, and platelet count was within normal limits. The patient was transferred to the Surgical Intensive Care Unit (SICU) due to the mechanism of injury, and initial management for the aforementioned fractures included bilateral proximal tibial traction and left arm splinting.

Over the first 24 hours, the patient remained lucid. On hospital day (HD) 1, the patient underwent definitive fixation with bilateral femoral intramedullary nails. After intubation the patient was placed in the lateral decubitus position and a piriformis start point was used for nail entry bilaterally. Both femurs were sequentially reamed using flexible reamers to 10.5-mm, and then 9-mm diameter antegrade nails with proximal and distal locking screws were placed [Figure 1]. The left olecranon fracture was also fixed with open reduction and internal fixation by a second surgical team during fixation of the left femur. Total operative time was four hours and ten minutes and the patient had 500cc of blood loss. In order to closely monitor ventilatory and oxygenation status post-operatively, the patient remained intubated following the procedure and returned to the SICU. Shortly after arriving to the intensive care unit, nursing documented a normal mental status exam.

Approximately twelve hours after surgery, the patient was unable to follow commands during wake-up examination tests. His GCS score deteriorated to 9 compared to 15 pre-operatively. In addition to his altered mental status, he became difficult to ventilate, his hemoglobin dropped from 10.6 to 6.5, and his platelet count dropped from 122,000/mm³ to 51,000/mm³. Upon examination, he was found to be unresponsive to verbal command and had a mildly disconjugate gaze to the right, but otherwise was able to open his eyes without other apparent focal neural deficits and was able to move all four extremities spontaneously. A brain CT and MRI showed several hypointense punctate infarcts on diffusion restriction imaging (DWI), consistent with cerebral fat embolism syndrome along with diffusion restriction in the watershed territory between the ACA and MCA.

<table>
<thead>
<tr>
<th>Points</th>
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<tbody>
<tr>
<td>Diffuse petechiae</td>
<td>5</td>
</tr>
<tr>
<td>Alveolar infiltrates</td>
<td>4</td>
</tr>
<tr>
<td>Hypoxemia (&lt; 70 mm Hg)</td>
<td>3</td>
</tr>
<tr>
<td>Confusion</td>
<td>1</td>
</tr>
<tr>
<td>Fever &gt; 38 degrees C</td>
<td>1</td>
</tr>
<tr>
<td>Heart rate &gt; 120 beats/min</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory rate &gt; 30/min</td>
<td>1</td>
</tr>
<tr>
<td>FES = 5 or more points</td>
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</tbody>
</table>

Table 2: Schonfeld's Fat Embolism Index (FEI) score. A score of five or more points over the first three days of hospitalization is diagnostic for FES$^{13}$. 

<table>
<thead>
<tr>
<th>Major Features</th>
<th>Minor Features</th>
</tr>
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<tbody>
<tr>
<td>Petechial rash</td>
<td>Tachycardia</td>
</tr>
<tr>
<td>Respiratory symptoms plus bilateral signs with positive radiographic changes</td>
<td>Pyrexia</td>
</tr>
<tr>
<td>Cerebral signs unrelated to head injury</td>
<td>Retinal fat or petechiae</td>
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<tr>
<td></td>
<td>Urinary fat globules or oligoanuria</td>
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<td></td>
<td>Sudden drop in Hg-level</td>
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<td></td>
<td>Sudden thrombocytopenia</td>
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<td></td>
<td>High erythrocyte sedimentation rate</td>
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<tr>
<td></td>
<td>Fat globules in sputum</td>
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</tbody>
</table>

Table 1: Gurd and Wilson's major and minor criteria for fat embolism. The presence of one major feature, four minor features, and fat macroglobulinemia is diagnostic for FES$^{11}$. 

Fat Embolism Syndrome after Femur Fracture Fixation: A Case Report

Figure 1: Preoperative and post-operative films of the left femur (A) and right femur (B). Both femurs were definitively fixed with Synthes 9mm diameter titanium anterograde intramedullary nails and locking screws.

Figure 2: SWI-sequence brain MRI showing numerous punctate foci on post-operative day (POD) 1 (A), with interval worsening of punctate foci on POD 5 extending into the splenium, bilateral frontoparietal white matter, thalamus, basal ganglia, and pons, suggesting superimposed micro-hemorrhaging (B).

(R > L) [Figure 2 A and B]. Chest radiographs obtained showed ground-glass airspace disease [Figure 3]. The patient remained on propofol for sedation and fentanyl for pain control and was provided supportive care. Over the next few days, the patient remained unresponsive to command, but had increased spontaneous opening of his eyes. On HD4, the patient was extubated and placed on BiPaP. Diagnostic workup was performed including an echocardiogram bubble study which was negative for a patent foramen ovale or other cardiac defects. Other studies obtained including neck MRA, chest CT angiogram, and bronchoscopy were also negative.

The patient continued to have poor neurologic function for several days and also had three bouts of tonic clonic seizures related to his brain injury. On postoperative day (POD) 8 the patient's neurologic status began to markedly improve, regaining the ability to follow commands in all four extremities and spontaneous eye opening. The patient's hemoglobin and platelet counts began to steadily improve as well. On HD11,
the patient was weaned off pressure support ventilation and was stable on room air. At this time the patient was disoriented but was able to converse. Throughout the remainder of admission, the patient’s mental status continued to improve to a GCS of 15. The patient was discharged on HD20 awake and oriented without neurologic deficits to a rehabilitation facility. At the time of discharge the immediate family felt that the patient had returned to his baseline cognitive and neurologic status. At his two month follow up, the patient was noted to have a mild decrease in visual acuity without cognitive deficits or seizure activity, and was allowed to return to work without restrictions.

**DISCUSSION**

We have presented a case of a young male patient with closed bilateral femur fractures that went on to develop fat emboli syndrome with cerebral sequelae. FES most commonly occurs in the second to third decade of life, 12 to 72 hours following traumatic long bone fractures. Less common non-traumatic causes of FES include TKA and THA, soft tissue injury, liposuction, hepatic failure, propofol infusion, burns, acute sickle cell crisis, acute pancreatitis, and altitude sickness. It is important to make the distinction between fat embolism and fat embolism syndrome. While fat embolism is a subclinical phenomenon that occurs in over 90 percent in patients with traumatic injury, 3 to 4 percent of patients with long bone fractures present with clinically relevant symptoms of FES. As modern techniques in fracture fixation have improved, the early operative fixation of long bone fractures has reduced the incidence of FES to as low as 0.5 percent.

Although poorly understood, the pathophysiology of FES can be explained by two theories that originated in the 1920s. The mechanical theory proposed by Gauss in 1924 is often associated with traumatic injury and the release of fat droplets into the circulation from the site of trauma. These fat droplets subsequently pass through the right side of the heart into the lung capillary bed, causing ventilation-perfusion mismatching and subsequent acute respiratory distress syndrome (ARDS). Recent studies describe the intramedullary pressure in long bones as being the most decisive pathogenic factor for developing FES. Further supporting evidence of the mechanical theory comes from autopsy studies of multiply injured patients, post mortem lung intravascular fat was shown to be similar in composition to bone marrow fat. The biochemical theory proposed by Lehman in 1927 is thought to be supported by non-traumatic FES. The mobilization and lysis of excess triglycerides leads to the incomplete binding to albumin and eventual triglyceride entry into the circulatory system. Once present within various tissues such as the lungs and brain, an inflammatory cascade is initiated, causing end organ injury. Additionally, circulating free fatty acids are associated with an increase in acute phase proteins and catecholamine release, leading to further increases in lipolysis. Various mediators such as catecholamines, free fatty acids, protein degradation products, and C-reactive proteins increase the agglutination of chylomicrons (normally 1 µM) to form fat globules 10 to 40 µm in diameter.

FES is an entirely clinical diagnosis. Our patient was diagnosed with FES after fulfilling Gurd and Wilson’s one major and five minor criteria. These clinical signs
Pulmonary dysfunction may progress to respiratory pulse oximetry monitoring for earlier detection. Initial subclinical hypoxia, although common after long bone fracture, cyanosis, and hypoxemia. Although hypoxemia of FES patients, often manifesting as tachypnea, dyspnea, cyanosis, and hypoxemia. Although hypoxemia has been previously associated with subclinical FES, Talucci indicated that the incidence of critical hypoxemia is similar between trauma patient with and without FES. Additionally, Wong found that continuous pulse oximetry monitoring was able to detect subclinical desaturations in 100 percent of long bone fractures post-operatively in comparison to zero percent with daily arterial blood gas monitoring. Therefore, the authors recommended that subclinical hypoxia, although common after long bone fracture, should be monitored closely with continuous pulse oximetry monitoring for earlier detection. Initial pulmonary dysfunction may progress to respiratory failure in 10 percent of patients. Other presenting symptoms include mental status changes (59 percent), petechiae, fever, tachycardia, thrombocytopenia, and anemia.

Although macroglobulinemia was included in Gurd and Wilson’s criteria of 1974 included macroglobulinemia as a laboratory criterion our patient did not receive this lab. There has been much debate on its significance in detecting FES. In Gurd and Wilson’s 1970 study, it was determined that fat particles from bone marrow larger than 8 μm in diameter can embolize. Allardyce et al. found that low oxygen tension levels due to pulmonary failure from systemic emboli. However, Allardyce et al. found that low oxygen tension levels did not correlate with the development of cerebral FES.

This patient’s management for FES included continuous vital signs in the SICU, neuro-monitoring, daily CBCs, chest radiographs, echocardiogram, CT scan, and serial MRI scans. Initial emergency management of FES includes ruling out other pulmonary and cerebral pathologies such as pulmonary embolism, pneumonia, vascular injury of the neck, and meningococcal septicemia. With any disorder, standard arterial blood gas analysis, complete blood cell count, coagulation profile, and a search for petechiae should be obtained. Chest radiographs are often non-specific but often show diffusely increased pulmonary markings (snow-storm appearance) and right heart dilatation. Electrocardiogram may show signs of right-sided heart strain. A high-resolution chest CT scan will show bilateral or cerebral ground-glass opacities. Neutral lipid concentration obtained from bronchoalveolar lavage may assist with the diagnosis of FES.

Obtaining a transthoracic echocardiogram may show evidence of an intracardiac shunt, which is present in 20 to 34 percent of the population and may predispose a patient to develop CFES. However, a case report by Eriksson suggested that systemic manifestations of FES can occur in the absence of an intracardiac shunt. A proposed theory is that an increase in pulmonary arteriovenous anastomosis occurs during periods of exercise and hypoxia, potentially creating a conduit for fat emboli to be systemically released. Head CT is usually negative for any abnormalities the first one to two days post-injury.

However in symptomatic patients, multiple hypointense white matter lesions can arise that typically resolve with residual subdural effusion and cerebral atrophy. Brain MRI imaging is the most sensitive imaging technique for diagnosing cerebral fat embolism, and will show multiple hyperintense nodular or punctate foci on T2 sequences as early as four hours after the onset of cerebral fat embolism. These punctate lesions are often confluent with extension within the white and gray matter of the subcortical and watershed regions with extensive cytotoxic and vasogenic edema. The pathognomonic starfield pattern seen on diffusion-weighted MRI sequences is thought to be caused by cytotoxic edema from multiple microemboli. Pfeffer showed that a large quantity lesion burden on DWI correlated with irreversible brain injury and poor long-term clinical outcomes.
Our patient underwent volume resuscitation with crystalloid fluids prior to bilateral definitive fixation within 24 hours of injury. Recommended prevention and treatment of fat emboli syndrome includes definitive fracture management, supportive care, and treatment of shock\textsuperscript{6,11}. Albumin is recommended for volume resuscitation to retain blood volume and to bind fatty acids to decrease the extent of lung injury\textsuperscript{7}. Although 5% ethyl alcohol, heparin, and hypertonic glucose are historically described as treatment options for FES\textsuperscript{33}, only methylprednisone has limited evidence in the treatment of FES\textsuperscript{11,13}. A meta-analysis of seven double-blind randomized studies and 389 patients with isolated tibia and femur fractures showed that corticosteroids reduced the risk of FES by 78 percent and hypoxia by 61 percent. However, a closer look at the studies showed that corticosteroid treatment failed to significantly reduce the incidence of FES\textsuperscript{31} or hypoxemia\textsuperscript{32}. Additionally, these studies are not generalizable to the modern trauma patient given delayed fracture stabilization\textsuperscript{32,32}, differences in fracture severity between treatment groups\textsuperscript{33}, and varying diagnostic criteria\textsuperscript{12,13,31-33}. Even more troublesome is that none of these randomized controlled trials looked at long-term outcomes after steroid treatment\textsuperscript{34}.

In regards to fracture stabilization, our patient underwent close hemodynamic monitoring during sequential intramedullary nail placement, over-reaming with a flexible AO driver, and subsequent placement of bilateral 9.0mm intramedullary nails. Kuntscher was the first to describe the systemic effects of intramedullary nailing due to increased intramedullary pressures and fat emboli\textsuperscript{35}. It has been shown that inadequately stabilized fractures and delayed operative fixation led to a higher incidence of FES\textsuperscript{32,37}. Additionally, a retrospective study by Pinney found that there was a higher incidence of fat embolism syndrome in patients that received delayed definitive intramedullary fixation after ten hours, especially in patients with isolated femur fractures\textsuperscript{38}. Pell found that intraoperative transesophageal echocardiogram showed fat extravasation into the lung vascularity during reaming\textsuperscript{39}. In Pape’s 10-year retrospective study, it was reported that early fracture fixation in the setting of a chest injury led to a higher incidence of ARDS. Therefore, it was suggested that patients with chest injuries should undergo unreamed intramedullary nailing\textsuperscript{40}. Technologic advances such as slow insertion of hollow nails, distal venting, narrower reamers, and reamer irrigator aspirator devices have been developed in an attempt to reduce intramedullary pressures\textsuperscript{31-33,41-43}. In a 2011 prospective study, Richards found that reamed intramedullary nails were a moderate risk factor for developing cognitive impairment one year post-injury\textsuperscript{44}. Müller compared the conventional AO reamer system with a short reamer, a hollow reamer, and different diameter flexible driver sizes. The study concluded that most of the pressure build-up was dependent on the diameter of the flexible driver, with significant pressure decreases going from a 9mm to a 7mm diameter driver. Additionally, it was reported that using a 9.5mm hollow reamer with a 7mm driver and decreased in vitro pressures by 61 to 66 percent\textsuperscript{65}. In another comparison study, Volgas monitored intracardiac fatty emboli with intraoperative transesophageal echocardiogram during the standard sequential reaming technique and compared it with the reamer irrigator-aspirator (RIA) system\textsuperscript{66}. Results showed that the RIA group had a strong trend for decreased fatty deposit released during the second pass and nail insertion steps. A significantly lower level of fatty emboli was also detected in the nail insertion step in the RIA group\textsuperscript{66}. Although the data suggest that irrigator-aspiration reaming effectively reduces intramedullary pressures, the significant expense and bulkiness of the RIA system precludes its widespread use in the orthopaedic trauma population. Overall, the technologic advances in the commonly used reamer systems have allowed for more aggressive fracture fixation with reduced risk of systemic extravasation of medullary fat and subsequent development of FES.

**CONCLUSION**

FES is a rare clinical entity that most commonly occurs after high-risk orthopaedic injury. The patient’s collective risk factors for FES included closed bilateral femur fractures, mild hypoxia, tachypnea, critical hypoxemia, and mild tachycardia. Intraoperative risk factors include bilateral intraoperative reaming, intramedullary nail insertion, and tenuous ventilation associated with respiratory acidosis. Preventative measures taken included early fixation, flexible reamers, and narrow size 9 nails. Prophylactic corticosteroids were not administered due to limited clinical evidence in the setting of isolated femur fractures and unknown long-term effects. The patient’s eventual development of CFES was marked by unresponsiveness and a disconjugate gaze. Imaging showed pathognomonic diffuse hypointense punctate foci and watershed involvement of primarily white matter. Given that the foci were not confluent, the patient is likely to continue to have a good cognitive outcome, despite having coma and in-hospital delirium prior to recovery from CFES. In conclusion, our patient developed the rare episode of FES with cerebral manifestations after definitive bilateral femur fracture stabilization. The patient fortunately went on to full cognitive and respiratory recovery due to early diagnosis and aggressive supportive therapy.
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ABSTRACT

Introduction: Operative fixation of displaced inferior pole patella fractures has now become the standard of care. This study aims to quantify clinical, radiographic and functional outcomes, as well as identify complications in a cohort of patients treated with non-absorbable braided suture fixation for inferior pole patellar fractures. These patients were then compared to a control group of patients treated for mid-pole fractures with K-wires or cannulated screws with tension band wiring.

Methods: In this IRB approved study, we identified a cohort of patients who were diagnosed and treated surgically for a displaced patella fracture. Demographic, injury, and surgical information were recorded. All patients were treated with a standard surgical technique utilizing non-absorbable braided suture woven through the patellar tendon and placed through drill holes to achieve reduction and fracture fixation. All patients were treated with a similar post-operative protocol and followed up at standard intervals. Data were collected concurrently at follow up visits.

For purpose of comparison, we identified a control cohort with middle third patella fractures treated with either K-wires or cannulated screws and tension band technique. Patients were followed by the treating surgeon at regular follow-up intervals. Outcomes included self-reported function and knee range of motion compared to the uninjured side.

Results: Forty-nine patients with 49 patella fractures identified retrospectively were treated over 9 years. This cohort consisted of 31 females (63.3%) and 18 males (36.7%) with an average age of 57.1 years (range 26 - 88 years). Patients had an average BMI of 26.48 (range 19 – 44.08).

Thirteen patients with inferior pole fractures underwent suture fixation and 36 patients with mid-pole fractures underwent tension band fixation (K-wire or cannulated screws with tension band). In the suture cohort, one fracture failed open repair (7.6%), which was revised again with sutures and progressed to union. Of the 36 fractures repaired with a tension band fixation, 11 underwent secondary surgery due to hardware pain or fixation failure (30.6%).

At one year, no difference was seen in knee range of motion between cohorts. All fractures healed radiographically. Those patients who required reoperation or removal of hardware had significantly diminished range of motion about their injured knee (p = 0.005).

Conclusions: Patients who sustain inferior pole patella fractures have limited options for fracture fixation. Suture repair is clinically acceptable, yielding similar results to patella fractures repaired with metal implants. Importantly, patients undergoing suture repair appear to have fewer hardware related postoperative complications than those receiving wire fixation for midpole fractures.

Keywords: Patella fracture, suture fixation, wire fixation

INTRODUCTION

Patella fractures comprise 1% of all fractures encountered in the emergency department, and only a third of these require surgical intervention\(^1\,^2\). Among patellar fractures treated surgically, approximately 20% involve the inferior patellar pole\(^3\). Historically, a debate existed between resection of the inferior pole versus surgical reduction and fixation. Currently, clinical and biomechanical studies have provided definitive evidence that...
resection disrupts the extensor mechanism by decreasing the lever arm at the knee joint\(^4,5\). Operative fixation of displaced patella fractures has now become the standard of care for these injuries\(^6\).

The Modified Anterior Tension Band technique with Kirschner wires (K-wires) is one of the most common methods used for fixation of simple mid-pole patella fractures. Although the K-wire and tension band technique remains popular, patients frequently complain of discomfort secondary to prominent hardware, leading to high rates of removal of hardware (ROH). Other techniques, such as the fixed angle plate and the basket plate, intended for use in distal pole fractures, have been developed\(^7,8\). These alternatives have yet to supplant techniques involving tension banding, which are still considered the gold-standard for fracture care\(^9,10\).

Furthermore, some comminuted and inferior pole fractures are not amenable to standard fixation techniques. Recent studies have suggested that sutures such as 5-Ethibond and Fiberwire are similar in strength to, yet avoid the irritation associated with, 18-gauge stainless steel wires\(^12,13,14\).

This study aims to quantify clinical, radiographic and functional outcomes, as well as identify complications in a cohort of patients treated with non-absorbable braided suture fixation for inferior pole patellar fractures. These patients were then compared to a control group of patients treated for mid-pole fractures with K-wires or cannulated screws with tension band wiring. We hypothesize there will be no observable difference in outcomes between the two groups.

**METHODS**

In this IRB approved study, we performed a retrospective chart review which identified 49 patients who sustained 49 displaced patella fractures and were treated surgically over a 9 year period (2002-2011); no patients were excluded. Patient demographics, injury pattern and mechanism, and surgical information were extracted from the record. The treating surgeons followed each of their patients at standard intervals. Radiographs and functional data were recorded at these follow-up visits.

A standard surgical technique for suture repair was employed. Two non-absorbable braided sutures were placed in a Krackow type fashion yielding four proximal suture ends. Three longitudinal drill holes were made along the long axis of the patella. Suture ends were passed through the drill holes with a Beath Needle, and following reduction with a tenaculum clamp, tied down over top of the patella (Fig 1a, 1b and 1c). Correction of
patella alta and fracture reduction was confirmed using intraoperative image intensification. Post-operatively, all patients were allowed to bear weight in extension while in a knee immobilizer for six weeks. Knee range of motion was limited for six weeks. Radiographs were obtained at standard intervals to assess fracture healing. Lysholm Knee Score and Tegner Activity Scale scores were obtained to objectively quantify knee function and SF-36 was used to assess general well-being. Data were collected at follow up visits.

For purpose of comparison, we utilized a control cohort of patients who sustained a mid-pole patella fracture treated with either K-wire or cannulated screws and wire tension band technique. This procedure was performed using a modified AO technique where 18-gauge wire is crossed in a figure-of-eight fashion over the anterior patellar surface and tensioned with knots superiorly. Patients were followed by their treating surgeon and outcomes, including self-reported function and knee range of motion compared to the uninjured side, were recorded. Statistical comparison was made with Fisher’s exact test and students paired t-test with a significance threshold set at \( p = 0.05 \).

**RESULTS**

We identified 49 patients who sustained 49 displaced patella fractures that were treated surgically by 2 surgeons over a 9 year period, from 2002 to 2011. This cohort consisted of 31 females (63.3%) and 18 males (36.7%) with an average age of 57.1 years (range 26 - 88 years). Patients had an average BMI of 26.48 (range 19.7 - 44.1). Patients in each surgical intervention cohort had statistically identical BMI and age. The most common cause of injury reported was a low energy fall; one patient was involved in a MVA. Patients were followed clinically at standard intervals and functional outcomes were assessed at one year (Table 1).

<table>
<thead>
<tr>
<th></th>
<th>Suture Cohort</th>
<th>Tension Band Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>30.8% Male</td>
<td>38.9% Male</td>
</tr>
<tr>
<td>BMI</td>
<td>25.8 (19.7 - 38.9)</td>
<td>26.7 (20.2 - 44.1)</td>
</tr>
<tr>
<td>Age</td>
<td>55.3 (36 - 75)</td>
<td>57.8 (26 - 88)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>SF-36</td>
<td>84.1 (68.4 - 96.9)</td>
<td>75.8 (14.1 - 99.4)</td>
</tr>
<tr>
<td>Lysholm</td>
<td>82 (56 - 100)</td>
<td>78.4 (22 - 100)</td>
</tr>
<tr>
<td>Tegner</td>
<td>2.77 (1 - 4)</td>
<td>2.53 (1 - 4)</td>
</tr>
<tr>
<td>ROM Change (Degrees)</td>
<td>-9.6 (-50 - 0)</td>
<td>-8.3 (-30 - 0)</td>
</tr>
</tbody>
</table>

Figure 2. Cannulated screw and wire tension band construct.

Thirteen patients with 13 fractures involving the inferior pole of the patella underwent suture fixation (Fig 1) and 36 patients whose fractures involved the mid-pole region underwent K-wire or cannulated screw and wire tension band fixation (Fig 2). Of the suture cohort, one patient had an initial failed fixation (7.6%). Revision surgery consisted of inferior pole patellectomy and patellar tendon advancement. Of the 36 patients receiving tension band fixation, 11 had secondary surgery due to hardware pain or failure (30.6%). Hardware removal occurred at an average of 46 weeks. Though clinically relevant, the aforementioned reoperation results are not statistically significant (\( p = 0.14 \)). None of the patients with cannulated screw and tension band construct required re-operation (\( p = 0.016 \)); all secondary surgery occurred in patients treated with K-wires. No infections were reported in either cohort.

At one year, all fractures had healed radiographically. There was no significant difference in knee range of motion or functional score (Lysholm and Tegner scores) between the two cohorts. Patients undergoing wire fixation for midpole fractures had a lower composite total SF-36 score (75.8) compared to inferior pole fractures repaired with sutures (84.1) (\( p = 0.03 \)). Those patients who experienced reoperation or post-operative complication had a significantly lessened arc of knee motion.
(mean 113 degrees) about their injured knee compared to those who did not (mean 126 degrees) (p = 0.005). Finally, when compared to the contralateral knee, the injured knee of patients requiring removal of hardware had significantly greater decrease in range of motion than those patients not requiring removal of hardware: -17.1º versus -6.0º, respectively (p=.005).

**DISCUSSION**

Patients who sustain inferior pole patella fractures have limited options for fracture fixation. Suture repair is clinically acceptable and biomechanically verified\(^{18,19}\), and in our study, yielded results similar to midpole patella fractures that underwent ORIF with metal implants. In our study, patients undergoing suture repair had fewer hardware related postoperative complications and achieved higher composite SF-36 scores at one year follow-up. The reoperation rate was four times higher for patients receiving standard tension band fixation as opposed to suture fixation. This result is consistent with other reports demonstrating an increased reoperation rate for patients receiving metal implants\(^{20,21}\).

Partial patellectomy remains an option for treatment for comminuted inferior pole fractures; however, this treatment may potentially lead to patella baja, which is defined by an Insall-Salvati index less than 0.6\(^{11,22}\). Not only may patients report discomfort, but they may also lose proper functioning of the patellofemoral joint\(^{23}\) leading to patellofemoral arthritis\(^{34}\). A study by Hung, et al., on partial patellectomies confirms this relationship, noting radiographic evidence of arthritis in 55% of patients in a retrospective cohort and evidence of patella baja in many patients\(^{25}\).

Prior studies on patella fracture fixation have reported reoperation rates between 20% and 50% following use of Kirschner wires\(^{20,21,25,26}\). A recent study with 6.5 years mean follow-up by LeBrun reported a rate of 56% in a cohort similar to that used as a control in our study\(^{27}\). Interestingly, all hardware removals in our study occurred in the K-wire group, accounting for 93% of all reoperations in the cohort; the remaining reoperations were indicated due to treatment failure. No removal of hardware was required in the subset of patients treated with cannulated screws and tension band wiring. This discrepancy between removal of hardware rates for K-wire and cannulated screw is similar to a study by Tian, which showed no post-op complications for the cannulated screw group, but a 20% removal of hardware rate in the K-wire fixation group\(^{24}\). Furthermore, our study showed that patients requiring reoperation had significantly restricted range of motion in their affected knee, and remained significant after exclusion of patients receiving pole resection.

Though a previous study investigated the use of #5 Ethibond suture fixation over K-wire fixation\(^{20}\), it did not employ quantitative methods to assess patient outcome. Our study made use of accepted patient outcome metrics to quantify any differences between the two groups, as well as basic chart review. Aforementioned studies with rigorous outcome metrics, like LeBrun, et al., and Tian, et al., did not include a cohort treated with sutures.

Studies on basket plates, including a recent case series by Huang, are specific to inferior pole fractures but are limited by their small cohorts\(^8\) or control with pole resection\(^{34}\) – a method inferior to osteosynthesis due to reduced range of motion and increased incidence of patella baja\(^{25,28}\). In a study using basket plates by Kastelec et al., 64% of patients receiving internal fixation underwent hardware removal. Though the authors report no significant difference in functionality between patients who underwent hardware removal and those who retained hardware, no standardized outcome measure was used to compare the two groups.

Our study is limited by a small patient population, which limit the statistical analysis. There was no algorithm for selection of fixation type; the decision was solely based upon fracture pattern, which may have created a selection bias. In general, simple two-part fractures with large fragments were fixed with cannulated screws, comminuted fractures were fixed with K-wire tension band, and small inferior pole fractures were repaired with suture. Finally, the retrospective nature of our analysis is not ideal for a rigorous comparison of the two surgical methods. Despite this, our inclusion of quantitative outcome measures supported and expanded upon qualitative conclusions of previous studies.

This study demonstrates that mid-pole patella and inferior pole patella fractures treated surgically compared similarly with regards to knee outcome scores, range of motion, and healing. Distal pole fractures treated with suture technique did not necessitate removal of hardware whereas some patients in the tension band cohort required another operation. Suture fixation was also associated with a lower overall reoperation rate. Our results indicate that distal pole fractures are successfully treated with heavy braided non-absorbable suture fixation and achieve outcomes equal to or better than wire fixation for mid-pole fractures.

**REFERENCES**

ABSTRACT

Traditional interlocked intramedullary (IM) nails have recently been modified to provide enhanced angular stability. These so-called ‘angle-stable’ IM nails are designed to eliminate construct toggle and also provide increased axial, bending, and torsional stiffness. While this added stability is needed for small fracture gaps to heal, angle-stable nails may be too stiff for large fracture gaps to unite. Even though relative stability is recommended for large fracture gaps, recent in vivo data indicates that traditional nails may allow for too much motion for healing to occur. The current study evaluated a modified technique for implanting an angle-stable nail which allows for an intermediate amount of stability. The compliance of the nail construct was adjusted by over-drilling the near cortex interlocking hole. This led to increased construct motion in torsion, but less so in axial compression and bending. This modification creates stability which is partway between angle-stable and traditional IM nail designs. These findings were unchanged after 50,000 fatigue loading cycles. By carefully selecting the magnitude of over-drilling, the compliance of the construct can easily be modified as it is being implanted. This design modification may lead to more reliable fracture union since the surgeon can tailor the nail compliance to the injury and bone quality.

INTRODUCTION

Interlocked intramedullary nailing has been used for several decades to treat a variety of long bone fractures. One recent innovation is the so-called ‘angle-stable’ nail which eliminates screw-to-nail toggle. Such toggle is inherent in traditional interlocked nails which use screws that are intentionally undersized by ~0.13 mm relative to the nail holes (Figure 1a). The slightly oversized nail holes assist in targeting and insertion of the screws without binding. However, the screw-to-nail toggle leads to interfragmentary motion which is particularly noticeable in torsion. In vivo studies have shown that eliminating this toggle leads to superior healing for simple fractures in sheep. This work led to several commercially available angle-stable nail designs which all eliminate the screw-nail hole clearance inherent in traditional nails. As such, they require careful coaxial alignment of the bone and nail holes.

An alternative design proposed by Garlock et al. allows the bone and nail holes to be misaligned yet still create an angle-stable construct. The interlocking nail hole is threaded and an oversized collar is interposed between the screw head and nail (Figure 1b). As the screw is tightened, the collar compresses and the screw becomes secured to the nail. The collar allows the near cortical drill hole to be misaligned in any direction by up to 0.6 mm yet still retain angular stability. This reduces the alignment requirements of other angle-stable designs. Mechanical testing of these constructs revealed a reduction in angular deformation from 8.2° (traditional nail) to 2.7° (collared angle-stable nail) at ± 1.5 Nm of torque. Both nails were evaluated by Kubacki et al., in an in vivo canine femur fracture model with a 10 mm segmental defect and periosteal stripping. While all traditional interlocking IM nails progressed to a hypertrophic nonunion, 6/10 angle-stable animals progressed to union. The remaining angle-stable animals showed signs of stress-shielding and did not unite. The toggle inherent in traditional nails may explain the proliferation of tissue in those animals since callus formation is associated with greater interfragmentary motion for secondary healing. Findings of stress shielding from the angle-stable canine data suggest that these IM nails were likely too rigid for segmental defects.

In related work on locking plates, Bottlang et al., sought to reduce near cortex stress shielding by over-drilling the near hole by 0.8 mm for a 4 mm screw. This increased the interfragmentary motion adjacent to the plate, significantly increased the formation of callus, and led to better healing. Similar to Bottlang’s work,
the collared angle-stable nail described above relies on the purchase of the screw to the implant and purchase into the far cortex. The collared angle-stable IM nail can thus maintain angular stability even though the screw purchases into just the far cortex. By over-drilling the near cortex, the collared end of the screw would have more space to move which would likely increase the motion across the fracture. This is not the case for traditional interlocking IM nails which rely on bicortical screw purchase.

Currently, there are no data in the literature which show how to incrementally control the amount of torsional motion in an angle stable-nail at the point of surgery. In the current study, an angle-stable IM nail implantation technique was modified to create a controlled increase in construct motion by over-drilling the near cortex hole (Figure 1c). One concern was the robustness of this design. Thus, the construct was also subjected to fatigue testing to ensure the integrity of the construct. It was hypothesized that, similar to Bottlang, over-drilling the near cortex hole would increase the compliance of the construct while still maintaining fatigue resistance. Biomechanical data from this modified angle-stable IM nail was compared to historical controls for reference.

**MATERIALS AND METHODS**

A previously described angle-stable titanium IM nail-interlocking screw construct (Ti6Al4VELI, United Titanium, G&S Titanium, Wooster, OH) and bone analog was the basis for this study. The nails were 7.5 mm in diameter and had a length of 143 mm. Two 3.5 mm screws were used on either end to interlock the nail to the analog which was segmentally defected with a 30 mm gap (Figure 2). The collars had a 0.4 mm wall thickness and an internal diameter which was 0.6 mm greater than the screw. All screws were secured with a torque wrench to 1.5 Nm. Briefly, the bone analog (30% glass filled Nylon 6-6, McMaster-Carr) material mimicked the dimensional and mechanical properties of a canine femur. The bone analogs were machined to include larger diameters at the ends which gradually reduced to a smaller diameter centrally. This was designed to represent the basic hourglass shape of the femur. In addition to the segmental defect, the ‘endosteal’ diameter in the central third was 2.5 mm greater than the nail to ensure the nail and interlocking hardware were the sole load path. Pilot tests confirmed that the nail did not contact the bone analog anywhere along its length except via the interlocking hardware. Detailed dimensions can be found in Garlock et al. Six samples were tested; the number of replications was anticipated to provide a minimum power of 0.8.

The collared angle-stable IM nail design described previously allows for over-drilling of the near cortex without loss of stability. This is due to the screw-collar-nail union which creates a fixed angle construct (Figure 1b, 1c). Screw purchase solely in the far cortex still provides bone-to-nail interlocking and prevents toggle from occurring. Pilot tests revealed that progressively enlarging the near cortex hole in 0.2 mm increments caused proportional increases in construct compliance in torsion, axial compression, and bending. The effect was greatest, however, in torsion.

The pilot tests showed that over-drilling the near cortex 0.5 mm was anticipated to yield construct compliance which was partway between the angle-stable and traditional IM nails. The specimens were prepared for testing per Garlock et al. (Figure 2) by potting both ends of the construct in room temperature-curing epoxy in potting cups. The exposed portion of the construct between the cups was 174 mm, the typical femur length of a canine femur. The specimens were tested in torsion, compression, and bending for 10 sinusoidal cycles in separate experiments with a materials testing machine (8304 Test Resources, Shakopee, MN) before and after fatigue testing. The constructs were loaded to ±1.5 Nm.
120 N, and 1.43 Nm, in torsion (positive (counterclockwise) and negative (clockwise) rotation through neutral), axial compression, and bending, respectively, with the machine in load-control mode. The bipolar torsional test was performed at a cyclic frequency of 0.5 Hz (~1 Hz per direction); the remaining tests were performed in the compressive direction only at 1 Hz; all data were sampled at 80 Hz. The axial compression and bending load magnitudes represent physiologic magnitudes for a medium canine (20 kg). While the physiologic torque is estimated to be 0.6 Nm, 1.5 Nm was necessary to elucidate the linear range for stiffness calculations. Data from the tenth cycle from all tests were analyzed using established methods. Briefly, stiffness was assessed for all loading modes by taking the slope of the linear range of the load (torque, axial compressive or bending force) versus the test machine actuator motion (angular displacement, compressive or bending linear displacement). The torsional stiffness was determined separately for the positive and negative rotation directions. The maximum angular displacement for the torsional tests was taken as the angular displacement that occurred during the tenth ±1.5 Nm peak-peak torsion cycle.

Fatigue testing was performed for 50,000 cycles of combined axial (120 N) and torsional (0.75 Nm) loading. The supraphysiologic torque magnitude was used to challenge the constructs’ performance in its more vulnerable mode. The 50,000 fatigue cycle magnitude represents 12 weeks of unrestricted cage activity by a canine. The findings from these experiments were compared to historical controls of a traditional interlocked IM nail and a collared angle-stable IM nail that was not over-drilled with a one-way ANOVA and Fisher LSD post-hoc testing (α = 0.05). The historical controls were biomechanically tested with the same protocol used in the current study. Data from the current study were also compared before and after fatigue testing with the paired t-test (α = 0.05). Prior to all statistical analyses, normality was confirmed for all data.
RESULTS

All over-drilled angle stable specimens (Figure 1c) completed the fatigue testing protocol to 50,000 cycles. The stiffness tended to increase after increasing in axial compression and torsion and decrease in bending, though these findings were not significant (Table 1). The pre-fatigue axial stiffness of the over-drilled IM nails (1,351±167 N/mm) was significantly greater than the historical traditional IM nail (1,171±15 N/mm, p=0.032) (Figure 1a) but was not significantly different from the non-over-drilled angle-stable IM nails (1,445±28 N/mm, p=0.227) (Figure 1b). Following fatigue cycling, the axial stiffness of the non-over-drilled nail (1,664±201 N/mm) was significantly greater than the traditional nail (1,334±15 N/mm, p=0.005) and the over-drilled angle stable nail (1,461±123 N/mm, p=0.039). The over-drilled constructs were toggle free (zero degrees of toggle) similar to the angle stable nails without over-drilling and significantly less than the traditional nail (4.6±1.3° of toggle, p=0.001). The total angular deformation of the over-drilled IM nails (4.3±0.2°) was significantly less than the historical traditional IM nail (8.2±1.1°, p=0.001) and significantly greater than the non-over-drilled angle-stable IM nails (2.7±0.1°, p=0.002). The angle stable nail without over-drilling exhibited torsional positive and negative stiffness magnitudes which ranged from 1,137±68 to 1,189±15 N-mm/deg when considering all pre-fatigue and post-fatigue magnitudes for both rotation directions. These values were significantly greater (p=0.001 for all comparisons) than the corresponding torsional stiffness magnitudes for the traditional nail (range 802±4 to 843±79 N-mm/deg) and the over-drilled angle-stable nails (762±74 to 801±8 N-mm/deg). While the over-drilled angle stable nails tended to be lower for all comparisons with the traditional IM nails, this finding was not significant (p=0.065-0.876). None of the bending stiffness magnitude comparisons were significant (p=0.195), though the traditional nail tended to be greater than both angle stable nail designs.

DISCUSSION

The objective of this study was to biomechanically evaluate modifications to an angle-stable IM nail design. It was found that the mechanical behavior of the construct could be reliably adjusted by over-drilling the near cortex without affecting fatigue life. Over-drilling the near cortex affected the mechanical response of the construct in torsion more than axial compression or bending. Torsional loading with 0.5 mm of over-drilling produced 4.3±0.2° of angular deformation at ±1.5 Nm of torque. This was approximately half the motion observed with a traditional nail (8.2±1°), and 60% more motion than the non-over-drilled angle-stable nail (2.7±0.1°). Despite the increase in angular deformation and decreased torsional stiffness, the construct exhibited zero toggle. Over-drilling the near cortex is a simple technique which can be easily adopted intraoperatively; it only requires a range of drill bit sizes. Based on the pilot data from the current study, the increased motion is related to the magnitude of the over-drilling. For simple fractures with small interfragmentary gaps, no over-drilling is likely warranted. As the complexity of the fracture increases (long fracture gaps, comminution), progressive over-drilling may aid in creating a controlled amount of motion which is tailored to the fracture.

Prior in vivo canine data from several studies suggests that an optimal amount of construct stiffness exists when treating open, complex fractures with segmental loss and periosteal stripping. For example, Kubacki et al., showed that traditional canine IM nails led to hypertrophic nonunions which were attributed to excessive torsional construct motion (8.2°). Angle-stable IM nails allowed significantly less torsional motion (2.7°) though some fractures did not heal and showed signs of stress shielding. The optimal mechanical environment for this complex fracture likely lies between the two nails. While numerous studies have sought to establish the optimal mechanical environment for fracture healing, differences in host selection, test methods, fracture

| Table 1. The biomechanical behavior of the over-drilled angle-stable IM nail was compared to a traditional interlocked IM nail and an angle-stable IM nail without over-drilling. See Figure 1 and text for additional details. |
|-----------------|-----------------|------------------|-----------------|-----------------|-----------------|
|                  | Axial Compression (N/mm) | Toggle (°) | Total Angular Deformation (°) | Positive Stiffness (N-mm/°) | Negative Stiffness (N-mm/°) | Bending Stiffness (N-mm/mm) |
|                  | Pre-fatigue | Post-fatigue | Pre-fatigue | Post-fatigue | Pre-fatigue | Post-fatigue | Pre-fatigue | Post-fatigue | Pre-fatigue | Post-fatigue |
| Traditional Nail | 1.171±15 | 1.334±14.9 | 4.6±1.3 | 8.2±1.19 | 8.3±1.29 | 803±71 | 843±79 | 809±16 | 13.14±1.175 |
| (Figure 1a))     | 19%*       | 11%*       | 29%*       | 14%*       | 10%*       | 9%*       | 6%*       | 8.9%*      |
| Angle-Stable Nail | 1.445±28 | 1.664±201 | 0*** | 2.7±0.1| 2.6±0.1 | 1.137±88 | 1.185±13 | 1.157±63 | 11.96±2.675 |
| w/o overdrilling | 2%*       | 12%*       | 6%*       | 2%*       | 8%*       | 1%*       | 5%*       | 22.3%*     |
| Overdrilled Angle-Stable Nail | 1.351±167 | 1.461±123 | 0* | 4.3±0.2 | 4.2±0.2 | 762±74 | 774±73 | 765±78 | 11.13±1.221 |
| (Figure 1c))     | 12%*       | 8%*        | 6%*       | 5%*       | 10%        | 9%        | 10%       | 11%        | 10.72±4.97 |

* Significantly different than traditional nail; † Significantly different than angle stable nail w/o over-drilling; ‡ Data is presented as mean ± 1 SD (standard deviation); the coefficient of variation (ratio of SD to mean) is presented as an additional measure of data dispersion; † From Garlock et al., † From Donovan et al.; $ Not tested

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type, and implants make it difficult to establish definitive recommendations. That said, a variety of in vivo animal studies have shown that axial or shear motion can increase or decrease callus formation and maturation. Dejardin et al., studied an angle-stable nail in a 5 mm canine tibial fracture gap. This construct exhibited similar torsional behavior to the non over-drilled angle-stable collared nail. All five of Dejardin’s angle-stable animals formed a bony union while the traditional nail animals had several cases of nonunion. Kubacki et al., in vivo canine cases of nonunion from the non-over-drilled collared angle-stable IM nails may be related to the increased severity of injury and the longer bone defect. These factors have been shown to challenge the healing response.

One limitation of the current study was the use of a bone analog. However, this material has been validated as a model of canine bone by others. Further, the analog provides greater consistency such that the effect of the construct design can be more clearly determined. Another limitation is the relatively simple sinusoidal, combined torsion-compression loading mode in fatigue. While in vivo loading during gait is likely much more complex, the loading mode used in the current study is common in the literature for combined loading. While single mode fatigue loading could have been used, it would likely have been less challenging to the construct. An additional limitation is the in vitro nature of the data from the current study. However, Kubacki et al., used a version of this nail for in vivo canine experiments which showed that the angle stable design led to stress shielding and the traditional nail allows too much motion. As such, data interpolation of the available suggests that the increased motion afforded by the angle stable nail design in the current study would hopefully yield increased cases of union in vivo.

Further work is needed to determine if the over-drilled near cortex concept enhances healing in an animal model. Such in vivo work should include metaphyseal fractures and osteoporotic bone, both of which would likely benefit from the enhanced fixation of angle-stable screws. In cases of comminution or segmental loss, adjustable construct stiffness via over-drilling of the near cortex would allow interfragmentary motion to be progressively increased. The utility of controlled increases in interfragmentary motion has already been demonstrated in vivo with new plating methods such as the far cortical locking technique. Extending this concept to the nail via the technique described in the current paper will hopefully enhance fracture care by tailoring the interfragmentary motion to a specific case.

