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T H E
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THE IOWA ORTHOPEDIC JOURNAL

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INSTRUCTIONS FOR AUTHORS, 2017 EDITION

<http://www.uiortho.com/index.php/education/iowa-orthopaedic-journal.html>

We will consider any original article relevant to orthopedic surgery, orthopaedic science or the teaching of either for publication in *The Iowa Orthopedic Journal*. Articles will be enthusiastically received from alumni, visitors to the department, members of the Iowa Orthopaedic Society, residents, and friends colleagues.

Published articles and illustrations become the property of *The Iowa Orthopedic Journal*. The journal is peer reviewed and referenced in PubMed, *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. TITLE PAGE: The title page should list the author's names in the order in which they should appear. The **corresponding author** must be clearly identified with mailing address, telephone/fax number and an e-mail address. Manuscripts will not be returned unless requested.

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5. SUBMISSION OF MANUSCRIPT: Authors may submit a single manuscript file (word file or PDF) or may submit a primary manuscript and as many additional files (figures, illustrations, legends, etc.) as needed. Please visit <https://ioj.scholasticahq.com> to submit your manuscript.

6. Additional information may be obtained by visiting <http://www.uiortho.com/index.php/education/iowa-orthopaedic-journal.html> or by e-mailing the Iowa Orthopedic Journal at iorthojournal@gmail.com.

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2016 IOJ EDITORS' NOTE

It has been another very successful year for the 36th edition of the *Iowa Orthopedic Journal* (IOJ). As in previous years, we have continued to receive a large volume of high quality submissions from around the world. As the University of Iowa Department of Orthopedics has continued to grow as a national leader in orthopedic education, we have seen an increase in submissions focused on improving and evaluating resident education. We are excited about the increasing interest in this topic as our institution continues to focus on developing orthopedic leaders for generations to come.

We would also like to recognize and thank the departing senior residents, Drs. Jody Buckwalter, Shannon Cassel, Shane Cook, Chris Martin, Jesse Otero, and Robert Westermann. Aside from the excellent leadership and guidance provided by these residents during their five years at the University of Iowa, their class was particularly pivotal in advancing both clinical and basic science research during their training. While they will certainly be missed, we wish all of them the best as they continue their education during fellowship and advance during their future careers.

The IOJ would not be successful without the help multiple faculty and residents in the Department of Orthopedics. The peer review process, which allows all published articles to be indexed on PubMed, requires a great deal of effort from many faculty and residents, and we would like to personally thank all the individuals who helped during this process. We would like to specifically take time to thank Dr. Daniel Koehler for his role in securing corporate sponsorships in order to fund journal publication as well as helping with the general organization of the journal. Additionally, we would like to thank Dr. Jose Morcuende, who continues as the faculty advisor for the journal, as well as Renae Thompson, who continues to play an instrumental role while keeping things organized and on schedule.

It has been an honor and privilege to serve as the editors for the 36th edition of the IOJ. We have learned many things during our tenure as editors, and we feel that this year's publication reflects the excellence in



research that continues here at the University of Iowa as well as across the world. We are hopeful that the readership finds this year's publication particularly interesting, and we look forward to what the future has to hold for the Department of Orthopedics here at the University of Iowa.

Sincerely,
Kyle R. Duchman, MD
Joshua B. Holt, MD
Co-Editors
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2016 IOWA ORTHOPEDIC JOURNAL DEDICATION IN MEMORY OF ROBERT “BOB” C. VOLZ, MD

Jared Daniel, MD, Kyle Duchman, MD, Josh Holt, MD



Robert “Bob” C. Volz, MD

Each year, we dedicate the Iowa Orthopedic Journal (IOJ) to a distinguished alum or faculty within the University of Iowa Department of Orthopedics. These individuals have made a significant impact not only in the field of orthopedics, but also on their peers. This year, the IOJ will be dedicated to Robert “Bob” C. Volz, MD, an

Iowa Orthopedic Alum who passed away May 11, 2015. Like those who preceded him, Bob left a mark on his colleagues, patients, friends, family, and the Iowa Orthopedic Department as a whole that will never be forgotten.

Robert “Bob” Volz was born and raised in Arlington Heights, IL. He completed his orthopedic residency at the University of Iowa in June 2011. During his residency, Bob married his wife, Katie, who later gave birth to their first son, PJ, prior to completing his residency. After completing residency, Bob and Katie moved to Auckland, NZ where he completed his fellowship in pediatric orthopedics at Starship Children’s Hospital. Upon completion of his fellowship, Bob moved with his family to Lacrosse, WI where he practiced pediatric and general orthopedics at Gunderson Lutheran Hospital.

While orthopedics was a major part of his life, Bob’s greatest joys in life were his family, including his wife Katie, and two sons, PJ and Henry, and Jesus Christ. Bob’s co-residents remember him as a dedicated, compassionate individual, who even prior to his time at the University of Iowa, provided medical care to patients in Guatemala. Bob even managed to escape from residency for a short period of time to provide care in Haiti after the 2010 Haiti earthquake. Every staff who worked with him during his time at the University of Iowa and each of his co-residents can recall an endless list of entertaining stories that clearly paint a picture of a man who had endless love for his family and friends with the patience

and dedication required to teach junior residents how to take the best possible care of patients.

Bob is survived by his wife, Katie, two sons, PJ and Henry, two sisters, Jennifer Stotz and Christine Smerek, and his mother, Kathryn Volz. He was preceded in death by his father, Peter Volz. While Bob will be missed by all that knew him, his memories will never be forgotten, and we are forever thankful for the impact he had and will continue to have on our department as a whole.

A PICTURE IS WORTH A THOUSAND SMILES

Tim Vinyard, MD – Class of 2011

For those of you that have never experienced it, the last few months of residency can be extremely stressful. In addition to managing your team of residents and striving to provide the best patient care, we are also tasked with finishing our senior resident research project, selling our home, finding a new place to live, which in Bob’s case was literally on the other side of the Earth, and studying for the ever-intimidating written orthopedic board exam we are expected to pass immediately following completion of residency. Sleeping, eating, and spending time with your family become an afterthought, if not a near impossibility.

The accompanying picture was taken during the last few weeks of residency, and the story behind it is a perfect encapsulation of the Bob Volz that many of you knew and loved. Just like residency in general, I do not remember all of the details, and like any good story, each time I retell it, the story seems to get a little bit better.

I finished residency as the senior resident on the Blue Team, or the total joint replacement service. This service was well known to be difficult to manage, and everyone agreed that it was a less than ideal way to finish residency. Each morning, we had a meeting in which the on call team would discuss each consult they received the previous night to ensure that each patient was passed to the appropriate service.

Now, for those of you that never had the chance to meet Bob, he was constantly cracking jokes about his relative lack of height and strength compared to other orthopedic residents. Although he would likely deny it



to this day, he was probably standing on a step at the time of the above picture. However, it was very rare for anyone to specifically make fun of Bob regarding his physical attributes, probably because he was too busy making fun of himself. His self-deprecating brand of humor was loved by all.

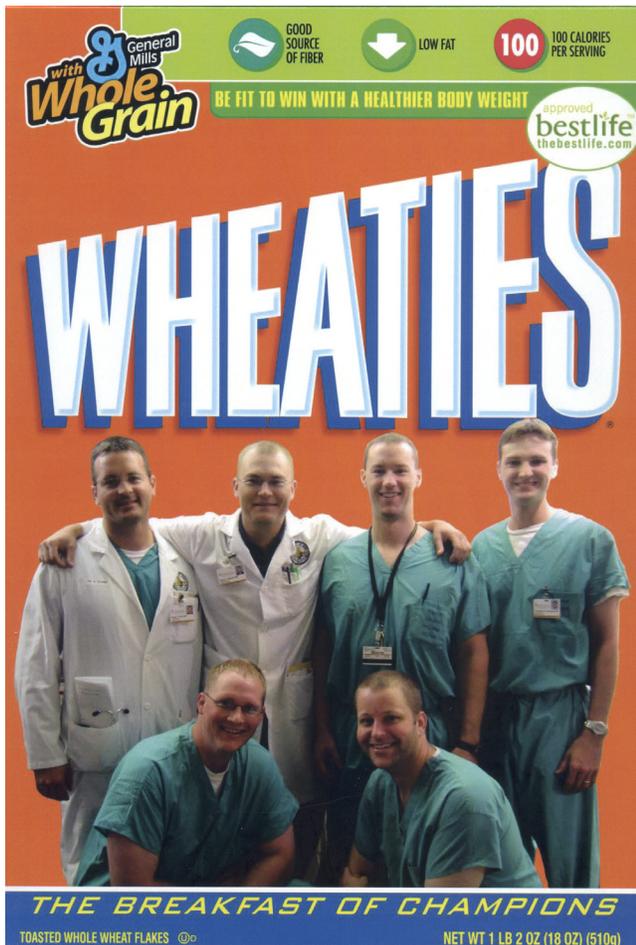
The morning of the above photograph, Bob staggered into the meeting looking more haggard than usual. He had endured a rough night of call with multiple consults and multiple surgeries. He had not slept at all. Every emergent surgery had been performed by Bob except for one. In the early morning hours, an elderly patient presented to the Emergency Room with an acute infection involving her knee replacement. Bob had tried to perform her surgery during the hours of his call shift, but simply ran out of time. The responsibility of performing her surgery was passed on to me, and her surgery was scheduled for later that same day. For those of you that may be unfamiliar with this process, this scenario occurred almost every morning. The process of passing on a patient's care to a well-rested surgical team was not only completely appropriate, it could easily be argued as the safest and best treatment for the patient.

However, Bob always looked extremely uncomfortable with the process of passing on the responsibility of a patient's care to another team. More so than any other resident I remember working with, Bob somehow felt like he was dodging his responsibilities. On that morning, Bob seemed particularly distressed about passing on this patient's care. Maybe he knew how busy and stressed I was at the time. Maybe he just felt like was letting his friend down. I assured Bob that he had done the right thing for the patient. I would perform her surgery that afternoon and everything would be fine. Trying to lighten the mood, I told Bob that he looked terrible and that he should go get some beauty sleep. He gave a tired chuckle, and we both went our separate ways.

I do not remember exactly what else I did that day. I probably performed a couple of surgeries. I do not know what Bob did either, but I am sure he spent the vast majority of the day double and triple checking that all of the patients from the night before had been properly cared for and were continuing to receive excellent care. I am sure that he made time to playfully heckle some of the junior residents and orthopedic staff as this was known to be one of his favorite pastimes. His infectious laugh would regularly echo throughout the hallways of the orthopedic department and always put a smile on everyone's face.

Around three o'clock in the afternoon, as I was in the operating room preparing to perform the surgery that Bob had passed on to me, a nurse handed me the phone. It was Bob on the other line. Now, I do not remember the exact rules at that time, but if you had been up all night operating, it was at least recommended that you go home at noon the following day. I do not think Bob ever left work early. Needless to say, I was not terribly surprised that he was still there. He asked if I had anyone to help me perform the surgery. I hesitated, but truthfully told him that I did not have any help. Bob replied, "I'm coming up." I started to protest. I started to tell him that was completely unnecessary and a waste of his time and that he should go home to spend some time with his wife and kids. I was too late. He had already hung up the phone. I laughed and continued preparing for the case.

I still was not fully convinced that Bob was coming up for the case, but I knew Bob to be a man of his word. Sure enough, just before I started the case, Bob strolled into the operating room. I simply smiled and shook my head. I could see there was no talking him out of helping me. I am sure that I cursed him as he scrubbed in and I told him what a fool he was, all of which fell on deaf ears.



I remember the case going very smoothly, and I remember very much appreciating having Bob's help. Obviously, at some point in the case, someone snapped the above photo. I remember glancing at the photo and thinking it was a great photo. I never anticipated it would hold as much meaning for me as it does to this day. After the case, we went our separate ways. Hopefully Bob finally got his beauty sleep. I think Bob's actions that day come at absolutely no surprise to those that knew him well and also perfectly encapsulate the man that he was and the life that he lived.

At his funeral, his friends and family recounted story after story of Bob's selflessness, leadership, and willingness to put other's needs before his own. Like the high school football game when Bob threw interception after interception. He could have easily melted down and lashed out at his teammates, but by all accounts, he simply accepted responsibility for each mistake. Numerous patients, families, and colleagues told stories about the incredible impact he made on their lives in the short time he was in practice.

As a resident, he chose to subspecialize in the field of pediatric orthopedics, a noble, well-respected path that, unfortunately, tends to be less financially rewarding compared with other orthopedic subspecialties. Bob knew this, of course, but he did not care. He felt drawn to use his talent and training to help injured and debilitated children.

When a devastating earthquake all but destroyed the impoverished nation of Haiti, Bob took precious time away from his family and own desires to help others that he did not know and would, in all likelihood, never see again.

Occasionally, my wife and I will look back at old photographs with our kids. It is one of our favorite things to do, and the kids seem to love looking at old pictures. However, we are somewhat dismayed and even a little disappointed that they do not remember some of our vacations and other activities that we seemed to spend so much time and effort planning. When we come across pictures of Bob, I always ask my two older boys if they remember Bob. They always say yes and look at me like I am mildly crazy. After all, who could forget Bob? They remember visiting his family in Wisconsin and swimming in his pool. They remember seemingly endless boat rides and laughs at his family's lake house at Green Lake. I like to think that most of all, they remember his smile, his laugh, his generosity, and the way he always made them laugh. As my boys grow older, I will continue to talk to them about Bob. At some point, we will talk about tragedy and how life is not always fair. We will talk about the importance of living every single day to the fullest. Mostly, we will talk about family, faith, and always striving to do the right thing.

When I think about Bob, of course I will remember all of the good times and laughs that we shared. I will remember the numerous tough conversations we had following his diagnosis. Naturally, these conversations were much more difficult for me than for Bob. He accepted his fate with remarkable grace and dignity. Rather than feel sorry for himself, he chose to spend those moments talking about his love for his beautiful wife and adorable kids.

When I look back at this picture, I will remember the day that my friend refused to go home and chose to help me when he had so many other things he could have been doing. I will remember his humility, compassion, and courage in the face of adversity. I will remember that laugh. Good grief, I will never be able to forget that laugh. I will always feel at least a twinge of pain and sorrow that he is no longer with us, but most of all, when I look at that picture, it will bring a smile to my face.

2016-2017
DEPARTMENT OF ORTHOPEDICS AND REHABILITATION
SCHEDULE OF LECTURESHIPS AND CONFERENCES

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

Carroll B. Larson Shrine Memorial Lecture

May 6-7, 2016

Min Kocher MD, MPH
Professor of Orthopaedic Surgery
Harvard Medical School
Associate Director, Division of Sports Medicine
Boston Children's Hospital
Department of Orthopaedic Surgery
300 Longwood Avenue, Hunnewell 2, BCH 3220
Boston, MA 02115

Spring 2017 to be arranged. Contact Nancy Love @ (319) 356-1872

2016 Senior Resident's Day

June 10-11, 2016

Michael S. Pinzur, M.D.
Department of Orthopaedic Surgery
Loyola University Medical Center
2160 South First Avenue
Maywood, IL 60153

William N. Levine, M.D.
Columbia University Medical Center
Department of Orthopaedic Surgery
622 W. 168th St, PH 1117
New York, NY 10032

Orthopedic Alumni Meeting

September 29-October 1, 2016

Marriott Hotel & Conference Center
300 East 9th Street, Coralville

Terrance Peabody, M.D.
Professor and Chair,
Department of Orthopaedic Surgery
Northwestern University
676 N. St. Clair Ave. Suite 1350
Chicago, IL 60611

David Templeman, M.D.
Professor, Department of Orthopaedic Surgery
University of Minnesota
Hennepin County Medical Center
701 Park Avenue South, G2
Minneapolis, MN 55415

32nd Annual Hawkeye Sports Medicine Symposium

December 8-9, 2016

Marriott Hotel & Conference Center
300 East 9th Street, Coralville

Guest Speaker – to be arranged
Contact Kris Kriener @ (319) 353-7954

2017 Senior Residents Day

June 16-17, 2017

Discussants to be arranged.

Department of Orthopedics

Lindsey Caldwell 2015-present	Arthur Steindler 1912-1949
Cassim Igram 2015-present	Theodore Willis 1917-1918
Heather Kowalski 2014-present	Joseph Milgram 1926-1932
Eric Aschenbrenner 2012-present	Ernest Freund 1932-1936
Apruva Shah 2012-2015	Thomas Waring 1932-1939
Melissa Willenborg 2012-present	James Vernon Luck 1936-1939
Mederic Hall 2011-present	Ignacio Ponseti 1946-2009
Carolyn Hettrich 2011-present	Eberly Thornton 1946-1952
Ryan Ilgenfritz 2011-2014	Robert Newman 1948-1956
Matthew Karam 2011-present	Michael Bonfiglio 1950-1995
Matthew Bollier 2010-present	Carroll Larson 1950-1978
Benjamin Miller 2010-present	Adrian Flatt 1956-1979
Christina Ward 2008-2009	Reginald Cooper 1962-present
Heather Bingham 2008-present	Howard Hogshead 1964-1965
Phinit Phisitkul 2008-present	Maurice Schnell 1964-1965
Nicolas O. Noiseux 2007-present	Richard Johnston 1967-1970,
Robert Yang 2007-2010	1998-present
Ericka Lawler 2006-present	Donald Kettelkamp 1968-1971
John E. Femino 2005-present	Gerald Laros 1968-1971
Joseph D. Smucker 2005-2014	Richard Stauffer 1970-1972
Jin-soo Suh 2004-2005	John Albright 1972-present
Neil A. Segal 2004-2014	Doug Mains 1972-1973
Brian Wolf 2003-present	Bruce Sprague 1972-1979
Michael O'Rourke 2003-2007	Richard Brand 1974-2002
Sergio Mendoza 2003-2015	Mike Mickelson 1976-1981
Jose Morcuende 2001-present	Stuart Weinstein 1976-present
Annunziato Amendola 2001-2015	Thomas Lehmann 1978-1987
Joseph Chen 2000-present	Joseph Buckwalter 1979-present
Todd McKinley 1999-2012	William Pontarelli 1980-1984; 1999-2004
R. Kumar Kadiyala 1998-2004	Charles Clark 1980-present
Leon Grobler 1996-1999	William Blair 1980-1997
Brian Adams 1993-2014	Barbara Campbell 1982-1984
Charles Saltzman 1991-2005	James Weinstein 1983-1996
John Callaghan 1990-present	James Nepola 1984-present
David Tearse 1989-2000	Fred Dietz 1984-2015
Ernest Found 1987-present	Curtis Steyers 1985-2006
Lawrence Marsh 1987-present	



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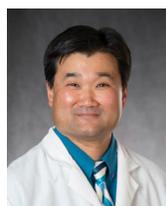
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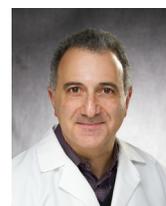
Dr. Jessica Goetz



Dr. Mederic Hall



Dr. Carolyn Hettrich



Dr. Cassim Igram



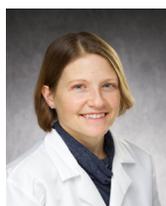
Dr. Richard Johnston



Dr. Matthew Karam



Dr. Heather Kowalski



Dr. Ericka Lawler



Dr. J. Lawrence Marsh



Dr. James Martin



Dr. Benjamin Miller



Dr. Jose Morcuende



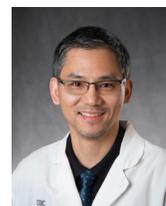
Dr. James Nepola



Dr. Nicolas O. Noiseux



Dr. Doug Pederson



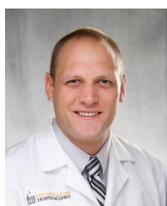
Dr. Phinit Phisitkul



Dr. Stuart Weinstein



Dr. Melissa Willenborg



Dr. Michael Willey



Dr. Brian Wolf



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| 1. Jesse Otero, MD, PhD | 14. Elizabeth Fitzpatrick, MD | 27. Molly Day, MD |
| 2. Michael Willey, MD | 15. James Gholson, MD | 28. Lindsey Caldwell, MD |
| 3. Chris Anthony, MD | 16. Josef Tofte, MD | 29. Ericka Lawler, MD |
| 4. Joshua Holt, MD | 17. Shannon Cassel, MD | 30. Brandon Wilkinson, MD |
| 5. Matthew Karam, MD | 18. Tyler CarlLee, MD | 31. Reginald Cooper, MD |
| 6. Joseph Buckwalter, MD | 19. Sean Sitton, MD | 32. Daniel Koehler, MD |
| 7. James Nepola, MD | 20. Heather Kowalski, MD | 33. Craig Akoh, MD |
| 8. Ben Miller, MD | 21. Jocelyn Compton, MD | 34. Nicolas Noiseux, MD |
| 9. Chris Martin, MD | 22. Zachary Ries, MD | 35. Carolyn Hettrich, MD |
| 10. Matthew Hogue, MD | 23. Kyle Hancock, MD | 36. Robert Westermann, MD |
| 11. Jacob Elkins, MD | 24. Nathan Hendrickson, MD | 37. Vinay Siddappa, MD |
| 12. Kyle Duchman, MD | 25. Shane Cook, MD | |
| 13. John Femino, MD | 26. John Callaghan, MD | |

2016 GRADUATING ORTHOPEDIC RESIDENTS



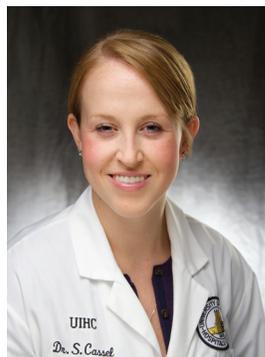
Jodie Buckwalter, MD

A fifth generation Iowan, Jody was born at University of Iowa Hospitals and Clinics and raised in Iowa City, Iowa. He graduated from Iowa City West High School in 1996 and headed to Duke University where he met his future wife, Allie Hart. Jody and Allie graduated in 2000 and Jody moved back to Iowa City to pursue a Ph.D. in neurosci-

ence, while Allie earned her JD at Northwestern. After graduation in 2005, Jody relocated to the University of California, San Diego for a post-doctoral position at the Center for Autism Research, where he studied neuropathology in autism. Jody and Allie married on Labor Day, 2007 and Jody began medical school the next day. During medical school, they welcomed their first child, Joseph, into the world. Inspired by a sub-internship in Pediatric Orthopaedics at Rady Children's Hospital, Jody decided to pursue a career in orthopedics and was fortunate to match at the University of Iowa. During residency, Allie and Jody welcomed Levi and Isla to their family.

Much of Jody's initial research focused on neural connectivity and neuropathology. As a resident, Jody broadened his research interests from pure basic science to include orthopedic clinical studies including an Iowa-style long-term follow up study of congenital hand deformities. His senior research project utilized the powerful Multi-center Orthopaedic Outcomes Network (MOON) to identify factors involved in return to baseline function at 6-months following shoulder instability surgery. Recently, he was awarded a grant that merges his neuroscience and orthopedic research interests in a study to evaluate eye-tracking and cognitive processes in interpretation of plain radiographs. Upon completion of his residency, Jody will be completing a hand fellowship at Barnes Jewish Hospital in Missouri.

Jody would like to acknowledge Chris, Jesse, Robby, Shane and Shannon as the greatest class of orthopedic residents at the University of Iowa. He is grateful to the faculty and staff at the University for their continued support and encouragement. Most of all, he is thankful for the love and support of his family; his parents, in-laws, sisters, and beautiful wife and three wonderful children.



Shannon Cassel, MD

Shannon grew up on the banks of the mighty Mississippi River in Davenport, Iowa. During her early childhood, she liked to tag along with her father, an Iowa-trained orthopaedist, to his Saturday morning sports clinics. Shannon knew, even then, that her dad had the best job in the world. She adopted her dad's love for "things broken or strained" and got to see plenty of both as she progressed through high school athletics, participating in

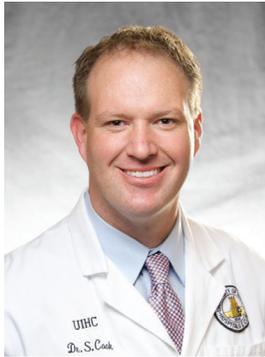
cross-country, basketball and track.

Shannon then attended the much loved (or reviled) University of Notre Dame where she earned four varsity letters in rowing. When not on the water, she studied world religions and cell biology graduating *cum laude* with Theology and Preprofessional Studies majors and an Anthropology minor. Following college, she returned to her roots and attended medical school at the University of Iowa. Throughout medical school, Shannon consistently found herself drawn to surgical cases and within the surgical world specifically orthopedics. During her third year of medical school, Shannon had the great fortune to be assigned to Dr. Stuart Weinstein's pediatric orthopedic team. Dr. Weinstein's care and dedication to his patients along with the enthusiastic residents on the service made it obvious to Shannon that orthopedics was where she belonged.

Shannon felt abundantly blessed to be invited to stay at the University of Iowa for residency. In addition to all of the great orthopedic mentors at Iowa, Shannon soon met the love of her life, Tameem Yehyawi. Thanks to great support from their families and co-residents, Shannon and Tameem shared two years of residency together followed by one year separated while Tameem honed his skills in a Sports Medicine fellowship in San Diego. Shannon and Tameem were married on May 16, 2015 and are excited to continue their life adventures together. Tameem is practicing orthopedics in Columbia, Missouri but makes frequent visits to Iowa City.

Hand surgery was an early love for Shannon and she has had incredible mentorship over the years from Dr. Shah, Dr. Adams, and Dr. Lawler. Designing a randomized control trial for her senior resident's project was a challenging and at times humbling experience. This project has motivated Shannon to continue to be involved in clinical research in her future career as a hand surgeon. She will be pursuing a hand fellowship at the Indiana School of Medicine upon completion of her residency.

Shannon would like to thank Dr. Shah for being her research mentor and encouraging her every step of the way. She would also like to thank her family for their endless love and support as well as her co-residents for making residency fun, even on the tough days. Most of all, she would like to thank her husband, Tameem, for all the love, the laughter and the many hours spent on FaceTime.



Shane Cook, MD

Shane was born and raised to James and Connie Cook in Lakewood, Colorado where he was brought up in a blue collar family. His older brother, Jaymie, excelled in academics and was the first in his family to obtain a college degree and taught Shane the importance of school. Shane attended Bear Creek High School where he had a great interest in both academics and athletics.

More importantly, unknown to them both at this time, this is where he first met his future wife, Jenny Hodges, where they remained just friends during high school.

Ultimately, Shane was honored with multiple football awards including the Denver Post Gold Helmet Award and Parade All-American as an offensive lineman at Bear Creek and received an athletic scholarship to the University of Colorado. At CU, Shane started at offensive tackle for three years and received a degree in Business Accounting. After graduation, Shane went on to play in NFL Europe with the Berlin Thunder and was in the NFL for a short period of time with the New Orleans Saints.

After football he tried business for a short period of time until he ultimately decided to pursue a career in medicine. He returned to college to finish his prerequisites for medical school and got accepted to the University of Colorado School of Medicine. During this time he found a strong interest in the musculoskeletal system and decided to pursue orthopedic surgery as a career.

During residency Shane found interest in several projects including multiligament knee injuries and distal radius fractures where he did the majority of his work. His senior research project titled *Surgical Treatment of Multiligament Knee Injuries* was published in *Knee Surgery, Sports, Traumatology, Arthroscopy (KSSTA)* in 2014. His research and residency experience has led him to focus on a career in hand and upper extremity and he plans to begin his fellowship at OrthoCarolina in 2016.

After finishing undergrad at the University of Colorado he received an unexpected email from Jenny, who just finished playing women's basketball at Boise State. Two years later they were married in Golden, Colorado. Jenny has been the foundation for Shane for over a decade. She has provided relentless support and love through the long journey they have endured. They have gone on to have 3 beautiful children, Micah (9), Mason (8) and Madison (6) who have brought them endless joy over the years. Shane's family and friends have also been there throughout, including Shane's mother-in-law, Pat Hodges, who let them live at her house during medical school.

Shane is forever grateful for the opportunity to train at the University of Iowa Hospitals and Clinics and the opportunity to learn from the faculty who are the leaders in their field. He would also like to thank his co-residents who have been on the front line with him during this process. Shane is especially thankful to his beautiful wife and 3 children who have been there throughout.



Christopher Martin, MD

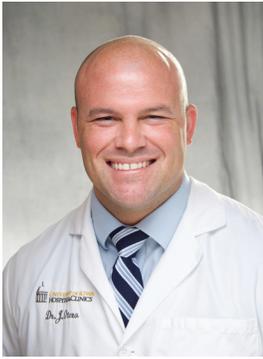
Christopher grew up in Kettering, Ohio, with one younger brother. When he was 11 years old, his family moved to Minnesota, where he met his future wife, Jody. After high school, Jody and Chris went to the University of Wisconsin-Madison. During his time in Madison, Chris was an active researcher, working with Dr. Douglas Maxwell to identify

the genetic location of the resistance gene to geminivirus in tomatoes, and with Dr. George Wilding on a new chemotherapeutic agent for prostate cancer. His research efforts were granted a Hilldale Research Award in 2005. He graduated with numerous academic honors, including a 4.0 GPA, a nomination to the Phi Kappa Phi Honor Society, multiple CALS Merit Awards, and a special designation for honors in research. In 2006, he was named the Wisconsin Alumni Association's Most Outstanding Student.

After undergrad, Chris and Jody moved together to Baltimore, where Chris attended the Johns Hopkins School of Medicine. He graduated in 2011, and was nominated to the Alpha Omega Alpha Honor Society. During this time, Jody studied for and attained her Master's Degree in Occupational Therapy, and Jody and Chris were happily married in 2008. After medical school, Chris matched into orthopedic residency at the University of Iowa, where he and Jody have subsequently spent 5 wonderful years, and together they have welcomed their first child, Annabelle, in 2014.

Residency has continued to be an academically productive time for Chris. His research has focused on issues related to quality and value in the changing healthcare arena, as well as on patient outcomes with an emphasis on risk factors for complications. Overall, he has authored or co-authored over 40 pubmed citable manuscripts, and has been the PI or Co-PI on four major grants including two from the OREF, and one each from the OTA and the IOS. He received the highest scaled score on the OITE (100) for three consecutive years. He also contributed to leadership in orthopedics, serving as the resident member of the Publications Committee for the AAOS, and as a grant reviewer for the Musculoskeletal Transplant Foundation. After residency, Chris has chosen to complete a fellowship year in Adult Spine at Emory University.

Chris would like to thank his wife Jody for her undying support through many late nights and early mornings. And finally, would like to thank his friends and co-residents by saying, "There is absolutely no better group of people. It has been an honor and a privilege."



Jesse Otero, MD

Jesse was born and raised in Albuquerque, New Mexico. Fascinated by the rich geography and beautiful landscapes, he developed an interest in natural history and science. He fondly recalls spending endless summer evenings digging through the mesa, chasing snakes and lizards. He was raised in a socioeconomically diverse environment where one must confront the problems with society face to face

on a daily basis. Through this experience, he developed a passion to ease the burden and suffering of others. Education and athletics were his priority through adolescence, and he was afforded the opportunity to attend Stanford University on a wrestling scholarship.

While at Stanford, his passion for science and service of others led him to explore biology and pre-medicine. He joined a lab to study the molecular mechanisms of bone disease early in his research career, earning research grants and publishing scientific articles on human bone sarcomas. During his time at Stanford, he met his wife, Emily, also from Albuquerque. Together, they shared the common interest of bodybuilding and fitness, and they spent their free time in the gym and on the beach. They were married senior year of college, and they graduated from Stanford together in the spring of 2004.

Jesse traveled with Emily to St. Louis, Missouri in the summer of 2004 to begin graduate studies at Washington University in St. Louis School of Medicine in the combined MD PhD program. He continued bone research in the laboratory of Yousef Abu-Amer, PhD, studying the essential signaling mechanisms for osteoclast differentiation. He earned an NIH research fellowship to fund his PhD studies. While in St. Louis, Jesse and Emily grew their family. They welcomed son, Gentry Cruz and daughters Samantha Fe and Leyla Isabel. With the tireless support of his family, Jesse graduated in the top 10% of his class from Washington University and was elected in the Alpha Omega Alpha Medical Honor Society. While at Washington University, Jesse was exposed to world class orthopedics and set his focus on a career as an orthopedic surgeon scientist.

The Otero family relocated to Iowa City to join the powerhouse Orthopedic Surgery program at the University of Iowa. Jesse continued to pursue basic science research exploring the role of osteoclasts in various orthopedic pathologies, earning grants from the Orthopaedic Research and Education Foundation and the Orthopaedic Trauma Association. After residency, Jesse will be pursuing the OrthoCarolina adult reconstructive fellowship in Charlotte, North Carolina. He is grateful for his mentors and colleagues at the University of Iowa who have inspired him to strive for excellence along the way.



Robert Westermann, MD

Robert “Robby” Westermann was born near Washington DC where his father was coaching football at Gallaudet University. He is the second of 4 children. His family eventually moved to the west coast where he attended Cedarcrest High School in Duvall, WA outside of Seattle. In high school, he competed in wrestling and football, and

was captain of each team. Robby then attended Pacific Lutheran University where he played football. He also worked as an athletic trainer during football’s offseason and began caring for injured athletes. Robby began his research career at PLU where he began operating on laboratory rats. Perhaps his greatest accomplishment while attending college was convincing his wife, Beth, to marry him and accompany him to medical school and residency. Robby stayed in Seattle for medical school attending the University of Washington. It is here where he fell in love with Orthopedics. Taking trauma call at Harborview and caring for injured athletes in the sports clinic he received sage advice to pursue a residency spot at the University of Iowa. Robby’s wife, Beth, was accepted to the nursing anesthesia program at Iowa and the two of them made the move to Iowa together.

While at Iowa, Robby became interested in both basic and clinical research. His basic science research projects include knee and ankle anatomic and cadaveric studies under Drs. Amendola, Wolf and Phisitkul. These basic science projects have been published in JBJS, Arthroscopy, and have been presented at AAOS and AOA meetings. The basic science research on the knee has led Robby to obtaining an OREF grant to assess ACL graft placement biomechanics and has led to a Basic Science Essay Award from the Arthroscopy Association of North America.

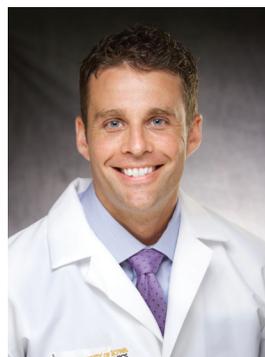
Robby has also participated in several clinical outcome studies. He has become involved in outcome studies in the MOON group through Drs. Wolf and Amendola. The study he performed on outcomes after meniscal repair has been published in AJSM and was awarded the Herodicus Award for Best Paper. He has had the ability to collaborate with members of the MOON group and develop relationships with leaders in the field across the country. Following residency, Robby will go to the Cleveland Clinic for a Sports Medicine Fellowship, and continue outcomes-based research with Kurt Spindler and the MOON group.

2016 GRADUATING FELLOWS



Samer Abdel Al, MD

Samer is the University of Iowa Orthopedic Oncology Fellow for 2015-2016. He is the first Orthopedic Oncology fellow to graduate from University of Iowa. He is from Amman, Jordan. He earned his medical degree from Jordan and completed his Orthopedic Surgery residency from Jordan in 2013. Samer moved to the USA and completed his first fellowship in Hand and Microsurgery at Kleinert Kutz Institute at the University of Louisville, Kentucky in 2015. Samer has been supported by his loving wife Wafa, a radiation oncology resident in King Hussein Cancer Center, Jordan. Currently, she's a research fellow in the Radiation Oncology Department at the University of Iowa. He would like to thank his loving wife, his caring mother Samira, his amazing father Dr. Abdel Fattah and his siblings for their great love and support. He is grateful for his outstanding mentor Dr. Miller for his great devotion to teaching and his continuous guidance. Samer would like to thank all members in orthopedic department, radiation oncology department and all the sarcoma team at the University of Iowa.



Joseph Carreau, MD

Dr. Carreau is a native of Colorado. He received his undergraduate degree in Biology at Colorado State University in Fort Collins, Colorado. Thereafter, he enrolled at Creighton University School of Medicine in Omaha, Nebraska and received his MD in 2009. He then traveled to San Diego, California where he completed residency training in Orthopaedic Surgery at the University of California, San Diego. He joined the University of Iowa in August 2015 as a Sports Medicine Fellow and will serve as an assistant team physician for UI Athletics. He is joined by his wife, Sherry and their three children - Isabelle, Elliot and Emmersen.



Peter Chimenti, MD

Peter grew up in Ames, Iowa. He attended the University of Iowa for his undergraduate degree, where he studied both Biology and piano performance. He completed medical school at Washington University in St Louis and spent the last five years in residency at the Univer-

sity of Rochester in Rochester, NY. Unable to stay away from Iowa for long, he returned this year to complete a Hand Fellowship at the University of Iowa Hospitals and Clinics. After this year he is planning to start practice in Cedar Rapids. Peter is honored to have had the opportunity to work with the outstanding residents and staff of the Department of Orthopedics. He would also like to specifically acknowledge the contribution of Dr. Lawler to his education and is very grateful for her mentorship and guidance over the year. Peter would also like to recognize the love and encouragement of his wife, Ruth Chimenti, DPT., PhD. Ruth has spent the year conducting postdoctoral fellowship research in the Department of Physical Therapy and Rehabilitation Science at the University of Iowa. Together with their daughter, Liana, they feel fortunate to have been welcomed into the Iowa family.



Vinay Hosuru Siddappa, MD

Vinay Hosuru Siddappa grew up in Bengaluru, India which is also known as the Silicon City of India. He attended medical school at Sri Siddhartha Medical College in Tumkur, India and spent the next 4 years as a General Practitioner. He did his residency at JSS Medical Col-

lege in Mysuru, India and at Sanjay Institute of Trauma and Orthopedics in Bengaluru, India.

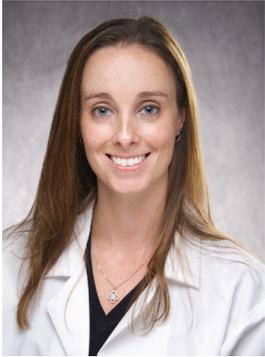
Realizing his passion for foot and ankle, flew all the way from the other half of the globe to complete a Foot and Ankle Fellowship at the University of Iowa Hospitals and Clinics. After this year, he will be returning to private practice and also as a Faculty at a teaching institution in Bengaluru, India.

Vinay is extremely honored to be in this program which according to him is one of the best institutions that continues to fascinate residents and fellows. Dr. Femino and Dr. Phisitkul have been great ambassadors of this specialty and an invaluable asset in shaping his knowledge and career. He would like to thank them a lot.

His unsung heroes, the residents and staff, have been amazing and would like to thank them for the unconditional help. Ms. Unni Stuart, Ms. Sarah Bensink, Ms. Janelle Schark, Ms. Christine Jehle, Ms. Randi Birkey, Ms. Kathy Gaunt, Ms. Sarah Burnett - You guys are awesome!!! He hopes that you all have enjoyed working with him as much as he did.

He would like to thank his wife, Ms. Veena Mahadevaiah and both their parents for the unconditional support, love and giving life to his dream. The family welcomes the people of Iowa to India. He can be reached at sidorthonex@gmail.com.

NEW ORTHOPEDIC FACULTY



Lindsey Caldwell, MD

Dr. Lindsey Caldwell is a hand and upper extremity surgeon who joined the Department of Orthopedics at the University of Iowa Hospitals and Clinics in 2015. She studied Brain and Cognitive Sciences at the University of Rochester as an undergraduate and earned her M.D. at SUNY Stony Brook School of Medicine in 2009. She completed her Orthopaedic Surgery residency at University of Rochester in 2014 and hand surgery fellowship at University of Massachusetts in 2015. She is currently a candidate member of the American Academy of Orthopedic Surgeons and the American Society for Surgery of the Hand and is board eligible for the American Board of Orthopedic Surgery.



Michael Willey, MD

Dr. Michael Willey joins the staff specializing in Orthopaedic Trauma. As far as we know, Michael is the only Quadruple-Hawk in the department. After completing his undergraduate education, medical school, residency, and fellowship at the University of Iowa he is very excited to continue his career as a Hawkeye. His wife, Lindsey, and three children, Audrey, Norah, and Owen will be joined by a new baby in March 2016.

The 2016 Michael Bonfiglio Award for Student Research in Orthopaedic Surgery

The 2016 Iowa Orthopaedic Society Medical Student Research Award for Musculoskeletal Research

The University of Iowa Department of Orthopedics and Rehabilitation, along with the Iowa Orthopaedic Society, sponsors two research awards 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.

The Iowa Orthopaedic Society Medical Research Award for Musculoskeletal Research is an award for a student in the Carver College of Medicine who completes a research project involving orthopaedic surgery during one of his or her first three years of medical school. The award consists of a \$2000 stipend, \$500 of which is designated as a direct award to the student and \$1500 of which is designated to help defray continuing costs of the project and publication. The student must provide an abstract and a progress report on the ongoing research.

The aim is to stimulate research in the field of orthopaedic surgery and musculoskeletal problems. This award is also presented at a medical convocation. In addition, the student presents his or her work at the spring meeting of the Iowa Orthopaedic Society and at a conference in the Department of Orthopaedics and Rehabilitation. This award is supported through the generosity of the Iowa Orthopaedic Society.

This year the selection committee consisted of Drs. Charles R. Clark, Joseph A. Buckwalter, John Femino and Jose Morcuende, all members of the Department of Orthopedics and Rehabilitation. They recommended that Justin Greiner, M4, receive the 2016 Michael Bonfiglio Student Research Award. Justin's award was based on his project, "Modular Acetabular Component Metal-on-Metal Bearing THA Construct at Five to Twelve Year Follow-up: Is Close Surveillance Warranted?" His advisor was Dr. John Callaghan.

The selection committee recommended that The Iowa Orthopaedic Society Medical Student Research Award be given to Thomas Meirick, M2, for his research titled "Determining the Prevalence and Costs of Unnecessary Referrals in Adolescent Idiopathic Scoliosis." His advisor was Dr. Stuart Weinstein.

The Michael Bonfiglio Award and the Iowa Orthopaedic Society Medical Student Research Award for Musculoskeletal Research are very prestigious, recognizing student research on the musculoskeletal system. These awards have indeed attained their goal of stimulating such research and have produced many fine projects over the years.

Charles R. Clark, M.D.
The Michael Bonfiglio Professor of Orthopaedic Surgery



Left to right: Charles Clark, MD, Michael Bonfiglio Professor of Orthopedic Surgery, Thomas Meirick, M2, winner of The Iowa Orthopaedic Society Medical Student Research Award, Justin Greiner, M4, winner of the 2016 Michael Bonfiglio Student Research Award and John Callaghan, MD.

SKILL ASSESSMENT IN THE INTERPRETATION OF 3D FRACTURE PATTERNS FROM RADIOGRAPHS

Geb W. Thomas, PhD^{1,2}, Salvador Rojas-Murillo, ME², Jessica M. Hanley, MD¹, Clarence D. Kreiter, PhD⁴, Matthew D. Karam, MD¹, Donald D. Anderson, PhD^{1,2,3}

ABSTRACT

Background: Interpreting two-dimensional radiographs to ascertain the three-dimensional (3D) position and orientation of fracture planes and bone fragments is an important component of orthopedic diagnosis and clinical management. This skill, however, has not been thoroughly explored and measured. Our primary research question is to determine if 3D radiographic image interpretation can be reliably assessed, and whether this assessment varies by level of training. A test designed to measure this skill among orthopedic surgeons would provide a quantitative benchmark for skill assessment and training research.

Methods: Two tests consisting of a series of online exercises were developed to measure this skill. Each exercise displayed a pair of musculoskeletal radiographs. Participants selected one of three CT slices of the same or similar fracture patterns that best matched the radiographs. In experiment 1, 10 orthopedic residents and staff responded to nine questions. In experiment 2, 52 residents from both orthopedics and radiology responded to 12 questions.

Results: Experiment 1 yielded a Cronbach alpha of 0.47. Performance correlated with experience; $r(8) = 0.87$, $p < 0.01$, suggesting that the test could be both valid and reliable with a slight increase in test length. In experiment 2, after removing three non-discriminating items, the Cronbach coefficient

alpha was 0.28 and performance correlated with experience; $r(50) = 0.25$, $p < 0.10$.

Conclusions: Although evidence for reliability and validity was more compelling with the first experiment, the analyses suggest motivation and test duration are important determinants of test efficacy. The interpretation of radiographs to discern 3D information is a promising and a relatively unexplored area for surgical skill education and assessment. The online test was useful and reliable. Further test development is likely to increase test effectiveness.

Clinical Relevance: Accurately interpreting radiographic images is an essential clinical skill. Quantitative, repeatable techniques to measure this skill can improve resident training and improve patient safety.

INTRODUCTION

In preparation for fracture fixation, orthopedic surgeons must accurately assess the relative position of the bones, bone fragments and fracture planes.^{1,2} Previous research identified that the interpretation of musculoskeletal radiographs is domain-specific³ and can be improved with deliberate practice.^{4,5} Expert observers are generally more effective than novices in translating raw images into domain-specific information, in this case perceiving fractured bone surfaces.^{6,7} Still, the details of how this skill is acquired remain incompletely understood.⁸ Orthopedic residency programs do not generally provide specialized training in the task of radiograph interpretation, relying instead upon task exposure during the residency experience.⁹

Existing research on musculoskeletal radiographic image interpretation has neglected the specific skill of three-dimensional (3D) spatial interpretation, a key competency for orthopedic surgeons. Instead, it has emphasized the detection of abnormalities in individual radiographs by radiologists.^{10,12} Research comparing the performance of orthopedic and radiology specialists has generally not found a statistically significant difference in their interpretation skills.^{10,12} Nevertheless, studies have found positive benefits with online and simulation technologies for training radiographic interpretation skills. For example, pediatric residents' accuracy in de-

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²Department of Mechanical and Industrial Engineering

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Conflict of Interest Statement: Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

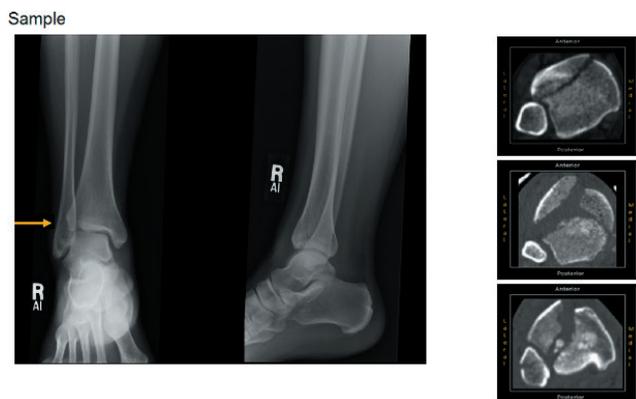


Figure 1. This is a sample multiple choice question from experiment 2. Participants decided which of the three alternative CT slices on the right were taken from the ankle fracture represented by the stem radiological image pair on the left. The yellow arrow in the AP radiograph indicates the level of the CT slice.

detecting ankle injuries in radiographs improved after using an online tool.⁵ Similarly, working with a radiographic simulator significantly improved first-year residents' skill in assessing cervical spine injuries with radiographs.¹³

Image interpretation expertise is likely related to the speed with which the image information is encoded into a situational model, a mental representation of the specific situation captured by the images. In orthopedics, the situational model would include a mental representation of where fractures and fragments are located and how fracture planes are oriented. The test developed here emphasizes the skill of converting image information into an appropriate situational model, particularly emphasizing the 3D aspects of the model. Accurately assessing this skill could help learners acquire the skill faster, identify trainees requiring additional training, and enable the quantitative analysis of training techniques designed to improve this skill.

The objective of this project is to determine whether 3D radiographic image interpretation can be reliably assessed. To achieve this objective, we conducted two experiments to evaluate the following hypotheses: 1) skill in 3D image interpretation improves with experience, and 2) computer-based testing of this skill can produce a reliable performance measure.

METHODS

In each of the two experiments, participants responded to a series of multiple choice questions consisting of a problem, known as the stem, and a list of alternative solutions. A sample test question is represented in Figure 1. The stem is a pair of reference radiographs: standard AP and lateral ankle images. Distal tibia fractures were selected as test cases because they are common¹⁴ and because the examination of radiographic images is a

standard part of fracture assessment.¹⁵ The three alternatives include one correct answer, and two incorrect or inferior alternatives, known as distractors. The answer alternatives each display a single axial CT slice, one of which was taken from the same fracture, and the other two taken from different cases.

The rationale for this testing mechanism was that participants would use the two radiographs to construct a situational model, and then compare each CT image against this model. The test options present alternative visualizations of fractures at an angle perpendicular to the visualization presented in the stem. This encourages participants to construct and rotate a situational model rather than pursue a feature-by-feature comparison strategy, which would likely be adopted if the alternatives were visualized from an angle more similar to the stem images.

No medical information was provided about the patient beyond the radiographs. Our Institutional Review Board approved the study for participation of orthopedic surgeons and residents from three different institutions. The first experiment served as a pilot to test the feasibility of the technique.

Experiment 1: Initial Feasibility Test

The first experiment tested the hypothesis that skill in 3D image interpretation improves with experience. Specifically, we expected that experienced orthopedic surgeons would choose the correct CT slice more often than orthopedic trainees with less experience.

Participants

Two orthopedic surgeons, 6 orthopedic residents and 2 medical students, all from a single institution, participated. The residents were distributed among their postgraduate year of training (PGY) as follows: 2 PGY1s, 1 PGY2, 1 PGY3, and 2 PGY5s. Each participant responded to nine multiple choice questions.

Procedure

The test was conducted during a weekly trauma conference. Each case was displayed for 90 seconds on a projection screen. Each participant recorded which alternative matched the stem for each question. No feedback was provided after the completion of the experiment. Statistical analysis included the standardized Cronbach coefficient alpha, a measure of test reliability that measures reliability in terms of internal consistency. For example, a test for which high scorers tend to answer hard questions correctly would yield a high Cronbach alpha. We coded years of experience, with 0 for medical students, 1 to 5 for current year of residency, and 7 for fellows and staff. The gap between residents and staff in the coding was applied to reflect the substantially different experience level.

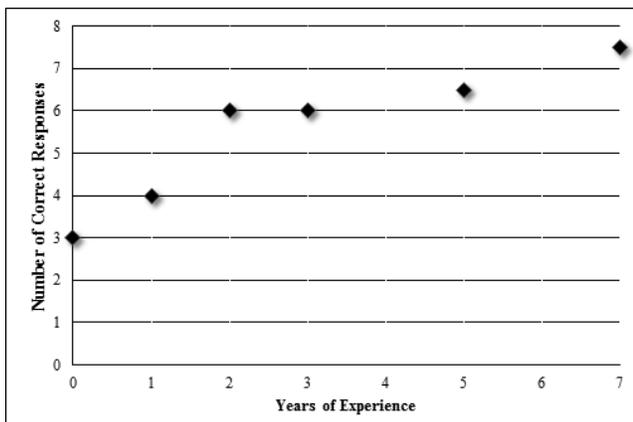


Figure 2. The number of questions correctly answered (out of 9 possible) is plotted versus years of experience for experiment 1.

Experiment 2: Test Refinement

The second experiment sought to determine whether a computer-based online test of this skill can produce a reliable performance measurement. The questions in the online version of the test were similar to those in the pilot test, with several changes. The number of questions was increased from 9 to 12 and balanced between left and right ankles. Standardizing the image contrast, image size and image orientation made the questions more consistent. The anatomical level from which the CT slice was taken was also standardized to be at a distance equal to the width of the distal tibial epiphysis above the talar dome.

Participants

There were a total of 52 participants, 42 from Institution 1 worked in radiology ($n=10$) or orthopedics ($n=32$), and the remaining 10 participants were in orthopedics at one of two other institutions ($n=8$ and $n=2$). The experience levels of the participants ranged between each of the five years of residency (from first year to fifth, $n=18$, 6, 7, 5 and 4, respectively) plus 12 staff physicians. All participants from the second and third institutions were first-year residents.

Procedure

The online test was conducted with no time restriction, although the test duration—the time interval between answering the first and last questions—was recorded for each participant. At the end of the exercise, participants were provided with feedback on their score, correct answers, and the rationale for those answers.

RESULTS

Experiment 1

The number of correct answers for each participant ranged from two to eight, with a mean of 5.4 (s.d. 1.9)

(Figure 2). The maximum possible score was nine. Only two participants correctly answered the most difficult question, and eight participants each correctly answered the two least difficult questions. The other six questions were each answered correctly by between five and seven participants.

The standardized Cronbach coefficient alpha for experiment 1 was 0.47. There was a significant positive correlation between test score and experience; the Pearson correlation coefficient was $r(8)=0.87$ ($p < 0.001$).

Although the sample size was small, the results from this first experiment suggested that the test correctly distinguished between skill levels and that skill level correlated with experience. The significance of the correlation was particularly striking given the limited power of the test, suggesting that the test was measuring a skill that clearly improved with experience. A larger experiment is required to determine whether this effect is generalizable.

The Cronbach alpha suggested that although the test would not be sufficiently reliable in its current form for high stakes decisions, a reliable measure of skill could be developed with more questions. A second experiment was designed to refine the test and conduct a larger experiment with more participants.

Experiment 2

Across all participants, the mean number of correct responses was 7.3 (s.d. 1.5) and the mean duration was 12.7 (s.d. 8.9) minutes. The Cronbach coefficient alpha was 0.03. Three questions performed poorly. One question was inappropriately difficult; only one of the 52 participants answered it correctly. Two other questions discriminated poorly, and further analysis revealed that the posing of the questions was confusing and there may have been motion of the fragments between the time that the radiographs and CT scan were obtained. The reliability of the results based on the remaining 9 questions was 0.28. The correlation of test score with experience was $r(50)=0.25$ ($p < 0.10$).

DISCUSSION

Our previous experience using a simulator in the training of orthopedic residents suggested that less experienced participants require more time to assess musculoskeletal images.¹⁶ This may be related to the time it takes for a novice to construct a 3D situational model from radiographs. This suggested that such a skill might be assessed independently from other surgical skills. The purpose of this project was to determine if: 1) skill in 3D image interpretation improves with experience, and 2) whether a computer-based test of this skill produces reliable performance measures.

The results of the first experiment were promising. It

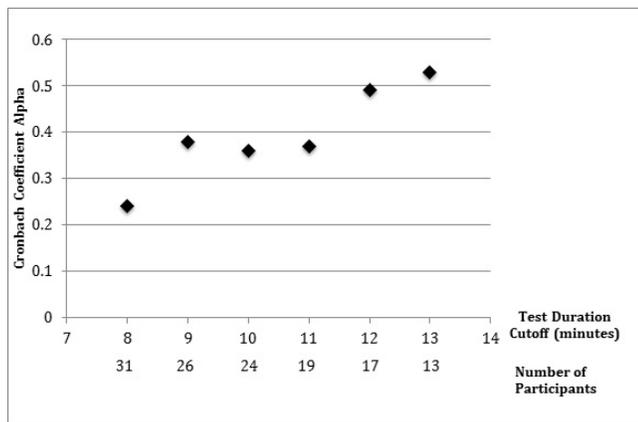


Figure 3. A plot of the Cronbach coefficient alpha calculated for subgroups consisting of participants who took longer to complete the test. The subgroup becomes smaller as the cutoff duration increases, but the test reliability substantially increases.

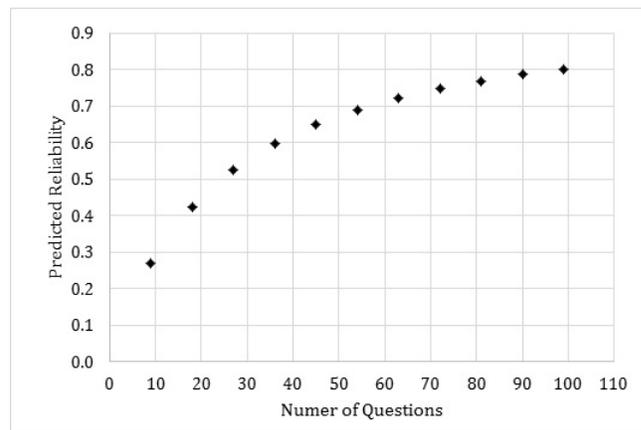


Figure 4. A plot of the projected test reliability as the number of questions is increased, assuming that added questions perform at the same level as those in experiment 2.

produced scores displaying good reliability for a 9-item exam, and the total score yielded a statistically significant positive correlation with experience. It showed that more experienced surgeons displayed greater accuracy in identifying CT slices that corresponded to the orthogonal radiographs than surgeons with less or no experience. This finding was inconsistent with Lesgold et al., who found that when reading chest radiographs, radiology residents at senior levels of residency are often outperformed by residents at junior levels.¹⁷

Our finding agrees with two recent eye-tracking studies that found that assessment speed and accuracy improve with experience.^{18,19} Experience improves speed and accuracy more for difficult-to-identify fractures than for clear and obvious fractures.

An online test would be easy to administer, report and maintain. The results from experiment 2 were consistent with those from experiment 1, although less compelling. Cronbach's alpha, the reliability measure, was lower (0.28 versus 0.47) and the correlation with experience was also lower (0.25 versus 0.87). There are several possible reasons for the difference between the results in the two experiments. It may be that the results from the first experiment were an anomaly, as there were relatively few participants, so the measure of reliability and correlation with experience may not generalize to other samples. The changes made to the questions may have unintentionally reduced the test's effectiveness. These changes included: more clearly specifying the location of the CT slice, standardizing the position of the CT slice, forcing participants to solve one question at a time versus allowing participants to move between questions, and changing the alternatives.

Perhaps the 90 seconds-per-image pace of the first experiment led participants to reflect longer than the

untimed format in experiment 2, in which participants spent an average of 62.2 seconds per question. The "dual process" theory from the clinical reasoning literature suggests that doctors perform a diagnosis either using "System 1," a rapid, unconscious and intuitive response, or "System 2," a slow, conscious and effortful approach.²⁰ Applied here, the theory suggests that participants who employed a system 2 approach generated results that increased the level of test reliability, even if their test scores were not higher. Figure 3 explores this possibility further by plotting the reliability of the nine questions in experiment 2 versus the subset of participants who took more than a given amount of time to complete the test. This trend supports the idea that people who took their time in answering the questions produced a more uniform set of results. It is important to note, however, that those who took more time did not necessarily have higher test scores.

The average number of correct answers between the duration-threshold groups was not significantly different. It may be that the motivation of the participants during the test was important. Experiment 1 was administered during a trauma conference, and the participants were proctored and able to observe senior surgeons working diligently to answer questions correctly. In a high-stakes testing environment, it is likely that motivation would be increased and it is possible that the test would perform more like it did in experiment 1 than experiment 2.

In either case, the test already performs reasonably well compared to other multimedia tests explored by the National Board of Medical Examiners for high stakes testing.²¹ The introduction of media into testing comes at a psychometric cost in terms of lower discrimination and less efficiency (more time). The classic validity-reliability paradox²² suggests that increased reliability

can sometimes come at the cost of decreasing validity. Nevertheless, the test already shows promise as a reliable instrument. Tests with more questions generally yield more reliable results. Figure 4 shows the projected reliability of the test if more questions were added, assuming similar discriminability, based on the Brown-Spearman prediction formula.²³ Assuming a response time of 90 seconds per question, the projection suggests that a three-hour test would yield a discrimination of experience with 80% reliability. While the duration of such a test might be too lengthy to be practical, it is possible that additional gains in test efficiency would come with further improvements in the test.

The experiments in this paper suggest that radiographic image interpretation is a measurable skill. The current approach is just one way to test the skill, and it suffers from limitations that we plan to address in our continuing investigation. Although the current version of the test addressed our theoretical perspective, surgeons do not normally need to perform a comparison between radiographs and a single CT slice. They do, however, often need to compare radiographs to a 3D model derived from a CT scan; this would be analogous to interpreting fluoroscopic images during surgery to assess progress in reducing a fracture. To that end, we have envisioned two new tests that could help generate a better understanding about the interpretation of musculoskeletal images. We seek to achieve this goal by dividing the problem into two separate tasks. First, we seek to understand if this is a problem of recognition or of interpretation. To this end, we will test participants' ability to recognize fracture patterns from different anatomical sites. Second, we will assess participants' ability to generate accurate mental fracture patterns from the observation of a pair of orthogonal radiographs. We will ask participants to observe a pair of radiographs, and then later to match their mental representation with one of four different 3D reconstructions.

This study suffered from several limitations. First, items were developed from a limited sample of fractures screened from historical cases at one institution. Second, the absence of clinical information in the task may have disadvantaged the orthopedic surgeons, since clinical information improves orthopedic surgeons' ability to detect fractures more than it does for radiologists.²⁴ Finally, the test only considered the interpretation of distal tibia fractures, and only a single slice from the CT scan was presented.

This project represents the first attempt in the orthopedic literature to define and measure this important clinical skill. Further research is needed to refine the definition of this skill and to develop a test that engenders appropriate motivation levels, provides clear face

and content validity, and provides reliable measurements in a short time period. Accomplishing this goal will reveal a new dimension of orthopedic skill that can be independently nurtured and trained to ultimately safer and more effective orthopedic care.

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VALUE ADDED: THE CASE FOR POINT-OF-VIEW CAMERA USE IN ORTHOPEDIC SURGICAL EDUCATION

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ABSTRACT

Background: Orthopedic surgical education is evolving as educators search for new ways to enhance surgical skills training. Orthopedic educators should seek new methods and technologies to augment and add value to real-time orthopedic surgical experience. This paper describes a protocol whereby we have started to capture and evaluate specific orthopedic milestone procedures with a GoPro® point-of-view video camera and a dedicated video reviewing website as a way of supplementing the current paradigm in surgical skills training. We report our experience regarding the details and feasibility of this protocol.

Methods: Upon identification of a patient undergoing surgical fixation of a hip or ankle fracture, an orthopedic resident places a GoPro® point-of-view camera on his or her forehead. All fluoroscopic images acquired during the case are saved and later incorporated into a video on the reviewing website. Surgical videos are uploaded to a secure server and are accessible for later review and assessment via a custom-built website. An electronic survey of resident participants was performed utilizing Qualtrics software. Results are reported using descriptive statistics.

Results: A total of 51 surgical videos involving 23 different residents have been captured to date. This includes 20 intertrochanteric hip fracture cases and 31 ankle fracture cases. The average duration of each surgical video was 1 hour and 16 minutes

(range 40 minutes to 2 hours and 19 minutes). Of 24 orthopedic resident surgeons surveyed, 88% thought capturing a video portfolio of orthopedic milestones would benefit their education.

Conclusions: There is a growing demand in orthopedic surgical education to extract more value from each surgical experience. While further work in development and refinement of such assessments is necessary, we feel that intraoperative video, particularly when captured and presented in a non-threatening, user friendly manner, can add significant value to the present and future paradigm of orthopedic surgical skill training.

INTRODUCTION

Factors both in and out of educators' control are changing orthopedic surgical education. Imposed restrictions on resident work hours have led to greater emphasis on surgical simulation and have increased scrutiny on how we provide surgical skills training. At the same time, an emphasis on surgical efficiency, as well as pressure to increase case volume and clinical throughput, has restricted opportunities for graduated responsibility. The American Board of Orthopedic Surgery (ABOS) mandate for a post-graduate year one (PGY-1) surgical skills training program has shifted baseline orthopedic skill acquisition towards simulated practice environments. Even as the quality of training simulation improves, orthopedic educators must also seek methods to enhance and add value to real-time trainee orthopedic surgical experiences in the operating room.

Orthopedic educators must foster and evaluate resident surgical skills. The Accreditation Council for Graduate Medical Education (ACGME) mandates review of resident performance based upon achieving designated milestones. There are 16 *patient care* milestones¹ that are directly or indirectly related to a trainee's surgical skill (Figure 1). Currently, individual faculty members assess resident performance by subjectively evaluating milestone ratings based upon limited and non-uniform observation of procedural experiences. The ACGME requires residents to maintain a log of cases they have participated in, but these logs do not include any objective assessment of the individual's involvement or performance.

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Patient and resident informed consent were obtained following protocol approved by the Institutional Review Board at the University of Iowa, IRB # 201409755.