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2. Non-Endorsement Disclaimer: The views, opinions, and findings contained in this research are those of the company and do not necessarily reflect the views of the Department of Defense and should not be construed as an official DoD/Army policy unless so designated by other documentation. No official endorsement should be made.

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DECLARATION OF CONFLICTING INTERESTS

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REFERENCES


A Method to Modify Angle-Stable Intramedullary Nail Construct Compliance


ABSTRACT
Diabetic muscle infarction (DMI) occurs as a rare complication of long standing or severe diabetes mellitus. The condition usually occurs spontaneously and patients usually present with acute pain and swelling of affected muscles which persists for weeks, and resolves spontaneously without intervention. Magnetic resonance (MR) imaging is the modality of choice in patients with suspected DMI based on appropriate clinical setting and plays a major role in the diagnosis, assessing the extent of involvement and differentiating DMI from other conditions. The DMI affected muscles are bulky and appear heterogeneous with hyperintense signals on T2-weighted and STIR sequences, hypointense on T1-weighted images with loss of normal fatty intramuscular septae. Subcutaneous and perifascial edema can be present. On post-gadolinium scans, there is diffuse heterogeneous enhancement with non-enhancing foci, which may represent areas of necrosis. Biopsy can be avoided as MR findings are highly sensitive and specific. Treatment is usually conservative. Surgical intervention is required only in patients who do not respond to conservative management. The common differential diagnosis includes cellulitis, abscess, necrotizing fasciitis and polymyositis. We present two cases below to highlight the clinical, MR imaging findings and differential diagnosis of DMI.

INTRODUCTION
Diabetic muscle infarction (DMI) was first described by Angervall and Stener in 1965 as ‘Tumoriform muscular degeneration’ in two patients with non-insulin dependent diabetes mellitus (NIDDM)1. DMI occurs as a rare complication of long-standing or severe diabetes mellitus. The condition usually occurs spontaneously, without concurrent or preceding infection or trauma. It is more frequent in diabetic women (61.53%) with mean age at presentation being 39 ±12 years2,4,5,6.

Patients who develop DMI present with acute pain and swelling of affected muscles which persist for weeks and resolve spontaneously without intervention. Rarely a mass can be palpated. Magnetic resonance imaging (MRI) is the modality of choice in patients with suspected DMI based on appropriate clinical setting, due to superior soft tissue contrast and multi-planar image acquisitions7. It also plays a major role in the diagnosis, assessing the extent of involvement and differentiating DMI from other conditions like cellulitis, abscesses and necrotizing fasciitis.

We present the report on two cases of DMI to highlight the importance of MRI findings in guiding non-invasive management of the condition.

Case report 1
A 44-year-old woman with history of insulin dependent diabetes mellitus (IDDM) for eight years presented with two weeks of pain and swelling in her right leg. There was no history of trauma and no clinical or biochemical evidence of infection. Clinical examination showed a non-erythematous tender swelling along the lateral aspect of right leg, extending from below knee to just above the ankle. Patient had no improvement of pain with analgesic medications and hence MRI was requested for further evaluation of the clinical condition.

Magnetic resonance imaging of the legs revealed involvement of muscles in the lateral compartment including the peroneus longus, peroneus brevis and extensor digitorum longus. The muscles were bulky and appeared heterogeneous with hyperintensities on T2-weighted and STIR (Short Tau Inversion Recovery) sequences with loss of definition of intramuscular septae on T1-weighted sequence (Figure 1). Post-gadolinium scans revealed heterogeneous enhancement within the muscles with focal hypointense non-enhancing areas (Figures 2, 3). The skin and subcutaneous fat over the leg was thickened and edematous. The clinical and MRI findings were highly suggestive of DMI and the patient was managed conservatively.
Case Report 2

A 39-year-old lady with history of IDDM for the past ten years presented with pain and swelling of her left leg of two months duration. There was no preceding history of trauma or infection. Clinical examination revealed tender swelling of her proximal left leg with tense, shiny and edematous skin. Hematological and biochemical parameters were normal. The patient was referred for MRI because of a clinical concern regarding a soft tissue sarcoma.

On MRI, the medial head of the gastrocnemius, soleus and flexor digitorum longus muscles were bulky. The muscles appeared hyperintense on T2-weighted and STIR sequences (Figures 4,5) while on T1-weighted sequence the muscles were uniformly hypointense with loss of normal fatty intramuscular septae. The skin and subcutaneous tissues along the anterior, medial and posterior aspects of the leg were thickened with replacement of subcutaneous fat. A diagnosis of diabetic muscle necrosis was offered and biopsy was deferred. The patient was managed with analgesics and bed rest. Follow-up in one week showed complete resolution of symptoms.

DISCUSSION

Diabetic muscle infarction has also been described as aseptic or ischemic myonecrosis. DMI can occur in both patients with IDDM and poorly controlled NIDDM on insulin therapy. Risk factors include long-standing diabetes mellitus (mean 15 years), poor glycemic control and diabetic vascular disease. Patients who develop DMI almost always have severe diabetic vascular disease at the time of presentation. According to Angervall and

Figure 1: Axial T1-weighted image showing homogenous low signal intensity within the muscle with loss of fatty intramuscular septae (open arrow). Thickened skin and subcutaneous fat can be noted.

Figure 2, 3: Coronal and axial fat suppressed gadolinium-enhanced T1-weighted images showing diffuse heterogeneous enhancement of the affected muscles with focal non-enhancing areas which may represent necrosis (white arrow).
Stener, diabetic microangiopathy and arteriosclerosis can be of importance in the pathogenesis of DMI1,6,8,9. Vascular endothelial damage and a hypercoagulable state precipitate small and medium vessel thrombosis resulting in myonecrosis2,10,11. Histopathology shows areas of muscle necrosis, infarction, hemorrhage and focal fibrosis.

The thigh muscles are most commonly involved followed by the calf muscles5,12. The upper limb is rarely involved. Multiple muscles or muscle compartments can be involved and at times involvement can be bilateral2,11,13,14. Systemic signs of infection like fever, leukocytosis or elevated ESR may be absent15. Laboratory investigations are not helpful in diagnosis, though some authors have reported transient elevation of creatine kinase, white blood cell count and erythrocyte sedimentation rate2,4,10,14,15,16.

For DMI, MRI is the diagnostic modality of choice. Axial MR images are ideal for diagnosis, although coronal and sagittal images can help in documenting the extent of involvement5. STIR and T2-weighted images closely reflect the underlying pathological processes as both are fluid sensitive sequences. The affected muscles are usually bulky and appear heterogeneous with hyperintense signals on T2-weighted and STIR sequences. This is secondary to increased water content from edema and inflammatory changes that accompany the infarction and sometimes due to presence of hemorrhagic foci10,14,15. The affected muscles appear hypointense or isointense on T1-weighted images with loss of normal fatty intra-muscular septae. Hyperintensity on T1-weighted images may likely represent hemorrhagic infarction4,17. Subcutaneous and perifascial edema can be present7,18,19. On post-gadolinium scans, there is diffuse heterogeneous enhancement with low signal, non-enhancing foci which may represent areas of necrosis. Rim enhancement can be seen around these areas of necrosis within the areas of ischemic muscle14,11. The bone and marrow changes can also be assessed simultaneously to rule out concurrent osteomyelitis. As MRI findings are highly sensitive and specific to some extent, biopsy can be avoided in these patients.

The common differential diagnosis includes infections (cellulitis, abscess, necrotizing fasciitis), inflammatory (thrombophlebitis, polymyositis), traumatic (muscle tear, intramuscular hematoma) and neoplastic causes (soft tissue sarcoma, lymphoma)2,8,12. In cellulitis, subcutaneous swelling is seen, but with no muscle involvement. Necrotizing fasciitis has MR findings including muscle swelling, edema and inflammatory changes similar to DMI. But when compared to DMI, necrotizing fasciitis has less pronounced muscle involvement and more extensive fascial involvement. Additionally, gas bubbles and fluid collection may be seen in the tissues. Also, clinically, they present with systemic signs of infection, including fever and elevated peripheral WBC count, in addition to cellulitis, and do not present with severe pain which is characteristic of DMI10,14. Soft tissue tumors usually present as masses within a single muscle or multiple muscle groups in a compartment. Multiple, discontinu-
ous muscle involvement and/or bilateral involvement is extremely unlikely in primary tumors. These masses may be enhancing or non-enhancing depending on the tissue types and may have intratumoral necrosis. They usually do not present with sudden and severe muscle pain.

Treatment includes bed rest, analgesics and careful metabolic control of diabetes to prevent possible recurrence. Surgical intervention is required only in patients who do not respond to conservative management. Short term prognosis is usually good with spontaneous resolution of symptoms in a few weeks. Long-term prognosis is generally poor, due to the fact that the patient already has widespread diabetic vascular disease by the time they present with DMI. Although self-limiting, recurrence is common, either in the same muscle or in another muscle. Mean mortality rate within two years of DMI onset is 10%, with cause of death being diabetic macroangiopathy complications.

In summary, presence of edematous and bulky muscles with high signal on T2-weighted and STIR sequences of MRI along with a clinical history of sudden onset, severe pain in the thigh or calf in a patient with long standing diabetes mellitus strongly favors a diagnosis of diabetes muscle infarction. With appropriate and adequate clinical history and typical MR findings, a confirmatory diagnosis of DMI can be made and biopsy or surgical intervention can be avoided.

REFERENCES
NINE YEAR FOLLOW-UP OF A CERAMIC-ON-CERAMIC BEARING TOTAL HIP ARTHROPLASTY UTILIZING A LAYERED MONOBLOCK ACETABULAR COMPONENT

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ABSTRACT

Introduction: Early ceramic bearing systems in total hip arthroplasty (THA) sought to provide long term wear improvement over traditional metal on polyethylene systems. However, previous designs exhibited fractures of the ceramic acetabular liner, leading to the development of the Implex Hedrocel ceramic bearing THA system where the ceramic liner was supported on a layer of polyethylene intended to transition liner loads to the metal shell, a so-called “sandwich” design. Unfortunately, the device trial was stopped to further enrollment when liner fractures were reported. The current study examines nearly 10-year follow-up on 28 devices implanted by two surgeons at one institution in order to document ceramic bearing system performance over a longer time period.

Methods: Radiographic and patient reported outcomes, in the form of Harris Hip Scores (HHS) and 12-Item Short Form Health Survey (SF-12), were collected.

Results: During the study period two cups were replaced, one at three years and a second at seven years. At the five year follow-up HHS were similar to those reported in the literature for devices with traditional metal-on-polyethylene bearing surfaces and for other sandwich ceramic bearing designs. At the nine year follow-up, the HHS had not changed significantly and SF-12 scores measuring overall physical and mental health were higher than age matched national norms (p<0.001). There were no signs of cup migration, stem subsidence, osteolysis or cup loosening at any time up to the last follow-up in this patient cohort. The 89% survivorship rate and device revisions due to delamination of the liner observed in this group were similar to those reported earlier for this device and for other “sandwich design” ceramic bearing systems.

Discussion: This cohort did not exhibit new failure modes and HHS and SF-12 scores indicated high functionality for the majority of patients. These data suggest that a focus on preventing ceramic liner fracture through design and/or materials improvements may result in a device with long-term functionality.

INTRODUCTION

In the United States, the majority of total hip arthroplasty (THA) involves a metal stem, head and acetabular component with a polyethylene liner. The primary drawback of this bearing surface is the osteolysis associated with wear debris generated by the polyethylene bearing surface. The development of highly cross-linked polyethylene (HXPLE) has improved outcomes for total hip arthroplasty, but is still not seen as the ideal bearing surface in young active adults. Low wear rates and longer lasting bearing surfaces are of specific interest in addressing the needs of young patients with a long life expectancy and a high activity level. One alternative is the use of ceramic-on-ceramic bearing surfaces.

Ceramic-on-ceramic bearing surfaces in THA have been used in an effort to combat the osteolysis and aseptic loosening associated with the wear debris generated by polyethylene. Excellent wear and biologically inert characteristics of ceramic appear to yield an ideal bearing surface, however, the risk of ceramic fracture presents a unique concern. Since the initial use of ceramics in THA in the 1970s, improvements in its mechanical properties, grain structure, purity, and proof testing have significantly improved the quality of modern ceramics. The improvements in physical characteristics decreased fracture rates but revealed aseptic loosening as another challenge. The mechanism for loosening was thought to be caused by a mismatch in the modulus of elasticity between the ceramic and bone. “Sandwich” designs utilize a ceramic inlay with polyethylene interposed between the ceramic inlay and the metal shell which decreases the stiffness mismatch, thus potentially reducing the rate of fracture and improving bony ingrowth.

A number of “sandwich” acetabular component designs have been trialed with varying degrees of success. The first commercialized “sandwich” acetabular design was...
produced in 1993 and consisted of polyethylene sandwiched between an alumina ceramic inlay and a titanium shell. Viste et al. studied the long term results of this cup and found a fracture rate of 3.3% (5 of 151) at an average of 9.9 years due to failure. Evidence of impingement of the femoral neck on the rim of the ceramic liner was also noted and thought to be involved in the failure. Iwakiri et al. utilized a unique alumina ceramic insert on a polyethylene shell that was directly cemented to bone with no metal backing. At an average of 5.6 years they reported a 5.6% (4 of 72) alumina fracture rate. Notching was again noted on the femoral neck, which suggested that impingement likely played a role in the ceramic failure. Park et al. reviewed 357 hips at an average of 3.9 years with a ceramic liner embedded in polyethylene which then had a Morris taper fit into a titanium shell. They reported an alumina fracture rate of 1.7% (6 of 357) (two alumina heads, four alumina liners). Based on microscopic and gross analysis of the fractured liner at revision, impingement of the femoral stem on the rim of the ceramic was seen as a primary cause of fracture.

A “sandwich” design with the goal of decreasing the impact of femoral stem impingement on the rim of the acetabular liner was developed. The Hedrocel ceramic bearing cup (Implex, Allendale, New Jersey) consists of a Trabecular Metal tantalum shell, compression-molded polyethylene, and a press fit ceramic inlay (Image 1). The alumina ceramic inlay was recessed so any femoral stem impingement would result in polyethylene contact, as opposed to ceramic contact, thus decreasing the risk of delamination of the alumina component and subsequent dislocation and/or fracture. A multicenter prospective randomized clinical study under the supervision of the United States Food and Drug Administration (FDA) was initiated in 1999 to evaluate this device. In 2003 enrollment in the study was suspended due to failures of the ceramic liner. Two measures of patient outcomes were used in the Hedrocel Ceramic Bearing Cup trial: the Harris Hip Score (HHS) and the 12-Item Short Form Health Survey (SF-12). The Harris Hip score is a well-known and often utilized measure of hip function that was initially described by William H. Harris in 1969. The SF-12 is a shortened version of the 36-Item Health Survey (SF-36) which generates a mental component score (MCS) and physical component score (PCS). These scores reflect overall health-related quality of life. The SF-12 provides a generic measure of health that is not related to a specific disease or condition. The score is scaled from zero, being the lowest level of health, to 100, representing the highest level of health. As patients age, the PCS component of the score tends to trend down while the MCS component of the score tends to trend up, thus any score must be compared to an age-matched control to be of any meaning. The SF-12 was utilized to provide a tool by which we can compare the patients with the ceramic total hip against the general population.

The current study examines 5 and 10 year functional outcomes and radiographic appearance of the Hedrocel ceramic bearing cup at our institution. Though this system is part of an investigational device trial and will never be commercialized, many patients received it as their THA and their long-term results are of interest.

METHODS

The Implex Hedrocel system is an investigational device implanted in 315 patients as part of a FDA monitored, randomized multicenter prospective trial from 1999 to 2003. The current study examines data collected from one site where a total of 28 experimental devices were implanted in 25 patients by two surgeons (NW, SB) between March 2001 and December 2002 with an average of 9.2 year follow-up. The control group was completed but was not required to be followed when the long term follow up was initiated. Average follow-up after exclusion of patients who died or underwent revision procedure (six patients) is 9.8 years (6.1-10.5). The device studied is a “sandwich” monoblock acetabular component consisting of an alumina ceramic inlay (BIOLOX forte; CeramTec, Stuttgart, Germany) press fit into a direct-compression-molded ultra-high molecular weight polyethylene backed by a porous tantalum shell. The cup and femoral stem were press fit. The femoral stem was a porous-coated cobalt-chromium-alloy implant (Implex ProxiLock design). Patients with clinical indications for a total hip replacement, age between 18 and 75
years, and having a body mass index (BMI) less than 40 were included in the study. Patients with bilateral hips replacements received the same implant on both sides. The protocol was approved by the site’s investigational review board. All study participants provided informed consent prior to participation.

The study group included 16 females and 9 males (Table 1). All prostheses were implanted using a lateral approach. The standard limited incision muscle-sparing anterolateral Watson-Jones approach for THA, as described by Kenneth Gustke M.D.17, was used with one exception: the leg, when dislocated, was placed over the anterior edge of the table, not the posterior edge. Briefly, the incision was made anterior and proximal to the greater trochanter and the joint exposed through a small opening created along the intermuscular interval between the gluteus medius and tensor fascia lata. Patients were seen pre-operatively, post-operatively at 2 weeks, 6 weeks, 3 months, 6 months, 1 year and annually thereafter. At each visit HHS and SF-12 data was collected. Radiographs obtained at 2 weeks, 3 months, 6 months, 1 year and at subsequent yearly visits were examined for evidence of osteolysis in the seven femoral Gruen Zones18 and three acetabular zones19. The cup inclination was also measured using a transischial line and the inferior and superior cup margins.

Harris hip score and improvement in score (HHS at follow-up – preoperative score) for the study device were compared to those reported in the literature for similar designs using student T-test statistics. Rates of revision and osteolysis were compared using the chi-square test. The post-op SF-12 data was compared to pre-operative data using the T-test statistic and compared to national norms by age group using both the Wilcoxon Signed Rank test and a 95th percentile confidence interval test based on the standard error of measure16.

**RESULTS**

The average age at the time of surgery was 63 years (standard deviation (SD) 8.9, range 42-75). The average BMI at the time of surgery was 29.68 (SD 4.5, range 23-39). The average pre-operative HHS and the SF-12 PCS were indicative of reduced joint function and quality of life (Table 1). Two patients underwent revision (7.1%, 2 of 28) during the course of study: one at 3.2 yrs due to perceived imminent failure (female, 63 yrs, BMI 25 revised to metal on polyethylene) and the other at seven years due to liner displacement (female, 68 yrs, BMI 23, revised to metal on polyethylene). The short-term revision case was excluded from the five year follow-up group, as the revision occurred outside of the five year window (as determined using Chauvenet’s criterion), while the longer term case was included in both the 5 and 10 year groups. Two patients died during the course of the study: 5.3 yrs and 7.9 yrs, of unrelated causes. Both patients were retained in the 5 year group and the latter was included in the 10 year group.

At the five year follow-up (4.9 yrs, SD 0.5, range 3.9-6.0) the HHS were significantly improved over the pre-operative scores at 88.7 (SD 13.6, range 50-100, p<0.001). The SF-12 PCS increased significantly from the pre-operative level to 46.7 (Table 2, p<0.001), while the MCS remained relatively high at 55.4. The average angle of inclination for the cup was 47.3 (SD 5.7, range 46.8-59). There were no clinically significant findings in either stem or cup radiographs.

At the 10 year follow-up (9.15 yrs, SD 1.19, 6.04-10.48) the average HHS, PCS and MCS scores remained high. Harris Hip Scores and SF-12 PCS increased significantly from the pre-operative state to the longest post-operative follow-up (p<0.001), but the scores did not significantly differ from those at the five year time point. The largest increase in the Harris Hip Score was 69.0 while lowest

### Table 1. Demographics of patients enrolled

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (patients/hips)</td>
<td>6/9</td>
<td>16/16</td>
</tr>
<tr>
<td>Average Age (yrs)</td>
<td>63.2</td>
<td>64.6</td>
</tr>
<tr>
<td>Average BMI</td>
<td>30.1</td>
<td>29.4</td>
</tr>
</tbody>
</table>

### Table 2. Comparison of outcome measures (average, standard deviation and range) between this study and similar components described in the literature

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative</th>
<th>5 years</th>
<th>9 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 Mental Component</td>
<td>54.4 (SD 10.9, 31.5-66.5)</td>
<td>55.4 (SD 6.6, 36.1-64.7)</td>
<td>58.6 (SD 3.1, 47-64)</td>
</tr>
<tr>
<td>SF-12 Physical Component</td>
<td>28.6 (SD 4.5, 18.9-37.5)</td>
<td>46.7 (SD 10.1, 26.1-56.2)</td>
<td>47.9 (SD 7.3, 30.6-55.5)</td>
</tr>
<tr>
<td>HHS: Current Study</td>
<td>43.5 (SD 9.0, 24-61.5)</td>
<td>88.7 (SD 13.6, 50-100)</td>
<td>91.9 (SD 5.3, 74.9-100)</td>
</tr>
<tr>
<td>HHS: Ceramic Comparable I</td>
<td>50.6 (SD 11.4; 26.95-78.03)</td>
<td>not reported</td>
<td>96.86 (SD 8.0; 48.85-100)</td>
</tr>
<tr>
<td>HHS: Ceramic Comparable II</td>
<td>47.89 (SD 10.7; 28.85-75.23)</td>
<td>not reported</td>
<td>96.176 (SD 5.9; 74-100)</td>
</tr>
<tr>
<td>HHS: Ceramic Non-Sandwiched</td>
<td>56 (SD not avail; 17-89)</td>
<td>not reported</td>
<td>96 (SD not avail; 57-100)</td>
</tr>
<tr>
<td>HHS: Metal-on-Poly Comparable</td>
<td>49.83 (SD 12.6; 21.35-87.25)</td>
<td>not reported</td>
<td>96.49 (SD 5.6; 74-100)</td>
</tr>
</tbody>
</table>
Nine Year Follow-Up of a Ceramic-On-Ceramic Bearing Total Hip Arthroplasty

The increase was 25.3. The MCS and PCS scores for the study group were significantly higher than those of the national population (p<0.001 and p=0.001, respectively). The greatest differences were exhibited in the mental health component with an average difference of 8.5 points (2.25 points greater than the 95th percentile) and 88% of patients showing improved mental health. No cup migration or stem subsidence was observed at any time. There were no signs of osteolysis or cup loosening at last follow-up in February of 2013.

DISCUSSION

The mid-term follow-up data, with the exception of the failed ceramic liner, was excellent for patients with the Hedrocel ceramic-on-ceramic bearing THA. These results are similar to other studies of ceramic bearing THA systems. The functionality and pain relief as measured by the HHS were similar to that of other traditional and ceramic bearing surfaces and the SF-12 scores were above average for age-matched controls. The acetabular component showed no signs of migration in the time frame studied. In addition, no evidence of osteolysis was observed, similar to findings in other ceramic on ceramic designs. Perhaps the most significant finding, however, was that no new failure mode was observed and the rate of device failure did not appear to be increasing.

Delamination of the ceramic liner from the polyethylene was the mode of failure identified in this study. This mode has been described in earlier reports for this design and in other similar designs. While no patient experienced ceramic liner fracture during the data collection period of the current study, following the conclusion of the study period, an atrumatic ceramic fracture was identified in one patient at 10.8 yrs. Again the failure mode appeared to be partial delamination and fracture of the ceramic liner. Revision surgery revealed well-fixed acetabular and femoral components. The implant was revised to a ceramic head on HXPLE implant to decrease the effect of third-body wear.

Two failure mechanisms for ceramic bearing surfaces have been proposed in the literature: impingement and physical property differences between the ceramic and polyethylene. The Hedrocel device design sought to decrease the incidence of device failures by eliminating the direct contact of the femoral stem with the ceramic edge by recessing the ceramic inlay and creating a “bumper” of polyethylene around the rim (Image 1). Physical property differences between the hydrophilic and absorbent ceramic on the hydrophobic polyethylene in a moist environment has been raised as a contributing mechanism of failure.

The revision rate for this study is similar to other studies of sandwich design acetabular components. Though the revision rate is higher than some comparable studies, the study period is longer allowing time for more device failures. These findings may discourage further development of polyethylene sandwich ceramic-on-ceramic designs. Indeed, the 8% revision rate for the study group exceeded the <3% norm for traditional metal-on-polyethylene systems based on data from the National Joint Registry of England and Wales. However, while the “sandwich” design appears sensitive to non-traumatic failures, those patients who did not experience the failure demonstrate the potential for long-term success. A recent report finds that a non-sandwich design ceramic cup provides long-term function without osteolysis or ceramic fracture. Sugano et al. conclude “cementless THA with the third-generation alumina COC hip bearings provided an excellent survivorship of 95.7% at 14 years and eliminated periprosthetic osteolysis for 11 to 14 years”. These data suggest that this bearing surface merits further consideration.

In the SF-12 data collected in the course of this study our patient group reported a more positive mental state as compared with age-matched US norms. This difference may be due to benefits realized by those who undergo hip replacement versus the general population, i.e., reduced pain and increased mobility compared to national norms. While the SF-12 has been utilized as a

<table>
<thead>
<tr>
<th>Study</th>
<th>Overall Revision Rate</th>
<th>Fracture Rate</th>
<th>Avg. Time to Fx</th>
<th>Avg. Follow-up time</th>
</tr>
</thead>
<tbody>
<tr>
<td>This study</td>
<td>7% (2/28)</td>
<td>0% (0/28)</td>
<td>5.25 yrs (3.5-7)</td>
<td>9.2 yrs (6.1-10.5)</td>
</tr>
<tr>
<td>Park et al. (7)</td>
<td>1.7% (6/357)</td>
<td>1.7% (6/357)</td>
<td>3.1 yrs (1.3-4.8)</td>
<td>3.9 yrs (3-6)</td>
</tr>
<tr>
<td>Poggie et al. (8)</td>
<td>4.4% (14/315)</td>
<td>3.8% (12/315)</td>
<td>2.1 yrs (.67-3.5)</td>
<td>2.5-5 yrs</td>
</tr>
<tr>
<td>Hasegawa et al. (4)</td>
<td>9% (3/33)</td>
<td>6% (2/33)</td>
<td>1.7 yrs (0.2-3.4)</td>
<td>5.8 yrs (5-6.5)</td>
</tr>
<tr>
<td>Lombardi et al. (10)</td>
<td>1.5% (1/65)</td>
<td>1.5% (1/65)</td>
<td>6yrs</td>
<td>6.1yrs (2.2-9)</td>
</tr>
<tr>
<td>Lopes et al. (19)</td>
<td>not reported</td>
<td>2% (7/353)</td>
<td>4.3yrs (1.3-7.6)</td>
<td>3.4yrs (0.5-8.8)</td>
</tr>
<tr>
<td>Viste et al. (3)</td>
<td>8.6% (13/151)</td>
<td>3.3% (5/151)</td>
<td>7 yrs (4.5-8.5)</td>
<td>9.9 yrs (8.5-11.5)</td>
</tr>
</tbody>
</table>

Table 3. Ceramic liner fracture rates compared to published data of other ceramic-on-ceramic sandwich design devices.
broad clinical measure of a patient’s mental and physical state, it has not been studied specifically in a large group of persons who receive a hip replacement. Recent work using the SF-3622 found significant emotional score improvement in a hip and knee replacement group over a seven year post-operative period. However, as the data was not compared to a control, the finding may not be directly attributable to the surgical intervention. Future efforts would be required to investigate whether the positive mental state observed in this study persists in a larger study group and whether it might be attributed to factors related to the hip replacement.

This study was limited for several reasons. First, the small sample size limits the power of this study. The initial investigational study was performed at 22 different sites with an average of 26.8 patients enrolled per site. Logistical limitations precluded inclusion of patients from other sites and further patient enrollment at this site was limited by cancelation of the device. Second, all the procedures were performed by two surgeons. While only two surgeons participated in the study at this site this also decreases the confounders. All the patients had surgery performed at one institution with the same operative approach utilized over a short period of time thus the operating room ancillary staff and post-operative care was similar. Third, the results were not compared with age-matched controls. The initial study utilized controls at a ratio of 2:1, however the controls were not followed beyond the conclusion of the trial. Comparison to metal-on-polyethylene devices of similar design were obtained from the literature in lieu of a control population. These provided larger sample sizes and comparable time frames.

In conclusion, the mechanical properties of ceramic make it a bearing surface with low wear and consequently a low incidence of osteolysis, with the primary drawback being the propensity to fracture. The Trabecular Metal acetabular cup provided a well-fixed bone-implant interface and the ceramic-on-ceramic bearing surface functions well, however the challenge of fracture or dislocation of the ceramic inlay continues to pose a concern. Further research into ceramic and ceramic like components that would better resist fracture as a mode of failure should be pursued as the number of young patients receiving THA continues to grow.

CONFLICT OF INTEREST STATEMENT

The current study was performed independent of financial support. Authors Norman Walter and Stephen Burton received financial support from Zimmer for their role in the initial device trial. No study member has a significant financial interest in the trialed device or Zimmer.

REFERENCES


ABSTRACT

Retrieval analysis of total joint arthroplasty components has primarily focused on assessing wear or other damage to polyethylene components. As damage to the opposing bearing surface can accelerate polyethylene wear and damage, and especially with the use of hard-on-hard articulations, retrieval analysis benefits from incorporating evaluation of hard bearing surfaces as well. The purpose of this study is to report six case studies of metal bearing surfaces with distinctive damage patterns, to interpret them in the context of adverse events plausibly responsible for their creation, and to suggest their likely clinical or scientific significance. The specific damage patterns reported here are 1) extensive scraping, 2) circumferential discoloration, 3) a long chain of periodic micro-indentations, 4) pitting with deposits, 5) scratches with small-radius directional changes, and 6) indentation with scraping.

INTRODUCTION

Retrieval analysis plays a critical role in the evaluation of total joint arthroplasty device performance. In addition to evaluation of the components themselves, retrieval analysis encompasses clinical, radiological, histological, and biological observations1,2. Retrieval analysis is valuable for identifying and understanding events and mechanisms leading to clinical failure1,3, especially due to processes that were not predicted or simulated by preclinical in-vitro studies3,4. Postmortem retrievals contribute information from cases that were successful or that may have been in the early stages of failure1,2. Ultimately, the insights gained from retrieval analysis help identify opportunities to enhance patient care by improving implant function1,3.

Damage to metal total joint arthroplasty bearing surfaces can accelerate wear of the opposing bearing surface. Increased wear, in turn, can lead to osteolysis, aseptic loosening, mechanically excessive wear, metallosis, adverse local tissue reaction, or elevated serum ion levels. Damage on retrieved components can be documented and analyzed. This information, in addition to clinical case data for each retrieval, can help identify likely causes of the damage.

Many previous investigators have documented metal bearing surface damage attributable to adverse events. Intraoperatively, a total hip arthroplasty (THA) femoral head can be damaged during the initial reduction5-7 or by dislocation/reduction during range-of-motion testing8. A total knee arthroplasty (TKA) femoral condyle can be damaged by contact with the tibial tray during polyethylene liner insertion9. Postoperative adverse events include dislocation with successful closed reduction10-12, dislocation with unsuccessful closed reduction10,13,14, subluxation with acetabular rim contact (for hard-on-hard bearings)15,16, third body particle entrapment17, and articulation between the head and the shell interior subsequent to liner wear-through18,19, dissociation20,21, or fracture22. During revision surgery, additional damage may result from dislocating the head15 or from contact with surgical instruments23.

Most damage features present on metal bearing surfaces can be classified as either macro-scratches, scrapes, or transfer deposits. Macro-scratches, which are discrete and usually multidirectional (Figure 1), can be caused by debris within the bearing couple, with the debris in that context referred to as third bodies24. These macro-scratches are different from the nanoscale scratches that are a consequence of the “normal” adhesive/abrasive wear. Scrapes take the form of strips with pronounced surface roughening, with strong directionality of the average roughness measure (Figure 2)25. The orientation of smaller features within a scrape can be different from the scrape’s longitudinal direction. A scrape may include both material removal and
small deposits of transferred material. Femoral heads that have experienced dislocation or subluxation often show such scraping damage as a result of contact with the acetabular shell. Transfer deposits typically present as large, darkened regions on the bearing surface (Figure 3). As the case for scrapes, transfer deposits typically result from unintentional contact with other hard surfaces, such as when there is liner dissociation or wear-through, or from contact with large embedded debris. The deposits themselves consist of bearing-foreign material (most commonly titanium alloy) that has been transferred onto and remains adherent to the head surface. Other frequently observed damage features include local indentations, pitting, discoloration, and massive wear.

Damaged metal bearing surfaces may display idiosyncratic patterns or mixes of damage features. Full documentation of component damage involves not only identifying the damage features themselves, but also the details of the features and the overall damage pattern. The purpose of this study is to report six case studies of metal bearing surfaces with distinctive damage patterns, to interpret them in the context of adverse events plausibly responsible for their creation, and to suggest their likely clinical or scientific significance.

CASE STUDIES

Extensive scraping – unsuccessful closed reduction after early dislocation

Case data: 28mm metal-on-polyethylene THA revised for dislocation at two months post previous revision. The patient presented with a dislocated hip, and two experienced orthopaedic surgeons separately attempted closed reduction without success. An open reduction was successful, but because of intraoperative instability the head and liner were revised to a 36mm head. The femoral stem was found to be loose at the cement interface, and was recemented in place.

Description of damage: The femoral head exhibited several longitudinal scrapes (Figure 4A), and an area with overlapping, multidirectional but mainly horizontal scrapes (Figure 4B). Both types of scrapes included numerous small deposits (Figure 4C) containing titanium alloy.
Interpretation of damage: The femoral head scraped against the acetabular shell during the dislocation and the repeated reduction attempts.

Significance: This case demonstrates the potential of closed reduction to severely damage the femoral head. Successful closed reductions that are easily performed, or carefully performed to minimize head-shell contact, may result in no or minimal femoral head damage. Unsuccessful and difficult closed reductions, however, may result in problematic femoral head damage. Neither of the experienced orthopaedic surgeons could successfully carry out a closed reduction, insinuating that this case was very difficult. Physicians who are less experienced with performing closed reductions may have an increased chance of causing femoral head damage during this procedure. Physicians (including emergency medicine specialists) who perform closed reductions should be aware of the potential for severe iatrogenic damage of the femoral head during closed reduction attempts, and should employ methods that minimize head-shell contact.

Circumferential discoloration – Oxidized deposits

Case data: 28mm metal-on-polymer THA revised for recurrent (8 total) dislocation at 11 years postoperatively.

Description of damage: In addition to scrapes, this femoral head also displayed brown and blue discoloration about much of its circumference (Figures 5A, B). Discoloration occurred both in the vicinity of and farther away from other head damage. Scanning electron microscopy of discolored areas showed deposits (Figure 5C). Energy dispersive spectroscopy of discolored areas detected a large peak characteristic of titanium, and also detected smaller peaks indicating constituents of titanium alloy and cobalt-chromium alloy (Figure 5D). No iron peaks were detected. Undamaged areas without discoloration did not display deposits or titanium alloy elements.

Interpretation of damage: Scraping damage and material transfer is characteristic of acetabular shell contact upon dislocation or closed reduction, as described earlier (Figures 2, 4). Discoloration similar to that reported here has been reported for retrieved metal-on-metal femoral heads. For metal-on-metal heads, birefringent color bands were observed at the periphery of the wear zone or at the periphery of a tribochemical reaction layer. These birefringent bands were hypothesized to consist of an adherent oxide layer, with variations in layer thickness altering light reflection. Darker, less-reflective areas, seen inside the wear zone, were attributed to a tribochemical reaction layer containing oxidized chromium and organic material, or to an altered surface finish due to wear.

Oxidized titanium can be brown or blue. Electrochemical anodization of a titanium alloy corneal prosthesis
changes its color to brown or blue based on the thickness of the oxide film. Thermal oxidation (at 600°C) of titanium alloy changes its surface color to brown, and also increases the surface roughness. Titanium dioxide powder doped with sodium hydroxide at 150°C becomes brown. The discoloration on the metal-on-polymer femoral head shown here likely results from transferred titanium alloy with discolored oxidation.

**Significance:** Discoloration, reported as common on metal-on-metal components, can occur on a metal-on-polyethylene femoral head that experiences recurrent dislocation.

**Long chain of periodic micro-indentations – rolling third body or surgical instrument damage**

**Case data:** 44mm metal-on-metal THA revised for recurrent (4 total) dislocation at 11 months postoperatively.

**Description of damage:** The acetabular cup exhibited a long scrape that began (or ended) near the rim (Figure 6A). Upon magnification, this scrape had a zipper-like appearance, consisting of a series of very similar, regularly-spaced parallel indentations that were transverse to the scrape direction (Figures 6B, C). The indentations were deepest near the rim and became shallower as the scrape moved farther into the cup, eventually tapering off into shallow, near-confluency before disappearing.

Energy dispersive spectroscopy of the indentations detected small peaks characteristic of titanium and iron (Figure 6D).

**Interpretation of damage:** The presence of titanium and iron within the indentations indicates that the indentations were formed by an object consisting of material that was foreign to the bearing surfaces. One possibility is that during the retrieval process a stainless steel surgical instrument was dragged along the acetabular cup, with the contact involving a “chatter” that created the indentations. Also, optical profilometry scans of individual indentations documented raised material on the edges (Figure 6C). Indentations formed earlier in the implant’s service life could have been substantially eroded by joint articulation by the time of retrieval.

Alternatively, the similarity and the regularity of the indentations could indicate that this damage pattern may have been created by a linear third body that rolled or shifted position between motion cycles. Iron can be detected as metal transfer from an embedded stainless steel trochanteric wire fragment, although this patient did not have trochanteric wiring. The opposing femoral head had scraping damage characteristic of dislocation, so third bodies formed by impingement or dislocation damage could have been the source of the titanium detected within the cup’s indentations.

Significance: During retrieval surgery, iatrogenic component damage may result from contact with surgical instruments\textsuperscript{23} or from dislocation of the head\textsuperscript{15}. It often is difficult, if not impossible, for the operating surgeon to know what future assessments might be made for a given retrieval. Possibilities include institutional/hospital or manufacturer quality assurance, regulatory or medico-legal forensic analysis, or damage documentation for research or educational purposes. Iatrogenic retrieval damage could interfere with or be mistaken for earlier legitimate damage. Any damage from the retrieval process itself should therefore be documented by the surgeon.

Pitting with deposits – corrosion underneath deposits that subsequently detached

Case data: 28mm monoblock metal-on-polymer THA revised for acetabular aseptic loosening at 21¼ years postoperatively. The femoral component was also revised because of intraoperative findings of cracked and debonded cement.

Description of damage: Isolated and consolidated pitting occurred at several places on this femoral head (Figures 7A, B). Deposition areas, which were higher than the baseline surface of the head, were seen within pitted areas.

Interpretation of damage: The pits were probably formed by corrosion underneath transfer deposit. Porous coating particles are the likely source of the deposited material; metallic particles that appeared to be from the cup’s porous coating were found embedded in the liner. The likely mechanism for the pitting and deposits is as follows: 1) titanium or titanium alloy is deposited on the cobalt-chromium (CoCr) head via contact with the embedded particles; 2) the titanium oxide film on the deposit (which should provide a kinetic barrier against corrosion) is removed by normal joint articulation; 3) galvanic corrosion\textsuperscript{39} removes CoCr underneath the deposit; 4) crevice corrosion removes more CoCr material, forming a pit, and, in some cases; 5) the deposit is detached once its physical attachment points to the CoCr have been undermined by pit formation. A “cave” observed on a separate femoral head provides further evidence for supporting this highly localized corrosion mechanism (Figure 7C).

Significance: Corrosion of a metallic bearing component may occur underneath transfer deposits. This can be an additional source of ion load, independent either of that caused by wear processes at the bearing surface, or from fretting/corrosion at modular junctions.

Figure 6: A) Scraper on metal cup from a case revised for recurrent (4 times) dislocation. B) Micrograph and C) 3-D optical profilometry of parallel micro-indentations that made up the scraper. D) Energy dispersive spectroscopy within an indentation, indicating presence of titanium and iron.
Scratches with small-radius directional changes – third body damage without embedment

Case data: 28mm metal-on-polyethylene THA revised for recurrent (5 total) dislocation at 5½ years postoperatively. One dislocation was early (at two months postoperatively) and the other four occurred within a few days of each other 2½ months prior to the revision surgery.

Description of damage: Thin macro-scratches with small-radius directional changes, including loops, were present on this head (Figure 8). These scratches had sub-micron peaks and valleys, and were not visible to the naked eye. Pairs of scratches tended to occur in parallel.

Interpretation of damage: Third bodies scratched the femoral head without being embedded in the liner, or in addition to being embedded in the liner. Scratches with directional variations, observed on retrieved metal-on-polyethylene femoral heads, have been attributed to a third body particle sliding and rolling within the head-liner articulation.40 Scratches that bend and reverse direction on a small scale have been observed on metal-on-metal retrievals, with these scratches referred to as “reversals.”15 During directional changes between metal-on-metal articulating surfaces, a period of low velocity results in a decrease in lubricating film thickness, which allows moving contact between the head and the cup, or between the head, cup, and third body debris. Surface asperities on the opposing surface or third body particles may then generate these “reversal” scratches. Here, no embedded particles were detected in the opposing liner. The third bodies may have been too small to detect within the liner, could have worn away, or could have escaped from the bearing couple.

Large-radius slide track patterns illustrating multidirectional relative motion between a femoral head and an acetabular liner have been calculated for gait motion and for hip simulators41,42. Slide track patterns on discrete locations on femoral heads were verified by embedding pins within an acetabular liner then having these pins scratch the femoral head during hip simulation cycles. However, the loops for those slide track patterns were on a much larger scale than the loops shown here.

Significance: Third body particles within a metal-on-polyethylene articulation may not always be embedded in a polyethylene liner.
Indentation with scraping – damage by a large third body particle

Case data: 28mm metal-on-polyethylene THA revised for femoral stem aseptic loosening at 6½ years post previous THA. There was a greater trochanter non-union from the previous THA, and multiple proximal femur fractures. The acetabular liner was also revised for loosening.

Description of damage: This femoral head exhibited an indentation having a maximum depth of about 6 µm and a maximum width of about 120 µm (Figures 9A, B). Extending from the indentation was a scrape having a width approximately equal to the length of the crater. The scrape contained deposits and shallower versions of the deep indentation, with deposits appearing to overlay these shallower craters. The indentation was located in the lower hemisphere of the head, near the anterior axis. The anterior sector of the opposing polyethylene liner displayed a crescent of severe damage, within which were embedded nonmetallic particles (Figure 9C).

Interpretation of damage: A large third body particle indented and scraped the femoral head. A nonmetallic particle larger than the indentation was found embedded in the liner, in a plausible location for causing the head indentation. Alternatively, a trochanteric wire fragment might have caused this damage and then escaped from the bearing surface. Indentation and scratching of a retrieved metallic femoral head by a third-body particle has been previously observed.

In a recent case report, a trochanteric wire fragment that got into an Oxinium-on-polyethylene THA bearing surface because of a dislocation/reduction episode caused damage to the head. The maximum depth (10 µm) and the mean width (75.5 µm) of that damage were similar to the indentation dimensions reported here, and metal transfer from the wire to the head was detected. “Micro-grooves” having a depth of up to 20 µm have been found on retrieved metal-on-metal heads. This damage feature was attributed to abrasion (ploughing) of large third bodies that were formed during impingement contact; titanium alloy elements were found within the micro-grooves.

Significance: A large third body particle may damage a metallic bearing surface via indentation. The particle may also scrape against a femoral head and transfer material to the head.

DISCUSSION

Retrieval analysis of total joint arthroplasty components has primarily focused on assessing wear or other damage to polyethylene components. However, since damage to the hard counterface is often the proximate cause of polyethylene wear, such damage is of interest in its own right. Routine documentation of damage on retrieved hard bearing surfaces allows for detection of potential problems or for surveillance of problems.
identified with these components. Classification systems for specific damage features aid this documentation\textsuperscript{15,27,28}. Also essential for full documentation of component damage are profilometric measures or other details of individual features, and the overall pattern of the damage. Presented here are case studies that incorporate aspects of this greater detail in the characterization process, accompanied by plausible causative mechanisms.

Advances in retrieval analysis capabilities for examining hard bearing surfaces have allowed for continually increasing rigor of damage characterization. Detailed characterization of such damage features as macro-scratches, scrapes, and transfer deposits, and of the patterns of those damage features, allows for that damage to be replicated for systematic scientific study. How this damage affects the opposing bearing surface can then be investigated during wear simulation via physical (in vitro) testing\textsuperscript{38,39} or computer modeling\textsuperscript{25,44}. To increase the fidelity of in vitro tests for reproducing in vivo conditions, damage that occurs during in vitro testing, either through ordinary or deliberately abnormal processes, can be compared to in vivo damage on retrievals\textsuperscript{15}, and the in vitro tests improved accordingly.

There are necessarily uncertainties related to analyzing damage on retrieved bearing surface components. The mechanisms by which the damage was created might be ambiguous, and damage mechanisms might need to be inferred. The sources of component damage may no longer be present at the time of retrieval, such as when third bodies that were embedded in a polyethylene liner wear down or escape\textsuperscript{45,46}. Likewise, earlier component damage may have subsequently worn away\textsuperscript{47-49}. The timing of the events that created damage features might not be known. For cases with recurrent dislocation, it may not be possible to deduce which scrapes were formed by which dislocation/reduction event. For cases with third body damage, there may be multiple timepoints during which third bodies were generated\textsuperscript{40,54}, entered the bearing surface\textsuperscript{49,52,53}, or migrated and created new scratches\textsuperscript{52}. The anatomic orientation of a retrieval femoral head is often not documented. Knowing the locations of component damage, relative to component orientation within the body (and relative to the other components), greatly enhances the understanding of the data emerging from retrieval analysis\textsuperscript{54,55}. Documenting anatomic orientation on retrieval components will allow investigators to better connect component damage to the mechanisms that created that damage.

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REFERENCES


ABSTRACT

Introduction: The purpose of this study was to develop and test techniques for tracking the path of contact between the tibial and femoral total knee replacement components during level over-ground walking. The tibio-femoral path of contact could be an indicator of the in vivo performance of a total knee replacement as an estimator of areas of contact between the implant components. A longer contact path, indicative of more sliding between the implant components during walking, could indicate an implant at risk for increased wear. In addition, the tibio-femoral contact path determines the position and length of the muscle and ligament lever arms about the knee, and can subsequently influence knee contact force calculations.

Methods: Two methods were developed to predict the tibio-femoral contact pathways for total knee replacement devices. Both methods used patient-specific knee kinematics obtained during gait analysis, standard radiographs obtained during clinical follow-ups, and point-clouds of the tibial and femoral bearing surfaces. The validity of the techniques was evaluated with knee wear simulator tests and comparisons to wear scars on postmortem retrieved tibial components.

Results: The average total anterior-posterior distance covered by the contact path for ten patients implanted with a total knee replacement was 29.01 mm on the lateral side, and 21.80 mm on the medial side. Both methods for predicting the tibio-femoral contact pathways yielded similar results, and fell within the wear scars of simulator-tested and postmortem retrieved implants.

Conclusions: The methods for predicting the tibio-femoral contact pathway using marker-based gait analysis and standard clinical radiographs are computationally simple, and reliably predict contact path characteristics as evaluated against wear scars from knee wear simulator tests and postmortem retrieved implants.

Keywords: tibio-femoral contact path, total knee replacement, marker-based gait analysis, knee contact mechanics

INTRODUCTION

The path of contact between the tibia and femur during activities of daily living (ADLs) is critical for calculating knee internal contact forces via numerical modeling. The tibio-femoral contact path location defines the moment arms for structures (muscles, ligaments, and contact forces) acting about the knee. Knee joint sliding distance and relative sliding velocity, important contributors to wear of total knee replacement (TKR) devices, can also be determined from the tibio-femoral contact path. Some of the error in modeling attempts to predict knee contact forces may be due to incorrect assumptions of the tibio-femoral contact pathway as seen by sensitivity studies to this parameter1,2.

The predominant technology for determining tibio-femoral contact is fluoroscopy3-13. Three-dimensional computer models of TKR components are fitted to the fluoroscopic images. The contact point is defined as the centroid of the intersection of the articulating surfaces, or the closest point between articulating surfaces. However, this technique is available in few laboratories and is not a standard-of-care procedure.

Our goal was to develop a method to reliably predict the tibio-femoral contact path during gait using subject-specific anatomy, prosthesis geometry, standard radiographs from clinical follow-ups, and three-dimensional relative TKR joint kinematics from marker-based motion analysis. The tibio-femoral contact paths were predicted for ten TKR patients during the stance phase of gait. We also compared the predicted contact pathways to wear scars from knee-wear simulator tests and postmortem retrieved tibial components for verification of the methods.
We hypothesized that we would find good agreement between two methods for predicting the tibio-femoral contact pathways, and that both methods would predict contact pathways that fell within wear scars on knee-wear simulator tested components and postmortem retrieved components.

METHODS

1. Motion Analysis, Point-Clouds, and Coordinate Systems

A four-camera optoelectronic system (Qualisys, Gothenburg, Sweden) tracked movements of reflective markers at 120 Hz during level walking from heel-strike to toe-off. The point cluster technique (PCT) measured six degree-of-freedom knee movements during stance: three displacements in the anterior-posterior (AP), medial-lateral (ML), and superior-inferior (SI) directions, and three rotation angles corresponding to knee flexion-extension, abduction-adduction, and external-internal rotation (Figure 1). All motions obtained with the PCT were reported with respect to the TEA in an anatomical-femoral coordinate system based on palpated landmarks: the medial and lateral femoral epicondyles, the greater femoral trochanter, the lateral-most and medial-most aspects of the tibial plateau, and the lateral and medial malleoli.

Point-clouds of the bearing surfaces of a Miller-Galante II TKR device were obtained using a touch-probe coordinate measuring machine (SmartScope, Optical Gaging Products, Inc., Rochester, NY). Coordinates of the articular surfaces were collected at one-millimeter increments for the tibial component and two-millimeter increments for the femoral component (Figure 2). The femoral point-cloud only encompassed the surface areas of the condyles that articulated with the tibia (Figure 2, inset).

2. Subject Demographics

Three-dimensional knee motions were obtained during level walking from ten TKR patients (6M/4F) after informed consent and IRB approval. Patients performed three walking trials at a “normal” self-selected walking speed. Contact paths of the index knee were calculated for the walking trial with a speed closest to 1 m/s for each subject. Mean walking speed was 1.07 ± 0.15 m/s for all patients for the chosen trials. All ten patients were implanted with a Miller-Galante II (MGII) TKR device (Zimmer Inc., Warsaw, IN) in the same hospital. Four devices were implanted in the left side, six in the right (defining the index knees).

3. Radiographic Measurements

Measurements from AP and lateral planar radiographs taken during post-operative clinical follow-ups were used to align the point-clouds with the anatomical coordinate system (Figure 3). AP radiographs were assumed to show the knee in a fully-extended neutral position. Lateral radiographs were chosen that showed the posterior femoral condyles superimposed to the greatest extent. On both views, rectangles were drawn bounding the femoral component. Rectangle width and height (Figure 3, labels 5, 6, 9, 10) were used to scale radiographic measurements to the known implant size for each patient.
Additional measurements were used to align the components with the anatomical coordinate system originating at the midpoint of the TEA (Figure 3, labels 1-4, 7, 8). On AP radiographs, the TEA connected the medial and lateral epicondylar processes and the midpoint was the anatomical coordinate system origin. Three translations were performed to move the point-clouds to the anatomical coordinate system origin. 1) The femoral point-cloud was translated in the ML direction (along the x-axis) by the average of the perpendicular distances from the rectangle sides to the epicondyles (labels 3, 4). 2) On the lateral radiograph, a circle was fit to the posterior femoral condyles, and the center of the circle was defined as the TEA. The femoral point-cloud was translated in the AP direction (along the y-axis) by the distance measured from the center of the circle to the lowest anterior-most point on the femoral component (label 7). 3) The femoral point-cloud was translated in the SI direction (along the z-axis) by the average of the perpendicular distances to the medial and lateral epicondyles (labels 1, 2). Finally, the femoral point-cloud was rotated about the anterior axis (y-axis) to align the TEA with the x-axis (labels 1, 2). The tibial point-cloud was translated and rotated by the same values as the femoral point-cloud and was rotated about the lateral axis (x-axis) by the posterior slope (label 8). After the point-clouds were properly aligned with respect to the bones, they could be transformed by knee kinematics.

4. Tibio-femoral Contact Path Algorithms: Shortest Distance Method (SDM) and Contour Distance Method (CDM)

Two methods were developed to determine the tibio-femoral contact pathway. For the Shortest Distance Method (SDM), the tibio-femoral contact pathway was defined as the shortest distance between the transformed femoral and tibial point-clouds at 100 instances during the stance phase walking. The tibial plateau point-cloud was fixed while the femoral point-cloud was transformed according to the knee kinematics in an orthopaedic Euler rotation sequence about the body axes of the TKR components, Equation (1). The femoral point-cloud was first transformed by translation ($x_{AP}$, $y_{ML}$, and $z_{SI}$, for AP, ML, and SI translation, respectively), second by internal-external rotation ($\theta$), third by adduction/abduction ($\phi$), and finally by flexion/extension ($\alpha$).

$$
T_{SDM} = \begin{bmatrix}
1 & 0 & 0 & 0 \\
0 & \cos(\theta) & -\sin(\phi) & 0 \\
0 & \sin(\theta) & \cos(\phi) & 0 \\
0 & 0 & 0 & 1
\end{bmatrix}
$$

For each instance of stance, the inferior-most point of the femoral point-cloud was defined as the “femoral contact point” because it was assumed that the lowest point would be the first to contact and/or penetrate the tibial plateau. The tibial point that generated the minimum linear distance to the femoral contact point was deemed the “tibial contact point”. The process was repeated for lateral and medial compartments. Although the positions of the TKR components were registered to the underlying bones using radiographs, the starting position of the femoral component on the
tibial component was unknown. To address this issue, an automated, iterative process was used to position the contact path on the tibial plateau. The initial AP position of the tibial point-cloud relative to the femoral point-cloud was chosen so that the range of AP femoral condylar motion was constrained to and centered on the tibial plateau. Next the contact paths were calculated. The relative locations of the centroids of the contact paths, compared to the average centroid location of wear scars on postmortem retrieved tibial plateaus23 (described below) were next determined. The tibial point-cloud was repositioned relative to the femoral point-cloud to match the contact path centroids with the wear scar centroids, and the contact paths were again calculated. The iterative process allowed subject- and walking trial-specific initial positioning of the femur with respect to the tibia.

The second method for calculating the tibio-femoral contact pathway, Contour Distance Method (CDM), was based on existing software24. For the CDM, the TKR point-clouds (aligned as for the SDM) were transformed by a Cartesian Euler rotation sequence, Equation (2), about fixed global reference axes. The tibial plateau remained fixed while the femoral component rotated according to the patient kinematics. Vectors were computed for all femoral points which defined the projection of the femoral component onto the tibial component. The contact point was defined as the centroid of the area of penetration between the femoral and tibial components, or the centroid of the area that enclosed 10% of the points closest between the two components.

\[
\begin{bmatrix}
0 & 0 & X_{AP} \\
0 & 0 & Y_{ML} \\
0 & 0 & Z_{bi}
\end{bmatrix}
= \begin{bmatrix}
\cos(\theta) & -\sin(\theta) & 0 & 0 & 0 & 1 \\
\sin(\theta) & \cos(\theta) & 0 & 0 & 0 & 1 \\
0 & 0 & 1 \\
0 & 0 & 0 & 1 \\
0 & 0 & 0 & 1 \\
0 & 0 & 0 & 1 
\end{bmatrix}
\]

Equation (2)

Contact path calculations were performed with custom software written in Matlab (v.7.8.0, The Mathworks, Inc., Natick, MA) and a C++ executable.

5. Comparison of predicted tibio-femoral contact paths to simulator-tested tibial components

Three left-sided Miller-Galante II TKR devices were worn using a knee simulator. Prior to testing, the surfaces of the tibial components were digitized in AP line scans at 100x100µm nominal XY point spacing with a low-incidence laser coordinate measuring machine (Optical Gaging Products, Inc., Rochester, NY) for input to the contact path algorithms. The superior articulating surface of each tibial insert was dotted with a permanent marker. Components were then loaded into a knee simulator of a certified testing laboratory (EndoLab GmbH, Rosenheim, Germany) and tested under the loads and motions specified by the ISO-force controlled standard ISO 14242-125 for 15,000 cycles at 1.0 Hz. The location of initial contact between the femoral and tibial component was measured. Flexion, anterior-posterior translation, internal-external rotation, and axial force data from each station were recorded for a full cycle every 5,000 cycles (Figure 4) such that full cycle recordings were taken three times. Following testing, wear scars were obtained by tracing the inner boundaries of remaining marker dots using the optical microscope (SmartScope).

The recorded motion applied by the knee simulator to each station was used for tibio-femoral contact path calculation. Because tibio-femoral contact is an area rather than a single point, a Hertzian contact area solution centered about each point on the contact path was computed. A rigid cylinder was assumed for the femoral component and a compliant flat plane was assumed for the tibial plateau. Contact area is a narrow rectangle of width “2b” by length “L” specified by Equation (3).

\[
b_i = \frac{4P_i r_i}{\pi L} \left(1 - \frac{u^2}{E}\right)
\]

Equation (3)

For a given instance of stance “i”, contact area is a narrow rectangle of width “2b” by length “L” under applied load “P”, femoral condyle radius of curvature “r”, Poisson’s ratio of the tibial component “ν”, and Young’s modulus of the tibial component “E”.

Applied load was taken directly from the simulator output for each test (Figure 4). Radius of curvature was calculated from the position of contact along an arc bisecting the femoral condyles. Poisson’s ratio was equal to 0.4; Young’s modulus to 930 MPa27. The rectangle length was equal to the width of the femoral condyles, 20 mm. Contact rectangles were calculated for all time points and overlaid to represent cumulative contact area centered about the contact paths.

![Figure 4](image-url)
We investigated 21 Miller-Galante II polyethylene inserts (Zimmer, Warsaw, IN, USA) retrieved postmortem 19 to 145 months after implantation. The retrieved inserts came from six men (8 inserts) and 11 women (13 inserts). The average age of the patients at time of the index arthroplasty was 75.2 years (range 59-87 years).

The video based measuring system (SmartScope) was again used to digitize the outlines of polished areas within the wear scars on the tibial plateaus. The outlines were normalized to the same implant size, mirrored if of a left implant to represent a right knee implant, and overlaid with a 5 mm by 5 mm square grid. A frequency count was performed to determine the prevalence of polishing across the tibial surface for all implants. The average contact path, predicted from the average knee joint kinematics of the ten subjects, was superimposed on the frequency plots to compare the predicted contact path to the frequency of areas of polishing.

### RESULTS

The mean age of the ten subjects with TKRs was 65.0 ± 5.3 years at surgery and 77.0 ± 5.7 years at the gait test. Mean TKR *in situ* time was 11.9 ± 1.1 years. The tibiofemoral contact paths for a sample subject are shown in Figure 5. The CDM and SDM resulted in similar contact pathways that were in close agreement in the AP direction. CDM and SDM were only significantly different for the ML positioning of the medial centroid (p = 0.009, Table 1). Although differences between methods were insignificant, a linear regression was performed to determine how well SDM results predicted CDM results. With alpha = 0.05, AP and ML position of the medial contact path centroid, AP and ML stretch of the lateral contact area, and AP and ML stretch of the medial contact area of the SDM reliably predicted the same variables for the CDM. When multiple independent variables entered the linear regression, the SDM variables of AP and ML stretch of the medial contact area and AP and ML position of the medial contact area reliably predicted the AP stretch of the medial contact area calculated from the CDM (p = 0.015, R² = 0.883). The same variables on the lateral contact area generated from the SDM predicted the AP stretch of the CDM lateral contact area (p = 0.017, R² = 0.876).

The contact path calculations compared well to the wear scars measured on the simulator tested components (Figure 6, Table 2). The calculated tibio-femoral contact paths and Hertz contact area solutions fell within the wear scars on the tested tibial components. The simulator tested components had an AP stretch of the lateral wear scars that were on average 5 mm longer than that calculated for the Hertz solution from the SDM (p = 0.002). The centroid of the lateral wear scar of the simulator-tested components were on average 3 mm farther lateral than the calculated Hertz solution from the CDM (p = 0.05), and the centroid of the medial wear scar of the simulator tested components were on average 1 mm farther medial than the calculated Hertz

Table 1. The contact path characteristics were not significantly different between the shortest distance method (SDM) and the contour distance method (CDM) except for the ML-coordinate of the medial centroid. Values are given in mm as mean ± SD. The centroids refer to the coordinates of the centroid of the entire contact path. AP and ML stretch refer to the AP and ML length of the box bounding the entire contact path. P values are from paired t-tests.

<table>
<thead>
<tr>
<th></th>
<th>Medial</th>
<th>SDM</th>
<th>Lateral</th>
<th>CDM</th>
<th>Medial</th>
<th>p</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>ML Centroid</td>
<td>-20 ± 7.7</td>
<td>13 ± 7.3</td>
<td>-16 ± 4.8</td>
<td>14 ± 2.4</td>
<td>0.009</td>
<td>0.92</td>
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<tr>
<td>AP Centroid</td>
<td>19 ± 3.8</td>
<td>19 ± 9.4</td>
<td>20 ± 2.5</td>
<td>21 ± 4.1</td>
<td>0.31</td>
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<tr>
<td>ML stretch</td>
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<td>20 ± 9.4</td>
<td>22 ± 7.6</td>
<td>19 ± 4.7</td>
<td>0.22</td>
<td>0.64</td>
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<tr>
<td>AP stretch</td>
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<td>29 ± 11</td>
<td>24 ± 11</td>
<td>28 ± 8.2</td>
<td>0.15</td>
<td>0.71</td>
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</tbody>
</table>

Figure 5. Sample subject contact path for: The shortest distance method (SDM), and the contour distance method (CDM).
Methods for Locating the Tibio-Femoral Contact Pathway in Total Knee Replacements

solution from the SDM method (p = 0.02). All other measurements were not significantly different. The average contact path compared well to the wear scars of postmortem retrieved tibial plateaus (Figure 7). The prevalence of polishing was 75% to 100% in areas covered by the average contact path.

DISCUSSION

The tibio-femoral contact pathway is an important parameter for determining knee loading and to estimate areas of contact between the tibial and femoral TKR components. In this study we developed two methods for determining the tibio-femoral contact pathway using marker-based gait analysis, standard radiographs obtained at clinical follow-ups, and point clouds of the TKR components. Both methods developed for predicting the tibio-femoral contact pathway resulted in accurate contact paths as shown by comparisons between the two methods and knee-simulator wear tests, consistent with our hypothesis.

In spite of our methodological rigor, this study was not without limitation. One limitation of the study involves measuring medial-lateral contact path movement. The medial-lateral contact path components, which were better predicted with the CDM than the SDM, are the most difficult to determine because this movement (movement towards the cameras) of the TEA is difficult to measure when all the cameras are on one side. Knee-joint simulators usually use flexion angle, AP translation, internal/external rotation angle, and axial force as inputs, while ML translation is unconstrained. Thus, the choice of method would not affect the input profile for knee wear simulation.

Another study limitation is the difficulty of registering the knee movements, measured with marker-based gait analysis, to the motion of the TKR components. The iterative process described in this study allowed the contact path to be positioned on the tibial plateau at locations that corresponded to the wear scars measured from retrieved components. For this study, two or three iterations were enough to match the contact path and wear scar centroids within 0.1 mm. Alternatively, radiographs or CT images that allowed registration between the skin markers and bones could be used with the same iterative process.

The contact paths produced by both methods compared well to the wear scars from components tested on a knee wear simulator, consistent with our hypothesis. Although not significantly different, the areas of the wear scars on the tested components were larger than the area of contact predicted by the Hertz contact solution, and the wear scars had areas of contact on the intercondylar eminence and the edges of the tibial plateau. The

<table>
<thead>
<tr>
<th>Method</th>
<th>ML Centroid</th>
<th>AP Centroid</th>
<th>ML stretch</th>
<th>AP stretch</th>
<th>Area</th>
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<td>25 ± 1.2</td>
<td>20 ± 5.0</td>
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<td>-21 ± 0.1</td>
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<td>0.02</td>
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<td>0.26</td>
<td>0.08</td>
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<table>
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<th>Method</th>
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<th>AP Centroid</th>
<th>ML stretch</th>
<th>AP stretch</th>
<th>Area</th>
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<td>261 ± 41</td>
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<tr>
<td>SDM Hertz Solution</td>
<td>21 ± 0.1</td>
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<tr>
<td>CDM Hertz Solution</td>
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Table 2. Few significant differences were seen between the contact path characteristics (mean ± SD, units mm or mm²) of TKRs tested on a knee simulator and predictions by the shortest distance method (SDM) and the contour distance method (CDM). The centroid coordinates refer to the centroid of the Hertz contact area calculated for the entire contact path. AP and ML stretch refer to the AP and ML length of the box bounding the entire contact path. Centroid coordinates correspond to Figure 2.

Figure 6. Results from the SDM contact path calculation (red lines) compared to wear scars on tibial plateaus worn in the simulator (black outline). Green bounding boxes indicate cumulative contact area predicted by a Hertz cylinder-on-flat solution centering at each point of the contact path. Tibial plateaus are mirrored and shown as right-sided implants where medial is to the left and lateral is to the right.

Figure 7. Frequency of polishing on 21 postmortem retrieved Miller-Galante II (Zimmer Inc., Warsaw, IN) tibial plateaus overlaid with the contact path predicted from the average knee joint kinematics of ten patients with the same implant. Medial-lateral contact path location is neglected on the graph. The medial and lateral contact path points are connected for each instance of the stance phase so that anterior-posterior translation and interior-exterior rotation of the femoral component can be visualized. Tibial plateau shown is right-sided where medial is to the left and lateral is to the right.
The tibial components used in the study had been previously placed on the simulator during setup of the tests and have some deformation on the surface, were only tested for a few cycles, and had some scratching during test set-up which could cause the irregular contact. Finally, the ML width of the wear scars on insert 3 is smaller than the width of the femoral condyles. This suggests that the femoral component was slightly out of alignment with the axis of rotation of the simulator, resulting in edge loading and smaller areas of contact. Despite these limitations, Hertzian solutions centered at the SDM- and CDM-produced contact paths were similar to the tested components, lending confidence to our methods.

The predicted average contact path of the ten subjects also compared favorably with wear scars on postmortem retrieved components. Most components (75-100%) showed highly polished areas in regions under the average contact path. Polishing is a surface feature which indicates intended use of the device. Components retrieved postmortem are considered well-functioning implants as they did not require a revision surgery. Hence, wear scars on the tibial inserts are a reflection of patient specific kinematics during activity.

Although both SDM and CDM produced reliable contact paths, a strength of the SDM technique is the simplicity of the method. The SDM technique allows testing of the tibio-femoral contact pathway for large cohorts of patients in clinical laboratories that use gait analysis equipment. The ability to accurately predict the path of contact between tibia and femur is important because of the significant effect of the tibio-femoral contact pathway on calculated knee-joint forces and moments imposed by muscles about the knee-joint.

CONCLUSIONS

The tibio-femoral contact pathway during gait can be reliably predicted for TKR patients using subject-specific anatomy, prosthesis geometry, standard radiographs from clinical follow-ups, and three-dimensional relative TKR joint kinematics from marker-based motion analysis. The pathways predicted in this study compared well to wear scars on knee wear simulator-tested components and components retrieved postmortem, indicating that the predicted tibio-femoral contact pathways could be used as an estimate of contact areas between the tibial and femoral TKR components in vivo.

ACKNOWLEDGMENTS AND AFFILIATIONS

This work was supported by grants from the NIH: R03 AR052039 (MAW), R01 AR05843 (MAW), T32 AR052272 (D.R. Sumner), and F32 AR057297 (HJL). Thanks to Martin Hinter and Endolab (EndoLab Mechanical Engineering GmbH, Germany) for performing the wear tests for model validation and to Sheryl Kompancaril for assistance with data analysis.

REFERENCES


OUTCOMES OF TOTAL JOINT ARTHROPLASTY IN HIV PATIENTS

Jonathan Falakassa, MD1, Alejandro Diaz, MD1, Michaela Schneiderbauer, MD1

ABSTRACT

Background: Advancement in human immunodeficiency virus (HIV) therapies has increased life expectancy. The need for joint replacement is expected to increase as this population develops degenerative changes from aging and avascular necrosis (AVN). Studies have shown a higher risk of peri-prosthetic joint infections (PJI) in HIV patients. However, these studies include a high percentage of hemophiliacs, which may be a confounding variable. With the advent of highly active anti-retroviral therapy (HAART) and evolving HIV demographics, we hypothesize the rate of PJIs in HIV patients are comparable to the general population.

Methods: We performed a retrospective cohort study using prospectively collected data from our arthroplasty database. We identified 24 HIV patients that underwent 31 primary hip and one primary knee arthroplasty between July 1, 2000 and September 30, 2012. Mean age was 50 years (range 31-74). Mean follow-up was 14 months (range 1.5-60).

Results: There were no PJIs in our HIV population. All HIV patients were non-hemophiliacs on HAART. Thirty-one total hip arthroplasties (THA) and one total knee arthroplasty were performed. Twenty-one HIV patients underwent THA for AVN. Eight patients had bilateral AVN. One patient needed revision for aseptic loosening. The mean CD4 count was 647 (194-1193). Mean viral load was undetectable in 19 patients and unavailable in five.

Conclusions: Our HIV population had a lower rate of PJI compared to infection rates in prior literature. Despite our limited patient population, our data suggests that well controlled HIV patients on HAART therapy with undetectable viral loads and CD4 >200 are at similar risk of PJI as the average population.

INTRODUCTION

According to the CDC, 1,148,200 people had a diagnosis of human immunodeficiency virus (HIV) in the United States at the end of 2010. The prevalence of HIV in the US continues to be high with an estimated 50,000 new infections in 2010. As the life expectancy in this population increases with improving therapies, patients will more frequently develop chronic conditions like degenerative joint disease in their hips and knees. In addition, this population has a 100-fold increased risk of developing avascular necrosis (AVN) of the femoral head. Both of these factors will contribute to the need for hip arthroplasty in this patient population.

Historically, HIV patients have been considered a high-risk population for musculoskeletal infections due to their compromised immune status. Infection in total joints can be detrimental, leading to multiple revision surgeries and poor outcomes. Current research concerning HIV infected individuals and total joint arthroplasty presents conflicting data. Some studies report complication rates as high as 57%. The most common complications included deep infection and aseptic loosening. However, prior studies included predominantly HIV patients with hemophilia, which may be a confounding variable. The majority of these studies found that these infections occurred late and were related to repeated episodes of transient bacteremia from breaks in aseptic technique during factor transfusion. The demographics of HIV individuals have changed over the past several decades. With improved technologies in blood screening and recombinant factor, hemophiliacs represent a smaller proportion of HIV patients. The purpose of our study is to describe complications, particularly prosthetic joint infections (PJI), in non-hemophilic HIV patients on HAART (highly active anti retroviral therapy).

MATERIALS AND METHODS

We performed a retrospective chart review using prospectively collected data from our arthroplasty database. We identified 24 HIV-positive patients who underwent 31 primary hip and one primary knee arthroplasty between the dates of July 1, 2009 and September 30, 2012 at Jackson Memorial Hospital and the University of Miami Hospital. These charts were reviewed for: diagnosis, comorbidities, date of surgery, procedure performed,
Outcomes of Total Joint Arthroplasty in HIV Patients

Table 1. Patient Characteristics

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<th>Sex/ Age</th>
<th>Diagnosis</th>
<th>Procedure</th>
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<th>Co-Morbidity</th>
<th>MRI</th>
<th>Follow-Up (Months)</th>
<th>Complications</th>
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*AVN (avascular necrosis), NA (not available), B (bilateral), OA (ozone arthritis), THA (total hip arthroplasty), TKA (total knee arthroplasty), HCV (hepatitis C virus), HPV (hepatitis B virus), HIV (human immunodeficiency virus), DM (diabetes mellitus), CAD (coronary artery disease), COPD (chronic obstructive pulmonary disease).

Follow-up period, preoperative CD4 count, viral load, anti-retrovirals, history of smoking, alcohol, intravenous drug abuse, corticosteroid use, and postoperative complications (venous thromboembolism, infection, aseptic loosening).

Patients with underlying AVN were classified based on the Ficat grading system using an anterior-posterior pelvic radiograph that was evaluated by a board certified orthopaedic surgeon. All patients reviewed were graded as Ficat III or IV. A Ficat III grade was assigned to radiographs that demonstrated evidence of subchondral collapse, appearance of a sequestrum with a break on the articular margin and a normal joint space. A Ficat IV grade was assigned to radiographs that had the changes noted above in addition to joint space narrowing.

Infection prevention protocols were the same throughout the study period. Patients received cefazolin and vancomycin for prophylaxis unless they had a severe penicillin allergy. Allergic patients received clindamycin and vancomycin. Due to the high prevalence of methicillin resistant staph aureus (MRSA) infections at our institution, vancomycin administration is standard protocol for all arthroplasty patients. Antibiotics were administered within 1 hour of the procedure and for 24 hours postoperatively. All arthroplasties were performed in operating rooms equipped with vertical laminar flow with all members of the surgical team wearing helmet aspirator suits. Skin preparation included the use of alcohol and chlorhexidine lavage.

Postoperative wound management consisted of application of a sterile dressing, which was placed over the incision in the operating room and kept for 48 hours. The wound was inspected and the dressing changed using sterile gauze once daily. Patients were encouraged to
contact their surgeon as needed or in the presence of fever, wound drainage, or any unexpected adverse events.

RESULTS

In our series, we identified 24 patients with HIV that underwent 32 primary total joint arthroplasties (31 total hip arthroplasties (THA) and one total knee arthroplasty (TKA)) with a mean follow-up of 14 months (1.5-60 months) Table 1. Of our 24 patients, two were lost to follow-up. The remaining 22 patients all had minimum six week follow-up. The mean age of our population was 50 years old (range 31-74 years old). There were 17 males and seven females. All HIV infected individuals included in this study were on HAART therapy. Two patients had a history of intravenous drug use (IVDU). Eight patients had Hepatitis C and six patients had type 2 diabetes mellitus. The etiology was AVN of the hip in 29/31 (93.5%) THA. Of the 21 patients with AVN, five had a documented history of hyperlipidemia. Eleven hips with AVN were Ficat grade III, 16 hips were Ficat grade IV, and X-Rays for Ficat staging were not available for two hips. Of the 21 patients with AVN, eight patients had bilateral AVN. No patients had a history of corticosteroid use. Only one patient had a history of alcohol abuse. The remainders of the total joint arthroplasties (TJA) were performed for post-traumatic arthritis (one THA) and osteoarthritis (one TKA and one THA). There were no recorded infections at the surgical site. One HIV patient required a revision surgery for aseptic loosening. This was diagnosed one year after the initial operation and pre-operative infection work-up with ESR, CRP and hip aspiration were negative. Intraoperative cultures also revealed no evidence of infection. No postoperative dislocations, deep venous thrombosis, or superficial infection were noted. One patient experienced MSSA sepsis treated with oxacillin for two weeks from an infiltrated IV, which was diagnosed on postoperative day four. Periprosthetic infection was ruled as based on clinical exam and complete resolution of symptoms. His CD4 count was 165 at the time of bacteremia and 454 preoperatively. Another patient went into respiratory failure on postoperative day seven requiring tracheostomy and prolonged mechanical ventilation secondary to pneumonia and sepsis. His cultures results were Acinetobacter baumanii, Pseudomonas aeruginosa, Enterobacter, Klebsiella pneumoniae. His CD4 count dropped to 189 during this episode from his preoperative CD4 count of 425. This patient also had a documented history of Hepatitis C, alcohol abuse, alcoholic pancreatitis, 30 pack year history of smoking and squamous cell carcinoma of the larynx.

The mean CD4 count at time of surgery was undetectable in 19 patients. Two patients did not have viral load available. The remaining three viral loads were detectable, but <100 copies/mL.

DISCUSSION

Assessing and predicting surgical outcomes for joint replacement surgery in HIV infected individuals has been a major challenge. Historically, studies have focused on joint replacement in HIV infected hemophiliac patients given this groups’ high risk of transmission and early joint degeneration. However, hemophiliacs represent a technically challenging population, as they tend to be young, have associated angular deformities, contractures and poor bone quality. In addition, they have been shown to have higher complication rates, which make interpretation of these studies difficult.

Studies have shown conflicting data concerning PJI in the HIV positive hemophilic population with rates ranging from 0-26.5%. A consensus regarding the safety of these elective procedures has been difficult to attain. Many studies have supported the use of preoperative CD4 counts to assess risks of PJI in HIV positive patients. In a retrospective review of 102 TJA in 73 HIV positive patients from eight hemophilia centers, Hicks et al. showed a correlation between a low CD 4 count and risk of infection3. The preoperative CD4 count was less than 0.2 x10^9/L in 62.5% (5/8) of the infected group, compared with 16.7% (7/42) in those not infected. Ragni et al. also showed an elevated rate of post-operative infections (15%) with CD4 counts below 0.2 x10^9/L. However, this study did not compare risk of PJI in HIV positive patients with CD4 counts greater than 0.2 x 10^9/L. Parviz et al. found that average CD4 for infected TJA was 239+/ - 112 compared to 523 +/- 171 in the non-infected group3.

Other studies have demonstrated CD4 counts to be unreliable for pre-surgical risk assessment. In a retrospective review of 55 total joint arthroplasties in 41 HIV positive patients Habermann et al. could not identify any differences when considering CD4 lymphocyte count6. Habermann also concluded that a difference in outcome between hemophilic patients with or without HIV could not be noted.

The majority (88.7%) of HIV disease transmission is now reported to occur through heterosexual and male-to-male sexual contact in otherwise healthy individuals7. Rather than joint degeneration from recurrent hemorrhage, the HIV population of today is predominantly undergoing joint replacement for AVN of the hip7. The exact pathophysiology of osteonecrosis in HIV patients remains unclear, however many predisposing factors have been described. Hyperlipidemia is a known complication of HIV infection and HAART, which may lead to induction of the atherosclerotic pathway leading to
osteonecrosis. In our study, 5/21 patients with AVN also had a documented history of hyperlipidemia. Thus, further investigation on the use lipid lowering agents, such as statins, for prophylaxis against AVN in HIV patients may be warranted. There has also been a significantly higher incidence of AVN of the femoral head since the introduction of HAART. However, it is currently unclear whether this is due to HAART itself or the fact that HIV patients are now living longer to develop the late sequelae of symptomatic AVN.

To our knowledge, there are three recent papers published that evaluate TJA outcomes in the modern HIV population. Tornero et al. looked at 18 THAs in 13 HIV-infected patients and 36 THAs in 27 non-HIV-infected patients. They found no significant differences in a variety of parameters including: mean time spent in surgery, the need for red cell transfusion, or the mean duration of hospitalization. The two groups showed similar postoperative functional results throughout the follow-up period (median 3.3 years in the HIV-positive group and 5.8 years in the HIV-negative group). In addition, they found no difference in the occurrence of complications.

Wang et al. reported on six HIV positive patients who underwent ten joint replacement procedures, including six total hip arthroplasties, two total knee arthroplasties, and one shoulder hemiarthroplasty. At an average follow-up period of 38.6 months, no infections were reported in their study.

In the most recent published report by Capogna et al. on 57 HIV patients (69 TJA), a non-significant difference in early deep infection was found (4.4% v 0.72%). The HIV group, as a whole, had a higher incidence of methadone use and history of IVDU compared to the control group. Of the three deep infections in the HIV cohort, two had a history of IVDU. Cultures in two of the three infections in this group were MRSA. While not statistically different, there was 6.22 times increased odds of deep infection in the HIV group compared to the control group. This rate is much greater than the other two recent publications on this patient population. This may be related to the high prevalence of IVDU history in this study, as this is an established risk factor for deep infection in TJA.

Our HIV population had a lower rate of PJI compared to infection rates in prior literature. Similar to these studies, all our patients were on HAART therapy and the majority underwent TJAs for AVN. No PJI or venous thromboembolisms were noted. However, our cohort did experience complications such as aseptic loosening requiring revision surgery, early line sepsis from an infiltrating IV, and postoperative pneumonia. Our patient who developed pneumonia both had a history of heavy smoking, laryngeal cancer and alcohol abuse. None of the other patients in our cohort had these identified risk factors. We feel that the risk factors of heavy smoking and alcohol abuse may play a more significant role in the predisposition to infection compared to well-controlled history of HIV.

Our study is limited by small sample size, limited follow-up and retrospective design. Early studies have shown that the majority of infections in the hemophiliac population occur late due to repeated transfusions of factor needed in this population. This trend of late infection no longer appears to be the case as evidenced by the lack of late infections in Wang and Tornero’s articles, which had mean follow-up periods greater than three years.

While some infections may develop beyond our study period, a 12-month follow-up would be sufficient to identify a predisposition to early infection in this population. This is also supported by Pulido et al. study that identified that the majority of PJI (65%) was diagnosed within the first year after surgery. Poor follow-up is a difficult limitation to overcome in a county hospital setting with a patient population that is often insufficiently insured and has limited access to care. Capogna et al. experienced this point as well with only 75% patient follow-up at 180 days and 55% at one year. Of our 24 patients, two were lost to follow-up. Of those who did follow-up, our average follow-up period was 14 months, which is where we would expect to see the majority of early PJI.

In the report by Capogna et al., of the postoperatively infected hip arthroplasties two-thirds of the patients grew MRSA in cultures. These patients only received Ancef for pre-operative antibiotics per their manuscript. Consideration should be given to adding vancomycin to this population for increased MRSA coverage. However, further studies are needed to determine the effect of adding vancomycin for preoperative prophylaxis.

The benefit of TJA, even in the era of high HIV-related morbidity and mortality, was well recognized. Our study provides support to the growing body of literature that shows more acceptable infection rates in the modern HIV population undergoing TJA. As with any intervention, patient selection remains critical. Thus, further research on other markers such as CD4 and viral load for pre-operative risk assessment will be helpful for medical decision making.

CONCLUSIONS

Despite our limited patient population, our data suggests that well controlled HIV patients on HAART therapy with undetectable viral loads and CD4 >200 are at similar risk of PJI as the average population. This may be attributed to the fact that our HIV population is younger and closely medically managed. Caution
should be exercised in the evaluation of elective joint arthroplasty for HIV positive patients. Each patient must be considered individually and optimized in coordination with their HIV/AIDS specialist prior to surgery. Patient specific factors include: IVDU, CD4 count/ HIV viral load, and co-morbidities (diabetes, obesity, tobacco use, alcohol use, Hepatitis C, inflammatory arthritides, etc.) Patients should be well informed of the increased risks and incidence of perioperative complications.

CONTRIBUTION OF AUTHORS
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REFERENCES
ABSTRACT
Pulmonary embolism is a life-threatening but treatable condition. Factors such as hypercoagulability and recent lower extremity surgery are associated with a higher incidence of thrombus formation and pulmonary embolism. Patients with sickle cell disease have a baseline hypercoaguable state and are at a greater risk forming deep vein thrombosis and pulmonary embolism than the general population. This increased risk is rarely cited in the literature. We describe a sickle cell patient two-weeks status-post total hip arthroplasty who presented with bilateral pulmonary embolism complaining of chest and shoulder pain. We highlight the need to include pulmonary embolism in the differential diagnosis of all sickle cell patients complaining of chest pain.

INTRODUCTION
Pulmonary embolism (PE) is a potentially fatal disease that requires prompt diagnosis and early treatment. The incidence of PE in the general population is between 0.023% and 0.205%1 and is even lower in children2. However, the mortality rate can approach 8.65-15.1% in treated patients1,3 and 25-35.5% in untreated patients4,5. Factors associated with an increased risk for PE and its usual precursor, deep vein thrombosis (DVT), include recent total knee or hip arthroplasty6-8, clotting disorders such as sickle cell disease2,9,10, cancer, obesity, decreased mobility, family history of venous thromboembolism11, and African American race1,10. As this case demonstrates, pulmonary embolism should be considered in the differential diagnosis for any sickle cell patient presenting with an insidious onset of chest or thorax pain, especially in those with other predisposing factors for venous thrombosis.

Case Report
An eighteen-year-old African American male with type SS sickle cell disease was admitted to the pediatric ward of the hospital 14 days status-post total hip arthroplasty (THA). He complained of left-sided chest and shoulder pain that began three days prior to admission. The pain initially started in the region of his left ribs and began radiating to the superior aspect of his left shoulder one day prior to admission. The patient had been discharged from the hospital after his surgery 12 days prior to this admission. Although our institution encourages early mobilization, the patient was not fully ambulatory until about five days prior to the onset of symptoms. The reasons for this delayed mobilization are unclear, although it was likely due to a combination of social factors and general fatigue postoperatively. He described his pain on readmission as sharp, severe, and worse with inspiration. He denied any trauma or recent respiratory infection.

His past medical history was significant for sickle cell disease, bilateral avascular necrosis of his hips, and multiple hospitalizations for vaso-occlusive crises, acute chest syndrome, and priapism. He had been treated prophylactically after surgery (starting 12 hours postoperatively) with low molecular weight heparin (LMWH) for two days until discharge, although he was not compliant with his outpatient LMWH. His current medications consisted of 1200 mg of hydroxyurea and 1 mg of folic acid daily.

On exam, the patient was afebrile and did not appear to be in respiratory distress, although he exhibited shallow respirations due to pain. He had no tenderness to palpation, ecchymosis, swelling, or erythema in the regions of his pain. His lungs were clear to auscultation bilaterally with diminished breath sounds in his left lower lobe. He had no swelling of his extremities and had a negative Homans sign. His pulse oximeter showed oxygen saturations of 96-98% on room air. All other vital signs and physical exam findings were normal. Chemistry studies were within normal limits except for a C-
reactive protein of 7.52 mg/L. His hemoglobin was 11.3 g/dL, hematocrit was 34.0%, and his reticulocyte count was 5.1%, all of which were improved from his lab values at discharge two weeks prior to admission. Prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR) were within normal limits. An AP and lateral chest X-ray did not show any pleural effusions, consolidation, vascular congestion, or other acute abnormalities or interval changes from prior chest X-rays. A PE protocol spiral CT scan (Figure 1) showed bilateral PE, worse on the left side, with a left lower lobe wedge infarct and subsegmental infarcts on the right side. The patient was started on 12,500 units of Fragmin.

On hospital day two, the patient had an ultrasound of the bilateral lower extremities, which was negative for deep vein thrombosis. The patient was clinically stable, denied shortness of breath, and complained of continued pain with respirations. His Fragmin was continued and he was started on 4 mg of Coumadin with a goal INR of 2.3. The patient’s clinical condition gradually improved, and on hospital day eight he reported no pain with inspiration. His INR was near therapeutic at 1.92. As the patient did not have a strong social support system and had a history of medication noncompliance, we planned to keep him admitted until his INR was therapeutic. However, the patient checked out against medical advice that evening.

DISCUSSION

Venous stasis, turbulent blood flow, and a hypercoagulable state often lead to DVT and PE. Patients with sickle cell disease exhibit an elevated baseline level of coagulation. Although this multifactorial hypercoagulability is a risk factor for thrombosis formation, DVT and PE are rarely cited as potential complications of sickle cell disease. Recent studies have demonstrated that patients with sickle cell disease, and even sickle cell trait, are at a higher risk for developing venous thrombosis and subsequent PEs. Since the treatment of a PE can greatly reduce mortality, a high index of suspicion should be maintained in sickle cell patients presenting with chest pain.