Hip Fracture – Patient Care				
Level 1	Level 2	Level 3	Level 4	Level 5
<ul style="list-style-type: none"> Obtains history and performs basic physical exam Appropriately orders basic imaging studies Prescribes non-operative treatments Provides basic peri-operative management Lists potential complications 	<ul style="list-style-type: none"> Obtains focused history and performs focused exam Appropriately interprets basic imaging studies Prescribes and manages non-operative treatment Recognizes and evaluates fragility fractures (e.g., orders appropriate workup and/or consult) Interacts with consultants regarding optimal patient management (e.g., timing of surgery, medical management) Completes pre-operative planning with instrumentation and implants Capable of performing a basic surgical approach to the hip fracture Provides post-operative management and rehabilitation Capable of diagnosis and early management of complications Assesses risk for thromboembolic disease 	<ul style="list-style-type: none"> Completes comprehensive assessment of fracture patterns on imaging studies- recognizes reverse obliquity fractures Interprets diagnostic studies for fragility fractures with appropriate management and/or referral Arranges for long-term management of geriatric patients (e.g., management of bone health, discharge planning to long-term care) Completes comprehensive pre-operative planning with alternatives Capable of surgical repairs to a simple fracture (e.g., stable intertrochanteric femur fracture, minimally displaced femoral neck fracture) Modifies and adjusts post-operative treatment plan as needed Provides prophylaxis and manages thromboembolic disease 	<ul style="list-style-type: none"> Capable of surgical repair to moderately complex fractures (e.g., unstable intertrochanteric femur fracture) Capable of treating complications both intra- and post-operatively (e.g., manages a post-operative infection) 	<ul style="list-style-type: none"> Capable of surgical repair of complex fractures (e.g., open reduction internal fixation of femoral neck fracture) Capable of surgical treatment of complex complications (e.g., revision fixation after failed ORIF, intertrochanteric osteotomy)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: <input type="checkbox"/> Not yet rotated <input type="checkbox"/>				

Ankle Fracture – Patient Care				
Level 1	Level 2	Level 3	Level 4	Level 5
<ul style="list-style-type: none"> Obtains history and performs basic physical exam Appropriately orders basic imaging studies Prescribes non-operative treatments Splints fracture appropriately Provides basic peri-operative management Lists potential complications 	<ul style="list-style-type: none"> Obtains focused history and performs focused exam; recognizes implications of soft tissue injury Appropriately interprets basic imaging studies Prescribes and manages non-operative treatment Performs a closed reduction Completes pre-operative planning with instrumentation and implants Performs surgical exposure of the lateral malleolus Provides post-operative management and rehabilitation Capable of diagnosis and early management of complications 	<ul style="list-style-type: none"> Appropriately orders and interprets advanced imaging studies (e.g., stress views, computed tomography [CT] scan) Provides a comprehensive assessment of most fractures on imaging studies Completes comprehensive pre-operative planning with alternatives Performs surgical reduction and fixation of a simple fracture (e.g., lateral or bimalleolar ankle fracture) Modifies and adjusts post-operative treatment plan as needed Capable of treating complications both intra-operatively and post-operatively (e.g., wound breakdown following malleolar fixation) 	<ul style="list-style-type: none"> Provides comprehensive assessment of complex fracture patterns on imaging studies (e.g., pilon fracture) Recognizes indications for and provides non-operative treatment of an unstable fracture (e.g., diabetes, medical comorbidities, non-compliance) Performs surgical reduction and fixation of a moderately complex fracture (e.g., open reduction internal fixation [ORIF] trimalleolar ankle fracture or simple pilon fracture) 	<ul style="list-style-type: none"> Performs surgical reduction and fixation of a full range of fractures and dislocations (e.g., ORIF complex pilon fracture) Develops unique, complex post-operative management plans Surgically treats complex complications (e.g., revision fixation after failed ORIF)
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Figure 1. ACGME Orthopedic patient care milestones for a) hip and b) ankle fractures.¹

In many skill trades and professions, teachable moments are preserved with the use of video recording technology.²⁻⁴ For example, it is not uncommon for athletic teams to video record games or practice scenarios for extensive review later.^{5,6} Likewise, it is common practice for aviation experts and law enforcement personnel to video record scenarios, both actual and simulated experiences, for later review. The benefits of retrospective video review in training are numerous. An individual or team can review processes of care, shared or unique practices, and preferences. Individuals can identify technical shortcomings or achievements with the benefit and knowledge of hindsight regarding the outcome of such technical performances. An ability to view one's own performance lends insight into particular strengths and weaknesses, perceived or real. Another key benefit of video review is that it can facilitate peer review. The peer review process allows trainees to understand strengths or weaknesses in the context of their training level. While specific evidence remains unclear, many experts believe that such a review process increases knowledge of and indirectly benefits procedure-specific skill. It also



Figure 2. Intraoperative photograph of a resident surgeon wearing a GoPro® camera.

affords the opportunity for a trainee to review surgical performance with an attending or faculty instructor in an environment that is controlled and free from the stress often experienced in surgical environments.

This paper describes the protocol whereby we capture specific orthopedic milestone procedures utilizing a GoPro® point-of-view video camera with subsequent review of video on a website. Two milestone procedures commonly encountered on our orthopedic trauma team, hip fracture and ankle fractures, served as the initial procedures of interest for the GoPro® program. We asked orthopedic residents to obtain a video recording of their participation in these procedures as primary surgeon during a two-month trauma rotation. These videos were then catalogued and remain part of the trainee's milestone portfolio. We report our experience regarding the details and feasibility of this protocol, including the acceptance of the residents and the operating room staff.

METHODS

Our institutional review board (IRB) approved the protocol for resident participation in this ongoing educational project. In addition, all participating patients provided verbal and signed written informed consent before taking part in the study. Upon identification of a subject with a hip or ankle fracture requiring operative management, a resident or staff surgeon discussed the study with the patient and enrolled participants in accordance with the IRB-approved protocol. Operating room staff, including anesthesia, nursing, and surgical technologists, were notified that a GoPro® point-of-view camera use was part of an ongoing educational initiative and the staff provided verbal consent before the video recording procedures.



Figure 3. Screenshot of a recorded procedure with embedded C-arm image accessible via a secured website.

Prior to surgical preparation, the resident surgeon placed the GoPro® point-of-view camera on his or her head (Figure 2). The Wi-Fi feature was enabled while the adjustments were being made so that the viewing angle and area of focus could be confirmed with use of a mobile application on a portable device (e.g., an iPhone®). After surgical scrub, the camera was turned on by an operating room scrub technician. The camera recorded the point-of-view of the primary surgeon, in this case, the resident learner. During the recording, the assistance of the attending surgeon was frequently visible within the field of view. This protocol allowed the learner to record the operation, including the lessons provided by attending surgeons. Upon completion of the surgical procedure or at any point throughout the case, the camera could be turned off or removed. All of the fluoroscopic images that were acquired were time stamped and saved for later incorporation in the video.

The camera (GoPro® Hero 3+, San Mateo, CA, USA) has a resolution of 1920 by 1080 pixels and a field of view of 69.5° by 118.2°. The camera view was aligned with the surgeon's line of site onto the surgical field, generally pointed slightly downward at an angle of approximately 50-60° from vertical. The videos were collected in the 1080p30 format setting (resolution of 1920 by 1080 pixels at 30 frames per second (fps)), which yielded a file size of approximately 140 megabytes per minute. For later review on a website, the video files were converted from 1080p30 format to a wide 480p24 format (resolution of 852 by 480 pixels at 24 fps). With a total bitrate under 1 megabyte per second (1Mbps), this format enabled streaming of the video content while retaining adequate viewing resolution.

After capturing the intraoperative video, the data were transferred from the micro SD card in the camera to a secure, dedicated website. Initially, we manually edited the fluoroscopic images (transferred separately as DICOM files from the fluoroscopy machine) into each surgical video at the appropriate time and place. This manual process took approximately two hours and 15 minutes per video.⁷ We subsequently developed a software algorithm to automate video format conversion and the superimposing of fluoroscopic images onto the streaming surgical video at the appropriate time (Figure 3). This largely avoided the need for human intervention with the exception of the synchronization of the video time with the timestamp on the images.

A purpose-built, interactive website accepts and catalogs the raw GoPro® video file and completes the necessary video conversion (Figure 4). The website was built using a combination of PHP, MySQL, JavaScript, HTML and CSS programming languages. This website

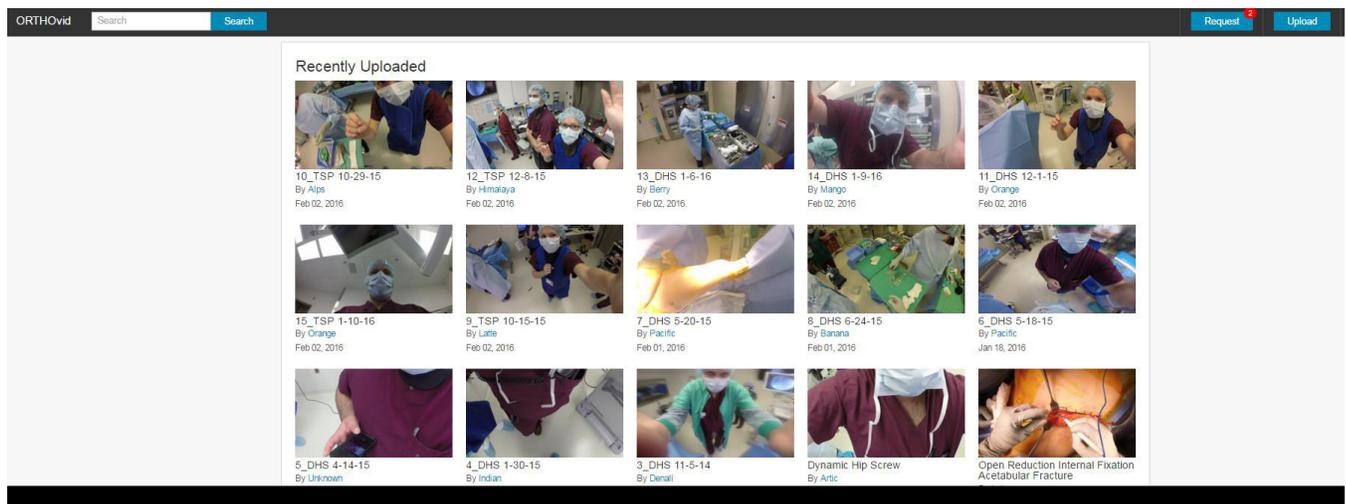


Figure 4. View of the OrthoVid website log, with videos cataloged including title, date, and operating resident (names shown are stage names assigned for confidentiality).

Category	Rating	Description
Preparation for Procedure	★☆☆☆☆	1. Did not organize equipment well. Has to stop procedure frequently to prepare equipment.
Respect for Tissue	★★★★★	5. Consistently handled tissues appropriately with minimal damage.
Time and Motion	★★★★★	3. Efficient time/motion, but some unnecessary moves.
Instrument Handling	★★★★★	2
Use of Fluoroscopy	★★★★★	4
Use of Kirschner Wires	★★★★★	1. Consistently placed wires in poorly placed positions or used in excess.
Flow of Procedure	★★★★★	3. Demonstrated some forward planning with reasonable progression of procedure.
Knowledge of Procedure	★★★★★	5. Demonstrated familiarity with all aspects of the procedure.
Overall Performance	★★★★★	1. Very Poor

Figure 5. Interactive grading platform with modified OSATS. The global rating scale was adapted from the scale used in articular fracture reduction simulation.²

enhanced the utility of video review in several ways. First, it provided context for the operation, by including the surgical procedure notes as well as the before and after radiographic images. Second, the website presented the opportunity to give and receive coaching on surgical video. Anyone logged onto the website could ask a question of another member of the website. Reviewers of each video were also given the ability to leave comments at any time on the video. All questions and comments were time stamped and appear at the appropriate time during video viewing. The individual posting the question or comment can be anonymous or identified. Finally, the website allows resident surgical performance to be assessed with a global rating scale / OSATS score. This assessment metric was presented below each surgical video (Figure 5).

While yet to be standardized, videos were reviewed by individual residents and faculty members involved in the care of the patient. During these reviews, attention was directed toward various aspects of the surgical performance thought to be important to the specific procedure (e.g., preparation for the procedure, surgical dissection, reduction, fixation technique). In addition, while not formalized, select videos were later used for instruction of PGY1 level residents or others as they rotated onto the trauma team. All orthopedic residents at our institution were invited to participate in a survey regarding their opinions of utilizing the GoPro® point-of-view camera during surgical cases.

RESULTS

The 51 surgical videos that capture the performance of 23 different residents include 20 intertrochanteric hip

fracture cases and 31 ankle fracture cases. The average duration of each surgical video was 1 hour and 16 minutes, with a range of 40 minutes to 2 hours and 19 minutes. Most surgeries were performed during a patient's index admission to the hospital for their specific injury.

In total, 21/24 (87.5%) surveyed residents felt that the ability to capture intraoperative, point-of-view video could add value to their orthopedic educational experience. Of 24 residents surveyed, 19 (79%) were interested in receiving a GoPro® video camera to document their surgical procedures over the course of a residency experience and 21 (88%) percent felt that capturing a video portfolio of select orthopedic milestone procedures would aid their surgical education. Regarding resident's rank order of how they would prefer to review learning materials to aid their orthopedic education, self-review was ranked most highly, followed by review by orthopedic staff, review with orthopedic staff, and lastly peer review. Nine residents (38%) reported headache as a downside to wearing the GoPro® camera. In one case, a member of the peri-operative team indicated that they were uncomfortable with the use of intraoperative video, and for this reason, the recording was abandoned during that particular case. Subsequent discussion with operating room staff helped convey and clarify the value and purpose of the video recording protocol. To our knowledge there have been no adverse patient consequences related to the use of the GoPro® camera to capture intraoperative video.

DISCUSSION

Changes to the residency training environment have led to restricted access to and a lack of uniformity in the surgical experience. It is clear that duty-hour restrictions, enhanced focus on patient safety, increased emphasis on high clinical throughput and operative efficiency all present challenges to the traditional paradigm. With decreasing reimbursements for individual procedures, the burden to operate more efficiently stands in direct conflict to the process of teaching and graduated responsibility. In addition, indirect metrics of surgical performance such as surgical site infection and hospital readmission rates are increasingly tied to provider and hospital reimbursement, further decreasing the tolerance for accommodating a resident learning curve. The present study describes our initial experience with a method for capturing and evaluating surgical video in an orthopedic training scenario.

Intraoperative education must remain a fundamental training component in orthopedic surgery. There is little debate that robust, objective assessments of orthopedic surgical skill simply do not exist. Yet with the advent of patient care milestones, educators feel enhanced

pressure to identify such metrics. Equally discouraging is that even experts, on occasion, fail to recognize or agree upon objective assessment techniques or on what represents a dangerous, proficient, or exceptional surgical performance. In a prior study that we conducted, residents who reviewed their recorded performance with a traumatologist showed significant improvement in OSATS scores and decreases in the number of fluoroscopic images utilized.⁷ While yet to demonstrate robust validation, the OSATS score represents a commonly utilized scoring metric for orthopedic surgical performance. Previous attempts to utilize intraoperative video in surgical training have been met with both success and failure.⁸⁻¹¹ Prior camera modalities suffered from poor resolution, static positioning and no contextual focus. For many operating rooms, a permanent audio-visual system is not possible due to cost and inflexibility with multiple operating rooms at a given medical center.¹² Wearable devices eliminate the need for a separate videographer and allow for the surgeon's vantage point to be recorded. For these reasons, our group trialed several point-of-view cameras including both Google Glass[®] and GoPro[®] (Table I).¹³⁻¹⁶ Notable differences include the higher price, limited battery life, and software limitations associated with Google Glass[®], as well as the higher resolution provided by GoPro[®] Hero 3+. In January 2015, Google indefinitely suspended its Explorer program, limiting access to Google Glass[®].¹⁶ For these reasons, we identified the GoPro[®] as the camera line most suitable to our needs.

With our protocol, we hope to add value to the operative educational experience by capturing, cataloguing and reviewing select surgical procedures on video. Video review reinforces teaching principles in a less stressful setting than typically encountered in an operating room. Birkmeyer et al. suggested that technical surgical skill can be assessed via video peer review and correlated to postoperative complication rates.¹⁷ In that study, 20 practicing bariatric surgeons submitted surgical videos for peer review. It was shown that the technical skill of a surgeon could be stratified based upon the OSATS score derived from video review. More importantly, it was noted that skillful surgeons had fewer postoperative complications and lower rates of reoperation, readmission, and visits to the emergency department.

An additional advantage of the video recording and review protocol is resident acceptance. We found a high acceptance rate of our technology platform by residents in our program. The merits of the line of work are largely self-explanatory. It is designed to enhance surgical skill training and education and to inform educators on best practice. The benefits seen will directly impact individuals responsible for much of the work.

Several iterations of this technology have led us to conclude that an effective video presentation of surgical performance requires a coherent narrative flow, including more than just the raw point-of-view video. Consequently, the surgical notes, pre- and post-operative radiographs, and the intraoperative fluoroscopic imaging must be presented passively and in context. When the narrative flow is disrupted—due to missing radiographic information, for example—viewers tend to become distracted and have trouble re-engaging with the surgery. Also, it must be easy for the viewer to scan back and forth through the video stream to quickly find moments of interest during the surgery.

Our long-term vision for this point-of-view educational surgical experience continues to evolve. We can envision our residency training program providing all entering orthopedic residents within our program with a personal GoPro[®] camera. Instructions could be provided on how to upload procedural video, as well as on how to obtain and provide peer or faculty assessments. A working repository for this data holds promise for both formative and summative surgical skill assessment. It might, for instance, be required that as part of a senior resident's graduating portfolio they provide the program director with a 16-item menu of patient care milestone videos demonstrating a minimal level of proficiency.

There are limitations to the present line of work. Notably, the informed consent process and potential for abuse should not go unnoticed. Using intraoperative video is relatively easy to do with this protocol; however, potential inclusion of identifiable subjects or personnel who have not been informed or consented could threaten the viability of the protocol. Additional limitations relate to the expense of the protocol. GoPro[®] cameras cost roughly \$300.00. Their successful operation depends upon a charged battery and removable memory in the form of a micro SD card. All of these items need to be available for use at a moment's notice. The tasks of uploading large files and editing video require time and effort. In our initial experience, videos had to be manually edited to add the fluoroscopic and radiographic images using specialty video-editing software. Our newer methods avoid this painstaking step by using timestamps in the fluoroscopic image DICOM metadata to automatically overlay the images on the video, which reduces the editing time to several minutes once the data have been acquired. We are hopeful that time and improvements in technology will make this process become even more efficient.

Changes in orthopedic surgical education are inevitable. For reasons previously highlighted, there is an increased emphasis being placed today on procedural skill development, particularly for surgical simulation. With

increased pressure to provide objective assessments of surgical skill there is a growing demand to extract the maximum value out of each surgical experience. While further work in development and refinement of such assessments is sure to occur, we feel that intraoperative video, particularly when captured, processed, and presented in a non-threatening, user-friendly manner, can add significant value to the present and future paradigm of orthopedic surgical skill training.

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OBJECTIVE EVALUATION OF MOTOR SKILLS FOR ORTHOPEDIC RESIDENTS USING A MOTION TRACKING DRILL SYSTEM: OUTCOMES OF AN ABOS APPROVED SURGICAL SKILLS TRAINING PROGRAM

Ashkan Pourkand¹, Christina Salas^{2,3,4}, Jasmin Regalado¹, Krishan Bhakta¹, Rachel Tufaro^{2,3}, Deana Mercer², David Grow^{1,2}

ABSTRACT

Background: Orthopedics is a motor skills-demanding surgical specialty requiring surgical skills training outside of the operating room. Unfortunately, limited quantitative techniques exist to determine the effectiveness of these surgical skills training programs. Using a variety of drill, surgeon, and specimen mounted sensors, we evaluated orthopedic surgery residents during a surgical skills training course approved by the American Board of Orthopaedic Surgeons (ABOS). This evaluation consisted of quantitative measures of various kinematic and kinetic parameters with the goal of relating these to clinically-significant outcomes.

Methods: Seven experienced surgeons and 22 surgical residents participated in this study, each performing 5 surgical drilling trials, pre- and post-training. Utilizing arm and tool kinematics, applied force, tool and bone vibration, and drill RPM were measured using a combination of force, acceleration, and optical tracking sensors. *Post hoc* screw pullout testing and resident survey data were also evaluated. Overall, 25 measured parameters were expressed as scalars and their covariance calculated.

Results: Non-trivial direct correlations whose magnitude exceeded 0.5 were: maximum penetration distance with applied force, drill toggle with drill roll angle, and drill RPM with force. Surgeons applying a high drill RPM also yielded a large force

which in turn gave an increase in tendency for over-penetration. As a whole, the differences between experienced and novice surgeons measured in these trials were not statistically significant. However, when looking at specific performance criterion individually (maintaining steady force, minimizing over-penetration, minimizing both the major and minor axis diameters, minimizing toggle and drill vibration), experienced surgeons tended to outperform their novice counterparts.

Conclusions: Objective assessment of surgical skills using sensor based technologies may help elucidate differences between novice and experienced surgeons for improved out-of-the-OR training methodologies.

INTRODUCTION

Orthopedics is a motor skills-demanding surgical specialty. Historically, much of the technical learning occurs in the operating room (OR). While this has proven to be an effective method of training for some cases, evolving surgical techniques and high risk scenarios require training in a more controlled environment. In these scenarios, motor skills tasks are often simulated in the lab prior to performing the tasks in the OR. General surgery has used this model to train their residents in laparoscopic techniques for many years.^{1,3} In the context of orthopedic drilling, successful task performance relates to creating a hole at the correct location with the correct orientation without the use of excessive force, heating, over-penetration, toggle, or skiving with the drill to maximize efficiency and prevent harm.^{4,6}

In 2009, the Patient Safety Committee of the American Academy of Orthopaedic Surgeons released results of a member survey which was used to identify common errors in orthopedic surgery.⁷ Results of the study showed that the orthopedic surgeon was directly involved in 60% of errors. Of these, 78% of errors occurred in the hospital with 54% occurring in the operating room. Although not all of these errors are directly attributed to motor skills competency, an improvement in motor skills training may reduce the overall percentage of surgeon related errors. As of July 2013, prompted by the quality initiative set forth by the Patient Protection and Affordable Care Act, the American Board of Or-

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The authors declare no relevant conflicts of interest

This study was approved by the Institutional Review Board at the University of New Mexico (HRR#15-087)

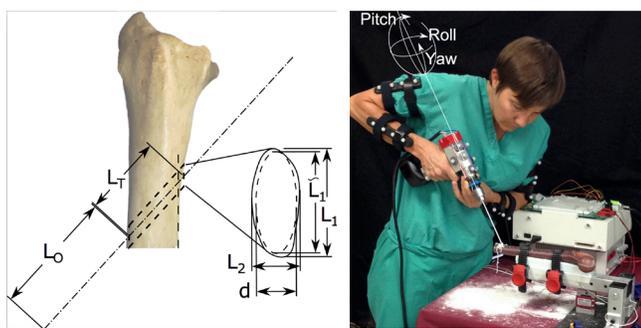


Figure 1. [left] Definitions of spatial parameters related to the bone, as measured during drilling are given. These are: over-penetration (L_0), the resulting hole major (L_1) and minor axis (L_2) lengths, ideal major length (L , for a given approach angle. Not shown, but measured is the distance between distal target and hole exit location (spatial error, L_E). [right] Definitions of the drill roll (θ_r), pitch (θ_p), and yaw (θ_y) angles are shown.

thopaedic Surgeons (ABOS) and the Residency Review Committee (RRC) for Orthopaedic Surgery mandated formal motor skills training outside of the OR.^{8,9} The ABOS and RRC believe that this training will enhance residents acquisition of basic surgical skills. However, despite this mandate, a standardized method of training outside of the operating room has not been developed for orthopedic surgery. To date, modules delineating the tasks deemed important by the ABOS have been provided as guidance in this endeavor and are publicly available for use.

The primary goal of our research was to quantitatively assess orthopedic drilling performance over the course of an ABOS-approved surgical skills training course for postgraduate year one (PGY-1) residents and to evaluate their skills relative to the instructors leading the course. This quantitative assessment of motor skills may reveal aspects of performance that are correlated with clinically significant outcomes and which may not be obvious without precise measurement and analysis.

METHODS

Human Subjects

This study was approved by the Institutional Review Board (HRRC#15-087). Subjects were recruited during the 2015 Surgical Skills Training Course held by the Southwest Orthopaedic Trauma Association (SWOTA) for PGY-1 orthopedic residents in Phoenix, AZ. This is an ABOS residency surgical skills training course with participation from orthopedic surgery residents from New Mexico, Arizona, Colorado, Texas, and Utah. In all, 22 residents and 7 attending surgeons were included.

Prior to the start of the course, we asked each resident to perform a single task: drill holes through both

cortices of a mechanically equivalent synthetic bone following a pre-defined trajectory. Participants in the course were then subject to guided training for four days on drilling skills associated with malleolar, ulnar, radial, and femoral fracture repair with locking and non-locking plate fixation. Additional motor skills training included: external fixation pin insertion techniques, k-wire fixation, tension band wire fixation, tibial and olecranon osteotomy using a sagittal saw, intramedullary nail fixation, and proximal femur arthroplasty techniques. Following the fourth day of the training period, we asked each participant to repeat the task. In addition to this, surveys were administered before and after the surgical skills course. In order to characterize the performance parameters and their relation to clinically-relevant outcomes, several parameters were measured (Appendix I & Figure 1).

Experimental Setup

The parameters described above were measured using a combination of motion tracking, force, acceleration measurements, and measurements taken directly from the synthetic drilled bone. A System 5 rotary handpiece (Stryker Orthopaedics, Mahwah, NJ) was adapted with sensors to measure acceleration (PCB-352C03, PCB Piezotronics, Depew, NY) and rotational speed (reed switch) while motion tracking markers allowed for tool position and orientation to be determined at all times. The bone fixture incorporated another accelerometer of the same type as well as a force sensor to measure loads generated during the drilling procedure (LSB302, Futek, Inc., Irvine, CA). Data from the sensors was measured using a modular DAQ system (NI cDAQ, National Instruments Corporation, Austin, TX) at a sampling frequency of 10 kHz. In addition to this, the arms of subjects were fit with motion tracking markers to monitor arm kinematics. Marker sets were oriented on the upper and lower arm using the greater tuberosity, lateral epicondyle, and ulnar styloid process as anatomical landmarks. The locations of all markers were measured using two OptiTrack (NaturalPoint Inc., Corvallis, OR) motion capture systems (one setup used eight Flex 13 cameras, the other used six Prime 13 cameras; two stations) with a capture frequency of 20Hz. Pre- and post-surveys were also administered to allow correlation between personal characteristics and training to measured drilling performance. Each subject was asked to drill 5 holes, before and after training, on the marked locations on a single bone mounted to a custom fixture as shown in Figure 1. The marked locations produced drill trajectories of approximately 0° (normal to bone surface), $\pm 25^\circ$, and $\pm 45^\circ$.

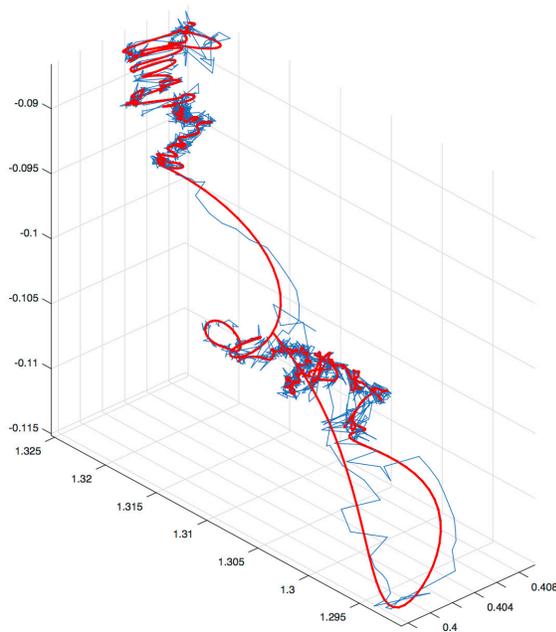


Figure 2. Calculated drill bit path from unclipped data are shown before (blue) and after (red) the low-pass filtering.

Data post processing

The force, acceleration, and reed switch data was post-processed with low-pass filtering, as necessary, before mean, max, and standard deviation values were determined (Figure 2). Motive Body software provided with the Optitrack system recorded the location and orientation of the drill ($\theta_R, \theta_p, \theta_Y$) and the rigid-body kinematics of the arms. The arm rigid bodies were used to calculate elbow and shoulder angles. The elbow center was determined by making a best fit of the upper- and lower-arm vectors obtained from the respective rigid bodies. The shoulder centers were then determined by moving in the known direction a distance determined by Dempster’s anthropomorphic table.¹⁰ Subsequently, trunk rotation relative to the orientation of the bone axis was determined. Finally, the authors developed forward kinematic equations to relate the drill body location and orientation to drill tip location. The force and drill

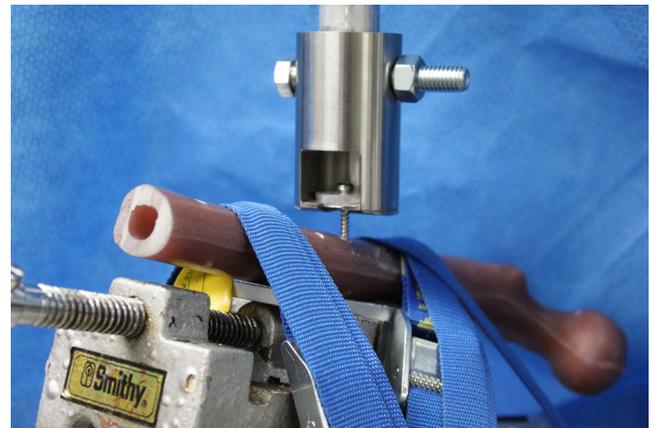


Figure 3. The pull-out test setup is shown.

trajectories were time correlated to the motion tracking data and manually clipped, using force data as the key indicator.

Post hoc analysis of bone specimens

The integrity and accuracy of drilled holes was measured directly in the laboratory after the conclusion of SWOTA. Digital calipers were used to measure the accuracy of the holes, as well as the major and minor axis lengths. The pull-out strength was measured by installing 3.5 mm cancellous bone screws into the mechanically equivalent synthetic bones (Sawbones, Pacific Research Laboratories, Vashon Island, WA; Figure 3). Specimens were mounted to a modified angle vise that allowed positioning the screws in line with the test actuator. The bones were cyclically loaded using an MTS 858 Mini Bionix II loading system using a protocol described by Ezechieli et al.¹¹

Computation of correlation coefficients

To assess the interdependency of the measured parameters, correlation coefficients were calculated. To do this, data were first vectorized, with elements for each of the parameters listed in Appendix I. The correlation coefficients were then calculated using MATLAB’s *corcoef* function.

Table I. Mean and standard deviation of values measured pre- and post-test.

param.	drill toggle	vmin	sho. angle	LO	LE	L1	L2	R	P	Y	Drill vibr.	Bone vibr.	years	RPM	Force	
units	in/s	in/s	deg	in	in	in	in	deg	deg	deg	in/s ²	in/s ²	yrs	RPM	N	
mean	Pre	2.480	.0018	81.3	.523	.191	.124	.0978	53.3	55.1	58.8	.0295	.0052	2.38	1877	91
	Post	3.751	.0017	61.8	.495	.175	.134	.0978	51.7	53.6	52.5	.0351	.0083	2.38	1982	88.7
std	Pre	.74	.0074	30.7	.181	.142	.110	.0047	.0026	.0101	.0091	3.13	.0029	1.56	4733	164
	Post	0.99	.0061	12.8	.172	.166	.122	.0047	.0031	.0084	.0072	3.13	.0025	1.56	2675	122

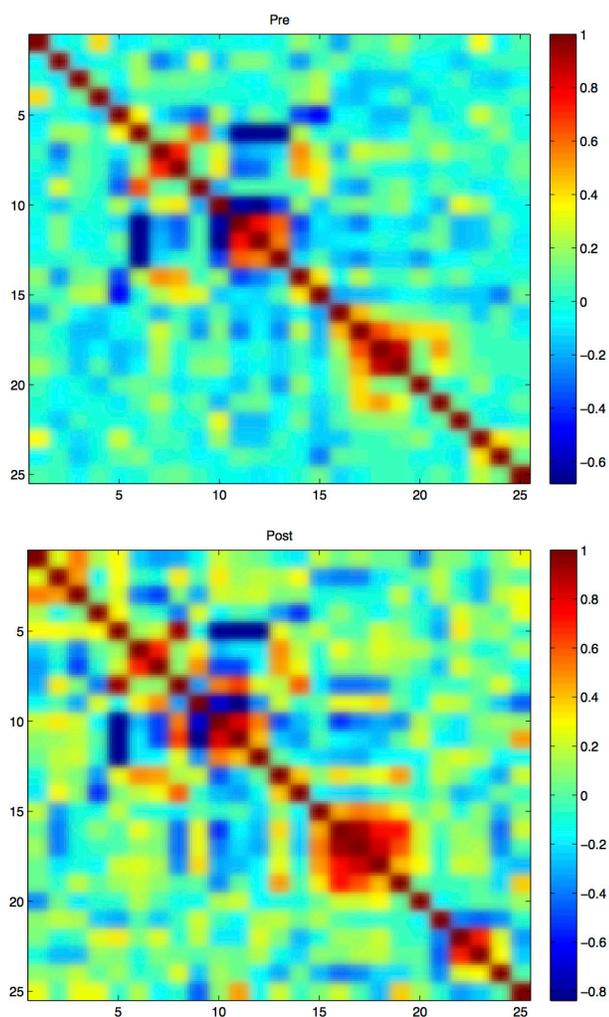


Figure 4. A visualization of how various parameters were found to co-vary is given by color-mapping correlation coefficients. Correlations on color map toward red include positive correlations. Correlations toward blue include negative correlations. Axes are defined by variables in Appendix I.

RESULTS

The post-processed data includes each of the parameters listed in Appendix I. The means and standard deviations for a key subset of these parameters, taken individually, are given in Table I. The results from comparing pairwise combination of parameters are given as correlation coefficients in Figure 4. Among these, non-trivial (e.g. sex with height) correlations whose magnitude exceeded 0.5 were (correlation values listed taken from *post* data set):

- Maximum penetration distance with force (std, 0.72)
- Maximum penetration distance with force (max, 0.73)
- Maximum penetration distance with force (mean, 0.91)
- Drill toggle with drill roll angle (mean, 0.70)
- Drill RPM with force (mean, 0.53)

The covariance matrices are not drastically different before and after the training, nor are the parameters themselves. This may not be a surprising result given that the training which occurred over the intervening time covered many skills, with no particular emphasis on improving drilling behaviors. The data suggests that when taken as a group, the experienced surgeons tested did not, on average, outperform the residents collectively.

However, when looking at clinically relevant parameters independently, an interesting pattern does seem to provide some insight into the effects of additional experience. The very best performers out of the total 29 participants, when looking at one performance aspect at time, came from the experienced surgeon subset with respect to: maintaining steady force (highest minimum before exiting the distal cortex), minimizing over-penetration, minimizing both the major and minor axis diameters, minimizing toggle and drill vibration. Additionally, an experience surgeon was nearly (second) best in terms of accurately targeting the mark on the distal cortex and (third) best in terms of the force before failure during subsequent screw pull-out testing.

No parameters related to arm or torso kinematics were found to vary in a patterned manner with respect to other parameters. This may be due to the varying height and handedness of participants as well as the observation that surgeons were quite unique in their chosen stance.

DISCUSSION

The present study was performed to evaluate the drilling skills of PGY-1 orthopedic residents before and after an approved ABOS surgical skills training program and to compare their performance to those of the program instructors. Using mechanically equivalent synthetic bones we were unable to identify an improvement in outcome measures from pre- to post-training evaluations or to identify a broad difference between novice and expert drill users. We did find correlations indicating that participants who applied the highest force to the bone during drilling also tended to over-penetrate the second cortex. Additionally, a high RPM drilling technique correlated with high force applied to the bone. These findings indicate a) an ineffective evaluation methodology (need for more sensitive or robust evaluation tools), b) a need to change from mechanically equivalent bones to soft foam models in order to evaluate more sensitive measures, and/or c) the SWOTA PGY-1 program may need to provide greater emphasis on skills to minimize over-penetration, to better control drill RPM to limit force applied to the bones, and provide bracing techniques to minimize drill toggle. We are preparing to conduct a repeat experiment at the 2016 SWOTA PGY-1 course and

have taken steps to focus our outcome evaluations on those correlations found to be most significant in 2015. Additionally, we have optimized the sensor technologies used for data collection, replaced polymer bone models with soft foam bone models, and provided feedback of 2015 outcomes to the 2016 SWOTA planning committee.

While we did not identify broad differences between novice and expert drill users, an expert user performed best (or near) in all relevant outcomes measures. It is important to note that the attending surgeons who led the program were trained in a broad range of orthopedic subspecialties (hand, sports medicine, arthroscopy, trauma, spine) and number of years post-residency varied widely. We hypothesize that the subspecialty programs require each surgeon to increase their proficiency in certain tasks that may not be as relevant in other subspecialties. For instance, limiting over-penetration is essential during spine surgery to avoid spinal cord damage. Thus, more care may be taken with that task than with drilling a hole in a mid-shaft femur for fracture fixation. In future studies we will attempt to identify subspecialty correlations to aforementioned outcome measures.

Since the inception of the ABOS mandate, some surgical skills simulation and structured resident evaluation have been implemented by residency programs.^{9,12-14} A study by Egol et al.¹³ used a written examination known as the Objective Structured Assessment of Technical Skills (OSATS) to assess the improvement of residents after a hands-on skills course and found that it was a valuable training source. This assessment is characterized by having an experienced surgeon evaluate a task and rate the participant based on whether the task was done correctly, partially done, or not done/done incorrectly. A recent study by Anderson et al.¹⁵ reported that OSATS scoring does not correlate with the quality of fracture reduction and thus is not as effective at determining surgical proficiency as objective measurement. A study by Hohn et al.¹⁴ evaluated outcomes of a surgical drilling course through measures evaluating the ability to hit an intended target. They found that repeated attempts at a targeted drilling task did help improve accuracy in trajectory. A more sophisticated assessment of surgical skill has been described by Karam et al.⁹ This group implemented a one month surgical skills training experience for PGY-1 orthopedic residents in their orthopedic program. Assessment was derived by a combined qualitative evaluation through OSATS as well as a quantitative evaluation of discrete hand motions used to perform desired tasks using a motion capture system. Unfortunately, the study did not report its quantitative findings

and thus cannot be compared to the present study. To our knowledge, our methodology of sensor based measurement tools for evaluation of surgical drilling skills is unique, and thus there does not yet exist a study in which to directly compare our findings.

Limitations of this study include the fact that three residents had to leave the event early and could not be retested, that the pool of experienced surgeons was small and perhaps not representative (some had moved into specializations that did not involve significant amounts of bone drilling), and that a significant fraction of the motion tracking data had to be excluded due to occlusions which resulted from the manner in which surgeons choose to position themselves during the task. Additionally, many surgeons commented in the post-survey that either the bones felt too hard or that the drill bit felt dull. Finally, it is important to note that resident training experiences may vary significantly prior to their participation in the PGY-1 training course because they come from different residency programs. This is important because the “learning curve” has been defined as a sigmoid shape where improvement can occur quickly in the growth phase, but more experienced users may show little improvement as their level of training increases. This may limit our ability to adequately identify the effectiveness of a 4 day training program.

Planned future work includes major revisions to the instrumentation as noted previously and expanding the study to include a larger participant pool. We expect that this will further elucidate the differences between novices and experienced orthopedic surgeons. Additionally, we will incorporate these instrumented tools into our residency training modules as part of a longitudinal study to evaluate resident performance throughout the five year residency program. Ultimately, we hope to translate the outcomes into improved surgical training methodologies. We will evaluate the effects of this training through quality improvement studies and prospective clinical studies evaluating operative care at our university.

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Appendix I. Variable definitions and explanations

	Parameter	Notes
1	Hole Loc	Which of four locations drilled on bone
2	L_E	
3	L_1	
4	L_2	
5	Subj Num	
6	Year	Year in residency, where applicable
7	Sex	
8	Height	
9	Holes	Estimated total number of holes drilled in bone
10	Days Since	Days since most last bone drilling
11	Program Q1	Does residency program have cadaveric training
12	Program Q2	Does residency program have dedicated skills training
13	PVC	Have they practiced with PVC bone analogs
14	OR Exp	Have they extensive OR experience
15	Ave RPM	
16	Max Pen	Over-penetration distance
17	Ave Force	
18	Max Force	
19	Std Force	
20	Bone Vibr	Bone-fixtured-mounted accelerometer (std)
21	Drill Vibr	Drill-body-mounted accelerometer (std)
22	Toggle	Change in drill orientation (std)
23	Ave Roll	
24	Ave Pitch	
25	Ave Yaw	

COMPARISON OF THREE VIRTUAL REALITY ARTHROSCOPIC SIMULATORS AS PART OF AN ORTHOPEDIC RESIDENCY EDUCATIONAL CURRICULUM

Kevin D Martin, DO, MAJ, MC¹, Craig C Akoh, MD², Annunziato Amendola, MD², Phinit Phisitkul, MD²

ABSTRACT

Purpose: Orthopedic education continues to move towards evidence-based curriculum in order to comply with new residency accreditation mandates. There are currently three high fidelity arthroscopic virtual reality (VR) simulators available, each with multiple instructional modules and simulated arthroscopic procedures. The aim of the current study is to assess face validity, defined as the degree to which a procedure appears effective in terms of its stated aims, of three available VR simulators.

Methods: Thirty subjects were recruited from a single orthopedic residency training program. Each subject completed one training session on each of the three leading VR arthroscopic simulators (ARTHRO mentor-Symbionix, ArthroS-Virtamed, and ArthroSim-Toltech). Each arthroscopic session involved simulator-specific modules. After training sessions, subjects completed a previously validated simulator questionnaire for face validity.

Results: The median external appearances for the ARTHRO Mentor (9.3, range 6.7-10.0; p=0.0036) and ArthroS (9.3, range 7.3-10.0; p=0.0003) were statistically higher than for ArthroSim (6.7, range 3.3-9.7). There was no statistical difference in intraarticular appearance, instrument appearance, or user friendliness between the three groups. Most simulators reached an appropriate

level of proportion of sufficient scores for each category ($\geq 70\%$), except for ARTHRO Mentor (intraarticular appearance-50%; instrument appearance-61.1%) and ArthroSim (external appearance-50%; user friendliness-68.8%).

Conclusion: These results demonstrate that ArthroS has the highest overall face validity of the three current arthroscopic VR simulators. However, only external appearance for ArthroS reached statistical significance when compared to the other simulators. Additionally, each simulator had satisfactory intraarticular quality. This study helps further the understanding of VR simulation and necessary features for accurate arthroscopic representation. This data also provides objective data for educators when selecting equipment that will best facilitate residency training.

INTRODUCTION

Orthopedic education continues to move towards an evidence-based curriculum in order to comply with new Accreditation Council for Graduate Medical Education (ACGME) and Resident Review Committee (RRC) requirements.^{1,2} Orthopedic training programs throughout the country are working to incorporate new simulation mandates into their residency programs. The RRC defines simulation as: "the imitation of the operation of a real world process or system." Orthopedic educators have been using simulation models such as cadavers, wood models, Styrofoam anatomic models, and box trainers. Historically, these methods have been successfully used in residency skills training. Unfortunately, the cost of maintaining a functioning cadaveric lab and arthroscopic equipment can be inhibitory. Direct faculty instruction and resident education is often limited due to clinical and surgical obligations while remaining compliant with the mandated 80 hour work week.³⁻⁵ These factors have created the need for the development of arthroscopic knee and shoulder virtual reality (VR) simulators to allow trainees to practice basic skills and receive objective feedback on performance.

VR simulation technology has drastically improved over the past decade from unrealistic low fidelity models⁶ to current high fidelity models with nearly unlimited procedures and tasks to improve basic arthroscopic

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Ethical Review Statement: This article is IRB exempt and was HIPPA compliant

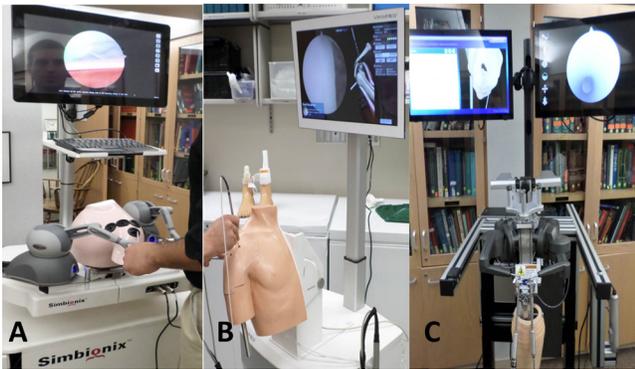


Figure 1. Arthroscopic simulators including A) ARTHRO mentor (Symbionix), B) ArthroS (Virtamed) and C) ArthroSim (Toltech).

skills.^{8,10,11} High fidelity models provide trainees with realistic anatomic features with tactile feedback while allowing manipulation of relevant structures using appropriately-sized arthroscopic instruments.⁷ VR simulators have achieved varying levels of high fidelity while incorporating task-specific modules that reinforce skills, such as simple triangulation, palpation, suture passage, and grasping techniques. Various curriculum and assessments give educators the ability to objectively track trainee performance, thus meeting ACGME requirements.

Based on the changing environment of orthopedic education and the development of several VR arthroscopic simulators, the aim of the current study is to assess face validity, defined as the degree to which a procedure appears effective in terms of its stated aims, of three available VR simulators. The current investigation is a prospective comparative study to evaluate the face validity of the three leading arthroscopic VR simulators as evaluated by orthopedic trainees and staff surgeons at a single training institution. The four variables that comprised face validity in this study were outer appearance, intraarticular appearance, instrument appearance, and user friendliness. We hypothesized that the three leading VR arthroscopic simulators would have no significant difference in face validity.

METHODS

Participants

We recruited thirty volunteer participants from a single orthopedic residency training program during June 2014. Participants included nineteen orthopedic residency trainees, two medical students, and nine arthroscopy-trained staff members. Academic standing was not affected by study involvement and individual performance was not evaluated for academic purposes. Per the study design, the subjects' arthroscopic experience varied by postgraduate year, prior training experiences, and years of practice. Hence, study participants provided

a wide variety of arthroscopic experience. Except for possible brief exposures at academic meetings, all subjects were naïve to each of the simulators. The simulation evaluations took place over a three-week period during June of 2014. Each simulator was randomly assigned to participating subjects during scheduled academic time.

Simulators

We prospectively collected data while evaluating three arthroscopic VR simulators. Three companies were sent an invitation to participate in the study which included utilization of their simulator over a two-day period with a representative present to provide instruction and technical support. The three companies that were invited all agreed to participate and included ARTHRO Mentor (Symbionix, Cleveland, OH), ArthroS (Virtamed, Zurich, Switzerland), and ArthroSim (Touch of Life Technologies, Aurora, CO) (Figure 1). Each simulator was then randomly assigned a test date and time and subjects randomly assigned to each simulator as previously described. For consistency, a training module that included examination and palpation of structures within the glenohumeral joint was selected to assess face validity and user-friendliness of each arthroscopic VR simulator.

Simulation Evaluation

Prior to the tutorial session, each participant reviewed the study objectives and scoring system. Each participant was given a two minute tutorial session, during which subjects were able to manipulate each simulator, similar to a previously established protocol.⁸ Participants were then given five minutes of undirected arthroscopy time to become further familiarized with each of the three simulators. Following the tutorial, participants completed 1) anatomic identification of specified structures within the glenohumeral joint and 2) palpation of specific anatomic landmarks using a specific glenohumeral module for each arthroscopic simulator. After completing these modules, each subject immediately and anonymously completed a previously established questionnaire for face validity variables, including external appearance of each simulator, intraarticular appearance, instruments, and user-friendliness (Table I). A sufficient representation of validity was defined as a median score of 7 per category.¹² All testing and questionnaires were proctored by a single individual to maintain consistency between groups.

Statistical Analysis

Data processing and statistical analyses were performed based on previous studies.¹¹ Variables were assessed for normality using the Kolmogorov-Smirnov test, histograms, and normal probability plots. Results revealed that questionnaire variables were not normally distributed. Therefore, nonparametric analyses were

Table I. Participant Post Assessment Questionnaire

<i>Outer Appearance</i>									
What is your opinion of the outer appearance of this simulator? (circle one)									
1 (unreasonable)	2	3	4	5	6	7	8	9	10 (reasonable)
Is it clear in which joint you will be operating?									
1 (unclear)	2	3	4	5	6	7	8	9	10 (very clear)
Is it clear in which joint you will be operating?									
1 (unclear)	2	3	4	5	6	7	8	9	10 (very clear)
<i>Intraarticular Appearance</i>									
How realistic is the intra-articular anatomy?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the texture of the structures?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the color of the structures?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the size of the structures?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the size of the intra-articular joint space?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the arthroscopic image?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
<i>Instruments</i>									
How realistic do the instruments look?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic is the motion of your instruments?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
How realistic does the tissue feel when you are probing?									
1 (unrealistic)	2	3	4	5	6	7	8	9	10 (realistic)
<i>User-Friendliness</i>									
How clear are the instructions to start an exercise on the simulator?									
1 (unclear)	2	3	4	5	6	7	8	9	10 (very clear)
How clear is the presentation of your performance by the simulator?									
1 (unclear)	2	3	4	5	6	7	8	9	10 (very clear)
Is it clear how you can improve your performance?									
1 (unclear)	2	3	4	5	6	7	8	9	10 (very clear)
How motivating is the way the results are presented to improve your performance?									
1 (not motivating)	2	3	4	5	6	7	8	9	10 (very motivating)

completed to assess face validity. Specifically, scores for external appearance, intraarticular appearance, instrument appearance, and user-friendliness were compared among the three simulators using the Kruskal-Wallis and Wilcoxon Rank Sum tests. These scores were presented as medians with an associated range. Differences in the proportion of simulators that met sufficient were compared using Fisher’s exact test. Proportion of training level within each group were compared using Fisher’s exact test. Statistical significance was reached with a p-value <0.05 while employing Bonferroni adjustment. Post-hoc analysis between groups reached statistical significance with a p-value of < 0.017 (0.05/3). All analyses

were completed using SAS software version 9.3 (SAS Institute, Cary, NC).

RESULTS

In total, 28/30 (93.3%) subjects enrolled in this study completed the designated modules. Each of the individual simulator evaluation groups was similar in size and demographics with no significant differences when comparing proportion of training level between groups (p = 0.097) (Table II). Eleven out of 28 subjects (39.3%) completed questionnaires for all three simulators. Seventeen out of 28 subjects (60.7%) completed one or two evaluations due to scheduling conflicts. All medical students (100%)

Table II. Distribution of Participants Completing Simulation Tasks

	Faculty (n=11)	Resident (n=15)	Medical Student (n=2)	Total
Simulator				
Arthro Mentor	9	7	2	18
Arthro S	9	7	2	18
Arthro Sim	6	8	2	16
Simulators completed				
One	4	11	0	15
Two	1	1	0	2
Three	6	3	2	11
Total	11	15	2	

and 6 out of 11 arthroscopy-trained staff subjects (54.5%) completed all three simulator evaluations.

The median external appearance score for the ARTHRO Mentor (9.3, range 6.7-10.0; p=0.0036) and ArthroS (9.3, range 7.3-10.0; p=0.0003) were statistically higher than for ArthroSim (6.7, range 3.3-9.7) (Table III). However, a difference in external appearance failed

to reach statistical significance when comparing ARTHRO Mentor and ArthroS (p = 0.2587). The median intraarticular appearance score for each of the three simulators did not reach statistical significance. Similarly, there were no significant between-test differences in instrument appearance or user friendliness. All face validity median parameters met a sufficient realistic representation score of at least 7, except for intraarticular appearance for ARTHRO mentor and outer appearance for ArthroSim.

Overall, most simulators reached sufficient frequency scores for each face validity category. Both ARTHRO Mentor (94.4%, p= 0.056) and ArthroS (100%, p= 0.007) had statistically higher percentages for proportion of sufficient scores for external appearance when compared to ArthroSim (50%) (Table IV). User friendliness for ArthroSim was rated as sufficient by 11 out of 16 participants (68.8%). ARTHRO Mentor did not reach an appropriate level of proportion of sufficient scores for intraarticular appearance (50%) and instrument appearance (61.1%). Overall, there were no statistical differences between simulators when comparing the frequency of sufficient scores achieved for intraarticular appearance, instrument appearance, and user friendliness.

Table III. Median Scores for Face Validity by Simulator*

Variables	ARTHRO mentor (S) (n=18)	ArthroS (V) (n=18)	ArthroSim (T) (n=16)	p-values
Outer Appearance	9.3 (6.7-10.0)	9.3 (7.3-10.0)	6.7 (3.3-9.7)	S vs V:0.2587 S vs T:0.0012† V vs T:<0.001†
Intraarticular Appearance	6.9 (4.3-10.0)	8.0 (6.2-10.0)	7.8 (3.7-9.0)	S vs V:0.0476 S vs T:0.1515 V vs T:0.8762
Instrument Appearance	7.3 (4.3-9.3)	8.3 (6.0-10.0)	8.2 (4.0-9.3)	S vs V:0.1924 S vs T:0.2320 V vs T:0.9861
User Friendliness	8.0 (5.8-9.8)	8.6 (5.8-10.0)	7.3 (2.5-9.8)	S vs V:0.1124 S vs T:0.2383 V vs T:0.0330

*Values expressed as mean (range). †Statistically significant when adjusted for multiple comparisons.

Table IV. Proportion of Sufficient Scores (≥7) by Simulator*

Variables	ARTHRO Mentor (S) (n=18)	ArthroS (V) (n=18)	ArthroSim (T) (n=16)	p-values
Outer Appearance	17 (94.4)	18 (100.0)	8 (50.0)	S vs V: 1.0000 S vs T: 0.0056 V vs T: 0.0007
Intraarticular Appearance	9 (50.0)	15 (83.3)	13 (81.3)	S vs V: 0.0750 S vs T: 0.0796 V vs T: 1.0000
Instrument Appearance	11 (61.1)	16 (88.9)	14 (87.5)	S vs V: 0.1212 S vs T: 0.1251 V vs T: 1.0000
User Friendliness	15 (83.3)	16 (88.9)	11 (68.8)	S vs V: 1.0000 S vs T: 0.4920 V vs T: 0.2143

*Values presented as no.(%).

DISCUSSION

The results of the current study indicate that there is a significant difference in external appearance for the three current arthroscopic simulators. However, ARTHRO Mentor failed to reach a face validity score of 7.0 for intraarticular appearance and the ArthroSim group failed to achieve a face validity score of 7.0 for external appearance. There continued to be a significant difference for external appearance even after adjusting for multiple comparisons. On the other hand, intraarticular appearance did not reach statistical significance after adjusting for multiple comparisons. ARTHRO Mentor tended to have worse face validity for intraarticular appearance when compared to the ArthroS group. To the best of our knowledge, this is the first three way head-to-head arthroscopic VR simulator study using previously validated metrics.

As simulation continues to be refined and incorporated into orthopedic education, residency curriculum across the country will be increasingly based on evidence and proven outcome measures of simulator education. The current study is intended to assist orthopedic educators in making evidence-based decisions in regards to VR simulation. The current study findings differ from a previous comparative VR simulator study that found the InsightArthroVR1Arthroscopy Simulator to score significantly better when compared to ArthroSim in user friendliness. The previous study also showed no statistical difference in external appearance and intraarticular appearance.¹² The addition of a third simulator in our study established a statistical difference in external appearance between the lower-performing ArthroSim group and the higher-performing ARTHRO Mentor and ArthroS groups. The most notable strength of the study is the number of simulators evaluated, as no previous study has completed a three-way head-to-head VR simulator trial using previously established metrics. A second strength is that nearly a quarter of subjects evaluating each simulator were made up of expert level staff physicians with extensive arthroscopic experience. Our study expounded upon the prior work by adding a third simulator that allowed subjects to see a more diverse spectrum of features and quality along with product upgrades from the previous study.

The ability to assess face validity will allow for residency programs to select the arthroscopic simulator that will fit their specific needs. As our institution moves towards meeting the ACGME requirements for resident experience, purchasing the simulator with the highest overall face validity will give residents the optimal arthroscopic training experience. However, other factors

such as price, service potential, and future curriculum development will affect the feasibility and ultimately our selection of an arthroscopic simulator.

The most notable limitation of the present study is the small sample size. Sample size has been a constant problem with simulation studies due to program size and trainee availability, leaving nearly all simulation studies underpowered.^{6,8,9,11} However, our sample size of 30 is similar to previous head-to-head studies while comparing all three currently available arthroscopic VR simulators.¹² In order to limit selection bias, all available trainees participated. Unfortunately, training level affected participation with all three simulators. Only 20% of the resident subjects completed all three simulator modules. Resident availability for this study was likely limited due to clinical and educational responsibilities. A second limitation was that the order of exposure to the three simulators was not randomized. Individual randomization was not logistically possible given the limited availability of each simulator and participant. We were also not able to perform comparative timed-based task completion due to the vast differences in simulator designs. We also did not compare whether the skills obtained from each of the three arthroscopic simulators translated to realistic cadaveric models. Thirdly, the only conclusion that could be drawn from the results is that external appearance statistically differed between the three simulators. The transfer of arthroscopic simulator skills likely does not solely depend on external appearance. This also brings the question of which face validity variable is most important when selecting arthroscopic simulators for training. Although this study found there was a statistical difference in external appearance between the three simulators, other variables such as intraarticular appearance and user friendliness are likely important for face validity. Future studies including more rigorous head-to-head validation that evaluates the transfer of surgical skills to successful surgeries and improved patient outcomes are recommended.

In conclusion, these results demonstrate that ArthroS has the highest overall face validity of the three current arthroscopic VR simulators. However, only external appearance for ArthroS reached statistical significance when compared to the other simulators. Additionally, each simulator had satisfactory intraarticular quality. This study helps to further the understanding of VR simulation and necessary features for accurate arthroscopic representation. This data will help educators determine which simulator will best facilitate training for their individual program needs.

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THE ECONOMIC BURDEN OF ORTHOPEDIC SURGERY RESIDENCY INTERVIEWS ON APPLICANTS

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ABSTRACT

Background: The intense competition for orthopedic surgery residency positions influences the interview process. The financial impact on residency applicants is less well understood. The purpose of the present study was to define the economic burden of the orthopedic surgery residency interview process while additionally describing how applicants finance the expense.

Methods: We distributed surveys to 48 non-rotating applicants at our institution's residency interview days for the 2015 match year. The survey consisted of eleven questions specific to the costs of interviewing for orthopedic surgery residency positions.

Results: The survey response rate was 90% (43/48). Applicants applied to a median of 65 orthopedic surgery residency programs (range 21-88) and targeted a median of 15 interviews (range 12-25). The mean cost estimate for a single interview was \$450 (range \$200-800) and the cost estimate for all interviews was \$7,119 (range \$2,500-15,000). Applicants spent a mean of \$344 (range \$0-750) traveling to our interview. Seventy-two percent borrowed money to finance their interview costs and 28% canceled interviews for financial reasons.

Conclusions: The financial cost of interviewing for orthopedic surgery is substantial and a majority of applicants add to their educational debt by taking out loans to finance interviews. Future considerations should be made to minimize these costs for an already financially burdened population.

INTRODUCTION

Orthopedic surgery is one of the most competitive residencies for applicants who participate in the National Residency Matching Program (NRMP).^{1,3} Despite modest increases in available orthopedic residency positions, the number of orthopedic surgery applicants continues to outpace the number of available positions. In 2014, 994 applicants competed for 695 positions, yielding a match rate of 77% for U.S. applicants and 28% for international applicants.¹ Since orthopedic surgery programs fill 99% of available positions through the match process, orthopedics is consistently amongst the most competitive specialties that fill positions with U.S. senior medical students.^{2,3}

The intense competition for orthopedic surgery residency positions influences the interview process. An applicant is eligible to match at a program only if they participate in an interview. The probability of matching in any program is directly related to the number of interviews an applicant goes on. For example, recent NRMP data shows that an applicant's chances of matching are approximately 90% when ranking 11 programs, compared to just 50% when ranking 5 programs.¹ Thus, there is strong incentive for applicants to participate in as many interviews as they are offered.

The financial impact of interviews on residency applicants is less well understood. The interview process demands a commitment of time and money from the applicant. The applicant is usually responsible for all expenses associated with each interview, which potentially includes air and/or ground transportation and lodging. The cumulative cost of multiple interviews can quickly escalate. Moreover, this cost is in addition to the expense of applying to programs through the Electronic Residency Application Service (ERAS), a central application agency that distributes applicant data to participating institutions.⁴

Other specialties have investigated the cost of interviewing for their applicants. A 2008 publication in the *Journal of Urology* reported that students applying for urology residency spent a median of \$4,000 (range 2,000-5,200) during the interview process. The median number of interviews was twelve and the median expense per interview was \$330.^{5,6} Similarly, in 2010, ophthalmology applicants spent an average of \$4,530 to complete their

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Table I. Applicant Survey

- 1) To how many orthopedic surgery residency programs did you apply? _____
- 2) What is your target number of interviews?

- 3) At the beginning of the application process, how much did you anticipate spending for **ALL** interviews (i.e. flight, hotel, car, etc.)? \$ _____
- 4) Has that initial cost estimate changed?
 - a. Yes, my new cost estimate is \$ _____
 - b. No
- 5) How are you financing costs for interviews? (choose all that apply)
 - a. Federal student loan
 - b. Private student loan
 - c. Loan from family/friend
 - d. Gift from family/friend
 - e. Personal savings/earnings
- 6) Did you turn down any interviews for financial reasons?
 - a. Yes (How many? _____)
 - b. No
- 7) What is your average expense for a **single** interview
\$ _____
- 8) Please estimate your travel expenses for your Loyola interview:
 - a. Flight \$ _____
 - b. Taxi/Car rental/gas \$ _____
 - c. Lodging \$ _____
 - d. Total \$ _____
- 9) Approximately how many miles did you travel to get here?

- 10) Do you feel that the interview process, separate of application cost, is too expensive?
 - a. Yes
 - b. No
- 11) To help lower costs, what would you change about the interview process?

interviews while some applicants reported total interview costs as high as \$10,000.⁷ It is reasonable to expect a similar situation for orthopedic surgery residency applicants. However, there is a paucity of information on how orthopedic residency applicants finance the interview process and balance the cost of interviewing with the competitiveness of applying to orthopedics.

The purpose of this study was to define the economic burden of the orthopedic surgery residency interview process and how the applicants finance this expense using a survey-based approach. We hypothesize that the cost of interviewing for orthopedic surgery applicants is similar to that reported by other specialties.⁵⁻⁷

MATERIALS AND METHODS

Study Participants and Survey Administration

A one-page survey was generated consisting of eleven questions specific to the costs of interviewing for orthopedic surgery residency positions (Table I). The survey was prepared by three orthopedic surgery attendings and two orthopedic surgery residents. This survey was distributed to all interviewees at our institution's residency interview days for the 2015 match year. Forty-eight applicants were invited to participate in the study. The purpose of the survey was explained by the study principal investigator who emphasized the voluntary and anonymous nature of the study. Interviewees were asked to complete the survey during the interview day and to place completed surveys in an unmonitored container in the applicant meeting area. This study was reviewed and assigned a status of exempt from our institutional review board.

Data Collection and Analysis

Completed surveys were compiled into a single database. If an applicant's response to a question was a range of numbers (e.g. 15-20), then the average was used. Surveys were categorized as "in-town" if the travel distance was 30 miles or less and "out-of-town" if the applicant traveled more than thirty miles to the interview. Survey results were compiled and means and medians were calculated using Microsoft Excel.

RESULTS

The survey response rate was 90% (43/48). One applicant did not list an anticipated cost estimate or an estimate at the time of survey completion (questions 3 and 4), one applicant did not provide a mean expense for an interview (question 7), and three applicants did not list how many miles they traveled for the interview (question 9).

Table II. Comparison of “In-town” and “Out-of-town” Applicant Survey Results

	“In-town” ¹ Applicants (n=4)	“Out-of-town” ¹ Applicants (n=36)	All Applicants (n=43)
No. of Miles Traveled	16 (8-20)	475 (90-3,000)	400 (8-3,000)
No. of Programs Applied to	57 (50-80)	68 (21-88)	65 (21-88)
Target No. of Interviews	19 (15-25)	15 (12-20)	15 (12-25)
Initial Total Cost Estimate	\$7,125 (2,500-15,000)	\$7,405 (2,500-11,000)	\$7,345 (2,500-15,000)
Total Cost Estimate at Time of Survey Completion	\$7,125 (2,500-15,000)	\$7,041 (2,500-11,000)	\$7,119 (2,500-15,000)
No. of Applicants Who Turned Down Any Interview(s) for Financial Reasons	0	12	12
Expense for Single Interview	\$400 (250-750)	\$456 (200-800)	\$425 (200-800)
Travel Expenses for Our Interview			
Flight ²	N/A	\$317 (98-500)	\$322 (98-500)
Taxi/Car Rental/Gas ²	\$17 (10-30)	\$71 (30-200)	\$68 (10-200)
Lodging ²	N/A	\$113 (50-200)	\$120 (50-250)
Total	\$13 (0-30)	\$363 (50-750)	\$344 (0-750)

Results are expressed as median (range).

¹Travel distance of 30 miles used as cut-off. Three applicants did not provide miles traveled.

²Values represent applicants who listed an expense

Applicants had applied to a median of 65 orthopedic surgery residency programs (range 21-88) with the goal of completing a median of 15 interviews (range 12-25). At the beginning of the application process, the total cost of interviewing was anticipated by respondents to be \$7,345 (range 2,500-15,000). The total cost estimate at the time of survey completion was \$7,119 (range 2,500-15,000), only a 3.1% decrease. Six respondents said their initial total cost estimate was an underestimation and nine said it was an overestimation; the remainder listed no change. Applicants were surveyed in November and December, well before having completed all of their interviews, which typically continue through the end of January.

The median total cost for a single interview was \$425 (range 200-800). Applicants reported spending a median of \$350 (range 0-750) traveling to our interview. The cost was less for “in-town” applicants in comparison to “out-of-town” applicants (Table II). There were four students who traveled thirty miles or less for a median interview expense of \$10 (range 0-30). The 36 “out-of-town” applicants traveled a median of 475 miles (range 90-3,000) and spent a median of \$368 (range 50-750).

We asked applicants to breakdown their travel expenses for our interview by flight, ground transportation, and lodging. Airfare was the most expensive component. Of the “out-of-town” applicants, 72% flew to the interview. For these applicants, the flight was the most expensive component of their travel costs. Out-of-town applicants spent \$317 (range 98-500) on airfare, which was 70% of the applicant’s total travel expenses.

Interview related expenses were covered by various methods. Among the 43 respondents, 25 (58%) obtained money from personal savings/earnings, 21 (49%) from federal student loans, 13 (30%) from personal loans from a family or friend, 12 (28%) from gifts from a family or friend, and six (14%) from private institutional loans. In total, 26 (60%) cited multiple sources and 31 (72%) borrowed money to finance their interview costs.

Twelve of the surveyed interviewees (28%) reported that they had turned down from one to ten interviews for financial reasons. Eighty-six percent (37/43) felt that the interview process, separate of application cost, is unnecessarily expensive.

DISCUSSION

This investigation was conducted to gain insight into the financial burden of the orthopedic surgery residency interview process. The orthopedic and NRMP literature detail that orthopedic surgery is one of the most competitive specialties.^{1,3} Published data demonstrates that an applicant's chances of matching into an orthopedic surgery residency is directly related to the number of interviews participated in and subsequently programs ranked.^{1,8} With this knowledge comes an increased pressure on applicants to participate in, and therefore finance, as many interviews as possible to allow a reasonable chance at matching. This point is well demonstrated in our survey. Our interviewees listed fifteen interviews as their target (often referred to as the "magic number"), even though statistically one's probability of matching is already 90% with eleven interviews.³ While there certainly is benefit to going on any interview, one must also weigh the additional cost of an interview against the potentially minimal impact on chances of matching. We found that the current match system creates a significant financial burden for orthopedic surgery applicants.

Surveyed applicants estimated a total interview cost of over \$7,100. This is in addition to a median of \$1,265 spent applying to residency programs through ERAS.⁴ Twenty-nine percent of the respondents said they would ultimately spend \$10,000 or more on interviews, including one applicant who listed a total estimate of \$15,000. The \$7,100 estimate at the time of survey completion is only 3.1% lower than the initial cost estimate, and both are nearly double that of the estimates reported by other competitive specialties. Previously published studies in urology and ophthalmology, both competitive surgical subspecialties, reported an applicant's total expense to be \$4,000 and \$4,530, respectively. The urology and ophthalmology studies were both published within the past six years and thus the differences between our results and those previously published are not explained entirely by rising travel costs or inflation. Furthermore, the urology applicants went on a median of twelve interviews which is comparable to the number our respondents reported. This large discrepancy warrants further investigation, but at the very least, underscores the financial demands being placed on applicants applying for orthopedic surgery residency programs.

Applicants are financing their interview costs largely through some form of loan. This is added to the enormous educational debt that a majority of medical students accumulate by graduation. In their 2012 update, "Physician Education Debt and the Cost to Attend Medical School", the Association of American Medical Colleges reported that 86% of medical students were graduating with educational debt and that the median education

debt was \$170,000.⁹ While the cost of interviewing may just be a fraction of an applicant's total educational debt, it by no means legitimizes this additional expense. To this point, perhaps the most interesting data out of our survey is that 28% of our interviewees canceled at least one interview for financial reasons. Seven of these applicants canceled more than one interview and one said they canceled ten. Due to the anonymity of the survey, there is no way of knowing what each of those student's individual educational debt is or how many interviews they may have already received or attended. Some students may have canceled an interview because they saw minimal benefit to their overall prospects of matching and thus an additional interview was not worth the money. We would consider this a sound financial decision. Further research is needed to determine if applicants are truly losing an opportunity to interview because of unmanageable costs. If this is the case, then the fact that money, rather than merit, can determine who interviews for a residency position is alarming for the field of orthopedic surgery.

Other specialties have trialed different strategies to reduce applicant interview costs. Video conferencing has been employed for out-of-town applicants. A family medicine residency program cited an average savings of \$566 when applicants completed their interview via Skype (Microsoft, Redmond, WA) compared to the traditional face-to-face interview.¹⁰ A drawback to this strategy, however, is the inability to tour the hospital and city that may be an applicant's future place of training and residence. In fact, one ophthalmology program saw no difference in cost between video-conferencing and face-to-face interviews when applicants subsequently scheduled separate department tours.⁹ Clearly, visiting a program in person is an important factor to many applicants.

In Canada, the urology residency training programs implemented a single-site, one day event where applicants interview with each of the urology programs. Similar to using video conferencing, however, the reported cost savings did not take into account the applicants' separate site visits.¹¹ Moreover, the Canadian Urology Fair only involved nine programs and twenty-eight candidates, whereas the 2014 NRMP match included 162 participating orthopedic surgery programs and over 1,000 applicants.³ We believe a centralized, annual interview event for U.S. orthopedic surgery residency programs would be logistically challenging. An alternative strategy is for programs within the same metropolitan area to coordinate and schedule interviews on sequential days. Not only would this reduce the number of flights, the biggest driver of costs, but it also maintains the in-person visit important to the applicant. The American Shoulder

and Elbow Surgeons Fellowship Match has recently adopted this city-organized approach.

Our program has made a policy of interviewing applicants who rotate at our program at the end of their month-long rotation. While orthopedic surgery rotations during medical school are not a requirement to applying for residency, rotations at potential training institutions are popular and common amongst applicants.² Interviewing during a rotation is time efficient for the applicant. First, by not having to interview at a separate, later date the applicant can instead use that time to interview at another program, or at the very least, does not have to miss any additional time during their 4th year of medical school. Secondly, by including the interview with the rotation, our applicants avoid the financial costs associated with a separate interview visit. In light of the data from this study, we estimate that we save our rotating students an average of \$344. Considering that applicants today perform two or three away rotations, if every program interviewed applicants at the time of their rotation, an applicant could potentially save upwards of \$1,000. We strongly encourage all programs to consider this simple, cost-saving measure for rotating students.

There are several limitations to our study. First, we only surveyed 43 non-rotating applicants who interviewed at a single institution during one year. Additionally, the applicants were presented with the survey on their interview date, and while they may have recently been booking travel for upcoming interviews, it is unlikely that they reviewed these purchases when making cost estimates. It is therefore conceivable that their cost estimates are either an overestimation or an underestimation as significant recall bias was likely a factor. Because the survey was anonymous, it is not possible to follow up with the participants to determine the accuracy of their estimates. Lastly, our institution is located in a major U.S. city with multiple airports and air carriers. Airfare is relatively low compared to other cities and therefore our interview may not be a fair representation of what applicants typically spend on flights.

In conclusion, this study examined the financial costs that applicants incur while interviewing for orthopedic surgery residency and the potential implications on the match process. We found that applicants estimate spending over \$7,100 on interviews. Additionally, 72% had to borrow money to pay for interview costs, while 28% of respondents had canceled interviews for financial reasons. We provide several suggestions that we have anecdotally explored at our institution, including interviewing applicants at the time of their away rotation, in order to reduce the financial burden associated with interview travel. In light of the already enormous

educational debt that medical students are graduating with, our specialty has the responsibility to seek innovative and effective ways to reduce this financial burden in order to ensure that a diverse group of applicants can be interviewed.

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ACCESSIBILITY AND AVAILABILITY OF ONLINE INFORMATION FOR ORTHOPEDIC SURGERY RESIDENCY PROGRAMS

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ABSTRACT

Background: Prospective orthopedic residency applicants commonly use one of three databases to identify potential programs: Accreditation Council of Graduate Medical Education (ACGME), American Medical Association (FREIDA), or Orthogate.org. In addition, institutional websites are typically the primary source of information once programs are identified. We sought to evaluate the databases and websites used by prospective orthopedic surgery applicants for content and accessibility. We hypothesized that information would be more available in comparison to previous studies but would still fail to provide complete, up to date program information for the prospective applicant.

Methods: Three online databases were queried in December 2014 to compile a list of orthopedic residency programs in the United States. This combined list was used as a basis for evaluating individual institution websites. Previously described criteria were used to evaluate the availability of information contained within orthopedic surgery residency websites.

Results: At the time of online review, 157 programs were identified. Depending on the database in question, up to 33% of programs either did not provide a link or listed a non-functioning link. Among the variety of evaluated criteria, inclusion of the information varied between 12% and 97% for the individual program websites.

Conclusions: Online databases are useful in listing programs, but individual program details and direct functional links are lacking. Most program websites contain varying degrees of desired information; however, not all programs maintain

websites which consistently provide information to satisfy the evaluated criteria in this study. Improved online accessibility and availability of information for residency programs would increase their visibility and utility for prospective applicants.

INTRODUCTION

Each year, more medical students apply for orthopedic residency. With this increase in number of applicants, the competition for a position continues to increase as well, making it one of the most competitive specialties.¹ With these trends, the importance of maintaining an informative and accessible website continues to grow. The importance of web-based information has been evaluated for multiple orthopedic fellowships^{2,4} as well as various other surgical residencies.^{5,7} Rozental et al. performed a similar study for orthopedic residencies in 2001.⁸ Their study revealed at that time many academic orthopedic departments underutilized the Internet with subpar websites or lack of an Internet presence. Although the Internet has been established as a useful communication tool for quite some time, utilization has significantly increased since 2001.⁹ Increased utilization brings more up-to-date and accurate information, however not all academic departments take advantage of this useful communication tool.^{2,7}

Medical students frequently rely on online databases to identify available residency programs. Three commonly used databases are maintained by the Accreditation Council of Graduate Medical Education (ACGME),¹⁰ American Medical Association (Fellowship and Residency Electronic Interactive Database - FREIDA),¹¹ and the open-source website Orthogate (<http://www.orthogate.org>).¹² The purpose of this study was to determine the availability and accessibility of information on orthopedic residency programs obtainable through the three databases. We analyzed the information available on various program websites through the links provided by the three databases and from the results provided by a Google search. In addition, previous research by Rozental et al. allowed a comparison to gauge the improvement in several key categories over the past decade. We hypothesized that the ease of accessing individual program websites from databases and discovering relevant program information contained within indepen-

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Table I. Evaluation of Links Provided by Databases

Database	Programs	No Link	Non-functioning	Institution	Department	Residency
ACGME	156	4 (3%)	28 (18%)	41 (26%)	60 (38%)	24 (15%)
FREIDA	157	9 (6%)	9 (6%)	43 (27%)	62 (39%)	34 (22%)
Orthogate	153	13 (9%)	37 (24%)	28 (18%)	49 (32%)	26 (17%)

dent residency websites does not fully meet the needs of current orthopedic surgery applicants.

METHODS

Identification of orthopedic residency programs in the United States was accomplished with the use of the ACGME database, the AMA’s FREIDA online database, and Orthogate’s online database.¹⁰⁻¹² The database search only included allopathic orthopedic residencies, as there is not currently a combined process for osteopathic and allopathic residencies. The three databases were queried between December 21 and 23, 2014. Each database was assessed for availability and functionality of website links to each program by placing them in one of five categories: no link provided, a non-functional link, a link to the sponsoring institution requiring multiple clicks to navigate to the residency website, a link to the orthopedic department requiring multiple clicks to navigate to the residency website, and a link which led directly to the residency website. The databases were also evaluated for congruency of information, including programs listed, program director, and contact information.

A Google search (Mountain View, CA, USA)¹³ was also performed to evaluate website accessibility for each program as an alternative to searching the three online databases. Google was selected because it is the most popular search engine worldwide.¹⁴ A search was performed for each program using the phrase “program name + orthopedic surgery residency.” Each search evaluated the first page of results (first 10 listings) for direct links to the residency program website.

Each orthopedic residency program’s website was then evaluated for content using previously described areas of interest²⁻⁴ with examination of resident education details, resident recruitment details, and contact information. In addition to criteria described in similar papers, a study by Deloney et al, which performed a survey of radiology interviewees at a single institution, was used to compile a list of relevant details. The Deloney et al study characterized details as necessary, desirable, or superfluous.¹⁵ Resident education details included rotation schedule, didactic schedule, conference descriptions, research curriculum, and call schedules. Resident recruitment details included program description or director’s letter, application requirements, faculty educa-

tion, current residents, resident education information, career placement, and salary. Results were then analyzed as a proportion of programs containing the information compared to previous studies.

RESULTS

Database Information

The three databases revealed a varying number of total programs – 156 programs were listed in the ACGME database, 157 programs were listed in the FREIDA database, and 153 programs were listed in the Orthogate database. The databases provided either no link or a link that was non-functioning in 12% (FREIDA), 21% (ACGME), and 33% (Orthogate) of the program listings. A majority of programs provided a functioning link that, at a minimum, directed the user to an institutional website. A direct link to the unique residency website was provided by a small percentage of programs: ACGME listed 24 (15%), FREIDA listed 34 (22%), and Orthogate listed 26 (16%) (Table I).

Combining the search results of the three databases, 157 unique orthopedic residency programs were identified, including 149 civilian programs and 8 military programs. This combined list served as the basis for evaluation of institutional websites. All programs were found using a Google search that included “program name + orthopedic surgery residency.”

Most of the contact information, including phone number, email, name of the program director, was congruent across the ACGME and FREIDA databases. Orthogate did not provide any contact information. However, 64 (41%) programs had different email addresses and 36 (23%) programs had different phone numbers listed in comparing the ACGME and FREIDA databases

Resident Education

With respect to resident education, most programs included the evaluated criteria. A rotation schedule was provided by 118 (75%) programs. The majority of programs included information detailing their didactic schedules, research requirements, and meetings or courses attended by the residents. However, only a small number of programs presented information describing the resident call schedule (Table II).

Table II. Number (%) of websites with information pertaining to resident education

Education (n = 157)	No. (%)
Didactic Schedule	106 (67%)
Rotation Schedule	118 (75%)
Research Curriculum	93 (59%)
Conference Descriptions	94 (60%)
Call Schedules	19 (12%)

Table III. Number (%) of programs with information pertaining to recruitment

Recruitment (n = 157)	No. (%)
Program Description	153 (97%)
Application Requirements	129 (82%)
Current Residents	129 (82%)
Resident Education Information	109 (69%)
Alumni Career Placement	79 (50%)
Faculty Education Information	109 (69%)
Salary	55 (35%)

Resident Recruitment

In regards to resident recruitment, the majority of programs covered the evaluated criteria. Nearly all programs provided a description of the program. A list of current residents could be found on the websites of 129 (82%) programs while only 109 (69%) provided detailed educational background for those residents. Career placement was supplied by half of the programs (Table III).

Contact Information

Although contact information was listed for all 157 programs, the type of this information varied among programs. Eighty-one of the programs (52%) provided a telephone number and/or email for both the program director and residency coordinator, 70 (45%) listed information for only the coordinator, and 6 (3%) had only the director’s information available.

DISCUSSION

When researching residency programs, medical students typically begin with a search of available programs using one of the publicly available databases and then progressing to evaluation of individual programs. Multiple studies have examined the quality of information available for various surgical sub-specialties and orthopedic fellowships.^{2,7} In a comprehensive review of orthopedic programs in 2001⁸, Rozental et al. found that most orthopedic programs under-utilize the Internet as a tool for dissemination of information.

Our current research reveals improvement in utilization, both in accessibility and content, although room for improvement continues to exist. It appears academic departments are realizing the importance of an Internet presence in reaching potential applicants. Having multiple steps needed to access the website and out of date information reflects poorly on the individual program. Orthopedic residency websites compare favorably to websites for orthopedic fellowships; the shared criteria reveal similar proportions of inclusion.^{2,4} This does not serve as surprise as many of the same individuals are responsible for both residency and fellowship websites. Expanding the comparison to other surgical specialties shows similar proportions as well.^{6,7}

In 2014, seventy students applying to a radiology residency returned a survey prepared by Deloney et al.¹⁵ More than half agreed with a long list of elements necessary for a residency website (many of the same elements evaluated by this project), with another 30% to 40% responding that those elements were desirable. They suggested that websites are an important recruiting tool, maintaining them with current information is important to the recruitment process, and site navigation needs to be intuitive and efficient. A survey of orthopedic residency applicants would serve as an important future research avenue to more effectively determine what matters most to students pursuing a position in orthopedics.

Evaluation of the three available databases highlighted programs that did not provide a direct link to the residency homepage - 12% (FREIDA), 21% (ACGME), and 33% (Orthogate) of programs. Although the lack of functioning links is not necessarily reflective of the program, as the databases are maintained by the AMA, ACGME, or are open-sourced, it does reflect a shortcoming in providing ease of access for applicants. Additionally, the FREIDA database included one extra program not listed by ACGME; the reason for this remains unclear. Concerning database congruency, most programs had the same information provided. Although many of the numbers and addresses appear to be similar (e.g. likely would reach someone within the orthopedic department), the discrepancy makes contacting the program involve unnecessary additional steps.

Since Rozental et al.⁸ published their findings, the importance of having a useful web presence has increased significantly. As expected, each of the shared criteria between our studies shows an increased percentage of programs publishing the desired information. The improvement is likely tied to both an increased awareness of shortcomings as well as more individuals with a clearer understanding of the Internet’s importance with today’s students. Importantly, in 2001, only 73% of orthopedic programs maintained websites while in 2014,

all orthopedic programs were noted to have a website. The elements demonstrating the largest increases between the 2001 study and ours are contact information listed, 43% to 100%; rotation schedules, 21% to 75%; current resident listing, 45% to 82%; and career placement of alumni, 12% to 50%. These numbers reflect critical improvement in providing a clear description of what the program has to offer.

Many of the orthopedic programs provided information in the areas evaluated in this study. In only two areas did fewer than half of the programs report the desired information – call schedule (12%) and salary details (35%). Also of note, 79 (50%) programs included information concerning career placement of their alumni. This information provides an opportunity for the program to showcase the success of previous graduates and allows the applicant insight into post-residency opportunities based on these trends. Another criterion to note was the medical school attended by current residents; 69% of programs reported this information. This information could potentially be important to prospective applicants, as the educational background highlights connections between prospective applicants and current residents. Previous studies have not included this criterion, however this information serves as an important tool in networking.

This study has several limitations. Although multiple publications have arrived at a consensus concerning important criteria in the application process, individual investigators determine these elements. A survey of residents, applicants, and interested medical students would be beneficial in directing future studies as to which criteria are truly important. In addition, the determination of whether the information was included in the website was a binary decision – there was no consideration as to the varying degrees of quality of information. Also, some programs maintain more than one website as they are affiliated with multiple entities. We only evaluated the top result on Google and did not continue to search for additional websites. Another important understanding is that many programs do not have direct control in updating their pages; as most academic centers have a central website, changes must go through other departments prior to publication. Most importantly, we realize that the Internet is a dynamic entity. These websites were evaluated in December 2014, and programs could have added or subtracted information, which may change the reported results.

In conclusion, orthopedic residency programs can evaluate their improvement in disseminating information based off two studies separated by thirteen years. The overall trend shows improved utilization of the Internet; however, there are still areas in which individual programs can increase their appeal to applicants. Ensuring

that information is up to date on the centralized databases is one avenue. More directly under the program control is the information contained on their unique website. Most programs contain varying degrees of desired information, however, not all programs maintain up to date websites consistently including the same evaluated criteria. As this information is lacking, it is difficult for the applicant to perform head to head comparisons. Residency programs would benefit from routine analysis of their website to ensure the information is up to date and serving as a positive representation of what they have to offer to potential applicants. The Internet already has established itself as the primary source for information, and program websites serve as the initial impression for many prospective applicants.

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CONTENT AND ACCESSIBILITY OF SHOULDER AND ELBOW FELLOWSHIP WEB SITES IN THE UNITED STATES

Bradley L. Young, BS, Lasun O. Oladeji, MS, Kyle Cichos, BS, Brent Ponce, MD

ABSTRACT

Background: Increasing numbers of training physicians are using the Internet to gather information about graduate medical education programs. The content and accessibility of web sites that provide this information have been demonstrated to influence applicants' decisions. Assessments of orthopedic fellowship web sites including sports medicine, pediatrics, hand and spine have found varying degrees of accessibility and material. The purpose of this study was to evaluate the accessibility and content of the American Shoulder and Elbow Surgeons (ASES) fellowship web sites (SEFWs).

Methods: A complete list of ASES programs was obtained from a database on the ASES web site. The accessibility of each SEFWs was assessed by the existence of a functioning link found in the database and through Google®. Then, the following content areas of each SEFWs were evaluated: fellow education, faculty/previous fellow information, and recruitment.

Results: At the time of the study, 17 of the 28 (60.7%) ASES programs had web sites accessible through Google®, and only five (17.9%) had functioning links in the ASES database. Nine programs lacked a web site. Concerning web site content, the majority of SEFWs contained information regarding research opportunities, research requirements, case descriptions, meetings and conferences, teaching responsibilities, attending faculty, the application process, and a program description. Fewer than half of the SEFWs provided information regarding rotation schedules, current fellows, previous fellows, on-call expectations, journal clubs,

medical school of current fellows, residency of current fellows, employment of previous fellows, current research, and previous research.

Conclusions: A large portion of ASES fellowship programs lacked functioning web sites, and even fewer provided functioning links through the ASES database. Valuable information for potential applicants was largely inadequate across present SEFWs.

INTRODUCTION

Over the past two decades the Internet has become integral to accessing information. The increased access to information has impacted how medical students and residents learn about orthopedic residency and fellowship programs.^{1,8} Despite significant improvements in the content and usefulness of residency websites, fellowship websites generally lag behind with several fellowship programs still without a web presence and significant variations in the information content and quality among those available online.^{1,9-11}

The importance of program specific web sites in the residency match has been established for various specialties.^{1,8} Over half of anesthesiology residency applicants claimed that a program's web site influenced their decision to apply.⁴ Many emergency medicine residents considered program web sites as equivalent to their mentors' advice.^{5,6} In 2001, orthopedic residency web sites were deemed inadequate resources for applicants, but recent improvements in the accessibility and content of these web sites may have increased their usefulness.^{1,12}

Web sites may influence fellowship applicants as well.⁷ A survey of pathology residents found that the overwhelming majority of pathology fellowship applicants considered program web sites as their main source of information during their application process.¹³ Orthopedic hand fellowship applicants reported valuing web site content more than the opinions of attending physicians and family when selecting a program.⁹ Despite the growing importance of web sites, previous investigations have noted inadequacies in the accessibility and content of orthopedic sports medicine, pediatric orthopedics, and hand surgery fellowship web sites.^{9,11}

As a fellowship specialty, shoulder and elbow has expanded to nearly 30 fellowship programs available to

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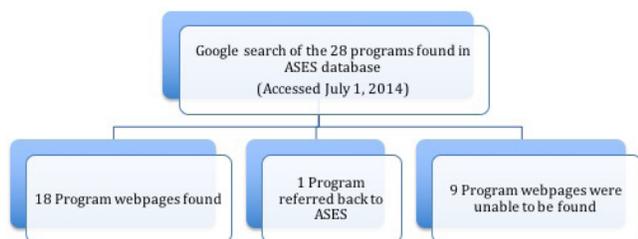


Figure 1. Flowchart detailing the accessibility of the accredited American Shoulder and Elbow Fellowship web sites through Google®.

graduating residents since its inception in 2004.¹⁴ Historically, the American Shoulder and Elbow Surgeons (ASES) fellowship match rate was 100%; this decreased to 93% by 2014 and 86% by 2015.¹⁵ Given the utility of residency and fellowship web sites as a recruitment tool, this study sought to determine if inadequacies were present ASES program web sites. The goals of the study were to (1) analyze the accessibility of Shoulder and Elbow Fellowship Websites (SEFWs) and (2) evaluate their content with respect to fellow education, faculty information, past fellow information, fellow recruitment, and applicant information. Our hypothesis was that SEFWs would be largely inaccessible and devoid of adequate content for browsing applicants.

METHODS

The current study did not require institutional review board (IRB) approval. We identified 28 accredited shoulder and elbow fellowship programs through the ASES web site (<http://www.ases-assn.org/?p=physic-fellowships>).¹ The central ASES database entries were assessed for functional links to program specific SEFWs. Programs lacking functional links in the database were searched for using Google® on July 1, 2014. Each SEFW was then evaluated for the inclusion of several criteria, described below. The database entries for each program were also evaluated for the same criteria, but the focus of this paper is the SEFWs content.

Accessibility

The accessibility of SEFWs were assessed by the availability of a direct link (functioning or not functioning) on the ASES web site and their access through Google®. Two search phrases were used to find program web sites: (1) “program name + shoulder and elbow fellowship” and (2) “program name + orthopedic surgery + shoulder and elbow.” Only the first page of results from the Google® search was analyzed.

Content Evaluation

Each SEFW was evaluated for the inclusion of information pertaining to the following areas: fellow educa-

tion, fellow and faculty information, and recruitment. These criteria were chosen after reviewing factors considered important to applicants applying to other orthopedic fellowships.⁷⁻¹¹

To appraise the content with respect to fellow education, we evaluated each SEFW for information concerning research opportunities and requirements, lists of current and previous research, rotation schedules, on-call expectations, journal club, case descriptions, meetings and conferences sponsored by the program, and information about teaching responsibilities. The educational criteria were deemed present if it were mentioned or expanded upon.

The fellow and faculty information section of each SEFW was also assessed by detecting the presence of a list of current fellows, previous fellows, medical school and residency choices of current fellows, and job choices of previous fellows were recorded. The web sites were also evaluated for a list of their attending shoulder and elbow faculty.

Recruitment criteria included a description of the application process, the program coordinator’s contact information, the program director’s contact information, the fellow salary, and a description of the program.

RESULTS

Accessibility

At the time of our query, 28 ASES fellowship programs in 16 states were identified. Some programs had multiple positions, resulting in 42 annual fellowship positions. Only 6 (21.4%) programs had direct links to their independent SEFWs through the ASES database, and one of those links did not function. A Google® search of the 28 programs found that 18 (64.3%) of the programs had individual SEFWs, one (3.5%) had a SEFW that referred visitors back to the ASES web site, and nine (32.4%) programs lacked a web site (Figure 1). The five functioning direct links in the ASES database were also accessible through Google®. The non-functioning link in the ASES database could not be accessed using Google®.

Education

All 18 (100%) of the SEFWs contained information regarding research opportunities, but information based on research requirements was provided by only 16 (88.9%). Two (11%) provided information about current and previous research performed by fellows. The remaining educational criteria included: rotation schedules in 7 (38.9%), on-call expectations in 4 (22.2%), journal clubs in 8 (44.4%), case descriptions in 16 (88.9%), meetings and conferences sponsored in 12 (66.7%), and teaching responsibilities in 13 (72.2%) of the 18 program web sites (Table I).

Table I. Educational Criteria

	<u>ASES</u>	<u>Individual Pages</u>
Number of Programs Listed	n=28	n=18
Research Opportunities	82.1% (23)	100% (18)
Research Requirements	82.1% (23)	88.9% (16)
Current and Previous Research	0% (0)	11.1% (2)
Rotation Schedules	28.6% (8)	38.9% (7)
On-Call Expectations	21.4% (6)	22.2% (4)
Journal Clubs	32.4% (9)	44.4% (8)
Case Descriptions	89.3% (25)	88.9% (16)
Meetings and Conferences Sponsored	50.0% (14)	66.7% (12)
Teaching Responsibilities	42.9% (12)	72.2% (13)

Table II. Fellow and Faculty Information List

	<u>ASES</u>	<u>Individual Pages</u>
Number of Programs	n=28	n=18
Current Fellows	0% (0)	27.8% (5)
Previous Fellows	0% (0)	27.8% (5)
Medical School & Residency of Current Fellows	0% (0)	22.2% (4)
Job Choice of Previous Fellows	0% (0)	22.2% (4)
Attending Faculty	22.4% (27)	77.8% (14)

Table III. Recruitment Information

	<u>ASES</u>	<u>Individual Pages</u>
Number of Programs	n=28	n=18
Description of Application Process	42.9% (12)	77.8% (14)
Coordinator Contact Info	28.6% (8)	27.8% (5)
Director Contact Info	32.1% (9)	38.9% (7)
Fellow Salary	57.1% (16)	27.8% (5)
Program Description	100.0% (28)	100.0% (18)

Fellow and Faculty Information

All 18 SEFWs portrayed a list of research opportunities available to fellows, 5 (27.8%) contained a list of the program’s current fellows, 5 (27.8%) showed a list of the program’s previous fellows, 4 (22.2%) made available the medical school and residency of the current fellows, 4 (22.2%) displayed the job choices of previous fellows, and 14 (77.8%) listed the attending faculty (Table II).

Recruitment and Accessibility

Of the 18 SEFWs, 14 (77.8%) gave a description of the fellowship application process, 5 (27.8%) provided contact information for the program coordinator, and 7 (38.9%) supplied contact information for the program director. Information about fellowship salary and a description of the program were provided by 5 (27.8%) and 18 (100.0%) of programs, respectively (Table III).

DISCUSSION

Current reports estimate that greater than 90% of orthopedic residents will acquire fellowship training.¹⁶ This is not surprising considering that over half of all orthopedic employment positions listed in the United States request fellowship trained surgeons.¹⁶ Furthermore, a growing number of physicians may pursue shoulder and elbow fellowships after finishing related fellowships in sports medicine or hand surgery.¹⁷ Applicants often look to the Internet to compare various programs and gather information about educational opportunities.^{4,6,18,19} Findings from this study demonstrate that shoulder and elbow fellowship web sites possess inadequate accessibility and insufficient content.

The ASES maintains a database on its central web site that contains basic information for each fellowship program, as well as additional information and an external web site link (if provided by each program). Applicants may revert to program specific web sites to access more information.¹⁷ Yet, the access and content vary widely despite being important to applicants.^{2,7,9-11} Rectifying these inadequacies may help resolve the current fellowship position surplus by recruiting surgeons who are interested in pursuing subspecialty training.¹⁷ Such improvements were made to orthopedic residency websites following a web site examination performed by Rozental et al.¹ Since then, the percentage of residency programs with web sites increased by 22%; and web site content increased for all investigated categories, including education, resident and faculty information, environment and recruitment.¹² In light of the increasing competitiveness and high match rate surrounding the orthopedic residency match, the potential benefits such information can provide to residency and fellowship programs in addition to browsing applicants may be significant.

Limited web site accessibility is not unique to ASES fellowships. It has also been noted among academic orthopedic surgery departments and several other orthopedic fellowships including sports medicine, pediatrics, hand and spine.^{3,4,7,9-11} Despite the known importance of accessible Internet information, it is apparent that several ASES fellowship programs were not optimizing this resource to recruit applicants. In comparison to

other orthopedic subspecialty fellowships, SEFWs were less accessible overall. Only 64% of ASES programs had readily accessible websites via Google®. Whereas hand (96%), pediatric orthopedic (72%), and sports medicine (71%) fellowship web sites were more accessible through Google®.^{2,9,11} Such web anonymity may lead to decreased awareness of important program details and attributes that shoulder and elbow fellowship applicants desire.²⁰ It is unknown what potential impact the poor quality of SEFWs has had upon the ASES match rate which has dropped in recent years.

Program databases do not appear to improve the accessibility of fellowship web sites. Our study found that the ASES database provided direct functioning links in less than 20% of SEFWs. The American Society for Surgery of the Hand was found to provide direct functioning links to 37% of their individual fellowship web sites.² The American Orthopaedic Society for Sports Medicine and San Francisco Match (SF Match) provided direct links to the web sites of only 3% and 5% of participating sports programs, respectively.¹⁰ Few direct functioning links to pediatric orthopedic fellowship web sites were provided by the Pediatric Orthopaedic Society of North America (0%) and SF Match databases (4%).¹¹ Regarding spine fellowship databases, the presence of viable links to program web sites were SF Match (0%), Fellowship and Residency Interactive Database (6%), North American Spine Society (3%).⁷ Many links provided in each of these databases were deemed indirect because they required significant web site navigation to actually find the fellowship information. Several fellowship programs for several orthopedic subspecialties could avoid being overlooked by browsing applicants by contacting their respective databases and providing direct web links to their respective fellowship information.

Inadequate content also appears to be common across various orthopedic fellowship web sites. Despite its recognized positive influence upon an applicant's decision process, the presence of content on SEFWs was highly variable and even missing in many cases. The benchmark criteria used to assess the content of orthopedic subspecialty fellowship web sites has been established in previous studies.^{2,7,9-11} For example, a minority of shoulder and elbow, sports medicine, pediatric orthopedic, spine, and hand fellowship web sites provided information concerning on-call schedules. On the other hand, SEFWs successfully provided information pertaining to research opportunities and requirements, when compared to hand, pediatric, spine, and sports medicine fellowship web sites.^{2,7,9-11} Salary information has been found to be important to graduate medical applicants, but few SEFWs nor other subspecialty web sites divulged salary information.^{2,3,6,21} In addition, the attending faculty

of a program has been established as a primary factor in many applicant's match decisions, but some SEFWs failed to provide this information.⁸

A rectification of SEFWs can benefit ASES programs by serving as a low-cost tool for programs to recruit applicants; therefore, their development would be a low-risk investment to programs.²¹ Also, accessible information about various programs allows applicants to be more selective in their interview process, saving money and time, which have been established as a primary concern of applicants.⁸ Niesen et al found that ASES applicants applied to an average of 20 programs, were offered 7 to 26 interviews, but only completed 5 to 18 of the interviews.⁸ The results of this report elude to a significant interview cancellation rate, testifying to the importance of pre-interview exposure to each program's assets in case an applicant were to consider canceling the interview. Also, ASES has a policy forbidding communication between applicant and program staff after an interview has occurred.¹⁴ Adequate SEFWs may serve as an important source of information for applicants with post-interviews questions, as well as for applicants undergoing retrospective reflection while forming their rank list.

A recent survey showed that many applicants, but few program directors, suggested that electronic applications and more accessible online content would improve the hand fellowship match experience. They concluded that hand fellowship programs should offer comprehensive online information to applicants.⁷ We concur that ASES programs could also improve the match experience for applicants by augmenting the SEFWs to meet content and accessibility standards. Another option would be for ASES to universalize their central database to include important information for each program. This is exemplified by the Orthopedic Trauma Association (OTA) fellowship database that allows applicants to compare programs on up to six criteria, encouraging more informed decisions.²²

This study contains several limitations. First, the evaluation of SEFW content described in similar studies^{2,5,10} was based on the mere presence of information rather than its quality. Further studies should scrutinize the quality of the information and delineate the degree of quality that content must reach for applicants to deem it helpful. Another limitation may lie with our use of Google® to analyze the accessibility of the web sites. Google® provides multiple pages of results, but we only assessed the first page for the web site in question as done in similar studies.^{2,11} Finally, the results of this investigation were based on an Internet search during a fixed time period. We understand that SEFWs may have been updated at anytime after our query was performed.

In conclusion, most ASES programs underutilize the Internet's ability to recruit and provide applicants with pertinent information. Programs interested in optimizing their online presence may be interested in the findings presented in this study. Rectification of SEFWs may improve the match experience for applicants and refine their decisions.

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THE BEGINNINGS OF ORTHOPEDIC SURGERY AT THE MAYO CLINIC: A REVIEW OF THE FIRST ORTHOPEDIC PATIENTS WHO PRESENTED OVER 100 YEARS AGO

Christopher L. Camp, MD, Bernard F. Morrey, MD, Robert T. Trousdale, MD

ABSTRACT

Background: Formalized training in the specialty of orthopedic surgery began at the Mayo Clinic nearly 100 years ago, and treatment of patients with musculoskeletal injuries and disease began even earlier. A robust historical patient database provides the opportunity for review of the first recorded orthopedic cases at our institution, which date back to 1907.

Methods: The first 400 sequential medical charts of the Mayo Clinic's patient record database were comprehensively reviewed in order to identify the first documented orthopedic cases.

Results: Of the first 400 patients reviewed, 15 (4%) received specific orthopedic diagnoses. All presented during a three week period in 1907, and they traveled from all over the region for evaluation. The diagnoses included skeletal tuberculosis (n=6), traumatic fracture (n=3), osteomyelitis (n=2), syphilitic pathologic fracture (n=1), syphilitic osteitis of the tibia and radius (n=1), painful flat foot (n=1), and Morton's toe (n=1). Included with the records are patient demographics, diagnoses, symptoms, physical examination findings, radiograph reports, operative reports, and detailed drawings of symptomatology.

Conclusions: Although the technology and science has advanced since the early practice of orthopedic surgery that took place over a century ago, we consider ourselves to be merely an extension of those who established the field before us. Just as the past relies on the future for the

continuation of what it began so many years ago, we rely on our founders for the groundwork that they laid in creating this field of surgical medicine.

INTRODUCTION

Although the exact date of inception of the "Mayo Clinic" is not clearly defined, the founders began treating patients in Rochester, MN in the late 1800's. This was soon followed by the creation of a comprehensive, permanent medical record system which was created and implemented by Dr. Henry S. Plummer in 1907 following nearly two years of travel and research into the subject. His dossier model assigned a sequential "clinic number" to each patient as they entered the clinic doors. The first patient was assigned the number 1, followed by 2, 3, 4, and so on.¹ This system has continued since that time and to date, over 7 million clinic numbers have been assigned to as many patients at the Rochester, MN campus alone. This charting system allowed for each patient's record to be stored in a centralized location rather than having separate charts spread out amongst all of the consulting physicians. This record system accomplished its goals of improving patient care, made retrospective review for academic research and education much more practical, and has served as a model for many other medical institutions.¹

Soon after the development of the patient record system, formalized resident training in orthopedic surgery began at the Mayo Clinic in 1915. The Department of Orthopedic Surgery was created in 1910, and was originally chaired by Melvin S. Henderson, M.D. During this time, other large medical centers in the region were also formalizing departments of orthopedic surgery. The University of Iowa Department of Orthopedics and Rehabilitation was officially founded in 1913.² In Minneapolis and St. Paul, MN, the first "Professor of Orthopedic Surgery" was named in 1888 when the medical school was founded.³ After first being exposed to orthopedic surgery during his initial training at the University of Minnesota, Dr. Henderson traveled to the Mayo Clinic in 1907 for additional surgical training. There he quickly developed a deeper interest in orthopedic surgery under the tutelage of Dr. Charles H. Mayo.⁴ Although Dr. Charles Mayo conducted a multidisciplinary surgical practice, he was initially responsible for the majority of

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Ethical Review Statement: This study received Institutional Review Board approval from the Mayo Clinic.

Table I. Patient Demographics

Age (yr)	Minimum:	2
	Maximum:	59
	Mean:	30
Sex	Male:	13 (87)
	Female:	2 (13)
Occupation	Farming	5 (33)
	Physician	1 (7)
	Engineer	1 (7)
	Bar Tender	1 (7)
	Finance Officer	1 (7)
	Barber	1 (7)
	Salesman	1 (7)
	Electrician	1 (7)
Home state	Minnesota	8 (53)
	North Dakota	3 (20)
	South Dakota	1 (7)
	Iowa	1 (7)
	Unknown	2 (13)

Data are given as no. (%) unless otherwise specified

the orthopedic cases while his brother and Mayo Clinic co-founder, Dr. William J. Mayo, focused primarily on abdominal pathology. Under the guidance of its first Chair, Dr. M.S. Henderson, the Department of Orthopedic Surgery has grown to a present day staff of 64 physician appointments and 68 residents and fellows.⁴ Although much is known and published about the histories of the Mayo Clinic Department of Orthopedic Surgery⁴ and the field of orthopedics in general, little is known about the first patients. The following is a retrospective review of the first orthopedic patients that presented to our clinic over 100 years ago (1907).

MATERIALS AND METHODS

Following approval from the Mayo Clinic Institutional Review Board, the complete medical records of the first 400 patients (clinic numbers 1-400) in the patient record database were comprehensively reviewed in order to locate the first orthopedic patients. The 1907 medical record system consisted of a single six by nine inch card that includes lines for the patients' clinic number, date of presentation, treating physician, demographics (name, address, age, sex, civil state, and occupation), diagnosis, referring physician, family history, previous diseases, and subjective symptoms. On the reverse side, skeletal diagrams are included for anatomic localization of pathology and a large section was available for objective symptoms. If an operation was performed, a very succinct operative note was included on the back of the card as well. Some of the records also included supplemental operative reports, pathology reports, and patient contact materials.

Table II. Patient Diagnoses

Diagnosis	No. (%) of patients
Skeletal tuberculosis	6 (40)
Traumatic fracture	3 (20)
Osteomyelitis	2 (13)
Pathologic fracture secondary to syphilis	1 (7)
Syphilitic ostitis	1 (7)
Painful flat foot	1 (7)
Morton's toe	1 (7)

Any patient receiving a specific orthopedic diagnosis was included in this study. Data extracted from the medical record system included patient demographics, medical history, presenting symptoms, diagnostic tests performed, treatments offered, and any additional pertinent physician patient correspondence. Photographs of selected charts were obtained and are included here for review.

RESULTS

Of the patients with clinic numbers 1-400, a total of 16 had charts that were missing or incomplete. This left a total of 384 charts available for comprehensive review. Each of these 384 patients presented within a three week period from July 22, 1907 to August 10, 1907. Of these patients, a total of 37 (9.6%) presented with some form of musculoskeletal chief complaint. Twenty-two (59%) of these 37 patients were excluded from the study due to a lack of specificity in diagnosis or involvement of bones outside the scope of general orthopedic practice (ie: cranium). The diagnoses in these excluded patients include the following: back pain (n=11), rheumatism/generalized arthritis (n=5), jaw osteomyelitis (n=2) paralysis/weakness (n=1), hip pain (n=1), non-specific joint contractures (n=1), and extremity swelling (n=1).

Of the remaining 15 (3.9%) patients with a specific orthopedic diagnosis, a wide range of patient demographics was observed. Although, they all came from the Midwest region of the United States, only 8 of 13 (62%) were residents of the state of Minnesota. The home state of two patients is unknown as that portion of the chart had been destroyed. After Minnesota, the next most common state of residence was North Dakota (n=3, 23%), followed by South Dakota (n=1, 7.7%) and Iowa (n=1, 7.7%). The youngest patient in the cohort presented at 32 months of age while the eldest was 59 years old. The average age was 29.6 years. Patient occupation was most commonly farming (n=5, 35.7%). Also included in the cohort was one of each of the following: physician, bar tender, finance officer, barber, engineer, electrician, traveling salesman, and the three youngest patients did not have occupations listed. Males far outnumbered females as they comprised 86.7% (n=13) of the patients and females represented 13.3% (n=2) (Table I). Three

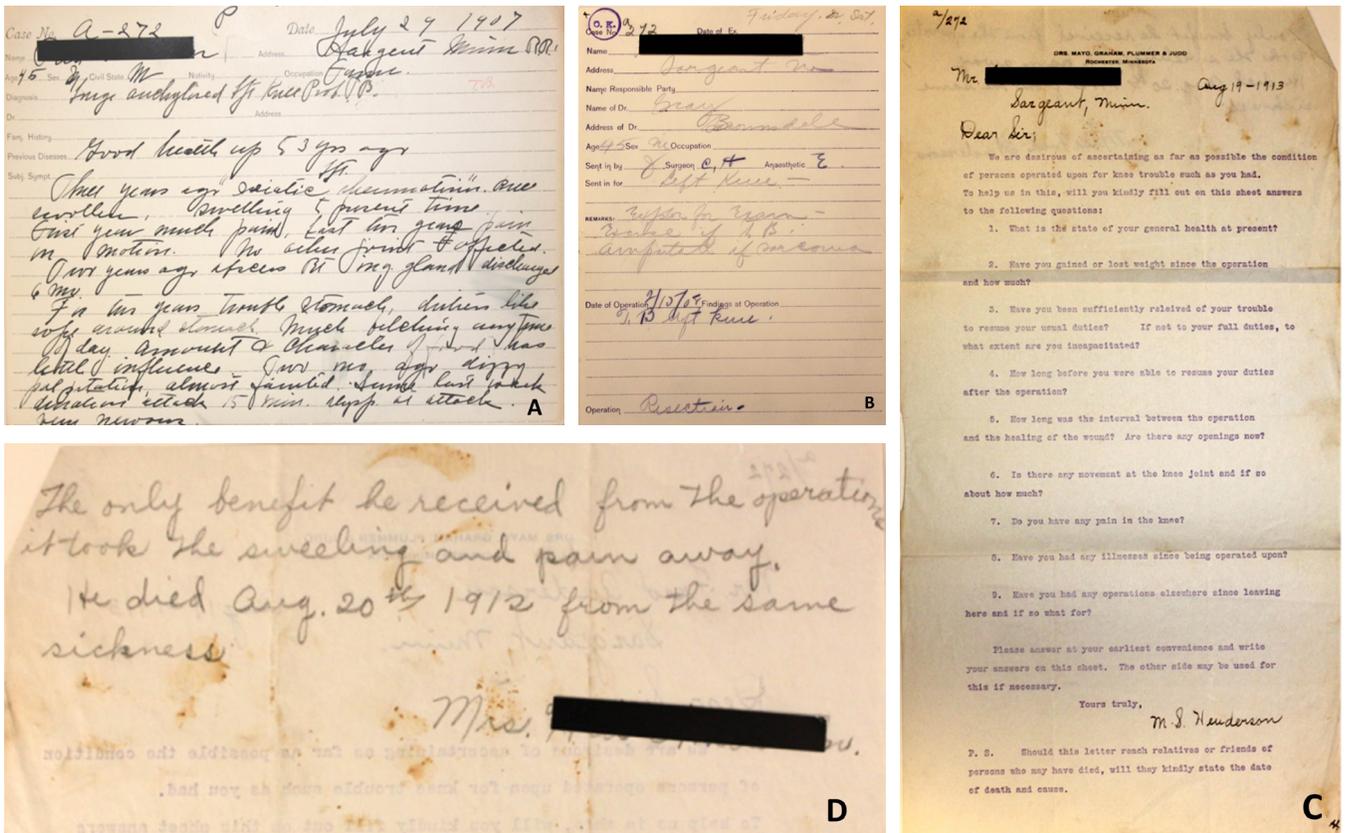


Figure 1: In this patient with tuberculosis of the knee, the complete medical record included the medical chart (A), an operative report from a surgical resection in 1908 (B), a follow up questionnaire signed by Dr. MS Henderson (C), and correspondence from the patient’s wife indicating that he had died of his disease (D).

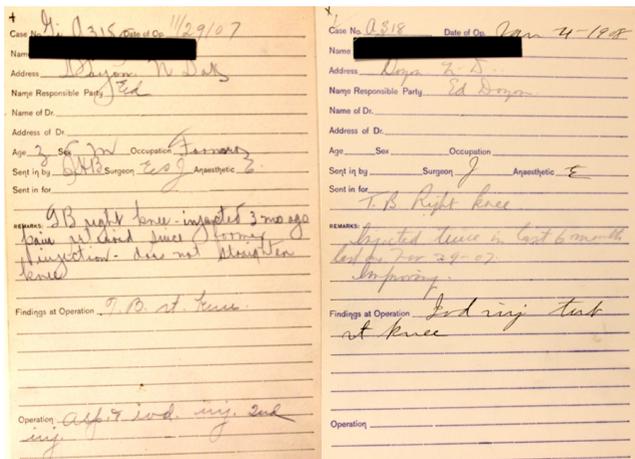


Figure 2: This patient with tuberculosis of the right knee underwent multiple procedures as indicated by these operative reports.

(20.0%) patients had the name of an outside referring physician in their chart. Three of the charts indicated that patients had paid for their services, but only one indicated the paid amount, which was \$5.

Regarding the orthopedic pathology of these 15 patients, the diagnoses included: musculoskeletal tubercu-

losis (TB) (n=6), traumatic fracture (n=3), osteomyelitis (n=2), luetic (syphilitic) ostitis of the tibia and radius (n=1), luetic (syphilitic) pathologic fracture (n=1), painful flat foot (n=1), and Morton’s neuroma (n=1) (Table II). Of the 6 patients receiving the diagnosis of TB, one was located in the ribs and spine, two were located in the hip, two localized to the knees, and one demonstrated TB of the humerus. These patients tended to present with pain, swelling, limp, inability to walk, inability to bear weight, leg length discrepancy, and/or joint deformities. At least two of the patients underwent surgery and a third received unspecified injections on two separate occasions. One of the patients with an angular deformity of the knee secondary to TB underwent subsequent resection that was complicated by a draining sinus post-operatively which required revision surgery. This patient’s record also included correspondence from Dr. MS Henderson in the form of a follow up questionnaire which suggests that the tracking of outcomes data was likely in practice even a century ago. Although the patient did obtain pain relief and his swelling diminished after the resection in 1908, he succumbed to his disease 4 years later in 1912 (Figure 1). One of the musculoskeletal TB patients was only 32 months old and had a

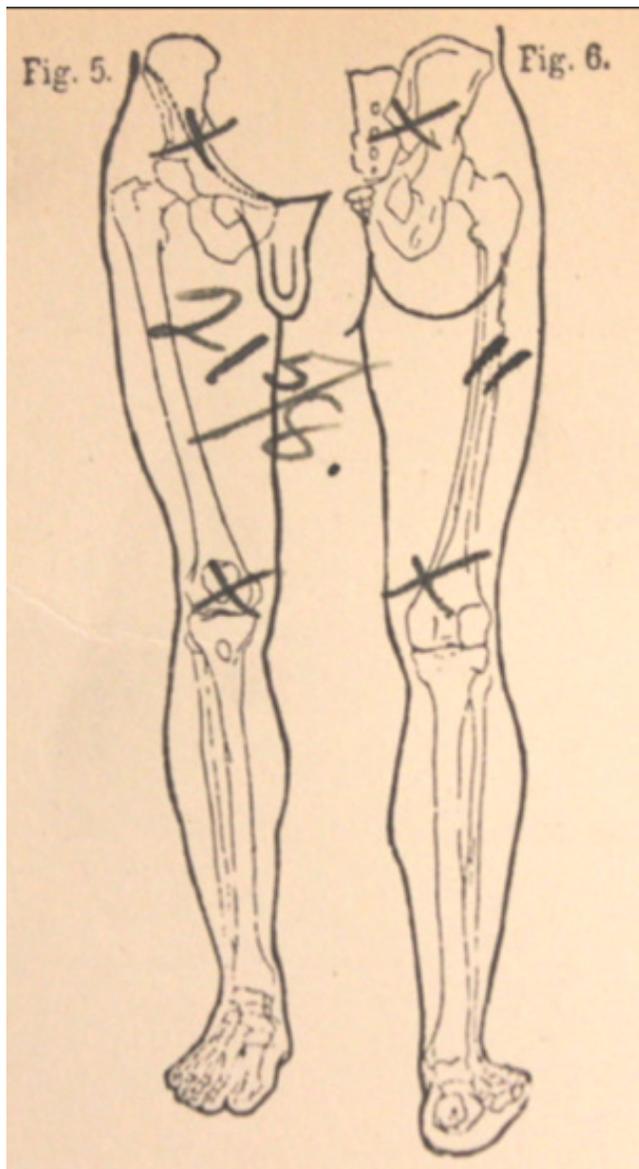


Figure 3: In a patient with “incipient TB of the hips,” a measurement of leg lengths was diagramed in the chart.

radiograph report included in his record that succinctly read: “tuberculosis”. This patient also had separate operative notes for each of his injections (Figure 2). An additional patient was diagnosed with incipient TB of the hip and had detailed drawings of his leg lengths, which were found to be equal (Figure 3).

Following TB, the next most common diagnosis was traumatic fracture (n=3). The first of these patients was a 3-year old male that sustained a left long finger fracture after having the digit caught in a hay rope. The next trauma patient, a 39-year old male, sustained proximal tibia and fibula fractures which resulted in injury to “the major artery of the leg” and loss of sensation below the

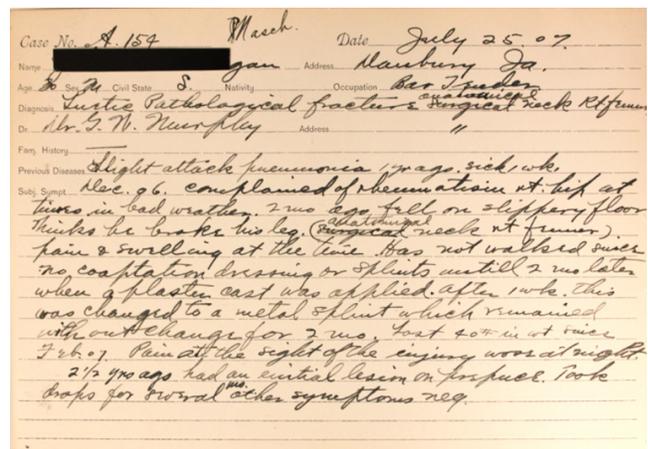


Figure 4: The medical record of patient who suffered a pathologic femur fracture contained one of the most detailed notes that appeared in the early chart system.

ankle. The exact mechanism of injury or treatment method was not recorded. Finally, the third fracture patient, a 29-year old male, presented with a non-union of prior tibia and fibula fractures that relegated him to a walking cane full time. No other details were provided. Whether or not any of these patients received surgical intervention is not documented.

In addition to the traumatic fractures mentioned above, a 30-year old male presented with a painful shortened limb after sustaining a fall two months prior. This case was diagnosed as a “Leucic pathologic fracture femoral neck right femur.” He had been treated non-operatively with casting and metal splinting but continued to have pain, deformity, and inability to bear weight. The patient had lost forty pounds in the five months prior to presentation (Figure 4). In addition to this orthopedic manifestation of syphilis, another patient was diagnosed with “Leucic osteitis lower 1/3 right leg and left wrist.” He was a 30-year old male who had been suffering from pain for five months that was worse at night. X-rays were obtained confirming the “ostitis” in both the tibia and radius.

Two other patients were noted to have orthopedic infections and were given diagnoses of osteomyelitis. One was a 20-year old electrician with radiographically confirmed osteomyelitis of the proximal phalanx of the small finger that presented with pain, swelling, and purulent discharge. The other patient had tibial osteomyelitis that had been present in 4-5 places with seven years of associated swelling. This too was confirmed on x-ray which was reported as “some cavity and diseased bone.”

The final two patients in the study both presented with chief complaints in their feet. The first was patient number 149, and he presented with an “Inflam. Flat Foot” and had been symptomatic with pain for five weeks.

Treatment was not specified. The second patient was diagnosed with neuralgic pain secondary to a “Morton’s Toe” and no specific treatments or interventions were discussed.

DISCUSSION

Although vastly different from the medical record system of today, the centralized charting system established by Dr. HS Plummer in 1907 was a significant leap forward for the field of medicine. Simple in its design and specific in its purpose, it managed to accomplish its goals of improving communication between physicians, improving care for patients, and facilitating scholarly research and progression of the science of medicine for future generations. The fact that we are able to access these records over 100 years later confirms that the latter goal was certainly accomplished.

Upon detailed review of these records, it is quite evident that many things have changed over the last century with respect to orthopedic diagnoses and management. One of the most notable changes may be the documentation itself. Although the patient record system at the Mayo Clinic has the same general design as many modern electronic medical records, much has changed. The simple paper charts of 1907 with their succinct descriptions of patient presentations, operative reports, and radiograph reports have become significantly more detailed, lengthy, and electronically filed now over 100 years later. The patients seem to have changed in some regards as well. Skeletal tuberculosis is no longer the most common cause of presentation, just as syphilis is now a much more rare cause of musculoskeletal complaint. The fact that one of the aforementioned patients paid \$5 for her visit without the mention of an insurance company is also a notable difference from today’s medical financial climate. After adjusting for inflation, this amount would have the same buying power as \$120 in 2015.⁵

Despite these differences, there are still a number of similarities that can be found between the first orthopedic patients presenting to the Mayo Clinic and today’s patients. For instance, nearly 10% of patients presented with some form of musculoskeletal chief complaint, indicating that musculoskeletal concerns were a common

reason to present to medical clinics. Of these, the most common symptom was back pain (n=11), which continues to be a common musculoskeletal complaint today. Also, in keeping with current surgical practice, these early physicians were likely quite busy as evidenced by the fact that they evaluated these 400 patients in less than a three week period from July 22, 1907 to August 10, 1907.

Although much has changed over the course of the last 100 years, there is still a great deal that can be learned from those who have gone before us in the field of orthopedics. Dr. Plummer was certainly one of the great innovators of the early 20th century and his contribution of the patient record system has had great influence on many areas of medicine. Similarly, the founders of the Mayo Clinic, Drs. William and Charles Mayo, who recognized the value of developing a multidisciplinary practice and were instrumental in creating the Department of Orthopedic Surgery at the Mayo Clinic at the encouragement of its first Chair, Dr. Melvin Henderson served as orthopedic innovators, particularly in the Midwest region of the United States. All of these individuals have had a profound impact on current orthopedic practices at our institution and have undoubtedly done the same at countless other medical institutions across the country.

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EXPEDITED CT-BASED METHODS FOR EVALUATING FRACTURE SEVERITY TO ASSESS RISK OF POST-TRAUMATIC OSTEOARTHRITIS AFTER ARTICULAR FRACTURES

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ABSTRACT

Background: Post-traumatic osteoarthritis (PTOA) is common after intra-articular fractures of the tibial plafond. An objective CT-based measure of fracture severity was previously found to reliably predict whether PTOA developed following surgical treatment of such fractures. However, the extended time required obtaining the fracture energy metric and its reliance upon an intact contralateral limb CT limited its clinical applicability. The objective of this study was to establish an expedited fracture severity metric that provided comparable PTOA predictive ability without the prior limitations.

Methods: An expedited fracture severity metric was computed from the CT scans of 30 tibial plafond fractures using textural analysis to quantify disorder in CT images. The expedited method utilized an intact surrogate model to enable severity assessment without requiring a contralateral limb CT. Agreement between the expedited fracture severity metric and the Kellgren-Lawrence (KL) radiographic OA score at two-year follow-up was assessed using concordance. The ability of the metric to differentiate between patients that did or did not develop PTOA was assessed using the Wilcoxon Ranked Sum test.

Results: The expedited severity metric agreed well (75.2% concordance) with the KL scores. The initial fracture severity of cases that developed PTOA differed significantly ($p = 0.004$) from those that did not. Receiver operating characteristic analysis showed that the expedited severity metric could accurately predict PTOA outcome in

80% of the cases. The time required to obtain the expedited severity metric averaged 14.9 minutes/case, and the metric was obtained without using an intact contralateral CT.

Conclusions: The expedited CT-based methods for fracture severity assessment present a solution to issues limiting the utility of prior methods. In a relatively short amount of time, the expedited methodology provided a severity score capable of predicting PTOA risk, without needing to have the intact contralateral limb included in the CT scan. The described methods provide surgeons an objective, quantitative representation of the severity of a fracture. Obtained prior to the surgery, it provides a reasonable alternative to current subjective classification systems. The expedited severity metric offers surgeons an objective means for factoring severity of joint insult into treatment decision-making.

INTRODUCTION

Post-traumatic osteoarthritis (PTOA) is a debilitating disorder resulting from trauma to an articular joint. PTOA most predictably develops after an articular fracture. Treatment of these fractures involves trying to restore the fragmented articular surface.¹ The severity of the fracture correlates highly with the risk of PTOA,¹ so treating surgeons evaluate fracture severity as part of their treatment decision-making. However, conventional systems for classifying the severity of the initial injury are highly subjective and have poor reliability,^{2,3} thus making it difficult to distinguish PTOA risk associated with the initial injury from that influenced by the treatment.

A CT-based method for assessing fracture severity was previously developed, with the goal of providing an objective, quantifiable measure.⁴ Relying upon fracture mechanics theory, the fracture severity assessment methodology used measures of interfragmentary surface area to infer the amount of energy absorbed during fracture,^{5,6} the amount of comminution in the resulting fracture, and the dispersion/displacement of the fracture fragments. Combining these components into a single overall severity score produced a reliable metric for objective assessment of fracture severity.⁴

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The authors have no conflicts to disclose related to this research. An Institutional Review Board approved the protocol used in this study, and informed consent was obtained from all patients.

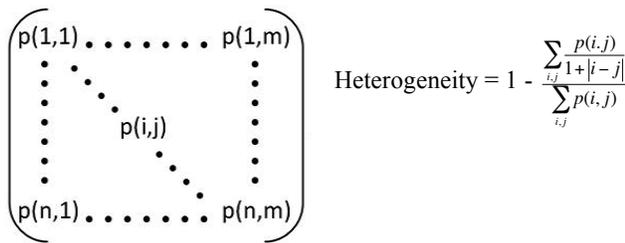


Figure 1. The GLCM (left) is shown along with the heterogeneity equation. The $p(i,j)$ term represents the value in the i^{th} row and j^{th} column of the GLCM. The heterogeneity increases when entries in the GLCM are further off the diagonal, i.e. when i and j differ substantially (as when bone and soft tissue, with disparate CT intensities, are in close proximity along fracture edges).

However, the fracture severity assessment methods presented serious practical limitations for clinical use. The greatest limitations of the prior methodology were the time and manual effort required to obtain a severity score. The roughly 8 to 10 hours of dedicated analyst time before a surgeon could get a score to assist in treatment planning was too long for routine clinical use. The method was further limited by requiring that a contralateral intact limb be included in the CT scan, which presents a challenge in the routine clinical setting. For the severity metric to ever be applied clinically the time required to obtain a severity score must be significantly reduced and the need for a CT of the contralateral limb must be eliminated.

To address these limitations, an expedited approach for severity assessment has been developed.⁷ The expedited approach builds upon the prior fracture mechanics methods, but it utilizes a textural analysis of CT images from the fractured bone to capture the disruption in the spatial distribution of CT intensities associated with an intact bone being fractured, in lieu of direct measurement of interfragmentary surface area. This approach leverages the fact that intact bone appears as contiguous similar intensity regions, and then following fracture there is a disruption in the ordered pattern with more dissimilar intensity regions in contiguity. The focus of this paper is to describe and implement an expedited fracture severity methodology that can be used more broadly. The specific objective was to establish how well the expedited fracture severity metric could predict two-year PTOA risk in patients with fractures of the tibial plafond.

METHODS

The same inclusion criteria were used for patient eligibility as in the prior study⁴: an isolated closed or open fracture treated using a splint or a spanning external fixator to return the limb to normal length and alignment, and a CT scan covering the entire length of the fracture.

One significant difference was that the expedited metric did not require the inclusion of an intact contralateral limb in the CT image, making it possible to include additional patients in the analysis. An Institutional Review Board approved the protocol used in this study, and informed consent was obtained from all patients.

Based upon preliminary evaluations of several candidate methods, an expedited fracture severity metric was computed from CT scans using the heterogeneity of the gray level co-occurrence matrix (GLCM) to quantify the order vs. disorder of each CT image slice. The GLCM is a well-established method for characterizing the texture of an image by counting how often specific intensity values occur near one another and then extracting statistical measures from this matrix.^{8,9} The heterogeneity, a GLCM-based statistical measure, was judged to be the most appropriate to use in this context because it best captured the interfragmentary surface area of the fractured bone (Figure 1). When comparing the heterogeneity value of a fractured limb to the limb before fracture, the fractured limb contains the same neighboring pixel relationships except for along interfragmentary surfaces, where the previous bone-to-bone relationships of the intact limb are replaced by bone-to-soft tissue relationships in the fractured limb. All of the expedited fracture severity analysis was programmed in MATLAB (The MathWorks, Inc., Natick, MA).

Prior to performing textural analysis of the CT image data, the portion surrounding just the tibia had to be identified. This process involved segmenting the tibia (i.e., identifying the tibia bone and fragments on CT slices) so as to exclude extraneous soft tissue, plaster casts, noise, and other bones from analysis. This was done using an existing 3D watershed-based segmentation method,¹⁰ supplemented with occasional limited manual intervention. The articular surface was then identified at the distal end of the tibia to provide an appropriate and repeatable landmark for the expedited fracture severity analysis. The differences between heterogeneity values from the fractured and intact contralateral limbs, when compared to the interfragmentary surface area along the fractured length of the tibia, generally correlated with each other (Figure 2), engendering confidence in this approach. However, in order for this methodology to truly be clinically useful, a method for analyzing these data in the absence of a CT scan from the contralateral limb is essential.