When venous stasis occurs, platelets aggregate, often in the valve cusps of lower extremity veins. A clot forms and is neutralized by fibrin. This process is repeated, forming multiple layers of fibrin and clots, ultimately resulting in a venous thrombosis. Anything that increases coagulability or causes venous stasis will increase the rate of DVT and PE. Factors associated with thrombosis and embolism in children include cancer, trauma, congestive heart disease, infection, lupus, liver failure, and sickle cell disease. Additional risk factors are prolonged bed rest, Factor V Leiden, smoking, increased blood viscosity, hip fracture, pelvis fracture, and recent lower extremity orthopaedic surgery.

Total hip arthroplasty (THA) is one of the most common surgeries associated with venous thrombosis, with DVT forming in up to 70% of patients with no prophylaxis. The pathophysiology of thrombus formation after a THA is partially due to endothelial injury. This can occur via kinking of the femoral vein during manipulation of the leg or through direct vascular injury, releasing clotting factors from the endothelium. In addition, venous stasis may occur as a result of immobilization after surgery or swelling in the affected leg, and coagulability may be increased by thromboplastin release from the femoral canal. Sickle cell patients often undergo THA due to osteonecrosis of the hip, and they are at an increased risk of thrombotic complications due to their hypercoaguable state.

A thrombus that breaks off and enters the pulmonary vasculature becomes a PE, and is a potentially fatal condition. Historically, up to 35.5% of untreated patients with PE died, and two thirds did so within the first thirty minutes. However, early diagnosis and proper treatment can reduce the mortality rate substantially. Recent studies have shown that the current all cause fatality rate for hospitalized patients with PE is as low as 7.4% and death from PE to be less than 1%. Over 50% of fatal PE’s occur in the second postoperative week and over 20% occur in the third postoperative week.
The median time to symptomatic DVT occurs at 17 days postoperatively4. Dyspnea, tachypnea, tachycardia, and pleuritic pain are often seen at presentation6. Common modalities used in diagnosis include pulmonary angiography8,12,15,21, nuclear medicine ventilation-perfusion scan8,12,15,21, spiral CT scan8,12,15,21, and D-dimer levels15,21. Doppler venous ultrasound and testing for the presence of Homans sign can be useful in detecting DVT12, and high pretest probability and positive physical examination findings increase the sensitivity of these tests12,15,21.

The prevalence of PE is higher for hospitalized sickle cell patients compared to similar non-sickle cell patients9, and is likely under-diagnosed10. The symptoms associated with PE are often mistaken for another pulmonary condition common in sickle cell disease, acute chest syndrome (ACS). ACS is a leading cause of death in sickle cell disease and manifests as a variety of respiratory symptoms including pulmonary infiltrates, chest pain, tachycardia, hypoxia, fever, and pulmonary hypertension25. As Stein et al. describe, ACS often leads to vascular occlusion and pulmonary infarction, likely due to thrombosis in situ16. While PE affects elastic vessels >1mm in diameter, thrombosis in situ affects the smaller muscular arterioles. This difference can be detected with standard or CT pulmonary angiography8. PE is not thought to be a cause of ACS, although some studies show that 17% of patients with ACS go on to develop PE19. Treatment for ACS and PE differ, and anticoagulation is not used therapeutically in ACS. Any patient with sickle cell disease who does not improve with standard ACS treatment modalities should be evaluated for PE.

Although the literature is sparse regarding prophylactic and treatment of PE in sickle cell patients after THA, the traditional management of symptomatic DVT or PE consists of anticoagulants and supportive therapy4,5,8,12. Intravenous heparin was formerly the mainstay of treatment4,5,8, but low-molecular-weight heparins are increasingly being used8. Both have been shown to substantially reduce the incidence of thrombosis7,12. Either of these therapies should be transitioned to long-term warfarin treatment, usually for three to six months8. Intravenous or low-molecular weight heparin should be discontinued after the INR level is 2.0-2.5 for two days8,8.

CONCLUSION

Patients with sickle cell disease exhibit a baseline hypercoagulable state and are at an increased risk for venous thrombosis and pulmonary embolism9,10. This association is rarely listed in the literature. Orthopaedic surgeries commonly performed on sickle cell patients11,12 can significantly increase the risk of thrombus formation8,12,14. Our case report demonstrates the need for a high index of suspicion in sickle cell patients presenting with pleuritic chest pain.


ABSTRACT
Introduction: The indications for vancomycin prophylaxis to prevent Methicillin-resistant Staphylococcus aureus (MRSA) surgical site infections are increasing. The recommended dose of vancomycin has traditionally been 1 gram intravenous. However, the increasing prevalence of obesity in our population coupled with increasing resistance of MRSA to vancomycin has resulted in recent recommendations for weight-based dosing of vancomycin at 15mg/kg. We hypothesize that the standard one gram dose of vancomycin is inadequate to meet the recently recommended dosage of 15mg/kg.

Methods: We performed a retrospective chart review on 216 patients who were screened positive for MRSA prior to undergoing elective total joint or spine surgeries between January 2009 to January 2012. All patients were given 1 gram of vancomycin within an hour prior to surgical incision as prophylaxis. Using the revised dosing protocol of 15mg/kg of body weight for vancomycin, proper dosage was calculated for each patient. These values were then compared to the 1 gram dose given to the patients at time of surgery. Patients were assessed as either underdosed (a calculated weight-based dose >1 gram) or overdosed (a calculated weight-based dose <1 gram). Additionally, we used actual case times and pharmacokinetic equations to determine the vancomycin (VAN) levels at the end of the procedures.

Results: Out of 216 patients who tested positive for MRSA, 149 patients (69%) were determined to be underdosed and 22 patients (10%) patients were determined to be overdosed. The predicted VAN level at the end of procedure was <15 mg/L in 60% of patients with 1 gram dose compared to 12% (p=0.0005) with weight base dose. Six patients developed post-operative MRSA surgical site infections (SSI). Of these six patients; four had strains of MRSA with vancomycin minimum inhibitory concentration of >1.0mg/L. Based on1g dosing, 5/6 patients with MRSA positive SSIs had wound closure levels of <15 mg/L and all six were <20 mg/L.

Conclusion: In settings such as hospitals, where the risk for resistant bacteria, especially MRSA, is high, it is becoming increasingly important to accurately dose patients who require vancomycin. In order to avoid incorrect dosing of vancomycin health care providers must use weight-based dosing.

Key Words: MRSA; surgical site infections; vancomycin; weight based dosing; total joint surgery; spine surgery

INTRODUCTION
As the cost of healthcare continues to escalate at an economically unsustainable rate, the payers of care, including the Federal Government, are focusing on strategies to deflect this cost curve without reducing the quality or accessibility of care. Decreasing the incidence of surgical site infections (SSIs) accomplishes both of these goals. SSIs lead to increasing morbidity and mortality, as well as higher health care costs with longer hospital stays2,9,12,17. To date, the prevalence of SSIs following joint replacement and spine surgery remains at 1-5%. Staphylococcus aureus (SA) is the leading causes of nosocomial infections17, accounting for as many as 48% of all SSIs17. Additionally, an increasing amounts of these infections are caused by resistant bacteria; especially Methicillin-resistant Staphylococcus aureus (MRSA)8. Thus strategies to prevent SSIs caused by both SA and MRSA are gaining importance.
Vancomycin (VAN) remains the standard of treatment and prophylaxis for MRSA. The goal of VAN dosing is to achieve a safe and effective minimum inhibitory concentration (MIC). With increasing VAN resistance of MRSA, hospitals have witnessed an increasing MIC to successfully treat MRSA infections. Steinkraus et al. reported a 1.5 fold increase in the geometric mean MIC of VAN with nearly 70% of patients having an MIC of 1mg/L, compared to just 10% five years earlier. We have noted a similar trend at our institution. In 2009, 95.5% of our MRSA isolates had a MIC of <1mg/L, compared to just 10% five years earlier. We have noted a similar trend at our institution. In 2009, 95.5% of our MRSA isolates had a MIC of ≤1mg/L and only 4.1% were >2mg/L. By 2012 only 90.3% of our MRSA isolates had a MIC of ≤1mg/L and the percentage of MRSA isolates with a MIC of >2mg/L increased to 8.3%; a 52% increase (Figure 1).

In addition to increasing resistance, VAN dosing has been affected by the rising trend of obesity. As an increasing number of patients are above normal healthy weight limits, giving a standard dose based on these guidelines is insufficient to achieve appropriate serum concentrations. Thus an increasing amount of patients are at risk for underdosing of VAN. Weight-based dosing protocols address this issue. Traditionally, the recommended preoperative dosage of VAN has been one gram given intravenously; however, recent clinical guidelines for antimicrobial prophylaxis recommend that each patient should receive VAN preoperatively according to a 15mg/kg weight-based protocol. The goal of this study is to demonstrate that weight-based VAN dosing is essential to provide adequate serum concentrations to reduce MRSA to eradicate MRSA in patients undergoing joint replacement and spine surgical procedures.

METHODS

This study was conducted at a university affiliated, single specialty, orthopedic hospital. We reviewed prospectively collected data on patients with positive MRSA nasal screens undergoing total joint and spine surgical procedures between January 2009 and January 2012. Patients’ gender, height, weight, and serum creatinine (Cr) were utilized in the pharmacokinetic analysis. In addition, we noted if a patient within the study developed a SSI during admission. All patients received VAN 1g within 1 hour prior to incision and VAN levels were calculated according to this dose. We calculated the VAN weight-based (WB) dose using the goal of 15mg/kg of actual body weight (ABW). The actual dose was rounded to the nearest 250mg for each patient. Patients were classified as either underdosed (calculated WB dose >1g dose) or overdosed (calculated WB dose <1g dose). We used pharmacokinetic formulas (Appendix 1) to estimate VAN levels at the time of incision (peak levels). Additionally, we used the actual duration of the operation (op-time) in conjunction with the pharmacokinetic formulas to determine and VAN levels at the time of wound closure. The percent of patients with estimated VAN levels <10 mg/L, 10-15 mg/L, 15-20 mg/L and >20 mg/L at the end of procedure were compared for each dosing regimen. For each patient who developed a MRSA SSI we calculated VAN levels at wound closure and compared these levels to the MICs of the MRSA cultured from that patient. McNemar’s test was used for categorical variables and an analysis was performed using SPSS version 20.

RESULTS

There were 216 patients with a positive MRSA nasal culture during our study period. Of the 216 patients, 68% underwent arthroplasty (knee n=75, hip n=66, shoulder n=6), 24% spine fusion, and 8% laminectomy (Table 1). Median surgical time was 124 (29-470) minutes. Mean age was 60 years, mean ABW was 86 kg (68% of patients had an ABW >20% of ideal body weight (IBW)). The mean VAN dose, clearance, and half-life were 12 mg/kg, 5 L/h and 10 h respectively. Vancomycin 1 g dose was appropriate in 21% of patients, 10% were overdosed, and 69% were underdosed (44% by 250mg, 32% by...
The Standard One Gram Dose of Vancomycin is not Adequate Prophylaxis for MRSA

A 500mg, 17% by 750mg, 7% by 1.0g) (Figure 2). There were no adverse effects observed in patients who were overdosed. Eighty-three percent of patients with WB dosing attained a peak level at incision of >20 mg/L, while only 25% of patients with 1g dosing achieved an incisional level of >20 mg/L (Figure 3). Predicted VAN levels at the end of procedure were <10 mg/L in 9% of patients with a 1g dose compared to just 2% of patients with a weight based dose (p=0.0002). Water-based dosing resulted in end-of-surgery VAN levels of >15mg/L and >20mg/L in 87.5% and 17.1% of patients respectively. In comparison, the standard 1g dose resulted in VAN levels of >15mg/L and >20mg/L in 39.8% and 10.6% of patients respectively. In total, the predicted VAN level at the end of procedure was <15 mg/L in 60% of patients with 1g dose compared to 12% (p=0.0005) with WB dose (Figure 4). Nine patients developed post-operative SSIs, and 6/9 had positive cultures growing MRSA. Of these six patients, four had strains of MRSA with VAN MICs of >1.0mg/L. Based on 1g dosing, 5/6 patients with MRSA positive SSIs had wound closure levels of <15 mg/L and all six were <20 mg/L (Table 2).

**DISCUSSION**

Our analysis determined that due to patient variability in weight and the increasing VAN MIC of MRSA, the standard 1g dose protocol consistently results in either overdosing or underdosing patients. Overdosing can induce severe drug toxicities, while underdosing may not provide sufficient drug concentrations for bactericidal effects. The appropriate dosing goal of VAN is best described by the area under the curve (AUC): MIC ratio (Appendix 2). The AUC:MIC ratio combines the pharmacokinetic (time course of antimicrobial concentrations) and pharmacodynamic (antimicrobial effect of the concentration) factors that determine efficacy. The pharmacokinetic parameters include the peak serum level (or time at incision) and trough level (time at wound closure) from which the AUC is determined. The pharmacodynamic parameter incorporates the amount of time serum drug concentrations remain above the MIC, and therefore have active bactericidal activity. It is imperative that VAN serum concentrations remain above the MIC for the entire surgical procedure (until complete wound closure) to truly have effective prophylactic effects. Taking these factors into account,

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age, years</th>
<th>ABW, kg</th>
<th>% above IBW</th>
<th>Procedure</th>
<th>Underdosed with vancomycin dose 1g/mg</th>
<th>Estimated level at wound closure with 1 g dose mg/l</th>
<th>Estimated level at wound closure with weight based dose</th>
<th>MIC of MRSA Isolates mg/L</th>
</tr>
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<tr>
<td>1</td>
<td>65</td>
<td>96.1</td>
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<td>20.3</td>
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</tr>
<tr>
<td>2</td>
<td>82</td>
<td>77.1</td>
<td>156</td>
<td>THR</td>
<td>250 mg</td>
<td>16.8</td>
<td>21.0</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>73</td>
<td>87.7</td>
<td>142</td>
<td>TKR</td>
<td>500 mg</td>
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<td>21.3</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>70</td>
<td>92</td>
<td>119</td>
<td>TKR</td>
<td>500 mg</td>
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<td>18.8</td>
<td>1</td>
</tr>
<tr>
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<td>46</td>
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<td>126</td>
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<td>15.2</td>
<td>≤0.5</td>
</tr>
<tr>
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<td>70</td>
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<td>110</td>
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<td>250 mg</td>
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<td>17.7</td>
<td>1</td>
</tr>
</tbody>
</table>
for isolates with an MIC = 1, the therapeutic level in plasma should be 16-20 mg/L. Gremmel et al.11 echoed this recommendation that therapeutic pre-dose levels be set at 15-20 mg/L, which can refer to wound closure level goals for our surgical patients. When used as surgical prophylaxis in a one-time dose, the wound closure levels at the end of surgery must remain at this level to provide coverage throughout the procedure. In addition, the wound closure concentration should always be > 10 mg/L to prevent resistance development. Steinkraus et al. highlighted the issues of increasing resistance by reporting a four-fold increase in the percentage of MRSA isolates that required an MIC of 2 mg/L.26

In our study, 69% of the patients receiving perioperative VAN prophylaxis were underdosed by >250mg and more than half of those patients were underdosed by > 500mg. This underdosing translates to 30% of patients failing to obtain the recommended 15-20 mg/L levels for a MIC = 1 at their peak concentrations. Furthermore, 8.8% had wound closure levels <10 mg/L at the end of their operations, which is the minimum level required to avoid developing resistant strains. Most notably four of the six patients in our study who developed MRSA SSIs each had serum VAN levels which were not high enough to address the actual MICs of the MRSA strains cultured from each of the patients. Obtaining these VAN concentration levels is essential as MRSA isolate MICs continue to increase and the development of resistance becomes more of an issue.

Steinkraus et al highlighted the issues of increasing resistance by reporting a four-fold increase in the percentage of MRSA isolates that required an MIC of 2 mg/L. As defined by Tenover et al., SA isolates with an MIC > 1 mg/L are considered heteroresistant and small populations of these isolates may progress to become VAN resistant, and are able to grow in VAN concentration of 8-16 mg/L.21 If patients are consistently underdosed in the hospital setting, SA will be more adept at evolving and gaining resistance genes, thereby furthering the bacteria’s resistance to VAN.25

Not only has increasing MRSA resistance caused potential underdosing, VAN dosing is a dynamic process, as levels vary according to multiple factors and change over time. Cheymol et al.6 illustrated that obesity increases both the volume of distribution (Vd), clearance of VAN (CL) thus decreasing its half-life. Vance-Bryan et al.26 demonstrated the increase in Vd, meaning that obese patients may require increased dosage to obtain serum concentrations greater than the necessary MIC. Bauer et al.3 explained that because VAN is renally excreted, and obese patients have higher CL rates, the drug will be excreted faster, requiring higher doses to maintain appropriate AUC:MIC ratios. Blouin et al.2 also recognized the increased Vd and CL in obese patients compared to those of normal, healthy body weights. Each of these authors recommended dosing VAN based upon patients’ total body weight due to the described pharmacokinetic factors.

It is also important to consider that not only are obese patients being underdosed perioperatively, but also that obese patients are at greater risk to undergo surgery. Obesity is a major risk factor for the development of osteoarthritis and patients undergoing lower extremity joint replacement and spine surgery are on average heavier than those not undergoing these surgeries1,22. Because of this, more and more obese patients are undergoing joint replacement surgery and spine surgery, and may be at risk to be underdosed for MRSA prophylaxis perioperatively. This can be seen in our patient population, as 61/75 (81.5%) of patients undergoing knee-replacement surgery had an ABW > 20% over IBW, as defined by Equation 1 of Appendix 1. Additionally, patients with positive swabs, such as those included in our study, are at an increased risk of SSIs and will remain so if VAN prophylaxis fails to reach the proper therapeutic levels13,18,27. The purpose of our study was to demonstrate that weight-based VAN dosing is essential to provide VAN serum concentrations high enough to be effective in protecting patients against MRSA. One may use a priori reasoning to correlate this increased dosing to a decrease in the risk of developing MRSA SSIs. However, the study was not designed to address this issue and is statistically underpowered to make any such claims.

Due to increasing cases of MRSA, resistant strains, MICs of MRSA are continually increasing. This, paired with a rise in obesity throughout the population and increased surgical procedures within the obese population, has made it more evident that a standard 1g dose of VAN for perioperative prophylaxis may no longer be sufficient. If the trend of underdosing continues, the MIC of VAN required to treat MRSA will continue to increase, forging more resistant strains. As described in our study, a protocol of weight-based dosing exposed the standard 1g dose as insufficient for a majority of patients. A weight based protocol provides necessary perioperative MRSA prophylaxis potentially decreasing the progression toward VAN-resistant strains, and preventing SSIs.
APPENDIX 1

**Equation 1:** Estimated creatinine clearance (CrCl) by Cockroft-Gault equation, mL/min
CrCl (male) = \[(140 - \text{age}) \times \text{ideal body weight (IBW)}\]/(72 \times \text{SCR})
CrCl (female) = \[(140 - \text{age}) \times \text{IBW (kg)}\]/(72 \times \text{SCR}) \times 0.85
Used minimum serum creatinine of 1 mg/dL if age > 70 y
IBW (males), kg = 50 + (2.3 \times \text{height in inches over 60 inches})
IBW (females), kg = 45 + (2.3 \times \text{height in inches over 60 inches})

**Equation 2:** Vancomycin clearance (Clearance), L/h
Clearance= \text{CrCl} \times 0.06

**Equation 3:** Vancomycin volume of distribution (Vd), L
Vd = DW \times 0.7 L/kg
DW = total (actual) body weight, kg

**Equation 4:** Vancomycin Ke, h\(^{-1}\)
Ke= Cl/Vd

**Equation 5:** Vancomycin half-life (T\(_{1/2}\)), h
T\(_{1/2}\) = 0.693/Ke

**Equation 6:** Estimated peak level (Cmax), mg/L
Cmax= \text{Dose}/Vd
Dose= vancomycin dose of 1000 mg or vancomycin calculated weight-based dose (15 mg/kg x DW, rounded to the nearest 250 mg)

**Equation 7:** Estimated level at the end of surgical procedure (Cmin), mg/L
Cmin = Cmax \times e^{Ke \times T}
T = \text{opTime}

APPENDIX 2

**Concentration**

**AUC:**

**MIC of Bacteria**
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DISTAL RADIAL FRACTURES: THE SIGNIFICANCE OF THE NUMBER OF INSTABILITY MARKERS IN MANAGEMENT AND OUTCOME

Rahul Bhattacharyya, MBChB, MRCS, MSc, Bethan Sian Morgan, MBChB, Pavel Mukherjee, MBBS. MRCS, Simon Royston, MBChB, MRCS, FRCS

ABSTRACT

Introduction: Distal radial fractures are one of the most common orthopaedic injuries. An effective treatment strategy is needed to ensure good outcome and better resource usage.

Aim: To identify the significance of the number of instability markers in distal radial fractures in predicting outcome and proposing a standardized management strategy.

Methods: Data was collected retrospectively over three months at the Northern General Hospital, Sheffield. All patients who had a distal radius fracture in the defined time period and matched our criteria were included. Relevant instability markers identified through a literature review were: age >60 years, dorsal angulation >20°, intra-articular fracture, ulna fracture, dorsal comminution, radial shortening and osteoporosis. The number of instability markers, management and outcome were recorded for each patient. The strategy of management was subdivided into: plaster cast immobilisation with subsequent rehabilitation, manipulation with subsequent cast immobilization and surgery (locked volar plating). Outcomes were graded as “good” or “poor” based on the complications and the function achieved at discharge from follow-up.

Results: Two hundred and seven patients were included in our study. One hundred and nineteen patients had ≤3 instability markers (Group A) and 88 had ≥4 (Group B). One hundred and sixty-two were female and 45 were male. The average age was 60 years and the age range was 19 to 96 years. In Group A, 91% achieved “good” outcome regardless of management strategy, versus 66% in Group B (p<0.001). In Group B, amongst patients who had surgery (29), 79% achieved “good” outcome, however those with manipulation alone (38), only 58% achieved “good” outcome (p = 0.03 (one tailed), p = 0.06 (double tailed)).

Conclusions: We have found that four or more instability markers are globally associated with a poorer outcome. Patients with four or more markers who underwent surgery did uniformly better than those with manipulation alone. However, in patients with three or fewer markers, non-operative management yielded equally good outcomes. We plan to use this as a pilot study for future primary research.

Keywords: instability markers distal radial fractures

INTRODUCTION

Distal radial fractures are very common and constitute a significant proportion of the workload for the Orthopaedic department. They are the most common osteoporotic fracture and in a rapidly aging population their incidence is set to rise.

Management of patients with distal radial fractures is controversial, with no clearly adopted management strategy. There is no clear evidence to guide when to adopt non-operative versus operative management and also no definitive evidence to support one surgical fixation method over another. In our practice we had noted patients with higher number of instability markers had better functional outcomes with surgical fixation when compared to non-operative management but had no data to support this.

A significant amount of work is available in literature, which is focused on identifying the instability markers in distal radial fractures. In 1989, Lafontaine et al. reported that age > 60 years, dorsal angulation (>20°), dorsal comminution, intra-articular fracture (radio carpal joint surface) and associated ulnar fracture were associated with an increased risk of secondary displacement, despite
Table A: The instability markers for distal radius fracture included in our study

<table>
<thead>
<tr>
<th>No.</th>
<th>Instability markers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>age &gt; 60 years</td>
</tr>
<tr>
<td>2</td>
<td>dorsal angulation &gt;20 degrees</td>
</tr>
<tr>
<td>3</td>
<td>intra-articular fracture</td>
</tr>
<tr>
<td>4</td>
<td>ulna fracture</td>
</tr>
<tr>
<td>5</td>
<td>dorsal comminution</td>
</tr>
<tr>
<td>6</td>
<td>radial shortening of greater than two mm</td>
</tr>
<tr>
<td>7</td>
<td>Osteoporosis</td>
</tr>
</tbody>
</table>

The following markers of instability for distal radial fractures5–8.

While the aforementioned studies identified markers of instability, but there is little published that has investigated the impact of the number of instability markers in distal radial fractures. Therefore the aim of this study was to identify the significance of the number of instability markers in distal radial fractures in predicting outcome and proposing a standardised management strategy.

**RESULTS**

In total, 207 patients were included in our study. Of these, 162 were female and 45 were male. The average age was 60 years and the age range was 19 to 96 years. Group A had 119 patients with ≤ three instability mark-
Table B: Comparison of demographics between Group A and Group B

<table>
<thead>
<tr>
<th>Management</th>
<th>No. of patients</th>
<th>Good Outcome</th>
<th>Poor Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaster cast immobilization only</td>
<td>82</td>
<td>78 (95%)</td>
<td>4 (5%)</td>
</tr>
<tr>
<td>Manipulation</td>
<td>23</td>
<td>19 (83%)</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>Surgery</td>
<td>14</td>
<td>11 (79%)</td>
<td>3 (21%)</td>
</tr>
</tbody>
</table>

Table I: Patients with ≤ 3 instability markers

<table>
<thead>
<tr>
<th>Management</th>
<th>No. of patients</th>
<th>Good Outcome</th>
<th>Poor Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaster cast immobilization only</td>
<td>18</td>
<td>13 (72%)</td>
<td>5 (28%)</td>
</tr>
<tr>
<td>Manipulation</td>
<td>38</td>
<td>22 (58%)</td>
<td>16 (42%)</td>
</tr>
<tr>
<td>Surgery</td>
<td>29</td>
<td>23 (79%)</td>
<td>6 (21%)</td>
</tr>
</tbody>
</table>

Table II: Patients with ≥ 4 instability markers

<table>
<thead>
<tr>
<th>Management</th>
<th>No. of patients</th>
<th>Good Outcome</th>
<th>Poor Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaster cast immobilization only</td>
<td>18</td>
<td>13 (72%)</td>
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</tr>
<tr>
<td>Manipulation</td>
<td>38</td>
<td>22 (58%)</td>
<td>16 (42%)</td>
</tr>
<tr>
<td>Surgery</td>
<td>29</td>
<td>23 (79%)</td>
<td>6 (21%)</td>
</tr>
</tbody>
</table>

As shown in Table I, amongst the patients with ≤ three instability markers (group A), 82 patients were treated with plaster immobilization and subsequent rehabilitation, without any manipulation or surgery. Out of these 78 patients (95%) had a “good” outcome and four (5%) had a “poor” outcome. Twenty-three patients had either one or multiple manipulations without subsequent surgery, of which 19 (83%) had a “good” outcome and four (17%) had a “poor” outcome. Out of the 14 patients who had surgery, 11 (79%) had a “good” outcome and three (21%) had a “poor” outcome.

In Group B (≥ four instability markers) – (Table II), 18 patients were treated with plaster immobilization and subsequent rehabilitation without any manipulation or surgery. Thirteen of 18 (72%) patients achieved a “good” outcome, whereas five (28%) achieved a “poor” outcome. Thirty-eight patients were treated with one or multiple manipulations without subsequent surgery, of which 22 (58%) had a “good” outcome and 16 (42%) had a “poor” outcome. Amongst the 29 patients who underwent surgery, 23 (79%) achieved a “good” outcome, whereas six patients (21%) had a “poor” outcome. It should be noted that in Group B, the remaining three patients who did satisfy the criteria of having ≥ four instability markers and were therefore initially included in the study had to be excluded as there was no information available on their follow up progress and outcome. Therefore, 85/88 patients in this group are accounted for in Table II.

We found that in Group A (≤ three instability markers), 91% achieved a “good” outcome regardless of the management strategy used as compared to 66% in Group B (≥ four instability markers). (P < 0.001). However amongst patients in Group B (≥ four instability markers) those who had surgery (29), 79% achieved “good” outcome, whereas those treated with manipulation alone (38), only 58% achieved “good” outcome (one tailed p = 0.03, double tailed p = 0.06).

DISCUSSION

Our study demonstrated that four or more instability markers in distal radial fractures are associated with a poorer outcome. Patients with four or more instability markers did better with surgery when compared to manipulation alone. Those individuals who underwent surgical fixation in Group B were more likely to regain a satisfactory range of motion and be able to return to their pre-injury activities of daily living.

Our findings corroborate with previous studies, demonstrating better results with surgery for unstable distal radial fractures. A study by Koenig et al.9 showed that in potentially unstable distal radial fractures treated with locked volar plating the probability of painless union was higher and provided a long term gain in quality adjusted life years which outweighed the risks of surgical treatment in the short term. Figl et al.10 reported that the treatment of unstable distal radial fractures with a volar fixed-angle plate osteosynthesis in elderly patients showed good anatomical reduction, early return to function and reduced morbidity. Secondary loss of reduction was also prevented by this procedure. Orbay et al. found similar results11, who reported that treatment of unstable distal radial fractures in elderly patients with volar fixed-angle plate provided a more stable fixation and earlier return to function. There is more published data demonstrating good outcome for unstable distal radial fractures treated with locked volar plating12-17.

The complications of volar locking plates are well documented. Drobetz et al.18 found flexor pollicis longus tendon rupture as the most common complication. Arora et al.19 reported that in palmar fixed angle plates, if the screws are too long then they can penetrate the extensor compartments and that distal screws in comminuted fractures can cut through the subchondral bone and penetrate into the radio carpal joint. Knight et al.20 studied 40 patients with volar locking plates, of which 25% had malunion and 12.5% had rupture of the extensor pollicis longus tendon.

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In our study the majority of patients in the group with 4 or more instability markers in fact had closed reduction (manipulation) with subsequent plaster immobilisation, without surgery. However, their outcome was not as good as the patients who had surgery within this group (58% v 79% “good” outcome).

A paper which studied the value of closed reduction in 60 distal radial fractures in the very elderly and low-demand demented patients, found that 53/60 (88%) healed in the malunited position\textsuperscript{21}. Therefore there is little benefit in manipulating these fractures as the position is rarely maintained. Hence these patients, if they are unfit for surgery, are best treated by plaster immobilisation and follow-up. In our study we found that the majority of the patients in the group with four or more instability markers who were not manipulated or operated upon were low-demand frail and elderly patients and they did reasonably well with plaster cast immobilisation only. A study by Arora et al.\textsuperscript{22} compared operative versus non-operative treatment for unstable distal radial fractures in low demand patients 70 years or older. They found that surgery yielded better radiological outcome but there was no significant difference in the functional outcome between the operative and non-operative group. Our results however showed that functional outcome is better in the surgical group as compared to the non-operative group in the patients with four or more instability markers, although in our case this is not limited to the 70 or above age group.

In our study, the vast majority (91%) of patients with ≤ three instability markers had a “good” outcome. There was no significant difference in outcome between the individual management strategies within this group of patients.

This was a pilot study aimed primarily at finding an association between the number of instability markers and management and outcome of distal radial fractures. We understand larger numbers are needed to add weight to the results. Therefore, our future plan is to undertake a prospective, multicenter study with standardised outcome scores such as the DASH (Disability of Arm, Shoulder and Hand) score to reduce the limitations and also to check the reproducibility of the results found in this study.

CONCLUSIONS

Four or more instability markers in distal radial fractures are globally associated with a poorer outcome. Patients with four or more instability markers have better outcomes with surgery when compared to manipulation alone. Patients with three or fewer instability markers have a good outcome regardless of the management strategy used. We have shown that looking at the number of instability markers in distal radial fractures is useful in guiding management and predicting outcome.

CONFLICT OF INTEREST
There are no conflicts of interest amongst any of the authors.

ACKNOWLEDGMENTS
We sincerely thank the audit and clinical governance department at the Northern General Hospital, Sheffield for their support and contribution in this project.

There was no additional funding required for this project.

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ABSTRACT

Background: The ideal treatment strategy for the dorsally comminuted distal radius fracture continues to evolve. Newer plate designs allow for variable axis screw placement while maintaining the advantages of locked technology. The purpose of this study is to compare the biomechanical properties of one variable axis plate with two traditional locked constructs.

Methods: Simulated fractures were created via a distal 1 cm dorsal wedge osteotomy in radius bone analogs. The analogs were of low stiffness and rigidity to create a worst-case strength condition for the subject radius plates. This fracture-gap model was fixated using one of three different locked volar distal radius plates: a variable axis plate (Stryker VariAx) or fixed axis (DePuy DVR, Smith & Nephew Peri-Loc) designs. The constructs were then tested at physiologic loading levels in axial compression and bending (dorsal and volar) modes. Construct stiffness was assessed by fracture gap motion during the different loading conditions. As a within-study control, intact bone analogs were similarly tested.

Results: All plated constructs were significantly less stiff than the intact control bone models in all loading modes (p<0.040). Amongst the plated constructs, the VariAx was stiffest axially (p=0.032) and the Peri-Loc was stiffest in bending (p<0.024).

Conclusion: In this analog bone fracture gap model, the variable axis locking technology was stiffer in axial compression than other plates, though less stiff in bending.

INTRODUCTION

Fractures of the distal radius exhibit a bimodal distribution with high energy injuries in the younger population and fragility fractures associated with simple falls in older patients. With the increase in average age of the population, it is not surprising that the incidence of distal radius fractures is increasing and this trend is projected to continue. The treatment of distal radius fractures has evolved over the last several decades. Conservative and operative treatment modalities have been evaluated with evidence supporting surgical treatment for displaced fractures. Successful outcome parameters have historically considered restoration of volar tilt to 11°, radial inclination of 23°, and/or radial shortening of less than 2 mm. Other articles cite excessive intra-articular displacement as the chief factor for negative outcomes including arthritis. Treatment guidance has been provided by the AAOS which has issued a 'moderate recommendation' for operative fixation instead of casting for fractures which exhibit: shortening >3 mm, dorsal tilt >10°, or intra-articular displacement >2 mm.

There is some debate as to the ideal surgical intervention. Successfully established techniques include closed reduction with percutaneous pinning, closed reduction and external fixation, external fixation and percutaneous pinning, open reduction and fixation with pins (ORIF), external fixators or internally fixed with either dorsal and/or volar plates. Several recent studies have demonstrated that ORIF techniques yield better patient outcomes. ORIF allows anatomic reduction and early stability which promotes the safe initiation of wrist and hand rehabilitation. More specifically, the use of locked volar plating has the advantage of avoiding the complications associated with dorsal plating including extensor tendon irritation, attrition, or rupture. In addition, biomechanical studies show that locked volar plates produce significantly greater stability than unlocked volar plates.

Despite the advantages of fixed angle locked volar fixation, there are potential disadvantages. For locked plates, it is not possible to truly lag a fracture fragment to the plate. Also, the fixed angle plate designs are dependent on conformance of the patient's distal radius anatomy and fracture pattern to the plate geometry. This problem can
often be adequately addressed via the availability of a variety of plate geometries. Regardless, some compromises may be necessary in either plate positioning or quality of subchondral support to facilitate fixed-angle fixation. Amongst different plate concepts, the so-called "variable axis" design provides the surgeon some flexibility on the trajectory of the 'locked' screws to facilitate fixation of variable fracture patterns and anatomy. The apparent design goal is to yield screw placement flexibility while providing equivocal fixation versus fixed angle designs. There is little data in the literature which compares the biomechanical stability of variable axis technology relative to traditional locked technology. The purpose of this study is to compare the biomechanical properties of variable axis technology with traditional fixed angle locked technology. Several different plates were evaluated for fixation using an established model of a dorsally comminuted distal radius analog. Uninstrumented, intact control analogs were similarly tested assessed to provide a basis for comparison.

MATERIALS AND METHODS

Per Willis and coworkers, an analog radius model (model 1027, Pacific Research Laboratories, Vashon, Washington) was utilized for this study to limit specimen-to-specimen variability frequently observed in cadaveric models. It is acknowledged that this bone model does not replicate the strength or stiffness of normal bone. However, this analog model has been used in the past to represent a consistent, suboptimal condition for the assessment of the stability and fixation for fracture plates. Twenty-four radius analogs were divided into four groups; three groups were instrumented with one of three different plates as described below, and the fourth group served as intact controls. In the three plated groups, an extra-articular wedge shaped dorsally comminuted radius fracture was simulated via osteotomy with a 1 cm dorsal gap and positioned 2 cm proximal to the distal articular surface.

All plates were implanted volarly per the manufacturers’ recommendations, leaving the volar cortices in contact. One plate featured the variable screw axis design (Titanium VariAx Distal Radius Locking Plate System, Stryker, Kalamazoo, Michigan) (Figure 1). The remaining two plates incorporated a fixed screw axis designs (Titanium DVR locking plate, Hand Innovations, Miami, Florida, and the Stainless steel Peri-Loc Volar Distal Radius Locking Plate, Smith & Nephew, Memphis, Tennessee). The distal locking screws were intentionally long to ensure bicortical purchase and consistency of fixation. The variable axis plate locking screws were positioned neutrally in their holes, which is within the company’s specifications (i.e. within 15° from neutral). Regardless of the mode of fixation, all of the distal locking screws for all plates exited out the dorsal cortex of the distal radius and not through the fracture gap or into the articular surface.

Locked volar fixation is designed to permit early hand and wrist range of motion. Therefore, the biomechanical testing was designed to closely replicate the in vivo forces at the fracture site shortly following fixation and described in detail below. A servohydraulic testing machine (MTS Bionix, Eden Prairie, MN) delivered axial compression, and dorsal and volar three-point bending at sub-failure, physiologic magnitude.

### Table 1. The cross section and axial and bending rigidity of each plate was assessed just proximal to the distal most shaft screw. This location coincided with the fulcrum for the three point bending test (see Figure 1).

<table>
<thead>
<tr>
<th></th>
<th>DVR</th>
<th>Peri-Loc</th>
<th>VariAx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width (w, mm)</td>
<td>7.62</td>
<td>10.03</td>
<td>17.15</td>
</tr>
<tr>
<td>Thickness (t, mm)</td>
<td>2.54</td>
<td>2.54</td>
<td>2.03</td>
</tr>
<tr>
<td>E (GPa or 10^3 N/mm^2)^*</td>
<td>Titanium= 110</td>
<td>Stainless steel= 190</td>
<td>Titanium= 110</td>
</tr>
<tr>
<td>Axial Rigidity (AE)^* (10^6 N)</td>
<td>2.13</td>
<td>4.84</td>
<td>3.83</td>
</tr>
<tr>
<td>Bending Rigidity (IE)^* (10^6 Nmm^2)</td>
<td>1.15</td>
<td>2.60</td>
<td>1.32</td>
</tr>
</tbody>
</table>

^*E=elastic modulus, A=cross section area=w t, I=area moment of inertia=w t^3/12, modulus values taken from [26].
Biomechanical Performance of Variable and Fixed Angle Locked Volar Plates

firstly, it is not typically included in the postoperative therapy and secondly, the plates are approximately 25 times stiffer in this direction based on the Moments of Inertia for plane vs. edge loading (Table 1). Thus, the dorsal/volar bending tests were designed to investigate the anticipated loading during healing which also corresponds to the weaker loading axis of the plates. Axial compression was similarly assessed since it is anticipated during healing and the compressive force also subjects the plates’ weak axis to bending moments. Such bending moments arise from the axial loads which were applied through the center of the radial lunate facet (Figure 2); this axial compression produced a combined loading condition of simultaneous plate compression and dorsal bending\textsuperscript{22}. The proximal end of the radius was potted with room temperature curing epoxy. For axial compression, the potting cup was secured in the machine and the specimens were loaded under displacement control (0.5 mm/sec) to a force of 250 N. For three point bending, the construct was horizontally mounted in the test machine and the potted proximal end was secured (Figure 3). Dorsal bending placed the dorsal surface up such that the distal bending force was applied to the dorsal surface; for volar bending the construct was rotated 180 degrees about its long axis\textsuperscript{22}. A 50 N force was applied to the distal central radius in displacement control at a rate of 0.5 mm/s. Per Willis, the bending fulcrum was positioned immediately proximal to the first screw proximal to the fracture site. Pilot failure axial and bending tests were performed on instrumented and control constructs to ensure that the physiologic test forces were well within the linear elastic range of construct. These tests confirmed that all specimens were significantly below the load at which construct yield would occur.

A differential variable reluctance transducer (DVRT) (M-DVRT-6, MicroStrain; Williston, Vermont) was mounted dorsally across the osteotomy (Figures 2,3) to measure interfragmentary displacement\textsuperscript{22}. For all tests, load data was recorded on a load cell attached to the test machine's base. The axial and bending stiffness were taken as the slope of the load vs. interfragmentary displacement curve for each construct. Each construct was tested three times with the construct stiffness taken as the average of the second and third tests (Figure 4)\textsuperscript{22}. Positive stiffness values were arbitrarily assigned to indicate dorsal diastasis which was typical during

Figure 2: Axial Compression Test. Constructs were axially loaded to a physiologic sub failure load of 250 N using the protocol from [22]. This dorsal view shows the displacement transducer which spanned the fracture gap to record interfragmentary displacement.

Figure 3: Dorsal and Volar Bending Tests. Three point bending was performed (A) dorsally and (B) volarly to a load of 50 N per [22]. The displacement transducer was again used to record interfragmentary motion.
Volar bending. Negative stiffness values thus indicated fracture gap shortening as would occur during dorsal bending.

The uninstrumented control analog radius was tested under the same conditions as above with the only difference being a lack of an osteotomy or plate. The DVRT was placed in the same region as the three plate tests. The control data was intended to assess the consistency of the analog distal radius as well as to study any biomechanical differences between the control and treated radii.

In all cases, normality was confirmed before performing statistical comparisons. For a given biomechanical test modality (axial or bending), the stiffness was compared for the four groups (3 plates, 1 control) with a one-way ANOVA (α=0.05) and Fishers LSD (Least Significance Difference) multiple pair-wise post-hoc comparisons.

RESULTS

The axial and bending stiffness magnitudes of the control specimens were significantly greater than all plated constructs (p=0.001 to 0.04) (Figure 5). The axial compressive stiffness of the control specimens was several times greater than the plates and was positive, indicating lengthening of the dorsal cortex. In contrast, all plated constructs exhibited negative stiffness values, which indicated compression at the fracture site. Visual inspection of the control specimens during loading revealed a first mode buckling shape such that the dorsal surface was in tension and the volar surface was in compression as was confirmed by the DVRT sensor. Similar evaluation of all plated constructs showed little observable deformation on the volar surface; rather the deformation appeared to be concentrated over the dorsal fracture gap. When comparing axial stiffness magnitudes between plates, the VariAx axial stiffness was significantly greater (651±169 N/mm) than the DVR (349±60 N/mm, p=0.032). The Peri-Loc (404±32 N/mm) was not significantly different vs. the Vari-ax (p=0.074) nor the DVR (p=0.679). With regard to volar and dorsal bending, the deformation was consistent between the control and all plated constructs: volar bending produced dorsal lengthening and dorsal bending caused dorsal shortening. The bending stiffness of the control analogs was several times greater than the plated constructs. Amongst the plated specimens, the Peri-Loc was stiffest in dorsal (283±78 N/mm) bending which was significantly greater than the DVR (99±29, p=0.024) but only tended to be greater than the Vari-ax (148±39 N/mm, p=0.089). In volar bending, the Peri-loc was again the stiffest plated construct (235±80 N/mm) which was significantly greater than both the DVR (111±13 N/mm, p=0.018) and Vari-ax (130±26 N/mm, p=0.041) specimens.

DISCUSSION

The current study sought to compare the biomechanics of different locked distal radius volar plate designs: a variable screw axis design and the traditional fixed screw angle plate. It was hypothesized that the variable axis technology (VariAx) would show no significant biomechanical difference when compared to more traditional fixed angle locked plates.

The biomechanical data from the current study revealed that all plated constructs were significantly less stiff than control analog radius models in axial loading and volar/dorsal three point bending. Amongst the plated specimens, the VariAx plate was axially stiffer than the other plates with the comparison to the DVR being significant. In bending, the Peri-Loc was significantly stiffer than the DVR in both dorsal and volar bending;
the Peri-Loc was stiffer than the VariAx in both bending modes though only the comparison in volar bending was significant. The axial and bending comparisons reject the study hypothesis since there were significant plate-to-plate differences. The different plate stiffness magnitudes appear to be related to the plate rigidities. The bending rigidity magnitudes of each plate at the level of the bending fulcrum (Table 1) correlate with the bending stiffness values for the plated specimens. Rigidity takes into account the plate cross-sectional dimensions and the plate materials’ modulus. A similar analysis of the axial rigidity at the level of the bending fulcrum (a consistently identifiable region) predicts that the Peri-Loc should have the greatest axial stiffness. However, the VariAx was actually stiffer. A comparison of the VariAx and Peri-Loc plate geometries shows that a gradual distal widening of the VariAx plate beyond the fulcrum may explain the higher resistance to axial loading of this plate.