A patient-specific method of normalization was therefore developed to serve as a surrogate for having CT data from the actual intact contralateral limb.¹¹ The surrogate was developed utilizing the 20 cases for which intact contralateral CT data were available, but it does not require that data for subsequent use. The normalization

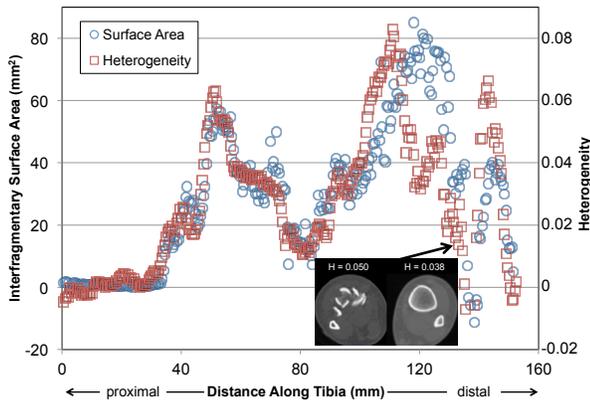


Figure 2. The interfragments surface area and the heterogeneity are plotted here along the length of the fractured tibia. Heterogeneity values are the difference between those of the fractured bone vs. its intact contralateral.

method accounted for patient height and weight, as well as for differences in CT scan settings (in-plane spatial resolution, slice thickness/spacing, and CT convolution kernels). The differences in CT scan settings presented a practical reality that needed to be accommodated in this work, and broader clinical utility is assured by reducing dependence upon any specific set of CT settings. A simple bi-linear surrogate model of the intact heterogeneity data and its dependence on these CT and patient-specific parameters was derived and saved for use later in the severity component calculations.⁷

A comprehensive fracture severity score that included the same severity components as in the prior full severity metric was derived using expedited methods. The components of fracture energy, fragment dispersion, and articular comminution were modeled after those of the prior full metric components, but derived only from the GLCM and heterogeneity. The expedited severity metric included a surrogate of the fracture energy by subtracting the intact heterogeneity surrogate from the fractured heterogeneity, summed over the length of the fracture. The expedited severity metric also included a surrogate for fragment dispersion by quantifying the amount of soft tissue-like CT intensities interspersed between fragments (Figure 3). The third and final component of the expedited severity metric was a surrogate for articular comminution, which was calculated from the fragment dispersion within 9 mm of the articular surface at the distal end of the tibia.

The final step in determining a severity score for the expedited metric was to combine the three components (fracture energy, fragment dispersion, and articular comminution) into a single comprehensive severity metric that best predicted PTOA risk. To do this, each component was normalized so that all computed values

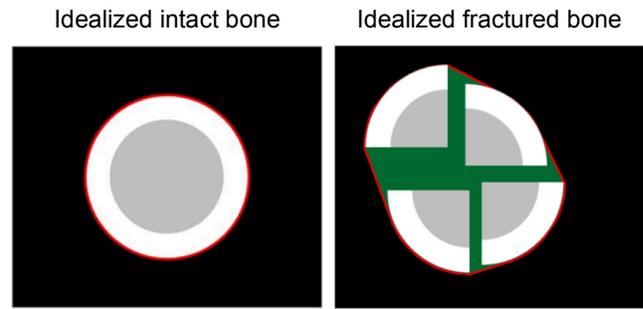


Figure 3. These idealized models show soft tissue-soft tissue neighboring relationships (green) within the circumscribing convex hull (red line) for the intact and fractured bones. The volumes of these green regions are summed over the length of the fractured tibia to reflect fragment dispersion.

ranged from 0 to 100. Their relative contributions to the combined metric were then evaluated at different weightings ranging from 0% to 100%. The expedited fracture severity approach was used to analyze the pre-operative CT scans of 30 patients with tibial plafond fractures (18 male and 12 female). In addition to the 20 patients previously analyzed using the full fracture severity assessment methods, an additional 10 patients were analyzed for the expedited severity metric. These cases could not be analyzed before as contralateral pre-operative CT scans were not obtained.

Expedited fracture severity metric values (a continuous measure) were compared to Kellgren-Lawrence (KL) OA scores of joint degeneration obtained from radiographs at a two-year follow-up exam.¹² The radiographs were examined and assigned a score by an experienced trauma fellowship-trained orthopedic surgeon. Due to the ordinal nature of the KL scores, concordance was used to evaluate the agreement between severity and KL scores.

The best weightings of individual components to produce a combined expedited fracture severity metric predictive of PTOA were determined among the 30 cases analyzed, and concordance values were calculated by comparing the combined values to their KL scores. The essential purpose of the metric is to be able to predict PTOA risk, thus differentiating between patients that do not develop PTOA (defined here as KL scores of 0 or 1) from those that do (KL score ≥ 2). Therefore, additional analyses were done to determine how much the expedited severity values varied between these groups, in addition to measuring the ability of the metric to predict binary PTOA risk. A Wilcoxon Ranked Sum test was used to test for significant differences between the cases with and without PTOA. A receiver operating characteristic (ROC) analysis was then performed on the expedited severity data to measure threshold-discriminative ability between cases developing or not developing PTOA.

Table I. Patient demographics and specific CT image reconstruction parameters for each case.

Case	Age	Sex	Height (cm)	Weight (kg)	Resolution (mm)	Slice Thickness (mm)	Convolution Kernel
1	26	F	160	61.4	0.47	0.50	FC01
2	42	F	160	69.4	0.35	0.30	B31s
3	40	F	170.2	170.5	0.66	0.30	B80s
4	23	F	160	69.6	0.28	1.00	FC01
5	55	F	162.5	72.7	0.43	0.30	B80s
6	49	F	152.4	59.9	0.41	0.50	FC01
7	28	M	190.5	70.0	0.39	0.30	B80s
8	29	M	188	97.0	0.33	0.50	FC01
9	21	M	179	87.2	0.49	0.50	FC01
10	20	M	175.3	55.0	0.51	1.00	FC01
11	37	F	162.5	79.5	0.33	0.50	FC01
12	48	F	162.5	62.0	0.55	0.50	FC01
13	57	F	158.8	89.8	0.41	0.50	FC03
14	36	F	170.2	72.3	0.68	0.50	FC01
15	41	M	180.3	95.3	0.46	0.30	B80f
16	54	M	181	80.4	0.36	0.50	FC01
17	40	M	180	84.1	0.68	0.50	FC01
18	24	M	177.8	80.9	0.66	0.50	FC01
19	57	F	180.3	86.2	0.63	0.50	FC01
20	25	M	170	90.9	0.28	0.50	FC01
21	64	M	178	95.0	0.25	0.50	FC01
22	26	M	175	120.5	0.33	0.30	FC01
23	21	M	190.5	113.6	0.59	0.50	FC01
24	41	F	167.6	75.0	0.33	0.50	FC01
25	42	M	177.8	109.0	0.24	0.50	FC01
26	40	M	177.8	86.2	0.39	0.50	FC01
27	26	M	180.3	110.0	0.29	0.50	FC01
28	34	M	180	83.0	0.24	0.50	FC01
29	42	M	184	89.3	0.41	0.30	B31s
30	56	M	182.9	154.2	0.78	0.50	FC01

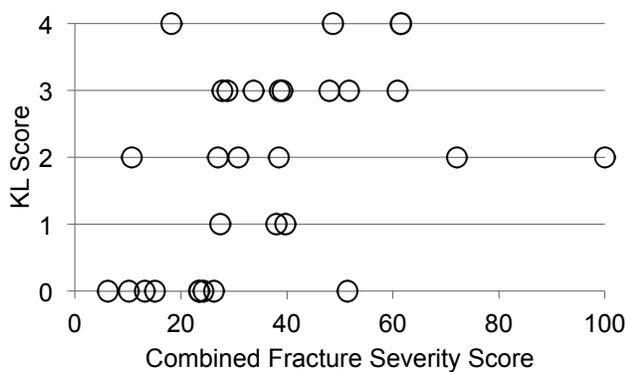


Figure 4. Comparison between the combined scores of the expedited fracture severity metric and the KL scores are plotted here for the 30 cases that were analyzed.

RESULTS

The age of the 30 patients enrolled in the study was 38.1 ± 12.7 years (mean \pm standard deviation). The heights were 173.8 ± 10.2 cm and weights 89.0 ± 25.7 kg. All of the patient demographics and CT acquisition parameters are shown in Table I.

The concordance between each component and the KL scores for all 30 cases was found to be 68.3%, 68.9%, and 68.3% for the fracture energy, overall fragment dispersion, and articular dispersion, respectively. The best combination of individual weightings for constituent elements in a combined severity metric were determined to be 33% fracture energy, 61% fragment dispersion, and 6% articular dispersion. For this set of weightings, the combined expedited severity metric scores showed a moderate predictive capability, having a 75.2% concordance with the KL scores (Figure 4).

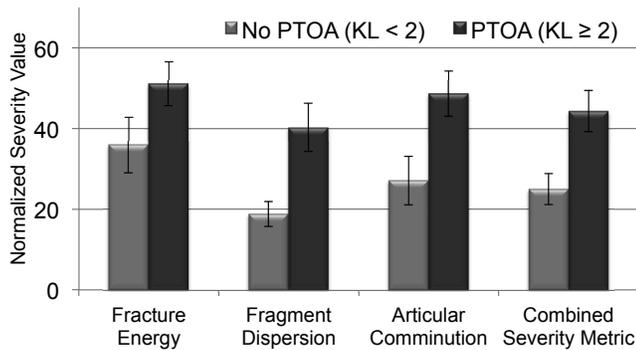


Figure 5. The expedited fracture severity constituent values and the combined severity metric values are shown here for those cases without OA (KL<2) vs. those with OA (KL≥2).

The cases that did not develop PTOA differed significantly ($p < 0.05$) from those that did for two of the three components of fracture severity (Figure 5). The most significant difference was in fragment dispersion ($p = 0.021$). The differences in articular comminution were the next most significant ($p = 0.024$). The only component whose values did not significantly differ was fracture energy ($p = 0.079$). When the components were assembled into a combined severity score, a significant difference was found between the cases in terms of OA development, with $p = 0.004$ using the Wilcoxon Ranked Sum test (Figure 5).

The ROC analysis varied the severity threshold values and then developed contingency tables for sensitivity and specificity (Figure 6). The expedited severity metric showed a good ability to predict PTOA outcome with the best results presented at a threshold value of 27.75 (represented by the green point on the ROC curve in Figure 6). This severity threshold predicted the true outcome in 80% of the cases.

The average time to obtain a severity score using the expedited analysis methods was just under 15 minutes (14.9 minutes). The amount of user intervention time averaged roughly 12 minutes (range: 3 to 25 minutes), or 80%, of the total analysis time. The majority of that time was spent segmenting the fractured tibia from the CT scan data. Of the 30 cases analyzed, 10 required some form of adjustment to the initial automated segmentation.

DISCUSSION

The prior full fracture severity metric had been used to analyze tibial plafond fractures from 20 patients.⁴ The fracture severity metric strongly predicted PTOA, showing an 88% concordance with two-year follow-up KL scores. The expedited fracture severity metric described here showed a 75.2% concordance with KL scores for a larger series of 30 patients with tibial plafond fractures. It is important to understand that perfect concordance

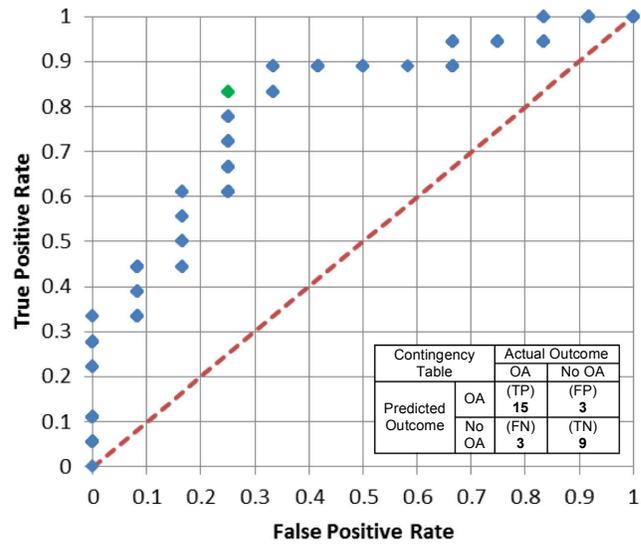


Figure 6. Receiver Operating Characteristic (ROC) curve for varying severity thresholds of the expedited severity metric. The green data point is for a severity threshold of 27.75, which corresponds to the inset contingency table showing an 80% success rate in predicting whether or not PTOA will ensue within two years following IAF.

with KL radiographic OA scores is not necessarily to be expected; chronic mechanical factors such as residual surface incongruity also influence the outcome of the joint.

Given its ability to predict PTOA outcome, the greatly reduced processing time, and its lack of reliance upon a CT scan of the contralateral limb, the expedited fracture severity assessment methodology is likely to be much more amenable to clinical application compared to the prior full fracture severity metric. This provides surgeons with an objective, quantitative representation of the overall severity of the fracture. Because it can be obtained prior to the surgery, there is potential for it to replace the current subjective classification systems (AO/OTA, Rüedi and Allgöwer), which have been shown to unreliably assess severity.^{2, 13, 14} The existing categorical classification systems, while undeniably useful in guiding treatment, poorly predict the risk of PTOA in patients with tibial plafond fractures. With the expedited metric in place, a surgeon would have an objective numerical score to determine severity of joint insult.

The expedited fracture severity metric possesses several attributes that make it more practical for clinical application than the prior full fracture severity metric. The first, and most significant, is the calculation time required to obtain a severity score. At about 15 minutes, this is significantly less time than the 8 hours required for the prior severity metric. Although not here presented, inter-user variability testing showed high reliability of the severity analysis methods, and new users were quickly able to learn how to use the software.⁷ An analyst is only

required to have basic anatomical knowledge to successfully perform the analysis. Another significant advantage of the expedited metric is that it provides a severity score that reliably predicts PTOA development without the need of an intact contralateral limb CT scan. This is an important step in developing a clinically applicable expedited metric, because a CT scan of the contralateral limb may not be routinely obtained. Additionally, retrospective clinical analyses in situations where there is no scan of the intact contralateral limb can be performed.

A limitation of the expedited metric is the small number of cases analyzed to date. Adding more cases (the focus of ongoing work) will further assess the ability of the metric to predict PTOA. Another limitation of the expedited metric is the limited number of cases used in constructing the intact surrogate model used for the expedited fracture energy assessment. While the curve shows a good relationship between cases, further work will be needed to more definitively establish its value. A final limitation is that the expedited severity metric in its current manifestation is only designed to analyze fractures of the tibial plafond. However, the metric has potential to be applied to other joints also subject to PTOA development, such as the knee or the wrist.

CONCLUSION

The ability to reliably assess the severity of articular fractures is critical to prognosticating the eventual fate of the joint. An assessment method that distinguishes the relative PTOA risk attributable to damage from the initial trauma versus other factors is needed. A previously developed objective CT-based fracture severity assessment methodology provided a reliable and valuable measure of severity for fractures of the tibial plafond. However, the amount of time and resources required made its clinical use impractical. The expedited CT-based methods for evaluating fracture severity presents a solution to the issues limiting the usefulness of previous fracture severity metrics. In a relatively short amount of time, the expedited methodology provides a severity score capable of predicting PTOA risk without needing to have the intact contralateral limb included in the CT scan.

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PREDICTORS OF PATIENT REPORTED PAIN AFTER LOWER EXTREMITY NONUNION SURGERY: THE NICOTINE EFFECT

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ABSTRACT

Background: Nonunion of long bone fractures is a serious complication for many patients leading to considerable morbidity. The purpose of this study is to elucidate factors affecting continued pain following long bone nonunion surgery and offer better pain control advice to patients.

Methods: Patients presenting to our institutions for operative treatment of long bone fracture nonunion were enrolled in a prospective data registry. Enrolled patients were followed at regular intervals for 12 months using the Short Musculoskeletal Function Assessment (SMFA), visual analog scale (VAS), physical examination, and radiographic examination. The registry was reviewed to identify patients with a tibial or femoral nonunion that went on to union with complete follow up. Univariate analyses were conducted to identify patient characteristics associated with postoperative pain. Identified patient factors with univariate p -values <0.1 were included in multivariate linear regression models in order to identify risk factors for pain 3 months, 6 months, and 12 months after nonunion surgery.

Results: Ninety-one patients with tibial or femoral nonunion who went on to union and had complete follow-up were identified. A Friedman test revealed mean pain score decreased significantly by 3 months postoperatively ($p<0.0005$). Univariate analyses demonstrated age ($p=0.016$), days from injury to nonunion surgery at our institution ($p=0.067$), smoking status ($p<0.0005$), wound status at time of injury ($p=0.085$), anesthesia ($p=0.045$), and nonunion location in the bone ($p=0.047$) were

associated with postoperative pain in at least one time point postoperatively. These were included in multivariate models that revealed nonunion location ($p=0.035$) was predictive of pain 3 months postoperatively, smoking status was predictive of pain 3 months ($p=0.012$) and 6 months ($p<0.0005$) postoperatively, and days from injury to nonunion surgery at our institution was predictive of pain 6 months ($p=0.024$) and 12 months ($p=0.004$) postoperatively.

Conclusions: Healed patients have improved pain levels after lower extremity nonunion surgery. Orthopedic surgeons should stress smoking cessation programs and minimize delay to nonunion surgery, in order to maximize pain relief in this patient cohort.

INTRODUCTION

Fractures are a common injury in the United States with an estimated 50% of Americans sustaining a fracture by age 65.¹ A possible complication after a fracture is failure to heal and subsequent fracture nonunion. In the United States, an estimated 100,000 fractures fail to heal and progress to nonunion each year.² Fracture nonunion leads to physical and psychological morbidity,³ and pain.⁴ Patients with tibial nonunions report physical and mental health outcomes worse than patients that have suffered a myocardial infarction.⁵ Nonunions are economically costly leading to increased treatment costs⁶ and numbers of days missed from work.⁷ With treatment, patients with nonunion can have significant improvement in function and pain relief.⁴

Despite reduction in pain levels following nonunion treatment, some patients may still have residual pain. In a cohort of patients followed after nonunion surgery, Egol et al. showed mean pain level on a visual analog scale (VAS) was 2.8 ± 2.5 12 months postoperatively.⁴ Similarly, Taormina et al demonstrated mean 12 month VAS pain levels of 2.6 in patients treated for fracture nonunion.⁸ This is consistent with findings by Tay et al., demonstrating that 72% of patients with fracture nonunion report continued pain 12 months after injury.⁷ Despite improvements in pain level, some patients have residual pain. Chronic pain can be difficult to treat. This is especially true in patients with fracture nonunion who are more likely to be prescribed

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Table I. Friedman Test comparing pain at 3, 6, and 12 months after nonunion surgery

Comparison	Adjusted p-value
3 months – 6 months	1.000
3 months – 12 months	1.000
6 months – 12 months	0.813

opioids for a prolonged period of time.⁶ The purpose of this study was to find patient and treatment specific variables predictive of pain following nonunion surgery.

METHODS

Patients treated operatively at our institution by one of three orthopedic traumatologists for long bone fracture nonunion were enrolled in a prospective registry using an institutional review board approved protocol. Nonunion was defined as lack of progression in radiographic and clinical healing over a three month period.^{9,10} Patients provided demographic information, preoperative Short Musculoskeletal Function Assessment (SMFA), VAS,^{11,12} and underwent preoperative physical and radiographic examination. Surgical details were obtained from review of patient charts. All patients were treated using a similar algorithm with patients without suspicion of infection undergoing primary or revision open reduction and internal fixation (ORIF). Patients with obvious infection were treated using external fixation or a staged protocol for internal fixation. Seventy-five (82%) patients were treated with ORIF with some type of biologic augmentation. Sixteen (18%) were treated with external fixation. Use of bone graft or bone morphogenetic protein (BMP) was at the discretion of the treating surgeon. Seventy-four percent of patients received iliac crest bone graft (ICBG), with or without BMP. Patients were followed at 3, 6, and 12 months after surgery using the SMFA, VAS, physical and radiographic examination. The registry was reviewed to identify patients with tibial or femoral nonunion that achieved union with complete 3, 6, and 12 month follow-up. Union was defined using a combination of radiographic and clinical factors including bridging callus on at least 3 of 4 cortices, no gross motion at the nonunion site, and pain free weight-bearing and palpation.

Statistical Analysis

A Friedman test was conducted to determine differences in pain level preoperatively, as well as 3, 6, and 12 months postoperatively. Pairwise comparisons were performed using a Bonferroni correction for multiple comparisons.

Univariate analyses were conducted to identify patient and treatment characteristics associated with postoperative pain. Each patient variable was tested for association with pain level 3, 6, and 12 months postoperatively. Mann

Whitney U tests were conducted to determine differences in mean postoperative pain level at 3, 6, and 12 months between pairs of dichotomous variables: gender, smoking status, wound status at time of injury (open vs. closed), bone involved (tibia vs. femur), nonunion location in the bone (metaphyseal vs. diaphyseal), energy of causative mechanism, anesthesia, use of ICBG, removal of hardware, addition of hardware, and presence of infection. Energy of causative mechanism was categorized as low or high energy with high energy mechanisms consisting of motor vehicle or motorcycle crash, being struck as a pedestrian, crush injury, or fall from greater than 10 feet. Spearman's rank order correlations were conducted to determine correlation between postoperative pain at 3, 6, and 12 months with continuous variables: age, body mass index (BMI), Charlson comorbidity index (CCI), and days from injury to nonunion surgery at our institution. A monotonic relationship between test variable and pain level was verified. A cut off of $p < 0.1$ was used for variables in univariate analyses for inclusion in multivariate models.

Variables associated with pain level at any time point after surgery were included in multivariate linear regression models predicting postoperative pain 3 months, 6 months, and 12 months after surgery. A significance cut off of $p < 0.05$ was used for multivariate analyses. The assumptions of linearity, independence of errors, and homoscedasticity were verified. Chi-square tests for association were conducted to determine associations between fracture location and wound at time of injury, and fracture location and energy of causative mechanism. All statistical analyses were conducted using SPSS version 20.0 software (IBM, Armonk, NY).

RESULTS

There were ninety-one patients available for analysis with 57 (63%) tibial nonunions and 34 (37%) femoral nonunions. The cohort consisted of 57 (63%) men and 34 (37%) women. On average, patients were 406 \pm 433 days from injury at time of nonunion surgery. Mean time to union following nonunion surgery was 6.8 \pm 4.2 months. Mean preoperative pain was 5.4 \pm 2.7. Chi-squared tests for association demonstrated no association between nonunion location and wound status at time of injury ($p = 0.495$) or nonunion location and energy of causative mechanism ($p = 0.062$). Friedman test demonstrated pain levels were statistically different at each of the observed time points. Post hoc analysis revealed significant differences in pain level between baseline and 3 months postoperatively ($p < 0.0005$), baseline and 6 months postoperatively ($p < 0.0005$), and baseline and 12 months postoperatively ($p < 0.0005$). However, there were no significant differences between pain levels when comparing any of the postoperative time points (Table I).

Table II. Results of univariate analyses comparing patient specific variables to postoperative pain

Variable	Mean/Proportion	3 month p-value	6 month p-value	12 month p-value
Age	46.1 years	0.352	0.083	0.016*
BMI	28.6	0.844	0.875	0.504
CCI†	0.5	0.734	0.986	0.247
Days to Surgery	406	0.925	0.143	0.067
Gender	57/91 Male	0.885	0.931	0.920
Smoking	21/91	0.011*	<0.0005*	0.040*
Wound	23/91 Open	0.631	0.356	0.085*
Mechanism	58/91 High energy	0.813	0.970	0.336
Anesthesia	61/91 General	0.144	0.057	0.045*
ICBG‡	67/91	0.276	0.335	0.909
Removal Hardware	55/91	0.818	0.860	0.705
Addition Hardware	58/91	0.904	0.601	0.228
Infection	18/91	0.409	0.537	0.707
Bone	57/91 Tibia	0.849	0.688	0.752
Section	53/91 Diaphysis	0.047*	0.400	0.451

*Denotes statistical significance.†CCI = Charlson Comorbidity Index.‡ICBG = Iliac crest bone graft

Table III. Multivariate Analysis of Patient Variables Associated with Postoperative Pain

Variable	3 month p-value	6 month p-value	12 month p-value
Age	0.294	0.935	0.159
Days to Surgery	0.566	0.024*	0.004*
Smoking	0.012*	<0.0005*	0.179
Wound	0.845	0.365	0.070
Anesthesia	0.219	0.323	0.243
Section	0.035*	0.278	0.898

*Denotes statistical significance.

Results of univariate analyses comparing each patient specific variable to pain at each tested time point are in Table II. BMI, CCI, gender, mechanism of injury, bone involved, ICBG harvest, removal of hardware, addition of new hardware, and presence of infection were not found to be significantly associated with postoperative pain at any tested time point. Age, days from injury to nonunion surgery at our institution, smoking status, wound status at time of injury, anesthesia, and nonunion location in the bone were all found to be significantly associated with postoperative pain for at least one of the tested time points, and were included in multivariate analysis to predict postoperative pain 3 months, 6 months, and 12 months postoperatively. Mean pain plateaued after surgery with patients reporting a mean VAS of 3.2 ± 2.7 3 months postoperatively, 3.5 ± 3.0 6 months postoperatively,

and 2.9 ± 2.7 12 months postoperatively. Multiple regressions conducted to predict VAS postoperatively using age, days from injury to nonunion surgery at our institution, smoking status, wound status at time of injury, anesthesia, and nonunion location in the bone demonstrated. active smoking (Odds Ratio [OR] =1.342, 95% Confidence Interval [CI] 0.391 to 3.055, $p=0.012$) and diaphyseal location in the bone ([OR] =1.342, [CI] 0.095 to 2.590, $p=0.035$) were predictive of increased pain 3 months postoperatively. Active smoking ([OR]=2.978, [CI] 1.631 to 4.326, $p<0.0005$) and greater number of days from injury to nonunion surgery ([OR]=0.002, [CI] 0.0005 to 0.003, $p=0.024$) were predictive of increased pain 6 months postoperatively. Increased number of days from injury to nonunion surgery ([OR]=0.002, [CI] 0.001 to 0.003, $p=0.004$) was the only variable found to be significantly predictive of pain 12 months postoperatively. Results from all multivariate regressions are available in Table III.

DISCUSSION

In concordance with previous studies, our results demonstrate a statistically significant improvement in pain after nonunion surgery.^{4,8} Pain levels significantly improved compared to baseline by 3 months postoperatively. This occurred despite the cohort healing at a mean time of 6.8 months, over 3 months after the initial drop in pain levels. Interestingly, there was no significant improvement in pain levels between 3 and 12 months postoperatively, during which the patients were finally healed. This suggests that initial healing of the nonunion site in the first

3 postoperatively provides sufficient stabilization to allow for reduction in pain.

An orthopedic surgeon can assist with healing and pain relief after nonunion surgery through treatments aimed at restoring a combination of biologic and mechanical factors. However, patients must be active in their own care as smoking is a known risk factor for development of fracture nonunion¹³ and is known to be associated with increased time to union postoperatively.⁸ Importantly, there is a greater improvement in pain in patients that achieve union after nonunion surgery.⁴ Our data regarding postoperative pain are consistent with these findings. Smoking was positively predictive of pain early after nonunion surgery. We postulate that patients who smoke are less likely to have meaningful healing early after nonunion surgery and are therefore at greater risk of pain than patients that have had a more abundant healing response. This creates a dangerous situation for the smoker in chronic pain. Animal models have begun to illustrate the complex relationship between nicotine and pain, demonstrating the effects of nicotine on the endogenous opioid system.¹⁴ Functional imaging demonstrated the connection between nicotine and the endogenous opioid system showing activation of opioid receptors in nicotine deprived adult smokers who were given nicotine.¹⁵ This connection between nicotine and opioid use becomes clinically important as Hooten et al. previously demonstrated that patients with chronic pain used increased opioid amounts if they were current smokers.¹⁶ In our study, active smokers were at higher risk of postoperative pain, scoring nearly 3 points higher on the VAS pain scale 6 months after surgery. Orthopedic surgeons should counsel patients that, in addition to the negative health effects associated with smoking that they may be more familiar with, active smokers are more likely to have significant pain postoperatively.

The only other early predictor of pain following nonunion surgery was location in the bone of the nonunion, with diaphyseal nonunions being predictive of greater pain early postoperatively. We postulate this is due to the delayed healing associated with diaphyseal fractures. Long bones have varying blood supply depending on the section of the bone. As has been demonstrated in the tibia, blood supply and healing rates of acute fractures are greater in the proximal metaphysis than the diaphysis.¹⁷ Increased metaphyseal blood flow allows for the biologic environment required for bone healing. The improved biologic environment at the metaphysis should allow for earlier healing after nonunion surgery and earlier reduction in postoperative pain. In acute fractures compartment syndrome is associated with worsening soft tissue injury.¹⁸ Park et al. demonstrated that compartment syndrome is more common in fractures of the tibial diaphysis than either metaphysis.¹⁹ Even without the full development

of compartment syndrome, subclinical compartment syndrome is a postulated cause of loss of muscle bulk following tibial shaft fractures.²⁰ Gaston et al. demonstrated that the degree of soft tissue damage measured using the Tscherne classification was predictive of return to activity following tibial shaft fractures.²¹ Despite the association between acute diaphyseal fracture and soft tissue injury, in our cohort, there were no associations between energy of causative mechanism or wound status at time of initial injury with nonunion location. It is unlikely that with similar mechanisms and wound status that there were significant differences in soft tissue injuries between diaphyseal nonunions and metaphyseal nonunions in our cohort. Despite the role of soft tissue injury in outcomes after acute fracture, it seems to have less of a role determining pain after nonunion surgery, which is more likely influenced by available blood supply and its effect on postoperative healing.

There continues to be disagreement in the definition of fracture healing²² and fracture nonunion.²³ This makes it difficult for an orthopedic surgeon to decide the optimal timing of intervention for fracture nonunion. On one hand, the orthopedic surgeon does not want to allow the patient to live with the disability of fracture nonunion. On the other hand, the orthopedic surgeon does not want to put the patient through an unnecessary procedure. It is this balance between alleviating morbidity and avoiding unnecessary procedures and the potential for further complication that guides nonunion care. The United States Food and Drug Administration (FDA) define nonunion as a fracture greater than nine months after injury that has not shown radiographic progression in healing for 3 months.²⁴ Subsequent research has advocated for intervention prior to the 9 month definition provided by the FDA. The Study to Prospectively Evaluate Reamed Intramedullary Nails in Patients with Tibial Fractures (SPRINT) demonstrated lower nonunion and reoperation rates in tibial shaft fractures when surgeons waited 6 months before operative treatment of nonunion.²⁵ SPRINT did not advocate delayed treatment based on patient postoperative outcomes including function and pain. Their strategy, while decreasing the number of unnecessary surgeries, still allows for patients with tibial nonunion to live with considerable morbidity for 6 months before nonunion surgery, and based on our data puts patients at higher risk for long term postoperative pain after nonunion repair.

In a retrospective review of 176 tibial fractures, Lack et al. demonstrated the predictive value of radiographs after tibial fracture surgery. They found that tibial fractures showing any cortical bridging 4 months after surgery eventually progressed to bridging of three cortices without further intervention.²⁶ However, there remains

further room for improvement in the early identification of lower extremity nonunions. Yang et al. demonstrated the ability of trained orthopedic traumatologists to predict nonunion from case vignettes of patients only 3 months after initial injury.²⁷ Our data show that there should be another factor in the orthopedic surgeon's consideration for earlier surgical intervention: postoperative pain. Our data demonstrate that delayed operative management of nonunion is predictive of pain 12 months postoperatively. This was the only factor predictive of pain 12 months postoperatively. The orthopedic surgeon and patient must consider and balance preoperative morbidity and postoperative pain with the potential for an unnecessary procedure or complication. Newer methods of determining nonunion not available to the SPRINT investigators are now available to today's orthopedic surgeon. While postoperative pain was statistically significant and should be part of the decision making process, the demonstrated effect size for days from injury to nonunion surgery was small, does not warrant intervention on its own, and may be considered too small to be clinically significant by orthopedic surgeon and patient.

Our study is limited by the disagreement between providers in diagnosing nonunion and postoperative union, which is well illustrated in the orthopedic literature. Through using a multivariate regression, we attempted to control for the individual effect of biologic augmentation. However, there remains the possibility of bias with use of biologic augmentation. The data is the result of investigation at a single institution without the availability of metabolic markers. All surgeons followed a similar postoperative protocol with extended time between study visits. This makes it difficult to assess the exact trends in postoperative pain. We know that pain is significantly improved at the 3 month postoperative time point and plateaus thereafter, but we are unable to comment on changes in pain levels in the early postoperative period, and any factors that may influence those pain levels.

Lower extremity nonunions provide significant diagnostic and therapeutic challenges for the orthopedic surgeon as well as significant morbidity for the patient. Supporting both the biologic environment and mechanical stability of a fracture nonunion allows for faster healing and decreased early postoperative pain. Patients should be advised of their role in the healing process, highlighting correction of metabolic abnormalities,²⁸ management of medical comorbidities,²⁹ and smoking cessation. Benefits of early recognition and operative treatment of nonunion, including small reduction in postoperative pain, must be weighed against the risks of unnecessary procedures and become a conversation between the patient and orthopedic surgeon.

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CONSTRUCT CHOICE FOR THE TREATMENT OF DISPLACED, COMMUNATED OLECRANON FRACTURES: ARE LOCKED PLATES COST EFFECTIVE?

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ABSTRACT

Background: Cost effective implant selection in orthopedic trauma is essential in the current era of managed healthcare delivery. Both locking and non-locking plates have been utilized in the treatment of displaced fractures of the olecranon. However, locking plates are often more costly and may not provide superior clinical outcomes. The primary aim of the present study is to assess the clinical and functional outcomes of olecranon fractures treated with locked and non-locking plate and screw constructs while providing insight into the cost of various implants.

Methods: We performed a retrospective chart review of a single institution database identifying Mayo IIB type olecranon fractures treated surgically from 2003 to 2012. All fractures were treated with either a locked plate or a one-third tubular hook plate construct. Clinical and radiographic outcomes were evaluated. Minimum 6-month follow-up was required. Outcomes were compared between fixation constructs, including rate of union, early failure, postoperative range of motion, and complication rates. Statistical analysis included Pearson's Chi-squared and Fisher's exact test for categorical variables, and the Student's t-test for continuous variables.

Results: The one-third tubular construct was equivalent to locking plate constructs with respect to union, post-operative range of motion, and rates of complications. There were no early or late failures. Locking plates were associated with a relative cost increase of \$1,263.50 compared to the one-third tubular hook plate per case.

Conclusion: Surgeons should consider the cost of implants when treating Mayo IIB olecranon fracture. In this cohort, one-third tubular plates provided equivalent outcomes to locked plates with a notable decrease in cost.

INTRODUCTION

Olecranon fractures are by definition intra-articular disruptions of the semilunar notch of the ulna.¹ Plate osteosynthesis using a locking or non-locking technique is a well-established treatment option for displaced olecranon fractures with few complications and good clinical outcomes consistently reported.^{2,9} Additionally, cadaveric studies have demonstrated that both implant choices provide similar stiffness and load to failure under bending loads.^{10,11} It is recommended that the implant be applied to the dorsal surface of the ulna, which allows the implant to act as a tension band plate. Beyond this, however, there are no hard recommendations or compelling evidence to guide choice of plate, and some surgeons may gravitate toward locking plates due to poor bone quality, personal preference or familiarity with a specific plating system.

Despite the fact that an implant choice exists, there is only little evidence directly comparing these two methods of fixation and clinical or functional outcomes. Understanding the clinical and functional outcomes of each of these constructs is important, particularly given the difference in costs between implants in an era where the value of care remains a high priority. The purpose of this study was to compare the clinical and functional outcomes following treatment of comminuted fractures of the olecranon with pre-contoured locking plates (LP) versus one-third tubular hook plates (HP) while also providing information on implant cost. We hypothesized that there would be no clinical or functional differences observed between patients treated for similar fractures with either a LP or a one-third tubular HP.

METHODS

Data Collection

Following approval by the institutional review board, we performed a retrospective review of case logs from two board certified orthopedic traumatologists. We

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The authors report no relevant conflict of interest

This study was approved by the institutional review board at the participating institution

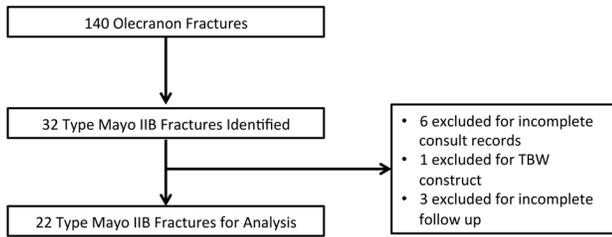


Figure 1. The patient population for study was derived from 140 identified olecranon fractures. After exclusion criteria were applied, 22 olecranon fractures were available for analysis.

identified patients who underwent open reduction and internal fixation (ORIF) for olecranon fractures between 2003 and 2012 by searching for ICD-9 codes 819.01 (closed fracture of olecranon process of ulna) and 819.11 (open fracture of the olecranon process of ulna). After identification, all patient charts and injury radiographs were carefully reviewed to confirm fracture pattern and identify any concomitant injuries. All fractures were classified according to the Mayo Clinic Classification¹². This analysis was restricted to Mayo IIB fractures, which are by definition displaced and comminuted, with a stable ulnohumeral joint. These patterns represent the most frequently treated olecranon fractures with plate and screw constructs.¹² Patients were included in this study if they were age 18 or older, sustained a Mayo IIB type olecranon fracture that underwent surgical management with a plate-screw construct, and had a minimum of 6-month follow up. Exclusion criteria were age less than 18 years, having a fracture pattern other than Mayo IIB, less than 6 months of follow up, treatment with a tension band construct, or those who presented for revision of a prior surgery.

During the 9-year period of this study, there were 140 acute olecranon fractures identified. Of those fractures, 32 (23%) were identified as Mayo IIB based upon their radiographic appearance and the details reported in the initial orthopedic surgery consult note. Of those 32 patients, 6 were excluded from analysis for having incomplete medical records, and one was excluded because it was treated with a tension band wire (TBW). Additionally, three patients were lost to follow up prior to bony healing, leaving 22 patients (69%) with 22 olecranon fractures available for analysis (Figure 1). The study cohorts consisted of 14 patients treated with HP and 8 patients treated with LP. There were a total of 8 males and 14 females within both groups. Three of these patients sustained concomitant fractures of the radial head, radial shaft, and proximal humerus. Patients were included regardless of the presence or type of concomitant injury.

Patient Characteristics

Patient demographic characteristics of interest included age, sex, laterality, associated injuries, and duration of follow-up. Operative variables of interest included the type of construct used as well as the screw density of the construct.

Outcomes

Each patient's last office follow-up visit was used as the benchmark for outcomes. Clinical outcomes of interest included the achievement of union, final range of elbow motion, development of hardware-related pain, and need for reoperation for any reason. Fracture union was determined radiographically and clinically. Post-operative radiographs were evaluated at 2-weeks, 6-weeks, 3 months, and 6 months to assess for union, which was defined as at least three healed cortices visible on orthogonal films. Union was assessed at each time point clinically by palpation of the fracture site. The absence of pain at the fracture site suggested a clinically united fracture. Functional outcomes were assessed using the Mayo Elbow Performance Index (MEPI). The MEPI is a validated, physician-completed measure of elbow function which takes into account post-operative elbow pain, range of motion, ulnohumeral stability, and the ability to complete five specific activities of daily living: combing hair, eating, performing hygiene, putting on a shirt, and putting on a shoe. The score ranges from 5-100 points, with scores between 90 and 100 considered excellent.¹³ In this study, the MEPI scores were constructed from the data documented in the clinical note from the last office follow-up visit. The implant list price was obtained from the manufacturers and was used for calculation of the overall implant costs in this study.

Operative Technique

All one-third tubular hook plates were contoured intraoperatively and applied by a single surgeon using a previously described technique.⁷ Briefly, a 6- or 7-hole one-third tubular plate is contoured to fit the posterior aspect of the proximal ulna. The plate is flattened and cut obliquely through the most proximal hole to create two prongs, which are bent at right angles to create a hook. A 3.5 mm intramedullary screw is then inserted through the most proximal aspect of the plate, but is not initially seated. This screw was directed to capture the anterior cortex of the olecranon if bone quality was judged to be poor. A second cortical screw is then inserted in the most distal hole using compression technique. The intramedullary screw is then advanced fully in order to gain further compression. A final cortical screw is then inserted through the plate and into the coronoid process to reinforce the construct (Figure 2).

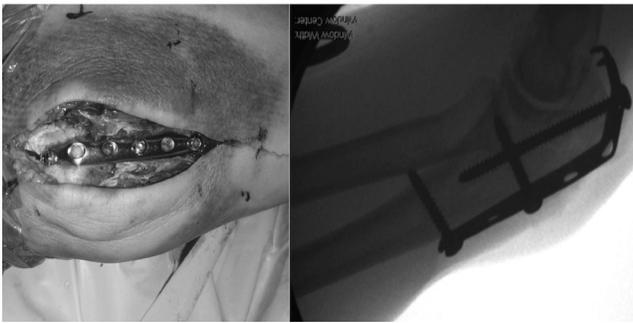


Figure 2. The one-third tubular hook plate is a construct that is fashioned intra-operatively from a 7-hole one-third tubular plate and fixed with three 3.5mm cortical screws. Based upon component list prices, the total construct cost is \$157.50.

Table I. Hardware List Prices

Hook Plate Components	
6-Hole One-third Tubular Plate	3.5mm Cortical Screw
\$94.50	\$21.00
Locked Plate Components	
2-Hole Pre-contoured LCP	3.5mm Locking Screw
\$1,206.00	\$173.00

Pre-contoured LP (Acumed (Hillsboro, OR), Stryker (Kalamazoo, MI), Zimmer (Warsaw, IN), or Dupuy-Synthes (Paoli, PA)) were utilized in several cases by both surgeons. Both surgeons used LP through a posterior approach to the olecranon. In all cases the ulnar nerve was identified and protected. The fracture was anatomically reduced and provisionally fixed with K-wires or pointed reduction clamps. A pre-contoured LP was applied and fixation of the olecranon fragment was performed in a fragment specific fashion. If the plate system allowed and the fracture was amenable, a homerun screw was inserted down the shaft of the ulna to obtain axial compression of the fracture.

Statistical Analysis

Statistical analysis was performed using SPSS Software, Version 20 (SPSS Inc., Chicago, IL). Outcome measures of interest were assessed using the Pearson Chi Square or Fisher Exact Test for categorical variables and the Student’s t-test for continuous variables. Significance was defined as $p < 0.05$.

The cost of one HP construct was calculated by obtaining the 2015 catalogue list cost of Dupuy-Synthes 6-hole one-third tubular plate and 3.5mm cortical screws (Table I). The construct cost was based on the cost of this plate and the use of three cortical screws as per the described techniques. The cost of one locking plate construct included the cost of one Dupuy-Synthes 2-hole locking compression plate (LCP) and five 3.5mm locking screws.

Table II. Cohort Age and Outcome Data

	Hook Plate	Locked Plate	p-value
n	14	8	
Age (Range)	62.1 (29-92)	54.1 (26-86)	0.393
Duration of Follow Up (Months)	12.1 (6-30)	11.3 (6-36)	0.834
Mean Flexion (°)	135	132.5	0.492
Mean Extension (°)	9.6	9.3	0.944
Motion Arc (°)	125.3	123.1	0.737
MEPI	94.6	90	0.338
Hardware-Related Pain	3 (21.4%)	2 (25%)	1.000

RESULTS

There were 32 Mayo IIB olecranon fractures identified, and 22 patients met criteria for analysis. Of the 22 patients, 14 were treated with HP and 8 were treated with LP. The average patient age of the entire cohort was 61.3 ± 21.27 years. There were no differences in patient age (HP = 61.3 years, LP=54.1 years, $p = 0.393$) and sex ($p= 0.513$) between groups (Table II). Mean duration of follow-up was 11.2 ± 8.5 months, which was similar between patients undergoing HP and LP fixation ($p=0.834$). Median locking screw density in a LP construct was 5 screws.

There were no early or late failures of fixation in either group. There were no differences in elbow range of motion based on implant choice. Elbow extension in the HP group was to a mean of 9.6 degrees, compared with 9.3 degrees in the locking plate group ($p = 0.944$). Elbow flexion in the HP group was to a mean of 135.0 degrees, compared with 132.5 degrees among the LP ($p= 0.492$). Total ulnohumeral arc of motion was 125.3 degrees for HP and 123.1 for LP ($p = 0.737$). The mean MEPI for the hook plate patients was 94.6 (range: 70-100) versus a mean of 90.0 for locking plates (range: 65-100) ($p = 0.338$).

A total of 5 patients (22.7%) reported post-operative hardware-related pain. All pain was reported as mild to moderate. Three of these occurred with hook plates, and two occurred with locking plates ($p = 1.000$). One late infection occurred in a patient treated with a hook plate after union was achieved, which was treated with irrigation, debridement, removal of hardware, and intravenous antibiotics with successful resolution.

A total of 2 patients (9%), one from each group, underwent reoperation. One reoperation was for treatment of a late infection of a HP as described previously, which included irrigation and debridement with hardware removal. The second reoperation occurred for hardware

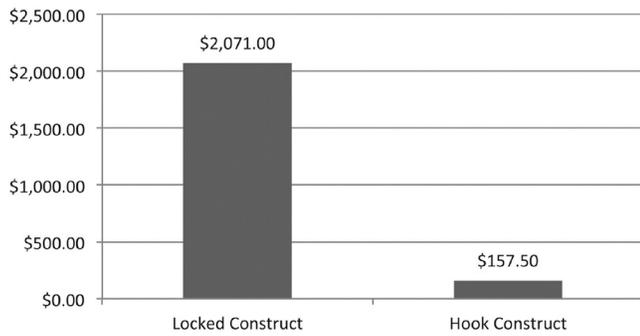


Figure 3. The cost of one pre-contoured locking plate construct with five locking screws is \$2,071, compared with the cost of the hook plate construct cost of \$157.50. This is a more than 13-fold cost increase for treatment of a Mayo IIB olecranon fracture.

pain in a patient treated with LP. Operative management included removal of hardware with no further complications noted.

The total cost of one HP construct including one 6-hole one-third tubular plate and three 3.5mm cortical screws was \$157.50 (Table II). Alternatively, the total cost of one pre-contoured locking plate and five locking screws was \$2,071. Five locking screw were used to calculate this cost. The cost based upon list price of one locking plate construct in this series was 13 times more expensive than one hook plate construct (Figure 3).

DISCUSSION

Open reduction and plate osteosynthesis of displaced olecranon fractures allows for anatomic reduction, stable fixation, and early motion, and this treatment method has historically yielded good results.^{2,4,7,8,14} The use of locked plating for these injuries has yielded good results, and may provide improved fixation in very comminuted fractures or osteoporotic bone.^{4,6,11,15} The cost of locking plates however is considerably greater than non-locking plate systems. In this small, retrospective review of patients with Mayo IIB olecranon fractures treated by either HP or LP, we observed similarly good clinical and functional outcomes between the two groups. Additionally, both groups had similarly low rates of hardware related pain with only a single case of LP requiring hardware removal for symptomatic hardware. While we did not objectively quantify the bone quality of each patient, we observed good outcomes for HP in both relatively young and old patients. There was a clear difference in the cost of hardware per patient, with higher costs associated with the application of the LP despite similar clinical outcomes in this series.

All patients in both groups achieved union. With respect to range of motion, we found no difference between groups. Both groups had approximately 120 degree flexion arc at final follow up, with both groups on

average losing 9-10 degrees of terminal extension. These results are comparable to those previously reported for olecranon fractures treated with both locking and non-locked plate options.^{6,14} We found no difference between groups with respect to functional outcome according to the MEPI, with mean MEPI 94.6 and 90.0, which is also comparable to previously reported outcome data for these injuries treated with locked and non-locked plating.^{6,8}

Over the last decade, locking plates have gained popularity among orthopedic surgeons, allowing preservation of the periosteal blood supply while optimizing gap strain at the fracture site.^{16,17} Clinical and biomechanical studies have validated their use, demonstrating that excellent fixation and rates of union can be achieved, particularly in complex periarticular fractures or in patients with poor bone quality or density.¹⁸ The potential downside to the use of locking plates, however, is their cost. In the present study, the list price of a single locked plate-screw construct with 5 locking screws was \$2,071, which represents a 13 times more expensive than the non-locking HP construct.

Olecranon fracture fixation is most frequently complicated by hardware-related irritation and pain in the post-operative period due to the naturally thin layer of subcutaneous tissue about the dorsal surface of the elbow.⁹ In this cohort, the rate of hardware pain and reoperation for hardware complications were consistent with previously reported data.¹⁹ There were no significant differences between the HP and LP groups with respect to hardware pain or reoperation.

There are several limitations of this study. The retrospective and non-randomized single-center design of this study presents several levels of bias including treating surgeon preference and subjective evaluation of bone quality. There is inherent selection bias in this study as it is not clear exactly why the decision was made to use a specific implant in each case. Implant choice is guided largely by a fracture's anatomic location, pattern, degree of comminution, quality of bone, and the integrity of the soft-tissue envelope. Each of these variables affects the character of the fracture, and in turn influences the surgeon's choice of fixation construct. Additionally, implant choice may be influenced a particular surgeon's own biases or company relationships. The two-surgeon design may also limit this study, as outcomes are also dependent on a surgeon's comfort and familiarity with a specific plating systems and techniques. Thus, not all surgeons or institutions may find these results reproducible. The costs reported in this study are implant list prices. Actual costs, however, may vary from institution to institution. Lastly, six-month follow-up may not be adequate to capture all post-operative complications.

In conclusion, plate and screw fixation of Mayo IIB olecranon fractures continues to provide consistent clinical results with few complications. In the present study, we found that similar clinical results were achieved with either HP or LP fixation. Given these findings and considerable cost difference between implant choices, future studies which utilize formal cost analysis are warranted.

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DELAYED PROXIMAL MIGRATION OF THE RADIUS FOLLOWING RADIAL HEAD RESECTION FOR MANAGEMENT OF A SYMPTOMATIC RADIAL NECK NONUNION MANAGED WITH RADIAL HEAD REPLACEMENT: A CASE REPORT AND REVIEW OF THE LITERATURE

John W. Karl, MD, MPH¹, Lauren H. Redler, MD², Peter Tang, MD, MPH³

ABSTRACT

Background: Long-term outcomes of radial head resection for radial head fracture have shown mixed outcomes, depending on the integrity of the soft-tissue stabilizers of the elbow, forearm, and wrist.

Methods: We report a case of a symptomatic delayed proximal migration of the radius after radial head excision for radial neck nonunion which was managed with a staged radial head replacement. Informed consent was obtained from the individual in this case report.

Results: At 7 months after radial head replacement, the patient had 90 degrees of forearm supination and 85 degrees of pronation. Elbow range of motion was from 10 degrees short of full extension to 155 degrees of flexion. Her Disabilities of the Arm, Shoulder, and Hand score was 21.4 at 7 months and 6.48 at 38 months.

Conclusions: There is insufficient evidence to reliably predict which patients can be managed definitively with radial head excision without risk of later proximal migration of the radius. The authors suggest the use of acute radial head arthroplasty when the index injury is secondary to a traumatic mechanism, reserving radial head excision for patients with radio-capitellar arthritis. Further research of the pathology and healing of concomitant soft-tissue injuries seen in conjunction with radial head fractures is warranted to guide their treatment.

INTRODUCTION

Many patients have good functional outcomes after radial head resection; however, those with inadequate stability may develop sequelae including valgus instability, proximal migration of the radius, or distal radial ulnar joint (DRUJ) subluxation with pain and dynamic instability.¹⁻⁵ Though opinions differ as to the clinical significance of proximal migration,⁶ some authors have advocated for early prosthetic replacement of the excised radial head to prevent this potential complication.⁷ More recently, use of a radial head replacement as a temporary spacer to allow for soft tissue healing with later removal of symptomatic hardware has been advocated.⁸⁻¹⁰ However, late symptomatic proximal migration after radial head replacement removal has also been described.^{9,11} The ideal management of these complicated patients is unclear. We provide a case report that describes management of a late, symptomatic proximal radial migration following prior radial head resection for symptomatic radial neck nonunion.

CASE REPORT

A 60-year-old right-hand-dominant female sustained right radial head and left radial neck fractures after a fall. She was initially treated non-operatively with a sling and early range of motion for both injuries. The patient presented to our institution 8 weeks after the initial injury due to persistent left elbow pain. Elbow range of motion on the right was from -5° to 145° flexion with 90° of pronation and 90° of supination, as measured with a goniometer. Elbow range of motion on the left was from -5° to 150° flexion with 90° of pronation and 90° of supination. Additionally, the patient had pain to palpation over the radial neck on the left with palpable clicking during forearm pronation and supination. She had no wrist or forearm pain with palpation or range of motion and her DRUJ was stable when shucked. At this time she was diagnosed with an asymptomatic delayed union of a right Mason I radial head fracture and a symptomatic delayed union of a left radial neck fracture.

The patient returned 6 weeks later, now 14 weeks post-injury, with persistent left elbow pain with activities of daily living and aching at rest despite anti-inflammatories and physical therapy. She was diagnosed with a persistent symptomatic left radial neck delayed union

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The authors declare that they have no conflict of interest relevant to this study.

This study was deemed exempt by the Institutional Review Board at the participating institution.

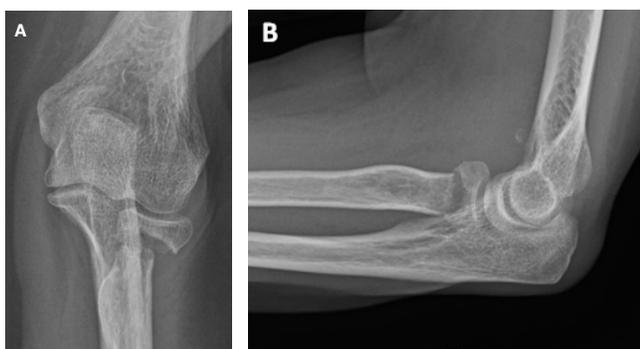


Figure 1. (A) Anteroposterior and (B) lateral radiographs taken of the left elbow 6 weeks after the initial visit (14 weeks after injury) show a radial neck nonunion. The patient continued to be symptomatic on this side.



Figure 2. (A) Postero-anterior radiograph of the left wrist taken 1 month after radial head excision shows neutral ulnar variance. Postero-anterior radiograph of the (B) left and (C) right wrist taken 4 months after radial head excision shows +5 mm positive ulnar variance on the left and +3.5 mm positive ulnar variance on the right. (D) An MRI of the left wrist shows evidence of ulnar impaction syndrome.

(Figure 1). She was taken to the operating room 5 months from the date of her injury for a left radial head resection via a Kaplan approach. Intraoperative exam under fluoroscopy revealed a stable ulnohumeral joint in flexion and extension, and a pivot-shift test assessing the status of the lateral ulnar collateral ligament confirmed posterolateral rotatory stability.¹² The elbow and DRUJ were stable after radial head resection. The elbow was

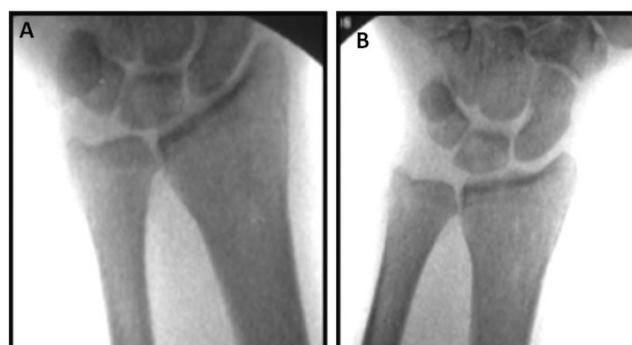


Figure 3. Intraoperative fluoroscopic images of the left wrist (A) with +5 mm positive ulnar variance before radial head replacement and (B) with +1 mm positive ulnar variance after replacement.

dressed in a soft, bulky dressing until 2 weeks, and the patient was allowed to move the elbow freely and started on a physical therapy program. There were no early postoperative complications.

The patient did well for 4 months, after which she developed wrist pain with daily activities. Clinical examination revealed elbow range of motion from -5° to 150° flexion with 90° of pronation and 90° of supination. Radiographs and magnetic resonance imaging (MRI) revealed proximal migration of the radius with 5 mm ulnar positive variance and increased signal on the coronal and sagittal T2 MRI sequences consistent with ulnar impaction syndrome (Figure 2). Clinical diagnosis was chronic longitudinal instability of the forearm with delayed proximal migration of the radius resulting in positive ulnar variance with subsequent ulnar impaction syndrome.¹³

Given the patient's symptoms and the findings of ulnar impaction on MRI, revision surgery was performed. Surgery consisted of delayed radial head replacement, 9 months after the initial injury and four months after her initial radial head excision. The radiocapitellar joint was exposed via the previous Kaplan approach and a radial head arthroplasty was performed (Acumed, Hillsboro, OR). Prior to placement of the implant, intraoperative fluoroscopy confirmed a 4 mm ulnar positive variance with the forearm in supination, which was reduced to 1 mm after radial head replacement (Figure 3). The elbow and DRUJ were stable to pronation and supination after the procedure and the DRUJ was stable to shuck testing (Figure 4). The patient was immobilized in a long arm splint until 2-week follow-up, at which point her wrist pain had subjectively started to improve. She then began physical therapy to improve range of motion. Radiographs of her wrist taken at 6 weeks postoperatively revealed a 3.5 mm ulnar positive variance, but the patient continued to report improved wrist pain compared with preoperatively (Figure 5). Radiographs

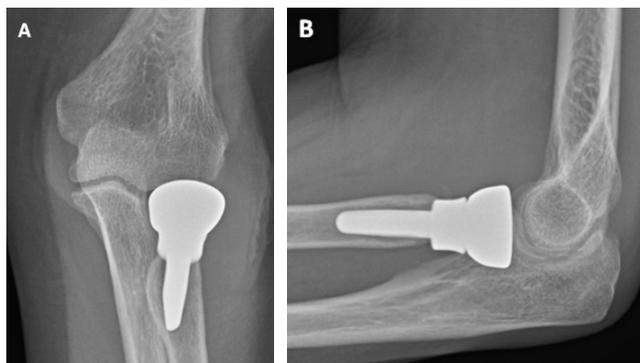


Figure 4. (A) Anteroposterior and (B) lateral radiographs of the elbow following radial head replacement.

of her wrists taken at 7 months post-operatively revealed a +2 mm ulnar positive variance compared to a +3 mm ulnar positive variance on the asymptomatic right side. At 7 months post-operatively she had 90 degrees of forearm supination in 90 degrees of flexion and 85 degrees of pronation. Elbow range of motion was from 10 degrees short of full extension to 155 degrees of flexion. Her Disabilities of the Arm, Shoulder, and Hand (DASH) score at that time was 21.4. At 38 months post-operatively she had a DASH score of 6.48, consistent with continued improvement and less disability.

DISCUSSION

Patients with operative fractures of the radial head and neck can be treated with fragment excision, open reduction and internal fixation, radial head replacement, or complete radial head excision. In addition to patient factors such as age, handedness, and activity level, the decision on how best to manage an individual injury is informed both by the pattern of the fracture and the concomitant soft-tissue injuries. The case presented here demonstrates how unrecognized or sub-clinical soft-tissue injury may result in proximal migration of the radius after isolated radial head excision, but that excellent clinical results may still be achieved if it is recognized in a timely manner and treated with radial head replacement.

Multiple studies have shown that the majority of patients have good functional outcomes after radial head excision.^{2,5,6,14-18} Antuna et al¹⁴ followed 26 patients younger than forty years of age with radial head fractures treated with primary radial head excision for a minimum of 15 years. Overall patients did well with a mean Mayo Elbow Performance Score (MEPS) of 95, mean DASH score of 6, and 92% with good or excellent results. However, 3 patients (11%) had wrist pain and radiographic evidence of proximal migration and 1 had



Figure 5. (A) Postero-anterior radiograph of the left wrist 6 weeks following radial head replacement shows some loss of the improved positive ulnar variance post-replacement (+5 mm → +1 mm → +3.5 mm). (B) Anteroposterior radiograph of the asymptomatic right wrist with +3.5 mm ulnar positive variance.

DRUJ instability. Similarly, Iftimie et al² reported on 27 patients who underwent resection arthroplasty after radial head fracture without elbow instability. At mean 17-year follow-up, they found overall very good functional results but noted symptomatic proximal migration (wrist pain) in 2 patients (7%) who were subsequently treated with an ulnar shortening osteotomy. The authors suggest these patients likely had unrecognized or sub-clinical Essex-Lopresti injuries, similar to our patient. Moreover, the timing of radial head excision does not seem to influence outcomes, as patients tend to do well after both early and late excision.^{15,16}

However, not all patients have successful results following radial head excision. In 1931, Brockman reported 2 cases of radial head excision for fracture with subsequent wrist pain due to proximal migration of the radius.¹ Taylor in 1964 described radiographic DRUJ subluxation in 37 of 58 cases of radial head excision, with symptoms of pain or instability present in 29 patients (50%) 7 years after surgery.⁴ Similarly, in 1957 McDougall and White reported that 12 of 44 patients (27%) had wrist symptoms after excision of the radial head for fracture due to proximal migration of the radius.³ They hypothesized that the degree of proximal migration was related to the severity of the soft tissue damage at the time of the initial injury, with acute migration occurring at the time of injury if the DRUJ was disrupted and the radial head dislocated while late migration occurred as a result of stretching of the articular disc and interosseous membrane. Proximal migration was also thought to be related to the activity of the patient, as it was found to be more common in manual laborers.

It should be noted that not all patients who have radiographic evidence of proximal migration have clinical symptoms. Morrey et al⁶ reported 20-year follow-up data on 13 patients after radial head excision with an average proximal migration of 1.9mm (0-5mm) and no

significant correlation between loss of motion (pronation/supination) and the amount of proximal migration of the radius. Only 4 of their 13 patients (30%) with proximal migration experienced wrist pain. Similarly, Yalcinkaya presented 14 elbows after radial head excision, 8 of which had proximal migration and an increase in carrying angle, with overall good clinical outcomes.⁵ Goldberg et al¹⁷ noted asymptomatic proximal migration in 8 of 37 patients (22%) despite radiographic evidence of migration as well as osteoarthritic changes.

In patients with radial head fracture with soft-tissue injury, such as medial collateral ligament tear, interosseous membrane injury (Essex-Lopresti injury), or DRUJ instability, lateral mechanical support must be provided by either the native radial head or by a radial head replacement in order to give the best chance of functional recovery. As early as 1953, some authors were advocating early prosthetic replacement of the excised radial head to prevent proximal migration.⁷ More modern implants have been shown to have overall excellent clinical outcomes.^{8-10,19} Nonetheless, some patients with acute complex elbow injuries who are treated with radial head replacement develop symptoms related to the arthroplasty itself, such as pain or a mechanical block to motion, and require later removal of the prosthesis. Knight and Rymaszewski suggested using the radial head replacement as a temporary spacer in unstable elbows, allowing the soft-tissue injuries to heal, and removing the prosthesis later if it becomes symptomatic.⁹ Harrington et al⁸ and Wretenberg et al¹⁰ both supported this idea and reported several patients with unstable elbow injuries who had radial head arthroplasties that were later removed after soft-tissue healing, leaving the patients with asymptomatic, stable elbows.

Even with adequate time for soft tissue healing, there can be symptomatic proximal migration of the radius. Van Riet et al. reported one case of radial head arthroplasty in whom soft tissues did not heal over a prolonged period of time, leading to a poor functional result after removal of the radial head implant.²⁰ Many authors believe that the interosseous membrane never truly heals but that it may scar down in a relatively contracted position, similar to many other soft tissue injuries.²¹ For this reason, chronic cases with established proximal migration are difficult to treat due to the radioulnar length inequality. Ulnar shortening does not offer a predictable solution in these patients,^{22,23} and one must consider the potential complication of nonunion of the ulnar osteotomy,²⁴ particularly in a patient like ours who has already shown poor potential for union. Szabo et al.²¹ presented a technically difficult solution to this challenging problem involving guided growth of the radius using Ilizarov technique followed by allograft

radial head implantation. An alternative salvage procedure is acute shortening of the ulna and creation of a one-bone forearm. This procedure is advocated for by some authors,^{22,23} but others have reported unpredictable results.²⁵

In our case of the radial neck nonunion, the radial head is analogous to the radial head replacement acting as spacer prior to its excision. Though the initial evaluation showed no evidence of interosseous membrane injury, she likely had a sub-clinical injury that did not heal despite the prolonged 5-month period after her original injury before the resection of her radial head. Alternatively, it is possible that the interosseous membrane and other soft-tissues were attenuated and could not stand up to the repetitive stresses they faced after radial head resection. She went on to develop symptomatic proximal migration of the radius after radial head excision, despite documented elbow stability without forearm or wrist pain at the time of radial head resection. It may be that all radial head and neck fractures have some element of an interosseous ligament injury, i.e. in order for these fractures to occur the radius must be loaded and forces are transmitted through the interosseous ligament resulting in some injury. The presence of this type of sub-clinical injury and potential reasons for poor healing or long-term interosseous ligament incompetence is a potential area for further research.

Fortunately, in our case, we had the option of performing a delayed radial head replacement, which resolved the patient's symptoms from ulnar impaction syndrome, without the need for gradual pre-implantation lengthening. We believe this offered our patient a more reliable recovery compared with procedures directed at the ulna, such as an ulnar shortening osteotomy because by replacing her radial head, we treated the cause of her wrist symptoms, which was the proximal migration of her radius, rather than the symptom of ulnar impaction. This relieved her pain despite losing some of the gained ulnar positive variance during the post-operative period and she continues to be functioning very well 3 years after surgery. It should be noted that there is some variability in the measurement of ulnar variance depending on the position of the arm and the quality of the radiographic technique that may contribute to the measured differences in this patient.^{26,27} The present case is novel as it demonstrates a sub-clinical Essex-Lopresti lesion that became apparent after radial head resection for a radial neck nonunion which was successfully treated with delayed radial head replacement.

At this point in time there is an insufficient body of clinical evidence to reliably predict which patients can be managed definitively with radial head excision that will not be compromised by delayed symptomatic proxi-

mal migration of the radius versus those that should be managed with acute radial head arthroplasty. Following experience gained from the present case presentation, the authors plan to adopt a clinical algorithm to proceed with acute radial head arthroplasty when the index injury was secondary to a traumatic mechanism. Radial head excision will be reserved for isolated presentations with radio-capitellar arthritis. Further research of the pathology and healing of concomitant soft-tissue injuries seen in conjunction with radial head fractures is warranted to guide their treatment.

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INCIDENCE, CAUSES AND PREDICTORS OF 30-DAY READMISSION AFTER SHOULDER ARTHROPLASTY

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ABSTRACT

Background: The Center for Medicare and Medicaid Service has identified several quality metrics, including unplanned readmission within 30 days of surgery, to assess and compare surgeons and hospitals. The purpose of this study was to identify the incidence, causes and risk factors for unplanned 30-day readmission after total shoulder arthroplasty.

Methods: We identified patients undergoing primary elective shoulder arthroplasty performed at American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) participating hospitals in 2013. Cases were stratified by readmission status. Univariate and multivariate analyses were employed to assess patient demographics, comorbidities and operative variables predicting unplanned readmission.

Results: 2779 patients undergoing shoulder arthroplasty were identified, with 74 (2.66%) requiring unplanned readmissions within 30 days of surgery. The most common surgical causes for unplanned readmission were surgical site infections (18.6%), dislocations (16.3%) and venous thromboembolism (14.0%). Medical causes for readmission were responsible for 51% of unplanned readmissions. Multivariate analysis identified pa-

tient age >75 (OR 2.62, 95% CI: 1.27 - 5.41), and ASA class of 3 (OR 1.79, 95% CI: 1.01 - 3.18) or 4 (OR 3.63, 95% CI: 1.31 - 10.08) as independent risk factors for unplanned readmission. Predictive modeling estimated that patients with ASA class of 4 and age >75 are 17.4 times more likely (95% CI 1.77-171.09) to be readmitted within 30 days of shoulder arthroplasty.

Conclusions: Unplanned readmission after shoulder arthroplasty is infrequent and medical complications account for more than 50% of occurrences. The risk of readmission exponentially increases when age and preoperative comorbidity burden are increased.

INTRODUCTION

Unplanned hospital readmissions are costly events¹ that have gained increased interest in recent orthopedic literature^{2,3} for good reason. The Readmissions Reduction Program, put forward in the Patient Protection and Affordable Care Act, would withhold payments from healthcare providers and hospitals with excessive unplanned readmission rates⁴. High volume orthopedic procedures in older patients are subject to unplanned readmission. The orthopedic community must perform comprehensive analyses of such procedures in order to understand factors associated with readmission.

Total shoulder arthroplasty (TSA) is a common treatment for glenohumeral arthritis⁵ with increasing surgical volumes in the United States^{6,7}. Previous studies have estimated 14-day readmission rates of 5.6%⁸ and 90 day readmission rates of 5.9%-7.3%^{9,10} following TSA. Medical complications have previously been found to comprise the majority of readmissions in TSA. Surgical site infection (SSI) and management of shoulder dislocation/instability are two of the more commonly cited operative complications necessitating readmission⁹. Increased age⁹, Medicaid insurance status⁹ and arthroplasty technique (hemi or reverse)¹⁰ have been associated with readmission following shoulder arthroplasty.

While descriptive studies^{9,10} exist, there is a paucity of studies in the current literature that comprehensively analyzes the incidence, causes, and risk factors for 30-day readmission following TSA in a large, multi-center cohort. Data on the frequency of and risk factors for

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Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

readmission may aid healthcare systems in assessing and setting benchmarks for quality. Additionally, modifiable risk factors that are recognized prior to surgery may allow surgical teams to optimize patients prior to surgical intervention. Patients who are identified to be at-risk for readmission may also be managed differently with regard to hospital discharge criteria and clinic follow-up practices. The aims of the current study were to identify: (1) the incidence, (2) the most common causes and (3) patient risk factors for unplanned readmission in a group of patients undergoing elective TSA.

METHODS

This study was deemed HIPAA-compliant and institutional review board-exempt. The American College of Surgeons National Surgical Quality Improvement Program (ACS - NSQIP) database is comprised of over 500 academic and private medical institutions from across the United States, which is well established in the orthopedic literature^{2,3,11}. The ACS- NSQIP collects prospective patient and operative data as well as 30-day outcomes. Patient morbidity and mortality data is collected for 30 days post-operatively. Trained surgical clinical reviewers (SCRs) hired by each institution review progress notes, operative notes and data from follow-up visits after surgery. SCRs may contact patients or surgeons in order to clarify any discrepancy in the medical record or find patients who have not presented for follow up within 30 days. SCRs abide by strict ACS NSQIP definitions to classify patient comorbidities and complications.

We surveyed the ACS NSQIP database using the Current Procedural Terminology (CPT) billing code 23472 to identify all cases of TSA performed in 2013. We excluded patients with preoperative wound infection, emergent surgery, preoperative sepsis, and patients with a contaminated surgical wound to create our elective cohort.

Patients who underwent unplanned readmission within 30 days after TSA were identified. Reasons for readmission were then assessed using NSQIP criteria and ICD-9 codes associated with subsequent hospital admissions. We conducted a univariate analysis to compare patients who were readmitted with those who were not. The analysis included assessment of patient demographics including age, gender, race, body mass index, current alcohol abuse, current smoking status, recent weight loss, dyspnea, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), hypertension, diabetes, peripheral vascular disease, esophageal varices, disseminated cancer, steroid use, bleeding disorder, dialysis, chemotherapy in the previous 30 days, radiation therapy in the previous 90 days, operation in the previous 30 days, American Society of Anesthesiologists (ASA) class, operative time, resident involvement, and patient

functional status. Multiple preoperative laboratory values were analyzed including sodium, blood urea nitrogen, albumin, white blood cell count, hematocrit, platelet count, and international normalized ratio. A two-tailed Student's t-test was used for continuous variables and a chi-square test for categorical variables. The univariate analysis identified unadjusted differences between those with an unplanned readmission after TSA compared with those not readmitted. In order to build our multivariate logistic regression model, any univariate variable with a p-value < 0.1 and that had > 80% complete chart data was identified and included. A multivariate logistic regression analysis was conducted in an attempt to control for confounders utilizing SAS (Version 9.3; SAS Institute, Cary, NC, USA). The outcome variable was unplanned hospital readmission following TSA compared with no hospital readmission. Statistical significance was considered as $p < 0.05$. Model quality was evaluated for calibration using the Hosmer-Lemeshow test and for discrimination with C statistics. The calibration test yielded a modified Chi-Square statistic, and a p value > 0.05 indicated that the model was appropriate and fit the data well. Data from the multivariate analysis was used to construct a predictive model for readmission.

RESULTS

2779 patients undergoing TSA in 2013 were identified at ACS NSQIP participating hospitals with 74 (2.66%) requiring unplanned readmission within 30 days of surgery. Of these, 28 patient required return to the operating room (1.01% overall). There were 5 deaths (0.18%) within 30 days of TSA.

Causes of Unplanned Readmission

The most common causes for unplanned readmission were surgical site infection (18.6% of readmissions $n=8$), management of dislocations (16.3% of readmissions, $n=7$), and venous thromboembolism (14.0% of readmissions, $n=6$). Medical causes for readmission (pneumonia/pulmonary, cardiac, renal, gastrointestinal, sepsis, altered mental status, $n=22$) were responsible for 51.16% of unplanned readmissions. Cause of unplanned readmission was not able to be identified in 31 patients using either ICD-9 or ACS NSQIP criteria.

Risk Factors for Unplanned Readmission

Patient variables were compared between patients requiring readmission ($n = 74$) with those not requiring readmission ($n = 2705$) using univariate analysis. Readmitted patients were older (70.3 vs 73.5 years $p=0.010$) and more frequently diagnosed with dyspnea ($p=0.03$) or hypertension ($p=0.01$) prior to surgery. Dependent functional status ($p=0.03$) and ASA class ($p=0.0003$) were also associated with readmission (Table I). Multivariate

Table I. Univariate Analyses of Patient Demographics and Surgical Characteristics[†]

Characteristic	No Readmission (n=2705)	Readmission (n=74)	Unadjusted P Value
Age, mean (standard deviation), yrs	70.32(9.57)	73.49(10.14)	0.0050*
Age (categorical), yrs			0.0114*
<60	12.94	12.16	
60-69	32.31	17.57	
70-75	23.77	22.97	
>75	30.98	47.3	
Gender			0.8009
Male	43.36	41.86	
Female	56.64	58.11	
Race			0.8330
Black	3.77	4.05	
White	85.99	87.84	
Other	10.24	8.11	
BMI (kg/m ²)			0.6319
≤ 35.0	77.37	79.73	
> 35.0	22.63	20.27	
Current Alcohol Abuse	2.57	4.55	0.4508
Current Smoker	9.57	9.46	0.9734
Dyspnea	6.06	12.16	0.0322*
COPD	6.40	9.46	0.2907
CHF	0.41	1.35	0.2771
Hypertension	67.54	82.43	0.0068*
Diabetes	17.38	17.57	0.9656
PVD	0.68	4.55	0.1693
Steroid Use	5.06	4.05	1.0000
Bleeding Disorder	3.40	4.05	0.7397
ASA Class			0.0003*
1 or 2 – No or Mild disturbance	48.93	29.73	
3 - Severe Disturbance	48.48	62.16	
4 - Life Threatening Disturbance	2.59	8.11	
Operative Time, hrs			0.1283
≤ 2	60.13	51.35	
Length of stay, days			0.0671
> 4	3.88	8.11	
≤4 days	96.12	91.89	
Functional Status			0.0263*
Independent	97.42	93.15	
Totally or Partially Dependent	2.58	6.85	

[†]Listed as percentages (%) unless otherwise noted. *Denotes statistical significance (p < 0.05).

analysis identified patient age >75 (OR 2.62, 95% Confidence Interval (CI): 1.27 - 5.41), and elevated ASA class of 3 (OR 1.79, 95% CI: 1.01 - 3.18) or 4 (OR 3.63, 95% CI: 1.31 - 10.08) as independent risk factors for unplanned readmission following TSA.

Predictive Modeling

A predictive model was built from the significant parameters identified by multivariate analysis. Patients with ASA class of 4 and age >75 are 17.40 times more likely (95% CI 1.77-171.09) to be readmitted within 30 days of TSA (Table II).

DISCUSSION

Unplanned readmissions within 30 days of TSA are rare events. We determined the incidence to be less than 3%. Medical causes for readmission account for the majority of readmissions after TSA. The most common surgical causes of readmission are SSI and management of dislocation. We have determined that several patient factors are strongly associated with 30 day readmission including age greater than 75 years and increasing comorbidity burden (as assessed by ASA class). This is the first study to systematically evaluate the incidence, causes and risk factors for readmission after TSA.

Mahoney et al. evaluated readmissions following shoulder arthroplasty between 2005-2011 from a single

Table II. Predictive Model of Combined Patient Age and ASA Class.

Variables	Odds Ratio	95% Confidence Interval
Age 60-69 and ASA 1 or 2	0.80	0.07 – 8.93
Age 60-69 and ASA 3	2.82	0.34 – 23.41
Age 60-69 and ASA 4	5.45	0.32 – 93.65
Age 70-75 and ASA 1 or 2	3.57	0.42 – 30.08
Age 70-75 and ASA 3	4.29	0.53 – 34.43
Age 70-75 and ASA 4	7.08	0.41 – 123.12
Age >75 and ASA 1 or 2	4.34	0.54 – 34.87
Age >75 and ASA 3	5.31	0.69 – 40.68
Age >75 and ASA 4	17.40	1.77 – 171.10

hospital system¹⁰. They determined the 90-day readmission rate to be 5.9%. Schairer et al. analyzed readmissions using independent state databases in 7 states from 2005 to 2010⁹. They determined the 90-day readmission rate to be 7.3%. Fehringer et al. reported a 5.6% fourteen-day readmission rate in their Veteran Health Administration (VHA) system study comparing complications between shoulder and lower extremity arthroplasty.⁸ Anthony et al¹¹, when reporting complications from the ACS NSQIP, determined the 30-day readmission rate to be 4% in 2011. Our reported 2013 readmission rate of 2.66% is one year after the implementation of CMS's Readmissions reductions program. As such, this may be a reflection of changes in practice of surgeons and hospitals aware of the consequences of unplanned readmission. Also, readmission rates at 90 days should intuitively be higher, especially since medical causes of readmission are common.

Causes for readmission in the present study support previous findings. Postoperative infections have been cited as a common cause of readmission following TSA^{9,10}. Mahoney et al. reported that SSIs were responsible for 20% of readmissions¹⁰. This compares favorably with our data as we determined that 18.6% of readmissions in the ACS NSQIP database were for treatment of SSIs. Management of dislocations was the second most common cause of readmission related to surgery in our study. Mahoney et al¹⁰ reported that instability was responsible for 8 of 40 readmissions in their cohort and Schairer et al. determined that dislocation was the second most common cause of readmission related to surgery amongst their patients⁹. Medical causes of readmission were responsible for more than 50% of the readmissions in our study, and this compares favorably with the literature^{9,10}.

No prior study has evaluated risk factors specifically for 30-day readmission following TSA. Two recent reports have evaluated 90-day readmission, but it is unclear if their data is generalizable to the RRP's 30-day readmission window. Medicaid insurance status^{9,12}, increasing age¹² and low shoulder arthroplasty volume hospitals⁹ have been associated with increased rates of readmission. Schairer et al.⁹ determined that age was not a risk factor for readmission after multivariate analysis. We determined that age greater than 75 years and ASA class of 3 or 4 were independent risk factors for readmission following TSA. ASA 4 classification is the strongest predictor of readmission, as these patients are nearly 4 times more likely to be readmitted than their otherwise similar counterparts. When combining these factors, our predictive model would suggest that patients aged >75 years and ASA class of 4 are 17.3 times more likely to undergo unplanned readmissions after TSA.

The present study has several strengths; first, the NSQIP database is robust, multicenter, and representative of general practice with an approximate 50/50 mix of private and academic institutions. It employs strict definitions for each complication, and comprehensive 30-day follow up is standardized and large patient numbers are accumulated over a short period of time. Limitations of our study include follow-up limited to a 30-day window. However, because CMS's Hospital Quality Initiative (HQI) has established 30-day readmission as an important quality metric, this limitation is relative. Cause for readmission was not available in all cases (41%). Preoperative laboratory results were not available in 80% of our patients, and could therefore not be built into our multivariate model. Finally, the CPT code used to identify cases in the ACS-NSQIP database does not differentiate between arthroplasty technique (reverse versus anatomic), so we are unable to comment on differences in readmission based on technique.

In conclusion, unplanned readmission after shoulder arthroplasty is infrequent and may be decreasing in response to increased focus resulting from the threat of a fiscal penalty. Medical complications are responsible for more than 50% of unplanned readmissions. Older patients (>75) with an increasing number of comorbid conditions (ASA 4) are 17 times more likely to undergo unplanned readmission after surgery. Since most patients are readmitted for medical reasons, and comorbidity burden is the strongest predictor of readmission, medical optimization prior to TSA is of utmost importance. Future studies aiming to decrease infection and dislocation rates will positively influence readmissions after TSA.

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PRIMARY RETROGRADE TIBIOTALOCALCANEAL NAILING FOR FRAGILITY ANKLE FRACTURES

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ABSTRACT

Background: Ankle fragility fractures are difficult to treat due to poor bone quality and soft tissues as well as the near ubiquitous presence of comorbidities including diabetes mellitus and peripheral neuropathy. Conventional open reduction and internal fixation in this population has been shown to lead to a significant rate of complications. Given the high rate of complications with contemporary fixation methods, the present study aims to critically evaluate the use of acute hindfoot nailing as a percutaneous fixation technique for high-risk ankle fragility fractures.

Methods: In this study, we retrospectively evaluated 31 patients treated with primary retrograde tibiotalocalcaneal nail without joint preparation for a mean of 13.6 months postoperatively from an urban Level I trauma center during the years 2006-2012.

Results: Overall, there were two superficial infections (6.5%) and three deep infections (9.7%) in the series. There were 28 (90.3%) patients that went on to radiographic union at a mean of 22.2 weeks with maintenance of foot and ankle alignment. There were three cases of asymptomatic screw breakage observed at a mean of 18.3 months postoperatively, which were all treated conservatively.

Conclusions: This study shows that retrograde hindfoot nailing is an acceptable treatment option for treatment of ankle fragility fractures. Hindfoot

nailing allows early weightbearing, limited soft tissue injury, and a relatively low rate of complications, all of which are advantages to conventional open reduction internal fixation techniques. Given these findings, larger prospective randomized trials comparing this treatment with conventional open reduction internal fixation techniques are warranted.

INTRODUCTION

The incidence of low-energy ankle fragility fractures has been increasing rapidly due to the increasing age and activity levels of the elderly population¹. However, patient-related factors and comorbidities pose several management challenges while increasing complication rates. By definition, fragility fractures occur in patients with osteoporotic bone, making traditional open reduction internal fixation techniques difficult in this population². Along with difficult fixation, the soft-tissue envelope in these patients is frequently compromised at the time of injury and poor host factors limit healing potential. The treatment of fragility fractures includes non-operative management as well as conventional and variations of conventional open reduction internal fixation (ORIF) techniques with varying results reported^{1,3,5}.

Use of a transarticular intramedullary Steinmann pin has been previously documented as a treatment option for unstable ankle fractures in the elderly³. We have used a modification of this technique, with the use of a retrograde intramedullary tibiotalocalcaneal (TTC) nail in this series of patients with fragility fractures³. Despite iatrogenically limiting motion of the tibiotalar and subtalar joints, we hypothesize that treatment with this biomechanically sound device allows early mobilization and return to function with adequate union and minimal wound complications

The goal of the present study is to retrospectively evaluate the use of the retrograde TTC nail in the setting of ankle fragility fractures both clinically and radiographically. We hypothesize that primary fixation with a TTC nail is a safe surgical option that not only leads to satisfactory fracture alignment and union, but also decreases the overall perioperative complication rate in this high-risk cohort.

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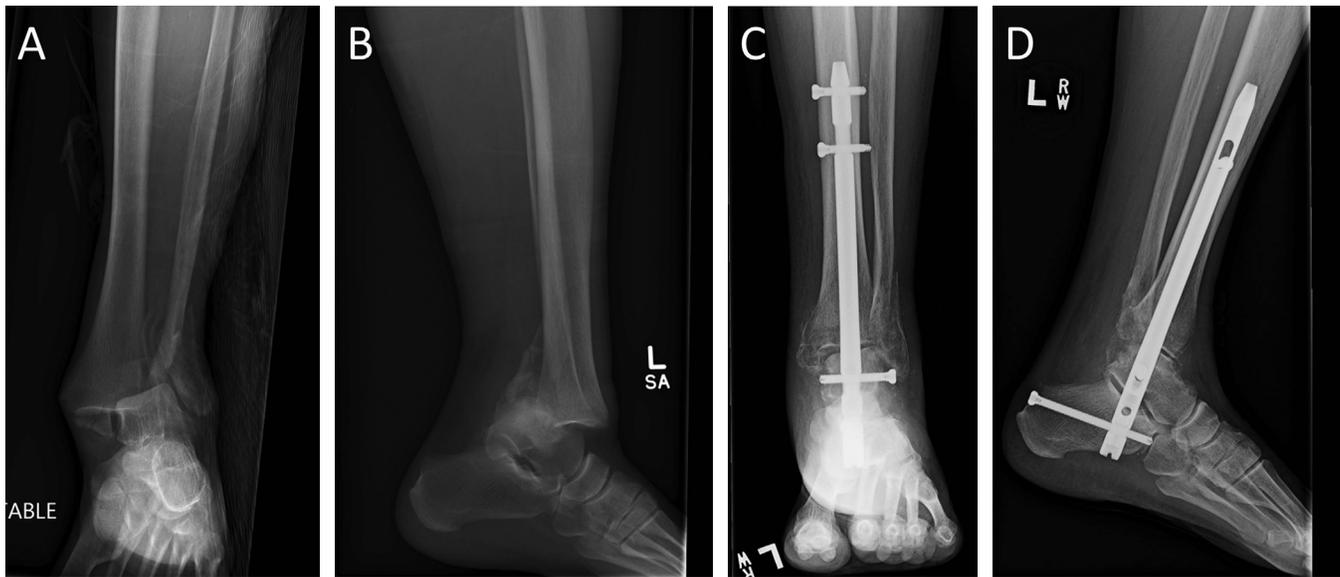


Figure 1. A trimalleolar ankle fracture-dislocation in an osteoporotic, poorly controlled diabetic patient is shown in A and B. Successful union is noted in Images C and D at three-month follow up after immediate postoperative mobilization and weightbearing.

MATERIALS AND METHODS

Data Collection

We retrospectively reviewed the database of a single urban, Level I trauma center for all ankle and pilon fractures treated from January 2006-December 2012. We included all patients over 18 years of age treated with retrograde TTC nail for primary treatment of any hindfoot or ankle injury, without formal arthrodesis of the tibiotalar or subtalar joints. After initial review, we identified 38 patients that met inclusion criteria. Four patients were excluded for follow up less than one year, while another patient passed away 10 days following surgery due to complications related to a polytrauma. Two patients were also excluded as they were treated for high-energy, non-reconstructible hindfoot fractures. This left 31 patients available for analysis.

Patient Demographics

Through retrospective chart and radiograph review, we evaluated this cohort for demographic data, type and severity of injury, comorbidities, employment status, ambulatory status, and operative details. We included both rotational ankle fractures and pilon fractures, but all were the result of low-energy mechanisms.

Operative Technique

All patients were primarily treated with retrograde TTC nail without joint preparation as primary and definitive fixation for their injuries. The ankle fractures were all reduced in a closed fashion and provisional retrograde pinning from the calcaneus to the tibia was performed in all cases. Pin placement was either anterior or posterior

to the tract of the definitive nail, to ensure no difficulties with tract preparation or nail insertion occurred. A starting guidewire was advanced in a retrograde fashion from the calcaneus into the talus and subsequently the tibia. The opening reamer was then advanced over this wire to the distal tibial physal scar. The wire and opening reamer were then removed and a ball-tipped guide wire was placed into the tract; this was advanced to the mid-diaphyseal level of the tibia. Minimal reaming was then performed, as most of the patient's canal diameters were large enough for easy passage of nails of 9 millimeters or more. However, reaming to 1 millimeter greater than the eventual nail size was executed in efforts to minimize risk of nail incarceration. All but two patients were treated with the Phoenix ankle arthrodesis nail (Biomet, Warsaw, IN), while the remaining two were treated with a short Synthes retrograde supracondylar femoral nail (Synthes, West Chester, PA); both of these nails are straight nails without any valgus bend. In all cases, two interlocking screws were placed proximally in the tibia, and at least one interlocking screw was placed through both the talus and calcaneus. No tourniquets were utilized during these procedures (Figure 1). Postoperatively, patients were allowed partial or full weightbearing according to surgeon preference, with all patients progressing to unrestricted ambulation as tolerated by six weeks after surgery.

Outcomes

The primary outcome of our study was union rate, with infection and implant-related complications being two other primary variables of interest. Superficial in-

Table I. Patient Characteristics

Variable	Results
Age (years)	63.0 ± 16.7 (37-90)
Sex (female)	17 (54.8%)
Body Mass Index (kg/m ²)	35.6 ± 10.8 (21.3-65.5)
Mechanism	Fall 77.4%, Motor Vehicle Collision 18.8%, Gunshot 3.2%
Fracture Pattern	
OTA 43A1	1
OTA 43B3	2
OTA 43C1	1
OTA 43C2	3
OTA 43C3	3
OTA 44A2	1
OTA 44B1	1
OTA 44B2	6
OTA 44B3	12
OTA 44C2	1
Open Injury	8 (25.8%)
Diabetes Mellitus	54.8%
Hgb A1C (%)	7.6 ± 1.9 (5.5-13.0)
Peripheral Neuropathy	16 (51.6%)
Paraplegia	1 (3.2%)
Tobacco Use	7 (22.6%)
Employment	5 (16.1%)
Ambulatory Status	
Unassisted	21 (67.7%)
Cane	1 (3.2%)
Walker	8 (25.8%)
Wheelchair	1 (3.2%)
Operative Variables	
Time to fixation (days)	2.4 ± 2.7 (0.1 - 10)
Operative Room Time (minutes)	76.7 ± 24.3 (43 - 140)
Estimated Blood Loss (mL)	65.6 ± 67.9 (5-250)
Hospital Length of Stay (days)	7.6 ± 4.4 (1-16)

fection was defined as anything requiring local wound care or antibiotics, while deep infection was defined as the need to return to the operating room for formal debridement.

Statistics

Mean, range and confidence intervals were calculated for continuous variables and compared using Student's t-tests. Frequencies were calculated for continuous variables and compared using Fisher's exact test for increased accuracy in small proportion analysis. A significance level of P < 0.05 was set as significant, with a trend being defined as a P value being between 0.05 and 0.10.

RESULTS

Table I shows demographic data on the patients included in our review. Only approximately 2/3 of the series were unassisted community ambulators (67.6%) prior to their injury, with over half of the series carrying

Table II. Patient Outcomes

Variable	Outcome
Follow-up Length (days)	407.89 ± 219.03
Bony Union	90.3%
Time to Union (weeks)	22.2 ± 6.2
Implant Failure	3 (9.7%)
Infection	
Superficial	2 (6.5%)
Deep	3 (9.7%)
Wound Dehiscence	0 (0%)
Amputation	1 (3.2%)

a diagnosis of diabetes or peripheral neuropathy (54.8% and 51.6, respectively). Eight patients (25.8%) sustained open injuries. No patient underwent any concurrent procedures, and there were no intensive care unit admissions postoperatively.

Average length of follow-up was 407.9 days in our series (Table II). There were two superficial and three deep infections in this cohort. All of the patients developing deep infections sustained open ankle fractures. These three patients subsequently underwent operative debridement, nail removal and antibiotic-impregnated cement rod placement. At most recent follow-up, there had been no recurrence of infection using this treatment algorithm. For the entire cohort, union was observed in 90.3% of patients at an average of 22.2 weeks postoperatively. There were three instances of broken proximal interlocking screws at average follow-up of 18.3 months postoperatively; however, all hardware failures remained asymptomatic at final follow-up.

DISCUSSION

Treatment of ankle and hindfoot fragility fractures by conventional means poses several challenges. There are numerous studies showing significantly worse outcomes in elderly patients treated with ORIF of ankle fractures when compared to younger cohorts⁶⁻⁸. Studies have shown several predictive risk factors for poor outcome with conventional ORIF of ankle fractures, including open injuries, diabetes mellitus, peripheral neuropathy, and peripheral vascular disease^{4,5,9-14}. Wukich and Kline found that diabetic patients with concomitant peripheral vascular disease and neuropathy are at an even greater risk¹⁵. Additionally, elderly patients who are forced to remain immobile after these injuries are at a much higher risk of developing perioperative complications, including pressure ulcers, pneumonia and deep vein thrombosis¹. In the present study, we describe the use of a TTC nail for treatment of ankle fragility fractures and found a low rate of overall complications.

Union rate of fragility ankle fractures is an increasing concern, and we were able to obtain an ankle fracture union rate of 90.3% with the current series. We feel that this is important, as a decreased union rate and increased complication rate in this population has been associated with decreased quality of life and self-reported functional outcomes at one year post-injury¹. Infection rates in this patient population are also increased, with patients greater than 80 years of age undergoing operative fixation of an unstable ankle fracture sustaining a 7% superficial infection rate and 4.6% deep infection rate, while only 86% of patients returned to pre-injury mobility^{5,6}.

Our study shows retrograde TTC nail can be a very useful treatment option in this difficult population. Some advantages of this procedure, as compared to traditional open reduction and fixation are: operative time and blood loss are decreased, soft-tissue dissection is kept to a minimum, and patients are allowed to mobilize and bear full weight earlier. We were able to show that primary hindfoot nailing is successful in treating fragility ankle fractures, especially in the setting of diabetes and peripheral neuropathy. There was a risk of deep infection as a complication in this group, but these were all in the setting of an open fracture, and we hypothesize that these infections were the result of the open injury as well as patient comorbidities. However, the majority of patients went on to radiographic union with minimal complications.

There are several limitations with this study. It is a non-randomized retrospective cohort study from a single institution. As such, we provide a description of our experience with the use of TTC in ankle fragility fractures. As there was no control group, comparisons are limited to those values that have been previously reported in the literature. The number of patients included in the study is small. However, as this is a relatively novel technique description, we feel that reporting our early outcomes is important. Further inclusion of functional outcome scores and prospective comparisons to a matched cohort with traditional fixation constructs would also be helpful to provide data to the practicing surgeon.

In conclusion, we found that retrograde TTC nail is a safe and effective treatment option for ankle fragility fractures. The use of retrograde TTC in this population provides the advantages of early mobilization, limited soft tissue injury, and relatively few complications as compared to previous studies evaluating the use of conventional ORIF in similar cohorts. Given these promising findings, future research comparing retrograde TTC and conventional ORIF using prospective methods and randomization should be considered.

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OPEN VERSUS ARTHROSCOPIC BICEPS TENODESIS: A COMPARISON OF FUNCTIONAL OUTCOMES

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ABSTRACT

Background: The proximal aspect of the long head of the biceps brachii (LHB) is a frequent source of anterior shoulder pain. Multiple techniques for LHB tenodesis have been described. However, comparative outcomes are lacking. The present study aims to compare functional results, patient reported outcomes, complications, and clinical failures for patients undergoing open versus arthroscopic LHB tenodesis.

Methods: All patients who underwent open or arthroscopic LHB tenodesis from 2009-2012 at a single institution were identified. Patient demographics, comorbidities, and operative variables of interest, including concomitant procedures, were recorded. Minimum 1-year follow-up was required for inclusion. Outcomes, including patient reported outcomes, physical exam findings, and complications were compared between open and arthroscopic LHB tenodesis patients.

Results: Overall, 45 patients (25 open, 20 arthroscopic) were available for analysis. In total, there was a single clinical failure in a patient who underwent arthroscopic LHB tenodesis. No other complications or failures were noted. Active shoulder forward elevation was increased in the open tenodesis group as compared to the arthroscopic

tenodesis group ($177.8 \pm 9.3^\circ$ vs. $171.3 \pm 11.7^\circ$; $p = 0.049$). Otherwise, there was no difference in range of motion or strength. For both groups, both the SF-36 and ASES scores improved significantly from preoperative values.

Conclusion: Both open and arthroscopic LHB tenodesis provide good to excellent outcomes with few complications. Given the recent increased utilization of LHB tenodesis, future studies should use randomization and prospective data collection in order to determine if discrete patient populations are better served by either open or arthroscopic LHB tenodesis techniques.

INTRODUCTION

The proximal aspect of the long head of the biceps brachii (LHB) is a common source of anterior shoulder pain. With failure of conservative treatment options, proximal LHB tenodesis has been described as a viable surgical treatment option for a variety of LHB pathologies, including LHB tendonitis, tendinopathy, instability, and superior labrum anterior-posterior lesions (SLAP)¹⁻³. While previous studies have failed to provide a definitive advantage for LHB tenodesis compared with tenotomy⁴⁻⁸, tenodesis provides the reported advantage of improved strength and decreased cramping pain through maintenance of the LHB length-tension relationship as well as more consistent cosmetic results⁹. Clinically, many patients under the age of 40 prefer tenodesis to tenotomy due to the more consistent cosmetic results and concerns with weakness and cramping associated with tenotomy in this young, active population.

Multiple techniques for LHB tenodesis have been described¹⁰⁻¹⁵. Technical considerations include open versus arthroscopic approach, fixation technique, and tenodesis location, which are generally described as suprapectoral or subpectoral. In some cases, the approach utilized for LHB tenodesis may be dictated by concomitant pathology, including rotator cuff or labral pathology, but this is ultimately at the discretion of the treating surgeon. While comparative studies are limited to Level III and IV evidence¹⁶⁻¹⁹, satisfactory results have consistently been reported regardless of approach and fixation technique²⁰⁻²². However, there is limited evidence to suggest that LHB tenodesis location, specifically with-

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in the bicipital groove, may result in inferior outcomes as compared to a more distal tenodesis location^{18,23}.

Few studies have previously compared outcomes following arthroscopic and open LHB tenodesis techniques¹⁶⁻¹⁸. Given the increasing incidence of biceps tenodesis^{24,25}, particularly arthroscopic biceps tenodesis, further study is warranted. The goal of the present study was to compare function, patient reported outcomes, complications, and clinical failures following arthroscopic and open LHB tenodesis.

METHODS

Institutional Review Board Approval

This study received approval from the University of Iowa Institutional Review Board.

Data Collection

All patients undergoing LHB tenodesis from January 1, 2009 to December 31, 2012 at a single institution were identified using Common Procedural Terminology (CPT) codes 23430 (tenodesis of long tendon of biceps) and 29828 (arthroscopy, shoulder, surgical; biceps tenodesis). A total of 93 patients were identified. In all cases, operative reports were reviewed to confirm that tenodesis was performed and to determine surgical technique (open versus arthroscopic). Study inclusion criteria included patient age \geq 18 years, proximal biceps tendon pathology including biceps tendonitis, tendinopathy, instability, or SLAP tears, diagnosed preoperatively with physical exam and/or imaging and confirmed during diagnostic arthroscopy, and minimum 1-year follow-up with a documented physical exam at the time of follow-up. Exclusion criteria included absence of a documented physical exam despite $>$ 1-year follow-up or follow-up $<$ 1 year. Using these criteria, a total of 45 patients (25 open, 20 arthroscopic) were identified for analysis from the original 93 patients who underwent arthroscopic or open LHB tenodesis during the time period of the study (48.4% inclusion). All procedures were performed by one of two fellowship-trained sports medicine surgeons.

Patient demographics, comorbidities, and operative variables of interest were recorded. Patient demographic characteristics included age at the time of surgery, sex, race, surgery on the dominant arm, and history of prior ipsilateral shoulder surgery. All relevant comorbidities required to calculate the Age-Adjusted Charlson Comorbidity index (AACI)^{26,27} were obtained. Additionally, the American Society of Anesthesiologists (ASA) classification and smoking status, which was further categorized as “non-smoker” for patients with no smoking history, “former smoker” for patients with a history of smoking but did not smoke within four weeks of surgery, and “current smoker” for patients

with a history of smoking within four weeks of surgery were documented. Operative variables of interest included open versus arthroscopic approach, concomitant procedures at the time of LHB tenodesis, including rotator cuff repair, labral repair, cartilage procedures, subacromial decompression, and distal clavicle resection, and method of fixation, including interference screw or suture anchor fixation.

Surgical Technique

Open subpectoral LHB tenodesis is typically performed following completion of any concomitant procedures. With pathology identified at the time of diagnostic arthroscopy, a biceps tenotomy is performed at the biceps-labral junction with an arthroscopic scissors or basket. A 3-4 cm incision is then made in the axilla centered over the inferior border of the pectoralis major tendon. The inferior border of the pectoralis major tendon is then bluntly retracted superiorly and the arm internally rotated to allow palpation of the bicipital groove and biceps tendon. The biceps tendon is then delivered from the wound and a #2 braided suture placed in a locked fashion 15-20 mm proximal to the myotendinous junction and excess proximal tendon excised. An 8 mm unicortical bone tunnel is then drilled just distal to the inferior border of the pectoralis major tendon insertion and an 8 mm bioabsorbable interference screw placed while attached to the tendon until the screw sits flat along the anterior cortical surface of the humerus. The tag ends of the locked suture are then tied and cut to complete the procedure.

Arthroscopic suprapectoral LHB tenodesis procedures were performed using the technique described by Romeo et al²⁸. Briefly, the biceps tendon is tagged using #2 braided suture placed through the tendon after diagnostic arthroscopy. With the suture in place, a biceps tenotomy is performed at the level of the biceps-labral junction. Posterolateral and anterolateral portals were then established, and depending on concomitant pathology, a limited subacromial bursectomy was performed to visualize the transverse ligaments overlying the biceps tendon within the bicipital groove. The bicipital groove and biceps tendon are then exposed using electrocautery. The tagged biceps tendon is then pulled out the anterolateral portal and the transverse ligaments overlying the biceps tendon is further released while pulling gentle traction on the tendon. Approximately 15-20 mm of the most proximal aspect of the tendon is excised and a locking #2 braided suture placed. A guidewire is then placed in the bicipital groove and unicortical bone tunnel drilled over the guidewire. The tendon is then fixed into the proximal humerus with a 7.0 or 8.0 mm bioabsorbable tenodesis screw.

Outcomes

Outcome measures of interest were broadly categorized into patient reported outcome measures, including general health and general shoulder measures, physical exam findings, and complications. The short form-36 (SF-36) physical component score (PCS) and mental component score (MCS) provided assessment of general health-related quality of life^{28,29}. General shoulder measures included the American Shoulder and Elbow Surgeons (ASES) score³⁰, the Disabilities of the Arm, Shoulder, and Hand (DASH) score³¹, the Single Assessment Numeric Evaluation (SANE)³², the Simple Shoulder Test (SST)³³, and the Constant-Murley score (CMS)³⁴. Additionally, during the postoperative assessment, all patients were asked “would you suggest your surgery to friends or family in the future?” warranting a simple “yes” or “no” response. Questionnaires were completed by all patients at their minimum 1-year follow-up. However, due to changes in data collection methods at the institution during the course of the study, not all measures were collected or available preoperatively.

Physical examination included an assessment of shoulder range of motion, strength, and special shoulder and biceps tests. All range of motion measurements were made on both the operative and contralateral extremity. Active shoulder forward elevation and abduction were measured with a goniometer in degrees. Active shoulder internal and external rotation were graded according to the criteria established by Constant and Murley for use with the CMS³⁴. Using these criteria for internal and external rotation, any decrease in motion between the operative and contralateral extremity was considered an internal rotation or external rotation deficit, respectively. Strength assessment included evaluation of elbow flexion and shoulder abduction strength using the MicroFet2 handheld dynamometer (Hoggan Scientific, L.L.C., Salt Lake City, UT, USA). Forearm supination strength was similarly measured using a Cybex dynamometer (Cybex International, Medway, MA, USA). All strength measurements were made in pounds (lbs) on both the operative and contralateral arm. Special tests and observations relevant to biceps pathology were also performed. All patients were observed for presence of a “Popeye” deformity, indicating failure of proximal fixation. Bicipital groove tenderness was assessed by palpation of the bicipital groove through the subpectoral triangle, as described by Mazzocca et al.²¹. The Speed’s test³⁵ and Yergason supination test³⁶ were also performed as previously described. The presence of pain with palpation of the bicipital groove, Speed’s test, or Yergason supination test was considered positive and dichotomously coded as “yes” or “no”. The biceps apex distance was measured on both arms and the difference between the two values

referred to as the biceps apex difference. The method of measurement was modified from the original description by Mazzocca et al.²¹, using the medial epicondyle as a reference point for measurement as this was found to be a more consistently reliable landmark than the inferior border of the pectoralis major tendon. Additionally, the biceps circumference at the apex of the biceps was measured on both arms and the difference between the two values referred to as the biceps circumference difference. All assessments were made at minimum 1-year follow-up by a single member of the research team to maintain consistent measurement technique.

Evaluated complications included wound infections requiring either antibiotic treatment or return to the operating room for irrigation and debridement, reoperation within the follow-up period, and loss of proximal fixation. The primary outcome of interest was clinical failure, defined as loss of proximal fixation with presence of the “Popeye” deformity at minimum 1-year follow-up.

Statistical Analysis

Comparison of outcomes between the arthroscopic and open tenodesis groups were performed using Student’s t-test and chi-square or Fisher’s exact test for continuous and categorical variables, respectively. Similarly, preoperative and postoperative outcomes were compared when there was >60% chart completion of both preoperative and postoperative measures. Several continuous variables were also categorically defined and reported to allow further comparison between arthroscopic and open tenodesis groups as well as preoperative and postoperative measures. All statistical analysis was performed with SPSS Statistics (IBM Corp., Armonk, NY, USA). A *p*-value of >0.05 was considered statistically significant.

RESULTS

Overall, there were 45/95 patients available for analysis (48.4%) between 2009 and 2012 that underwent proximal LHB tenodesis with mean follow-up of 3.2 ± 1.1 years. Of these, 25 (55.6%) underwent open tenodesis and 20 (44.4%) underwent arthroscopic tenodesis procedures. The was 43.8 ± 12.5 years, and the majority of patients were male (82.2%). Patients undergoing arthroscopic tenodesis were significantly older than those undergoing open tenodesis (49.9 ± 11.8 years vs. 38.9 ± 11.0 years; *p* = 0.003) (Table I). Concomitant procedures were performed in 41/45 (91.1%) of patients. Rotator cuff repair was the most commonly performed concomitant procedure (66.7%), and was performed more frequently in patients undergoing arthroscopic tenodesis as compared to open tenodesis (85.0% vs. 52.0%; *p* = 0.027). There were no other significant differences in demographic characteristics, comorbidities, and operative variables between the two cohorts.

Table I. Demographic Characteristics, Comorbidities, and Operative Variables of Open and Arthroscopic Biceps Tenodesis Patients

	All (n=45)	Open (n=25)	Arthroscopic (n=20)	<i>p</i> value*
<i>Demographic Characteristics</i>				
Age [†]	43.8 ± 12.5	38.9 ± 11.0	49.9 ± 11.8	0.003
Sex (%)				0.435
Male	82.2	88.0	75.0	
Female	17.8	12.0	25.0	
Race (%)				0.332
White	88.9	88.0	90.0	
Black	4.4	8.0	0.0	
Other	6.7	2.2	4.4	
Dominant Arm (%)	66.7	76.0	55.0	0.205
Prior ipsilateral shoulder surgery (%)	13.3	12.0	15.0	1.000
Follow-up (yrs) [†]	3.2 ± 1.1	3.1 ± 0.9	3.4 ± 1.3	0.428
<i>Comorbidities</i>				
Charlson Comorbidity Index [†]	0.9 ± 1.7	0.6 ± 1.8	1.2 ± 0.5	0.274
ASA [†]	1.7 ± 0.6	1.6 ± 0.5	1.8 ± 0.6	0.395
Smoking Status (%)				0.879
Nonsmoker	64.4	65.0	64.0	
Former smoker	17.8	20.0	16.0	
Current smoker	17.8	15.0	20.0	
<i>Operative Variables</i>				
Fixation (%)				1.000
Screw	88.9	88.0	90.0	
Suture Anchor	11.1	12.0	10.0	
Concomitant Procedures (%)				
Rotator Cuff Repair	66.7	52.0	85.0	0.027
Rotator Cuff Debridement	4.4	8.0	0.0	0.495
Labral Repair	8.9	16.0	0.0	0.117
Cartilage Procedure	2.2	4.0	0.0	1.000
Subacromial Decompression	80.0	72.0	90.0	0.260
Distal Clavicle Resection	11.1	8.0	15.0	0.642

*Open versus arthroscopic comparison. [†]Listed as mean ± standard deviation.

In total, there was a single clinical failure identified at 9 weeks postoperatively in a patient who underwent arthroscopic tenodesis with interference screw fixation, leading to an overall failure rate of 2.2%. There was no significant difference in clinical failures between the arthroscopic and open tenodesis cohorts (5.0% vs. 0.0%, *p* = 0.444). The single clinical failure was the only identified complication, as there were no wound infections or reoperations reported during the follow-up period.

Active shoulder forward elevation was significantly decreased in the arthroscopic tenodesis group as compared with the open tenodesis group (171.3 ± 11.7° vs. 177.8 ± 9.3°; *p* = 0.049) (Table II). Otherwise, there were no differences in active range of motion between

the two groups. Similarly, there were no differences in elbow flexion, shoulder abduction, or forearm supination strength between the two groups. Average biceps apex difference for the entire cohort was 0.6 ± 0.8 cm and was equivalent for open and arthroscopic groups (0.5 ± 0.5 cm vs. 0.9 ± 1.0 cm; *p* = 0.112). The percentage of patients who had a biceps apex difference of 0, or equal to the contralateral arm, was 44.0% and 30.0% for the open and arthroscopic tenodesis groups, respectively (*p* = 0.336). Persistent bicipital groove tenderness was noted in 15.6% of patients after LHB tenodesis, with no significant difference in the frequency of bicipital groove tenderness between the open and arthroscopic tenodesis groups (20.0% vs. 10.0%, *p* = 0.437).

Table II. Outcomes Following Open and Arthroscopic Biceps Tenodesis*

	All (n=45)	Open (n=25)	Arthroscopic (n=20)	p value [‡]
<i>Patient Reported Outcome Measures</i>				
SF-36 PCS	46.4 ± 11.5	48.2 ± 10.0	44.1 ± 13.0	0.272
SF-36 MCS	52.4 ± 9.3	53.0 ± 7.4	51.7 ± 11.4	0.675
ASES	81.1 ± 21.1	82.3 ± 20.4	79.6 ± 22.3	0.681
DASH	12.3 ± 14.4	11.3 ± 14.5	13.7 ± 14.8	0.649
SANE	88.9 ± 16.9	88.9 ± 18.0	88.8 ± 16.1	0.981
SST	10.9 ± 1.9	10.8 ± 2.2	11.1 ± 1.4	0.701
Constant-Murley Score	87.4 ± 16.3	88.0 ± 19.7	86.7 ± 11.1	0.774
Would recommend surgery again (%)	97.8	96.0	100.0	1.000
<i>Physical Exam Findings</i>				
Bicipital groove tenderness (%)	15.6	20.0	10.0	0.437
Positive Speed's test (%)	2.2	4.0	0.0	1.000
Positive Yergason's test (%)	4.4	4.0	5.0	1.000
Biceps apex difference (cm) [†]	0.6 ± 0.8	0.5 ± 0.5	0.9 ± 1.0	0.112
Biceps circumference difference (cm) [†]	-0.2 ± 1.3	-0.1 ± 1.2	-0.3 ± 1.4	0.609
<i>Strength (lbs)[†]</i>				
Elbow Flexion	-1.7 ± 8.9	-0.4 ± 7.4	-3.3 ± 10.6	0.307
Forearm Supination	-0.4 ± 2.3	-0.2 ± 1.5	-0.6 ± 2.9	0.654
Shoulder Abduction	-2.5 ± 5.1	-3.8 ± 5.3	-1.0 ± 4.6	0.057
<i>Range of motion</i>				
Shoulder forward elevation (degrees)	174.9 ± 10.7	177.8 ± 9.3	171.3 ± 11.7	0.049
Shoulder abduction (degrees)	174.9 ± 10.5	177.4 ± 9.3	171.8 ± 11.4	0.081
Internal rotation deficit [†]	6.7	4	10	0.577
External rotation deficit [†]	2.2	0	5	0.444
<i>Complications (%)</i>				
Wound Infection	0.0	0.0	0.0	1.000
Reoperation	0.0	0.0	0.0	1.000
Loss of proximal fixation	2.2	0.0	5.0	0.444

*Listed as mean ± standard deviation except where noted.[†]Compared to contralateral arm.[‡]Open versus arthroscopic comparison.

Table III. Pre- and Postoperative Outcome Measures Following Biceps Tenodesis

<i>Outcome Measure</i>	<i>Percent Available (%)</i>	<i>Preoperative</i>	<i>Postoperative</i>	<i>Difference</i>	<i>p value</i>
SF-36 PCS	77.8	41.6 ± 8.3	46.2 ± 11.2	4.6 ± 8.7	0.004
SF-36 MCS	77.8	51.6 ± 9.4	52.8 ± 9.7	1.3 ± 8.3	0.379
ASES	64.4	14.7 ± 6.3	81.6 ± 20.8	66.9 ± 19.6	<0.001

When comparing postoperative patient reported outcome measures, there were no significant differences between the groups. Only a single patient who underwent open tenodesis stated that they would not recommend surgery again. Due to changes in institutional data collection methods during the time period of the study, adequate chart completion for comparison of preoperative and postoperative outcomes was only available for SF-36 and ASES measures, which had 77.8% and 66.4% chart completion, respectively. For the entire cohort, both SF-36 PCS (41.6 ± 8.3 vs. 46.2 ± 11.2; *p* = 0.004) and ASES (14.7 ± 6.3 vs. 81.6 ± 20.8; *p* < 0.001) scores improved significantly compared to preoperative

values (Table III). Using established minimal clinically important differences (MCID) for the ASES score³⁷, all patients showed improvement postoperatively, regardless of open or arthroscopic surgical technique. While the MCID for the SF-36 PCS has been established previously for other joints³⁸⁻⁴⁰, it has not been established for the shoulder. Using a conservative MCID of 10 points for the SF-36 PCS, 25.7% of patients improved postoperatively, with equivalent results for open and arthroscopic tenodesis (26.3% vs. 25.0%; *p* = 1.000). Further stratification of patients by those who did and did not undergo concomitant rotator cuff repair revealed no significant difference in any outcome measure (Table IV).

Table IV. Patient Characteristics and Outcomes following Biceps Tenodesis with and without Rotator Cuff Repair*

	No Rotator Cuff Repair (n=15)	Rotator Cuff Repair (n=30)	p value
<i>Patient Reported Outcome Measures</i>			
SF-36 PCS	46.6 ± 12.3	46.2 ± 11.2	0.935
SF-36 MCS	52.0 ± 6.8	52.6 ± 10.6	0.843
ASES	77.4 ± 25.1	83.1 ± 18.6	0.455
DASH	19.2 ± 18.7	8.8 ± 10.7	0.112
SANE	85.7 ± 22.3	90.4 ± 13.7	0.463
SST	10.6 ± 2.6	11.1 ± 1.4	0.500
Constant-Murley Score	88.8 ± 14.8	86.7 ± 17.2	0.674
Would recommend surgery again (%)	93.3	100.0	0.333
<i>Physical Exam Findings</i>			
Popeye deformity (%)	6.7	0.0	0.333
Bicipital groove tenderness (%)	20.0	13.3	0.670
Positive Speed's test (%)	6.7	0.0	0.333
Positive Yergason's test (%)	13.3	0.0	0.106
Biceps apex difference (cm) [†]	0.9 ± 0.9	0.5 ± 0.7	0.178
Biceps circumference difference (cm) [†]	-0.3 ± 1.0	-0.2 ± 1.4	0.819
<i>Strength (lbs)[†]</i>			
Elbow Flexion	-4.4 ± 9.5	-0.3 ± 8.5	0.169
Forearm Supination	0.3 ± 2.0	-0.7 ± 2.3	0.146
Shoulder Abduction	-2.0 ± 5.1	-2.8 ± 5.2	0.597
<i>Range of motion</i>			
Shoulder forward elevation (degrees)	175.0 ± 12.4	174.8 ± 10.0	0.957
Shoulder abduction (degrees)	175.0 ± 12.4	174.8 ± 9.7	0.964
Internal rotation deficit [†]	6.7	6.7	1.000
External rotation deficit [†]	0.0	3.3	1.000
<i>Complications (%)</i>			
Wound Infection	0.0	0.0	1.000
Reoperation	0.0	0.0	1.000
Loss of proximal fixation	6.7	0.0	0.333

*Listed as mean ± standard deviation except where noted.†Compared to contralateral arm.

DISCUSSION

Proximal LHB pathology is a common source of anterior shoulder pain. LHB tenodesis has been shown to be an effective procedure for management of anterior shoulder pain associated with biceps tendinitis, tendinopathy, and SLAP tears, with increasing utilization within the last decade^{24,25}. While LHB tenodesis is a common procedure with consistent outcomes^{20,21}, multiple technique variations, including open and arthroscopic approaches, have been described with few comparative clinical studies¹⁶⁻¹⁸. The present study compared open and arthroscopic LHB tenodesis procedures with similar clinical results and only a single clinical failure at mean 3.2 year follow-up. These findings suggest that both arthroscopic and open tenodesis provide a safe and effective method for treatment of anterior shoulder pain related to proximal biceps tendon pathology. Several of these findings warrant further discussion.

The primary outcome of the present study was clinical failure, defined as loss of proximal fixation with development of the so-called “Popeye” deformity. We identified a single clinical failure in a patient who underwent arthroscopic biceps tenodesis. Despite the cosmetic deformity, the patient was asymptomatic and would recommend the surgery again. Additionally, no other significant complications were noted following either open or arthroscopic biceps tenodesis. In a comparison of open versus arthroscopic biceps tenodesis, Werner and colleagues noted no tenodesis failures and rare complications¹⁶. Similarly, Mazzocca and colleagues identified only a single clinical failure in their open tenodesis case series with minimum 1-year follow-up²¹. In a systematic review that included nearly 500 patients undergoing arthroscopic or open tenodesis, only 3 failures of fixation were noted following arthroscopic tenodesis and 2 failures following open tenodesis¹⁹. In concordance with

our findings, clinical failures and complications following LHB tenodesis are rare^{19,41}. In the appropriately indicated patient who has failed conservative management, LHB tenodesis remains a safe and effective treatment option for proximal LHB pathology.

Additionally, subjective and objective outcomes following open and arthroscopic tenodesis were evaluated. When comparing the two cohorts, we found no difference in patient reported outcomes, biceps apex difference, bicipital groove tenderness, or strength at minimum 1-year follow-up. Similar to previous studies, we noted a significant improvement in patient reported outcomes postoperatively as compared to preoperative values²¹. Additionally, the postoperative ASES scores following open and arthroscopic tenodesis studies in the present study compare favorably with previous reports, suggesting a good or excellent clinical outcome^{16,19}. With respect to range of motion, patients undergoing arthroscopic tenodesis had decreased shoulder forward elevation compared to patients who underwent open tenodesis. All other range of motion parameters were equivalent. It should be noted that patients undergoing arthroscopic biceps tenodesis were significantly older than those who underwent open tenodesis procedures and were also more likely to have undergone concomitant rotator cuff repair, which may provide an explanation for this finding. However, stratified analysis based on the presence or absence of concomitant rotator cuff repair failed to similarly identify a difference in range of motion between the two cohorts. In a comparative study of open and arthroscopic biceps tenodesis, Werner and colleagues noted an increased incidence of postoperative stiffness following arthroscopic tenodesis¹⁸. While acknowledging that prior research on this subject is limited, the authors speculated that extensive bursectomy, excessive fluid extravasation, and more proximal tenodesis location following arthroscopic tenodesis may contribute to this finding. Given that the use of open or arthroscopic technique is largely based on individual surgeon preference in addition to the fact that biceps tenodesis in the present study, as well as previous studies, is frequently performed in conjunction with other procedures^{16,21}, a well-designed, randomized, prospective study may improve interpretation of these results by eliminating several sources of bias.

As previously mentioned, a stratified analysis of patients who did and did not undergo concomitant rotator cuff repair at the time of LHB tenodesis was performed based on previous findings which suggested patients undergoing concomitant rotator cuff repair have lower

patient reported outcomes²¹. Interestingly, we did not find that concomitant rotator cuff repair significantly affected postoperative patient reported outcomes. Additionally, we found no difference in strength or range of motion between the two cohorts. While concomitant rotator cuff repair undoubtedly changes several aspects of postoperative management, in the present study, there was no apparent effect on outcomes at minimum 1-year follow-up. Additionally, as LHB tenodesis is often performed in conjunction with other procedures, it should be noted that the success of the procedure overall, as measured by patient reported outcomes, should not be solely attributed to the tenodesis procedure itself.

The present study does have several limitations, including those inherent to a retrospective review of a single institution's data. Limiting study inclusion to those patients with a minimum 1-year follow-up resulted in inclusion of only 48% of the patients undergoing the procedure during the study period. However, *post hoc* analysis of included patients and those excluded based on inclusion/exclusion criteria revealed no differences in demographic characteristics, comorbidities, previous ipsilateral surgery, and concomitant procedures at the time of LHB tenodesis. Due to changes in data collection methods at the institution during the time frame of the study, comparison of preoperative and postoperative patient reported outcome measures was limited. While the MCID for the ASES has been previously established, the MCID for the SF-36 for patients undergoing shoulder surgery has not been well-established, and as such, an arbitrary MCID was selected based primarily on data available following lower extremity arthroplasty procedures^{38,40}. Despite these shortcomings, the present study adds to the limited body of current evidence and further justifies the necessity of large, prospective, randomized trials to help clarify the appropriate indications and techniques LHB tenodesis.

In conclusion, we found that both open and arthroscopic LHB tenodesis consistently provide good to excellent clinical results with few complications. These results are consistent with previously reported outcomes which have failed to identify superior results with either open or arthroscopic LHB tenodesis techniques, leaving the choice of technique largely to the discretion of the treating surgeon. Given the recent increased utilization of LHB tenodesis, future studies should use randomization and prospective data collection in order to determine if discrete patient populations are better served by either open or arthroscopic LHB tenodesis techniques.

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CASE REPORT: ABSENCE OF THE LONG HEAD OF THE BICEPS BRACHII TENDON

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ABSTRACT

Background: Absence of the long head of the biceps brachii (LHB) tendon is rare with an unknown incidence. It can occur bilaterally in patients with or without associated congenital anomalies. Diagnostic difficulty exists with both magnetic resonance imaging and physical examination.

Methods/Results: We present the case of a 24-year-old female with a three year history of progressive right shoulder pain and instability with negative magnetic resonance arthrogram who was subsequently found to have absence of the LHB tendon.

Conclusions: There may be a potential relationship between absence of the LHB tendon and an increased risk of acquired shoulder pain and instability. However, the relationship between the absence of the LHB and subsequent pain and function remains unclear.

Level of Evidence: Level IV

INTRODUCTION

Disorders of the proximal portion of the long head of the biceps (LHB) tendon can frequently be addressed arthroscopically after failure of nonsurgical management. The biceps brachii has two tendinous origins with two associated muscle bellies that unite to form a single tendinous insertion on the radial tuberosity of the proximal radius. The short head tendon originates from the coracoid process of the scapula, while the LHB tendon originates intraarticularly from the superior glenoid tubercle and courses through the intertubercular groove of the proximal humerus descending to join the short head prior to its insertion on the radial tuberosity.

Cadaveric and electromyographic (EMG) studies have demonstrated an increase in tension on the LHB tendon and increased activation of the biceps muscle in response to anterior glenohumeral translation.^{1,2,3} The LHB tendon has also been reported to have a role as a depressor of the humeral head against proximal migration, but its function and role as a humeral head stabilizer still remains unclear.⁴ Perhaps one reason for the controversy is the few reported cases of congenital absence of the LHB tendon^{5,6,7,8,9,10,11,12,13,16} which could potentially serve to help clarify the role of the LHB tendon. We report a case of the absence of the LHB tendon in a 24-year-old, healthy, and active female with symptoms of progressive painful shoulder instability with clinical, magnetic resonance imaging (MRI), and arthroscopic findings provided as part of her diagnostic workup.

CASE REPORT

History

A 24 year-old right-hand dominant female chiropractic student was referred to the senior author for progressive right shoulder pain over a three year period. She was concerned about her future as a chiropractor because of progressive “popping and catching” in her right shoulder. She also described increased pain while sleeping on her right side. She described subjective symptoms of instability with her right shoulder which began three years prior to her initial visit after falling on her outstretched right hand while working with a patient. She had not sought medical attention at that time and there was no described attempt at reduction or radiographic evidence of dislocation. She stated that lately she had trouble performing chiropractic manipulation or simple hygiene tasks, including grooming her hair. She denied any numbness, tingling, or neck pain. She had no significant past medical history including no history of congenital abnormalities. Treatment prior to her presentation to the senior author consisted of four months of physical therapy and non-steroidal anti-inflammatory medications.

Physical Exam and Imaging

Physical examination of her right shoulder revealed a normal contour and symmetric range of motion in all planes compared to the asymptomatic left shoulder and no sensation of instability. The patient did not demon-

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The authors have no conflicts of interest relevant to this topic

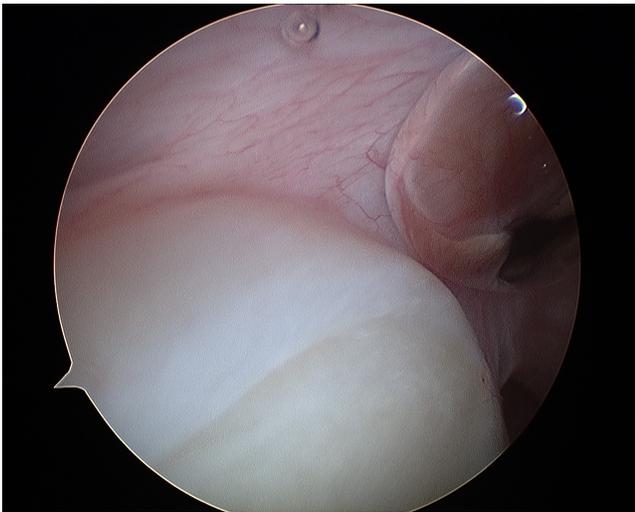


Figure 1. View through standard posterior portal of right shoulder. Absence of the LHB tendon. Pristine, smooth superior labrum with no evidence of ruptured bicipital stump or trauma is present.

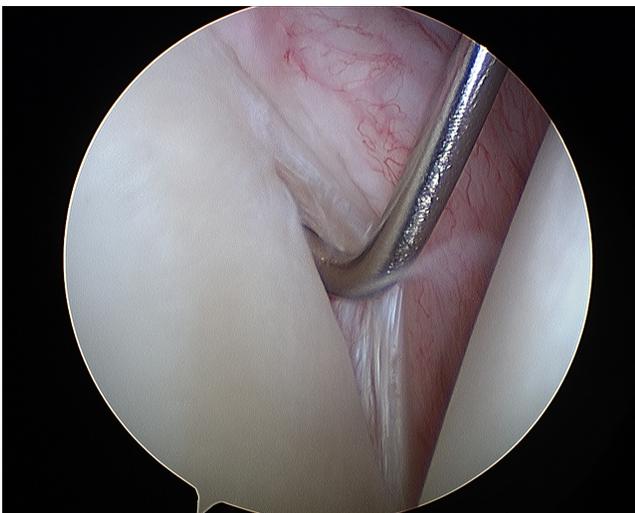


Figure 2. Viewed through standard posterior portal of right shoulder. An anterior inferior labral tear is detected.

strate signs of hypermobility in her upper extremities. There was no “Popeye” sign to indicate a torn, retracted LHB tendon. However, she did notice pain at near end range of abduction, external rotation, and with overhead forward elevation. She had positive O’Brien and O’Driscoll signs, but Speed test was negative.^{1,17} She had 5/5 strength with Jobe’s test, resisted external rotation, belly press, and bear hug tests but had pain with all but the bear hug test. She had no pain to palpation over the acromioclavicular, or sternoclavicular joints or along the course of the LHB tendon. She had a negative sulcus sign. Although she had pain, she did not have a significant apprehension or relocation sign with abduction/external rotation in the supine position. She



Figure 3. Viewed through standard posterior portal of right shoulder. Absent foramen through the bicipital groove with capacious rotator interval.

had no pain or apprehension with cross-chest adduction and posterior axial loading in the supine position. Radiographic findings revealed no bony abnormalities. A magnetic resonance arthrogram (MRA) was initially interpreted as demonstrating medial subluxation of the biceps tendon with no contrast within the biceps tendon sheath. The rotator cuff, including the subscapularis, and labrum were interpreted as intact with no superior labral anterior posterior (SLAP) tear noted.

Diagnostic Arthroscopic Findings

Given significant clinical findings of progressive/worsening pain for a three year period and MRA interpretation, the patient elected for surgery. She was placed in the beach chair position and underwent a diagnostic arthroscopy through a posterior glenohumeral portal and standard anterior rotator interval portal. During diagnostic arthroscopy, absence of the LHB tendon was immediately recognized. In addition, there was no stump of the proximal biceps tendon identified to suggest a ruptured biceps tendon (Figure 1). There was no fraying of the labral tissue. In fact, the entire superior labrum appeared pristine. A tear of the anterior-inferior labrum and attenuation of the superior, middle, and inferior glenohumeral ligaments were found at the time of arthroscopy (Figure 2). There was no evidence to suggest that the anticipated intraarticular segment of the LHB tendon was adhered to the articular surface of the rotator cuff or joint capsule as a thickened cord or synovial fold. The expected foramen to the bicipital groove was also absent in the capacious rotator interval (Figure 3). Subacromial arthroscopy revealed no evidence of trauma or inflammation. There was no evidence

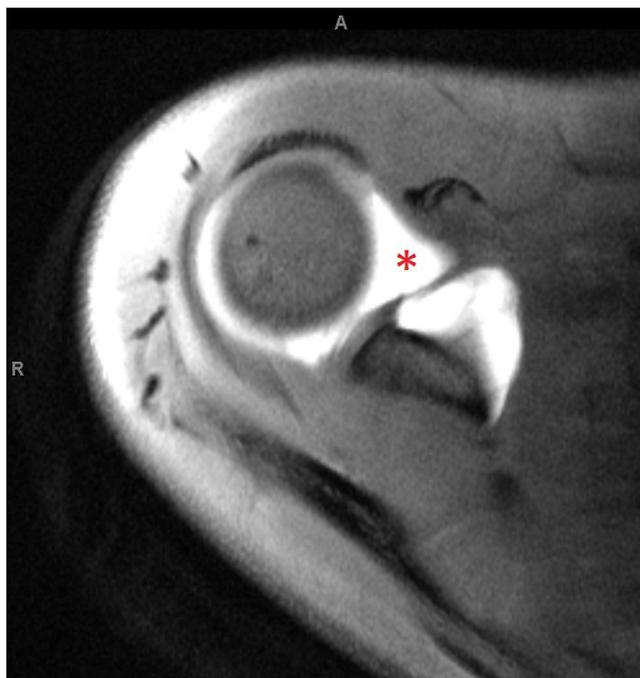


Figure 4. MRA axial T1 post-contrast image of the right shoulder. Asterisk denotes the absence of the LHB tendon in its usual course.