A comparison of the stiffness values from the current study may be directly made to Willis, et al. The methods from that study were adopted for the current study and both studies tested different versions of the DVR plate. The average DVR stiffness values from the current study are ~50% higher than Willis, et al., for all loading modes. One potential explanation for this difference is the increased number of distal screws for the DVR plate tested in the current study (seven in the current study versus four by Willis, et al.). Willis and coworkers note that of the volar locking and non-locking plates they tested, the DVR and AO locking plates provided similar stability that exceeded the non-locked plates. Combining the results of both studies would indicate that the Peri-Loc and VariAx plates would be stiffer than the AO volar locking plate. Comparisons with other studies highlight the influence of specimen type and test method. Other laboratories have tested the DVR plate but report widely varying axial stiffness values of 150 N/mm to 620 N/mm; in the current study the DVR stiffness averaged 349 N/mm.22. These other studies used different types of specimens than the current study and/or utilized grip-to-grip displacement measurements (as opposed to the interfragmentary displacement method used in the current study which was adopted from Willis, et al.).

The current study had several inherent limitations, first of which was the use of analog radius bone models. This model was adopted, however, to yield more consistent results which represented a suboptimal condition for stability and anatomic rigidity. We adopted the model from Willis, et al.; this allowed our findings to be compared to their work and expand the database for distal radius plates using a consistent model. That said, the findings from the current study should be interpreted with some caution since human tissues were not utilized as a test material. Relative comparisons between plates may be more relevant since the model was taken to be essentially constant between the current study and Willis, et al. In an effort to quantify the behavior of un-altered bone models, intact control bones were also tested. These data revealed data dispersion which was similar to the plated constructs thus indicating a similar variability from the combination of the specimen, specimen preparation, and test methodology. As with all biomechanical laboratory tests, the results are limited to time zero and must rely on clinical studies to elucidate their long-term performance. Another limitation relates to the single point measurement of displacement along the dorsal comminution. This location was chosen to maximize the measureable displacement signal since it was on the opposite cortex as the plate. In addition, three independent loading modes were tested, whereas in vivo loading modes would be expected to be more complex. However, as noted in the Methods, the loads tested here were thought to represent either the plates’ more vulnerable and/or common loading modes. Finally, one element of the plate designs which has not been addressed here is the influence of the length of the plate proximally and the diameter and number of diaphysis screws. The specific DVR and VariAx plates selected for the current study were similar in length and had four shaft screws each, though the DVR screws were of a larger diameter. Alternatively, the Peri-Loc plate was longer such that it could accommodate an additional shaft screw. The plate and screw configurations used in the current study were selected to represent what was thought to be most reflective of current clinical practice.

Regardless of the locking screw design, plate shape or material, all instrumented radius models were significantly less stiff than control in axial compression and bending. Amongst the plates, there was a trend for the Vari-Ax locking screw design to be stiffer than the traditional fixed, locked plates. In bending, the PeriLoc fixed angle locked plate was significantly stiffer than the VariAx or DVR plates. This finding was consistent with the bending rigidities of the different plates. Plate shape (i.e., cross-sectional geometry, length, etc.) and material selection appear to be the dominant variables influencing the plate stiffness magnitudes in this radius fracture model.

**COMPETING INTERESTS**

The authors have no competing interests.

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REFERENCES

ABSTRACT

Purpose: Tuberculosis can be responsible for extensive spinal lesions. Despite the efficacy of medical treatment, surgery is indicated to avoid or correct significant deformity, treat spinal instability, prevent neurological compromise, and to eradicate an extensive tuberculous abscess. In this paper we present our experience in the surgical management of spinal tuberculosis complicated with large abscess.

Patients and methods: Fifteen patients with spinal tuberculosis complicated with extensive abscess were identified; and nine of those patients had extension of the infection into the epidural space. The average age at treatment was 34 years old. Seven patients had thoracic infection, seven patients had lumbar infection and one had thoracolumbar infection. Six patients had neurological deficit at presentation. All patients were surgically treated with abscess debridement, spinal stabilization and concurrent antituberculous chemotherapy. A single anterior surgical approach was used in three cases, a posterior approach was used in four others and a combined approach was performed in eight patients.

Results: Surgical management allowed for effective abscess debridement and spinal stabilization in this cohort. In combination with antituberculous drugs, surgical treatment resulted in infection eradication and bone fusion in all patients at 24 month average follow-up. Satisfactory neurological outcomes with improved American Spinal Injury Association (ASIA) scores were observed in 100% of patients.

Conclusion: Surgical treatment for spinal tuberculosis abscess can lead to satisfactory clinical outcomes.

INTRODUCTION

Spinal tuberculosis accounts for over 40% of all spine infections. This clinical entity is socio-economic related, occurring more often in developing countries, although an increase in incidence has been documented in developed countries. About 10% of all tuberculosis cases present with musculoskeletal involvement and 50% of these involve the spine. Spinal tuberculosis can lead to destruction of the intervertebral disk space and the adjacent vertebral bodies, with collapse of the spinal elements resulting in characteristic angulation and gibbus formation. Multiple vertebrae are typically affected, and the vertebral body is more frequently affected than the posterior arch. The thoracic and lumbar spine are most commonly involved (90% of cases).

Diagnosis in the initial phase of the disease can be challenging. The cardinal symptoms of spinal tuberculosis are pain, mild fevers, chills, kyphotic deformity, paravertebral abscess or even progressive neurological impairment. The presence of paravertebral abscess is an important cause of morbidity and is usually associated with more severe deformity, instability and neurological impairment, particularly when epidural abscess is also present. Clinical exam, laboratory and imaging studies are helpful; however definitive diagnosis is made only via identification of Mycobacterium tuberculosis.

Antituberculosis chemotherapy is still the gold standard treatment for this condition, resulting in spontaneous fusion in about 80% of cases. Surgery has a role in the presence of vertebral instability, failure of chemotherapy, progressive deformity, neurological impairment or large abscess, with or without the presence of epidural involvement. Additionally, surgery can correct or decrease spinal deformity and improve neurological deficit. The approach can be anterior, posterior or even a combination of both. Recent data associates the best outcomes with posterior or a combined surgical approach.

We herein present our experience with surgical treatment of extensive paravertebral abscess in spinal tuberculosis, and discuss abscess characteristics, surgical management and clinical outcomes such as infection eradication, fusion and neurological outcome.
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PATIENTS AND METHODS

We analyzed the pre- and post-operative clinical notes and imaging studies of 34 patients treated for spinal tuberculosis in our department from June 1998 to December 2012. Of these, 15 had an extensive abscess. Kyphotic deformity was measured by the Cobb method. The imaging consolidation criteria used was the presence of bone bridge between involved vertebral bodies and the absence of lytic lesions.

Table 1 summarizes the patient characteristics. The majority of the 15 patients were young males (n=10; average age of 43 years old) and females (n=5; average age of 33 years old). The average age of the entire cohort was 34 years. Infection was noted in the thoracic (n=7), lumbar (n=7) or thoracolumbar spine (n=1). Neurological deficits were graded using the American Spinal Association (ASIA) Impairment Scale of motor and sensory

Table 1. Demographics of patients with spinal tuberculosis and extensive abscess

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Gender</th>
<th>Spine</th>
<th>Level</th>
<th>Initial ASIA</th>
<th>Final ASIA</th>
<th>Fusion</th>
<th>Time to fusion (months)</th>
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<tr>
<td>Patient 1</td>
<td>64</td>
<td>M</td>
<td>Lumbar</td>
<td>L2-L3</td>
<td>E</td>
<td>E</td>
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<tr>
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<td>58</td>
<td>M</td>
<td>Thoracic</td>
<td>T8-T9</td>
<td>E</td>
<td>E</td>
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<td>12</td>
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<tr>
<td>Patient 3</td>
<td>36</td>
<td>M</td>
<td>Lumbar</td>
<td>L4-L5</td>
<td>E</td>
<td>E</td>
<td>Yes</td>
<td>Not determined</td>
</tr>
<tr>
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<td>32</td>
<td>F</td>
<td>Lumbar</td>
<td>L4-L5</td>
<td>E</td>
<td>E</td>
<td>Yes</td>
<td>7</td>
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<td>E</td>
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<tr>
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<td>M</td>
<td>Lumbar</td>
<td>L3-L4</td>
<td>E</td>
<td>E</td>
<td>Yes</td>
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<td>32</td>
<td>M</td>
<td>Thoraco-lumbar</td>
<td>T12-L2</td>
<td>E</td>
<td>E</td>
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<td>10</td>
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<tr>
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<td>Thoracic</td>
<td>T1-T3</td>
<td>D</td>
<td>E</td>
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<td>9</td>
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<tr>
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<td>M</td>
<td>Thoracic</td>
<td>T8-T9</td>
<td>B</td>
<td>D</td>
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<td>Not determined</td>
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<td>L3-L4</td>
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<tr>
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<td>L1-L2</td>
<td>C</td>
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<td>D</td>
<td>E</td>
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<td>M</td>
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<td>T5-T12</td>
<td>E</td>
<td>E</td>
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</table>

Figure 1. Patient 8: A - Sagital MRI with Gadolinium showing a prevertebral abscess with epidural extension; B - Axial MRI with Gadolinium showing multilobulated configuration of prevertebral abscess with epidural extension; C - Three years post-op CT scan showing fusion obtained

Figure 2. Patient 1: Axial image of large right psoas abscess
impairment, which ranges from A (no motor or sensory function) to E (normal functioning)\(^a\). At presentation, six patients had neurological deficit (ASIA B, n=2, ASIA C, n=1 and ASIA D, n=3). All patients had an extensive tuberculous abscess with the epidural space involved in nine (Figure 1). Large psoas abscesses were identified on the right in three patients (Figure 2) and on the left in one (Figure 3). Eight patients presented with extensive pre-vertebral and para-vertebral abscesses (Figure 4). Combination of pre- and para-vertebral, and psoas abscesses were identified in three patients. Two patients also had a dorsal abscess (Figure 5) with active purulent drainage in one.

At presentation, 11 of 15 patients had significant vertebral body collapse with an average loss of 53% of the normal vertebral height (range 28%-80%). In three cases, the infection was limited to the peridiscal area. The mean initial kyphosis was 22°± 16° (Table 2).

The specific surgical procedure was selected based on degree of mechanical instability, location of the infection,
presence of the largest abscess and spinal neuro-axis compression with neurological impairment. Table 3 describes the location of the abscess and surgical details. A single anterior surgical approach was used in three cases, the Hong Kong procedure (anterior radical debridement with graft fusion) in two, the single posterior approach through costotransversectomy in four patients, and a combined approach (anterior and posterior) in the remaining eight cases. A tricortical iliac graft was used in the lumbar spine (five patients), vascularized rib graft in two and free rib graft in one patient, mainly in the thoracic spine. Patients operated via the costotransversectomy approach had the bone defect reconstructed with local rib and vertebrae autograft. A titanium cage was used in one lumbar case. The thoracotomy or retroperitoneal approach used for the anterior approach was through the left or right side depending on the site of the largest tuberculous abscess. In one patient, a bilateral retroperitoneal approach was necessary to successfully address an extensive bilateral psoas abscess (Figure 6). In these cases, after surgical exposure, the abscess was drained with a needle and a large syringe for proper identification and to decrease fluid dissemination through the normal tissue (Figure 6). After this initial drainage, the abscess was opened and irrigated thoroughly with warm saline. The capsule was left open and necrotic tissue removed prior to anterior column

<table>
<thead>
<tr>
<th>Patient</th>
<th>Vertebral loss %</th>
<th>Initial Cobb (º)</th>
<th>Pos-op Cobb</th>
<th>Final Cobb</th>
<th>Correction</th>
<th>Loss of correction</th>
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<td>4.5</td>
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<td>28</td>
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<td>6.4</td>
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<td>50</td>
<td>25</td>
<td>22</td>
<td>22</td>
<td>3.3</td>
<td>0</td>
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</table>
reconstruction. Instrumentation included posterior hybrid instrumentation (n=3) and seven patients received conventional posterior pedicle screws. Percutaneous pedicle screw fixation was performed in two other cases; three patients received no implants.

The infectious disease service was consulted and guided the anti-tuberculosis chemotherapy, which was initiated at least two weeks before each surgical procedure. All patients completed two to four months of standard anti-tuberculosis chemotherapy with isoniazid, rifampicin, pyrazinamide and ethambutol followed by an isoniazid and rifampicin regimen for a variable period. The average length of therapy was 14 months (range 10-20 months). Surgical infection prophylaxis included a first-generation cephalosporin in all cases.

**RESULTS**

The average post-operative follow-up of our study was 24 months (range 12-81 months). Infection eradication and spine fusion was achieved in all patients (Figure 7). The clinical and imaging criteria for bone fusion were met after an average of 11 months postoperatively (range 6-24 months). There was no apparent relationship between time to fusion and the type of bone graft used.

The average postoperative kyphosis was 15.6 degrees with an average final kyphosis of 17 degrees (range, 0 to 44 degrees). The average initial correction was 7.6 degrees (range, 0 to 26 degrees) and the average loss of reduction at final follow-up was 1.1 degrees (range 0 to 10 degrees) (Table 2). Correction varied by the surgical approach used. The posterior approach resulted in an average correction of 6.3 degrees (range, 1.2 to 9 degrees) with a subsequent average loss of correction of 1.3 degrees (range, 0 to 6.4 degrees) at the final follow-up. Correction from the combined approach was larger but with similar loss of correction (average correction of 13 degrees (range, 0 to 26 degrees) and average loss of correction of 1.4 degrees (range, 0 to 10 degrees)). These approaches in our series offered the best sagittal profile.

Figure 6. Patient 10: A – Axial image of bilateral extensive psoas abscesses; B – Intra-operative abscess drainage; C – CT scan control in postoperative day three

Figure 7. Patient 15: A – CT scan of extensive thoracic tuberculous lytic lesions; B - CT scan after surgery showing anterior column reconstruction with vascularized rib; C – Sagital MRI showing extensive pre and para-vertebral abscess; D – One year post-op CT scan exhibiting rib integration with maintenance of sagittal profile
Table 3. Surgical treatment, complications and abscess characterization

<table>
<thead>
<tr>
<th>Patient</th>
<th>Surgical approach</th>
<th>GRAFT</th>
<th>Abscess</th>
<th>Epidural</th>
<th>Abscess Approach</th>
<th>Complications</th>
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<tr>
<td>Patient 1</td>
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<td>Local</td>
<td>Right psoas</td>
<td>Yes</td>
<td>Right lombotomy</td>
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</tr>
<tr>
<td>Patient 2</td>
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<td>Rib</td>
<td>Paraspinal</td>
<td>Yes</td>
<td>Right thoracotomy</td>
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<td>Anterior</td>
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<td>Left Psoas</td>
<td>No</td>
<td>Left lombotomy</td>
<td>Lef iliac vein laceration</td>
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<tr>
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<td>Right psoas</td>
<td>No</td>
<td>Right lombotomy</td>
<td>No</td>
</tr>
<tr>
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<td>Left Paraspinal</td>
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</tr>
<tr>
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<td>No</td>
</tr>
<tr>
<td>Patient 7</td>
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<td>Paraspinal and Left psoas</td>
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<td>Transient neurological impairment to ASIA C</td>
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<td>Prespinal and paraspinal</td>
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<td>Costotransversectomy</td>
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DISCUSSION

Tuberculosis continues to have a worldwide impact with an estimated nine million new cases each year and a mortality rate of two million deaths each year. Simultaneously, we are witnessing the emergence of antibiotic resistance to many first-line drugs which is creating growing concern in Western societies.

Spinal tuberculosis accounts for over 40% of all spine infections and is the most prevalent spine infection globally. The most difficult cases to treat are those with extensive spine involvement, vertebral body collapse, severe deformity, neurological injury and large abscesses, which in turn can spread towards the spinal canal and invade the epidural space.

The literature supports anti-tuberculosis chemotherapy as the gold standard treatment for this condition, resulting in a spontaneous fusion in about 80% of all cases. However, there is controversy regarding the optimal duration of chemotherapy with these drugs. Suggested treatment programs can range from six to eighteen months. More recent literature supports a shorter treatment period, initially using four drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) for two months, followed by isoniazid and rifampicin for additional four months. This program results in satisfactory outcomes, although a nine to twelve month program continues to be the gold standard in specialized centres and our institution.

Chemotherapy should be combined with surgery if there is vertebral instability, failure of chemotherapy, progressive deformity, neurological impairment or presence of extensive abscess with or without epidural involvement. This combined treatment has proven over time to be extremely effective in treating spinal tuberculosis. This protocol results in high success rates, enables abscess eradication, including those with large dimensions, and achieves vertebral fusion in 97% of cases. Additionally, surgery has the advantage of controlling spinal deformity while also limiting or improving the neurological impairment associated with this disease. Surgery can be performed by anterior or posterior single approach, or a combination of both. Recent data associates the best outcomes with the posterior or combined surgical approaches. Our experience with these approaches is similar, and the best results concerning the deformity control have been obtained with the posterior or combined approach.

All patients in this series had severe cases of spinal tuberculosis. All were complicated by extensive abscess, including epidural abscess, significant deformity, instability and (in some) neurological impairment related to the infection and epidural involvement. Some patients experienced incomplete paraplegia for several months. According to Hodgson et al., paraplegia associated with spinal tuberculosis should be classified into two groups: neurological impairment of less than two years or of more than two years. Impairment of shorter duration is associated with the active disease and with the compression caused by the abscess and inflammation tissue. Longer duration of impairment is related to vertebral collapse, spinal deformity and secondary compression. All patients presented in this series had less than two years’ of dis-
ease. Our patients had neurological deficits that began two weeks to eight months prior to admission and all improved significantly after surgery. However, we must emphasize that there were no ASIA A cases. In our experience, the prognosis for ASIA A cases is not as promising.

Involvement of the adjacent structures in patients with spinal tuberculosis is frequent\(^\text{15}\). This involvement can affect the peri-vertebral area in the thorax or abdomen, the psoas muscle or the epidural space through abscesses formation\(^\text{15}\). These abscesses can become quite large without being diagnosed due to the insidious nature of this pathology\(^\text{15}\).

The presence of tuberculous abscess, especially large abscesses associated with extensive spine involvement, constitutes a challenge for the orthopaedic surgeon. According to Osborn et al., paravertebral abscess is present in 55-95% of the cases\(^\text{16}\). Gehlot et al. reported the presence of paravertebral tuberculous abscess in 98.5% of patients with spinal tuberculosis\(^\text{17}\). Miraedi et al. found psoas abscess in 14.3% of these patients and Gehlot et al. noted psoas abscesses in 37.1% of cases\(^\text{17,18}\).

Dorsal and lumbar spine abscesses can be seen on conventional radiology images as paravertebral soft tissues shadows\(^\text{19}\). The presence of calcifications within the abscess is virtually diagnostic of spinal tuberculosis and anterior detachment of the segmentary vessels is also frequent (Figure 8)\(^\text{15,19}\). Plain x-rays usually are normal in the early stages of the disease whereas CT scans and MRIs are more sensitive in detecting tuberculous lesions\(^\text{17}\).

In our experience, the identification of these abscesses can be difficult during the surgical procedure as they sometimes mimic tumour-like lesions. Moreover, it is difficult to identify the dissection planes. Initially, we treated abscesses with CT-guided aspiration but soon realized this approach was not always effective. Only in one case of a thoracic large abscess with an angular kyphosis was percutaneous aspiration effective in reducing the volume of the abscess. As all cases require some degree of anterior reconstruction, we began performing direct aspiration. This change resulted in no additional complications. In the 15 cases presented in this paper, we encountered one serious complication of a left iliac vein laceration, which was uneventfully repaired by a vascular colleague. This case illustrates the importance of staying within the abscess wall during spinal decompression and reconstruction, as soft tissue planes in these chronic infections can become scarred down. This complication led us to more frequently use the left side approach in the lumbar spine to avoid the vena cava and to drain the right-sided abscesses through the defect created in the column after vertebral body removal. We also noted a transient worsening of the neurological status in one patient, with pre-existing upper neuron signs, which worsened after decompression and posterior instrumentation with hooks (ASIA D to ASIA C). This patient recovered completely over time.

Treatment of all patients in this series resulted in eradication of the infection and achievement of a solid fusion without instrumentation failure or surgical site infection.

**CONCLUSION**

Surgical treatment combined with chemotherapy is a safe and effective approach to treat spinal tuberculosis infection. Although in less severe cases image-guided percutaneous aspiration and posterior percutaneous fixation can be an excellent therapeutic choice, in severe cases with large abscesses and extensive vertebral column involvement, aggressive treatment with direct aspiration and debridement, anterior reconstruction and posterior instrumentation can result in a rapid recovery and acceptable rate of complications.

**REFERENCES**

ABSTRACT

Introduction: Animal models are often used to make the transition from scientific concepts to clinical applications. The sheep model has emerged as an important model in spine biomechanics. Although there are several experimental biomechanical studies of the sheep cervical spine, only a limited number of computational models have been developed. Therefore, the objective of this study was to develop and validate a C2-C7 sheep cervical spine finite element (FE) model to study the biomechanics of the normal sheep cervical spine.

Methods: The model was based on anatomy defined using medical images and included nonlinear material properties to capture the high flexibility and large neutral zone of the sheep cervical spine. The model was validated using comprehensive experimental flexibility testing. Ten adult sheep cervical spines, from C2-C7, were used to experimentally ascertain overall and segmental flexibility to ±2 Nm in flexion-extension, lateral bending, and axial rotation.

Results: The ranges of motion predicted by the computational model were within one standard deviation of the respective experimental motions throughout the load cycle, with the exception of extension and lateral bending. The model over- and under predicted the peak motions in extension and lateral bending, respectively. Nevertheless, the model closely represents the range of motion and flexibility of the sheep cervical spine.

Discussion: This is the first multilevel model of the sheep cervical spine. The validated model affords additional biomechanical insight into the intact sheep cervical spine that cannot be easily determined experimentally. The model can be used to study various surgical techniques, instrumentation, and device placement, providing researchers and clinicians insight that is difficult, if not impossible, to gain experimentally.

INTRODUCTION

Animal models are essential for making the transition from scientific concepts to clinical applications1-2. Such models have proven valuable for spinal research3,4, providing insight into fusion techniques. The cervical spine of sheep, for example, compare favorably with that of human, exhibiting similarities in both vertebral geometry and lordotic curvature5. Although anatomic similarities are important, biomechanical correspondence is imperative to understand the effects of disorders, surgical techniques, and implant designs.

Several studies have focused on the biomechanics of the sheep cervical spine, utilizing both functional spinal units3,4,6 and multilevel specimen5,7. Such studies highlight the flexibility of the sheep cervical spine, especially in lateral bending (approximately ±65°). The sheep cervical spine also exhibits a large neutral zone, accounting for 50% to 75% of the total motion7. These studies provided details regarding the external biomechanics (i.e. motion, stiffness), however, oftentimes internal biomechanics (i.e. stresses, strains) are desired as well.

Finite element (FE) models afford the ability to study internal biomechanics in response to a given external stimulus. Consequently, to better understand spinal biomechanics, FE analyses are often performed. Several studies have focused on the human cervical spine8-11. To our knowledge there is only one study using FE analysis to study the sheep cervical spine, and it was limited to the C3-C4 level12. Since the sheep is often used for in vivo studies13-15, it is important to have a comprehensive understanding of both external and internal biomechanical parameters. Additionally, it is essential to model the multilevel spine as opposed to single levels because oftentimes in vivo studies focus on multiple levels. Therefore, the objective of this study was to develop...
N. A. DeVries Watson, A. A. Gandhi, D. C. Fredericks, J. D. Smucker, Grosland

and validate a C2-C7 sheep cervical spine FE model to study the biomechanics of the normal sheep cervical spine. Since the sheep spine is highly flexible, the focus of the validation study was on the large range of motion and neutral zone (external biomechanics).

MATERIALS AND METHODS

Model Development

A detailed, geometrically accurate FE model of the C2-C7 sheep spine was created using IA-FEMesh coupled with custom-written tools devoted to modeling the spine (Figure 1). The vertebral surfaces were defined using CT data (Siemens Sensation 64 CT scanner, slice thickness 0.6mm, 0.5mm in-plane resolution) by manually segmenting the regions of interest, similar to the methods described previously by DeVries and colleagues. The vertebrae were modeled using eight-noded hexahedral elements with an average element length of 1 mm, comparable to the mesh density reported by Kallemeyn,

resulting in 8640 elements for each vertebral body and 6,956 (C2) to 14,630 (C6) elements in the posterior region.

The mesh definitions for the intervertebral discs were defined by interpolating between the nodes of the adjacent vertebral bodies; the discs were divided into the nucleus and the surrounding fiber-reinforced annulus. The nucleus was modeled using fluid elements. The annulus grounds were modeled using eight-noded hexahedral elements with embedded rebar elements to mimic the annulus fibers. The rebar elements were angled at ±25° with alternating directions for each layer. The annulus was further divided into the anterior, posterior, and lateral regions to account for region-dependent variability in the material properties of the disc.

Table 1. The Young's Modulus and cross-sectional areas for each spinal ligament

<table>
<thead>
<tr>
<th></th>
<th>Young's Modulus (MPa)</th>
<th>Cross-Sectional Area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C23</td>
<td>20.6 (-11%), 25.06 (-11%)</td>
<td>12.78</td>
</tr>
<tr>
<td>C34</td>
<td>5.77 (-11%), 12.84 (-11%)</td>
<td>14.42</td>
</tr>
<tr>
<td>C45</td>
<td>8.95 (-11%), 12.94 (-11%)</td>
<td>12.49</td>
</tr>
<tr>
<td>C56</td>
<td>17.428 (-11%), 20.62 (-11%)</td>
<td>9.19</td>
</tr>
<tr>
<td>C67</td>
<td>0.86 (-11%), 16.496 (-11%)</td>
<td>11.61</td>
</tr>
<tr>
<td>PLL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C23</td>
<td>16.73 (-11%), 59.94 (-11%)</td>
<td>6.92</td>
</tr>
<tr>
<td>C34</td>
<td>1.62 (-27%), 28.264 (-27%)</td>
<td>7.46</td>
</tr>
<tr>
<td>CL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C23</td>
<td>4.08 (-5%), 56.88 (-5%)</td>
<td>84.97</td>
</tr>
<tr>
<td>C34</td>
<td>2.87 (-32%), 33.19 (-32%)</td>
<td>109.06</td>
</tr>
<tr>
<td>IS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C23</td>
<td>3.04 (-11%), 68.03 (-11%)</td>
<td>32.74</td>
</tr>
<tr>
<td>C34</td>
<td>1.22 (-15%), 58.74(-15%)</td>
<td>28.98</td>
</tr>
<tr>
<td>LF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C23</td>
<td>52.64 (-5%), 120.43 (-5%)</td>
<td>17.22</td>
</tr>
<tr>
<td>C34</td>
<td>1.89 (-27%), 40.78 (-27%)</td>
<td>24.15</td>
</tr>
<tr>
<td>C45</td>
<td>2.65 (-37%), 52.23 (-37%)</td>
<td>22.76</td>
</tr>
<tr>
<td>C56</td>
<td>1.03 (-27%), 100.83 (-27%)</td>
<td>9.95</td>
</tr>
<tr>
<td>C67</td>
<td>2.22 (-37%), 70.90 (-37%)</td>
<td>14.13</td>
</tr>
</tbody>
</table>
The five major ligaments of the cervical spine (anterior longitudinal ligament, posterior longitudinal ligament, ligamentum flavum, interspinous ligament, and capsular ligaments) were modeled using two-noded truss elements in tension only. The anterior and posterior longitudinal ligaments were defined to span from mid-body to adjacent mid-body. The ligamentum flavum was defined between adjacent lamina; the interspinous ligaments spanned between adjacent spinous processes. The capsular ligaments were defined between corresponding facets, angled to mimic the physiological orientation. Each ligament element was assigned a cross-sectional area so that the total ligament area represented the physiological cross section reported by DeVries (Table 1).

Additionally, the facet joints were defined as finite-sliding surface interactions. The cartilage was represented by an exponential pressure-overclosure relationship, mimicking a uniform cartilage layer. The relationship was defined such that as the distance between the facets decreases the contact pressure increases, eventually reaching the modulus of the posterior bone. The capsular ligaments were defined between corresponding facets, angled to mimic the physiological orientation. Each ligament element was assigned a cross-sectional area so that the total ligament area represented the physiological cross section reported by DeVries (Table 1).

### Material Properties

Since bone is significantly stiffer than soft tissues and the main focus of this study was to capture the overall motion, the bone material properties were simplified as homogenous isotropic material. Note, if bone stress and strains are of particular importance, specimen-specific material properties could be easily incorporated using the relationship between the CT Hounsfield value and bone density. For this study, the vertebral body was subdivided into cancellous and cortical regions, where the cortical bone was defined as the outermost layer of elements. Linear elastic material properties were incorporated for all the bony anatomy. The material properties are summarized in Table 2.

As previously mentioned, the nucleus was modeled as fluid elements to capture the nearly incompressible nature. The nonlinear nature of the annulus fibers was represented using hypoelastic material properties. The nonlinearity of the annulus grounds was captured using the Yeoh hyperelastic function, similar to the technique used to model the human lumbar disc. The Yeoh model defines the strain energy function as follows:

\[
U = C_{10}(I_1 - 3) + C_{20}(I_1 - 3)^2 + C_{30}(I_1 - 3)^3 + \frac{1}{D_1}(J^{el} - 1)^2
\]

where \(C_{10}, C_{20}, C_{30},\) and \(D_1\) are the material coefficients, \(I_1\) is the first invariant of the deviatoric component of the Cauchy-Green strain tensor, and \(J^{el}\) is the elastic volume ratio. The elastic volume ratio accounts for the compressibility of the material and is determined based on the Poisson's ratio. The annulus material properties were based on the stress-strain curve reported by Fujita and colleagues for the human lumbar intervertebral disc. This curve was used as a baseline model that was then altered to depict varying levels of stiffness. The material properties for each disc were determined using the experimental flexibility data described in a later section. Thus, for more flexible levels (i.e., C5-C6 and C6-C7), the stiffness was decreased as compared to the baseline properties, and vice versa for levels with minimal motion (i.e., C2-C3). Yeoh material coefficients for the various curves were determined using Abaqus CAE (SIMULIA, Providence, RI). Table 3 summarizes the material coefficients for the annulus.

The nonlinearity of the ligaments was captured using hypoelastic material properties based on the sheep cervical spine ligament stress-strain curves reported by DeVries. Table 1 summarizes the ligament properties.
Boundary Conditions
To mimic the experimental testing conditions described below, the nodes of the inferior endplate of C7 were fixed in all directions. A nondestructive, physiologic moment of 2.5 Nm was applied at the superior endplate of C2 using a rigid surface. Moments were applied in flexion (+), extension (-), right (+) and left (-) lateral bending, and right (-) and left (+) axial rotation. At C2, the model was unconstrained in the remaining uncontrolled degrees of freedom. The finite element software Abaqus 6.11 (Dassault Systèmes Simulia, Providence, RI) was used to perform the analyses. The spinal motions throughout the entire loading curves were analyzed.

Experimental Biomechanics for FE validation
Experimental flexibility tests were performed on ten adult Suffolk sheep cervical (C2-C7) specimens to determine the average moment-rotation curves for flexion-extension, lateral bending, and axial rotation. The specimens were tested to ±2.5 Nm at a rate of 5.0 Nm/minute. Specimens underwent three loading and unloading cycles (the first two served as specimen preconditioning) with data captured on the third cycle. Refer to the study by DeVries et al. for detailed information regarding these methods. For model validation, the predicted FE motions were compared to the average experimental motions for the complete loading curve, focusing on the entire spinal segment (C2-C7) as well as each individual spinal level.

RESULTS
The finite element model successfully simulated the nonlinear moment-rotation behaviors observed experimentally in each of the loading directions. In general, the range of motion predictions were within one standard deviation of the sample mean throughout the load cycle (Figure 2). For all loading directions, the motion was within one standard deviation of the loading curve up to 1.0 Nm. During extension, after 1.8 Nm the model overpredicted the motion; at -2.5 Nm the model-predicted motion was 6.6° greater than the average experimental
motion (-39.82° ± 4.08°). The FE model under predicted lateral bending after 1.0 Nm. At ±2.5 Nm, the model-predicted motion was about 16° less than the mean experimental motion (62.94° ± 9.61°) for right lateral bending; for left lateral bending, the model-predicted motion was approximately 20° less than the experimental motion (-67.04° ± 9.62°). For axial rotation, the model underpredicted at the C5-C6 and C6-C7 levels and overpredicted at the C2-C3 level.

DISCUSSION

To date, there has only been one finite element study focusing on the sheep cervical spine; the study was limited to a functional spinal unit (C3-C4). However, it is important to study the multilevel spine in order to have a more detailed comparison between the sheep and human cervical spine. Since sheep are often used for in vitro studies, it is important to have a comprehensive understanding of both external (i.e., motion) and internal (i.e., bone stress and strains, disc pressures, facet contact, etc.) responses for the sheep. To address this, we developed and validated the first multilevel model of the sheep cervical spine. Overall, the model compared well with experimental studies, thus providing a method for researchers and clinicians to study the biomechanical effects of various surgical procedures and device placement. Details of these findings are further discussed.

There are several benefits of FE analyses. First, it allows researchers to study several scenarios using one model. Due to the cost of cadavers, researchers are looking to other methods to obtain relevant information. Animal models are one way of doing this; however, animal testing can be expensive as well, depending on the species and the number of specimen needed. Finite element analysis allows researchers to study the effects of different scenarios by modifying the computational model as opposed to testing several specimens. Another advantage of finite element analyses is that computer simulations can be done without the expense of fabricating and testing multiple prototypes, saving significant time and money. Using an FE model, design changes can be made and a new analysis rerun within a short period of time. In addition, FE analyses provide thorough information that physical testing cannot provide. For example, stress and stain can be obtained at any location in the finite element model; it could be prohibitively expensive or impossible to collect all of this data in an experimental test. As an example, Figure 4 shows the von Mises stress distribution in the sheep cervical spine at 2.5 Nm of flexion. That being said, an FE model relies on experimental studies for validation. Once validated experimentally, FE models provide a powerful design tool.
Overall, the model corresponds well with the experimental data, capturing the high flexibility. Although the model over- and underpredicted some of the peak ranges of motion, the model compared well throughout the majority of the loading curve. The model predicted the C2-C7 motion during flexion and axial rotation very well (within one standard deviation). The model overpredicted extension and underpredicted lateral bending; however, due to the highly nonlinear behavior seen experimentally it is difficult to determine material properties that can account for the large neutral zone while still capturing the elastic zone. Additionally, the material properties must accommodate the motions in all six directions, thus accounting for different levels of stiffness (i.e., axial rotation vs lateral bending).

The experimental data was shifted such that the neutral position was calculated as the mid-point of the neutral zone and centered about zero. The neutral position (i.e., starting position) is different for each loading direction (i.e., flexion-extension, lateral bending, and axial rotation). However, the FE model assumes the same neutral position for each loading direction, which could account for the discrepancies between the model-predicted motions and experimental motions.

To more accurately predict all motions, future studies should focus on determining the intervertebral disc material properties at each spinal level in addition to any regional variations within the levels. The annulus properties of the current model were based on variations of the stress-strain curves for the human lumbar spine. Although this curve was adjusted to capture the more flexible nature of the sheep cervical spine, experimental testing of sheep intervertebral discs would provide species-specific properties to better define the annulus grounds and fibers.

Additionally, determining the annulus fiber orientation and material properties on a regional basis would be beneficial. Currently, the model incorporates the same fiber angle throughout the entire annulus. Previous studies of the human lumbar spine have reported that the fiber orientation and material properties vary between annular layers (i.e., inner versus outer) as well as annulus regions (i.e., posterior versus anterior). This may be true for the sheep intervertebral disc as well. The regional differences were taken into consideration with the region dependent annulus ground material properties, but in the future this should be extended to the annular layers as well.

Overall, this is the first multilevel finite element model of the sheep cervical spine. The FE model predicted the large neutral zone and captured the high flexibility shown experimentally. The model affords additional biomechanical insight into the intact sheep cervical spine that cannot be easily determined experimentally. The model can provide stress distributions for the given loading conditions and can be used to predict regions of high stress concentration in the bone, facets, and intervertebral discs. Additionally, this validated model can be used to study changes in disc pressures and facet contact, as well as the effects of various surgical techniques and material properties of new implant designs.

REFERENCES

PROGRESSIVE ADULT SPINAL DEFORMITY FOLLOWING PLACEMENT OF INTRATHECAL OPIOID PUMP: A REPORT OF FOUR CASES

Jared W. Daniel, MD and Geoffrey F. Haft, MD

ABSTRACT

Introduction: Placement of intrathecal opioid pumps (ITOP) for chronic pain is a rare, but described cause of progressive spinal deformity. Over the last two decades there has been several suspected cases at our institution. In this case series, we described the apparent association between placement of an intrathecal opioid pump and progression of spinal deformity.

Methods: The medical records of a single surgeon working at a single institution were retrospectively queried for patients seen between 1995-2010 to identify patients with spinal deformity and an ITOP. All hospital records including notes, radiographs, and labs were reviewed and analyzed. Spine radiographs were measured using standard techniques and reported as Cobb angles. This project was IRB approved and no external funding was used.

Results: In total, we identified four patients with spinal deformity after placement of an ITOP. These patients were adults, two males and two females (ages: 48-80 years), with a unique medical history. Each participant’s radiographs showed a progression of the spinal deformity following placement of ITOP. All patients underwent subsequent posterior spinal fusion for treatment of their progressive spinal deformities.

Conclusion: In this series, we have shown an apparent association between the placement of ITOP and progression of deformity in both patients with and without existing spinal deformity. While it is impossible to discern causality, all patients in our series had radiographic and clinical evidence of spinal deformity progression after placement of intrathecal pumps. These findings may raise awareness of this rare, but major, complication. In those performing pump placement, we recommend continued clinical and radiographic monitoring, through routine follow-up.

Level of Evidence: Level 4 - Case series; case control study (diagnostic studies); poor reference standard; analyses with no sensitivity analyses.

Keywords: Spinal deformity; intrathecal opioid pump; scoliosis; kyphosis

INTRODUCTION

Intrathecal opioid pumps (ITOP) have been available for use since the mid-1990s when they received FDA approval for the intrathecal (IT) infusion of morphine in the treatment of chronic intractable pain\(^1,2\). Neurosurgeons and anesthesiologist have placed ITOP for the treatment of chronic pain from conditions such as cancer, back or leg pain, complex regional pain syndrome, and painful neuropathy. Contraindications for ITOP include infection (i.e. meningitis, ventriculitis, or bacteremia), insufficient body habitus (pump must be implanted deeper than 2.5 cm from skin surface), or history of spinal anomalies. From August 2003 to October 2008, the Implantable Systems Performance Registry followed 3,786 patients who had IT drug delivery system for the following indications: non-malignant pain (53%), intractable spasticity (29.3%), and malignant pain (17.7\%)\(^3\). This subset of patients were then followed to evaluate adverse effects and overall pump survival. Most of the adverse effects associated with IT pumps are secondary to the delivery of the medications, like morphine\(^4\). Other adverse effects include: infection, cerebrospinal fluid leakage, migration of catheter tip and formation of catheter associated granuloma\(^5,6\).

A rarely described iatrogenic cause of progressive spinal deformity is the placement of an ITOP. Sciubba et al. introduced this concept with a case report describing a single patient who developed scoliosis following ITOP placement\(^7\). A similar concept of progressive spinal deformity has been described in spastic cerebral palsy patients receiving baclofen therapy with an IT pump\(^8\). Our objective is to describe an apparent association between placement of an ITOP and the development of spinal deformity. With the lack of a national device registry, it is essential to report potential adverse effects through small case series.
Progressive Adult Spinal Deformity following Placement of Intrathecal Opioid Pump

MATERIALS AND METHODS

We retrospectively reviewed four cases of spinal deformity progression following the placement of an ITOP. All study participants presented to a single spine surgeon due to progressive spinal deformity and pain. Each patient had prior placement of an ITOP for chronic pain by a different spine surgeon. Study design approval was obtained from Institutional Review Board at the medical institutions. There was no funding required or used for the review of this study. There was no conflict of interest related to this study. Informed consent was obtained from each participant. Patient’s age, gender, health co-morbidities, ITOP placement, number of ITOP revision operations, history of spine surgery, and eventual spinal fusion was obtained. Serial radiographs were reviewed. Cobb angle measurements as described by Spinal Deformity Radiographic Measurement Manual were measured to evaluate the magnitude of deformity before and after placement of ITOP. Pre-pump rate progression was calculated by comparing the oldest known radiograph to the radiograph prior to or at the time of pump placement, and then post-pump progression was determined.

CASE REPORTS

Case #1

Patient 1 is an 80-year-old female with history of osteoporosis, who had no spinal deformity prior to spine surgery. She underwent a L3-4 and L4-5 microdiscectomy and posterior lumbar interbody fusion with titanium cages in 1997. She also had anterior cervical diskectomy and fusion of C4-5, C5-6, and C6-7 in 1998. In June 2005, she underwent another spine surgery which included a right L2-3 foraminotomy and L2-3 posterolateral fusion with autologous iliac crest bone graft and pedicle screw instrumentation. Initial radiographs after the June 2005 surgery showed a 17 degree convexity to the right at L1-4 (Figure 1a). Subsequent radiographs in 2005 and 2006 showed no change from initial measurements. She had an ITOP placed in September 2006 for chronic post-surgical low back pain or so-called “failed back syndrome”. Follow-up radiographs in December 2007 began to show progression of spinal deformity with an increase to 25 degree convexity to the right at L1-4. Four months later, her spinal deformity progressed to 42 degrees at L1-4 (Figure 1b). The rate of change in spinal deformity prior to placement of IT pump was 1.1 degrees per year following placement of the ITOP.
degrees per year. After placement, the rate of change increased to 12.5 degrees per year. She underwent correction of her spinal deformity in July 2008 with posterior spinal fusion of T6-S1 with instrumentation and extension to the pelvis.

**Case #2**

Patient 2 is a 61-year-old female who had a 10 degree convexity to the right at L1-4 in 1994. She had no previous history of spine surgery. She had an initial ITOP placed in 2003 for severe fibromyalgia associated with chronic low back pain. Initial radiographs at the time of pump placement showed a 14 degree convexity to the right at L1-4 (Figure 2a). Four years following the pump placement, radiographs displayed a progression of spinal deformity to 41 degrees convexity to the right at T12-L3 (Figure 2b). The rate of change in spinal deformity prior to placement of IT pump was 0.4 degrees per year. After placement, the rate of change increased to 6.5 degrees per year. She underwent correction of her spinal deformity in May 2007 with posterior spine fusion with instrumentation from T9-L5.

**Case #3**

Patient 3 is a 62-year-old male with two previous spine surgeries in 1977 including a laminectomy and discectomy at L4-L5 and L5-S1, and spinal fusion from L4-S1. Initial radiographs in 2002 showed no signs of spinal deformity. He had an ITOP placed in August 2002 for post-laminectomy syndrome with intractable low back and bilateral lower limb pain. Subsequent radiographs in 2007 started to show the development of spinal deformity with an 18 degree Cobb angle from T7-L2 and lateral Cobb angle from T11-L4 of 39 degrees. The rate of change in spinal deformity prior to IT pump was zero degrees per year. After placement, the rate of change was 3.6 degrees per year. The most profound change was in the patient's sagittal spine balance. His thoracolumbar kyphosis progressed from 0 to 39 degrees. He had a revision of his ITOP in September 2007 and eventually went on to have spinal deformity correction with posterior spinal fusion with instrumentation from T7-L5 in October 2007.
Case #4

Patient 4 is a 48-year-old male with no previous history of spinal deformity. He had an extensive history of low back pain for which he had placement of spinal cord stimulator (SCS) in 1998. In 2000, he had his SCS removed and underwent placement of an ITOP for chronic low back pain. Pre-pump radiographs were destroyed by the health system as part of their routine management of films older than seven years. In 2004, he had a 21 degree Cobb angle to the right from T12-L4 (Figure 3a). He had two revisions of his IT pain pump in 2006 and 2007 due to device malfunction. Subsequent radiographs in early 2007 showed no significant progression with a 23 degree convexity to the right at the same levels. Later in 2007, he had a significant progression of his spinal deformity to a 38 degree convexity to the right at T12-L4 (Figure 3b). His rate of change from 2004 to 2006 was 3.5 degrees per year, but following the first revision of his ITOP, his progression rate increased to 10 degrees from 2006 to 2007. He underwent corrective surgery with posterior spinal fusion and instrumentation from T9-L5 in December 2007 for his progressive spinal deformity.