Figure 5. MRA coronal T1 post-contrast image of the right shoulder. Absence of the LHB tendon in its usual course.

of an extracapsular segment of the LHB tendon. The coracoacromial ligament was intact, and the short head of the biceps tendon as well as the tendinous insertion of the pectoralis major were identified anteriorly and ap-

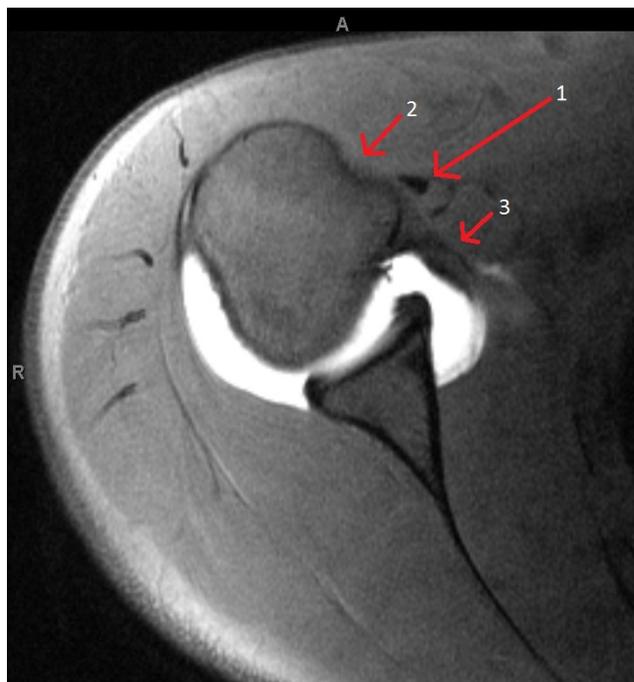


Figure 6. MRA coronal T1 post-contrast image of right shoulder. The number one corresponds to a robust short head of the biceps tendon at the coracoid. The number 2 denotes a shallow bicipital groove. The number 3 corresponds to an intact subscapularis tendon.

peared normal. A radiofrequency wand was then used to release the transverse ligaments overlying the bicipital groove which confirmed absence of the LHB tendon within the notably shallow bicipital groove. Given the arthroscopic findings and progressive clinical course, an open exploration was performed through a 5 centimeter deltopectoral approach. The bicipital groove was identified and again confirmed to be absent of the LHB tendon. The right shoulder and arm was placed in flexion to help decrease the tension on the anterior deltoid and open the space for better visualization with the illumination from the arthroscope to look for the LHB tendon or any resemblance of a palpable cord. After arthroscopic and open confirmation of the diagnosis, the arthroscope was placed back through the standard posterior portal and the anterior-inferior labrum was repaired along with an arthroscopic capsulorrhaphy using knotless 3.5mm biocomposite anchors.

Based on the arthroscopic findings, a postoperative review of the MRA images by the senior author and two musculoskeletal fellowship-trained radiologists (including the radiologist who made the initial readings) confirmed the absence of the LHB tendon and a shallow intertubercular groove. In retrospect, there was no intraarticular portion of the biceps on either the axial or coronal images (Figures 4 & 5), and the short head of the biceps tendon appeared robust (Figure 6).

Table I. Current Literature on Absence of the Long Head of the Biceps Tendon

Author	Presenting History	Congenital Anomaly
Franco et al. [3]	37 y/o male with bilateral shoulder weakness and anterior instability	Spina bifida occulta, congenital inguinal hernia and right undescended testicle
Smith et al. [17]	16 y/o male with R shoulder instability	VATER*
Ghalayini et al. [4]	37 y/o female with bilateral shoulder instability	Congenital upper limb deformities
Ghalayini et al. [4]	28 y/o female with instability following traction-type shoulder injury	None
Ghalayini et al. [4]	34 y/o female with shoulder pain and stiffness following whiplash injury	None
Sayeed et al. [16]	18 y/o male with posterior shoulder instability secondary to a posterior labral tear	Bilateral glenoid dysplasia
Glueck et al. [5]	25 y/o female with unilateral multidirectional instability and pain	None
Koplas et al. [8]	40 y/o male with bilateral shoulder pain and full thickness supraspinatus tears	None
Kuhn et al. [9]	30 y/o male with progressive bilateral shoulder pain	None
Maldijan et al. [11]	42 y/o male with bilateral shoulder pain post-trauma	Radial hypoplasia
Mariani et al. [12]	23 y/o male weight lifter with unilateral shoulder pain	None

*VATER – Vertebrae, anal atresia, tracheoesophageal fistula, renal abnormalities

However, there was an anterior-inferior labral tear on MRA that was initially overlooked but later confirmed, consistent with the arthroscopic findings. Arthroscopy confirmed an anterior-inferior labral tear as demonstrated in Figure 2.

Clinical Outcome

The patient’s postoperative recovery and rehabilitative course were unremarkable. She did well after discharge and at her 15 month follow-up she was back to activities of daily living without pain. Specifically, she denied pain with routine hygiene or sleeping on her right side. She denied pain or instability with chiropractic manipulation techniques or with swimming.

DISCUSSION

We present a case of absence of the LHB tendon in a healthy, 24-year-old female without any known congenital anomalies. To our knowledge, 11 cases of absence of the LHB tendon have previously been reported in the orthopedic and radiologic literature (Table I).^{6,7,8,9,10,11,12,13,16} Of those cases, five cases were described in patients with other known congenital anomalies. The majority of patients described in the literature presented with progressive shoulder pain without a definite inciting event and symptoms concerning for instability, which is consistent with our case report.

The presented patient is the 12th case known to the authors of complete absence of the LHB tendon. What is unique in this case report is the finding of a pristine superior labral tissue without any remnants, folds, or cord-like structures to suggest an incomplete or retained LHB tendon, either intraarticular or extraarticular, and

without any associated congenital anomalies. Although absent in our patient, congenital anomalies have been reported in five out of eleven patients thus far in the literature (45%). This common associated finding in a rare condition should raise the surgeon’s index of suspicion for the possibility of absence of the LHB tendon when there is a history of congenital anomalies and shoulder pain and/or instability. Conversely, a further review of the medical history to detect other congenital anomalies should be considered when there is a diagnosis of absence of the LHB tendon.

Our patient’s primary complaint of pain and symptoms of instability especially with overhead activities and performing chiropractic manipulation, physical examination, and MRA readings by the radiologist all led to the consideration of a dislocated LHB tendon or SLAP lesion. She was offered a diagnostic arthroscopy versus open exploration with plans to treat the LHB tendon. After extensive exploration both arthroscopically and open, it was clear that she had a complete absence of the LHB tendon. Moreover, the finding of an intact superior labrum without any evidence of the expected intra-articular segment of the LHB tendon gave us confidence that the source of the patient’s pain was from the anterior inferior labral tear. However, it is unclear if the prior history of falling on her outstretched right hand caused the anterior inferior labral tear which in turn led to progressive pain and instability or if the absence of the LHB tendon contributed to microinstability and eventual clinical painful instability. Given the frequency of pain and instability described in the reported literature coupled with the biomechanical, cadaveric, and EMG² studies demonstrating the LHB tendon as an important

anterior stabilizer of the glenohumeral joint, particularly with the arm in abduction and external rotation, the absence of the LHB tendon may lead to acquired shoulder pain and instability.^{1,2,3} However, some EMG studies have conflicting results regarding shoulder stability and the role of the LHB tendon. Therefore, the role of the LHB tendon may be limited.^{14,15}

Diagnosing pathology of the LHB provides challenges both on clinical exam and radiographically. Studies have shown that biceps tests, such as Speed's and O'Brien, are not reliable for detecting intraoperative biceps pathology especially with concomitant rotator cuff pathology.^{17,18} However in hindsight, it may be helpful to recognize absence of the LHB tendon as a diagnostic possibility.^{8,16} After a postoperative review of the MRA images, we felt this may have been overlooked. Another MRA clue is there was no retraction of the muscle belly of the arm. In fact, there were no "Popeye" deformities in any of the case reports. Biceps instability is commonly associated with subscapularis tears. Intraarticular subluxation or dislocation can occur with complete rupture of the subscapularis tendon. Subluxation within the substance of the subscapularis tendon can occur with partial tears, displacing the LHB tendon medial to the lesser tuberosity. Lastly, extraarticular or anterior dislocation can occur over an intact subscapularis tendon with disruption of the rotator interval.¹⁹ We found none of the above scenarios at the time of arthroscopy, which are key imaging findings.

In conclusion, absence of the LHB tendon is rare and can occur in patients with or without associated congenital anomalies. Three case studies reported bilateral absence of the LHB tendon.^{8,9,10} At this time, the overall incidence is unknown. Diagnostic difficulty exists with both MRA and physical examination. Several clinical and diagnostic imaging clues previously noted and again identified in the present study include absence of a "Popeye" deformity and shallow or hypoplastic bicapital groove. As there is no consensus as to the role of the LHB tendon as it pertains to shoulder function and pain, it remains unclear whether absence of the LHB tendon may serve as a potential pain generator or result in microinstability as has been suggested in previous case reports. There may be a potential relationship between absence of the LHB tendon and the increased risk of acquired shoulder pain and instability, but this link remains unclear. A much larger sample size may help to accurately define this relationship.

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CLINICAL ACCURACY OF J-SIGN MEASUREMENT COMPARED TO MAGNETIC RESONANCE IMAGING

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ABSTRACT

Background: The J-sign is defined as lateral patellar translation over the anterolateral femur proximal to the trochlear groove during active leg extension. Dynamic magnetic resonance imaging (MRI) techniques allow for quantification of the J-sign using a variety of published indices. However, to date, clinical quantification of the J-sign has not been reliably described. The purpose of the present study is to assess the accuracy of clinically quantifying the J-sign compared with objective MRI data.

Methods: All patients in this case series were indicated for Fulkerson osteotomy due to recurrent lateral patellar instability and examined preoperatively for the presence of J-sign. The J-sign was estimated by placing a finger on the lateral edge of the trochlea and estimating the lateral translation of the patella while the patient actively extended the knee from 30 degrees of flexion to maximum extension. Independent preoperative measurements were obtained by both the senior author and a resident and compared to dynamic MRI measurements read by independent investigators.

Results: Preoperative physical examination for the presence of the J-sign was conducted on 10 patients (10 knees). The average difference between clinical and MRI J-sign measurement was 4.32 mm (range 0.2 – 10.4 mm). There was no significant difference between the clinical and MRI J-sign measurements ($p = 0.2579$). Clinical measurements of the J-sign differed by an average of 2.2 mm between the two examiners (range 0 – 5 mm).

Conclusions: Clinical quantification of the J-sign showed relative imprecision when compared with MRI measurements of the modified lateral patellar edge (LPE), though in several patients we did achieve accurate J-sign assessment. If further research can validate this technique as accurate and consistent using larger patient populations, it could aid in the development of surgical treatment plans for patients presenting with patellar instability, and serve as an objective assessment of alignment in the postoperative period.

INTRODUCTION

Patellofemoral joint movement is a complex mechanism involving soft tissue restraints, bony anatomy, and dynamic skeletal muscle action. Abnormalities in any one of the aforementioned structures or mechanisms can lead to lateral patellar translation. The J-sign is a clinical sign defined as lateral patellar translation over the anterolateral femur proximal to the trochlear groove during active leg extension.¹ Magnetic resonance imaging (MRI) techniques allow quantification of the clinical J-sign using the surrogate lateral patellar edge (LPE) or modified LPE measurements.^{2,3} As the dynamic action of the quadriceps has been noted to have a significant role in lateral patellar tracking, previous quadriceps active MRI techniques have been described in order to take into account this important dynamic factor.^{1,3}

While the presence of the J-sign has been used as an indicator for realignment procedures, it does not describe the degree of lateral translation if the patella is subluxated through the full range of motion. However, previous literature has demonstrated moderate interobserver reliability when simply assessing for the presence or absence of the J-sign, with Kappa coefficients higher than many other physical exam tests used to assess patellofemoral instability.⁴ It is hypothesized that the J-sign can provide an objective clinical measurement when assessing patients with patellar maltracking. Therefore, the purpose of the present study is to assess the accuracy of clinical quantification of the J-sign by comparison to objective MRI data. Through this comparison, we aim to correlate the clinical J-sign, currently a dichotomous outcome characterized by its presence or absence, with a patellofemoral index in order to quantify the clinical J-sign.

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The authors declare no relevant conflicts of interest

This study received institutional review board approval from the University of Iowa

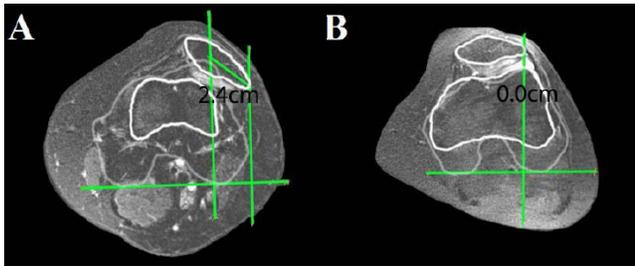


Figure 1. Modified lateral patellar edge (LPE) measurement. Reproduced with permission (McDermott SE, Anthony CA, McCunniff P, Duchman K, Albright JP. A clinical and radiographic approach for establishing proper tibial tubercle transfer when using quad active femoral nerve stimulation. *Iowa Orthop J.* 2013;33:84-9.)

MATERIALS AND METHODS

Following IRB approval, 10 consecutive patients indicated for Fulkerson osteotomy for patellar realignment by the senior author were analyzed for the presence or absence of the J-sign during preoperative examination. Inclusion criteria for this study were multiple frank instability episodes, gross evidence of a J-sign clinically, radiographic evidence of patellofemoral incongruency on Merchant views, and no previous ipsilateral knee surgery.

The J-sign was quantified in millimeters by placing a finger on the lateral edge of the trochlea and estimating the lateral translation of the patella through the arc of motion from 30 degrees flexion to maximum extension while the patient actively contracted their quadriceps. Quadriceps active MRI (axial views of patellofemoral relationships in MRI at 30 degrees flexion and full extension) was conducted on all patients preoperatively, and used to measure the modified LPE (Figure 1) as described by McDermott et al.³ The results of the MRI modified LPE measurements were compared to the clinical estimates of the J-sign using the average of the two clinical estimates.

Table I. Comparison of clinical and MRI J-sign measurements

Knee Number	Avg. Clinical J-sign Measurement (mm)	MRI J-sign Measurement (mm)	Absolute Difference – Clinical vs. MRI
1	4.5	1.9	2.6
2	5	6.4	1.4
3	0	10.4	10.4
4	7	14.4	7.4
5	12	20.7	8.7
6	17.5	9.8	7.7
7	9	10.7	1.7
8	17.5	17.3	0.2
9	9	11.5	2.5
10	8.5	7.9	0.6

Statistical analysis included a Student’s paired t-test to compare the clinical estimate of the J-sign with the modified LPE measurement. Statistical significance was considered with a p-value < 0.05. Intraclass correlation coefficient (ICC) was calculated for three independent, blinded investigators measuring the modified LPE on MRI of five patients.⁵ ICC results were categorized as “Excellent” (>0.75), “Good” (0.4 – 0.75), or “Poor” (<0.4).⁶

RESULTS

The mean age of patients included in the study was 31.1 years (range 14-54). Females comprised 70% of the included cohort. The average patient BMI for all included patients was 30.1 kg/m² (range 19.7 – 41.2).

The average difference between clinical and MRI J-sign measurement was 4.32 mm (range, 0.2 – 10.4 mm). There was no significant difference between the clinical and MRI modified LPE measurements (p = 0.2579). Comparison of the clinical and MRI J-sign measurements are further demonstrated in Table 1. Clinical measure-

Table II. Average clinical J-sign measurements and modified LPE measurements

Knee Number	Avg. Clinical LPE – 30deg Flexion (mm)	MRI Modified LPE – 30deg Flexion (mm)	Avg. Clinical LPE – Full Ext (mm)	MRI Modified LPE – Full Ext (mm)
1	2	23.5	6.5	25.4
2	2	13.9	7	20.3
3	0	7.5	0	17.9
4	3	7.1	10	21.5
5	0	8.5	12	29.2
6	0	25.5	17.5	35.3
7	3.5	18.6	12.5	29.3
8	0	12.1	17.5	29.4
9	1	4.2	10	15.7
10	0	2.3	8.5	10.2

ments of the J-sign differed by an average of 2.2 mm between the two examiners (range 0 – 5 mm). The ICC of the three independent investigators measuring modified LPE on MRI was 0.9442. Full comparison of the clinical and MRI measurements at 30 degrees flexion and full extension are shown in Table 2.

DISCUSSION

Given that chronic recurrent patellar instability is difficult to treat and may involve a variety of underlying pathology, it is imperative to maximize the preoperative assessment and physical exam in patients prior to surgery. Our clinical quantification of the J-sign showed relative imprecision and accuracy when compared to MRI measurements of the modified LPE. The most striking result was the misinterpretation of patients having little to no lateral patellar translation at 30 degrees flexion clinically, when the MRI modified LPE measurements showed half of our patient cohort with subluxation greater than 10 mm at 30 degrees flexion. This could be confounded by a number of reasons, including technical error, or an incongruence between patient's force of quadriceps contraction in clinic versus the MRI. However, we saw more accuracy and precision when estimating the J-sign through the entire arc of motion rather than making estimates at any of two particular points, in this case 30 degrees of flexion and terminal extension. This leads us to believe it is difficult to quantify the static position of the patella within the trochlear groove clinically, but it may be more feasible to quantify dynamic lateral translation using the technique we described for the J-sign.

The technique used in this study is a simple, easily teachable aspect of the physical exam for patients presenting with patellar maltracking. The results of this study warrant further investigation into the accuracy of this clinical technique in a larger population of patients. If the results of additional research show significant accuracy and reproducibility, we hope that a classification system for the J-sign can be established using objective language. For example, the terms "mild", "moderate", and "severe", could be assigned to a specific range of numerical values that describe exactly how far the patella translates laterally during an arc of motion.

The distance from the tibial tubercle relative to the trochlear groove (TT-TG) has historically been used to guide intraoperative decisions during realignment procedures, but it is unclear exactly how well this measurement describes the extensor mechanism and thus the dynamic kinematics of the knee joint.^{7,9} Edwards et al.¹⁰ recently reported a stronger correlation between the modified LPE and the actual tibial tubercle transfer

distance using intraoperative femoral nerve stimulation conducted by the senior author than the TT-TG. This suggests that the modified LPE may in fact be a better patellofemoral index when the goal of realignment surgery is to achieve maximum patellofemoral congruency. Therefore, it is our belief that if the J-sign can be validated clinically as an accurate estimation of LPE measurement, quantification of the J-sign would provide significant benefit for surgeons considering the type of operative intervention required to achieve patellofemoral stability, including medial transfer versus MPFL stabilization.¹¹ This would also allow more objective communication and discourse for the purpose of research, particularly in evaluation of the postoperative kinematics of the patella.

This study has several limitations. Only 10 patients (10 knees) were examined with two clinical measurements of the J-sign. Future research into this topic should include a larger and more diverse patient population, as well as expanding the number of clinical evaluators to further determine if the technique is both accurate and reproducible. The limited number of patients also limits our statistical power. As such, despite a >4 mm difference between the clinically quantified J-sign measurement and quadriceps active MRI LPE measurement, the underpowered nature of the study may have played a role in the nonsignificant statistical result. Also, no consideration was given to tilt of the patella, depth of the trochlear groove, or other risk factors for recurrent patellofemoral instability. On the other hand, we felt it was necessary limit the patient population and complexity of measurements in our initial stage of this research topic, as we believe this study represents the first time in the literature the J-sign has been quantified in the clinical setting and compared to objective MRI measurements.

In conclusion, this study presents the initial step in our attempt to validate the clinical method of quantifying the J-sign using objective MRI data for comparison. Although the accuracy and precision of the technique was limited in this initial study, in several patients we showed success in assessing the dynamic patellofemoral relationship and feel this warrants further study in a larger patient population.

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THE TREATMENT AND OUTCOMES OF EXTRASKELETAL OSTEOSARCOMA: INSTITUTIONAL EXPERIENCE AND REVIEW OF THE LITERATURE

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ABSTRACT

Background: Extraskeletal osteosarcoma is a rare tumor with a poor prognosis. The purpose of this study is to examine the oncologic outcomes of this disease as they relate to surgical treatment and use of adjuvant therapies.

Methods: We retrospectively analyzed all patients treated at our institution for high-grade extraskeletal osteosarcoma of the limb or chest wall. We recorded demographic data, presenting stage, surgical margin, use of adjuvant chemotherapy or radiation, incidence of local recurrence, metastases, and death. Overall and event-free survival were calculated using Kaplan-Meier survival methods.

Results: There were 12 patients treated with primary wide resection or re-excision of a previously operated tumor bed. Four patients presented with metastases. Seven patients received chemotherapy and four patients received radiation therapy. There were two local recurrences, six patients developed new metastases, and nine patients died. There was no difference in overall survival in patients who received chemotherapy. There was, however, a trend towards increased length of survival in patients who received chemotherapy compared to those who did not (16.4 months vs. 9.3 months, $p=0.16$).

Conclusions: Despite no difference in overall survival, patients treated with adjuvant chemo-

therapy have a trend towards increased length of survival. We suggest that extraskeletal osteosarcoma be treated with standard osteosarcoma chemotherapy regimens in addition to wide resection.

INTRODUCTION

Extraskeletal osteosarcoma is an extremely rare tumor accounting for approximately 1% of all soft tissue sarcomas and 4% of all osteogenic sarcomas^{1,4}. Unlike conventional osteosarcoma, the extraskeletal variant more commonly affects adults, with most patients being diagnosed after age 40⁵. The lower extremity is the most common location⁵. The lesion typically demonstrates a central pattern of ossification (Figure 1A) which demonstrates contrast enhancement on magnetic resonance imaging and positron emission tomography (PET) avidity (Figures 1B and 1C) and histologically mimics its bony counterpart (Figure 1D). The prognosis has been demonstrated to be quite poor with a five-year overall survival rate reported as low as 28%⁵, with more recent series demonstrating five year disease-specific survival of only 45% for patients presenting with localized disease^{6,7}. There is a paucity of literature regarding this disease and few have attempted to address the role of adjuvant therapies on outcomes⁸.

Given the relative rarity of the disease, there is no universally accepted treatment algorithm for extraskeletal osteosarcoma. Unlike its conventional counterpart, the role of chemotherapy in the treatment of extraskeletal osteosarcoma is unclear. Current literature reflects this lack of consensus, with most patient series appearing quite heterogeneous in terms of their treatment algorithms. Recent evidence, however, suggests that outcomes may be improved if extraskeletal osteosarcoma is treated similarly to conventional osteosarcoma with an aggressive chemotherapeutic regimen^{8,9}. A retrospective series of 17 patients published in 2005 found that three year overall survival was 77% when patients were treated with multi-agent chemotherapy and surgery; however, this study was limited by short follow-up⁸. Another report of 20 patients, 15 of which were treated with chemotherapy, noted a 5 year overall survival of 66%⁹. In contrast, and further strengthening the argument for chemotherapy, a series of 40 patients, in which only two were treated with chemotherapy, reported a 5 year overall survival of 37%¹⁰.

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The remaining authors (LMN, NBR, JDR) have no financial disclosures.

This investigation was reviewed by the Institutional Review Board at the University of Florida and assigned a status of exempt.

Table I. Patient and tumor characteristics, treatment and outcomes for the entire patient cohort.

Patient	Gender	Age (yrs)	Location	Size (cm)	Volume (cc)	MSTS stage	Prior unplanned excision	Final Margins	Limb Salvage	Chemo-therapy	Radiation	Status	Follow-up (mos)
1	F	72	distal thigh	19x7x7	931	IIB	Y	wide	N	N	N	DOD	2
2	M	76	chest wall	unknown	unknown	IIA	Y	wide	Y	N	Y	DOD	9
3	M	83	proximal thigh	1.5x2.4x1.4	5	IIA	Y	wide	Y	N	Y	NED	64
4	F	64	buttock	8x5x1.5	60	III	Y	wide	Y	Y	N	DOD	1
5	F	32	proximal thigh	7x6.5x3	137	IIB	N	radical	N	Y	N	DOD	18
6	F	52	buttock	14x14.9x14.8	3087	IIIA	N	wide	Y	Y	N	DOD	28
7	M	58	chest wall	15x17x10	2550	IIIB	N	wide	Y	Y	Y	DOD	12
8	F	71	proximal thigh	13x10x7	910	IIB	N	wide	N	N	N	DOD	9
9	M	57	proximal thigh	10x10x8	800	IIB	Y	wide	N	N	N	DOD	17
10	F	40	buttock	4.3x5.3x5.1	116	III	N	wide	Y	Y	N	NED	12
11	M	69	calf	7x5x3.5	123	IIA	N	wide	Y	Y	N	DOD	23
12	M	43	thigh	4x3.8x2.5	38	IIB	Y	wide	Y	Y	Y	AWD	12

The objective of the current study is to evaluate the experience of a large referral institution and add to the current literature regarding the multidisciplinary treatment of extraskelatal osteosarcoma.

METHODS

We performed a retrospective analysis of our orthopedic oncology database to identify all patients with extraskelatal osteosarcoma treated at our institution. The database contains prospectively collected data on all surgically treated patients treated from 1960 through 2012. The study protocol was approved for a waiver of informed consent by our Institutional Review Board prior to the beginning of data collection. We included all patients treated for high-grade extraskelatal osteosarcoma of the limb or chest wall. All diagnoses were made by a pathologist specializing in musculoskeletal oncology. Surgical notes, radiology reports and actual images, when available, and pathology reports were reviewed to confirm that the mass occurred exclusively in the soft tissues. Exclusion criteria were patients with incomplete charts, those with low-grade tumors, those with periosteal or juxtacortical locations, those who were treated surgically at other institutions, those with unclear survival outcome, or those documented as living but with less than 12 months of clinical follow-up.

We recorded patient demographic data, tumor size and presenting stage, surgical interventions prior to referral to our institution, final surgical margin status

after surgery at our institution, use of chemotherapy or radiation, presence of metastatic disease on presentation, development of new metastatic disease during follow-up, development of local recurrence, and death.

Statistical analysis was performed utilizing SPSS software (IBM Corporation, Armonk, NY, USA). Overall survival (OS) and event-free survival (EFS) was assessed using Kaplan-Meier survivorship methods. Survival was defined from the date of surgery to the date of last follow-up. Univariate analysis was utilized to assess differences in OS based upon tumor size, prior unplanned excision, type of adjuvant therapy, and presence of local recurrence or metastatic disease. Variables were compared utilizing the Mann-Whitney U test and p-values less than 0.05 were considered statistically significant.

RESULTS

We identified 18 patients in our database with extraskelatal osteosarcoma. Three patients were excluded due to having all of their treatment exclusively at outside institutions; three additional cases were excluded, including one case that refused further treatment, a second case that transferred care to another institution prior to treatment, and a third case that did not have clinical follow-up or outcome data beyond one month postoperatively. Twelve patients were available for analysis, with an average age of 60 years ± 16 years. The demographic, treatment, and final outcome data for the 12 patients comprising our case series are summarized in Table I.

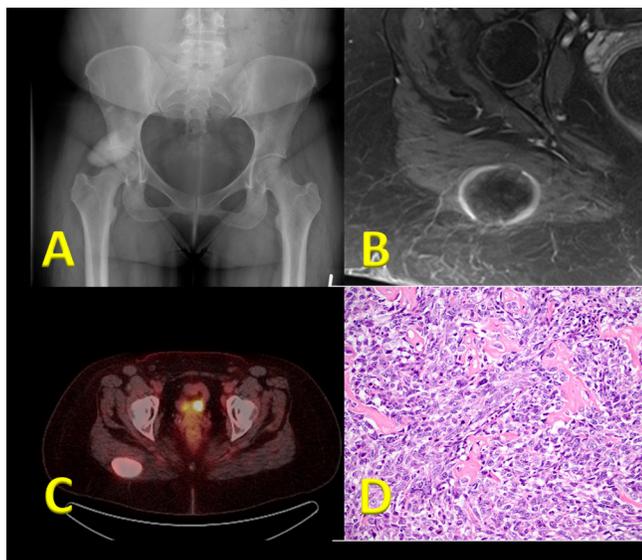


Figure 1. (a) Plain radiographic image demonstrating an ossific mass in the region of the right hip. (b) Axial T1 post-contrast MRI demonstrating the mass arising from the right gluteal musculature with a thin peripheral rim of enhancement. (c) Positron emission tomography scan demonstrating the mass with very high standardized uptake value. (d) Hematoxylin and eosin slide demonstrating immature osteoid formation by malignant appearing spindle cells.

There were six males and six females. Ten tumors were in the lower extremity (6 thigh, 3 buttock, 1 lower leg), and the remaining two tumors were in the chest wall. All were high-grade osteosarcoma at presentation. Two cases are believed to be radiation-associated secondary osteosarcomas in patients who had radiation treatment for unrelated malignancies greater than 15 years prior to extraskelatal osteosarcoma being diagnosed at the margin of their radiation field. The average tumor volume was $796 \text{ cc} \pm 1070 \text{ cc}$ (range 5 – 3087 cc).

All of the remaining 12 patients were managed surgically. Surgical intervention at our institution consisted of either a wide or radical resection of the mass or wide or radical re-excision of a previously operated tumor bed. Limb-sparing surgery was performed in eight patients, and four patients were treated with amputation. Seven patients received chemotherapy and four received radiation therapy. Two patients were treated with both chemotherapy and radiation. Three patients were managed with surgery alone. Of those who received chemotherapy, one of the regimens was unknown as that patient was treated at an outside institution with no available records regarding the specifics of their treatment. The other six patients all had doxorubicin-based chemotherapy regimens. Four patients received therapy only in the adjuvant setting and two received both neo-adjuvant and adjuvant chemotherapy. Of the four patients who were treated with radiation therapy, one was treated pre-operatively with the remaining three

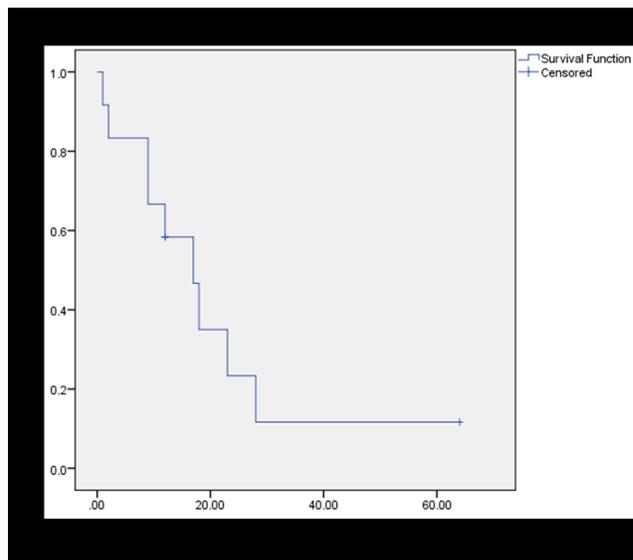


Figure 2. Kaplan-Meier survival plot of overall survival (OS) for the twelve patients in this series.

being treated post-operatively. All patients treated with adjuvant radiation therapy were treated with a minimum dose of 5040 centigray (cGy).

There were six unplanned resections prior to referral to our institution. The average tumor volume in patients with an unplanned resection was 367cc, compared to 1154cc in those with no prior unplanned resection ($p=0.24$).

Of the twelve patients, four (33.3%) had metastatic disease on presentation. Five patients without metastases at diagnosis subsequently developed metastatic disease. There were two local recurrences, at an average of 6 months post-operatively. At the time of final analysis, there were three patients living at an average follow up of 29.3 months (range 12 – 64 months). Two of the three living patients received chemotherapy as part of their treatment. All three patients treated with surgery alone died of disease at 2, 9, and 17 months after surgery.

In total, nine patients died of disease at an average of 13 months post-operatively. Kaplan-Meier survival analysis demonstrated a median survival of 17 months and a 5-year OS of 11.7% (Figure 2). When evaluating OS stratified by patients who received chemotherapy compared to those who did not, there was no significant difference in survival (Figure 3). 5-year EFS was 10.4% (Figure 4). Among the patients who died, there was a trend towards increased length of survival in patients who received chemotherapy compared to those who did not receive chemotherapy (16.4 months vs. 9.3 months,

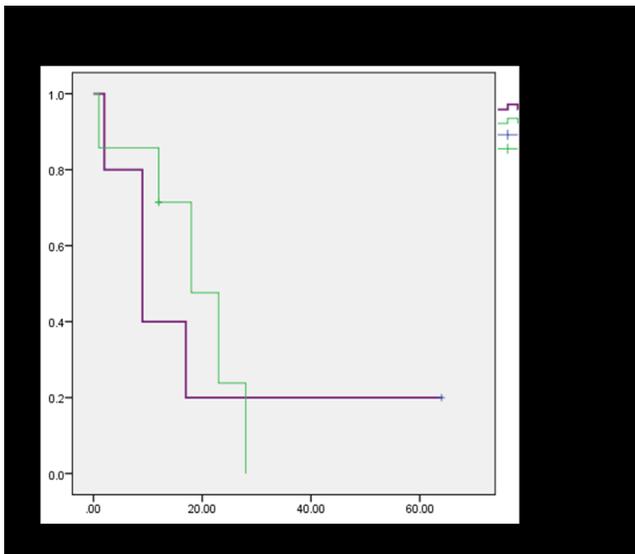


Figure 3. Kaplan-Meier survival plot of OS in patients who received chemotherapy compared to those who did not.

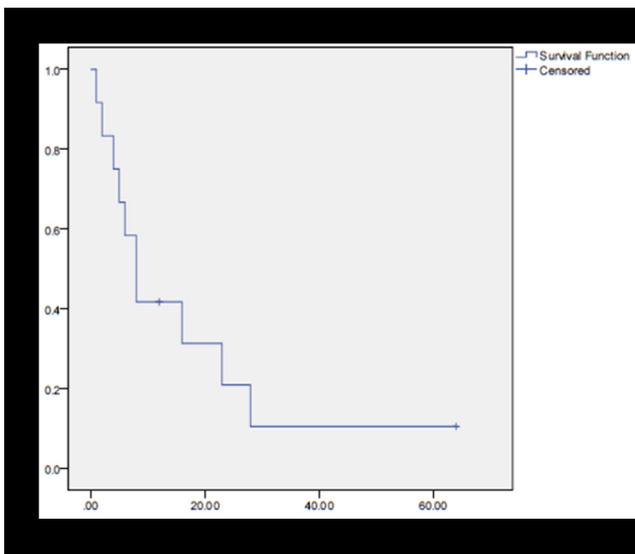


Figure 4. Kaplan-Meier analysis of event-free survival (EFS) for the entire patient cohort.

p=0.16), and in those who were managed with primary wide excision compared to unplanned excision prior to referral (18.0 months vs. 7.3 months, p= 0.07). Univariate analysis did not reveal any statistically significant differences in survival among tumor volume, previous unplanned excision prior to referral, presentation with metastatic disease, development of new metastases, local recurrence, and use of chemotherapy or radiation (Table II).

Table II. Univariate analysis of individual tumor and treatment factors on overall survival.

Group	Mean Survival (mos)	95% CI	p-value
Size			
>500cc	13.6	(-4.2, 31.4)	0.47
<500cc	21.7	(5.4, 38.0)	
Previous Unplanned Excision			
Yes	17.5	(1.6, 33.4)	0.96
No	17.0	(1.1, 32.9)	
Metastases on Presentation			
Yes	13.3	(-5.9, 32.4)	0.58
No	19.3	(5.7, 32.8)	
New Metastatic Disease			
Yes	12.8	(-2.4, 28.1)	0.38
No	21.7	(6.4, 36.9)	
Local Recurrence			
Yes	10.5	(-16.5, 37.5)	0.56
No	18.6	(6.5, 30.7)	
Chemotherapy			
Yes	15.1	(5.4, 21.4)	0.63
No	20.2	(0.6, 29.7)	
Radiation Therapy			
Yes	24.3	(5.8, 42.7)	0.33
No	13.8	(0.7, 26.8)	

DISCUSSION

The largest reported series on extraskelatal osteosarcoma in the literature includes 53 patients over a 30 year time period from a large urban referral institution, highlighting the rarity of this disease⁷. This is further supported by the fact that the database at our large referral institution identifies only 15 cases spanning a period of over 50 years. Incidence and outcomes from prior reports are summarized in Table III. The rarity of the disease likely contributes to difficulty in making the diagnosis of extraskelatal osteosarcoma. Corroborating this claim, six of the 12 patients in our series had unplanned excisions prior to referral to our institution. Review of the records indicates that several of these patients were erroneously thought to have myositis ossificans. Furthermore, our data indicate that those

Table III. Comparison of oncologic outcomes between the current investigation and previously published results of extraskeletal osteosarcoma.

Study	Years of Enrollment	# patients	Chemotherapy	Median Survival (mos)	Overall Survival	Event Free Survival	Metastasis Rate	Local Recurrence Rate
Chung et al. 1987 ⁴	1946-1982	65*	NR	NR	NR	NR	63%	43%
Bane et al. 1990 ⁵	1950-1987	26	13/26	NR	~28%	NR	61.50%	50%
Lee et al. 1995 ⁹	1915-1988	40	2/40	NR	37%	NR	65%	45%
Ahmad et al. 2002 ⁶	1960-1999	30**	NR	NR	46% 5-year	47% 5-year	30%	20%
Goldstein-Jackson et al. 2005 ⁸ (Cooperative Osteosarcoma Study Group)	1986-2002	17	16/17	NR	77% 3- and 5-year	56% 3- and 5-year	17.60%	23.50%
Torigoe et al. 2007 ⁹ (Japanese Musculoskeletal Oncology Group)	1991-2003	20	15/20	NR	66% 5-year	NR	NR	15.80%
Choi et al. 2014 ⁷	1982-2012	42***	13/42	45.8	39% 3 year cumulative incidence of death from disease	50% 3-year	38%	19%
Current Study	1960-2012	12	7/12	17	11.7% 5-year	10.4% 5-year	75%	16.70%

* 88 cases reported, follow-up only available for 65

** 60 patients in series, analysis limited to 30 patients with localized disease treated at author's institution

*** 53 patients in series, analysis limited to 42 patients with localized disease

with unplanned excisions had tumor volumes that were approximately one third the size (367cc vs. 1154cc, respectively) of those who were treated with primary wide or radical excision, which may indicate that the more aggressive behavior was not anticipated based on the modest size of the lesion.

Our study noted two cases of local recurrence. The small numbers in our series make definitive conclusions impossible, however, this number compares favorably to other reports in the literature noting recurrence from 45- 50%^{5,10}. Comparatively, the time to local recurrence in our series (mean 6 months) was similar to that reported in the previously noted studies (7-9 months).

Four patients in our series presented with metastatic disease, and there were six cases of new metastatic lesions that developed after or during treatment. One of these new metastatic lesions was a brain metastasis that occurred in a patient who presented initially with only pulmonary metastatic disease. In total, 9/12 (75%) patients developed metastases. This rate is again similar to others reported in the literature which noted rates of metastatic disease to be 62-65%^{5,10}.

The five-year overall survival in this series was 11.7%. This is lower than previously reported⁸⁻¹¹. Although no statistically significant difference was found with respect to overall or disease-free survival, two of the three patients who remained living received chemotherapy

as a part of their treatment regimen. Furthermore, of those who died, survival was increased at 16.4 months compared to 9.3 months for those who received adjuvant chemotherapy, although this finding did not achieve statistical significance. Previous literature has suggested that survival is improved when extraskeletal osteosarcoma is treated with conventional chemotherapy regimens⁸. In a 2005 retrospective study from the Cooperative Osteosarcoma Study Group, 17 patients from 17 different institutions were identified with extraskeletal osteosarcoma. All patients, except for one, were treated with chemotherapy according to high-grade conventional osteosarcoma protocols and surgical resection. This study reported an overall survival of 77% at three years and event-free survival of 56% at three years⁸. Limitations of this investigation include small patient numbers, retrospective design, poor margin descriptions, and short overall time of follow-up. A 2007 study from the Japanese Musculoskeletal Oncology Group inferred that chemotherapy may be beneficial in this disease⁹. This conclusion was reached by noting a 5 year overall survival of 66% in their series where 15 of 20 patients were treated with chemotherapy, compared to other series noting a significantly lower overall survival rate of 25% when treated without chemotherapy¹¹.

Tumor size has previously been reported to be a major predictor of survival in this disease⁵. Among the pa-

tients who were living, it was noted that their tumor size tended to be smaller at the time of initial presentation, with an average volume of 57 cc. Our analysis showed that tumor volume less than 500 cc had a mean overall survival of 18.7 months, compared to 13.6 months for tumors greater than 500 cc. However, this again failed to reach statistical significance.

As previously noted, the small number of patients in this series, as with many before it, precludes the ability to make any definitive statements regarding the treatment of this exceedingly rare disease. However, our data, when taken together with the modest current literature, suggests that when treated as conventional osteosarcoma, this disease may have an improved prognosis. Standardized treatment protocols and larger scale studies are needed to delineate the role of chemotherapy in this disease.

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STAGED SOFT TISSUE RECONSTRUCTION FOLLOWING SARCOMA EXCISION WITH ANTICIPATED LARGE CUTANEOUS DEFECTS: AN ONCOLOGICALLY SAFE ALTERNATIVE

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ABSTRACT

Background: We hypothesized that select patients undergoing planned soft tissue sarcoma (STS) excision with anticipated skin and soft tissue deficits could be treated with a two stage surgical procedure which would allow some flexibility in coverage options while not significantly increasing local recurrence rate or wound complication rate.

Methods: A retrospective review was undertaken in a series of consecutive patients with a minimum 2-year follow-up treated by a single orthopedic oncologist and a single reconstructive plastic surgeon who were managed with a staged approach STS excision and reconstruction.

Results: There were 73 patients identified over a ten-year period that underwent staged STS excision and soft tissue reconstruction. There were 12 (16%) initial positive margins resected to negative final margins, and a variety of coverage procedures performed. Wound complication rate was 21%. Local recurrence rate was 11%.

Conclusion: Staged STS excision and reconstruction is an acceptable tool in the armamentarium of the orthopedic oncologist for managing major soft tissue deficits without an increase in local recurrence rates.

INTRODUCTION

Surgical excision remains the mainstay for local management of STS. Due to the propensity for tumor cell seeding in a wound, *en bloc* excision has been recommended in order to improve local control^{1,2}. Furthermore, negative margins after excision have been correlated with a reduced likelihood of local recurrence^{3,4,5}. Tumor bed re-excision is considered feasible to attain negative surgical margins if unable to do so at the time of the index procedure^{6,7}. Intraoperative frozen section of tissue margins has proven to be a poor predictor of final negative margins based on subsequent histologic processing⁸, and as a result, re-excision may take place several days following the index excision procedure.

Adjuvant radiation therapy (RT) has been shown to diminish local recurrence rates following STS excision, including excision with negative margins, and has become the standard of care for the majority of patients following STS excision. Local recurrence rates are reduced from 25% to about 2% with the utilization of postoperative RT⁹. However, wound complications are common following RT, and include wound dehiscence and infection. It is our standard of practice to perform post-operative radiation when possible because we feel it has a lower wound complication rate compared with pre-operative RT. The development of a chronic draining wound is particularly problematic following soft tissue reconstruction with split thickness skin grafting¹⁰. For this reason, flap reconstruction is preferred over skin grafting in this setting whenever possible.

Large skin and soft tissue defects are frequently created following STS excision, especially in cases of subcutaneous lesions. Additionally, nearly half of all patients with STS will undergo an initial surgical procedure prior to referral to a sarcoma center which may compromise outcomes^{5,11,12}. Because of the need to resect skin and subcutaneous tissues, excision of these tumors often requires complex soft tissue coverage^{13,14}.

Reconstructive plastic surgery techniques have evolved for the coverage of large cutaneous defects. The mainstay for coverage for large skin loss traditionally has been split thickness skin grafting or free tissue transfer. More recently, perforator flaps, including keystone V-Y advancement and propeller flaps, have allowed coverage of large cutaneous defects using local or regional tis-

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Figure 1. A) A wide excision of a proximal thigh superficial soft tissue sarcoma (STS) with a planned keystone fasciocutaneous flap marked out. B) Mobilization of the keystone flap for soft tissue defect coverage one week after excision and clearance of tumor margins. Note the large surgical field adjacent to the tumor excision. C) After final wound closure, it is difficult to determine anatomic landmarks of the original resected specimen subsequent to the rotation of soft tissue for coverage.

sue¹⁴. These techniques have the advantage of allowing primary skin closure without grafting even in patients with relatively large cutaneous loss.

If final pathologic examination of the specimen reveals positive margins after a flap has been done, subsequent management is complicated by several concerns. Re-excision to negative margins may be compromised due to distortion of the local anatomy and large area of the tumor bed as a result of the flap dissection. In addition, the local options for reconstruction may be expended, dictating a more complex and extensive reconstruction after the second excision (Figure 1).

One way to avoid these potential disadvantages is to stage the surgeries. An initial excision is completed first, with temporary dressing of the wound bed for several days while permanent margins are analyzed. Final coverage is deferred to a subsequent day following complete examination of the resected specimen. Focal positive margins may then be accurately addressed by re-excising appropriate portions of the intact host surgical bed. In the case of extensively positive margins, wide re-excision or other appropriate surgical procedures can be considered. Most importantly, the original tumor bed has not been disturbed by flap reconstruction so the concern of a wider field of tumor seeding is eliminated.

In this study, we examine our experience with staged soft tissue reconstruction following *en bloc* STS excisions with large cutaneous defects, assessing local recurrence rate and wound complications. We hypothesized that patients treated with this regimen would not have a higher local recurrence or wound complication rate than those treated with a more conventional approach of definitive coverage at the time of excision.

METHODS

During an 11-year period from June 2000 through June 2011 at a single institution, selected patients who had anticipated cutaneous defects following excision of STS from the appendicular and axial skeleton were con-

sidered for staged excision and subsequent soft tissue reconstruction. All excision procedures were performed by a single orthopedic oncologist (JSB), and all soft tissue reconstructions were performed by a single reconstructive plastic surgeon (WMK) at a tertiary referral center. Patients underwent an index excision with the specimen sent for permanent processing. Titanium clips were placed at the margin of tumor excision to direct subsequent postoperative radiation.

The excision bed was covered provisionally with either a skin allograft or vacuum assisted closure device. If allograft was used, it was meshed and petroleum impregnated gauze was placed over the graft and a dense foam bolster stapled into place to reduce shear stress. The reconstructive surgery was completed at a median 7 days (range 3-32 day) after pathologic analysis of the specimen. Re-excision for positive margins was undertaken prior to definitive soft tissue coverage.

Using an IRB approved protocol, patients were identified from the institutional surgical database. A retrospective chart review was conducted, using the institutional records as available for follow-up. Only patients with a minimum two years of follow-up were considered for inclusion in the study. Generalized statistical comparisons were performed using chi-squared analysis, and all computations were performed in Microsoft Excel.

RESULTS

A total of 425 patients with STS were identified as having undergone excision by the senior orthopedic oncologist during the study period. Of these, 107 had planned two-stage soft tissue reconstructions. Of these patients, 73 patients were identified with minimum 2 year follow-up. Nine patients were lost to follow-up, 1 was incarcerated, and 24 patients had deferred follow-up to their local physicians, and as such, did not have further follow-up beyond the perioperative period available for review.

Of the 73 patients, 50 had high grade sarcomas, 14 low grade sarcoma, 5 dermatofibrosarcoma protuberans, and

Table I. Demographics and Results

Demographics	No. (%) of Patients
Male	42 (58%)
Female	31 (42%)
Average Age (Years)	52.0 (17.7-86.3)
Average BMI	30.2 (19.4-45.2)
Average follow-up (Months)	57.1 (24.5-125.9)
Tumor and Treatment Characteristics	
High Grade lesion	48 (66%)
Average Defect Size (Range)	135 cm ² (14-528)
Previous Positive Margin Resection	51 (70%)
Preop Chemotherapy	14 (19%)
Postop Chemotherapy	4 (5%)
Postop Radiation	53 (73%)
Wound infections	7 (9.5%)
Wound healing complications	15 (21%)
Local Recurrence	8 (11%)
Amputation	4 (5%)
Death	7 (9.5%)

4 ungraded sarcomas. Of these, 51 (70%) patients had prior unplanned positive margin excision at outside facilities and 22 had biopsy only prior to presentation at our institution. Postoperative RT was performed in 53 (73%) patients. There were no wound healing complications in 58 (79%) patients while 7 (10%) patients developed wound infection, and 8 (11%) patients developed other wound complications. Positive margins were found in 12 patients (16%) after their first procedure at our institution, and a total of 13 re-excisions to achieve negative margins were performed (a single patients had two re-excisions). There were 61 (84%) patients who had negative margins at the time of the index tumor excision. A list of demographics and results are summarized in Table I.

The average soft tissue defect was 135 ± 141 cm² after initial excision. Temporary coverage was performed with allograft skin in 57 (78%) patients and by a negative pressure wound device in 16 (22%) patients. Use of the negative pressure device was discontinued following a bleeding episode with one patient in the post anesthesia care unit, necessitating a return to the operating suite (no active bleeding was identified). Aside from this one patient, no wound complications were noted in the interim period between the index STS excision procedure and definitive soft tissue coverage.

Patients most frequently had a period of 7 days (range 3 - 32) between procedures. Definitive coverage was

Table II. Final Wound Coverage

Local Rearrangement no STSG	5 (6.8%)
Local Rearrangement + STSG	15 (20.5%)
STSG Alone	16 (21.9%)
Keystone with V-Y Advancement No STSG	23 (31.5%)
Keystone with V-Y Advancement + STSG	7 (9.6%)
Free Flap No STSG	4 (5.5%)
Free Flap + STSG	3 (4.1%)
Total	73
STSG = split thickness skin graft	

achieved by various methods as shown in Table II, with the most common modes of coverage being keystone flap (41%), split thickness skin graft (STSG) (22%), and myocutaneous local flap with STSG (21%). Twelve of the 73 patients (16%) required a total of 23 revision surgeries to achieve closure. These surgeries included wound debridement, skin grafting, and delayed closures.

There were 8 (11%) local recurrences in the study group overall, including 5 in the positive margins excision group and 3 in the negative margin group. Two of the 8 patients went on to amputation, 2 died, and 4 underwent re-excision of their local recurrences and were subsequently disease free at an average follow-up of 50 months. There were seven deaths in the group overall (10%), including five patients who died of disease, and 2 who died from causes unrelated to their malignancy. Therefore, overall oncologic survival was 93%.

DISCUSSION

A majority of the patients included in this study had prior suboptimal surgical excisions. Despite continued efforts at education, the inadvertent initial surgical misadventure remains a consistent problem in sarcoma management^{11,12}. This, unfortunately, puts patients at increased risk for local recurrence and metastatic disease^{15,16}. Large volume excisions frequently require more complex coverage needs in sarcoma surgery¹⁷, and in our series, the majority of patients had undergone excisions prior to referral. Managing this high-risk patient population led to our hypothesis that a two-staged approach would allow more coverage options while not affecting wound complication or local recurrence rates.

Patients who have a surgical excision with positive margins prior to referral to a sarcoma center have a 20-34% chance at local recurrence if the specimen is completely re-excised, and as high as a 60% risk in high-grade tumors^{7,16,18,19,20}. The rate of local recurrence in planned wide-margin excisions ranges from 6-25% in the literature^{2,4,18,19,20,21}. Metastasis occurs in 13.7-27% of patients after undergoing unplanned excision^{4,7,16,20}.

Metastasis occurred in 8.3-24% of patients undergoing planned wide-margin excision^{4,20}. In our study, the overall local recurrence rate of 11% is not different from published series of STS, suggesting that this treatment approach does not adversely affect the local recurrence rate. Overall survival was 90% and disease free survival was 79%.

The wound complication rate of 21% in the present study included infections and other wound complications. The majority of patients received postoperative RT to decrease the risk of wound complications. Wound complication rates after pre-operative RT are 35% compared with 17% in post-operative RT²², which is not significantly different from our study. Additionally, our patients had a relatively high average body mass index (BMI), a factor also associated with higher wound complications.

This study is limited in that it is a single arm, retrospective review with a short follow up from a single institution. Patients were selected for inclusion by the senior author based on clinical experience and were not randomized. However, like most sarcoma studies, due to the rarity of the disease, the protean presentations, and the wide variety of treatment options, Level 1 randomized controlled studies are exceedingly difficult to perform for surgical management in this disease. We felt that comparing a cohort of patients undergoing a single-stage surgical approach would not be possible in our institution owing to the underlying bias in choosing these treatment protocols considering the differences in these populations. As such, we elected to provide our experience with the staged excision and reconstruction approach, as it has provided a suitable treatment option in our hands.

Several non-tumor related advantages led to the incorporation of this staged surgical treatment. Patients are able to understand their reconstructive procedure prior to surgery and as such, are more knowledgeable about the operation at hand. Additionally, while no official cost-analysis was run, the surgeons anecdotally noted that staging results in more efficient scheduling and use of operating room time, surgeon time, and hospital resources. We recognize that this is an additional surgical procedure, and attempt to select our patients with that in mind. As these patients typically go home between surgeries, we feel this does not significantly negatively impact their quality of life.

In conclusion, for select patients in whom large cutaneous defects are anticipated, delayed soft tissue coverage offers the potential to revise unplanned positive margins while still availing the patient of the benefits of local tissue rearrangements. In our small single arm study, the local recurrence rate of 11% in this

relatively high risk group was consistent with previously published local recurrence rates, and reoperations for wound complications were only 16%. This technique is an acceptable addition to the armamentarium of the orthopedic oncologist and reconstructive plastic surgeon in achieving wound closure in this difficult clinical situation.

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PULMONARY SURVEILLANCE STRATEGIES FOLLOWING SARCOMA EXCISION VARY AMONG ORTHOPEDIC ONCOLOGISTS: A SURVEY OF THE MUSCULOSKELETAL TUMOR SOCIETY

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ABSTRACT

Background: Pulmonary surveillance protocols following sarcoma excision based on clinical evidence and outcomes are limited in current literature. The purpose of this study was to determine the method, frequency, and reasoning behind pulmonary surveillance strategies in patients treated for sarcoma among members of the Musculoskeletal Tumor Society (MSTS).

Methods: SurveyMonkey, an online survey tool, was used to create and distribute a questionnaire to 211 members of the MSTS in 2011. The 16 questions focused on current pulmonary surveillance algorithms and their reasoning.

Results: Of the surveyed members of the MSTS, 65% follow high-grade sarcoma with routine chest CT scans. Most disagreement involved low-grade sarcomas, where radiographs (34%), routine CT (33%), or selective CT scans (31%) were evenly distributed. Selective CT scans in low-grade lesions were warranted with an indeterminate nodule on prior CT (81%), local recurrence (40%), or large/deep tumor characteristics (31%). Most protocols were based on continuation of training protocols (46%), clinician's interpretation of the current literature (23%), or personal experience (14%).

Conclusions: Significant clinician variability exists in terms of pulmonary surveillance of sarcomas, most notably in low-grade lesions. The results

of this study represent an area in need of further study to develop an evidence-based protocol for sarcoma pulmonary surveillance.

INTRODUCTION

Following excision of primary musculoskeletal sarcoma, patients are routinely monitored for evidence of distant metastasis, which is the most common cause of cancer-related mortality, affecting 30-50% of patients with high-grade sarcoma¹. Most metastases occur in the first two years following treatment of the primary tumor^{2,3}, with the lungs representing the most common site of distant disease. The early identification of pulmonary metastatic disease is thought to be important as surgical removal of limited disease can result in a survival benefit. For example, 25-40% of patients undergoing complete resection of metastatic disease confined to the lungs will survive long-term, compared to 17% who do not have a complete resection⁴⁻⁷.

The two most commonly used imaging techniques for pulmonary surveillance are chest radiographs (CXR) and computed tomography (CT). Radiographs are quick, accessible, and inexpensive but cannot unequivocally detect subcentimeter pulmonary nodules. While CT scans provide greater detail and information, they are more expensive and expose the patient to two orders of magnitude higher doses of radiation than plain radiographs⁸. Recent reports have raised concerns about a causative effect with excessive radiation exposure from CT scans and subsequent development of malignancy⁸⁻¹⁰. Therefore, the elimination of unnecessary CT scans may be beneficial to both patient safety and healthcare costs.

The National Comprehensive Cancer Network (NCCN) provides guidelines for follow-up and surveillance of extremity sarcoma, but these guidelines do not differentiate between chest radiographs and CT scans in terms of pulmonary surveillance^{11,12}. For low-grade soft tissue sarcoma (American Joint Committee on Cancer [AJCC] stage IA and IB), the NCCN¹² simply recommends to "consider chest imaging every 6-12 months." For AJCC stage II, III, and IV disease, the NCCN recommends "chest imaging [plain radiograph or chest CT] every 3-6 months for 2-3 years, then every 6 months for next 2 years, then annually." Several authors have reported on surveillance protocols and strategies

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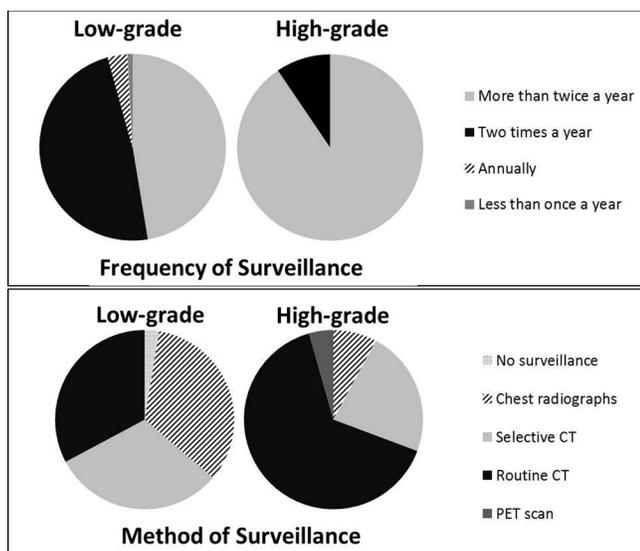


Figure 1. Results illustrating the difference in surveillance methods and frequency between low-grade and high-grade sarcomas.

following excision of primary sarcoma¹³⁻²³, with no clear consensus obtained. Given the large disparities among musculoskeletal oncologists in both method of pulmonary surveillance and frequency, we designed a survey to determine the scope of the disagreement and identify potential questions for further investigation.

MATERIALS AND METHODS

We used SurveyMonkey (www.surveymonkey.com), an online survey tool, to create and distribute a questionnaire to 211 members of the Musculoskeletal Tumor Society (MSTS). Sixteen questions were created focusing on current algorithms, patient concerns regarding radiation exposure, personal interest in further research, and clinical experience.

The survey was designed by the senior author (BJM) and reviewed prior to distribution by two fellowship-trained musculoskeletal oncologists (MTS, CPG) (Appendix A). The questions were intended to be hypothesis-generating, and focused on the current preferences of individual surgeons in the means and timing of chest imaging, the reasoning behind their personal protocol, concerns about radiation from medical imaging expressed by their patients, and their perceptions on the overuse or underuse of imaging for pulmonary surveillance. The current membership of the MSTS was then sent two emails in February 2011 with a link to the survey and explanation of the project. The results were compiled and percentages calculated according to responses of the participating surgeons.

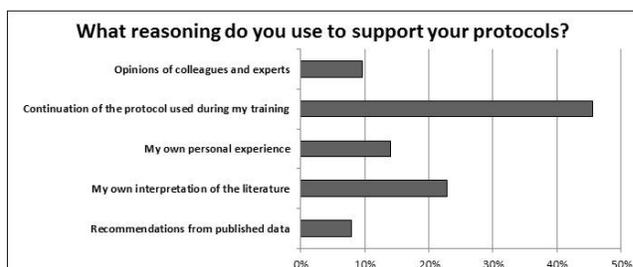


Figure 2. Most respondents reported that their current surveillance protocols were a continuation of the methods used during training. Less than 10% based their protocols on recommendations from published data.

RESULTS

Of the 211 active members of the MSTS in 2011, 118 members (55.9%) completed the survey. The complete survey questionnaire and associated results are displayed in Appendix A.

The most apparent disagreement involved surveillance of low-grade sarcomas. In terms of surveillance method, there was a nearly equivalent distribution among chest radiographs, selective use of CT scans (generally chest radiographs with CT scans reserved for particular clinical scenarios), and routine use of CT scans (Figure 1). There was also an equivalent distribution in the frequency of monitoring, with half of respondents electing to monitor more frequently than twice per year and half choosing to monitor every 6 months initially and decreasing over time.

In contrast, there was less disagreement in both the method and frequency of surveillance for high-grade sarcoma (Figure 1). Nearly 65% of respondents indicated preference for chest CT scans for surveillance, while nearly 23% use primarily chest radiographs with select CT scans for certain patients. Frequency of monitoring high-grade sarcoma was more consistent, with over 90% of MSTS members electing to monitor more than twice a year initially, with decreasing frequency over time.

Most respondents (45.6%) indicated that their surveillance protocols were a continuation of the practices used during training (Figure 2). Less common reasons for an individual's surveillance protocols were the physician's own interpretation of the literature (22.8%), personal experience (14.0%), and opinions of colleagues and experts (9.6%). Interestingly, only 7.9% of respondent's based their surveillance protocols on recommendations from published data. Two-thirds of respondents felt that chest CT scans are currently overused for monitoring of low-grade sarcomas, while one-third felt chest CT scans were overused for monitoring of high-grade sarcomas.

The presence of an indeterminate nodule found on a previous chest CT scan was the most common clinical

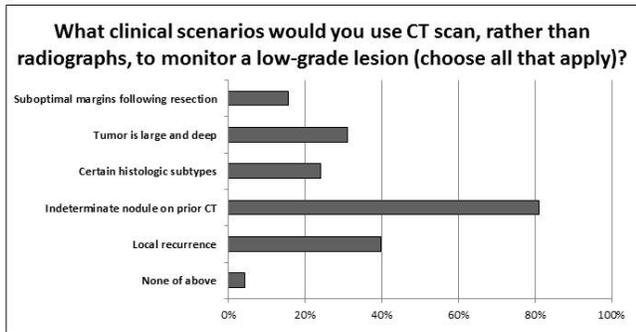


Figure 3. The most common clinical scenario in which respondents elect to monitor low-grade lesions with CT is an indeterminate nodule from a previous CT scan (81%), followed by local recurrence (39.7%) and if the tumor is large and deep (31%).

scenario for monitoring a low-grade lesion using CT scans (81.0%) (Figure 3). Less frequently cited reasons for use of CT scan for surveillance of low-grade lesions included local recurrence (39.7%), large and deep tumors (31.0%), certain histologic subtypes (24.1%), and suboptimal resection (15.5%). Most MSTs members indicated similar monitoring protocols for both bone and soft tissue sarcomas (82.8%).

Of the participating respondents, 62.9% indicated that they have had patients express concerns regarding the health risks from radiation exposure in CT scans within the past year, while 19.0% have had patients express this concern at some point in their career (Figure 4). Greater than 75% of clinicians cited limiting radiation exposure as a reasonable justification to reduce the number of CT scans performed for pulmonary surveillance. In fact, 60.9% felt that CT scans are not always necessary for routine surveillance and 45.2% reported cost savings as reasonable justifications for reduction in CT scans for pulmonary surveillance of sarcomas. In contrast, 19.1% of respondents felt that the number of chest CT scans should not be reduced as the risk of missing metastatic disease outweighs any potential benefit of reducing the number of CT scans performed.

Lastly, most MSTs members felt there is a need for further studies regarding appropriate protocols for pulmonary surveillance (93.0%) and nearly all were willing to contribute their patients to research efforts to further investigate the issue of pulmonary surveillance for sarcomas (98.2%).