RESULTS

The study population consisted of four adult patients, two males and two females (ages 48-80 years), with unique medical history (Table 1). All participants showed progression of the spinal deformity following placement of ITOP (Table 1). Three out of the four cases had a revision of their ITOP with a mean pump survival of 5.6 years (range: 1-6 years). Pre-pump placement progression for the population was 1.1, 0.4, 0.0, and 3.5 degrees/year, respectively. Following the placement of ITOP, the rate of progression increased dramatically to

Figure 3: a) In radiographs from four years following the placement of the ITOP, there was a 21 degree convexity to the right from T12-L4. b) After two ITOP revision surgeries, the spinal deformity progressed to a 38 degree convexity from T12-L4.
12.5, 6.5, 3.6, and 10.0 degrees/year, respectively. All patients underwent subsequent posterior spinal fusion for treatment of their progressive deformities (Table 1).

**DISCUSSION**

The proposed theory of placement of an ITOP contributes to progressive spinal deformities is based upon a pattern recognized within a single spine deformity surgeon’s practice. To our knowledge, there has only been one other published case report describing this association with ITOP. Our article reinforces the possible relationship between ITOP and progressive spinal deformities.

The mechanism by which IT drugs, specifically opioids, might cause progressive spine deformity is unclear. The paraspinal muscles play an essential role in providing major stability for the spine. Paraspinal muscle imbalance by the indirect inhibition of motor neurons via polysynaptic nociceptive reflex pathways may constitute an etiology for progression of deformity. However, intrathecally administered drugs are cleared from the CSF by diffusion into the epidural space which means nearly 70% of intrathecal opioids, particularly morphine, is cleared into the systemic circulation from the epidural space. Therefore, a systemic effect on muscles may provide potential etiology.

Our case report has several inherent weaknesses. First, this cohort represents a minute fraction of the total number of patients receiving ITOP within the authors’ community and only a careful longitudinal analysis of a large consecutive series of patients would allow understanding of the breadth of the problem. However, as with many medical devices in the United States, the lack of a national device registry often necessitates the identification of rare complications through small case series. Due to complex spine histories, it is difficult to explain whether the progressive spine deformity is related to ITOP or other possible causes like adjacent segment disease or the natural history of pre-existing spinal deformity.

In conclusion, we described four cases of progressive spinal deformity following the placement of an ITOP. At present, there exists only an association between the use of an ITOP and the progression of a spinal deformity. Intrathecal opioids appear to be playing a role, but these drugs can only be considered an association, not a cause. Physicians or other pain specialists recommending the implantation of an ITOP should be aware of a possible association with progression of spinal deformities. We recommend careful monitoring, through routine follow-up radiographs, of patients with an ITOP for development of spinal deformities.

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**Table 1**

<table>
<thead>
<tr>
<th>Case</th>
<th>Age</th>
<th>Gender</th>
<th>Prior Spine Surgery</th>
<th>Baseline Spinal Deformity</th>
<th>ITOP revision</th>
<th>Spinal cord stimulator</th>
<th>Co-morbidities</th>
<th>Curve progression: pre-ITOP (degrees/yr)</th>
<th>Curve progression: post-ITOP (degrees/yr)</th>
<th>Management of progressive deformity</th>
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<td>80</td>
<td>F</td>
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<td>No</td>
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<td>Osteoporosis, hypertension, atrial fibrillation, irritable bowel syndrome.</td>
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<td>12.5</td>
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<tr>
<td>2</td>
<td>61</td>
<td>F</td>
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<td>Yes</td>
<td>No</td>
<td>Depression, anxiety, fibromyalgia with chronic low back pain.</td>
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<tr>
<td>3</td>
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<td>M</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Osteoarthritis, depression, hypertension</td>
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<td>3.6</td>
<td>T7-L5 posterior spine fusion with instrumentation</td>
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<tr>
<td>4</td>
<td>48</td>
<td>M</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Hypertension, myocardial infarction, depression, smoker</td>
<td>3.5</td>
<td>10.0</td>
<td>T9-L5 posterior fusion with transforaminal interbody fusion at L1-2 and L2-3.</td>
</tr>
</tbody>
</table>

Table 1: Summary of patient cohort, including prior medical history. Overall, there was an increase in curve progression following the placement of an ITOP.
Progressive Adult Spinal Deformity following Placement of Intrathecal Opioid Pump

BIBLIOGRAPHY


ABSTRACT

Laminectomy has been regarded as a standard treatment for multi-level cervical stenosis. Concern for complications such as kyphosis has limited the indication of multi-level laminectomy; hence it is often augmented with an instrumented fusion. Laminoplasty has emerged as a motion preserving alternative. The purpose of this study was to compare the multidirectional flexibility of the cervical spine in response to a plate-only open door laminoplasty, double door laminoplasty, and laminectomy using a computational model. A validated three-dimensional finite element model of a specimen-specific intact cervical spine (C2-T1) was modified to simulate each surgical procedure at levels C3-C6. An additional goal of this work was to compare the instrumented computational model to our multi-specimen experimental findings to ensure similar trends in response to the surgical procedures. Model predictions indicate that mobility was retained following open and double door laminoplasty with a 5.4% and 20% increase in flexion, respectively, compared to the intact state. Laminectomy resulted in 57% increase in flexion as compared to the intact state, creating a concern for eventual kyphosis – a known risk/complication of multi-level laminectomy in the absence of fusion. Increased disc stresses were observed at the altered and adjacent segments post-laminectomy in flexion.

Key terms: cervical spine, laminectomy, laminoplasty, miniplates, spacer, finite element

INTRODUCTION

Cervical myelopathy is caused by spinal canal narrowing leading to spinal cord dysfunction. Laminoplasty techniques have become increasingly popular for treating multilevel cervical spinal stenosis, when a clinically relevant diagnosis such as cervical myelopathy is present. By retaining the dorsal elements of the spine, laminoplasty has the potential to preserve spinal stability and alignment and decreases the risk of post-laminectomy kyphosis and instability. Moreover, bone graft and fusion-related complications are avoided.

Since its introduction, several modifications have been made to the basic procedural theme of laminoplasty. The numerous laminoplasty techniques can be divided into two basic types (1) the midline splitting technique, otherwise known as a double door or “french door” laminoplasty (DDL), in which the laminae are opened via splitting of the spinous process and bilateral hinges at the lateral aspect and (2) the open door laminoplasty (ODL) procedure that consists of an osteotomy on one side of the lamina while a “hinge” is created on the other side, allowing for rotation of the entire lamina away from the lateral mass. Both techniques have demonstrated long-term success in increasing the spinal canal diameter and preventing worsening of the myelopathy. Reported limitations, however, include inadequate decompression on the hinge side, the potential for reclosing of the door, as well as range-of-motion (ROM) restriction.

Achieving and maintaining an increased diameter of the spinal canal is critical to facilitating neurological recovery. Current laminoplasty techniques may include use of sutures, suture anchors, allograft or autograft bone, synthetic spacers and miniplates. The non-rigid nature of sutures may lead them to cut out, break, or stretch over time and such changes have been associated with premature laminoplasty closures at rates ranging from 1.5% - 34%. Bone struts and ceramic blocks have the potential to dislodge, which may also lead to premature laminoplasty closure. Plating is a relatively new laminoplasty fixation technique, and plate-only constructs have increased in popularity. However, potential instrumentation issues, such as broken miniplates and screw back out pose as possible disadvantages.

The majority of studies addressing laminoplasty procedures are retrospective clinical studies. Few experi-
mental investigations have addressed the biomechanical response to the procedure, and hence little is known about the biomechanical benefits and complications of plate fixation. The purpose of this study was to build upon our previous experimental and computational work13-15 to address multilevel cervical laminoplasty, specifically a plate-only ODL and a DDL, and compare them to the standard laminectomy procedure in a specimen-specific computational model. Computational models enable information to be gathered that is difficult, if not impossible to attain experimentally, let alone clinically (i.e., stresses, facet loads). Consequently, our goal was to investigate not only the overall and intersegmental motions of the cervical spine in response to the laminectomy and laminoplasty procedures, but also to determine the stresses that developed throughout the individual spinal components and surgical implants.

**METHODS**

A detailed three-dimensional (3D) finite element model of the cervical spine (C2-T1) was adopted and modified for this study14,16. The vertebral bodies were segmented from CT images of a cadaveric specimen and were meshed with hexahedral elements using a multi-block meshing technique (IA-FEMesh)17. Each vertebral body was divided into cortical and cancellous regions and elastic moduli of 10GPa and 450MPa were respectively assigned18. The intervertebral discs were each modeled with distinct annular and nuclear regions (Table 1)19, 20. The annular grounds were defined using a hyperelastic material definition featuring the Mooney–Rivlin formulation, while the nucleus was represented by 3D fluid elements. The five major cervical spine ligaments consisting of the anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), ligamentum flavum (LF), interspinous ligament (ISL), and capsular ligaments (CL) were incorporated into the model. Additionally, the facet gap was modeled using the tabular pressure-overclosure relationship available in ABAQUS (Dassault Systèmes), thereby simulating the behavior of the articular cartilage.

The following sections detail the modifications made to the intact finite element mesh to simulate the laminectomy and laminoplasty procedures at levels C3-C6. These surgical simulations were in accordance with our previous experimental and finite element (FE) investigations13,15.

**Laminectomy (C3-C6) Simulation in the C2-T1 model**

The spinous process and both lamina were resected from the intact model (Figure 1A) for vertebrae C3-C6, while the facet joints remained intact. Additionally, the associated ligaments (ISL, LF) were removed. The final laminectomy model was comprised of 165,865 nodes and 158,957 elements. Figure 2A shows the resulting C2-T1 laminectomy model.

**ODL (C3-C6) Simulation in the C2-T1 model**

A bicortical cut was simulated along the junction of the lamina and the lateral mass of each C3 through C6

---

**Table 1: Regional hyperelastic material constants for the annulus fibrosis**

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Figure 1: Superior view of a vertebra following: (A) Laminectomy, (B) Open Door Laminoplasty stabilized with plates and screws, (C) Double Door Laminoplasty stabilized with a spacer; highlighting the Laminar Opening Space (LOS) of 10 mm.

Figure 2: C2-T1 finite element model showing (A) Laminectomy, (B) Open Door Laminoplasty (ODL), and (C) Double Door Laminoplasty (DDL) at levels C3-C6.
intact vertebral mesh by completely removing a layer of elements. On the contralateral side, a hinge of approximately 3-4mm was created along the junction of the lamina and lateral mass by removing elements representing the uncortical layer. The spinous processes of the involved vertebrae (C3-C6) along with the ISL were excised. Additionally, to simulate the surgical procedure, the LF at the adjacent levels (C2-C3 and C6-C7) was partially cut on the open side of the lamina to allow for the laminar opening. Two screw holes in the lateral mass and one hole in the lamina were created based on the desired plate position. The lamina of each vertebra (C3-C6) was opened towards the hinge by applying a uniform load until a laminar opening space (LOS) of 10mm was obtained as illustrated in Figure 1B. Our goal was to account for the stresses that arise as the hinge is opened to accommodate the implant which are ultimately transferred to the plate/screws once implanted. Consequently, the principal stresses developed in the vertebral bodies and surrounding ligaments after laminar opening were extracted from the model and applied to the laminoplasty model as initial conditions. Computer Aided Design (CAD) models (ProE; PTC, Needham, MA) of the titanium plates and screws (Medtronic Sofamor Danek, Memphis, TN) were generated from their respective physical dimensions and were meshed with hexahedral elements using IA-FEMesh. Each component was assigned an elastic modulus of 116GPa and Poisson’s ratio of 0.3. Small sliding contact was formulated at the interface between the bone and the laminoplasty plates, while the surfaces of the bone/screw and the screw/plate were tied during the analysis. Such contact formulations have been used previously to model the contact between the screw and bone. Figure 2B shows the C2-T1 finite element model with ODL simulated at the C3-C6 levels.

**DDL (C3-C6) Simulation in the C2-T1 model**

Two bilateral hinges at the junction of each lateral mass and lamina were created as described for the single hinge of the ODL procedure. The spinous process was split along the mid-sagittal plane and opened until a laminar spacing of 10mm was obtained (Figure 1C). The tip of the spinous process was removed with care to preserve enough bone to hold the spacer. Based on the surgical procedure, the ISL at each of the involved levels were resected and the LF was partially removed at the midline from C2 to C7 to allow for the laminar opening. Again, the stresses developed during laminar opening were introduced to the model as initial conditions. Because these stresses tend to close the lamina back, a 10mm trapezoidal shaped hydroxyapatite (HA) spacer (elastic modulus of 26GPa and Poisson’s ratio of 0.27), meshed with hexahedral elements, was introduced to stabilize the lamina in the open position. Bony union between HA spacers and spinous processes has been observed in many clinical studies and was therefore simulated using the TIED command in ABAQUS. Figure 2C shows the final C2-T1 DDL model.

**Flexibility Study**

The intact and all three surgical models (ODL, DDL and laminectomy) were tested in flexion/extension (±MX), right/left lateral bending (±MZ), and right/left axial rotation (±MY). The inferior nodes of the T1 vertebral body were fixed in all directions and a moment of 2Nm was applied to the superior surface of C2. The analysis was performed using the finite element software ABAQUS 6.9; enabling the biomechanical response of the intact, laminectomy, and both laminoplasty procedures to be compared. The ROM, facet loads, stresses in the annular regions of the intervertebral discs, and the stresses in the cortical regions of the vertebral bodies were analyzed for all four models (intact, laminectomy, ODL and DDL). Stresses in the laminoplasty plates/screws were also analyzed.

The current FE model was developed from the original experimentally validated specimen-specific C2-C7 model. T1 was added for this investigation and the intact flexibility data was compared to in-house multispecimen experimental studies as well as to data reported in the literature. These validation efforts ensured that the computational response was within the range of normal cervical spine behavior in each loading direction for an applied 2 Nm moment (Figure 3). Figure 4 compares the ranges of motion of the individual vertebral levels between the finite element model and the experimental data. The intact model predicted motions that were comparable to the experimental data for the majority of loading modes. Furthermore, we focused on the changes in flexibility predicted by the instrumented computational models as compared to the respective instrumented experimental specimens, thereby establishing confidence in the ability of the specimen-specific model to predict the post-surgical response of the spine.

**RESULTS**

The percent changes in C2-T1 ROM post laminoplasty and laminectomy with respect to the intact state are shown in Figure 5. The greatest change in motion was observed during flexion for all procedures. During flexion, the ODL and DDL resulted in a 5.4% and 20% increase in C2-T1 ROM respectively, while the laminectomy resulted in a substantial 57.5% increase in the C2-T1 motion. For the remaining loading directions, the greatest change in ROM did not exceed 4.3%.

The intersegmental motions in response to the six loading modes were also compared following the surgi-
During flexion, after ODL the adjacent levels C2-C3 and C6-C7 showed a 39% and 20% increase in the motion respectively; while no substantial changes were observed at the altered levels (Figure 6). The percent increase in motion after DDL varied from 4.3% to 34.6%. Compared to the intact model, laminectomy at C3-C6 led to a profound increase (37.5% to 79.6%) in motion across the levels C2-C3 to C6-C7. During extension, the
superior adjacent level C2-C3 showed an increase in motion of 8.5% and 28.8% after ODL and DDL respectively, while minimal changes were seen at the other levels. For left lateral bending, a decrease of 11.7% and 20.3% in motion was observed at the inferior adjacent level C6-C7 after ODL and DDL respectively, while minimal changes were seen at the other levels. Similarly, left axial rotation resulted in 13.2% and 15.1% decrease in motion at C6-C7 after ODL and DDL respectively. After laminectomy, both lateral bending and axial rotation led to minimal changes in the motion (<5%).

Figure 7 shows the percent changes in the annular stresses (von Mises) of the intervertebral disc after the simulated surgical procedures. After ODL, the adjacent discs (C2-C3 and C6-C7) showed an increase in the stress values while DDL and laminectomy resulted in an increase in the stresses across the surgically altered levels (C2-C3 to C6-C7) during flexion (Figure 7). Minimal changes in the disc stresses were observed at most of the levels during the other loading modes. During flexion, no facet loads were recorded as they were not engaged. In the other loading modes, the inferior (C6-C7) and superior (C2-C3) unaltered levels recorded ~ 30% change following the open and double door laminoplasty. The changes observed at the other levels post laminoplasty and laminectomy was less ~ 10%.

During all six loading modes the von Mises stresses in the laminoplasty constructs, namely the screws and plates (~250MPa) (Figure 8) of the ODL and the HA spacer (~ 200MPa) of the DDL, were within the yield
The Effect of Multi-Level Laminoplasty and Laminectomy on the Biomechanics of the Cervical Spine

Both laminoplasty models (ODL and DDL) resulted in increased vertebral cortical body stresses at the C3-C6 levels during laminar opening, with the posterior vertebral body demonstrating higher stresses than the anterior regions (Figure 9).

DISCUSSION

Understanding the effect of surgical procedures on the biomechanics of the spine may help a clinician better treat, and perhaps prevent spinal instability. Various experimental studies have demonstrated concerns for instability of the spine after laminectomy compared to multi-level laminoplasty. Subramaniam et al.28 reported that laminectomy resulted in a 14.2% increase in the ROM (for ±1.5Nm moment) during flexion/extension when compared to intact state. Under a moment of 1.5Nm, Kubo et al.29 tested fresh cadaveric cervical specimens and observed an increase of 2.6% in motion in flexion/extension, 6.2% in lateral bending, and 8.4% in axial rotation after four-level DDL. Nowinski et al.30 tested nine cervical spines after C3-C6 open door laminoplasty to show a 4% increase in flexion/extension, 2.3% increase in lateral bending, 14% increase in axial rotation. This increase in axial rotation after laminoplasty could be attributed to altering the facet capsules for stabilizing the lamina in an open position using sutures after laminoplasty. In an in vitro study13, we reported that ODL stabilized with titanium miniplates led to insignificant (p>0.05) changes in motion (<1% decrease in Flexion/Extension; 3.6% increase in Lateral bending; 6.3% increase in Axial rotation) while laminectomy led to a significant (p<0.05) increase (20% in Flexion/Extension; 8.2% in Lateral Bending; 15% in Axial rotation) in motion during the primary three loading modes.

While several experimental studies have addressed the biomechanical effects of single and multi-level laminectomy procedures, previous computational models have been limited to single-level studies. Kumaresan et al.31 and Wan et al.32 used 3D validated finite element models of cervical spines to show increased ROM and stresses at the adjacent level post-laminectomy. Since only a three-level finite element model (C4-C6) was used by Kumaresan et al.31, the loading and boundary conditions might affect the applicability of the results. Also, both the above mentioned studies have addressed only single-level laminectomy. It is well-known that the posterior surgical technique involving laminoplasty or laminectomy may be preferred when multiple levels of cervical spine are involved in a compressive disorder. This is the first computational study looking at the differences in terms of flexibility and stress distribution in the implants, vertebral bodies and intervertebral discs using a specimen-specific model.

Table 2 compares the percent changes of the C2-T1 ROM (relative to the intact motion) with our in-house experimental data as well as literature data after ODL, DDL and laminectomy. The findings from the above mentioned studies of laminoplasty and laminectomy are consistent with our finite element results where we observed a 3.4% increase in the ROM after C3-C6 ODL and 30% increase in the motion after C3-C6 laminectomy in flexion/extension. The DDL finite element model predicted an approximate 12% increase in C2-T1 ROM during flexion/extension, thereby explaining the role of lamina-ligamentum flavum complex in the stability of spine.33 Changes less than 4% were observed in other loading modes (lateral bending and axial rotation) after C3-C6 ODL and DDL. The current findings after laminectomy (changes < 3% in lateral bending and axial rotation) also agreed with clinical observations where post laminectomy deformity is more predominant in flexion-extension than in lateral bending and axial rotation34,35.

In addition, the current finite element predictions demonstrated similar trends compared to our in house
The current study showed laminoplasty as superior to laminectomy in terms of ROM at the altered and unaltered levels. Finite element predictions suggest the preservation of ROM after open door laminoplasty, which was in agreement with our experimental results. It also addressed the role of ligaments in maintaining the stability of the cervical spine as extensive ligament resection could substantially affect the motion following a DDL. It also showed that unilateral resection of ligaments during ODL results in asymmetric distribution of stresses/motions during lateral bending and axial rotation.

ACKNOWLEDGEMENTS

The authors would like to thank Srinivas C. Tadepalli for assistance in simulating the laminoplasty techniques. The authors acknowledge receipt of laminoplasty plates from Medtronic Sofamor Danek (Memphis, TN). No formal funding was received in support of this study. Medtronic Centerpiece® plates are FDA approved for cervical laminoplasty.

REFERENCES

The Effect of Multi-Level Laminoplasty and Laminectomy on the Biomechanics of the Cervical Spine


ABSTRACT

Introduction: Chronic back pain treatments have generally been costly and/or ineffective despite advances in medical technology. Patient selection and factors intrinsic to patients, including beliefs and behaviors, have been increasingly looked upon as possible predictive factors for success following multidisciplinary intervention for chronic back pain. The current study investigated the value of using patients’ perceived control over health changes (health locus of control) and their perceived ability to engage in pain management behaviors (pain-related self-efficacy) to predict physical and mental health outcomes.

Methods: We retrospectively analyzed 61 patients who completed a two-week multidisciplinary chronic back pain rehabilitation program at our institution between 2007 and 2009. Patient demographics were identified and categorized. Pre- and post-intervention functional surveys, including the Multidimensional Health Locus of Control Form C, Chronic Pain Self-Efficacy Scale, Medical Outcomes Study Short Form-36 Version 2, Beck Depression Inventory-II, and Oswestry Disability Index Version 2, were used to evaluate benefit from back pain intervention and to examine patient factors that may predict physical and mental health outcomes.

Results: Participants included 28 males and 33 females, ages 28 to 72, completing chronic back pain rehabilitation. Locus of control, self-efficacy, and physical and mental health demonstrated treatment-related changes, with notable improvements in physical and mental health. Regression analyses examined the value of pre-treatment health locus of control and pain-related self-efficacy as predictors of physical and mental health one month following treatment. Higher internal and lower doctor health locus of control, and higher self-efficacy at baseline predicted higher lift scores one month after treatment (p < .05; p < .01; p < .01, respectively). Higher baseline self-efficacy also predicted better physical functioning (p < .01) and lower disability (p < .01) at one month.

Conclusions: In addition to supporting the multiple benefits of multidisciplinary rehabilitation, this study suggests that pain-related self-efficacy and health locus of control may be valuable predictors of treatment benefit for chronic back pain patients. These results provide direction in screening for factors that may maximize the potential to benefit from multidisciplinary intervention for chronic back pain.

KEY WORDS: self-efficacy, health locus of control, multidisciplinary, chronic back pain, treatment outcomes.

INTRODUCTION

Chronic back pain is costly to society due to lost workdays, lower productivity, and healthcare expenditures. The 5% of workers with low back pain who never return to work account for 75% of costs for work-related back pain.20 Because of the high costs of chronic back pain and surprisingly low response to advanced medical or surgical treatments, the tasks of predicting treatment outcomes and developing maximally beneficial treatment programs for individuals with this health problem have received growing emphasis.

Health locus of control (HLOC) refers to expectancies regarding whether health is controlled by one’s own behaviors as opposed to factors such as chance, luck, fate, or powerful others.26,27,31 Studies have demonstrated that internal health locus of control (IHLC) is related to better physical and mental health24 and more proactive health behaviors.9 Chance locus of control (CHLC) is related to poorer physical and mental well-being9 and less proactive health behaviors24; and powerful others locus of control (PHLC) is related to stronger adherence to medical recommendations but higher likelihood of chronic pain or disability.31 Pain-related self-efficacy...
refers to the belief that one is capable of performing
pain-management behaviors. Higher pain-related self-efficacy has demonstrated correlation with increased maintenance of treatment benefits, lower depression, engagement in active pain coping strategies, more effort in functional capacity evaluations, better physical functioning, and shorter duration of back pain.

Multidisciplinary intervention (MI) refers to the use of physical intervention with any combination of psychological, social, and/or occupational interventions. Studies involving MI have demonstrated efficacy, albeit inconsistently, for the treatment of chronic back pain. Individuals with high internal HLOC and high pain-related self-efficacy theoretically have a high likelihood of making the changes recommended within MI. More research in this area is needed to validate theoretical relationships between HLOC, self-efficacy, and back pain.

This study evaluated whether MI affected changes in patient mental health, physical function, and pain-related beliefs (i.e., HLOC and self-efficacy). Additionally, the study examined whether health locus of control and pain-related self-efficacy predicted treatment-related changes in depression, general mental health, and physical function following intervention.

**MATERIALS AND METHODS**

**Participants**

Data collection included consenting patients in an IRB-approved study completing the two-week spine rehabilitation program at the University of Iowa Spine Center from September 2007 to April 2009. The Spine Rehabilitation Program involves an interdisciplinary treatment approach including physical therapy, cognitive-behavioral group therapy, vocational rehabilitation, and group discussions with a physiatrist. Participants were at least 18-years-old and English speaking.

**Instruments**

The Multidimensional Health Locus of Control (MHLC), Form C, consists of four scales assessing HLOC in medical populations. These scales measure the extent to which patients attribute their pain to behaviors by themselves (internal health locus of control; IHLC), chance (CHLC), doctors (DHLC), or other people (OHLC). Alternate forms of the MHLC combine DHLC and OHLC into a powerful others locus of control scale (PHLC). Higher scores reflect higher levels of each construct. The MHLC forms demonstrate adequate reliability, test-retest stability, and validity.

The Chronic Pain Self-Efficacy Scale (CPSS) consists of three subscales measuring patients’ self-efficacy in pain management, ability to cope with their pain, and general functional ability. The CPSS has demonstrated adequate internal reliability and validity.

The Medical Outcomes Study Short Form 36, Version 2 (SF-36v2) is a well-validated measure of physical and mental health. The SF-36v2 measures eight health concepts (physical functioning; role limitations due to physical functioning; bodily pain; general health; vitality/energy; social functioning; mental health; and role limitations due to emotional functioning). The eight subscales fall under two broad dimensions, the physical health component summary (PCS) and the mental health component summary (MCS). The SF-36v2 has demonstrated high internal reliability.

Physical functional capacity was evaluated by a physical therapist, as the maximum number of pounds safely lifted in one trial without an increase in back or neck pain. Participants in the program are typically expected to lift between 10 and 30 pounds at baseline. Similar lift measurements have demonstrated reliability.

The Oswestry Disability Index (ODI) has been termed the “gold standard” in disability measurement and has been recommended as part of a standardized battery of outcome assessment for back pain patients. The questionnaire assesses to what extent pain currently interferes with patients’ ability to perform various functions. Version 2 of the ODI (ODIv2) has demonstrated acceptable internal reliability and validity. In the current study, higher scores on the ODIv2 indicate lower disability and better outcomes.

The Beck Depression Inventory-II (BDI-II) is used to detect possible depression in normal populations and assesses severity of depression in diagnosed patients. Items on the scale correspond with diagnostic criteria for depression. When used with medical patients, the BDI-II has demonstrated high internal consistency and validity.

To maximize the inclusion of predictor variables in final analyses, missing items on the MHLC and CPSS were substituted with the mean of the items that were completed on the relevant subscale. If a particular subscale was less than 67% complete, the subscale score was omitted completely from analyses.

**Procedures**

Patients participated in an intensive, interdisciplinary, two-week rehabilitation program. The Spine Rehabilitation Program involves an interdisciplinary treatment approach with a number of components including physical therapy, cognitive-behavioral group therapy, vocational rehabilitation, and group discussions with a physiatrist. All measures except the ODI were administered to par-
Table 1. Demographics (N = 61)

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Note: Numbers for education and relationship status represent a subset of patients for whom this information was provided. H.S. = high school; GED = General Educational Development; T.C. = technical college.

Table 2. Descriptive statistics (N = 61)

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Note: T0 = baseline; T1 = end of treatment; T2 = one-month follow-up; CPSS = Chronic Pain Self-efficacy Scale; IHLC = internal health locus of control; CHLC = chance health locus of control; DHLC = health locus of control for medical professionals; OHLC = health locus of control for others; Lift Score = floor-to-waist lift; BDH II = Beck Depression Inventory - II; PCS = Physical Component Scale; MCS = Mental Component Scale; ODIv2 = Oswestry Disability Index version 2.

RESULTS

Ninety-seven individuals were provided the opportunity to participate in the current study. Seventy-eight participants (42 females and 36 males) initially agreed to participate in the study and completed forms before participating in the program (T0), creating an 80% recruitment rate. Table 1 lists demographic information for the 61 participants who ultimately completed forms at baseline (T0), immediately following the program (T1), and one month following the program (T2). Independent-samples t tests were conducted to compare those who completed data at one-month follow-up to those who did not. Patients who completed one-month follow-up measures (completers) were significantly older (M = 47.6, SD = 11.1) than non-completers (M = 36.2, SD = 10.2), t(76) = 3.87, p < .001. Additionally, completers at T2 lifted less weight from floor to waist at baseline (M = 28.8, SD = 17.9) than non-completers (M = 40.8, SD = 19.0), t(64) = 2.093, p = .04. These groups demonstrated no significant differences on baseline measures of health locus of control, self-efficacy, depression, or physical and mental well-being.

Table 2 lists sample ranges, means, and standard deviations for all variables at all time points. All subscales of the Multidimensional Health Locus of Control scale (MHLC) demonstrated means similar to those reported by other researchers studying pre-treatment chronic pain samples. The sample for the current study demonstrated levels of emotional and physical difficulties (including pain), and limitations related to these difficulties, similar to those previously reported in back pain patients who received rehabilitative intervention. Internal consistency was obtained for each variable as measured in the 61 participants, using Cronbach's alpha (see Table 2). Outlier scores were eliminated.
for each separate variable differ as a result of different participants failing to complete scales or having outlier scores eliminated for different measures.

Cronbach’s alpha was calculated when possible (see Table 2). The Oswestry Disability Index (ODIv2), Beck Depression Inventory (BDI-II), and Chronic Pain Self-Efficacy Scale (CPSS) demonstrated acceptable levels of internal consistency with alpha values similar to those found in previous studies\textsuperscript{3,4,14}. The MHLC subscales were adequately internally consistent, with the exception of the other people health locus of control (OHLHC) sub-scale, which was therefore omitted from all subsequent data analyses.

Separate one-way repeated-measures ANOVAs compared scores on functional capacity (lift) and self-reported physical health (PCS) between baseline, end of treatment, and follow-up measurements. Both indices of physical health demonstrated significant change over time, increasing significantly from T0 to T1 ($p < .001$ for both measures), and from T0 to T2 ($p = .007$, $p < .001$, respectively; see Figure 2). Scores on both scales peaked at T1, and the decline from the end of the program to follow-up was also statistically significant for both scales (IHLC, $p = .03$; CPSS, $p < .001$). CHLC demonstrated a significant decline from T0 to T1, $p = .006$, and from T0 to T2, $p = .02$, with no significant difference between program completion and follow-up.

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Table 3 includes results of regression analyses examining the relationship between T0 predictor variables (IHLC, CHLC, DHLC, and CPSS) and the outcome variables (lift scores, ODIv2, PCS, MCS, and BDI-II). These findings indicated that T0 lift scores and gender were positively predictive of lift scores at T2 (T0 lift, $p < .001$; gender, $p < .01$). Individuals who lifted more at
## Table 4. Hierarchical regression analysis for prediction of physical outcome variables

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Note: Standardized β values listed. T0 = baseline; CPSS = Chronic Pain Self-efficacy Scale; IHLC = internal health locus of control; CHLC = chance health locus of control; DHLC = health locus of control for medical professionals; MCS = Mental Component Scale; BDI-II = Beck Depression Inventory II.

*p < .05, **p < .01, ***p < .001
baseline obtained higher lift scores at T2 than individuals who lifted less at baseline, and males demonstrated higher lift ability at T2 than females.

After controlling for Block 1 variables, analyses demonstrated that higher CPSS and IHLC scores at baseline were related to the ability to lift more weight at one-month follow-up (CPSS, p < .01; IHLC, p < .05). As expected, higher doctor locus of control (DHLC) was predictive of lower lift scores at T2 (p < .01). Surprisingly, higher baseline CHLC was associated with higher lift scores at one-month follow-up (p < .01). After controlling for age and gender, higher CPSS scores at baseline were related to lower disability levels on the ODIv2 at one-month follow-up (p < .001; see Table 4). MHLC scores were not related to level of disability level at follow-up.

Physical health, mental health, and depression scores at one-month follow-up were positively predicted by their scores at baseline. After accounting for Block 1 variables, analyses showed that higher baseline CPSS scores predicted higher self-reported physical health (PCS) at one-month follow-up (p < .01). Subscales of the MHLC were not uniquely significantly related to T2 PCS scores. Depression and self-reported mental health were unrelated to predictor variables (IHLC, CHLC, DHLC, or CPSS).

**DISCUSSION**

In this study, we have shown the benefits of a multidisciplinary intervention program for treatment of chronic back pain. Patients not only subjectively rated their physical and mental health as significantly improved following rehabilitation, they also demonstrated increased lifting abilities, with changes maintained one month later. Many of our findings merit further discussion.

The increase of internal health locus of control (IHLC) following treatment aligns with what we might expect, given the focus of the rehabilitation program on patients managing their own pain. The decline in chance health locus of control (CHLC) from pre-treatment to post-treatment supports the prediction that chronic back pain rehabilitation decreases the perception that chance factors are responsible for one's pain. The expectancy that medical professionals were responsible for health status (i.e., DHLC) was not significantly impacted by multidisciplinary intervention (MI) in this study. It appears individuals may experience increased internal expectancies for control of their pain without necessarily abandoning their expectancies related to the impact of medical professionals on their pain.

Chronic pain self-efficacy demonstrated treatment-related change in the expected direction, as it increased from baseline to the end of the two-week rehabilitation program, and the increase remained significant one month following the program. Nicholas and colleagues found cognitive-behavioral intervention, which is included in the Spine Center's program, to be an essential component leading to treatment-related changes in pain-related self-efficacy. Further research into specific components of treatment that may impact self-efficacy would be beneficial to assist in maximizing cost-effectiveness.

In contrast to other studies in this area, the regression analyses in the current study were longitudinal in nature, controlling for the effects of baseline relationships between predictors and outcomes. Individuals with higher internal and lower doctor health locus of control experienced more improvement in lift capacity than those with lower IHLC and higher DHLC, respectively, supporting expectations within Social Learning Theory (SLT). This study also extended previous research offering support for expectations within Social Cognitive Theory that pain-related self-efficacy predicts treatment benefit. Higher scores on the CPSS were related with higher functional capacity, lower disability, and better self-reported physical functioning measured one month following treatment. It is noted the predictor variables were not related to post-treatment mental health outcomes (depression and self-reported mental health).

This study supports the utility of assessing pain-related self-efficacy and health locus of control to assist in formulating an understanding of which patients are most likely to benefit physically from MI for chronic back pain. This study does not support using self-efficacy and HLOC to predict mental health outcomes. Overall, the combination of clinical judgment and pre-treatment assessment of chronic pain self-efficacy, HLOC, depression, and self-reported mental health status may offer useful information in predicting patients who may benefit physically and mentally from MI for chronic back pain. Knowledge of these factors may assist in adequately accommodating patients on an individual basis through varied types of motivation to engage in treatment-related behaviors. In some cases, referral to other, more appropriate treatment may be beneficial when low likelihood of benefiting from MI is predicted. Alternatives to treatment may include psychoeducational or efficacy-promoting components, potentially preparing patients to benefit more from MI in the future. While denial of a potentially beneficial service is not a general recommendation, it is important to consider the potential costs of providing treatment that may lead to little benefit under certain circumstances.

Interpretation of the current results must be considered within the context of the specific type of treatment provided within our Spine Center’s rehabilitation program. This program involves a variety of treatment modalities...
in an interdisciplinary format. Thus, the predictive value of health locus of control (HLOC) and pain-related self-efficacy in the current study reflects treatment-related change in the context of a specific interdisciplinary treatment program. Thus, results of the current study support the use of the Multidimensional Health Locus of Control scales (MHLC) and Chronic Pain Self-Efficacy Scale (CPSS) as screening instruments for programs that involve an interdisciplinary treatment approach.

Comparison of scores on instruments such as the MHLC and CPSS to clinician ratings of the variables is an area for future research. This comparison may facilitate greater ability to conceptually apply the results of studies such as the current study to clinical practice. Future research may also include additional measures to maximize prediction of outcomes from MI, such as personality traits or self-reported mental health. Finally, replication of the current study with greater time between the end of treatment and the measurement of follow-up functioning would provide more information regarding the duration of relationships noted in the current study.

Limitations of this study include small sample size, variable sample size across analyses, and variation in time from end of treatment to completion of one-month follow-up measures, due to the use of mailings for participants who did not present for follow-up. Regression analyses in the current study measured relationships between predictor variables measured at a point in time prior to the outcome measures they predicted, while accounting for baseline relationships between the factors. Therefore, the regression results provide new information regarding the predictive value of HLOC and pain-related self-efficacy for chronic back pain. It must be noted, however, that this study was not performed in an experimental fashion. Therefore, care must be taken when interpreting the findings of these analyses, and replication with control group comparisons may provide more conclusive results.

A significant gap in the literature that was not addressed in this study concerns the lack of attention to cultural differences in HLOC or self-efficacy. It is not clear how or whether these constructs apply to racially or ethnically diverse individuals. Due to the fact that participants were recruited in a healthcare setting in a location with relatively low levels of racial and ethnic diversity, care must be taken in attempting to generalize these findings to ethnically and racially diverse groups.

In conclusion, results of the current study validate previous research indicating the physical and mental benefits of engaging in multidisciplinary treatment programs for chronic back pain. Furthermore, the findings suggest that measures of HLOC and chronic pain self-efficacy may offer utility in predicting physical benefit from such programs. Specifically, individuals with high internal HLOC, low doctor LOC, and high pain-related self-efficacy may be more likely to benefit from MI than others. Interestingly, mental health outcomes may be best predicted by examining pretreatment mental health status, rather than using locus of control or self-efficacy measures. Additional research in this area may be beneficial in assessing the cost-effectiveness of using screening measures to predict outcome, or to more clearly delineate the components of programs most linked to noted changes.

ACKNOWLEDGMENTS

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DISCLOSURES

No conflicts of interest exist for the authors of this manuscript, in connection with the research conducted.

REFERENCES

ABSTRACT

Introduction: Pediatric femur fractures are common injuries presenting to tertiary care trauma centers. Transportation of these patients occurs most commonly via ambulance or flight. The purpose of this study is to evaluate whether mode of transportation affects time to surgery or hospital stay for pediatric patients with femur fractures.

Methods: Utilizing a trauma registry we queried pediatric femur fractures between January 2001 and December 2009. Patient age, gender, mechanism of injury, month of injury, type of fracture, transportation, county of origin, time to operating room (TTOR), hospital length of stay (HLOS), and treatment received were identified and compared.

Results: In total, 519 femur fractures were identified, 257 (49.5%) of which were isolated injuries. Flight transportation was utilized in 13.6% (35 of 257) of these isolated fractures. Mean TTOR for flight patients was 29 hours, HLOS 3.2 days. For ambulance transportation mean TTOR was 41 hours, HLOS 3.2 days. Neither variable was statistically different between transportation groups (TTOR p = 0.50; HLOS p = 0.95). No statistical difference was seen in HLOS (p = 0.47) and TTOR (p = 0.71) for patients originating further distances from the hospital.

Conclusion: Transportation method and distance from the hospital did not affect the TTOR and HLOS for isolated pediatric femur fractures. The use of air transportation for this group of patients, many of whom are injured by relatively low energy mechanisms, may be excessively costly and does not accelerate treatment.

INTRODUCTION

A traumatic femur fracture is the most common pediatric orthopedic injury requiring hospitalization, accounting for 21.7% of all pediatric orthopedic trauma, with an incidence of 27.2 per 10,000 children. Femur fractures are often a result of trauma and are complicated by the evolving nature of a pediatric skeletal system. Understanding the nature of these fractures is important part of providing care. Epidemiological data on pediatric femur fractures does exist but no studies to date have specifically looked at pediatric femur fractures at a United States tertiary care center.

It has been shown that distance to hospital is associated with an increased mortality in those with life-threatening injuries, and treatment at a trauma center may have survival benefit. Studies comparing the effect of helicopter versus ambulance transport on survival have shown both improved survival and no effect. However these studies have all focused on generic trauma, not specifically orthopedic injuries, and the differences in outcomes appears to be confined to the more severe injuries. Hip fractures have been examined, showing that distance traveled to the hospital did not affect hospital length of stay, time to operating room, or mortality. The purpose of this study is to evaluate whether mode of transportation affects time to surgery or hospital stay for pediatric patients with femur fractures.

METHODS

The University of Kentucky Chandler Medical Center maintains a registry on all patients admitted through the trauma service. The International Classification of Disease, ninth version (ICD-9), codes 820 and 821 were utilized to identify all femur fractures in patients under 17 years of age between January 2001 and December 2009. Five hundred and nineteen patient records were found. Patient age, gender, mechanism of injury, month of injury, type of fracture, mechanism of transportation to hospital, county of origin, treatment type received, time to operating room (TTOR), and hospital length of stay (HLOS) were recorded for each patient. Treatment received included spica casting, internal fixation, percutaneous fixation, closed reduction, intramedullary (IM) nailing, and no surgical or casting treatment. Due to database limitations, both flexible and rigid nails are
Transportation of Pediatric Femur Fractures to a Tertiary Care Center: A Retrospective Review

Included in the IM nail category. The type of fracture was determined by the assigned ICD-9 code. The county of the hospital plus those counties immediately adjacent to the hospital are termed a “proximal” site of origin. All other counties are termed “outlying.” Transportation mechanisms include ambulance referred from an outside hospital, ambulance from the scene, helicopter referred, helicopter from the scene, and patient’s personal transportation. A two tailed T-Test was utilized to identify significant differences (P < 0.05). This study was reviewed and approved by the University of Kentucky Institutional Review Board.

RESULTS

In total, 519 patients were identified; 371 (71.48%) were male and 148 (28.51%) female, a 2.5:1 ratio. Motor vehicle accidents (MVAs) (27.75%) and falls (25.82%) were the most common mechanism of injury, followed by all terrain vehicle (ATV) accidents (10.02%), unspecified causes (8.67%), and motorcycle accidents (7.90%). Eight of the nine (88.89%) assault injuries occurred in children under one year of age, and was the second most common mechanism of injury in this age group. Females had higher incidence rates of MVAs and fall fractures, and fewer sports, ATV, motorcycle, and gunshot wounds than males. Table 1 details the various mechanisms of injury. The average age of female patients, 7.92 years, was significantly different (P = 0.015) than that of males, 9.14 years.

Of all fractures, 93.42% were closed, and 6.58% open. The most common type of fracture was an unspecified closed shaft fracture, which accounted for 65.04% of all fractures, followed by closed distal fractures at 12.59%. Figure 1 details the percentage of each type of fracture observed. Of the 519 total fractures, 257 (49.5%) were isolated injuries.

For treatment received, an IM Nail (44.70%) and spica casting (16.96%) were the most common, followed by no surgical or casting treatment (15.22%). No significant differences were observed between males and females. Treatment correlated with age. Patients under 12 months of age received no surgical or casting treatment 84.62% of time. Patients from 1-5 years of age most commonly received spica casting, and patients over 5 years of age an IM nail (Figure 2). No significant difference was seen in HLOS for spica casting versus IM nail (P = 0.74).