DISCUSSION

Current guidelines for pulmonary surveillance of soft tissue sarcoma (STS) do not specify a specific imaging modality or periodicity, leading to controversy regarding both the method and frequency of pulmonary surveillance among practicing orthopedic oncologists. With

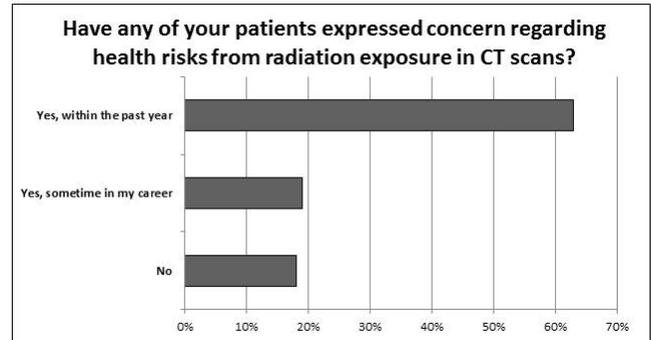


Figure 4. Nearly two-thirds of clinicians had patients express concerns in the last year over health risks due to radiation exposure from CT scans.

concerns about secondary effects of radiation from CT scans, many have questioned the need for advanced imaging for routine surveillance purposes, especially for lower-grade lesions with minimal risk of metastases. Additionally, reports from other solid tumor types challenge the usefulness of multiple follow-up imaging and laboratory studies in terms of cost-effectiveness, efficacy, and survival benefit^{18,24-27}. The results of this survey of MSTs members highlight the lack of evidence-based recommendations for pulmonary surveillance strategies, with the surveillance of low-grade sarcomas representing the largest area of disagreement.

The lungs are the most common site of STS metastatic disease, and most new metastases occur within two years following treatment of the primary tumor, although current guidelines recommend surveillance for at least 5-10 years or longer. However, these guidelines do not specify a specific imaging modality or periodicity, and controversy exists among practicing orthopedic oncologists regarding both the method and frequency of pulmonary surveillance.

While chest CT scans provide greater detail and information, concerns over excessive radiation, health-care costs, and unnecessary interventions prompted by incidental discovery of benign lesions have led many to question the necessity of advanced imaging for routine surveillance purposes, specifically in lower-grade lesions with a minimal risk of metastatic spread. Additionally, reports from other solid tumor types challenge the usefulness of multiple follow-up imaging and laboratory studies in terms of cost-effectiveness, efficacy, and survival benefit (18, 24-27). Given the disagreement and lack of widely-accepted guidelines regarding appropriate surveillance strategies for STS, this survey was designed to define the scope of the problem and determine the current state of practice and controversy for pulmonary imaging.

The results from the current report indicate that surveillance of low-grade sarcoma represents the most apparent area of disagreement amongst members of the MSTs, with a nearly even split between chest x-ray, chest CT, and selective CT scans. Additionally, roughly half of respondents prefer to initially monitor these patients twice per year, with the remainder electing for more frequent clinic visits initially (a higher frequency than the current NCCN guidelines¹²). There was less discrepancy with respect to high-grade sarcomas, as a majority of respondents preferred chest CT scans for routine surveillance, with a lower number electing chest CT scans for select patients. Likewise, over 90% of MSTs respondents elect to initially follow patients with high-grade sarcoma more than twice per year, consistent with the NCCN recommendations.

Previous surveys of surgical oncologists have attempted to better understand practice patterns. In a 1997 survey on surveillance strategies among members of the Society of Surgical Oncology, Beitler et al. reported that office visits and chest radiographs were the most frequently used modalities during each year of follow-up¹³. While 74% believed routine follow-up testing would result in detection early enough to institute potentially curative treatment, only 26% believed that current literature supported a survival benefit to follow-up testing. Reanalyzing the same survey data, Sakata et al. reported tumor grade and size significantly impacted physician practice patterns in postoperative treatment follow-up¹⁹. In another survey, Gerrand et al. found that clinic visits and radiographs were the most commonly used method of surveillance, and most respondents based their follow-up protocol on the perceived risk of local or systemic relapse¹⁵.

Previous reports suggest chest radiography may be sufficient for pulmonary surveillance following primary treatment of extremity STS with reported positive and negative predictive values of surveillance chest radiograph of 92% and 97%, respectively^{7,17,18,20,22}. Cool et al. concluded that the vast majority of metastasis detected by routine surveillance/CXR or restaging has proved successful in identifying pulmonary metastases before they became clinically apparent in 67% of cases¹⁷. Puri et al. randomized 500 non-metastatic patients to demonstrate non-inferiority with primary end point of overall survival at 3 years and disease free survival at 3 years²². CXR as an imaging modality did not lead to worsened survival and was not inferior to CT scan in terms of detecting pulmonary metastases. While most studies did not find added benefit with routine chest CT scans for pulmonary surveillance, Cho et al. reported a significant survival advantage at 2 and 4 years in patients followed with routine chest CT after surgical treatment of primary extremity sarcoma¹⁴. However, no survival benefit was

seen at 5 years. They concluded that serial monitoring with chest CT could give rise to early detection of pulmonary metastases, providing a chance for pulmonary lesion excision and survival advantage.

With most reports suggesting recurrent or metastatic disease occurs within the first two years following primary surgical treatment of soft tissue sarcoma, more aggressive follow-up and surveillance methods should be weighted during this time period^{2,7,16,18}. Several authors advocate risk stratification, with more frequent and intense follow-ups for high-risk patients^{16,18,21}. Another potential area of disagreement among surgical oncologists is length of follow-up, which was not specifically addressed in the current study. Sawamura et al. noted that 95% of metastases developed by 7.3 years and the rate of metastases was extremely high for high-grade tumors during the first two years²³. The authors suggest that follow-up beyond 10 years does not yield a sufficient number of local recurrences or metastases to warrant further monitoring.

The health risks secondary to the accumulation of low-dose radiation from medical imaging deserve specific discussion and several reports have addressed these concerns^{8,28-31}. Extrapolating upon data reported in previous studies, Brenner and Hall estimated that 1.5-2% of all cancers in the United States were caused by radiation exposure in medical imaging⁸. Patients are aware of these risks, with nearly two-thirds of survey respondents having patients express concerns regarding repeated radiation exposure. Patient concerns over accumulated radiation exposure are legitimate, and a discussion of potential risks and benefits from additional imaging studies should be standard practice for treating clinicians.

Inherent limitations are unavoidable with any study based on questionnaire to survey a large group of individuals. There are uncertainties and difficulties in interpreting responses. Inherent to this specific survey is the difficulty in categorizing follow-up protocols into a select few choices, as some clinicians likely perform additional testing based on results of physical examination or previous clinical data. There is also no way of knowing whether the results obtained in this survey actually translate into clinical practice. Additionally, this is a limited sampling of orthopedic oncologists, and should be generalized to other sarcoma specialists with care. Finally, the relatively low rate of MSTs member participation (118/211) was another limitation of this study.

The disagreements amongst members of the MSTs are secondary to variations in personal opinion in combination with lack of high-quality, evidence-based recommendations. As it was evident that most orthopedic oncologists were likely to monitor patients in a similar

manner to their fellowship training, it is not surprising that surveillance protocols are not uniform. This issue is complex with theoretically dramatic consequences. Certainly it is a justifiable goal to limit “unnecessary” imaging studies. This would result in cost savings, less radiation from medical imaging, and no consequence for overall survival. However, this decision is based on risk-stratification and a judgment of the “likelihood” of metastatic disease, and it is conceivable that a less intensive surveillance protocol would result in delayed detection of treatable metastatic disease in select patients.

What is clear from these data is that the current level of knowledge is not adequate to reflect a consensus opinion of pulmonary surveillance. Encouragingly, the overwhelming majority of those surveyed think that further research would be meaningful, and they would be willing to contribute patients to a society-wide effort. Our hope is that this simple report will stimulate further conversation and thought into determining the ideal protocol that balances metastatic risk, medical imaging radiation dose minimization, cost consciousness, and detection of asymptomatic disease that can be treated for a survival benefit.

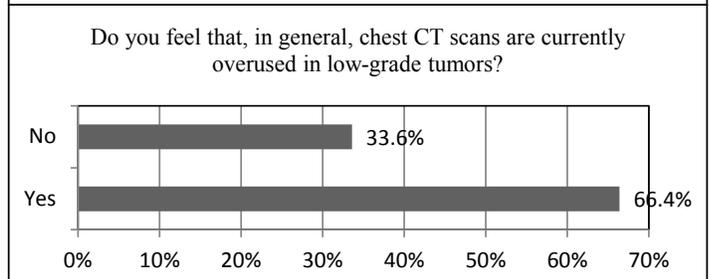
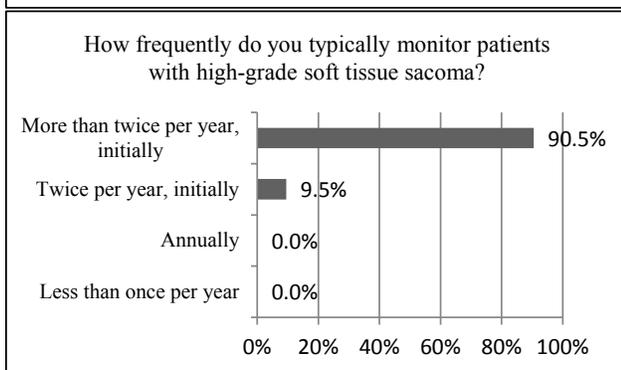
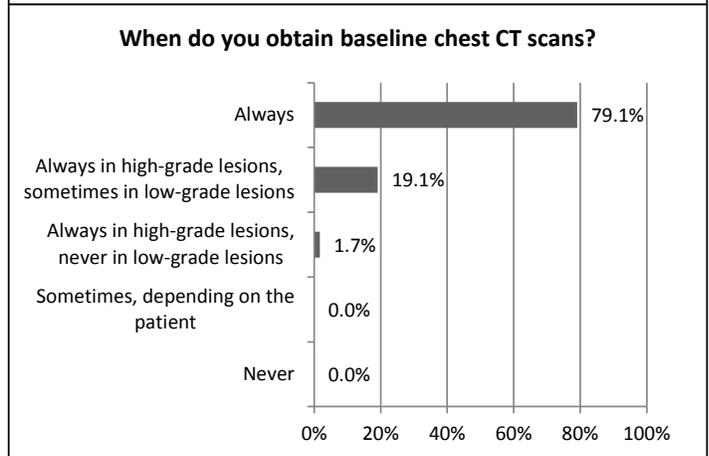
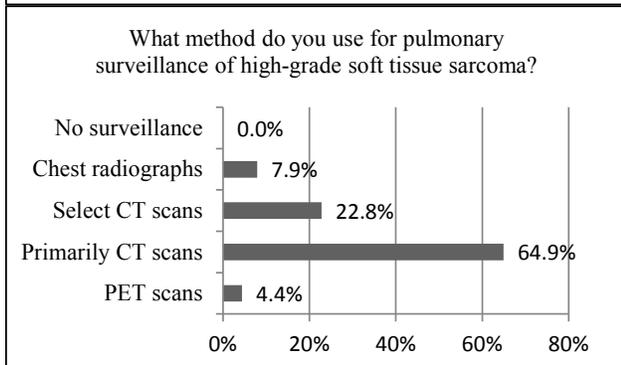
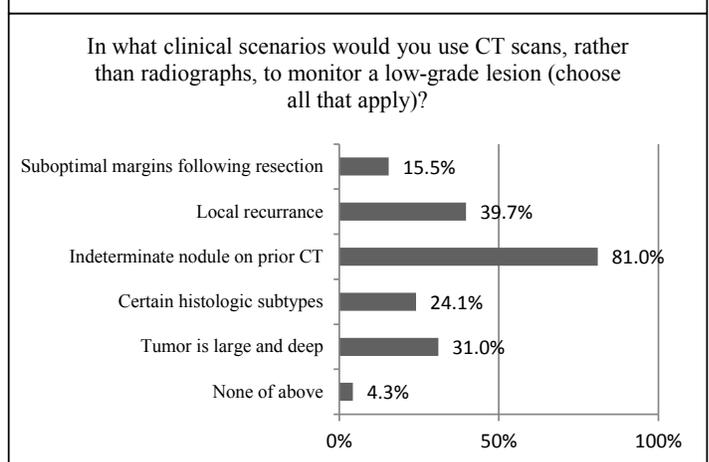
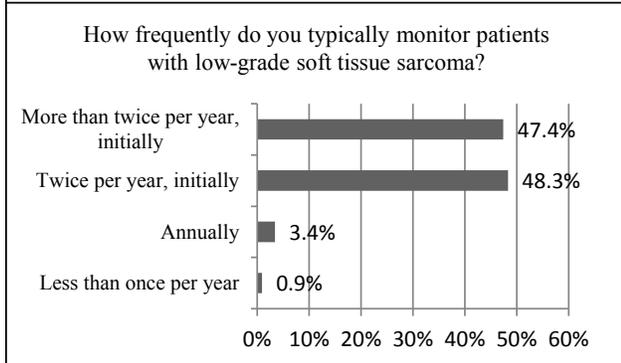
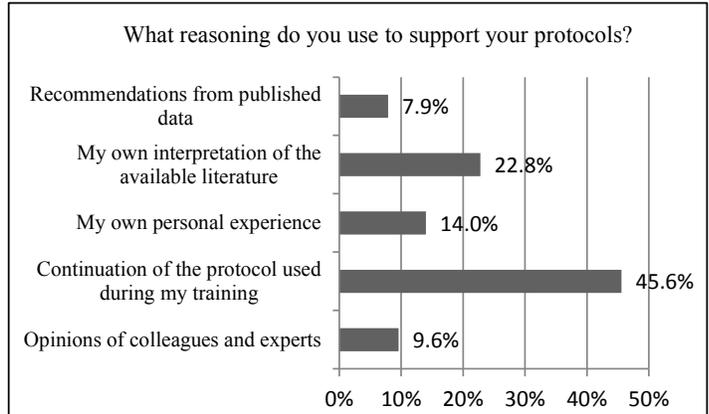
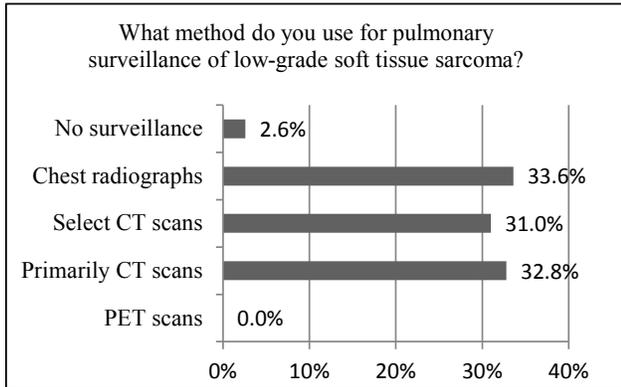
In conclusion, evidence-based recommendations on pulmonary surveillance strategies are lacking in the literature and this is highlighted by the results of this survey. The largest disagreement among clinicians involves surveillance of low-grade sarcomas and most strategies are a continuation from protocols used in training. Based upon these results, we believe a prospective, multi-center, comparative study design focusing on low-grade sarcoma would be the most informative and supported effort.

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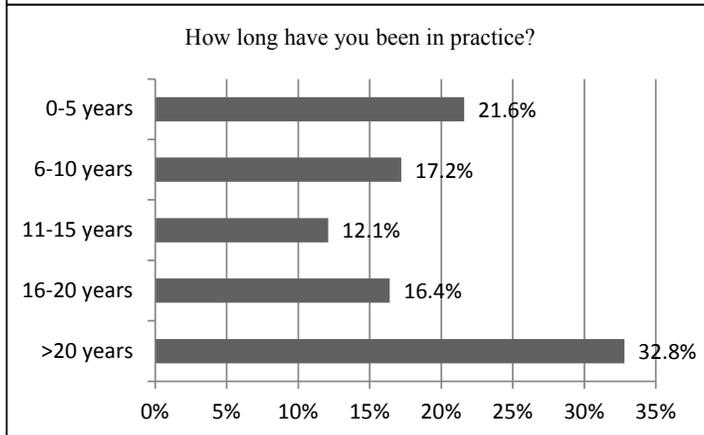
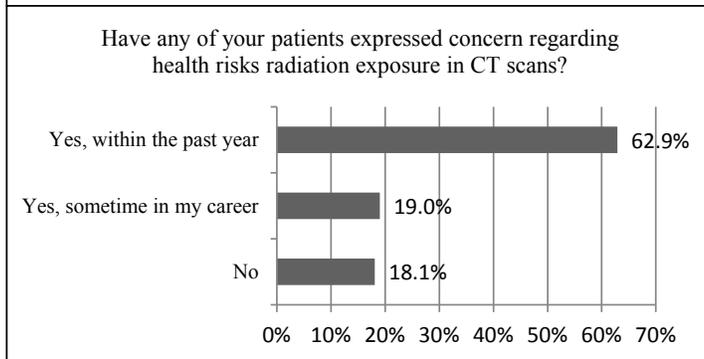
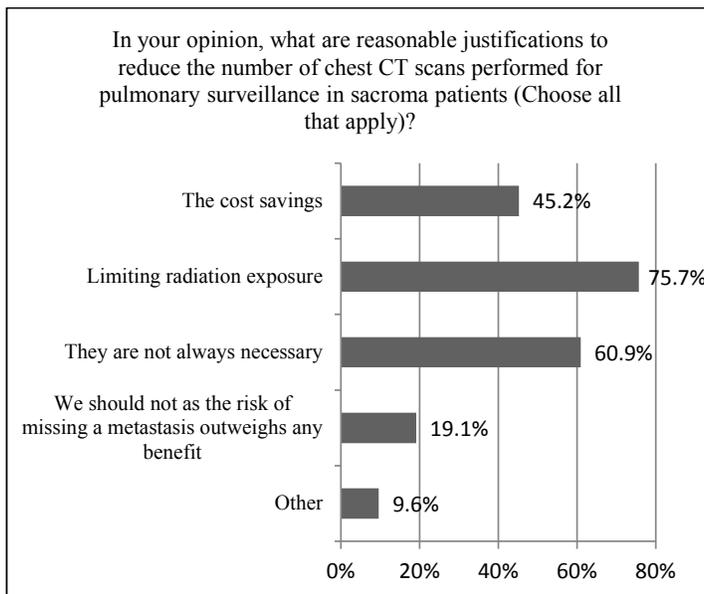
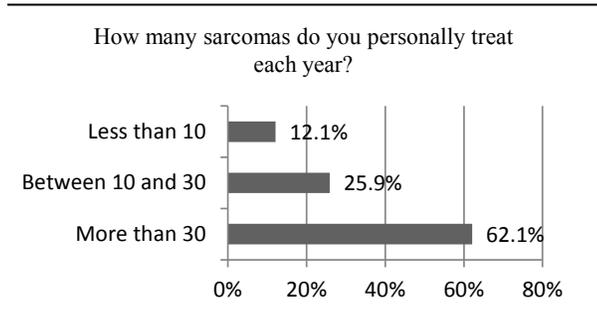
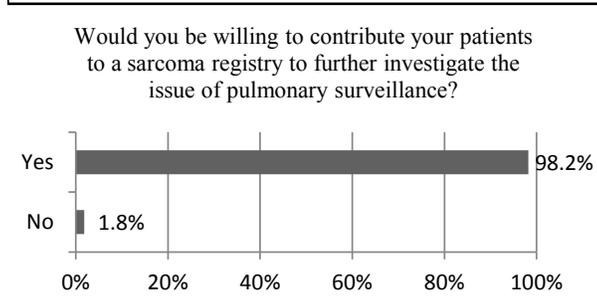
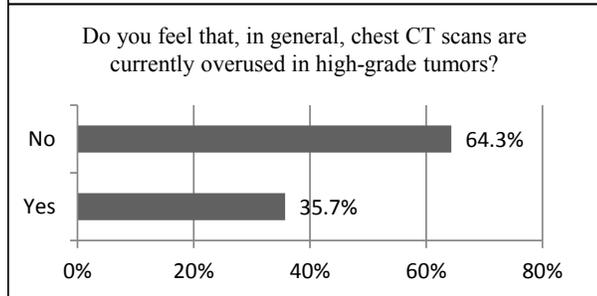
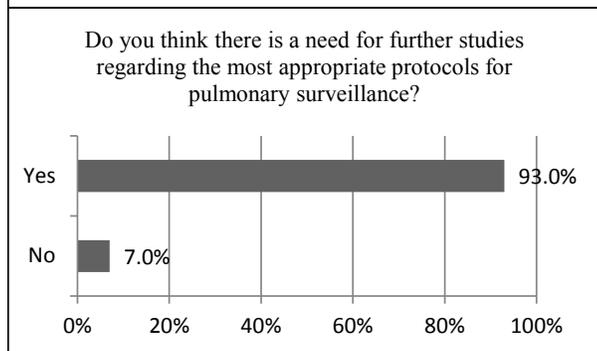
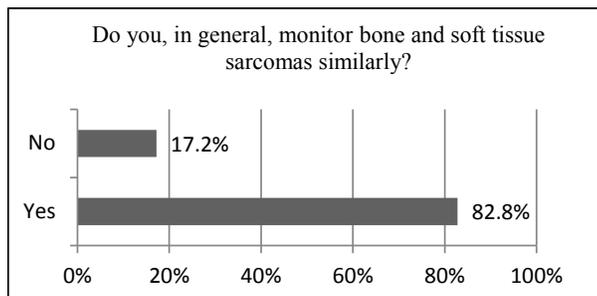
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Appendix A – Results of Pulmonary Surveillance Questionnaire



Appendix A – Results of Pulmonary Surveillance Questionnaire (cont'd)



TRANSCUTANEOUS OXIMETRY MAY PREDICT WOUND HEALING COMPLICATIONS IN PREOPERATIVELY RADIATED SOFT TISSUE SARCOMA

Lukas M. Nystrom, MD, Benjamin J. Miller, MD, MS

ABSTRACT

Background: Preoperative radiation is frequently used in management of soft tissue sarcoma. We hypothesize that anoxic tissue from preoperative radiation contributes to surgical wound complications and that transcutaneous oximetry (TcO₂) measurements made preoperatively can predict wounds at risk.

Methods: Ten consecutive patients were prospectively enrolled. TcO₂ was recorded at five time points. Wound complications (defined as major or minor) and healing outcomes were recorded out to 120 days postoperatively. Means between groups with and without wound complications were compared by use of a Student's t-test ($p < 0.05$).

Results: There were three major and one minor wound complication. During the time from radiation to surgery, patients with wound complications had a 13.1 mmHg decrease in mean TcO₂ while those who healed uneventfully had an increase of 2.3 mm Hg ($p=0.09$). Patients with complications had a low preoperative TcO₂ of 18.7 mmHg compared to those without complications (18.7 vs. 33.4 mmHg; $p=0.09$). No patient with a TcO₂ greater than 25 mmHg immediately preoperatively developed a wound complication.

Conclusions: This data suggests an earlier recovery of tissue oxygenation in patients that healed without complication. The TcO₂ measurement immediately preceding surgery seems to be the most important in predicting wound complications.

Larger scale investigation may determine if TcO₂ measurement is a viable clinical tool to aid in risk assessment for potential wound complications.

INTRODUCTION

Radiation combined with surgical resection is considered the standard of care in the treatment of most soft tissue sarcomas. Preoperative radiation is often preferred as it requires a lower treatment dose, smaller treatment field size, and resultant improved function in the spared limb¹. Furthermore, it may potentiate limb salvage by allowing safe marginal resection along vital neurovascular structures and bone². The benefits of preoperative radiation, compared to postoperative, come at the cost of an increased wound healing complication rate^{1,3-5}. One of the most widely cited studies in sarcoma literature notes a complication rate of 35% in preoperatively radiated surgical wounds in the lower extremity¹. What is less well understood is which patients are at risk of developing wound complications and what factors may contribute to those complications. This lack of knowledge is a barrier to progress in improving wound outcomes in patients with soft tissue sarcoma treated with preoperative radiation.

We hypothesized that anoxic tissue from preoperative radiation may contribute to surgical wound complications and that TcO₂ measurements made preoperatively can predict wounds at risk. To investigate this hypothesis we identified two primary questions: 1) Does radiation negatively affect skin oxygenation and does radiated tissue predictably recover its skin oxygenation during the rest period from the time of radiation completion to surgical resection and 2) Do low transcutaneous oxygen measurements correlate with wound healing complications?

METHODS

This study was designed as a pilot project to establish a proof of concept for a future larger scale prospective clinical trial. As such, sample size was not based upon a power analysis but rather on the economic and temporal feasibility of patient accrual. The study was conducted at a single academic tertiary referral center over a 12 month time period. This investigation was given full board approval by the institutional review board at the University of Iowa.

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This study was approved by the Institutional Review Board at the University of Iowa.

Table I. Patient/tumor characteristics treatment variables and wound outcomes for the entire patient cohort.

Patient	Age (years)	Size (cm)	Location	Grade	Time to Surg (days)	Rest Period Mean Change (mmHg)	Low Pre-Op (mmHg)	Flap	Complication	Complication Type
1	35	14.3	Deep	High	27	0.2	36.1	No	No	n/a
2	44	13.7	Deep	High	28	17.2	56.9	No	No	n/a
3	48	5.4	Superficial	High	25	-10.5	15.0	Yes	No	n/a
4	64	27.3	Deep	High	34	-6.1	20.4	No	Minor	Wound Drainage
5	20	22.0	Deep	High	21	23.2	48.9	No	No	n/a
6	72	30.6	Deep	High	30	-7.4	16.4	No	Major	Deep Infection
7	56	5.5	Deep	High	24	-26.1	22.4	No	Major	Infected Hematoma
8	61	11.7	Deep	Low	36	-17.6	19.8	No	No	n/a
9	70	16.2	Deep	High	29	1.2	23.8	No	No	n/a
10	55	12.7	Deep	High	29	-12.8	15.7	No	Major	Radiation Necrosis
Average	52.5	15.9			28.3	-3.9	27.5			

All patients with a suspected lower extremity soft tissue sarcoma were staged with appropriate imaging and confirmatory biopsy. The study concept was discussed with eligible patients at the time of diagnosis and enrollment was offered following a multidisciplinary team recommendation for preoperative radiation followed by limb sparing surgical resection. Criteria for inclusion were age 18 or older, treatment with preoperative radiation, and tumor amenable to limb salvage surgery. Exclusion criteria were patients with upper extremity or trunk sarcoma, patients with prior open surgical intervention to the area (excluding incisional biopsy), prior radiation in the area of the surgical site, recurrent soft tissue sarcoma, and patients with a known vascular disorder requiring prior intervention to the affected limb.

During the one year period for study enrollment, there were 10 patients eligible for enrollment and all agreed to participate. All 10 patients completed follow-up at a minimum of 120 days postoperatively and were included in the analysis. All wounds had healed at the time of final follow-up. Due to the pilot study design and limited availability of funds, the study was ended as planned after the enrollment of the tenth patient. The average age of the patient cohort was 52.5 ± 15.4 years. There were seven male and three female patients (Table I). Average tumor size was 15.9 ± 8.0 cm in the maximal dimension. There were nine tumors that were subfascial and a single tumor that was superficial. All but one sarcoma was high grade. Average time from completion of radiation to surgical resection was 28.3 days.

Following enrollment, all patients were treated at the senior author's (BJM) institution with a standard dose of 50 Gray (Gy) of preoperative external beam radiation

given in 25 fractions over a five week period. At the conclusion of radiation, surgery was scheduled following a four week "rest period" to allow for tissue recovery. All patients were treated by the same surgeon (BJM) with a standard wound closure protocol which consisted of a layered closure over a deep suction drain and non-absorbable 2-0 monofilament vertical mattress suture for the skin layer. All patients were treated with 24 hours of perioperative cefazolin, clindamycin or vancomycin depending on their penicillin allergy and screening methicillin resistant *Staphylococcus aureus* (MRSA) status. Drains were left in place until output was less than 30 milliliters (mL) per 8-hour shift for three consecutive shifts. Sutures were left in place for a minimum of four weeks. One patient was treated with a planned rotational muscle flap and skin graft at the time of sarcoma resection. No other flaps or skin grafts were utilized, and all other wounds were closed primarily. All participants were followed for a minimum of 120 days postoperatively to assess their wound outcome. If a patient experienced a wound complication, it was treated according to the surgeon's best judgment. Wound complications were defined as major or minor. Major complications included all those requiring unplanned operative wound management (irrigation and debridement, revision wound closure, skin graft, or flap), readmission for intravenous antibiotics, and need for dressing changes or wound packing for beyond 120 days postoperatively. Minor complications were defined as need for aspiration of a seroma, need for oral antibiotics, and need for dressing changes or wound packing for greater than four weeks.

Oxygen sensors were placed at five locations on the operative site based on the planned incision drawn

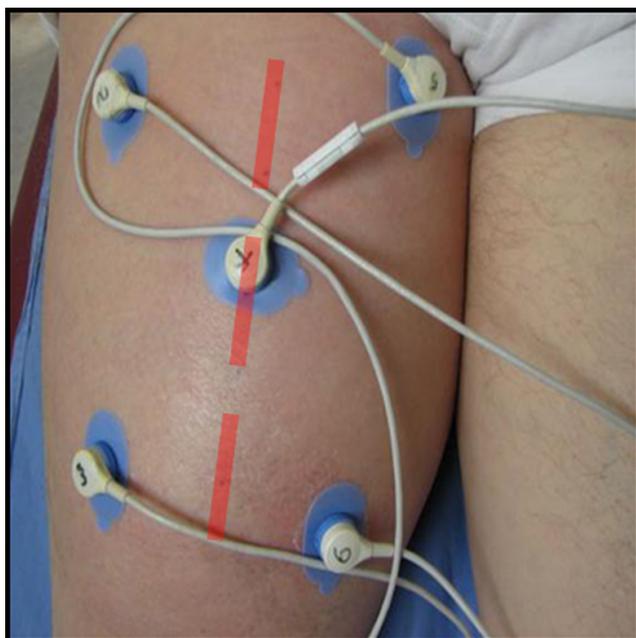


Figure 1. A clinical photograph demonstrating the placement of leads around a planned incision for resection of a medial thigh soft tissue sarcoma. The red line demonstrates the planned incision.

by the surgeon. One lead was placed centrally on the planned incision and two leads were placed at both the proximal and distal extent of the planned incision and spread approximately 3-5 cm from the incision (Figure 1). Photographs were taken at the time of the initial measurement to ensure consistent lead placement for subsequent measurements. An additional lead was placed on the contralateral limb (corresponding the central lead), serving as a control measurement. TcO₂ was measured and recorded in millimeters of mercury (mmHg). The measurements were taken by a hyperbaric oxygen lab technician trained in the use of the transcutaneous oximeter. Given that there were five leads on the operative extremity, analysis was performed for the average of all five leads, as well as the lowest recording from any of the five leads. TcO₂ was measured at five time points across the patient's treatment course: prior to the start of radiation, during the middle of radiation therapy (day 12 or 13), at the conclusion of radiation therapy, immediately preoperatively, and two weeks following surgical resection. Patients were seen in follow-up at two weeks, six weeks, and three to four months postoperatively, as well as when needed for further wound follow-up. The final TcO₂ measurement was taken at the two week postoperative visit. All patients were also seen routinely for further sarcoma surveillance after the immediate postoperative period, which extended beyond their commitment to the study protocol.

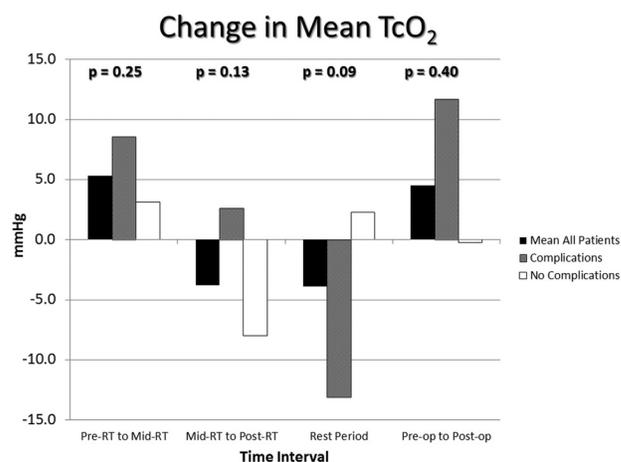


Figure 2. This chart demonstrates the change in the mean TcO₂ measurement for each time interval for the whole patient series (black), as well as divided between cohorts with (diagonal lines) and without (gray) complications. Interval 1 represents the time from start of radiation to the middle of radiation. Interval 2 represents the time from middle of radiation to completion of radiation. Interval 3 (the “rest period”) represents the time from completion of radiation to immediately prior to surgical resection. Lastly, interval 4 represents the time from immediately preoperative to two weeks postoperative.

A two-tailed Student's t-test was used to compare the mean TcO₂ of for patients with complications and those that healed uneventfully. Statistical significance was defined as a p-value of <0.05.

RESULTS

All patient, tumor and treatment variables are reported in Table I. There were three major complications and one minor wound complication. Major complications included one deep infection identified six weeks after surgery, one wound radiation necrosis identified at five weeks after surgery, and one infected hematoma requiring operative irrigation and debridement two months after surgery. The single minor complication noted was in a patient who had prolonged wound drainage greater than six weeks which eventually ceased by three months postoperatively. This patient was treated with daily dressing changes but no operative intervention or antibiotic therapy.

For the entire cohort, the mean change in average TcO₂ (averaged across all 5 leads) and the mean change in the lowest TcO₂ reading are depicted in Figures 2 and 3, respectively.

When we separated the cohort into patients who did or did not have a major or minor wound complication, patients with wound healing complications had a decrease in mean TcO₂ of 13.1 ± 7.9 mmHg whereas those who healed uneventfully had an increase in mean TcO₂ of 2.3 ± 14.3 mmHg during the “rest period” (p=0.09).

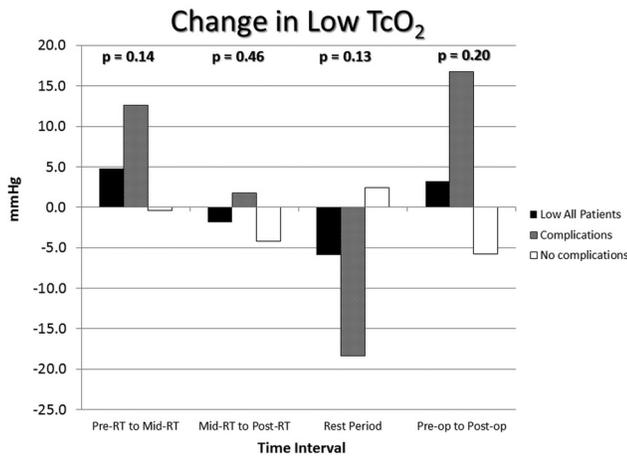


Figure 3. This chart demonstrates the change in the lowest TcO₂ measurement for each time interval for the whole patient series (black), as well as divided between cohorts with (diagonal lines) and without (gray) complications. The intervals are as described in Figure 2.

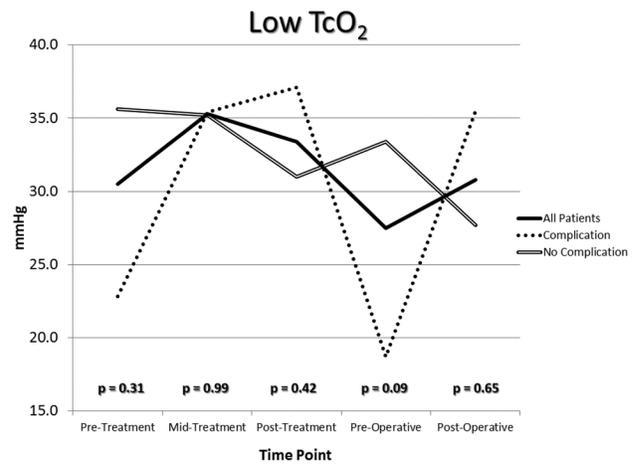


Figure 5. This graph represents the lowest TcO₂ measurement for each time point for the whole patient series as well as those patients with and without wound healing complications.

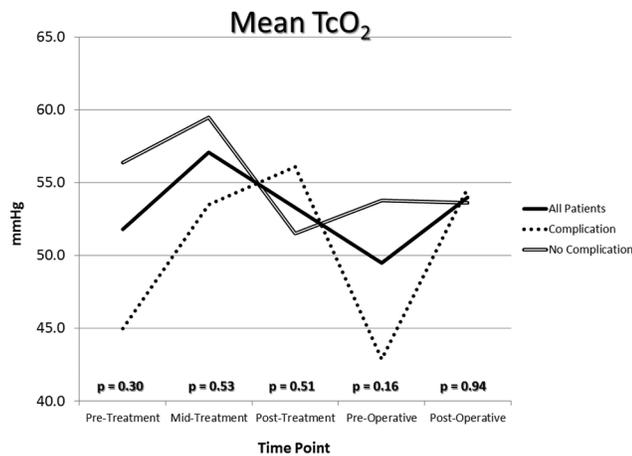


Figure 4. This graph represents the mean TcO₂ measurement for each time point for the whole patient series as well as those patients with and without wound healing complications.

Patients without complications had a mean preoperative TcO₂ of 53.8 mmHg compared to 42.9 mmHg in patients with complications (p=0.16) (Figure 4). Patients without complications had a low preoperative TcO₂ of 33.4 mmHg compared to 18.7 mmHg in patients with complications (p=0.09) (Figure 5). All patients with a TcO₂ of greater than 25 mm Hg on the immediate preoperative measurement healed uneventfully, while 57% (4/7) of patients with TcO₂ of less than 25 mm Hg had a wound complication.

DISCUSSION

Transcutaneous oximetry (TcO₂) is a non-invasive method by which to quantify local skin perfusion. This diagnostic tool has been investigated as a predictor of healing of diabetic foot ulcers and also as a predictor of

successful healing in amputations of the diabetic and dysvascular patient⁶⁻¹¹. To our knowledge, there is only one study in the soft tissue sarcoma literature that has previously evaluated the use of TcO₂ as it relates to wound healing. That investigation evaluated TcO₂ in 24 patients during the post-operative period and found that the post-operative day one value of TcO₂ was significantly lower in wounds with healing difficulties than those without¹². This study was limited by its heterogeneous patient cohort, as not all patients were treated with radiation and those that were received postoperative brachytherapy. Thus, although there was a suggested correlation between TcO₂ and wound healing, it is unclear given the timing and type of radiation used. Furthermore, as the measurements were done after surgery, it does not provide any predictive factors that may change operative or perioperative management to reduce complication rates. Although prior investigations have suggested a decrease in skin perfusion¹², and subsequent tissue hypoxia, in response to radiation, this effect is not yet clear. The quantitative effect of radiation in terms of local skin perfusion has not been described, nor is it understood whether the previously reported increase in wound complication rates is related to inadequate skin perfusion. Despite the knowledge that surgical wound complications are increased when radiation is used preoperatively, we do not have a method of determining which patients are at risk of developing a wound complication. A clinical tool that could accurately predict patients at higher risk of wound complications would enhance patient counseling, clinical decision-making, and surgical outcomes. Measurement of preoperative TcO₂ represents a novel application of a simple, noninvasive method by which to assess skin oxygenation¹³.

While there are clear advantages of preoperative radiation, there are significant negative consequences with regard to healing of the surgical wound. With 30% of patients developing a major wound healing complication in this pilot study, we corroborated the previously described 35% complication rate following lower extremity sarcoma resection in those who received preoperative radiation¹. The impetus for this investigation was the absence of a clinical tool to predict patients at risk of developing a wound complication. This, in combination with the rarity of the sarcoma diagnosis, has prevented significant improvement in wound outcomes in sarcoma patients undergoing surgical resection.

The results of our pilot investigation indicate that the TcO₂ measurement does not respond in a predictable fashion during the course of radiation treatment. However, we did identify that patients without a wound healing complication seemed to have their TcO₂ levels return to values more similar to their pre-radiation values while those patients who had a complication did not exhibit this interval improvement. This suggests that there may be some component of measureable tissue recovery that is associated with healing potential that could be quantified with a non-invasive measurement. To our knowledge these findings have not been previously reported or hypothesized. This has potential implications to the treating surgeon, as it is possible that our rest period was insufficient for some patients to regain their oxygenation and that a longer interval could have been beneficial. Theoretically, a longer rest period in those who had not yet recovered their tissue oxygenation could have decreased the potential for wound problems. Certainly, further investigation is needed and our results are far from conclusive, but the possibility of a modifiable risk factor to diminish wound complications is an idea worth pursuing.

This study is clearly limited by its small enrollment. More patients are required to adequately power the study to detect a true difference in TcO₂ between those patients who experienced a complication and those who healed without complication. Furthermore, we recognize that wound healing is a multifactorial process^{3,4} and that tissue oxygenation may only be one contributing factor. Other factors such as patient comorbidities and nutritional status are other known factors that were not formally assessed in this pilot investigation due to the limited nature of our study design. Despite these limitations, we believe this data represents novel and useful information with compelling preliminary data to justify further investigation.

Our results also indicate that patients with a TcO₂ value above 25 mmHg for their lowest lead recording immediately preoperatively did not experience a wound

complication. Four of seven patients with a measurement in any lead below 25 mmHg experienced a complication. This threshold is consistent with the level reported in the diabetic foot ulcer and amputation literature which points to a threshold between 20-30 mmHg as predictive of successful wound healing¹⁰. Similarly, while our results are neither conclusive nor generalizable given the limited scope of the investigation, this result should be further investigated as it introduces the potential for a clinically relevant measurement at a time point where surgical decision-making could influence treatment outcomes. For instance, in a patient with a low measurement, and thus based on our preliminary data a higher risk for wound complications, the surgeon could delay the operation to wait for recovery, plan on performing a soft tissue reconstruction with healthy tissue instead of primary closure, or use an incisional vacuum-assisted closure.

In conclusion, we found that there may be a relationship between oxygen recovery in the rest period and the likelihood of a postoperative wound healing complication. Additionally, the TcO₂ measurement immediately preceding surgery was the most predictive of wound healing complications, with a threshold of 25 mmHg serving as a threshold for experiencing complications. These results have the potential to give clinicians a tool to aid in perioperative decision-making and are deserving of further investigation in a larger patient cohort to confirm the findings of this pilot study. If confirmed, TcO₂ could serve to guide perioperative management by delaying surgical intervention or utilizing other wound closure methods in order to reduce complications in this at risk patient population.

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THREE METHODS OF GUIDED GROWTH FOR PEDIATRIC LOWER EXTREMITY ANGULAR DEFORMITY CORRECTION

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ABSTRACT:

Background: Different methods of guided growth are used for correction of angular deformity in growing children. The differences between these different methods are not well described in the literature.

Methods: A retrospective review was undertaken comparing the effectiveness and complication rates of titanium staples, titanium eight-plates, and the stainless steel Pedi-plate at a tertiary pediatric hospital after IRB approval.

Results: 77 patients were included in the analysis. Average follow up was 18 months after implantation (range 7-22). Stainless steel implants showed significantly lower complication rate compared to the other groups with significantly faster rate of deformity correction when compared to titanium staples.

Conclusion: Our data can be used to guide implant choices for guided growth.

INTRODUCTION

Angular deformity of the lower extremity in the coronal plane may be the result of many etiologies including exaggerated physiologic angulation, trauma, infection, skeletal dysplasia, and metabolic disease¹. Deformities can be unacceptable in appearance, affect gait, cause knee pain, alter knee biomechanics leading to ligamentous instability, and may be detrimental to long term joint function. No long term study has correlated angular deformity with joint degeneration but it has been implicated in placing larger than normal loads across the joints predisposing to cartilage breakdown and joint degeneration². Treatment of a growing child's angular deformity to avoid these sequelae via manipulation of the physis is a well-accepted treatment method^{1,3-5}.

Techniques utilized to manipulate physal growth in order to achieve angular correction via guided growth have changed over time. The permanent partial physal arrest was initially described over 70 years ago but requires specific timing and can lead to over or under correction due to the unpredictable nature of skeletal growth. Temporary, reversible techniques using staples, plates, or percutaneous screws have been developed to place more control over the correction into the hands of the surgeon^{1,6}. These devices are not without complications, related to both the technique as well as the hardware. Staples have been used successfully for many years but there have been many reports of breakage, backing out, malpositioning, and difficulties with placement and removal leading to possible irreversible physal arrest^{1,5,7}. More recently plate and screw devices have been developed to allow for more reliable and secure implant positioning, utilizing only one implant. Furthermore, a biomechanical advantage has been proposed to focus the forces more peripherally than a fixed angle staple improving the working distance^{4,7}. Hardware breakage has also been reported with these devices, leading to several design changes over time^{4,7,8}.

Surgeons at our institution have utilized several different temporary guided growth techniques. The purpose of this study is to document angular deformity correction and complications in patients undergoing guided growth treatment at our institution. We hypothesized that these devices provided similar amounts of radiographic angular correction with fewer complications and revision surgeries with the newest device, a stainless steel guided growth plate.

MATERIALS AND METHODS

This data was collected in a retrospective manner, identifying patients by a query of operating room implant utilization databases following Institutional Review Board approval. We analyzed the use of three different implants, the titanium hemiepiphysal staple (Smith and Nephew, Inc., Memphis, TN) (Group S), the titanium eight-plate (Orthofix Inc., Lewisville, TX) (Group E), and the stainless steel Pedi-plate (Orthopediatrics Inc., Warsaw, IN) (Group P). A total of 77 patients were identified from 1999 through 2010 who met our inclusion criteria which included any patient with a coronal plane angular

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The authors declare no relevant conflict of interest

This study received institutional review board approval

Table I. Descriptive Results

	All	Group S	Group E	Group P
Number of Patients	77	18	24	43
Number of Physes Treated	188 (avg 2.44)	47 (avg 2.61)	55 (avg 2.29)	86 (avg 2.0)
Average Follow-up Months	18	7	22	13
Average Age at procedure	11.64	10.91 (5.9-15.1)	11.72 (6.2-19)	11.46 (2.4-16.7)
Average BMI at procedure	30.24	31.49	30.29	29.71
Top diagnoses by percentage				
Blount's %	31.6	31.9	40	14
Idiopathic genu valgum %	23.2	2.1	12.7	32.6
Hypophosphatemic Rickets %	20	8.5	25.5	11.6
Epiphyseal Dysplasia %	9.7	23.4	7.3	11.6

Group S: Staples, Group E: Titanium eight-plate, Group P: Stainless steel Pedi-plate

Table II. Angular correction

	All	Group S	Group E	Group P
MTFA:				
Pre op	15.8	18.5	14.1	15.4
Post op	10.76	12	11	9
Change	5.1	6.5*	3.1*	6.4
Correction per year in degrees	3.73	4.16	2.09	4.34

*: statistically significant with p:0.028 (between groups E and P)

		All	Group S	Group E	Group P
Valgus	LDFA:				
	Pre op	81	80	81	81
	Pos top	87	87	84	87
	Change	5.6	7	3.1	5.5
	MPTA:				
	Pre op	94	94	92	94
	Post op	91	92	93	90
	Change	2.94	2.1	1.29#	4.33#
Varus	LDFA:				
	Pre op	95	98	94	95
	Post op	91	94	90	91
	Change	3.7	4	3.7	4.2
	MPTA:				
	Pre op	77	75	79	79
	Post op	81	79	82	82
	Change	3.25	4	3.17	4

#: statistically significant with p:0.010 (between groups E and P)

MTFA: Mechanical Tibiofemoral Angle, LDFA: Lateral Distal Femoral Angle, MPTA: Medial Proximal Tibial Angle, Group S: Staple, Group E: Titanium eight-plate, Group P: Stainless steel Pedi-plate

deformity about the knee, secondary to any underlying diagnosis, with at least six months of clinical follow up. We excluded patients who had concomitant procedures during the initial six months that would affect the angular and mechanical axis measurements or did not have pre- and post-implantation full length standing radiographs.

The mechanical tibiofemoral angle (MTFA), lateral distal femur angle (LDFA), and medial proximal tibial angle (MPTA) were measured as described by Paley⁹. Early in

the study, the mechanical axis and anatomic angles were measured by hand with goniometer by a senior orthopedic resident. After implementation of a digital imaging system, these angles were determined by utilizing digital software (OrthoView LLC, Jacksonville, FL). Statistics were calculated using SPSS software with a significance level specified at p<0.05. ANOVA with subsequent post-hoc Tukey HSD analysis was performed for any significant relationships as well as Chi-square analysis.

Table III. Mechanical axis analysis

	All	Group S	Group E	Group P
Preop MAZ	2.61	2.45	2.67	2.7
Postop MAZ	1.97	1.89	2.12	1.9
Change	0.64	0.56	0.55	0.8

MAZ: Mechanical Axis Zone, Group S: Staples, Group E: Titanium eight-plate, Group P: Stainless steel Pedi-plate

RESULTS

A total of 77 patients were identified that met our inclusion criteria, these patients underwent a total of 188 instrumentations (97 distal femur physis procedures, 91 proximal tibial physis procedures). Average follow up for all patients from the initial surgery was 18 months.

Descriptive Analysis

Descriptive information for the population and each group is included in Tables I and II.

Angular Correction Analysis

Analysis of the angular correction based on the radiographic measurements, including the MTFa, LDFA, and MPTA are summarized in Table III. Absolute values of MTFa were used for analysis in order to combine the data from both varus and valgus deformities. Analysis of the angular correction obtained did show that the MTFa change between the groups was significant. *Post hoc* analysis revealed that the correction in Group S was significantly more than that obtained in Group E (3.81 degrees, $p = 0.028$, 3.81). The correction obtained in Group P compared to Group E approached statistical significance (2.97 degrees, $p = 0.056$). A separate analysis was performed grouping the patients into varus and valgus preoperative deformity and comparing LDFA and MPTA (Table III). This revealed that in the patients with preoperative valgus deformity, the change in MPTA was significant for a greater correction attained in Group P compared with Group E. (5.62 degrees , $p = 0.010$).

We also measured the rate of correction of MPTA, LDFA, and MTFa as degrees per month and compared that between different groups using ANOVA followed

by *post hoc* analysis. This analysis showed significantly faster correction of MPTA in Group P compared with Group S ($p = 0.007$). This was not seen between Groups E and S ($p = 0.8$). Correction of LDFA and MTFa was also significantly faster in Group P than S, with p values of 0.001 and 0.007, respectively. The difference between other groups failed to reach statistical significance.

Complications

A list of complications are shown in Table IV. Overall, complications occurred in 21 of the 77 patients in our analysis (27.3%). Complications included any documented problems including loosening, breakage, pain, knee stiffness, worsening deformity, and inadequate correction. In three cases, the complication necessitated an additional operative intervention.

There was a statistically significant difference in complication rate between Group P and both Group S ($p < 0.001$) and Group E ($p = 0.002$). There was no statistically significant difference between Group S and Group E ($p = 0.35$). In the plate groups, all broken screws were observed in the metaphysis, a phenomenon that has been described previously⁸. Complications mostly occurred in patients with abnormal physes, with 95% of patients that developed a complication having a diagnosis of Blount’s disease, skeletal dysplasia, fibular hemimelia, mucopolysaccharidosis, or hypophosphatemic rickets.

DISCUSSION

Our results support the hypothesis that newer implants and evolving clinical practices have decreased the complication rate over time for patients undergoing angular deformity correction about the knee. The comparison of angular correction did find that all three devices provided angular correction, with some notable differences. The expectation would be that the two different tension-band plate constructs used (Pedi-plate and eight-plate) would behave similarly with respect to angular correction. In fact, our data indicate that the eight-plate did not perform as well as the Pedi-plate or the staple. In 2009, Wiemann et al. found a similar

Table IV. Complications

	All	Group S	Group E	Group P
Complications # Patients (%)	21/77 (27.3%)	9/18* (50%)	7/24# (29.2%)	5/43*(11.6%)
Most common reasons (# patients)		-Backing out (5) -Broken, Painful, and Inadequate Reduction (2 each)	-Broken Screw (4) -Screw backing out, lost to follow-up, inadequate reduction (1 each)	-Broken screw (2) -Knee stiffness, screw backing out, inadequate reduction (1 each)

*: statistically significant with $p:0.000$ (between groups S and P)

#: statistically significant with $p:0.002$ (between groups P and E)

Group S: Staple, Group E: Titanium eight-plate, Group P: Stainless steel Pedi-plate

amount of angular correction when comparing Staples (9.9°) to the eight-plate (11.1°)⁷. We also found that the angular correction occurred more quickly in the staple group (4.16°/year) and Pedi-plate group (4.34°/year) than the eight-plate group (2.09°/year). Stainless steel plates (Group P) showed significantly faster correction of MPTA, LDFA, and MTF A compared to staples which was not seen with the titanium plates (Group E). In 2007, Stevens⁴ cited a 30% faster correction rate with the eight-plate compared with staples, which was not the case with our population.

Our complication rate, at 27%, was somewhat higher than other series, even accounting for complications that did not lead to further surgical intervention. Previous work has shown 8-17% rate of complications requiring further surgery during guided growth treatment^{5,7,10}. Our data indicates a statistically lower complication rate in patients treated with the Pedi-plate than both the eight-plate and staple groups. Wiemann reported a similar relationship when he compared eight-plates to staples⁷.

The reasons behind the different effectiveness of the tension band constructs may be related to the implant material type. Both the eight-plate and the Pedi-plate designs are very similar with cannulated screws which are placed into a 2-hole plate. Thus, the stainless steel material must convey increased strength for angular correction. This may be related to the relative pressure felt by the physis using this material; however, this is only conjecture on our part. In addition, most of the implant failures occurred at the junction of the head and neck of the screw, the portion of the screw that is the weakest. The stainless steel may increase the relative shear strength of that implant as we have not seen any hardware failures with the Pedi-plate. It must be noted that Orthofix has recently released a stainless steel version of the eight plates. We have only limited experience with this implant.

Analysis of our angular correction and complication rates based strictly on implant used is useful and allows for the broad generalizations noted above; however, population factors and evolving surgical practices may also have played a role in these results.

One weakness of this study is the difference in diagnoses between groups. While our study population was fairly homogeneous with respect to age, BMI, preoperative deformity, and number of physes treated, there were differences in etiology of angular deformity between our groups, with 40% of the patients in the eight-plate group having a diagnosis of Blount's disease. However, this was not significantly more than the 31.9% incidence of Blount's in the staple group. There have been several studies that showed less angular correction in patients with a diagnosis of Blount's disease^{8,10,11}. This difference

in correction could account for some of the difference in angular correction seen between the eight-plate and the Pedi-plate devices, as only 14% of the patients in the Pedi-plate population had Blount's disease. This same discrepancy may have played into the complication rates as well, as 9 of the 21 patients that had a complication had a diagnosis of Blount's disease. Additionally, the rate of correction could also depend on the rate of growth at the time of implantation. This rate varies between the boys and girls with the same chronological age and depends more on the level of skeletal maturity. We did not collect skeletal age and did not separate boys and girls in our data analysis. Although the chronological age was not different between our groups, the skeletal age could have been different and may have played a role in the differences seen. The patients in the Pedi-plate group have undergone surgery more recently than the other two groups. The surgeons' experience with this procedure may have also played a role in our results.

From our data, we conclude that tension band constructs have a significantly lower complication rate than staples used for hemi-epiphyseodesis around the knee. Moreover, this study demonstrated advantages in both angular correction and decreased complications of the stainless steel implant, the Pedi-plate, which is most likely due to implant material properties. Confounding these results was a difference in the number of Blount's disease patients in each group, the lack of control for skeletal age at the time of implantation, and the possible effect of surgeon experience. Further study, in the form of a prospective randomized trial, would more precisely clarify the differences in performance between these implants.

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A RANDOMIZED PROSPECTIVE STUDY OF THE USE OF IPADS IN REDUCING ANXIETY DURING CAST ROOM PROCEDURES

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ABSTRACT

Background: Cast room procedures can be a source of anxiety for children. Various techniques, including music therapy, have been evaluated as a way to ease this anxiety. The use of iPads as a form of distraction during cast room procedures has not previously been evaluated and was the purpose of the current study.

Methods: 146 children and adolescents who underwent cast room procedures during June-August 2015 were randomly assigned to one of three groups: no-iPad, iPad with video, or iPad with game. Patient heart rates were measured using a pulse oximeter in the waiting room, before the procedure, during the procedure, and after the procedure. Mean values for each group were calculated at each time interval and compared both between groups and within groups over time.

Results: There were no significant differences in baseline (waiting room) heart rate between the no-iPad and iPad groups. When compared with the no-iPad group, there was a trend toward decreased heart rate in the video group ($p=0.13$) and a significant increase in heart rate in the game group ($p=0.026$) before the procedure. There were no significant decreases in heart rate within any of the groups when comparing the waiting room heart rates with the during procedure heart rates. There was a significant difference between the no-iPad and video groups ($p=0.047$) when comparing the change in heart rate from baseline to before the

procedure, with a decreased heart rate observed in the video group.

Conclusions: The results of this study show a significant decrease in heart rate when transitioning from the waiting room to the cast room while watching videos on the iPad. iPad-based video delivery appears to decrease anxiety prior to cast room procedures. iPad-based game play is difficult to assess as elevations in heart rate prior to the procedure are presumed to be related to game play and confound the observed effect it may have on anxiety related to the procedure.

INTRODUCTION

Cast room procedures can be a source of anxiety for children during orthopedic visits. Anxiety can make procedures difficult for both the patient and the physician, and, in extreme cases, can even be harmful to the patient.¹

Heart rate has been used in prior studies as a marker for anxiety, and increases in heart rate have been shown to correlate with anxiety, stress, and cardiac autonomic function.² In studies evaluating preoperative patients, anxiety was associated with an increase in heart rate and had negative outcomes on postoperative recovery.^{3,4} Additional studies have utilized heart rate to assess physiological anxiety during colonoscopy and cardiac catheterization.^{5,6}

Many methods of anxiety reduction have been evaluated previously. Ear protection has been shown to decrease heart rates in children <13 years old undergoing cast removal.⁷ Our institution has previously demonstrated that music therapy effectively decreases heart rates during cast room procedures.⁸

iPads and tablets have been shown to decrease anxiety and comfort children during anesthesia induction, immunization shots, and wart cryotherapy.^{9,10,11} iPad tablets were used as an alternative to oral sedatives to calm perioperative anxiety and were shown to decrease anxiety in children and increase parental satisfaction.¹² To our knowledge, the use of iPads has not yet been studied in children undergoing cast room procedures. The purpose of this randomized, prospective study was to evaluate the use of iPads as a distraction tool in effort to decrease anxiety in children during typical cast room procedures.

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The authors declare no relevant conflict of interest

This study received Institutional Review Board approval

TABLE I. Patient Demographics by Group

	No iPad	iPad with video	iPad with game
Average age (P=0.77)	8.7	9.1	8.7
Race ($\chi^2=0.65$)			
African American	19	22	22
Caucasian	26	27	25
Asian/Indian	2	1	0
Middle Eastern	0	1	0
Central American	0	1	0
Sex ($\chi^2=0.16$)			
Male	22	34	28
Female	25	18	19

TABLE II. Procedural Breakdown by Group

Procedure	No-iPad	Video	Game	Total
Cast Removal	20	27	19	66
Cast Placement	19	17	16	52
Other Procedures				
Cast overwrap	3	2	2	7
Splint placement	1	1	4	6
Fracture reduction	1	0	0	1
Joint injections	0	0	1	1
Dressing changes	1	1	1	3
Suture Removals	0	1	0	1
Aspirations	0	1	0	1
External Fixator Strut Change	1	0	0	1
Pin removals	1	1	3	5
Not specified	0	1	1	2
Total	47	52	47	146

METHODS

Institutional review board approval was obtained prior to beginning this study. Children and adolescents (aged 1-18 years) undergoing a cast room procedure (cast removal, cast placement, pin removal, fracture reduction, cast overwraps, and splint placement) were enrolled in the study over a 3-month time period from June 2015 to August 2015. Patients were recruited in the clinics of

three orthopedic physicians by one of two investigators. Patients meeting inclusion criteria for age and scheduled procedure were approached in the waiting room regarding study enrollment. Two previously calibrated portable pulse oximeters were used to measure heart rate as the objective measurement of anxiety. Baseline heart rate was measured in the waiting room for one minute using 15-second intervals. Patients were then randomly assigned to one of three groups: no iPad, iPad with game, or iPad with video using a random number generator application. Patients were then transitioned to the cast room and allowed to select a video or game of their choice, based upon their group assignment. A “before procedure” heart rate reading was obtained upon entering the room, prior to starting the procedure, at 15-second intervals for a total of one minute. During the first two minutes of the procedure, patient heart rates were recorded at 15-second intervals for the “during procedure” measurements. Immediately after the procedure, heart rates were recorded at 15-second intervals for one minute as the “after procedure” recordings.

Statistical Analysis

Mean values for each portion of the visit, including waiting room (baseline), before, during, and after the procedure, were calculated. Mean values for each group were calculated at each time interval and compared both between groups and within groups over time periods. Two-tailed, two-sample t-tests were performed using Microsoft Excel (Microsoft, Redmond, WA) to assess significance.

RESULTS

There were 146 patients enrolled in the study and randomized to the no iPad (n=47), iPad video (n=52), or iPad game (n=47) groups. Demographics for each of the groups are shown in Table I, and the procedural breakdown for each group is shown in Table II.

There were no significant differences in baseline (waiting room) heart rate between the no-iPad and iPad groups (Table III). When compared with the no iPad group, there was a trend toward decreased heart rate in the video group (p=0.13) and a significant increase in heart rate in the game group (p=0.026) before the procedure. There were no significant decreases in heart rate within any of the groups when comparing the waiting

TABLE III. Mean Heart Rate (beats per minute) by Time Period*

	Waiting Room	Before Procedure	During Procedure	After Procedure
No iPad (N=47)	92.7	93.6	95.9	93.8
iPad with video (N=52)	93.0 (P=0.47)	89.6 (P=0.13)	94.0 (P=0.301)	93.4 (P=0.45)
iPad with game (N=47)	94.9 (P=0.28)	96.9 (P=0.026)	99.5 (P=0.19)	98.2 (P=0.088)

*No iPad group used as reference group when calculating the p-value comparing treatment groups within each time period

TABLE IV. Changes in Heart Rate (beats per minute) Between Time Periods by Procedure*

Procedure	Study Group	Waiting Room vs. Before Procedure	Waiting room vs. During Procedure	Before vs. During Procedure	During vs. After Procedure
All procedures (N=144)	No iPad	0.9	3.2	2.3	-2.2
	iPad w Video	-3.3 (P=0.047)	1.0 (P=0.22)	4.3 (P=0.16)	-0.6 (P=0.19)
	iPad w Game	2.0 (P=0.32)	4.6 (P=0.31)	2.5 (P=0.17)	-1.3 (P=0.305)
Cast removal (N=66)	No iPad	3.1	3.3	0.2	-2.9
	iPad w Video	-4.6 (P=0.013)	1.7 (P=0.36)	6.2 (P=0.047)	-0.2 (P=0.18)
	iPad w Game	1.1 (P=0.30)	0.9 (P=0.30)	-0.2 (P=0.46)	-1.9 (P=0.36)
Cast application (N=52)	No iPad	0.5	4.6	4.1	-1.3
	iPad w Video	-1.1 (0.36)	0.1 (P=0.18)	1.1 (P=0.13)	-1.2 (P=0.49)
	iPad w Game	4.8 (P=0.14)	7.5 (P=0.26)	2.8 (P=0.27)	1.6 (P=0.105)

*No iPad group used as reference group when calculating the p-value comparing treatment groups between time periods

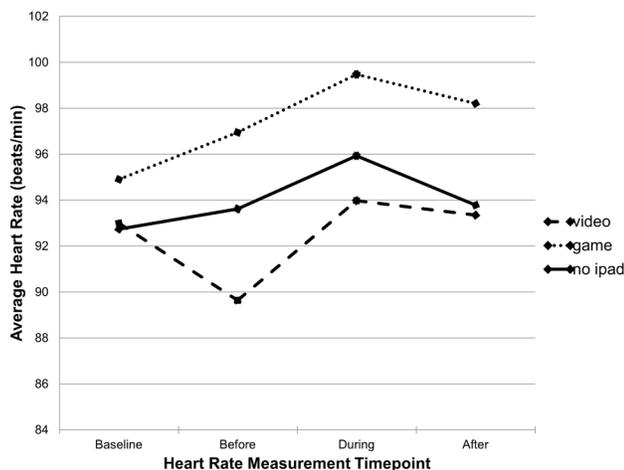


Figure 1. Trend of mean heart rate (beats/min) during each time point by treatment group.

room heart rate with the during procedure heart rates. There was a significant difference between the no-iPad and video groups ($p=0.047$) when comparing the change in heart rate from baseline to before the procedure, with a decrease of 3.3 beats/minute observed in the video group (Table IV). Heart rate before the procedure was significantly higher in the game group ($p=0.026$) when compared with the no-iPad group.

Figure 1 shows the average heart rates for each of the groups during the four different time points.

DISCUSSION

Cast room procedures often cause significant anxiety in children. This may interfere with the efficiency of the procedure and may result in adverse events. One of the most common cast room procedures is the removal of a cast, which requires the use of a saw. In the report by Katz et al.¹, the fluctuating level of high-frequency noise was cited as a possible cause for the anxiety reaction.