The average HLOS was 4.97±6.30 days. The average TTOR was 40.33±99.31 hours. There was no difference between male and female HLOS (P = 0.47). For TTOR, males averaged 46.02 hours versus 24.94 hours for female patients, which was close to being significantly different (P = 0.059). No significant differences were seen in TTOR and HLOS for proximal patients versus

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Table 1. Mechanism of injury for all fractures recorded.

![Figure 1. Percentage of each fracture type based on ICD-9 coding.](image-url)

![Figure 1](image-url)
outlying patients. No significant differences were seen in HLOS and TTOR for patients when divided into the age groups of <2 years old, 2-5 years old, 6-12 years old, and 12-16 years old.

Among patients with isolated femur fractures, 13.62% utilized flight transportation. Mean TTOR for flight patients was 29±84 hours, HLOS was 3.2±4.3 days. For ambulance transportation mean TTOR was 41±90 hours, HLOS was 3.2±3.6 days. For personal transportation mean TTOR was 40.24±95.37 hours, HLOS was 2.54±3.49 days. No significant difference was seen in TTOR or HLOS for any of the methods of transportation for isolated femur fractures.

**DISCUSSION**

When isolated fractures are examined there were no differences in HLOS or TTOR for any of the transportation mechanisms. Isolated fractures were examined in this instance to control for polytrauma. Patients flown in via helicopter did not reach the operating room any quicker than those brought in by ambulance or via personal transportation. This data suggests that in cases of isolated fractures, the utilization of helicopter transportation does not increase the speed of treatment.

Based on the costs of helicopter use, an ambulance is likely a more cost efficient alternative. This is particularly applicable when patients are being transferred from an outlying hospital, where it has been shown helicopter use may not actually increase transport times. Additionally, Crandall et al. has shown that provider determined transfer times for trauma cases that exceed two hours have no adverse effect on patient outcome, supporting the idea that urgent use of helicopters for faster transfer times is not necessary. Matsushima et al. also showed that surgical team workload, ISS, and caseload had no correlation to TTOR, minimizing confounding variables for this statistic. We hypothesize that this lack of significant difference in TTOR for isolated femur fractures would hold true for other isolated pediatric orthopedic injuries.

According to our findings, significantly more fractures occurred in males than females. This has been previously described and is likely due to males’ increased disposition for riskier behaviors, as seen by their higher incidence of motorcycle, gun shot, and ATV injuries. These differences in injury mechanism may also account for the higher average age for males. Falls and MVAs represented over half of all fractures, and were the first and second most common causes of injury in those under 12, respectively. This is largely consistent with prior research that has shown either falls or MVAs being first and second throughout this age range. One exception is a study by Heideken et al. that showed sports accidents to be the most frequent cause in the 4 – 12 age range. The high rate of ATV injuries is representative of the rural population base of the care center.

In children under one year of age, 30.77% of fractures were a result of assault, which was most common mechanism of injury in this age group after MVAs. This is especially disturbing considering assault is often only reported when the physician has concrete evidence abuse has taken place. Many suspected cases of assault or non-accidental trauma are not reported, and this percentage may in fact be much higher. The American Academy of Orthopedic Surgeons recommends that all diaphyseal fractures in children under 36 months of age be evaluated for child abuse. The existing data relating non-accidental trauma to femur fractures is highly variable. For children less than a year old, femur fractures due to abuse range from 8.5% - 90%. Loder et al. reported 15% of fractures in those less than two being due to abuse. Beals and Tufts report 30% in those less than four, and Beuress and Kaelin report 7% in those less than four. One common theme is that age is the biggest factor in determining non accidental trauma. In a study by Rex et al. on femoral fractures owing to definite abuse, 92.8% of their cases occurred in children younger than one, similar to our study’s 88.89%.

Treatment received correlated with age. The majority of infants received no further surgical or casting treatment after the fracture was reduced and set. Young children between one and five years of age most often received spica casting, and those over five years most often an intramedullary nail. Due to database limitations we are unable to report on the breakdown of flexible versus rigid nails, though we presume based on standard faculty practices that the use of titanium elastic nails predominated in this group. Management of femur fractures in children ages 6-10 has evolved away from spica casting and towards intramedullary flexible nails, and our data parallels this trend. Titanium elastic nails have been shown to hasten fracture union, reduce the rate of malunion and shortening, and allow earlier re-
habilitation and return to school for ages those aged 5-15\textsuperscript{22,23}. However evidence for use of methods other than titanium elastic nails for unstable fractures has recently emerged\textsuperscript{24}.

The average HLOS of 4.97 days was less than that of two older studies\textsuperscript{1,2} and consistent with that found by Heideken et al. in 2005. This may be due to a more current data set, indicating that evolving treatment methods and techniques are having a beneficial effect. When examining these studies in chronological order the HLOS does decrease, something that Heideken et al. also demonstrated\textsuperscript{1}. In contrast to Loder et al, a longer HLOS was not seen in the older age groups\textsuperscript{2}. The average TTOR for females was very close to being significantly shorter than that for males (P = 0.059). This is counter-intuitive as males are more likely to be involved in gunshot, motorcycle, and ATV injuries which would presumably require more urgent care. However a proportionally higher percentage of females sustain femur fractures in MVAs, which are also a priority at trauma centers. There was no significant difference in HLOS or TTOR for patients brought in from outlying counties versus those from proximal counties. Distance from the hospital does not appear to play a role in the timely delivery of treatment for this patient population. This is consistent with a prior study on isolated hip fractures\textsuperscript{13}, though is in contrast to studies on all cause trauma\textsuperscript{10}. However even when examining all cause trauma, the difference in outcomes appears to be confined to the most severe injuries. This would further support the notion that pediatric femur fracture outcomes are largely unaffected by distance travelled.

In conclusion, transportation method and distance from the hospital did not affect the TTOR and HLOS for isolated pediatric femur fractures. The use of air transportation for this group of patients, many of whom are injured by relatively low energy mechanisms, may be excessively costly and does not accelerate treatment.

REFERENCES:
A CASE REPORT OF BILATERAL MIRROR CLUBFEET AND BILATERAL HAND POLYDACTYLY

Mai P. Nguyen, MD, Ericka A. Lawler, MD, Jose A. Morcuende, MD, PhD

ABSTRACT

We report a rare case of a patient with bilateral mirror clubfeet and bilateral hand polydactyly. The patient presented to our orthopaedic clinic with bilateral mirror clubfeet, each with eight toes, and bilateral hands with six fingers and a hypoplastic thumb. The pattern does not fit any described syndrome such as Martin or Laurin-Sandrow syndrome. Treatments by an orthopaedic pediatric surgeon and an orthopaedic pediatric hand surgeon are described. The patient achieved excellent functional and cosmetic outcomes at four year follow-up.

INTRODUCTION

Mirror polydactyly of the feet is a rare diagnosis with symmetrical duplications of the digits and is usually associated with deficiency of the thumb or hallux\(^1,2\). They can occur in isolation or as part of syndromes\(^3,4\). A thorough history and physical examination is paramount because there is a spectrum of associated anomalies involving face features and other extremities\(^1,4\). Treatments must be tailored individually to correct each deformity and restore functions for the patients. Coordination among different care teams should be pursued to ensure optimum care for patients.

CASE REPORT

A two-year-old female was referred to our clinic for evaluation of bilateral hand and foot deformities. The patient was adopted from China and her family history was unknown. She was born full-term and weighed seven pounds at birth. Upper extremity examination revealed hands with six fingers including a Blauth type IIIB thumb hypoplasia with deficiency of carpometacarpal joint on the right and type IV thumb hypoplasia (Pouce Flottant) on the left (Figures 1 and 2)\(^5\). She had six metacarpals

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on the right and five on the left. The long bones of the arms were normal. In her lower extremities she had bilateral hind foot equinovarus, metatarsal adductus, and cavus deformities consistent with clubfeet. Each foot had eight toes, and none appeared to be a hallux (Figure 3). She had large calluses laterally from weight bearing on the outside of her feet. Radiographic examination showed eight sets of phalanges with seven metatarsals; the central toe did not have an associated metatarsal (Figure 4). She had no other anomalies and growth and development were normal.

**TREATMENT**

The patient was evaluated by an orthopaedic pediatric specialist (JM) and an orthopaedic pediatric hand specialist (EL) to address her bilateral mirror feet and clubfoot deformities as well as her six fingered hands with bilateral hypoplastic thumbs. No other abnormalities were found. Surgeries were coordinated between the two surgeons to optimize care and minimize patient morbidity.

The patient was treated initially with the Ponseti clubfoot protocol. After four months of serial casting, she underwent surgical intervention with bilateral extra digit resection, anterior tibialis tendon transfer (to the lateral cuneiform) and Achilles lengthening. The medial two rays, along with the central digit which had no metatarsal, were resected. The patient was placed in bilateral long leg casts and kept non-weight bearing with transitioning to a Mitchell brace at two months post-operatively. At the same time of her foot surgery, the patient’s hands were treated with amputation of the
A Case Report of Bilateral Mirror Clubfeet and Bilateral Hand Polydactyly

A hypoplastic and non-functional thumbs as well as pollicization of her adjacent accessory digit. The patient returned to the operating room three years later at age six for a left tibia derotational osteotomy for tibial torsion. She required no further surgery for the right leg. The patient was last seen in clinic four years after initiation of treatments. She wore normal shoes without pain or discomfort (Figure 5). She used her hands without limitations (Figure 6). Overall, she was doing well, was active at a level comparable to her peers, and was participating in all school events.

DISCUSSION

In this report, we present a case of two-year old female with bilateral mirror clubfeet and polydactyly of the hands and feet. This case highlights several important topics which merit further discussion. Clubfoot or congenital talipes equinovarus is one of the most common congenital deformities involving the musculoskeletal system with a prevalence of 0.6 per 1000 to 6.8 per 1000. The Ponseti method with sequential manipulation and cast application has been accepted worldwide as the standard for non-operative management of clubfoot. In contrary, mirror image duplication of the foot is a rare congenital anomaly. There are approximately only 30 case reports on this topic with even fewer described treatments and outcomes. Mirror foot may occur as an isolated deformity or may be associated with a spectrum of other deformities such as fibula dimelia, tibia hypoplasia, nasal abnormalities, or upper extremities abnormalities. The patient did not have any other anomalies associated with the known syndromes such as Laurin-Sandrow or Martin syndrome.

Limb development occurs along three axes, proximal-distal, dorsal-ventral, and anterior-posterior. Mirror polydactyly appears to result from a disturbance of limb pattern formation in the anterior-posterior axis. Several genes have been shown to influence this process including the Sonic Hedgehog gene which is expressed by the zone of polarizing activity, the Homeobox genes, BMP-2,13-15. Saunders and Gasseling demonstrated mirror image duplication in chicks by grafting a small piece of posterior border mesoderm (zone of polarizing activity) into an anterior position. In humans, ectopic expression of the zone of polarizing activity and the Sonic Hedgehog gene has been linked to mirror image deformities. There have been case reports of tetramelic mirror image deformities affecting all four extremities. Since the anterior-posterior axis formation includes radial/ulnar axis formation for the upper extremities and tibia/fibula axis formation for the lower extremities, congenital abnormality of feet are sometimes associated with hand deformities such as the patient in this case. Interestingly, these deformities of the hands and feet are usually associated with missing of the hallux and thumb, similar to what was seen in this patient.

This case report highlights the challenges that our orthopaedic surgeons face in treating patients with congenital deformities affecting all four extremities. There is no protocol for treatments of such complex deformities. Thus, an analysis of each limb is important in order to adequately address every deformity. While thumb reconstruction is crucial to improve upper extremity function, hallux restoration is not absolutely necessary. In contrast, the goals of foot reconstruction are more cosmetic, but also to allow for painless plantigrade feet that accept normal shoewear. The treatments may be staged, allowing the patient to recover while limiting anesthesia time and the number of return trips to the operating room. Outcomes have been reported to be fair to good with surgical intervention in the literature. Treatments in patients with mirror feet require careful considerations of other associated anomalies and the best outcomes require collaboration between multiple surgeons.
REFERENCES


ABSTRACT

Background: Pediatric comminuted talar fractures are reported to be rare, and treatment options such as minimal internal K-wire fixation without using a tourniquet to prevent avascular necrosis have not previously been investigated.

Case Description: We report a case of a comminuted talar body and a non-displaced neck fracture with dislocation of the tibiotalar, talonavicular and subtalar joints with bimalleolar epiphyseal fractures in an 11-year-old boy due to a fall from height. We present radiological findings, the surgical procedure and clinical outcomes of minimal internal K-wire fixation without using a tourniquet.

Literature Review: Avascular necrosis rates are reported to be between 0 % and 66 % after fractures of the neck of the talus and the talar body in children. The likelihood of developing avascular necrosis increases with the severity of the fracture.

Clinical Relevance: To avoid avascular necrosis in a comminuted talar fracture accompanied by tibiotalar, talonavicular, subtalar dislocations and bimalleolar epiphyseal fractures, a minimal internal K-wire fixation without the use of a tourniquet was performed. The outcome was evaluated by the American Orthopedic Foot and Ankle Society score (AOFAS). A score of 90 (excellent) was found at the end of the second year of follow up. Radiology revealed preservation of the joint with no evidence of avascular necrosis, and clinical findings revealed a favorable functional outcome after two years.

Key words: talus; fracture healing; tourniquets; avascular necrosis

Level of Evidence: 4

INTRODUCTION

Talar body fractures are rare in children with an incidence of less than 0.08 %. Fractures of the neck of the talus are more common and usually have a better prognosis than talar body fractures. Jeremy et al. reported a talar neck:talar body ratio of 17:13 in a series of 33 cases of pediatric talar fractures. The mechanism of injury for pediatric talus fractures is usually a fall from height with a forced extension injury at the ankle with some supination component, resulting in associated malleolar fractures. An increasing likelihood and severity of complications, such as avascular necrosis and arthrosis, have been reported in literature with respect to the severity of the fracture or fracture dislocation. In addition, it has been suggested that children older than 10 years with talar fractures should be treated according to the same treatment principles as fractures in adults, especially with open reduction and internal fixation.

Here, we report a case of an 11-year-old child in which we did not use internal fixation or a tourniquet during the operation. To our knowledge, no other reports have used minimal internal percutaneous K-wire fixation without using a tourniquet to treat talar fractures in children older than 10 years.

The most significant complications arising from surgery are avascular necrosis (AVN) and posttraumatic malalignment with subsequent arthritis. In the past, many authors thought that AVN of the talus would not appear after pediatric trauma. Now, however, many authors believe that AVN of the talus can occur in children and that it is the main cause of disability after a fracture of the talus. It is known as the most common complication with regards to talar fractures in children. The available literature for therapy and outcomes after talar fractures in children is sparse and consists mainly of descriptive series with small patient numbers. Therefore, it is very important to develop a clear therapy regimen. To do so, long-term follow-up after this injury is necessary. The research question in this study was...
whether minimal internal K-wire fixation without using a tourniquet might prevent AVN and improve functional outcome. We therefore treated a talar injury with minimal internal K-wire fixation without using a tourniquet and followed up with the patient after two years.

**CASE REPORT**

An 11-year-old male patient presented to our emergency department one hour after falling from five meters onto his left ankle. The foot was deformed and capillary recirculation of the lateral side of the ankle was delayed. Radiographs and CT scan of the ankle revealed a comminuted talar body, non-displaced talar neck fracture and bimalleolar epiphyseal fracture with dislocation of the talonavicular, tibiotalar and subtalar joints (Figures 1 a, b, c). The injury was classified as a type 5 crush fracture of the talus according to Delee.

Surgical treatment was performed as early as possible. With medial and anterolateral approaches, an open reduction and percutaneous multiple K-wire fixation were

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**Figures 1 a, b, c:** AP, lateral X-rays and CT of fracture-dislocation patterns. Talonavicular, subtalar dislocation and a non-displaced talar neck fracture were visualized by tomography.
performed without using a tourniquet (Figures 2 a, b, c). The patient was discharged wearing a long leg cast. After 1.5 months, the long leg cast was shortened below the knee. The cast and K-wires were removed after 2.5 months when radiological union of the fractures was evident (Figure 3 a, b). Active and passive ankle exercises were started at this time, however, total axial loading was not allowed until four months after the injury. The patient was pain free and the ankle had nearly full range of motion six months after the injury. The outcome was evaluated by the American Orthopedic Foot and Ankle Society score (AOFAS). The patient’s AOFAS was 90, an excellent score, at the end of the second year. Control Radiographs at two-year follow-up showed no signs of AVN (Figures 4 a, b).
Although the treatment of children older than 10 years should be similar to the treatment of adults with talar fractures, we treated our patient using percutaneous K-wires instead of internal fixation, which is the method of choice for children. This treatment approach was employed, at least in part, because the fracture pattern of the talus was comminuted and was not suitable for internal fixation devices.

Eberl et al. reported that even when there is no apparent difference in the cause of the trauma leading to fractures of the talus, adolescents present with more severe fractures of the talus compared with children younger than 12 years. Furthermore, they observed that AVN is not persistent and resolved at follow up in patients younger than 12 years and patient outcome is favorable in most cases irrespective of the mode of treatment.

Some authors declared that complications including pain, AVN, and osteoarthritis are common following open reduction and internal fixation of the fracture. Long-term complications may become a more significant problem in the pediatric age group as a result of longer life expectancy. It seems that anatomic reduction and internal fixation of displaced talar fractures have key roles in lowering complication rates.
AVN is the most critical complication following talar fracture and is well described in adults; its incidence is directly related to the location of the fracture, fracture-dislocation and the amount of fracture displacement. The reported incidence of AVN with fractures of the talar neck is 0 - 10 % for type 1 fractures, 40 - 50 % for type 2 fractures, 80 - 90 % for type 3 fractures and 100 % for type 4 fractures. Relatively, little is known about the pediatric talar fractures, as there is only a few series in the literature. These were determined predominantly from adult populations and may not reflect the true incidence of AVN in the pediatric population. In addition, newer treatment techniques such as earlier reduction with stable internal fixation of these displaced fractures may improve results.

In review of the literature, the few reports on pediatric talar fractures offer conflicting data with respect to AVN. Letts and Gibbault reported a 25% incidence of AVN in 12 patients; however, two of these three patients had non-displaced fractures that were undiagnosed at the time of fracture and AVN developed later. Similarly, Linhart and Hollwarth reported a 27 % incidence of AVN in children, some of whom also had non-displaced fractures. Mazel et al. reported that two of seven children older than 6 years with complete talar neck fractures developed AVN at a later time. In contrast, Jensen et al. reported no occurrence of AVN in 11 cases of non-displaced fractures and three cases of displaced talar fractures in children.

Blood supply to the talus is very important and well described in literature. It is susceptible to disruption following the displacement of the talar neck or body fracture with subsequent development of AVN. There are four main sources of extraosseous blood supply: the deltoid branch of the posterior tibial artery, the artery of the tarsal canal, the branches of dorsalis pedis artery and the artery of the tarsal sinus. These arteries normally provide a significant intraosseous blood supply within the talus; however, the blood supply becomes compromised in displaced and comminuted fractures.

When the talus fractures, the vessels become disrupted; until reduction is performed, reperfusion does not occur completely. For this reason, ischemia occurs between the occurrence of the fracture and reduction of the talus. Longer ischemic time may lead to osteonecrosis of the talus. Application of a tourniquet, which lengthens ischemic time, can therefore be a negative factor for blood supply and can contribute to subsequent osteonecrosis. In fact, improper use of a tourniquet can lead to arterial injury, muscle injury, and edema.

Due to complications associated with the use of tourniquets, the recommended maximum time for their use is two hours. A pH of 6.9, which corresponds to the fatigue point of muscle, and lower may produce irreversible damage that leads to postoperative muscle weakness. Histology generally shows changes after one hour, but muscle degeneration and cell necrosis occur after two to three hours. Therefore, it can be concluded that there is no safe maximum tourniquet time and the safest time is the shortest time.

The Hawkins sign is described as radiolucency in the subchondral area and indicates that the body of the talus has not undergone avascular processes. If the Hawkins sign is present, there is a high probability that the talar body has a good blood supply and will remain viable. This sign presents six to eight weeks after injury. We saw this sign four weeks after injury and therefore decided not to perform an MRI or scintigraphy at the early postoperative period, which could be considered a limitation of our study (Figure 5).

There has been no other case report of unusual presentation of comminuted talar fracture dislocation in a child. The use of a tourniquet for this kind of comminuted talar fracture may contribute to avascular necrosis in the talus.

ACKNOWLEDGEMENT

The Hawkins sign of talus in this case report is presented as a poster presentation at the 33 International Congress of Turkish Radiology Society.

REFERENCES

A REVIEW OF THE ROLE OF SIMULATION IN DEVELOPING AND ASSESSING ORTHOPAEDIC SURGICAL SKILLS

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ABSTRACT
Orthopaedic surgical skill is traditionally acquired during training in an apprenticeship model that has been largely unchanged for nearly 100 years. However, increased pressure for operating room efficiency, a focus on patient safety, work hour restrictions, and a movement towards competency-based education are changing the traditional paradigm. Surgical simulation has the potential to help address these changes. This manuscript reviews the scientific background on skill acquisition and surgical simulation as it applies to orthopaedic surgery. It argues that simulation in orthopaedics lags behind other disciplines and focuses too little on simulator validation. The case is made that orthopaedic training is more efficient with simulators that facilitate deliberate practice throughout resident training and more research should be focused on simulator validation and the refinement of skill definition.

INTRODUCTION
Orthopaedic surgical skill is traditionally acquired during training in an apprenticeship model that has been largely unchanged for nearly 100 years. However, increased pressure for operating room efficiency, a focus on patient safety, work hour restrictions, and a movement towards competency-based education are changing the traditional paradigm. Surgical simulation has the potential to help address these changes. This manuscript reviews the scientific background on skill acquisition and surgical simulation as it applies to orthopaedic surgery. It argues that simulation in orthopaedics lags behind other disciplines and focuses too little on simulator validation. The case is made that orthopaedic training is more efficient with simulators that facilitate deliberate practice throughout resident training and more research should be focused on simulator validation and the refinement of skill definition.

The Need for Deliberate Practice in Surgical Skill Acquisition
It is widely accepted that surgeons benefit from practice. The more often a surgical procedure is performed, the lower its morbidity1-6 and the better the outcome7. However, practice should not be confused with repetition; performance does not improve simply because a task is repeated. The key to consistent improvement is “deliberate practice” combined with structured training. Deliberate practice involves engaging learners in focused, effortful skill repetition in progressive exercises that provide informative feedback. Trainees must receive immediate, informative feedback while trying to improve, with the particular feedback matching the characteristics of the task. Trainees should also perform the same or a very similar task repeatedly to increase performance8.

Motor skills are essential to surgical precision. Deliberate practice improves motor skills9-10. Learners advance quickly by repeating well-defined, level-appropriate tasks and receiving immediate feedback that allows for error correction. For example, the steep learning curve for a radical prostatectomy, a mildly complex surgery, does not plateau until 250 performed operations11-12. For a hip fracture surgery, residents require an average of 20-30 trials before attaining expert speed, but learning curves vary widely13.

Ericsson, Krampe, and Tesch-Römer proposed a theoretical framework for the acquisition of expert performance through deliberate practice10. Using the framework of deliberate practice, Ericsson et al. found the time to achieve expertise depends on cumulative time spent deliberately practicing, rather than the time since the activity was initiated. The famous standard of 10,000 hours of deliberate practice to become an expert is based on a study of the number of hours of deliberate practice by violinists (Fig. 1). By the age of 20, the most advanced group of expert violinists accumulated
10,000 hours, while the next most accomplished group had 2,500 fewer hours. The least accomplished group of experts accumulated 5,000 hours of deliberate practice.

The concept of deliberate practice has also been explored in the medical domain. Residents who distributed practice on a drilling task over four weeks outperformed residents who logged all of their practice in one day. The benefit of periodic practice over lumped practice is consistent with research in many other domains. This advocates for repetitious skills practice throughout a curriculum, rather than an all-day session focusing on a specific skill.

Of fourteen studies reviewed in a meta-analysis, deliberate practice using simulation-based techniques was found overall to be a superior method of training compared to the apprenticeship model in the medical field. The current apprenticeship model in orthopaedics does not facilitate deliberate practice, because it is organized around ad hoc experiential opportunities driven by patient needs rather than providing repetition of key skills based on learner needs. The key to facilitating deliberate practice is effective simulation.

**The Role of Dedicated Simulation in Surgical Skills Training**

Over the past decade, the role of surgical simulation in the acquisition of cognitive and technical skills has grown, particularly for minimally invasive and limited-exposure surgery. Many disciplines have shifted away from the apprenticeship model to teach surgical skills. The field of orthopaedics has not kept pace with these developments. Medical students and residents trained on simulators demonstrate improved performance in actual surgeries. For example, experts performed reliably better on a bronchoscopy simulator than doctors with less or no experience. Residents who had been trained to a certified level of competency on a laparoscopic simulator performed their first actual surgery with fewer errors, and caused fewer injuries, than a control group of residents without simulator training.

A primary factor motivating programs to search for new, more efficient surgical training methods is a 2003 ACGME-mandated reduction in residents’ work hours to a maximum of 80 hours per week. Although these changes threaten the amount of time residents have to practice surgical skills, it does not necessarily follow that their competency will decrease. Some practice is more effective at increasing skills than others, so the number of hours of practice may not be the most reliable measure of skill acquisition. To borrow a sports analogy, a baseball player comes up to bat three to four times a game. During each at-bat, the player sees an average of four pitches. This means in a game that averages nearly three hours, a batter sees roughly 12-16 pitches. There are simply not enough in-game hours to reach the expert batting level. In a batting cage a player can hit 50 balls in five minutes, the equivalent of playing four consecutive games. Simulation could supplement apprenticeship training by enabling residents to effectively practice more in less time.

**The High Cost of Resident Training in an Apprenticeship Model**

The apprenticeship model is the epitome of “hands-on, real world” training, but it comes at a cost. Any increased time in the operating room is expensive, a cost which is passed to the patient and the health care system. Bridges and Diamond compared operating times in general, pediatric, vascular, plastic, urologic, and trauma surgery procedures where residents were present to those with no residents in attendance. In their four-year study, operations with residents took a net duration of 12.64 minutes longer on average, from the first incision to leaving the room. Over a total of four years, the lost time was approximately 11,184 minutes per resident. In orthopaedics, a study of ACL reconstruction noted an average increased cost of $661.85 due to longer operative time when a resident completed the surgery compared to a faculty surgeon.

Thus, the extra cost of resident training in the operating room further justifies the expense of simulation training. Simulation training before entering the operating room significantly decreases operation time. Thus, simulation has the potential to decrease the cost of training. In order to realize these potential cost savings, the simulation must represent the skills to be trained well enough that training on simulators will reliably improve performance.
Developing and Validating Surgical Simulators

Building an effective simulator requires the designer to understand both the simulated task and the underlying skills required for the effective task execution. This requires an assessment of the procedure and its constituent tasks. Some surgical tasks are common among different procedures. Other tasks are unique to a particular surgery or situation. Some skills are applicable to many tasks. Other skills are task-specific. There may always be skills that need to be learned in the operating room, but many skills can and should be acquired elsewhere. Often, the initial acquisition of a surgical skill depends on developing the necessary psychomotor skills. Psychomotor skill is the coordination between the physical movement of the trainee and their cognitive processes. Psychomotor skills effectively develop through deliberate practice and structured training.

Kneebone proposed the following criteria for critically evaluating a new or existing simulation:

- Simulations should allow for sustained, deliberate practice within a safe environment, ensuring that newly acquired skills are consolidated within a defined curriculum that assures regular reinforcement.
- Simulations should provide access to expert tutors when appropriate, ensuring that such support fades when it is no longer needed.
- Simulations should map onto real clinical experience, so that learning supports the experience gained within communities of practice.
- Simulation-based learning environments should provide a supportive, motivational, and learner-centered milieu that is conducive to learning.

Physical and virtual reality surgical simulators, alone or in tandem, have proven themselves as viable training platforms. Physical simulators range in sophistication from low-fidelity representations of a prescribed task, such as laparoscopic suturing, to very realistic, instrumented mannequins. Some simulators are task trainers. These are designed to teach a solitary task in a procedure through repetition. Other simulators are full procedural trainers. These are designed to replicate the entire scope of a complex scenario, such as a surgical procedure.

Some virtual reality surgical simulations involve haptic force-feedback (Fig. 2). This is useful when the targeted technical skill includes both tactile force-feedback and eye-hand coordination, such as fluoroscopic wire navigation. When forces do not play an important role, basic eye-hand coordination may be trained without force feedback.

Figure 2. Haptic force-feedback shown in orthopaedic drilling simulation. (Left) Tsai and Tsai, (middle) Froelich, et al., and (right) Vankipuram, et al., each used with permission.

The determination of a simulator’s psychometric properties (i.e., its reliability and validity) is one of the most important facets in the development of a simulator. Reliability refers to the degree of consistency or reproducibility with which an instrument measures what it is intended to measure. If something cannot be measured reliably, then the question of validity is rendered largely moot. The concept of validity addresses the question of whether the measurements obtained from the simulator vary with the educational construct the simulator is intended to measure. The most common categories of validity found in the medical simulation realm include face, content, construct, concurrent, and predictive validity. Each type of validity should ideally be defined within the context of the particular assessment.

Ultimately, a new simulator should pass multiple validity tests in order to be considered for skills training and competency assessment. Face validity addresses the question, “To what extent does the platform simulate what it is supposed to simulate, e.g., the surgical procedure?” It refers to the subjective opinion about a test – its appropriateness for the intended use within the target population. Face validity is important for a test’s practical utility and success of implementation, particularly with respect to whether or not trainees will accept the simulation as a valid educational tool. Face validity is usually assessed with expert responses to questionnaires or surveys.

Content validity addresses the question, “Does the simulation measure the relevant dimensions of the task under study?” Content validity is often assessed with a thorough search of the literature and by interviewing expert surgeons. Face and content validity are subjective and arguably not as rigorous as some other assessments of a simulator’s validity.

Construct validity defines the extent to which the simulator measures the specific trait or traits that it was designed to measure. Many construct validity studies demonstrate that different learner skill levels are associated with variations in the measurements made by the simulator. Demonstrating a significant difference in expert and novice scores demonstrates that the simulator correctly identifies quantifiable aspects of surgical skill.

Concurrent validity measures the extent to which the simulator agrees with an existing performance measure of a surgical task or procedure. The concurrent validity
of surgical simulators is often assessed by comparing simulator scores with the Objective Structured Assessment of Technical Skill (OSATS) or against another, previously validated, simulator. It is frequently difficult and often impossible to assess transfer of learning when attempting to validate educational simulation technology. The most convincing evidence is provided when researchers can correlate performance on the simulator with real world performance. With appropriate estimates of reliability of both the simulation measure and the measure obtained from actual practice, a correct correlation can provide a ‘true score’ correlation between the constructs measured by the two assessments.

Validity is not a binary determination, but reflects a gradual judgment, depending on the purpose of the measurement and the proper interpretation of the results. A single instrument may be used for many different purposes, and resulting scores may be more valid for one purpose than for another. This means that validity statements based on the evaluation of one task can be, and probably will be, different than those based on another task. Indeed, it is fundamental for creating a useful simulator-based teaching environment to recognize that a surgical procedure has to be divided into a series of steps that can be trained and measured separately.

A validated simulator can address the lack of opportunities for deliberate practice in surgical training. It will also provide residents with immediate skill feedback, an indispensable component of deliberate practice and the development of expertise. Residents need carefully devised educational variations providing incremental challenges to improve their surgical skills. The apprenticeship model struggles to control the real world challenges faced by the residents, and feedback requires time and attention from busy staff surgeons. Simulators can provide real-time feedback and instruction outside the operating room.

**Simulator Fidelity, Complexity, and Transfer of Skill to the Operating Room**

Training simulators recreate aspects of reality. The degree of verisimilitude affects the cost, time, complexity, and technology required in development. The current trend in simulation is to strive towards building the highest fidelity simulator possible. Unfortunately, in trying to mimic minute details, these ultra-realistic simulators occasionally include irrelevant tasks.

The complement to physical fidelity is psychological fidelity. Caird defines psychological fidelity as “the degree that a simulation produces the sensory and cognitive processes within the trainee as they might occur in operational theaters.” It is important to note that physical fidelity and psychological fidelity are not mutually exclusive. In some cases, they have synergistic effects. In many other cases, higher physical fidelity simulators produce little to no quantifiable benefit in training over lower physical fidelity simulators.

Skill transfer from the simulator to real scenarios should be the pinnacle of all training simulator development goals. Skill transfer is much more closely tied to psychological fidelity than to physical fidelity. A simulator’s psychological fidelity with a task is more difficult to assess than its physical fidelity. The designer must distill the essential task elements that must be supported in the simulated environment. If the correct elements are distilled, training on a simulator will transfer to the real task environment.

Each simulator presumes that some perceptual cues are important and others may be ignored. The designer’s insightful selection of the correct cues is tightly coupled to the success of the training transfer to the real environment and to the cost and complexity of the simulator. A simulator in orthopaedics must make simple, explicit assumptions about what is important in the task it represents: the relative position of the hand, tool and bone; the obfuscation of the direct view of the bone; the accurate haptic sensation of the task; and the presentation of the basic bone and tool geometry in the simulated environment.

**Simulation in the Training and Assessment of Orthopaedic Surgeons**

Orthopaedic surgery has lagged behind other surgical disciplines in developing and incorporating simulation of surgical skills into education and assessment paradigms, particularly in comparison with laparoscopic surgery, a leader in the simulation field. Previous simulation in orthopaedics has mostly emphasized learning anatomy and surgical approaches on cadavers, and placing products supplied by the medical device industry on naked surrogate bone specimens. Models for surgical skills training outside the operating room have been implemented in a few orthopaedic sub-specialties, primarily arthroscopy and hand surgery. Thus, it is difficult to build on previously established simulators that demonstrate which perceptual cues are essential to orthopaedic surgery.

A 2010 review of virtual reality simulators for orthopaedic surgery found only 23 articles that dealt with specific simulators, compared with 246 citations for laparoscopic simulators. Most of the other recent contributions to orthopaedic simulation technology have emphasized haptic feedback. Several such systems have been built to simulate drilling, and to simulate the forces in amputation surgery. Other simulators emphasizing 3D graphics over haptics have enjoyed some success. Blyth and co-workers have developed a highly idealized virtual reality training system (Fig. 3) for basic hip fracture fixation, including a surgical simulator and an assessment component.
Unfortunately, few of these orthopaedic simulators have yet been rigorously evaluated. In a recent literature review, Schaefer et al. identified three critical evaluative aspects of simulation in healthcare education: (1) the validity and reliability of the simulator; (2) the quality of the performance measures used to assess learning outcomes; and (3) the level of inquiry of strength of educational study design to support the evolution of theoretical perspectives. Of 4189 simulation articles reviewed, only 221 qualified as having adequate study design, only 51 meaningfully evaluated their simulators, and only 39 documented significant translational outcomes. Less than 30% examined their simulator’s validity, typically assessing only face and content validity, the two most subjective validation methods.

Because simulation is increasingly being contemplated for use in high-stakes evaluation-related licensure and certification, and for identifying mechanisms to mitigate error and decrease mortality and morbidity, it is essential that data supporting the validity and reliability of simulators be vigorously pursued. When a performance assessment is conducted with a simulator, the validity and reliability of the assessment can be evaluated independently from that of the training. This allows the scoring procedure to be separated from the simulator designs, and therefore increases the generality of the work. Performance assessment validity evaluations are made with respect to the performance characteristics of the trainee, rather than with respect to the simulator. For example, simulator researchers typically assess the construct validity of a performance assessment by determining whether or not the assessment measures a performance difference between experts and novices.

Program directors and orthopaedic faculty assess orthopaedic residents using methods mandated by the Accreditation Council for Graduate Medical Education (ACGME). For procedural skills the ACGME requires residents to document surgical experience using a web-based case log system. The Residency Review Committee in orthopaedic surgery uses these case logs to assess the overall experience of residents in terms of the numbers of procedures performed. However, case logs consist only of resident self-reported participation in cases and do not specifically assess the demonstration of actual skill or competency.

Orthopaedic residents are but one group whose competency in this area needs to be assessed. The most important and widely accepted method to assess competence of orthopaedic surgeons in practice is through Board Certification. The American Board of Orthopaedic Surgery (ABOS) mandates recertification every ten years, and it has recently adopted an evolving program of more continuous maintenance of certification. This ongoing process of board certification assesses orthopaedists’ competency in medical knowledge, professionalism, communication, and judgment. However, the assessment of a candidate’s surgical skill is indirect, relying on radiographic review and case discussion rather than a direct measure of procedural skill.

High-fidelity simulations may be too expensive for implementation within orthopaedic surgery certification, but many of the foundational skills could be economically implemented as part of an objective structured clinical examination. For example, once the relationship between foundational skills and performance in high-fidelity environments is established, it becomes possible to test such skills as part of competency-based assessment. Moreover, to the degree that there is an aptitude aspect to skills, skills-testing may also be an important tool for resident applicant selection.

Education in general surgery has adopted surgical simulation into a robust curriculum that has been widely adopted into general surgery Graduate Medical Education programs. Residents progress through three phases that are divided into a series of modules. The Residency Review Committee in general surgery
highly recommends that this curriculum be adopted by general surgery training programs. The American Board of Surgery requires passing the Fundamentals of Laparoscopic Surgery program as a basic skills competency for their certification and recertification programs in general surgery. There is no fundamental barrier preventing orthopaedics from adopting similar practices, except for the lack of validated surgical simulation training and assessment approaches.

Recommendations for Future Research

Simulation has a great potential to facilitate faster and more effective learning in orthopaedic surgery. In order to capture the benefits of this training, it is important that researchers and practitioners organize their efforts to gain the maximum advantage in the shortest time with the least cost. This summary of research reveals a number of opportunities for growth in the future of orthopaedic surgery simulation.

Residents need opportunities for regular, deliberate practice. Simulators should be designed so that residents can exercise their surgical skills at regular intervals, with clear feedback. Some skills may require dozens of repetitions while others require hundreds, but one or two repetitions with cadaver parts or plastic models is likely insufficient for complex skills requiring the development of specific psycho-motor behaviors.

Training opportunities for many surgical skills should be repeated in simulation until many of the underlying skills are at a level of automaticity for the residents. In fact, if an effective and valid simulator can be developed for a surgical skill at a reasonable cost, that skill should be simulated.

Orthopaedic surgery simulation should extend beyond the needs of first-year residents to later years of training. The performance of general practitioners in the area of orthopaedic surgery is likely to plateau or even diminish over time without opportunities for deliberate practice. Simulators should be developed to facilitate the assessment and improvement of their skills.

Research should provide a greater emphasis on validity studies that go beyond establishing simple face validity. They should specify and, ideally, benchmark the performance of simulator elements designed to replicate critical tasks and they should design performance measures that can be tied back to the task model.

Research is also needed to further understand what specific skills are needed for orthopaedic surgery, how they are currently trained, and how effective the current approaches are. Work on new simulators should specifically describe the training and assessment procedure that is used with the simulator.

Finally, we would caution researchers to focus their simulator development on key task elements and psychological fidelity rather than focusing on the realism of the simulation.

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ABSTRACT

Background: The physical demands and high rates of musculoskeletal injury among practicing orthopaedic surgeons have been previously recognized in the literature. However, there is a paucity of data regarding musculoskeletal symptoms among resident orthopaedic surgeons. We sought to answer the following questions: (1) are there significant levels of musculoskeletal symptoms among resident orthopaedic surgeons?; (2) do residents attribute these symptoms to their work as surgeons?; and (3) is our survey instrument reliable enough for use in future investigations?

Methods: We developed an online, cross-sectional survey based on the previously validated Nordic Musculoskeletal Questionnaire and distributed it to 39 resident orthopaedic surgeons at our institution in 2011, with 82% responding. Fifteen participants repeated the survey to assess agreement and reliability between repeated administrations of the survey.

Results: Significant levels of musculoskeletal symptoms were found in the resident surgeons, with the most common self-reported symptoms reported in the neck (59%), lower back (55%), upper back (35%), and shoulders (34%). Large proportions of these symptoms were self-reportedly attributed to the residents’ work as a surgeon. Intrarater reliability revealed moderate to almost perfect agreement in nearly all repeated survey items.

Conclusions: Given that there are similar rates of musculoskeletal symptoms among our resident orthopedists and practicing orthopedists, more attention needs to be paid to the ergonomic and physical environments in which we are training the next generation of surgeons, especially when considering the extensive societal investment in training for these specialists.

INTRODUCTION

Orthopaedic surgeons are exposed to a particularly hazardous day-to-day working environment with risks of exposure to infection, radiation, smoke, chemicals, excessive noise, emotional and physiological disturbances, and musculoskeletal injuries. When the primary focus is appropriately placed on the patient, it is easy to overlook these very real physical threats. In 1995, Mirbod found higher rates of subjective physical injuries in orthopedists as compared to general surgeons, with the most commonly injured areas reported as the back, neck, shoulders, arms, and hands. In 2011, Auerbach and colleagues conducted a survey of spine surgeons and reported a similarly high incidence of low-back, neck, shoulder, wrist, and hand pain. Additionally, Auerbach found that the incidence of cervical and lumbar disk herniation with radiculopathy, lateral epicondyritis, and carpal tunnel syndrome was higher in those surveyed than in the general population. Barbar-Craig and colleagues found that 72% of Ear Nose and Throat (ENT) surgeons in the United Kingdom (UK) have either back pain or neck pain and that 53% attributed their symptoms directly to their work as a surgeon. The literature has also found a high prevalence of back and neck pain among ophthalmologists; Sivak-Callcott identified that the use of loupes and headlamps were potentially contributing sources of pain. A 2004 survey conducted by Esser and colleagues found 16 of 17 Mayo Clinic surgeons performing Mohs surgery had musculoskeletal symptoms caused by or made worse by performing surgery, with the most common complaints being stiffness in the neck, shoulders, and lower back.

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Ethical Review Committee Statement: As a symptom survey, this study was approved for committee review exemption by the University of Minnesota Institutional Review Board.
Orthopaedic surgeons spend much of their working hours in ergonomically challenging postures. These awkward postures have been identified as risk factors for musculoskeletal injury in the dental profession. Similar flexed neck and elevated arm positions are required to perform surgery, with additional extremes of motion, contorted body positioning, and prolonged standing seen in surgeons. Given the extensive societal investment in medical school, residency, and fellowship training, the societal costs for injury to surgeons is immense. Despite this, to date, there is a paucity of data on the rates of musculoskeletal symptoms among resident orthopaedic surgeons. Furthermore no reliable means to assess and track these data exists. This is required in order to plan or follow the results of ergonomic education programs.

We sought to answer the following questions: (1) are there significant levels of musculoskeletal symptoms among resident orthopaedic surgeons?; (2) do residents attribute these symptoms to their work as surgeons?; and (3) is our survey instrument reliable enough for use in future investigations?

**METHODS**

**Subjects**

As a sample of convenience, the study population consisted of all 39 orthopaedic surgery residents at our institution for the 2011-2012 academic year.

**Questionnaire**

This study was approved for committee review exemption by our Institutional Review Board (IRB). We developed an online, web-based, cross-sectional survey adapted from the previously validated Nordic Musculoskeletal Questionnaire (NMQ) using an online survey generator. The survey included two main sections: demographics and symptoms by body part as guided by the NMQ and figure (Figure 1). The first page of the survey was an informed consent page, as required by our IRB. Demographics collected included gender, age, height, weight, postgraduate year, average hours in the operating room per week, handedness, most commonly used eyewear, and most commonly employed operating position.

The symptom portion of the questionnaire inquired about the nine different anatomic regions used in the NMQ: neck, shoulders, elbows, wrists/hands, upper back, lower back, hips/thighs, knees and ankles/feet. The survey skipped to the next region if a respondent indicated no issues with a particular body region. If they answered positively, however, further questions followed. These included questions about interference with work over the last year, difficulties over the last week, and characterization of the difficulty (pain, stiffness, weakness, paresthesia, or other), severity (mild, moderate, or severe), whether the symptoms stopped the resident from operating, and whether the resident attributed their symptoms to their work as a surgeon. The first three questions for each anatomic region were directly used from the NMQ. This study was conducted electronically between October 2011 and January 2012, with a total of three contacts (two reminders) made resulting in an 82% response rate (32 of 39 residents responding). Additionally, the online survey was able to track the amount of time required to complete the survey. Of note, one participant did not finish the entire survey and stopped after the elbow line of questioning. Seeing as this participant completed the demographics section and provided valid responses for the first three anatomic regions (neck, shoulders, and elbows) the decision was made to keep his data and calculate all survey percentages as valid percentages, that is, the percentage of participants who completed each question.

![Figure 1. The Nordic Musculoskeletal Questionnaire figure used in the online survey to guide symptom questions. Figure used with permission.](image-url)
Agreement analysis

Fifteen volunteer participants repeated the survey approximately four weeks later to assess agreement and reliability between repeated administrations of the survey. The kappa statistic (k) was chosen to analyze test-retest agreement between repeated administrations of the survey. The percent observed agreement between repeated survey items (P0) and the kappa statistic (k) were calculated for each survey item. The statistics were then stratified and compiled by question type and reported for each type of question.

RESULTS

The characteristics and demographic data of our study population are summarized in Table 1. The results of the survey were stratified and are shown in Table 2 as the number and valid percentage of participants responding positively (valid percentage excludes non-issued questions given the streamlined nature of the survey). The prevalence rates by anatomic region for the group are demonstrated in Figure 2. The most common symptoms were in the neck (59%, 19/32), lower back (55%, 17/31), upper back (35%, 11/31), and shoulders (34%, 11/32). The most common complaints were characterized as pain and stiffness in the neck and lower back, followed closely by pain and stiffness in the upper back and shoulders. The valid percentages of symptom characterization by anatomic region are displayed in Table 1. Other symptoms from free text responses included: “aching” and “swelling”. The impact on work was found to be quite variable among subjective complaints and is displayed in Table 2. Overall, 4/39 residents indicated that they have had to stop operating because of neck (2), hand (1), or thigh (1) difficulties. Lastly, the symptom severity was predominantly reported as mild with increasingly

TABLE 1: Subject Characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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<tbody>
<tr>
<td>Number of Participants</td>
<td>32</td>
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<tr>
<td>Men</td>
<td>24</td>
</tr>
<tr>
<td>Women</td>
<td>8</td>
</tr>
<tr>
<td>Age (years)</td>
<td>29.5 ± 2.5</td>
</tr>
<tr>
<td>Year in residency</td>
<td>2.9 ± 1.5</td>
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<tr>
<td>Height (inches)</td>
<td>70.1 ± 3.6</td>
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<tr>
<td>Weight (pounds)</td>
<td>170.8 ± 31.7</td>
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<tr>
<td>BMI</td>
<td>24.3 ± 3.3</td>
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<tr>
<td>Time spent operating per week (hours)</td>
<td>33.8 ± 17.0</td>
</tr>
<tr>
<td>Operating Position</td>
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</tr>
<tr>
<td>Standing</td>
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<tr>
<td>Sitting</td>
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<tr>
<td>Corrective eyewear/magnification</td>
<td></td>
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<tr>
<td>None</td>
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<tr>
<td>Glasses</td>
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</tr>
<tr>
<td>Contacts</td>
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</tr>
<tr>
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<td>Left</td>
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</tr>
<tr>
<td>Time taken to complete survey</td>
<td>00:04:44 ± 00:02:40</td>
</tr>
</tbody>
</table>

[Data are reported as number or mean ± SD]
Musculoskeletal Pain in Resident Orthopaedic Surgeons: Results of a Novel Survey

reported moderate symptoms lower in the body with highest rates of moderate symptoms in the knees, hips/thighs, and ankles/feet.

Of the subjective complaints, large proportions of these symptoms were attributed by the residents to their work as a surgeon, with 84% of neck, 91% of upper back, 35% of lower back, and 64% of shoulder symptoms being attributed to their work (Figure 3). For those that were unsure, free text responses included: “my work as a surgeon contributes, but may not be the only thing,” “not enough time in surgery to correlate my pain directly with surgery,” “I get stiff while standing in one place for an extended period of time with lead on,” and “not as an initial cause, but work does aggravate my previous injury.”

The calculated kappa statistic for each repeated type of survey question was positive, indicating the presence of agreement between repeated administrations of the survey across all compiled question types. Using the benchmarks proposed by Landis and Koch\textsuperscript{14}, moderate to almost perfect agreement (k > 0.4) was shown in nearly all repeated survey items (Table 3). The only compiled values that were calculated to show poor to fair agreement (k < 0.4) were: have you had trouble at any time during the last seven days and in characterizing symptoms as pain. Kappa values were undefined for two of the compiled questions due to an initial prevalence or retest prevalence of zero.

TABLE 2: Symptom Data Generated from Survey Responses

<table>
<thead>
<tr>
<th>Question</th>
<th>Neck n (valid %)</th>
<th>Shoulders n (valid %)</th>
<th>Elbows n (valid %)</th>
<th>Wrist/Hands n (valid %)</th>
<th>Upper Back n (valid %)</th>
<th>Lower Back n (valid %)</th>
<th>Hips/Thighs n (valid %)</th>
<th>Knees n (valid %)</th>
<th>Ankles/Feet n (valid %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you at any time during the last 12 months had trouble (ache, pain, discomfort) in your…?</td>
<td>19 (59.4)</td>
<td>11 (34.4)</td>
<td>1 (3.1)</td>
<td>6 (19.4)</td>
<td>11 (35.5)</td>
<td>17 (54.8)</td>
<td>3 (9.7)</td>
<td>7 (22.6)</td>
<td>7 (22.6)</td>
</tr>
<tr>
<td>Have you at any time during the last 12 months been prevented from doing your normal work (at home or away from home) because of your symptoms?</td>
<td>3 (15.8)</td>
<td>1 (9.1)</td>
<td>1 (16.7)</td>
<td>2 (18.2)</td>
<td>2 (11.8)</td>
<td>1 (33.3)</td>
<td>1 (14.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you had trouble at any time during the last 7 days?</td>
<td>8 (42.1)</td>
<td>7 (63.6)</td>
<td>1 (100)</td>
<td>5 (45.5)</td>
<td>6 (35.3)</td>
<td>3 (100.0)</td>
<td>5 (71.4)</td>
<td>5 (71.4)</td>
<td></td>
</tr>
<tr>
<td>Symptom characterization:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>15 (78.9)</td>
<td>10 (90.9)</td>
<td>6 (100.0)</td>
<td>10 (90.9)</td>
<td>11 (76.5)</td>
<td>2 (66.7)</td>
<td>7 (100.0)</td>
<td>5 (71.4)</td>
<td></td>
</tr>
<tr>
<td>Stiffness</td>
<td>14 (73.7)</td>
<td>6 (54.5)</td>
<td>2 (33.3)</td>
<td>8 (72.7)</td>
<td>10 (58.5)</td>
<td>1 (33.3)</td>
<td>2 (28.6)</td>
<td>1 (14.3)</td>
<td></td>
</tr>
<tr>
<td>Weakness</td>
<td>1 (5.3)</td>
<td>1 (9.1)</td>
<td>2 (33.3)</td>
<td>1 (14.3)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paresthesia</td>
<td>1 (100)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td>1 (5.9)</td>
<td>2 (28.6)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>15 (78.9)</td>
<td>9 (81.8)</td>
<td>1 (100)</td>
<td>5 (83.3)</td>
<td>9 (81.8)</td>
<td>13 (76.5)</td>
<td>2 (66.7)</td>
<td>4 (57.1)</td>
<td>5 (71.4)</td>
</tr>
<tr>
<td>Moderate</td>
<td>3 (15.8)</td>
<td>2 (18.2)</td>
<td>1 (16.7)</td>
<td>2 (18.2)</td>
<td>4 (23.5)</td>
<td>1 (33.3)</td>
<td>3 (42.9)</td>
<td>2 (28.6)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>1 (5.3)</td>
<td>1 (16.7)</td>
<td>1 (33.3)</td>
<td>1 (33.3)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td>14 (20.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had to stop operating as a result of your symptoms?</td>
<td>2 (10.5)</td>
<td>1 (16.7)</td>
<td>1 (33.3)</td>
<td>1 (33.3)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td>14 (20.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever lost time from work due to symptoms?</td>
<td>1 (5.3)</td>
<td></td>
<td>1 (33.3)</td>
<td></td>
<td></td>
<td></td>
<td>14 (20.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time lost (in days):</td>
<td>1</td>
<td></td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td>14 (20.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you attribute your symptoms to your work as a surgeon?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (84.2)</td>
<td>7 (63.6)</td>
<td>3 (50.0)</td>
<td>10 (90.9)</td>
<td>6 (35.3)</td>
<td>2 (28.6)</td>
<td>7 (100.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1 (5.3)</td>
<td>3 (27.3)</td>
<td>1 (100)</td>
<td>3 (50.0)</td>
<td>1 (9.1)</td>
<td>10 (58.8)</td>
<td>3 (100.0)</td>
<td>3 (42.9)</td>
<td></td>
</tr>
<tr>
<td>Unsure</td>
<td>2 (10.5)</td>
<td>1 (9.1)</td>
<td></td>
<td>1 (5.9)</td>
<td>2 (28.6)</td>
<td>1 (5.9)</td>
<td>1 (14.3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

The physical demands and high rates of musculoskeletal injury among practicing orthopaedic surgeons have been previously recognized in the literature. This study identifies that musculoskeletal symptoms are similarly high in resident orthopaedic surgeons and that these symptoms were primarily attributed by the subjects to their work as a surgeon. In addition, this study identifies this survey instrument to be reliable for potential use in future investigations. The items with less than acceptable agreement were those where true change would be expected over the timeframe of retesting.

The study has several limitations. First, our sample may not be representative of other residency programs. Our study contains a relatively small sample size of 39 residents at one institution. While small, the high participation rate in this study (82%) reduces bias toward response by only those experiencing symptoms. Another limitation is the self-reported nature of the data which is consistent with all surveys. While subjective reports are not alone diagnostic of musculoskeletal pathology, subjective complaints remain the most common manifestation of musculoskeletal occupational injury. Occupational research has commonly used the prevalence of subjective symptoms to assess musculoskeletal disorders within a given population.

Significant levels of musculoskeletal symptoms were found in our resident surgeons, with the most frequently encountered symptoms reported in the lower back (54.8%), neck (59.4%), shoulders (34.4%), and upper back (35.5%). Furthermore, our survey results are comparable to previously documented rates of musculoskeletal injury among practicing orthopaedic surgeons.

<table>
<thead>
<tr>
<th>Question</th>
<th>Neck (Po)</th>
<th>Shoulders (Po)</th>
<th>Elbows (Po)</th>
<th>Wrists/Hands (Po)</th>
<th>Upper Back (Po)</th>
<th>Lower Back (Po)</th>
<th>Hips/Thighs (Po)</th>
<th>Knees (Po)</th>
<th>Ankles/Feet (Po)</th>
<th>Compiled (Po)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you at any time during the last 12 months had trouble (ache, pain, discomfort) in your?</td>
<td>0.842 (0.933)</td>
<td>0.602 (0.800)</td>
<td>1.0 (1.0)</td>
<td>0.815 (0.933)</td>
<td>0.842 (0.933)</td>
<td>0.737 (0.867)</td>
<td>1.0 (1.0)</td>
<td>1.0 (1.0)</td>
<td>0.634 (0.933)</td>
<td>0.839 (0.933)</td>
</tr>
<tr>
<td>Have you at any time during the last 12 months been prevented from doing your normal work (at home or away from home) because of your symptoms?</td>
<td>* (0.900)</td>
<td>1.0 (1.0)</td>
<td>0.400 (0.667)</td>
<td>1.0 (1.0)</td>
<td>* (0.857)</td>
<td>1.0 (1.0)</td>
<td>1.0 (1.0)</td>
<td>1.0 (1.0)</td>
<td>0.618 (0.914)</td>
<td></td>
</tr>
<tr>
<td>Have you had trouble at any time during the last 7 days?</td>
<td>0.194 (0.500)</td>
<td>0.333 (0.667)</td>
<td>0.400 (0.667)</td>
<td>* (0.75)</td>
<td>-0.077 (0.429)</td>
<td>1.0 (1.0)</td>
<td>-0.800 (0)</td>
<td>* (0)</td>
<td>0.007 (0.514)</td>
<td></td>
</tr>
</tbody>
</table>

Symptom characterization:

- Pain
  - * (0.800) | 1.0 (1.0) | 1.0 (1.0) | * (0.75) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 0.356 (0.914)

- Stiffness
  - * (0.800) | 0.250 (0.667) | * (0.333) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 0.400 (0.667) | 1.0 (1.0) | 0.505 (0.800)

- Weakness
  - * (0.800) | * (0.833) | 1.0 (1.0) | 1.0 (1.0) | * (0.857) | 1.0 (1.0) | * (0.667) | 1.0 (1.0) | * (0.888)

- Paresthesia
  - 1.0 (1.0) | 1.0 (1.0) | 0.400 (0.667) | 1.0 (1.0) | * (0.857) | 1.0 (1.0) | 1.0 (1.0) | 0.635 (0.943)

- Other
  - * (0.9) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | * (0.971)

- Symptom severity (mild vs. moderate vs. severe)
  - 0.348 (0.700) | 0 (0.5) | 1.0 (1.0) | 0.500 (0.75) | 0.696 (0.857) | 1.0 (1.0) | 0.400 (0.667) | 1.0 (1.0) | 0.460 (0.743)

- Have you ever had to stop operating as a result of your symptoms? | 1.0 (1.0) | * (0.833) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 0.785 (0.971)

- Have you ever lost time from work due to symptoms? | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0) | 1.0 (1.0)

- Do you attribute your symptoms to your work as a surgeon? (yes vs. no vs. unsure)
  - 0.615 (0.800) | 0.739 (0.833) | 1.0 (1.0) | 0.500 (0.75) | * (0.571) | 1.0 (1.0) | 0.400 (0.667) | 1.0 (1.0) | 0.651 (0.771)

* Kappa statistic (measure of test-retest agreement between repeated administrations of the survey). Po Percent observed agreement between repeated administrations of the survey. †Compiled statistics across anatomic regions by question type. *Kappa statistic undefined due to an initial prevalence or retest prevalence of zero.
complaints in similar populations. Mirbod reported the prevalence of subjective complaints among practicing orthopedists highest in the lower back (50.0%), neck (38.9%), shoulders (31.5%), and upper back (24.1%). Auerbach found similar rates in practicing spine surgeons: lower back (62.2%), neck (59.4%), and shoulders (48.5%). Given that our study population are in the very early stages of their careers and are relatively young, these reportedly high rates of musculoskeletal pain are a concerning finding.

The residents attributed a large proportion of their somatic findings to their work as a surgeon. Specifically, 84% of neck, 91% of upper back, 35% of lower back, and 64% of shoulder symptoms were directly attributed to their work. Comparatively, Barbar-Craig and colleagues found that 53% of ENT surgeons in the UK attributed their back and neck pain symptoms directly to their work as a surgeon. Our survey also looked at the impact that these symptoms have had on the normal work of our residents and on their ability to operate. Even in this relatively young cohort, over 10% of our respondents had missed time in the operating room because of their musculoskeletal difficulties. This raises concern about the long-term consequences of these early symptoms.

Our survey is a reliable instrument to gauge the prevalence of musculoskeletal complaints among surgeons. It is based on a previously validated survey and is adapted into an easy to use, and streamlined, online format. The only items from our survey that had poor to fair agreement between repeated administrations of the survey were items that one would expect to fluctuate over the course of a four-week period of time (i.e., findings in the last seven days). Furthermore, the survey takes less than five minutes on average to complete, which is acceptable for the busy life of a surgeon.

While there are various physical stresses and hazards applied to physicians in general, orthopaedic surgery is one of the most physically taxing of the medical specialties. Prolonged working hours in ergonomically challenging postures have been identified as risk factors in other professions. The high prevalence of musculoskeletal complaints among our residents could also be due to poor ergonomics in the operating room. While it is hopeful that as these residents advance in their careers they will learn how to operate with more appropriate body positions and to perform their tasks more ergonomically, earlier education in orthopaedic ergonomics may reduce these rates and limit lifetime exposure to hazardous body positions. The general surgery literature is replete with evidence acknowledging that laparoscopic surgery is associated with higher rates of pain and musculoskeletal disorders. Nguyen and colleagues attributed their findings of pain with laparoscopic surgery to the static positions of the neck and trunk and associated frequent movements of the upper extremities. Arthroscopic surgery is no different in this regard, with the additional physical burden of maintaining proper patient extremity position throughout the operation. The intense psychological and emotional challenges of surgical training, coupled with the focus on the safety and health of the patient, and a lack of education regarding surgical ergonomics creates an environment that may contribute to these high rates of body pain.

Our data show that there is a similar incidence of body pain in trainees as in practicing orthopaedic surgeons despite the younger age of trainees. Consequently, we believe more attention needs to be paid to the ergonomic and physical environments in which we are training surgeons, especially when considering the extensive societal investment in medical residency, and fellowship training for these specialists. The ideal time to foster a knowledge and awareness of ergonomics with a focus on the prevention of musculoskeletal injury is in residency. We believe training programs should work towards the adoption of ergonomic education programs in an effort to reduce occupational musculoskeletal injuries. Our survey can be used as a tool to monitor the progress of implemented ergonomics programs and to help decide which of the implemented measures are most beneficial for our future surgeons. Furthermore, programs should be encouraged to track progress objectively, by means of a survey such as ours or by other means to ensure that the changes being made can be defended by evidence.

REFERENCES
LEVEL OF EVIDENCE TRENDS IN THE JOURNAL OF BONE AND JOINT SURGERY, 1980-2010

M. S. Reich, MD, J. Shaw, MD, I. Barrett, MD, V. M. Goldberg, MD, E. Schnaser MD

ABSTRACT

Introduction: The Journal of Bone and Joint Surgery (JBJS-Am) began publishing the level of evidence (LOE) for manuscripts in 2003. From 1975 to 2005 JBJS-Am saw a trend towards higher leveled studies. We aimed to demonstrate trends in the country of origin of manuscripts published in JBJS-Am, and hypothesized that not only were more publications coming from groups outside of North America, but that the studies originating within North America were of higher LOE.

Methods: All articles published in The Journal of Bone and Joint Surgery (American) in 1980, 1985, 1990, 1995, 2000, 2005, and 2010 were independently evaluated by two reviewers and graded based on country, LOE (using the JBJS-Am LOE guidelines), and study type. For articles published after 2003 we used the level and study type published within the manuscript.

Results: The proportion of publications from North America decreased in 2005 and 2010 when compared to the previous 20 years (p=.03), but the overall number of publications appeared stable. Overall, there was an increase in Level I (r=.74, p=.03), Level II (r=.79, p=.02), and Level III (r=.95, p<.001) evidence studies. There was a statistically significant decrease in North American Level IV studies (r=.81, p=.01) and an increase in international Level IV studies (r=.70, p=.04). International groups have increased therapeutic (r=.86, p<.01) and diagnostic studies (r=.93, p<.001). In North America and internationally, prognostic studies have not changed. North American groups have increased economic and decision analysis research (r=.69, p=.04).

Conclusions: Over the past 30 years JBJS-Am has become more internationally diverse. International groups are publishing more therapeutic and diagnostic research than in the past, while North American groups have increased economic and decision analysis research. There has been a global effort towards higher leveled research.

INTRODUCTION

The Journal of Bone and Joint Surgery (JBJS-Am) began publishing the level of evidence (LOE) for manuscripts in 20031, an idea developed in the 1980s by Sackett2. JBJS-Am uses five tier-levels for each of four study content types: therapeutic, prognostic, diagnostic, and economic and decision analysis. LOE is derived from evidence-based medicine, a philosophy which promotes physicians and surgeons acting in the best interest of their patients and making recommendations founded in the best available data3. Publishing the study type and LOE with each manuscript helps the reader understand the quality of the research presented4,5. The JBJS-Am system is easily understandable; epidemiologically trained reviewers can use the system with high reliability and individuals without such training can use it proficiently4,5.

Previous studies have shown greater number of international publications found in major research journals6. In addition, journals such as JBJS-Am saw a trend towards higher leveled studies between 1975 and 20057. In light of seemingly fewer contributions from North America, we questioned if this would be associated with higher LOE studies, particularly since the system was implemented and published in 2003. To our knowledge, no study has previously investigated trends in the country of origin of manuscripts published in JBJS-Am. We hypothesized that a greater number of manuscripts have been published from groups outside of North America, and that the studies originating within North America were of higher LOE.

MATERIALS AND METHODS

Study Design:

Medical Education, Current Concept Reviews, and Instructional Course Lectures were excluded from analysis. The country of origin of each article was recorded. For data analysis, countries were grouped by continent with Australia and New Zealand classified together and multinational studies classified as collaborative projects. Papers published from Canada and the United States were grouped in the North America group with papers from other countries referred to as international. Each article was independently assigned a LOE and study type (therapeutic, prognostic, diagnostic, economic and decision analysis) by two of the authors with the JBJS-Am LOE guidelines (based on the standards of the Centre for Evidence-Based Medicine, Oxford, UK) in hand. Each author was blinded to the other author's reviews. LOE and study type assignments were compared after all articles were reviewed and in situations in which level assignments differed, the two reviewers discussed each article until an agreement was reached. Articles for which agreement could not be reached were reviewed by a third reviewer; a LOE was assigned to four articles based on majority agreement and two articles were discarded due to three different evaluations.

### Statistical Analysis:

Statistics were performed with SPSS (Statistical Packages for the Social Sciences) 18 (International Business Machines, Armonk, NY, USA). The total number of studies were summed by year and separated by LOE and then by geographic location. Pearson's correlation coefficient was calculated by comparing the year to the sum of the variable of interest (LOE and location). A separate analysis was carried out for each LOE category (Level I, II, III, and IV). Pearson's correlation coefficient was calculated with one-tailed statistics as we predicted increasing Level I-III data and decreasing Level IV data. Statistical significance was defined as p<0.05.

### RESULTS

**Geographic Location and Number of Publications**

A total of 1261 articles from the years 1980, 1985, 1990, 1995, 2000, 2005, and 2010 were reviewed. Of these, 821 articles met our inclusion criteria. Thirty-two countries including the United States produced the 821 articles.

The majority of articles, 618/821 (75%), were from North America (Table 1). In 1980, 91% of the publications in the JBJS-Am were from North America (83/91). In 2000, 2005, and 2010, there was a decline in the proportion of publications from North America (Figure 1); the number of publications remained relatively stable. On average, 84% (74-91%) of publications were from North America from 1980 to 2000; in 2005 and 2010, 65% and 57% of the articles were from North America, respectively (p=.03). International contributions increased in 2005 and 2010 with Europe and Asia producing more articles in these years (Table 1, Figure 1).

**Geographic Location and Level of Evidence**

There was greater than 99% agreement between the two different independent raters when comparing the LOE assigned to each article. Due to differing evaluations, six articles were reviewed by a third reviewer; a LOE was assigned to four articles based on majority agreement and two articles were discarded due to three different evaluations.
Overall, there were increases in Level I, II, and III evidence and decreases in Level IV evidence from 1980 to 2010 (Appendices 1-4). Level I evidence increased over the 30-year interval ($r=.74$, $p =.03$). When analyzed by geographic location, there was an increase in Level I studies from international sources ($r=.84$, $p<.01$), but no significant increase in Level I studies from North America ($r=.57$, $p=.09$) (Figure 2). International contributions were largely from Europe and Asia. There was a significant increase in the proportion of Level II ($r=.79$, $p=.02$) and Level III ($r=.95$, $p<.001$) evidence studies from 1980 to 2010 with significant increases in both Level II and III studies in North American (Level II: $r=.75$, $p=.03$; Level III: $r=.84$, $p=.01$) and international publications (Level II: $r=.83$, $p<.01$; Level III: $r=.84$, $p=.01$) (Figures 3 and 4). However, there has been an overall trend towards fewer Level IV studies ($r=-.48$, $p=0.14$). Yet, there has been a significant decrease in Level IV studies from North America ($r=-.81$, $p=.01$), whereas there has been an increase in international Level IV studies ($r=.70$, $p=.04$) (Figure 5).

**Geographic Location and Study Type**

Of the 821 previously included articles, the reviewers reached consensus on study type for all but one article. Of the remaining 820 articles, 590 were therapeutic, 64 were diagnostic, 161 were prognostic, and 5 were economic and decision analyses (Table 2). There has been an increase in international therapeutic ($r=.86$, $p<.01$) and diagnostic ($r=.93$, $p<.001$) publications. Neither North American nor international countries demonstrated changes in prognostic studies. All of the economic and decision analyses we evaluated were from North American groups and they have increased this type of research ($r=.69$, $p=.04$); no economic and decision analyses were published from 1980 to 1995.

**DISCUSSION**

To our knowledge, this is the first study to analyze publication trends in orthopaedic literature with regard to geographic location and LOE. The principle aim of this study was to determine changes in the number and proportion of studies contributed to JBJS-Am by international investigators. Our second goal was to detect changes in the LOE published over the past 30 years.

Our data demonstrates that there has been a significant increase in international contributions and that most of these publications are from Europe and Asia. Interestingly, while the proportion of North American contributions is decreasing, the number remains constant. In a world embracing simpler transfers of knowledge and sharing of ideas, this suggests that rather than shrinking the impact of North American groups in JBJS-Am, research globalization is broadening the research published.
We show that globally there have been more Level I, II, and III studies published and there has been a trend towards decreasing Level IV studies. There are cost and time savings by performing research in developing countries, but since these changes were noted globally, they likely reflect a medical culture emphasizing evidence-based medicine in which investigators are executing more thorough research projects to promote the best possible patient outcomes. It may also reflect JBJS-Am’s position in the orthopaedic literature with a high impact factor, as it was shown that the percentage of Level I or II studies positively correlated with impact factor. As Ombresky et al. noted, achieving a higher LOE could be achieved easily; by adding a control group, a case series could potentially be upgraded to a Level II or III cohort study. However, we cannot comment on the LOE mix of JBJS-Am submissions versus publications.

These trends are also interesting given that the surgeon-patient encounter does not provide an ideal research setting. Treatment studies must be randomized to be Level I but a common obstacle to a randomized controlled trial (RCT) is patient preference for one procedure over another if they are perceived to be unequal in terms of benefit or side-effects. Other barriers include the commonality of the condition being treated surgically, lack of community equipoise, complicated methodologies, and lack of surgical familiarity with all studied treatment alternatives. Surgical RCTs were deemed possible in less than 40% of cases.

In spite of these trends, and a statically significant decrease in Level IV studies from North America, Level IV studies are commonly published in JBJS-Am. With the breadth of orthopaedic knowledge growing at ever-increasing rates, these are often necessary to publicize new findings. A case series can be a well-designed, prospective, study with well-defined inclusion and exclusion criteria, treatment protocols, follow-up intervals, and validated outcomes measures. It can publicize the rare consequences of procedures which cannot be accomplished with randomized and cohort studies; it can also be used to present low prevalence diseases or clinical situations. 2010 marked the first year (using our five-year cohorts) that Level IV studies were not the most prevalent study published. These results lead us to believe that there is a conscious effort to redesign research studies as well as publish higher quality articles.

There may be further explanation for our results. Institutional Review Boards in the US, and comparable committees in European countries, are essential for ensuring the ethical treatment of human subjects in medical research, but also present obstacles to performing clinical research. Economic, educational, and social issues may facilitate research in developing countries, and there are nuances between the rules guiding research within the United States and elsewhere. It is possible that these factors may account for some of our findings.

The greatest strengths of the present study are its thoroughness and completeness. We believe that the publications included in the present study were accurately and reliably assessed for LOE. Studies evaluating reliability demonstrated that epidemiologic training is not necessary to accurately and reliably assess a manuscript’s LOE.

There are limitations to this study. First, we used manuscripts published in five-year cohorts. More specific trends could be obtained by using smaller time intervals. This study could also be conducted using additional orthopaedic journals to determine if these trends persist across the orthopaedic literature as a whole. It is also important to point out that while a higher LOE is a surrogate for higher quality research, it does not always correspond to higher quality research. Prior research has demonstrated substantial variability in the quality of even Level I studies, and that the quality of Level I and Level II work is not statistically significantly different. Further evaluating not only the LOE but the quality of research published would be useful.

The country of origin, LOE, and types of studies published in JBJS-Am have changed over the past 30 years. There have been increases in Level I, II, and III studies; an increase in therapeutic and prognostic studies from abroad; and an increase economic and decision analyses from North America. There are many reasons that may account for these changes, but the ease of information sharing and a motivation to produce higher quality research likely play major roles.
REFERENCES


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<td>61</td>
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<td>47</td>
<td>32</td>
<td>52</td>
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<td>331</td>
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<td><strong>Total</strong></td>
<td>68</td>
<td>76</td>
<td>77</td>
<td>60</td>
<td>49</td>
<td>84</td>
<td>38</td>
<td>452</td>
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PATIENT PERCEPTIONS AND PREFERENCES WHEN CHOOSING AN ORTHOPAEDIC SURGEON

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ABSTRACT

Purpose: Information regarding patient preferences is important to develop more diversity in healthcare providers. To our knowledge, no information exists regarding how patients choose their orthopaedic surgeon. The purpose of this study is to determine which demographic factors, if any, affect patient preferences when choosing an orthopaedic surgeon.

Methods: Five hundred new patients presenting to a large, urban, academic orthopaedic clinic from May 2011 to May 2013 were prospectively asked to participate in this study. Patients were asked to complete a survey designed with the help of the Division of Population Health that focused on demographic, professional and physical attributes of theoretical surgeons. Specifically, patient preference of surgeon age, gender, race, religion, importance of education prestige, training program prestige and number of medical publications were evaluated. Patients were then stratified by age, gender, race, religion, educational level and income level to assess whether their own demographics were related to their preferences. The data was then analyzed to determine whether correlations existed between patient preferences and their own demographics.

Results: Five hundred patients agreed to participate in the study. There were 195 (39.0%) males and 281 (56.2%) females with an average age of 40.8 years (SD=20.5), 24 patients (4.8%) did not respond to the question. Two hundred and twelve (42.4%) patients were Caucasian, 116 (23.2%) were Hispanic, 53 (10.6%) were African American, 44 (8.8%) were Asian, 32 (6.4%) were listed as other and 43 (8.6%) did not answer. 78.0% of patients had no preference for their surgeon’s gender, but for those who did, both men and women preferred male surgeons (weak positive correlation, not statistically significant, r=0.096, p=0.373). The majority of patients (84.8%) had no preference for the race of their surgeon, but those that had a preference tended to prefer surgeons of their own ethnicity (p<0.001). With increasing patient education level, medical school, residency and fellowship training prestige had more importance as a selection criterion. Increasing patient education level also demonstrated a corresponding increase in the perception of residency training program prestige (p=0.04). A majority of patients (84.0%) had no preference for their surgeon’s religion, but for those who did there was a strong correlation (r=0.65), between the patients’ own religion and that of the physician (p<0.001). There was universal agreement in perception that neither physician age nor years in practice made any difference as selection criteria when choosing an orthopaedic surgeon (p>0.05). Finally patient income level had no effect on specific criteria when choosing a surgeon.

Conclusion: The vast majority of patients surveyed had no preference in age, gender, race, or religion of their potential surgeon. However, patients who had preferences in these categories tended to choose surgeons of the same age, race and religion. These findings neither support nor refute the need for diverse health care providers in the field of orthopaedics.

Keywords: orthopaedic surgeon, preference, diversity, perception

INTRODUCTION

Diversity within Orthopaedic programs has recently become an increasingly focal concern. According to Gebhardt et al., programs all over the United States consist mainly of Caucasian men. In some cases, this may impair aspects of the quality of orthopaedic care and hinder the development of positive physician-patient relationships. It has been shown that physicians from different backgrounds enrich other physicians’ under-
understanding of patients whose cultures are different from their own, and therefore improve their ability to successfully serve heterogeneous populations.

The purpose of this investigation was to identify preferred qualities of an orthopaedic surgeon that patients seek when given an opportunity to select their orthopaedic surgeon. We explored the value placed by patients on physician characteristics: racial background, religious affiliation, spoken language, gender, age, socioeconomic status, and educational status.

**METHODS**

Patients presenting to a large urban, academic medical center general orthopaedic clinic over a 24-month period were prospectively asked to participate in this study. They were given a survey designed with the help of the Division of Population Health from our university. Photographs of ethnically and racially diverse male and female orthopaedic surgeons within our department were used within the survey. With each surgeon, all educational and practice information was provided as a caption beneath the picture. Patients both read the professional information about the provider and were able to visualize that specific provider. The relative age, gender and ethnic background of the provider was inferred from the picture. Within this survey, patient demographic data and information pertaining to educational status and income level was self-reported. For our analysis, participants were given questions regarding specific preferences for a theoretical orthopaedic surgeon. The survey was divided into two sections. The first section focused on the importance of educational prestige (medical school), training program prestige (residency, fellowship) and medical publication amount. The second section focused on how strongly or mildly participants felt about having a surgeon of a certain religious background, race or age group. Once decisions regarding these parameters were made, surgeon religion, race, age, and number of years in practice was specifically asked. Participants’ responses were anonymous, and surveys were labeled only with numbers. Not all questions were answered on every survey. About 44.0% of the surveys were incomplete, however, questions that were not answered were included in the final analysis and categorized as “no answer noted”.

Descriptive statistics were used to report the outcomes of the survey. Subgroup analysis was performed to see if the patient’s own demographic information was associated with their surgeon preference. Spearman’s correlation tests and ANOVA were used to evaluate these relationships in this subgroup of patients. Statistical analysis was performed using Spearman’s rho along with ANOVA to find correlations for preferences among subgroups of patients. Patients who did not report preferences for specific surgeon attributes were excluded from statistical analysis of those attributes. All statistical analyses were performed with SPSS version 19.0 software (SPSS, Inc., Chicago, Illinois) and significance level was set at p < 0.05.

**RESULTS**

Five hundred patients agreed to be enrolled into this study. The demographics of the cohort are described in Table 1. Anticipating that patient preferences might vary as much within, as between, age, gender, and race groups, we decided to focus on relationships between seven different patient and surgeon attributes.

**Race**

The racial distribution in our cohort was Caucasian (42.4%) followed by Hispanic (23.2%), African American (10.6%), Asian (8.8%) and other (6.4%). The majority of patients 424 (84.8%) had no preference for the race of their surgeon. However, a moderate positive correlation (r=0.627, p<0.001) was seen among patients who demonstrated preference to surgeons who were similar in race. This trend was seen amongst patients who indicated a racial preference, preferring surgeons of their own race.

**Gender**

The gender distribution in our cohort was 281 (56.2%) females, 195 (39.0%) males, and 24 (4.8%) who did not answer. The majority of participants, 390 (78.0%), had no preference for the gender of their surgeon. Amongst those with a preference, 14.2% versus 4.0% preferred male or female surgeons, however this was not statistically significant (p=0.373).

**Age**

The average age in our cohort was 40.8 (SD=20.5). The majority of participants, 261 (52.0%), had no preference for the age of their surgeon. However, of those patients with an age preference, a trend was seen demonstrating preference to surgeons who were similar in age (Table 1).

**Religion**

The religious distribution in our cohort was Christian (48.6%) followed by Jewish (14.6%), Agnostic (5.6%),

### Table 1. Preference of surgeon age based on patient age

<table>
<thead>
<tr>
<th>Surgeon Age Preference (Years)</th>
<th>Mean value for Patient's Age (Years)</th>
<th>Number of Patients Participating in this Question</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-40</td>
<td>38.0</td>
<td>35</td>
<td>14.2</td>
</tr>
<tr>
<td>40-50</td>
<td>47.3</td>
<td>133</td>
<td>16.0</td>
</tr>
<tr>
<td>50-60</td>
<td>51.9</td>
<td>42</td>
<td>17.0</td>
</tr>
<tr>
<td>&gt;60</td>
<td>55.3</td>
<td>3</td>
<td>15.3</td>
</tr>
<tr>
<td>No preference</td>
<td>43.6</td>
<td>261</td>
<td>17.3</td>
</tr>
</tbody>
</table>
Table 2. Ranking of medical school, residency and fellowship prestige categorized by patient’s education level

<table>
<thead>
<tr>
<th>Patient Education</th>
<th>Medical School Prestige (scale 1-10)</th>
<th>Residency Prestige (scale 1-10)</th>
<th>Fellowship Prestige (scale 1-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; High School</td>
<td>4.0</td>
<td>4.1</td>
<td>4.2</td>
</tr>
<tr>
<td>High School</td>
<td>4.48</td>
<td>4.8</td>
<td>4.7</td>
</tr>
<tr>
<td>Technical School</td>
<td>4.91</td>
<td>4.7</td>
<td>5.2</td>
</tr>
<tr>
<td>4-year College</td>
<td>4.86</td>
<td>5.4</td>
<td>4.9</td>
</tr>
<tr>
<td>Graduate School</td>
<td>5.34</td>
<td>5.6</td>
<td>5.6</td>
</tr>
</tbody>
</table>

Athen (4.4%), Muslim (3.2%) and other (3.0%); 20.8% did not answer. The majority of participants, 420 (84.0%), had no preference for the religious background of their surgeon. A strong, statistically significant, positive correlation (r=0.65, p<0.001) was seen for those indicating a religious preference, demonstrating preference of surgeons of their own religious background.

Educational Background

Participants were asked to rate on a scale of 1 to 10 (1 being not important at all and 10 being very important) the importance of a given item on choosing their surgeon. The educational background distribution of our cohort was less than high school (8.8%), high school (24.4%), technical school (11.8%), 4-year college (26.2%), and graduate/professional level schooling (20.2%). A positive trend demonstrated that as patient education level increases, more emphasis is placed on the prestige of a surgeon’s medical school, residency, and fellowship (Table 2); however, no significant correlations were seen.

Academic Production

We used number of publications as an estimate of academic production. Participants were asked to rate on a scale of 1 to 10 (1 being not important at all and ten being very important) how important the amount of research articles published by their theoretical surgeon was. The income level distribution of our cohort was less than 50K (45.0%), 50-100K (17.6%), 100-250K (9.0%), greater than 250K (4.2%) and the rest had no answer (24.2%). The trend in mean values of importance showed no significant correlation (Table 3).

Patient Education Level

Participants were asked if they had a preference for their theoretical surgeon’s amount of years of experience, and if so, how many they would prefer. The largest group of participants, 155 (31.0%), preferred 11-20 years in practice, however, the next largest group, 110 (22.0%), had no preference for years of experience. No significant difference or correlation was seen with patient education.

Table 3. Trend in mean values for importance of number of medical publications by treating physician

<table>
<thead>
<tr>
<th>Patient Income</th>
<th>Mean Rating Value of Importance</th>
<th>Number of Patients Participating in this Question</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50K</td>
<td>3.8</td>
<td>215</td>
<td>3.4</td>
</tr>
<tr>
<td>50-100K</td>
<td>4.4</td>
<td>85</td>
<td>3.0</td>
</tr>
<tr>
<td>100-250K</td>
<td>3.8</td>
<td>45</td>
<td>2.9</td>
</tr>
<tr>
<td>&gt;250K</td>
<td>4.6</td>
<td>21</td>
<td>2.7</td>
</tr>
</tbody>
</table>

DISCUSSION

Diversity within the orthopaedic surgeon population has the potential to improve patient care. Studies have shown that patients who identify with their physicians have quicker recovery rates and better adherence. This emphasizes a pertinent question: what can we do to make patients more comfortable with their orthopaedic surgeons?

Although several investigations analyzing patients’ preferences for general practitioners have been done, few studies have considered patients’ preferences for surgeons, and to the best of our knowledge this topic had not been explored in orthopaedic surgery.

We were able to draw several conclusions on patient preferences within our diverse patient population. With regards to patient and physician race, our data showed a majority of patients do not particularly have a preference for their surgeons’ race. However, patients demonstrating a preference for race tend to choose surgeons of a similar ethnic background. According to Simon et al., this is attributed to a sense of comfort patients feel when communicating with someone of a similar racial background. Patients’ experiences with illness and treatment are unique and often influenced by their beliefs, culture, and family; thus, a physician with similar values or those that are sensitive to such values can better care for and treat such patients.

When analyzing patient and surgeon gender, our data showed that most patients do not place emphasis on the gender of their surgeon. Yet, amongst those patients with a preference, both male and female patients preferred male surgeons. Communication is certainly important in determining patient outcomes. Weisman et al. discuss several methods in which physician gender may affect the patient-physician relationship. First, gender differences in nature and attitude may affect the physician-patient interaction: females tend to be more nurturing and sensitive while males are more reserved. Second, physician gender influences patient expectations: female physicians are expected to “sugar-coat” situations while males are expected to be direct. Finally,
same-sex physician patient relationships are presumed to result in greater status equivalence\textsuperscript{10}. However, no definitive conclusions proving these factors affect the patient-physician relationship have been reported. Nonetheless, studies suggesting female patients prefer female physicians have been published; the female patients in these studies were choosing physicians for physical exams or procedures of women-related health issues\textsuperscript{11}. This begs the following question: are patients more comfortable with physician genders stereotyped to certain fields? For example, orthopaedics has traditionally been a male dominated specialty, and the percentage of female orthopaedic surgeons is the smallest of any surgical subspecialty. This observation may lead to the impression that orthopaedic procedures are best suited to male surgeons\textsuperscript{12}. This could potentially explain why both female and male patients in our cohort who had a preference in surgeon gender choose male surgeons. However, more studies must be carried out to investigate this suggestion further.

Our next analysis focused on the relationship between patient and surgeon age. The data showed that most patients had no preference for the age of their surgeon. For those who displayed preference, a non-significant trend was seen demonstrating older patients prefer surgeons similar in age. Jung et al. also saw this trend in a study observing patient preferences for primary care physicians\textsuperscript{13}. In a study looking at age preferences for emergency physicians, the majority of patients preferred physicians in the 30-40 age group; 41-50 was favored next; however the age of the patients were not recorded and therefore no correlation was tested. Overall, 79% of patients favored emergency medicine physicians between 30-50 years of age; 31.4% of our cohort favored orthopaedic surgeons in the 30-50 age group. Studies have regarded these findings to be due to patients’ desire of having a physician with many years of experience who also remains up to date with the current knowledge on newer treatment methods\textsuperscript{14,15}.

When investigating the relationship between patient and surgeon religion, we found the majority of participants had no preference for the religious background of their surgeon. However, a strong positive correlation was seen for patients with a religious preference indicating patients preferred surgeons of their own religious background. No studies regarding this association have been published to our knowledge, however, studies that discuss end-of-life care do show patient preferences for physicians with a spiritual background of any kind\textsuperscript{16}. We propose the positive correlation seen in our data further reflects a patient’s desire for commonality; common religious background may render a physician more apt in understanding values and beliefs heavily influencing the type of care one requires.

A positive correlation was seen between increasing patient educational background and emphasis on prestige of surgeon medical school, residency, and fellowship, however this was not significant. We hypothesize that patients who have achieved higher levels of education place an increased value on the quality of training their surgeon has received, however this proposition is not supported by the literature. The relationship between patient income levels and number of surgeon publications showed no discernable trend of importance.

Finally, surgeon experience as a predictor was explored. The majority of participants preferred surgeons with 11-20 years in practice; however, the next largest group had no preference for years of experience. No significant difference or correlation was seen with patient gender. In orthopaedics, there has been a trend of increasing female residents and surgeons, therefore a preference for female surgeons would align with patient age and experience. This is supported by the literature. Although some studies have demonstrated patients prefer female surgeons, our data showed no definitive conclusions proving these factors affect the patient-physician relationship yields superior patient outcomes. As such, further investigation identifying how patients identify their ideal orthopaedic surgeon is warranted. Although some studies have demonstrated patients select physicians based on race and gender, other studies have shown that physician capability, skill, and compassion are the most important deciding factors\textsuperscript{17}. Despite some gains, orthopaedic training programs demonstrate one of the lowest female and minority resident percentages compared to other fields\textsuperscript{18,19}, resulting in potential barriers in care of diverse patient populations. This study makes no judgment regarding the quality of care received by the patients. While there are many reasons for diversification in all fields of medicine, patient perceptions about their orthopaedic physicians seems to be based upon the quality of education and experience within the field rather than age, sex and race of the provider.
REFERENCES