Katz studied how the use of ear protectors reduced anxiety. They found that ear protectors significantly decreased the heart rate elevation in patients undergoing plaster cast removals. Other forms of calming methods have also been studied to reduce anxiety in children during procedures. Music therapy has been one of the more popular methods. Liu et al.⁸ performed a randomized prospective study of 69 children who were assigned to cast rooms with or without lullaby music playing. In the music group, they noted lower heart rates both when entering the cast room and during the procedure when compared with baseline heart rates in the waiting room.

iPads were chosen for this study because of their popularity among children of all ages and the common use of iPads by the parents of children during these procedures. The use of video as a form of distraction was shown to reduce anxiety in children during induction of anesthesia for ambulatory surgery.⁹The effectiveness of iPads and tablet computers at decreasing anxiety levels in children during perioperative anesthesia was shown by Seiden et al.⁷ when they demonstrated the superiority of tablet computer-based interactive distraction to oral sedating medications in decreasing patient anxiety in a randomized study of 108 patients. Parental perception of patient's anxiety and the amount of crying from the child during immunizations and cryotherapy have also been effectively reduced with use of iPads.¹⁰ In a study by Tey et al.¹¹, a portable video player was implemented at a dermatology clinic. High anxiety levels decreased from 86% to 43% when comparing children seen during the pre-intervention group to those seen during the post-intervention period.

Our study addresses the use of iPads for anxiety in a new setting and incorporates the aspect of choice for patients in order to offer a more personalized experience. We hypothesized that iPad use would decrease anxiety in the setting and stress of cast room procedures. Previ-

ous literature for cast room procedures often catered to reduction of noise or hearing-related distractions. Our study used video, which has been successfully utilized in other specialties, and interactive games to decrease anxiety. Furthermore, similar to the study by Mifflin et al.⁹, each patient was able to choose a video or game from a pre-selected list of items. Our aim was to cater the distraction to the patient in hopes that they would remain focused on the iPad during the procedure.

Heart rate was used as an objective measurement for the assessment of anxiety in our study because of previous studies that have demonstrated positive correlation between the two variables. For instance, in a report by Kantor et al.⁸, self-reported anxiety was noted to correlate with elevations in physiological measurements of heart rate, and Smolen et al.⁵ assessed the effectiveness of music therapy on anxiety during colonoscopies through decreases in heart rate.

The results of our study demonstrated significant differences in heart rate between the waiting room and the cast room when comparing the video group to the control group. This may indicate a benefit to using iPads and tablets prior to the start of procedures. A subgroup analysis of the patients undergoing cast removal demonstrated a significant increase in heart rate in the video group when evaluating the change in heart rate during the procedure. This would suggest that the noise of the cast saw may have negated the benefits of the videos. Noise cancelling headphones could be considered in the future.

Contrary to our hypothesis, the game group showed increases in heart rate in almost all segments of the visit when compared with the control and video groups. It is believed that the excitement of playing a game elevated the heart rate and masked any potential decreases in anxiety. While a decrease in heart rate was not seen consistently across all test groups when compared to the control, physicians and orthopedic technicians subjectively noted a substantial change in the cooperation of patients. The use of iPads during cast room procedures has been implemented in our clinics since the start of this study and anecdotal differences continue to be reported. Based on these results, a study design assessing anxiety using methodologies outside of heart rate would be necessary to clarify the role of games.

Although age can be an important factor in anxiety, we did not see any clear correlations in this study even after performing multiple regression analysis with age stratification.

There were several limitations to our study. The data was collected by two investigators, which may have accounted for some differences in measurements.

However, the two investigators developed the protocol together and enrolled 77 patients together in attempts to create a uniform experience for patients. As no power analysis was performed prior to study enrollment, the role of sample size and magnitude of the effect required to demonstrate statistically significant changes remains unknown. The trend toward smaller increases in heart rates for those in the video group during and after the procedure may have shown significance with a larger sample size. In addition, while multiple anecdotal cases of decreased anxiety in both the game and video groups were seen, no formal subjective anxiety scale was used in our study.

In conclusion, watching videos on the iPad resulted in a significant decrease in heart rate when transitioning the patient from the waiting room to the cast room, and there was a trend toward lower heart rates during and after the cast removal procedure. Although not directly assessed in the current evaluation, this may represent improved patient cooperation and family member satisfaction through the use of iPad videos prior to and during cast room procedures. Further work in this area should include the investigation of additional forms of distraction and other objective measurements of anxiety as changes in heart rate are undoubtedly multifactorial and not perfect measures of anxiety.

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A BIOMECHANICAL COMPARISON OF PIN CONFIGURATIONS USED FOR PERCUTANEOUS PINNING OF DISTAL TIBIA FRACTURES IN CHILDREN

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ABSTRACT

Background: Percutaneous pin fixation is often used in conjunction with closed-reduction and cast immobilization to treat pediatric distal tibia fractures. The goal of this procedure is to maintain reduction and provide improved stabilization, in effort to facilitate a more anatomic union. We conducted a biomechanical study of the torsional and bending stability of three commonly used pin configurations in distal tibia fracture fixation.

Methods: A transverse fracture was simulated at the metaphyseal/diaphyseal junction in 15 synthetic tibias. Each fracture was reduced and fixed with two Kirschner wires, arranged in one of three pin configurations: parallel, retrograde, medial to lateral pins entering at the medial malleolus distal to the fracture (group A); parallel, antegrade, medial to lateral pins entering at the medial diaphysis proximal to the fracture (group B); or a cross-pin configuration with one retrograde, medial to lateral pin entering the medial malleolus distal to the fracture and the second an antegrade, medial to lateral pin entering at the medial diaphysis proximal to the fracture (group C). Stability of each construct was assessed by resistance to torsion and bending.

Results: Resistance to external rotation stress was significantly higher in group A than group B ($P = 0.044$). Resistance to internal rotation stress was significantly higher in group C than group B ($P = 0.003$). There was no significant difference in torsional stiffness when comparing group A with group C. Under a medial-directed load, group B and C specimens were significantly stiffer

than those in group A (28 N/mm and 24 N/mm vs. 14 N/mm for A; $P = 0.001$ and $P = 0.009$, respectively)

Conclusions: None of the three pin configurations produced superior results with respect to all variables studied. Group A configuration provided the highest resistance to external rotation forces, which is the most clinically relevant variable under short-cast immobilization. Parallel, retrograde, medial to lateral pins entering at the medial malleolus provide the greatest resistance to external rotation of the foot while minimizing the potential for iatrogenic injury to soft tissue structures.

INTRODUCTION

Tibia fractures are the most common pediatric lower extremity fracture^{1,2} and the second most common fracture resulting in hospitalization.³ Most pediatric tibia fractures are isolated occurrences resulting from low-energy, indirect torsional stress.^{4,6} About 50% of these fractures occur in the distal third of the tibia.^{5,7}

Pediatric distal third tibia fractures have traditionally been described as complex injuries that can be challenging to manage because of articular involvement, proximity to the fibula, and open physes.⁸ For unstable fractures of long bones, intramedullary fixation is a common surgical intervention as this permits earlier mobilization and facilitates optimal alignment.^{3,5} In pediatric distal tibia fractures, however, locked intramedullary rods are typically avoided because of the risk of physeal injury.^{9,11} External fixation was formerly the preferred procedure for treating distal tibial fractures, especially severely unstable fractures with soft tissue involvement or comminution.^{8,12} The use of external fixation has declined, however, because of recent reports of complications with the technique, including infection, skin necrosis, delayed union, limb overgrowth, and a need for re-manipulation.¹² Elastic Stable Intramedullary Nailing (ESIN) is now commonly used for fixation of pediatric long-bone fractures. This approach is minimally invasive, with percutaneous placement of the nails.^{11,13-16} However, ESIN has been associated with complications resulting from insufficient nail thickness, malreduction during implant placement, and inadequate stabilization of fractures.^{2,17} Supplementation of cast immobilization with percutaneously

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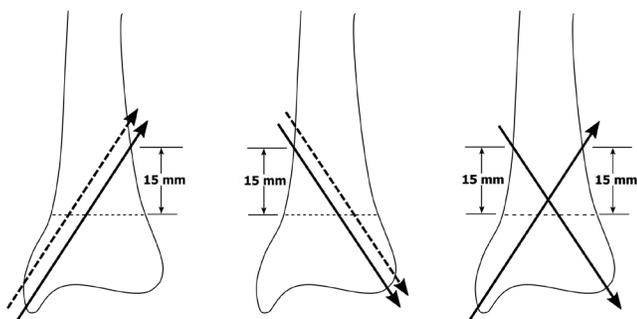


FIGURE 1. Kirschner-wire pin configurations. Left: parallel, retrograde pins entering medially through the medial malleolus and ending laterally, 15 mm proximal to the fracture site (group A). Middle: parallel, antegrade pins entering medially, centered 15 mm proximal to the fracture site, and ending at the fibular notch (group B). Right: cross-pin configuration with one retrograde pin entering through the medial malleolus and the second pin entering medially, 15 mm proximal to the fracture site and ending at the fibular notch (group C).

placed Kirschner wires across the fracture site has been reported to add adequate stabilization of unstable tibial fractures in children.⁵ Maintenance of alignment of the tibial shaft using this approach allows early mobilization and callus formation while minimizing infection risks.^{3,10,18} Percutaneous pinning is most appropriate for fractures that can be reduced by closed manipulation, such as simple, transverse fracture patterns.⁸ However, placement of percutaneous pins in the distal tibia can be difficult as a result of the need to avoid the tibiofibular and tibiotalar joints, muscular and tendinous structures, and other neurovascular structures.

The ideal percutaneous pinning technique would be relatively simple and achieve maximal stabilization without injuring surrounding structures. Stability and union can be affected by torsional and bending stresses, especially those resulting from external rotation of the leg during immobilization. In the present biomechanical study we compared three pin configurations used to enhance stabilization of transverse fractures at the diaphyseal-metaphyseal junction in the distal tibia. We aimed to identify a technique that allows for enhanced structural stability with limited potential for injury of the surrounding soft-tissue.

METHODS

Fifteen fourth-generation synthetic composite tibiae (Pacific Research Laboratories, Vashon Island, WA) were used in this study. Each specimen was predrilled with an undersized hole (2.38 mm; 3/32-inch bit) to prevent deviations in pin trajectories. A transverse cut was then made 25 mm from the distal articular surface to simulate a simple transverse fracture of the distal tibia. Cutting and drilling were done with a custom jig to maintain consistent fracture locations and pin trajectories among



FIGURE 2. Torsional testing construct for applying a fixed support at the distal end and a torsional moment at the proximal end.

the specimens in each group. Each fracture was reduced and fixed with two smooth 3.5 mm Kirschner wires placed in one of three pin configurations (Figure 1): (A), parallel, retrograde, medial to lateral pins entering at the medial malleolus distal to the fracture and ending laterally, 15 mm proximal to the fracture (group A; n=5), (B), parallel, antegrade, medial to lateral pins entering at the medial diaphysis centered 15 mm proximal to the fracture, and ending at the fibular notch (group B; n=5); or (C), a cross-pin configuration with one retrograde, medial to lateral pin entering the medial malleolus distal to the fracture and the second an antegrade, medial to lateral pin entering at the medial diaphysis 15 mm proximal to the fracture site and ending at the fibular notch (group C; n = 5).

Biomechanical testing was performed using an MTS 858 Mini Bionix II servohydraulic machine (MTS Systems, Eden Prairie, MN). The specimens were loaded sequentially for six tests: external rotation, internal rotation, anterior-directed bending (fracture apex pos-



FIGURE 3. Bending construct for applying a fixed support at the proximal end with a roller support 10 cm proximal to the fracture site and a force through the distal fragment.

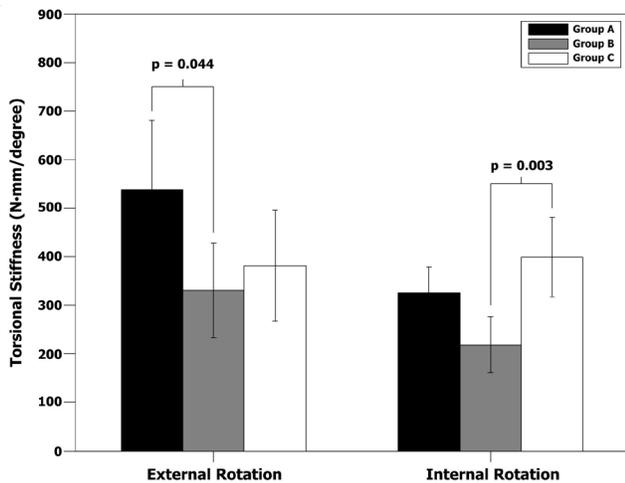


FIGURE 4. Torsional stiffness results for the 3 pin configurations in internal and external rotation. Error bars represent one standard deviation. In external rotation, the difference between Groups A and B was significant. In internal rotation, the difference between Groups B and C was significant.

terior), lateral-directed bending (fracture apex medial), posterior-directed bending (fracture apex anterior), and medial-directed bending (fracture apex lateral). For torsional loading, the tibia was rigidly attached to the actuator proximally and to an axial/torsional load cell distally (Figure 2). Each specimen was preloaded with 50 N in axial compression. Each specimen was then loaded from 0 to 5 N-mm in internal rotation at a rate of 0.5 N-mm/s, unloaded to zero, loaded to 5 N-mm in external rotation at a rate of 0.5 N-mm/s, and again unloaded to zero. This was repeated three times, and the stiffness was calculated from the linear region on the torque-rotation curve. The mean value of the three tests was used for comparisons between groups.

In each of the bending tests, the tibia was oriented perpendicular to the actuator in a simply supported cantilever configuration. The proximal end was fixed, and a roller support was placed 10 cm proximal to the

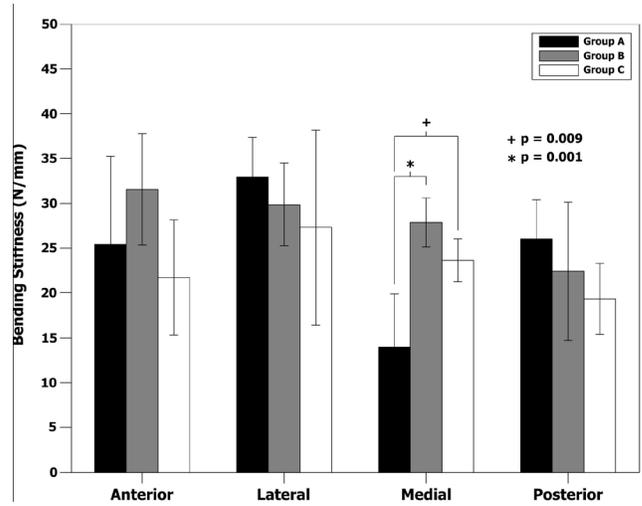


FIGURE 5. Bending stiffness results for the 3 pin configurations in 4 load directions. Error bars represent one standard deviation. Groups B and C had significantly more stiffness than Group A in the medial direction.

fracture line to concentrate the load directly through the distal fragment (Figure 3). The distal fragment was loaded to a maximum displacement of 4 mm at a rate of 0.5 mm/sec and unloaded. Each specimen was loaded sequentially three times, and then rotated 90 degrees, for each of the four bending directions. The mean value from the results of the three tests was used to compare the bending stiffness of the various pin configurations.

Statistical Analysis

One-way analysis of variance (ANOVA) was used to compare each of the 6 tests for each of the 3 pin configurations. The Tukey post-hoc test was used to determine which groups differed significantly from others. A *P* value of 0.05 was considered to represent a significant difference.

RESULTS

Torsional stiffness outcomes for external and internal rotation loads are shown in Figure 4. Group A had the highest mean value for torsional stiffness in external rotation (530 N-mm/degree). This was significantly higher than that for group B (330 N-mm/degree; *P* = 0.044). Group C had the highest mean value for torsional stiffness in internal rotation (400 N-mm/degree), and this was significantly higher than that for group B (220 N-mm/degree; *P* = 0.003). There was no statistical difference in torsional stiffness between groups A and C in external or internal rotation.

Bending stiffness outcomes for anterior-, lateral-, medial-, and posterior-directed bending loads are shown in Figure 5. There was little difference between groups in values for resistance to bending under an anterior-,

lateral-, or posterior-directed load. Under a medial-directed load, however, group B and C specimens were significantly stiffer than those in group A (28 N/mm and 24 N/mm vs. 14 N/mm for A; $P = 0.001$ and $P = 0.009$, respectively).

DISCUSSION

We conducted a biomechanical study to test the resistance to torsion and bending of three different pin configurations used to treat pediatric distal tibia fractures. We found that of three pin configurations studied, the group A configuration (parallel, retrograde, with pins entering medially through the medial malleolus and ending laterally, proximal to the fracture) provided the highest resistance to external rotation, but was not statistically different from group C. Resistance to bending was similar in group A to that of the other two configurations, except in the medial direction. Torsional stiffness in this orientation is clinically important because external rotation of the foot, possibly leading to rotational deformity, may occur in patients during immobilization.¹⁹ In addition, group A configuration may be easier and more safe to use than the other two configurations because penetration of muscles and other key structures may be avoided. Although cross pin configurations have been shown to provide more stability in clinical^{20,21} and biomechanical^{22,23} studies involving supracondylar fractures of the humerus, biomechanical²⁴ and clinical^{25,26} investigations have suggested that cross-pinning does not produce improved results in distal tibia fractures. We found that the cross-pin configuration (group C) is only slightly more stiff in internal rotation than group A.

This study has several limitations. Pediatric cadaver tibias are difficult to obtain thus requiring the need for a suitable synthetic model. The fourth-generation synthetic composites used have been found to accurately replicate the torsional, axial compressive, and bending characteristics of natural bone.²⁷⁻³⁰ Additionally, we tested only an isolated tibia fracture; thus, the contribution to bending stiffness and torsional stability of an intact fibula was not included in our assessment. In a previous study, Thambayah and Pereira assessed the role of the fibula in the torsional stability of the lower extremity and found that a fractured fibula resulted in a 5% loss in torsional stiffness and a completely removed fibula resulted in an 11% loss in stiffness.³¹ Thus, although the fibula provides some torsional stability, the tibia alone is still responsible for 90% of the rotational stiffness of the lower limb. This said, the presence of the fibula (both fractured and intact) should be considered in future work, since an intact fibula can present difficulty in successful reduction of tibial fractures and have been shown to induce varus deformity if remaining intact.^{6,32} In this study, a

transverse fracture at the diaphyseal-metaphyseal junction was chosen as a model for evaluating the different configurations. Although a slightly less common fracture pattern among tibia fractures, in our experience this particular pattern can be more unstable and challenging to treat with a cast alone, often requiring supplemental percutaneous pinning to maintain reduction of displaced fractures. Thus, this fracture type was chosen as the mode of failure in which to test the different percutaneous pinning techniques. Furthermore, in order to standardize the methodology, holes were predrilled in the femurs prior to pin placement to prevent deviations in pin trajectory. This is not clinically feasible and may influence stiffness outcomes. Finally, because the bending and torsional tests were conducted on the same specimen, weakening of the models may have occurred. However, because all stiffness testing was maintained within the elastic range of the specimens, it is unlikely that any permanent deformation occurred.

In conclusion, this study demonstrated that two, parallel, retrograde, medial to lateral directed pins provide improved stability to a simple, transverse distal tibia fracture when exposed to external rotation forces. External rotation is the most common stress experienced during short-leg casting of the tibia due to the weight of the cast and tendency for external rotation of the foot. Crossed pinning is the most common configuration currently used but when doing so it is difficult to place the lateral pin and does interfere with placing the ankle in neutral position. Our study has shown adequate stability provided by the parallel retrograde pins initiating at the medial malleolus. It is less technically demanding, requires fewer intraoperative radiographs, and minimizes the risk of iatrogenic injury to surrounding structures.

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PEDIATRIC STRESS FRACTURES: A PICTORIAL ESSAY

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ABSTRACT

More children are participating in organized and recreational athletics at a younger age. It has been well documented that increased athletic specialization and year-round activities have resulted in higher incidences of overuse injuries, including stress fractures and stress reactions. Initially, stress fractures can be radiographically occult. Continued stress on the injured bone or cartilage can lead to progressive radiographic changes. Because of the prevalence of these injuries, both orthopedic surgeons and radiologists should be aware of the radiographic and magnetic resonance imaging (MRI) features of common stress fractures in children. This article reviews frequently encountered stress fractures involving various bones in the pediatric population.

INTRODUCTION

A recent increase in the number of children participating in competitive sports has resulted in an increase in stress injuries¹. These stress injuries can be difficult to diagnose. In young children, the clinical examination is often difficult given the inability of children to provide detailed histories or fully participate in the physical exam. Detection of the hallmark features of common stress injuries on both radiographs and MRI can aid in the diagnosis.

Stress fractures are the result of repetitive forces on the musculoskeletal system that has not had sufficient time to recover². In children, factors such as weaker osteochondral junctions, thinner cortices, hormonal changes, and decreased mineralization predispose to stress fractures^{3,4}. This is further compounded by participation in sports with demanding schedules which may not allow adequate time for the child to recover. The physis and the apophysis, which are among the weaker

parts of the musculoskeletal system in children, are common sites for stress fractures. Abnormal stresses at these sites may result in disruption of endochondral ossification, ultimately resulting in physeal widening⁵. Repetitive microtrauma also leads to bony cortical defects and stress fractures, which can be in the form of fatigue fractures (excessive forces on normal bone) or insufficiency fractures (normal forces on abnormal bone)². This article reviews the classic radiographic and MR findings of common stress fractures in children.

Spine: Spondylolysis

Spondylolysis is a stress fracture which occurs through the pars interarticularis, and occasionally through the pedicle. It is the result of repeated bouts of extension and rotation about the spine⁶. It has been observed with higher frequency not only in young athletes, but



Figure 1. 13-year-old basketball player complaining of low back pain. (A) Axial T1 image demonstrates transversely oriented low signal (arrow) through the L5 pedicle and pars. (B) Axial T2 image demonstrates corresponding edema (arrow), confirmed on sagittal T1 (C) and STIR (D) sequences (arrows). Findings are consistent with unilateral stress fracture through the left pars interarticularis.

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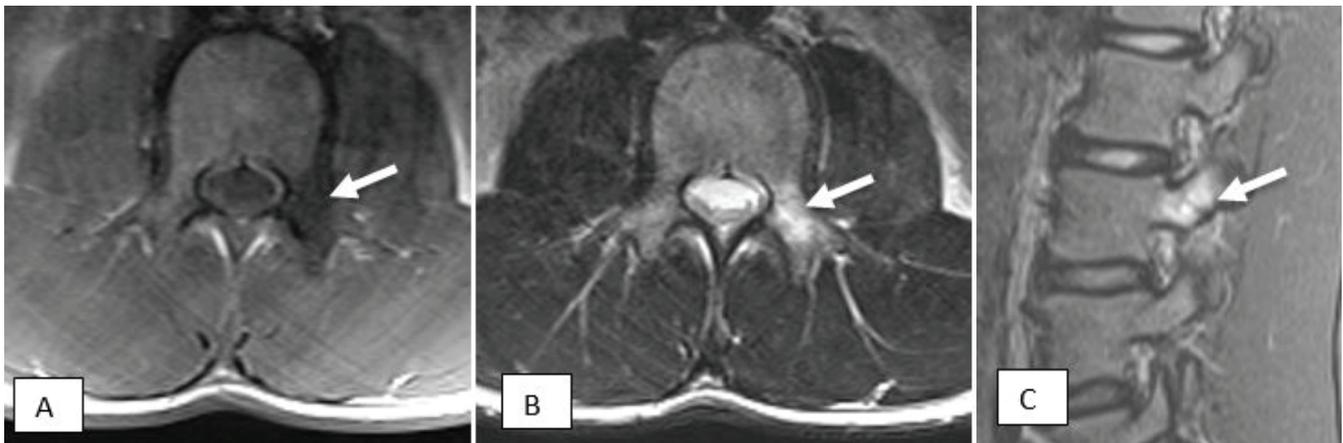


Figure 2. 16-year-old baseball pitcher with recent onset of low back pain. (A) Axial T1, (B) T2 and (C) sagittal STIR images demonstrates bone marrow edema (arrows) in the left L3 pedicle, consistent with non-displaced stress fracture.

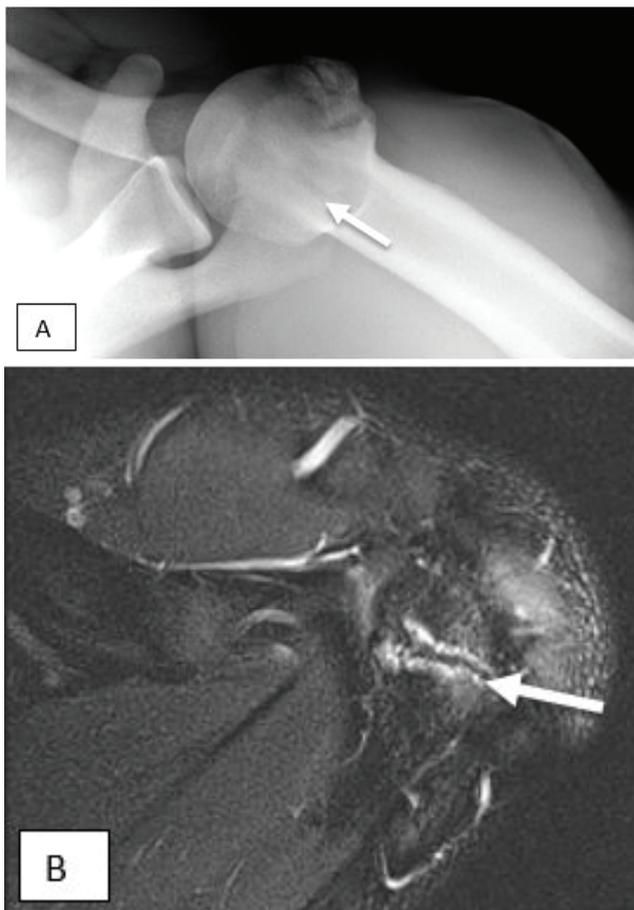


Figure 3. Collegiate American football player with shoulder pain and known lesser tuberosity avulsion. (A) Axillary shoulder radiograph performed to follow up lesser tuberosity avulsion demonstrates an unfused apophysis (arrow) at the acromion. (B) Follow up MRI demonstrates edema at the apophysis (arrow), consistent with acromial apophysiylolysis.

in certain populations that require repetitive flexion and extension of their spine, such as the Eskimos^{7,8}. Lower back pain in the young patient should prompt a search for spondylolysis⁷. Conventional computed tomography (CT), MRI, and single photon emission computed tomography (SPECT) are all acceptable diagnostic modalities. CT is superior to MRI in the detection of spondylolysis, but involves the use of ionizing radiation. SPECT can help confirm the diagnosis in cases which are indeterminate on MRI^{9,10}. Typical MRI findings include low signal on T1 and increased signal on T2 or STIR sequences at the pars interarticularis and/or pedicle (Figures 1 & 2).

Shoulder

Acromial Apophysiylolysis/Os Acromiale

One to four ossification centers are seen at the acromion by 15-18 years of age. From anterior to posterior, these ossification centers are the pre-acromion, the meso-acromion, the meta-acromion, and the basi-acromion. Failure of fusion of the acromion in the background of chronic repetitive traction forces from the deltoid has been termed acromial apophysiylolysis¹¹. Without healing, this may progress to an os acromiale, which can in turn lead to impingement symptoms in the shoulder. Patients typically present with chronic shoulder pain of insidious onset. In younger patients, differentiating between an os acromiale and normal apophyseal development can be challenging, as the age range of acromial fusion can vary from 18 – 25¹². However, irregular cortical margins and abnormal marrow signal with adjacent bony edema favors the diagnosis of acromial apophysiylolysis¹³ (Figure 3).

Little Leaguer's Shoulder

“Little leaguer’s shoulder” is a term used to describe injury to the proximal humeral physis typically caused by repetitive overhead throwing. It is often observed in

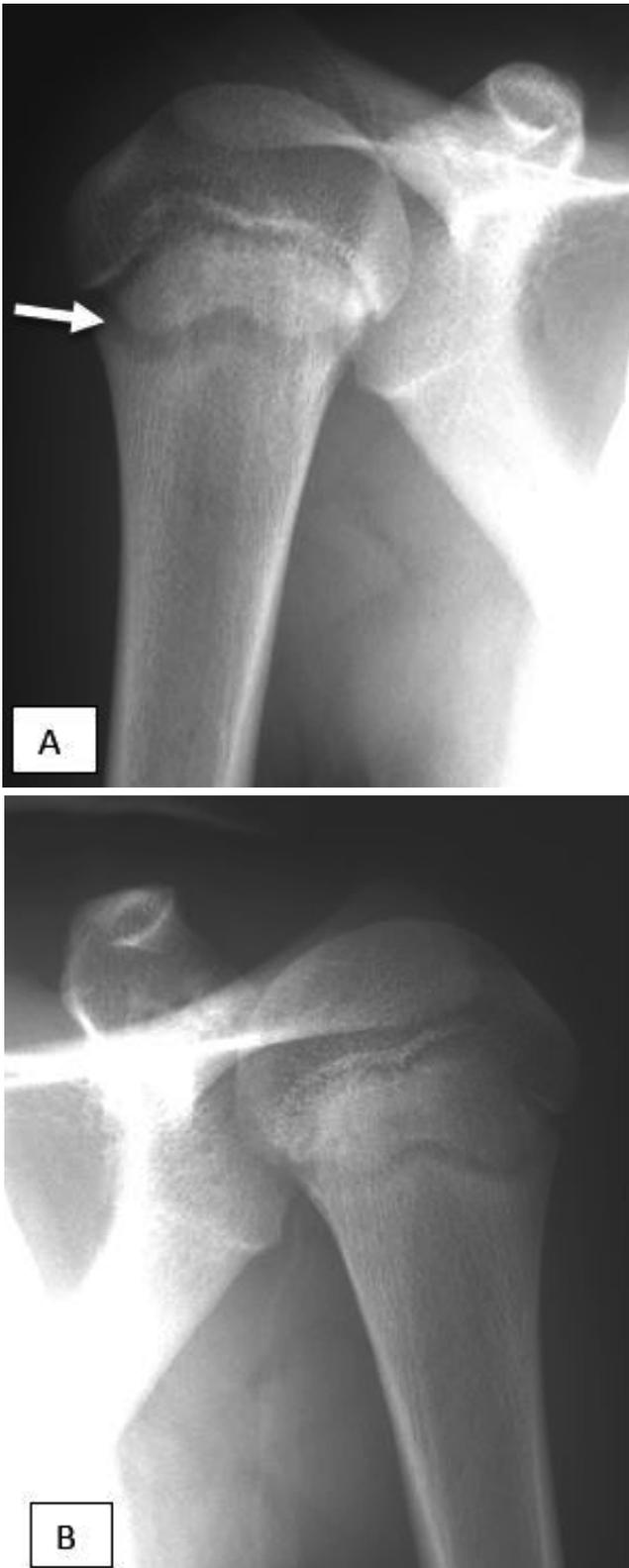


Figure 4. 13-year-old baseball pitcher. AP radiograph of the (A) right shoulder shows diffuse widening of the right proximal humeral physis (arrow). (B) For comparison, the left shoulder demonstrates normal width of the physis.

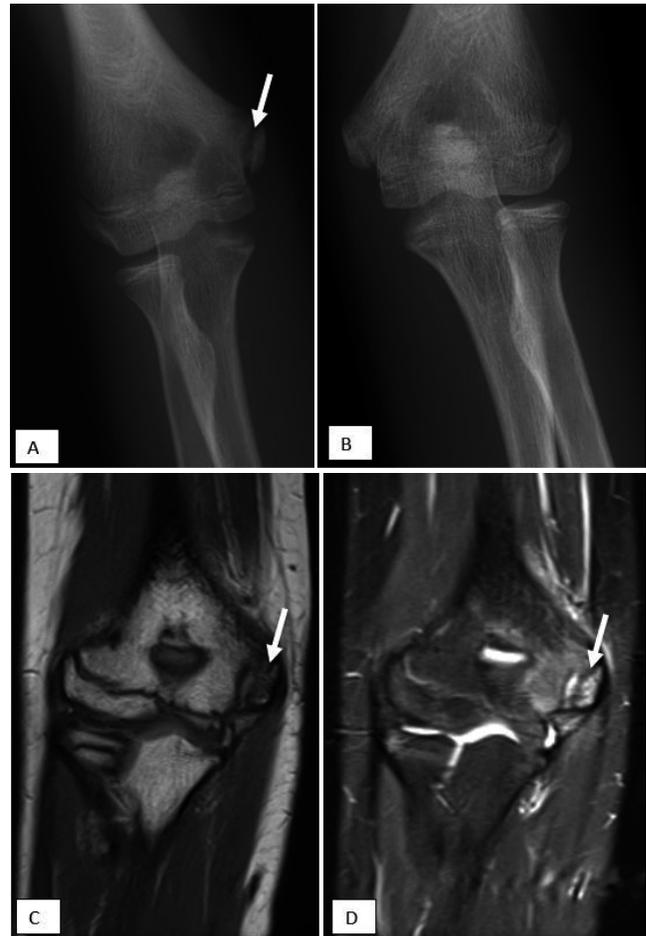


Figure 5. 14-year-old baseball pitcher with medial elbow pain for 1 month duration. (A) AP radiograph demonstrates asymmetric widening of the right medial epicondyle physis (arrow). (B) The left elbow, submitted for comparison, is unremarkable. (C,D) MRI performed the following day demonstrates edema within the medial condyle epiphysis (arrow) and the adjacent metaphysis of the humerus. The ulnar collateral ligament (not fully shown) was intact.

male baseball pitchers between the ages of 11 and 16 in whom the excessive rotational forces of overhead throwing lead to physeal injury¹⁴. Patients tend to present with focal pain over the anterolateral shoulder that is worse with overhead throwing. Radiographs demonstrate physeal widening and irregularity¹⁵ (Figure 4). MR findings include similar findings of widening of the physis, along with marrow edema on fluid sensitive sequences¹⁶.

Elbow: Little Leaguer's Elbow

“Little Leaguer’s elbow” is a term used to describe injury to the medial epicondylar apophysis¹⁷. Patients are usually young adolescent pitchers or catchers presenting with medial elbow pain either with direct palpation or valgus stress to the elbow. Children can present with mild flexion contracture at the elbow secondary to pain¹⁷. While generally the physical examination is sufficient

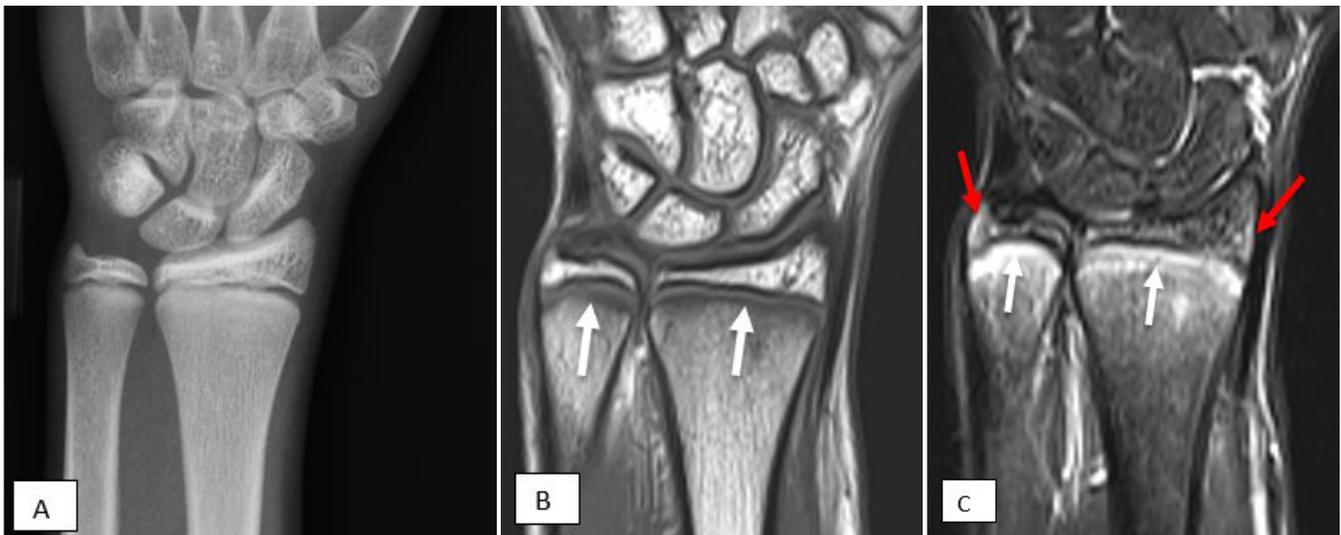


Figure 6. 11-year-old gymnast just days away from a championship meet, with ongoing wrist pain. (A) AP radiograph of the wrist is essentially unremarkable. Specifically, there is no evidence of physal widening, irregularity, or fraying. (B, C) T1 and T2FS coronal MRI images demonstrate marrow edema through the distal metaphyses of the radius and ulna (white arrows), and to a lesser extent, the radial and ulnar styloids (red arrows).

for making the diagnosis, radiographs demonstrate widening or fragmentation of the apophysis (Figure 5). The contralateral asymptomatic elbow can be used for reference in determining physal widening. MRI demonstrates marrow edema and aids in determining the integrity of the common flexor tendon and ulnar collateral ligament¹⁸.

Wrist: Gymnast’s Wrist

Gymnasts frequently start intense training at a young age, when repetitive stress on the upper extremities can lead to physal injury. Mechanical forces of dorsiflexion and compression triggers physal injury at the distal radius¹⁹. Similar forces can lead to the same injury in weight lifters. Analogous to Little Leaguer’s shoulder, radiographs can demonstrate widening and fraying or irregularity of the physis, while MRI demonstrates edema through the metaphysis (Figure 6). Severe or chronic

disease can lead to premature fusion and positive ulnar variance, TFCC injury, and scapholunate or lunotriquetral ligament disruption¹⁹.

Pelvis

Sacral Stress Fractures

Sacral stress fractures are known to have a higher incidence in female athletes, particularly in runners²¹. The female athlete triad describes the relationship between caloric imbalance, hormonal dysregulation, and impaired bone health²². The injury, therefore, has components of both a fatigue and insufficiency fracture. Radiographs are often normal, while MRI demonstrates linear low signal intensity on T1 images with corresponding edema (Figure 7). In endurance athletes, similar findings of a stress fracture can be seen in the inferior pubic rami²³ (Figure 8).

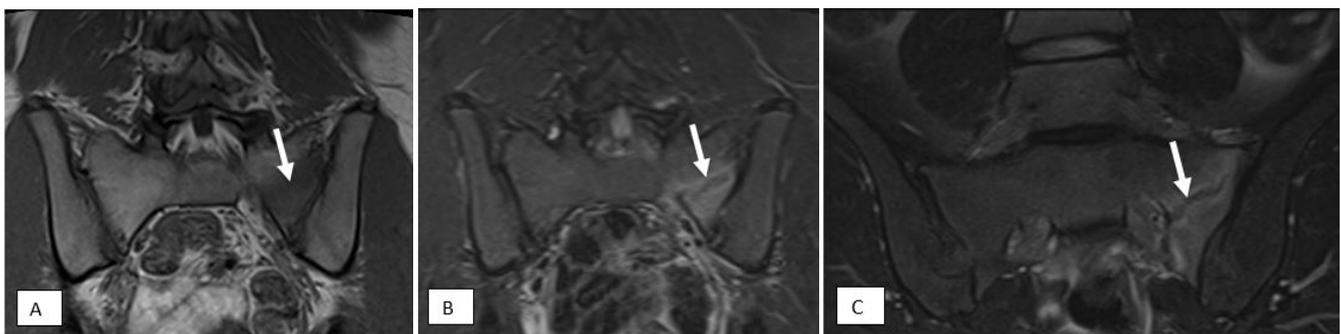


Figure 7. 18-year-old female cross country runner with gradually worsening low back pain. (A) Coronal T1, (B) coronal STIR, and (C) oblique coronal T2 fat saturated images demonstrate a stress fracture of the left sacral ala extending to the sacral foramen.

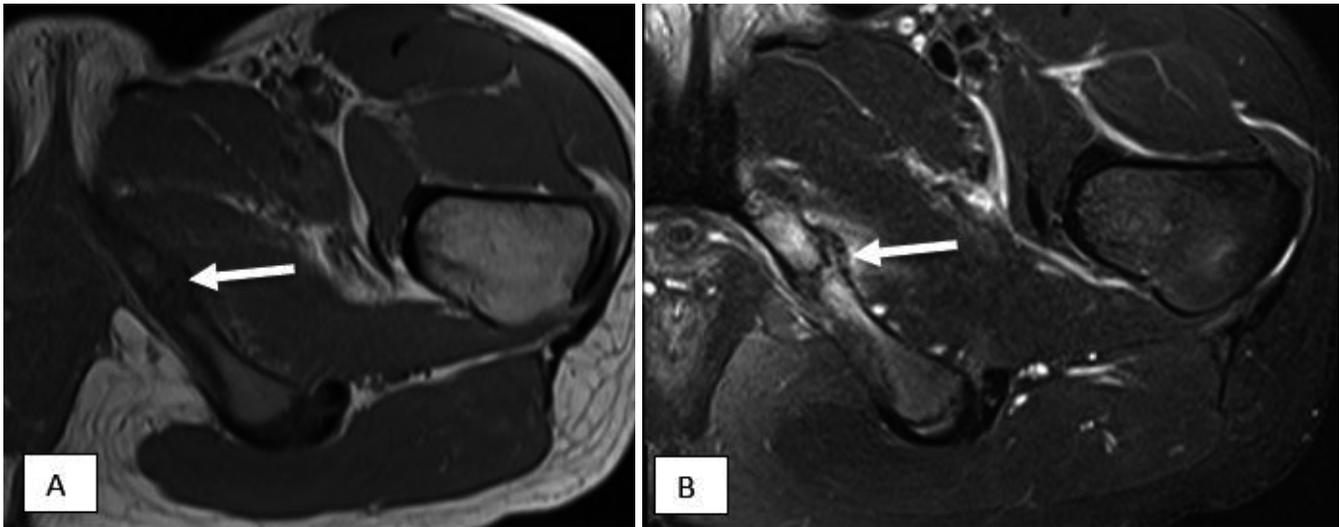


Figure 8. 15-year-old female cross country runner with pubic pain, referred for MRI to “rule out sports hernia.” (A) Axial T1 and (B) T2FS images demonstrate a healing fracture (arrows) through the left inferior pubic ramus. This was radiographically occult.

Pelvic Apophyseal Injury

Traction apophysitis in the pelvis is a commonly recognized overuse injury in children. When chronic, children can present with dull pelvic or hip pain. This injury is more frequently found in athletes involved in twisting activity resulting in traction on the apophyses, such as dancers, runners, football and lacrosse players. The most common sites of injury include the anterior superior iliac spine (origin of the sartorius and tensor fasciae lata), the anterior inferior iliac spine (origin of the rectus femoris), and the ischial tuberosity (origin of the hamstrings)²⁴. Radiographs can demonstrate a spectrum of findings from cortical irregularity to frank avulsion of bone. MRI most typically demonstrates marrow edema and variable signal intensity in the corresponding tendons, depending on the extent of their injury (Figure 9).

Femur: Stress Fracture

Femoral stress fractures are relatively rare in comparison to stress fractures of the tibia, fibula, and foot²⁵. Stress fractures of the femur result from repetitive loading, and are most common in endurance runners, jumpers, and dancers. Repetitive loading results in subperiosteal bone resorption and microfractures which are not given sufficient time to heal. Femoral stress fractures can present with pain at the groin, hip, or knee, and are typically aggravated by activity. While the most common site of fracture is the femoral neck, fractures can occur anywhere along the femoral diaphysis (24). While lacking in sensitivity early in the disease, radiographs will classically show linear sclerosis, periosteal elevation, and cortical thickening, consistent with a protracted healing response. MRI reveals the problem earlier, showing linear low signal intensity on T1 sequences and corre-

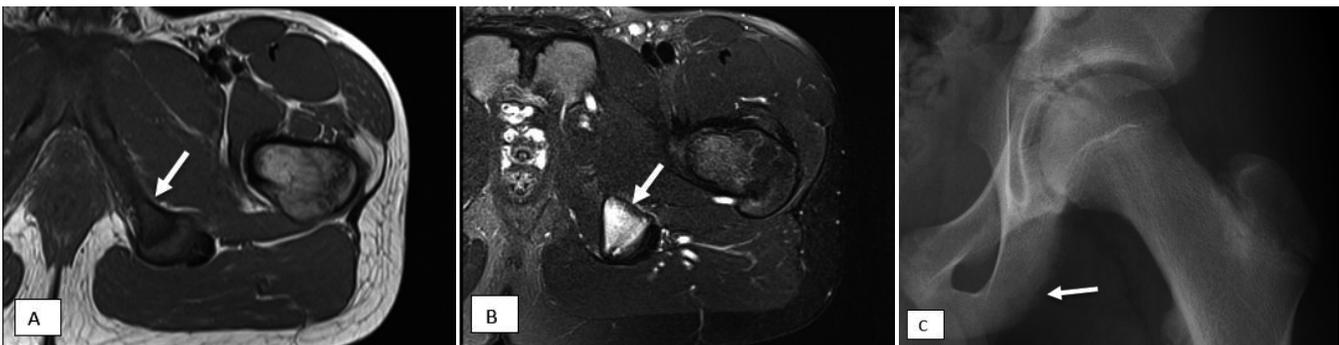


Figure 9. 13-year-old baseball player (shortstop) with gradually worsening groin pain. (A) Axial T1 and (B) axial T2FS images demonstrate bone marrow edema at the left ischial tuberosity (arrows). The hamstring tendons appeared normal. (C) Retrospective review of the radiograph shows subtle cortical irregularity along the lateral aspect of the left ischium (arrow).

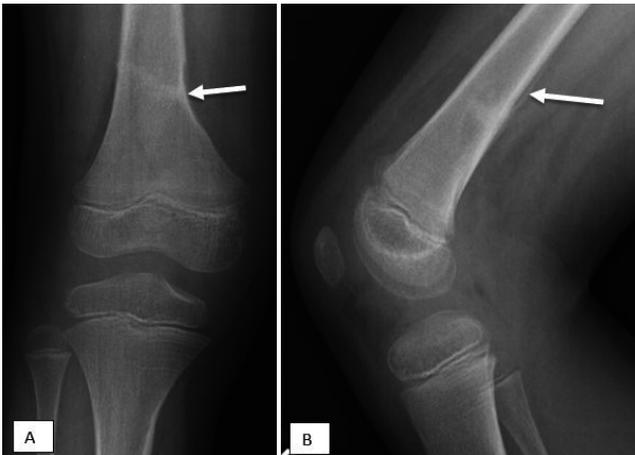


Figure 10. 9-year-old boy with history of renal transplant on chronic immunosuppressive therapy presenting with thigh pain. (A, B) Frontal and lateral radiographs demonstrate a linear band of sclerosis (arrow in A) through the distal femoral metaphysis and periosteal reaction (arrow in B), consistent with healing stress fracture. Incidental note is made of fracture progression through a non-ossifying fibroma along the medial cortex.



Figure 11. 16-year-old female runner with prior history of pelvic stress fracture, now complaining of tibial pain. Sagittal STIR image demonstrates edema at the insertion of the patellar ligament (arrow), consistent with active Osgood Schlatter disease. There is mild pre-tibial edema in the soft tissues anterior to the tuberosity. There is minimally increased signal within the ligament itself.



Figure 12. 3-year-old girl with a limp. Lateral radiograph demonstrates an area of uninterrupted periosteal reaction along the posteromedial aspect of the left tibia at the middle third of the tibia, consistent with stress fracture.

Table I. Fredericson MRI Classification System for Tibial Stress Injury

Grade	MR Findings
0	Normal
1	Periosteal edema only
2	Periosteal edema and bone marrow edema (on T2 only)
3	Periosteal edema and bone marrow edema (on T1 and T2)
4a	Multiple foci of intracortical signal abnormality and bone marrow edema on both T1 and T2
4b	Linear areas of signal abnormality on both T1 and T2



Figure 13. Two different patients. The patient in (A) is a 12-year-old-girl who had been immobilized following a Lisfranc injury. The second patient in (B) is a 12-year-old girl who had been immobilized following medial cuneiform osteotomy. (A) Lateral radiograph demonstrates a vertically oriented sclerotic line in the calcaneal tuberosity (arrow). (B) AP radiograph demonstrates periosteal reaction (arrow) surrounding the second metatarsal, consistent with stress fracture.

sponding edema on fluid sensitive images (Figure 10). Subperiosteal fluid, when present, is a useful finding to confirm the diagnosis³.

Tibia/Fibula

Osgood-Schlatter Disease

Osgood-Schlatter is one of the most common causes of anterior knee pain in young athletes, caused by repetitive microtrauma and subsequent traction apophysitis of the tibial tuberosity. It is commonly seen in 12-15 year old boys or 8-12 year old girls who participate in jumping activities²⁴. Patients present with anterior knee pain and swelling. Physical examination is usually diagnostic, with radiographs demonstrating soft tissue edema overlying the anterior tibial tuberosity, and some degree of fragmentation and irregularity of the tibial tubercle. MRI demonstrates edema in the tibial tuberosity and distal patellar tendon. Hoffa’s fat pad may also show increased signal on fluid sensitive sequences (Figure 11).

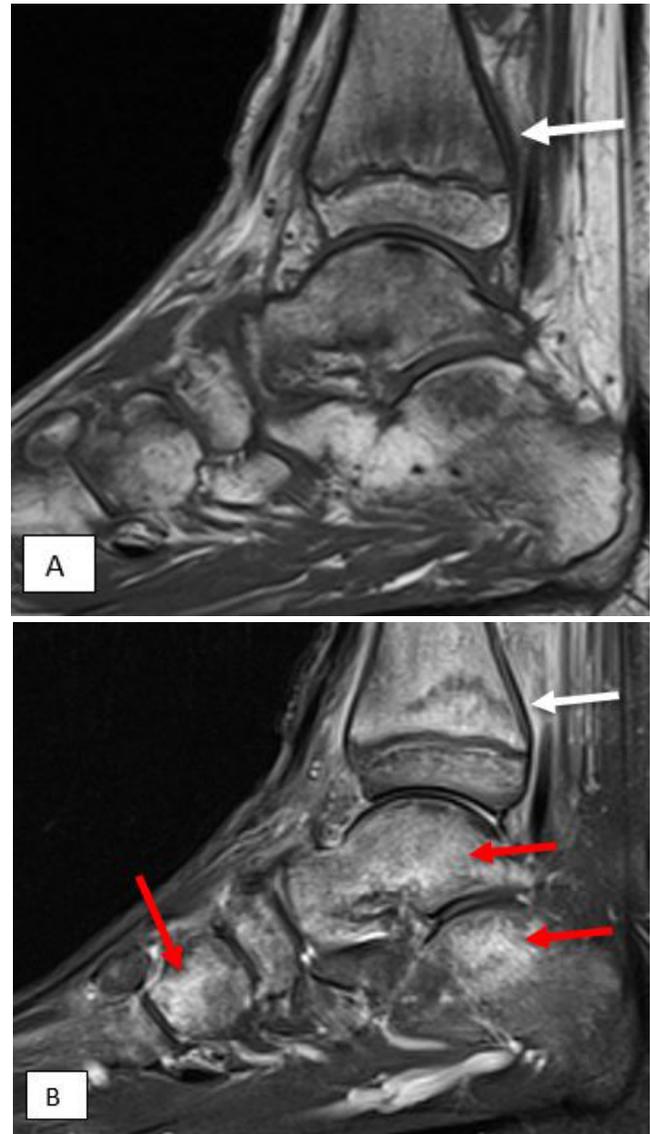


Figure 14. 14-year-old boy involved in multiple sports presents with worsening ankle pain. (A) Sagittal T1 and (B) T2FS images of the ankle demonstrate linear signal abnormality in the distal tibia consistent with stress fracture (white arrow). Multiple additional areas of signal abnormality (red arrows) are also consistent with stress reaction.

Diaphyseal Stress Fracture

A common site for stress fractures in adolescents is the tibia, followed by the fibula²⁵. They are commonly found in children participating in football, soccer, tennis, and running. Radiographs demonstrate cortical irregularity and periosteal reaction, typically along the posteromedial proximal third of the tibial shaft (Figure 12). MRI can be useful in equivocal cases. The Fredericson classification system classifies MR findings for tibial stress injury, with grades 1-3 deemed as “stress response” and grade 4 as “stress fracture”²⁶ (Table I).

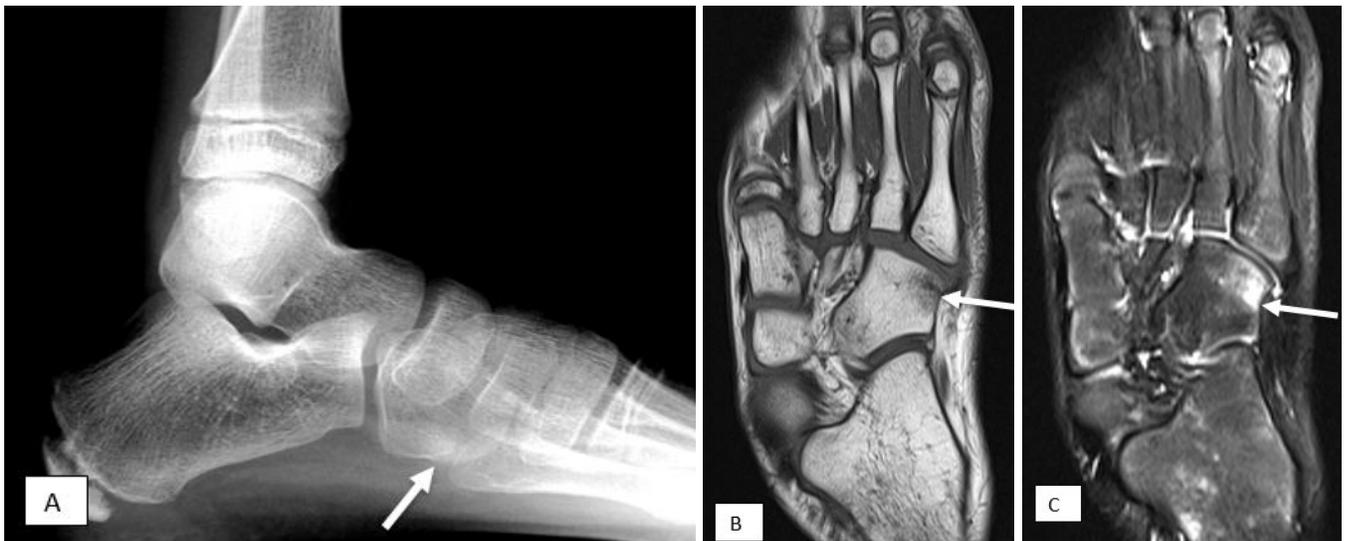


Figure 15. 8-year-old girl with foot pain and a limp. (A) Lateral radiograph demonstrates subtle sclerosis in the cuboid (arrow). (B) Follow up MRI demonstrates a linear low T1 signal intensity focus (arrow) through the lateral aspect of the cuboid with (C) corresponding edema on T2 (arrow), consistent with stress fracture.

Ankle and Foot

In children, the most common sites of stress fractures in the foot are the metatarsals and calcaneus, followed by the cuboid, talus, and navicular²⁷. It has been postulated that following lower extremity immobilization for conventional traumatic fractures, the child is more susceptible to subsequent stress fracture distally in the ipsilateral extremity²⁷. At our institution, a ten year informal review of lower extremity fractures in children who were previously immobilized for other fractures yielded several cases of stress fractures (Figure 13). Radiographic findings of sclerosis and marrow edema are equivalent to stress fractures at other sites (Figure 14, 15).

CONCLUSIONS

With the increasing number of children participating in sports, it is important for orthopedists and radiologists to be aware of the radiographic and MRI findings associated with common overuse injuries. Familiarity with these findings leads to prompt diagnosis and helps prevent future disability.

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RELIABILITY OF A SURGEON-REPORTED MORBIDITY AND MORTALITY DATABASE: A COMPARISON OF SHORT-TERM MORBIDITY BETWEEN THE SCOLIOSIS RESEARCH SOCIETY AND NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM DATABASES

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ABSTRACT

Background: There exists a lack of comparison between large national healthcare databases reporting surgical morbidity and mortality. Prior authors have expressed concern that the Scoliosis Research Society (SRS) membership may have underreported complications in spinal surgery. Thus, the purpose of the present study was to compare the incidence of morbidity between the SRS and National Surgical Quality Improvement Program (NSQIP) databases.

Methods: We reviewed patients enrolled between 2012 and 2013, with a total of 96,875 patients identified in the SRS dataset and 15,909 in the combined adult and pediatric NSQIP dataset. Patients were matched based on diagnostic category,

and a univariate analysis was used to compare reported complication rates in the categories of perioperative infection, neurologic injury, and mortality. The SRS database only requires detailed demographic data reporting on patients that have had a complication event. We compared the demographics and comorbidities of this subgroup, and used this as a surrogate to assess the potential magnitude of confounders.

Results: Small differences existed between the SRS and NSQIP databases in terms of mortality (0.1% v. 0.2%), infection (1.2% v. 2%), and neurologic injury (0.8% v. 0.1%) ($p < 0.001$ for each comparison). Infection rates were consistently lower across multiple diagnostic sub-categories in the SRS database, whereas neurologic injury rates were consistently lower in the NSQIP database. These differences reached statistical significance across several diagnostic subcategories, but the clinical magnitude of the differences was small. Amongst the patients with a complication, modest differences in comorbidities existed between the two cohorts.

Conclusion: Overall, the incidence of short-term morbidity and mortality was similar between the two databases. There were modest differences in comorbidities, which may explain the small differences observed in morbidity. Concerns regarding possible under-reporting of morbidity and mortality data by the SRS membership seem largely unfounded. This study may be useful for future investigators using the NSQIP and SRS datasets.

INTRODUCTION

A key feature of membership in the Scoliosis Research Society (SRS) is the voluntary self-reporting of perioperative morbidity and mortality (M&M) data. Thousands of cases have been registered, and the database is the largest known repository of short-term M&M outcomes for spinal deformity patients. Multiple reports have summarized the data across several diagnoses and complication types.¹⁻¹⁸ These reports have served to benchmark surgeon and institution performance, and have proven useful for surgical planning and patient counseling

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Table I. Definition of Included Morbidities

Patient Death	The SRS defines patient death, as “death that is attributable to a complication of the surgery, or during the surgery.” NSQIP defines patient death as, “any mortality within 30-days of the operation.”
Wound Complication	NSQIP includes four categories of wound complications, including superficial surgical site infection, deep surgical site infection, organ space infection, and wound dehiscence, each within 30-days of the operation. In contrast, the SRS dataset includes only a single category titled “acute infections that occur at the operative site up to 12 weeks from the date of surgery.” The three types of infection from the NSQIP dataset were combined into a single “NSQIP wound complication” category for the purpose of comparison. Wound dehiscence was not included.
Neurologic Deficit	NSQIP contains a category for post-operative neurologic injury, which is defined as an, “injury to the nerve fibers, nerve cell body, or myelin sheath during surgery.” This category was compared against the SRS category termed, “new neurologic deficit.”
Blindness	NSQIP does not record post-operative blindness, and thus this morbidity was not included in our analysis.

perioperatively. In spite of these strengths, the dataset does have several limitations. In particular, the M&M reporting is voluntary, and relies on the honesty of the membership. External validation of the reported complication rates is limited,¹⁹ and prior authors have speculated that some complications are underreported.¹ Thus, external validation is warranted.

The purpose of the current study is to compare the incidence of complications from the SRS M&M database against the incidence reported to the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP). The ACS NSQIP prospectively collects morbidity and mortality data from adult cases at over 500 hospitals across the United States, and for pediatric cases from 60 hospitals. Data collection is performed by trained on-site personnel, who prospectively review operative notes, postoperative progress and clinic notes while remaining in direct contact with the surgical team for clarification when necessary. Thus, the NSQIP database is a suitable source of independently collected M&M data with which to compare the SRS dataset. The results should serve to help validate the accuracy of voluntary member reporting to the SRS, and may be useful for future researchers using the two databases.

METHODS

Description of Datasets

This study was Health Insurance Probability and Accountability Act (HIPAA) compliant and received an Institutional Review Board (IRB) exemption. The adult NSQIP database is a prospectively collected clinical registry, with over 500 participating hospitals from around the United States, and with a roughly equal mix of private and academic institutions. Each participating hospital employs a surgical clinical reviewer (SCR) who is responsible for collecting patient data for 30-days post-operatively. The SCR reviews operative notes, progress notes, post-operative clinical visits, and if clarification is needed, directly contacts the surgical team. Patients who do not return for clinical follow-up within 30-days are

contacted via telephone, and in this way, both inpatient and outpatient complications that occur after discharge are captured. Over 200 data-points are collected, with the detailed description of the methodology available from the ACS.²⁰ The dataset is routinely audited, with interobserver disagreement rates less than 2%,²¹ and its use has been widely accepted in the orthopedic literature.²²⁻²⁹ The pediatric NSQIP database has similar collection methods, and enrolls patients less than 18 years of age. As of 2013, 60 hospitals participated in pediatric enrollment. There are a small number of variables unique to the pediatric NSQIP, and a full description of the methodology is available from the ACS.³⁰

The SRS M&M dataset consists of voluntary data entry from participating surgeon members of the SRS. Each year, the SRS requests that surgeons report their morbidities using an online entry system. The included patients are limited to those with a diagnosis of idiopathic scoliosis, congenital scoliosis, neuromuscular scoliosis, other scoliosis, spondylolisthesis, congenital kyphosis, Scheuermann’s kyphosis, or other kyphosis, as diagnosed by the surgeon. Surgeons are asked to retrospectively report their total number of cases for the year, and also the number of each type of case with a complication. For patients that sustained a complication, detailed demographic and comorbidity data is then requested. However, for patients without a complication, no additional information is entered. Thus, demographic and comorbidity information is available only for a small subset of the total cohort.

Since its initial conception, the SRS database has evolved considerably, and current iterations have focused on the collection of data pertaining only to major perioperative events, including blindness, death, neurologic injury, and wound complications. The simplified collection system has been found to have higher member compliance, with similar reported complication rates.⁹ Post-operative blindness is not reported in NSQIP, but the other three outcomes are indeed captured. Since blindness is a rare perioperative event, a comparison of the two datasets in terms of mortality, wound complica-

Table II. Un-Adjusted Comparison of The Incidence of Perioperative Morbidity and Mortality

	SRS Dataset			NSQIP Dataset			
Mortality							
Diagnosis	Cases (#)	Deaths (#)	%	Cases (#)	Deaths (#)	%	p value
Idiopathic Scoliosis							
<18 yrs	22980	3	0.01	1618	1	0.06	0.24
≥18yrs	8544	6	0.1	529	4	0.8	0.002
Congenital Scoliosis	5238	6	0.1	192	0	0	1
Neuromuscular Scoliosis	7373	11	0.2	58	0	0	1
Other Scoliosis	11442	26	0.2	479	2	0.4	0.31
Spondylolisthesis	31178	13	0.04	11012	23	0.2	<0.0001
Kyphosis	10102	33	0.3	192	2	1.0	0.14
Totals	96875	98	0.10	14080	32	0.23	<0.0001
Infection							
Diagnosis	Cases (#)	Infections (#)	%	Cases (#)	Infections (#)	%	p value
Idiopathic Scoliosis							
<18 yrs	22980	138	0.6	1618	22	1.4	0.001
≥18yrs	8544	83	1.0	529	16	3.0	0.0002
Congenital Scoliosis	5238	41	0.8	192	5	2.6	0.007
Neuromuscular Scoliosis	7373	256	3.5	58	2	3.5	1
Other Scoliosis	11442	178	1.6	479	11	2.3	0.2
Spondylolisthesis	31178	304	1.0	11012	196	1.8	<0.0001
Kyphosis	10102	172	1.7	192	8	4.2	0.01
Totals	96875	1172	1.2	14080	260	1.9	<0.0001
Neurologic Injury							
Diagnosis	Cases (#)	Neurologic Injuries (#)	%	Cases (#)	Neurologic Injuries (#)	%	p value
Idiopathic Scoliosis							
<18 yrs	22980	73	0.3	1618	6	0.4	0.71
≥18yrs	8544	68	0.8	529	0	0	0.03
Congenital Scoliosis	5238	63	1.2	192	0	0	0.17
Neuromuscular Scoliosis	7373	47	0.6	58	0	0	1
Other Scoliosis	11442	140	1.2	479	2	0.4	0.13
Spondylolisthesis	31178	224	0.7	11012	2	0.02	<0.0001
Kyphosis	10102	153	1.5	192	1	0.5	0.37
Totals	96875	768	0.8	14080	11	0.08	<0.0001

tion, and neurologic injury was felt to provide a reasonable assessment of the accuracy.

The definition and recorded timing of complications between the NSQIP and SRS datasets are not identical. Thus, for the purpose of comparison, some of the NSQIP complications types were combined into a single category (Table I).

All ages are captured in the SRS dataset. However, NSQIP did not begin enrolling pediatric cases until 2012. Thus, we chose to retrospectively query the NSQIP and SRS datasets for the years 2012-2013, which included all of the years with available data for both adult and pediatric cases. The NSQIP dataset was queried using CPT codes to identify cases of thoracolumbar spinal fusion and international classification of disease, 9th edition (ICD-9) codes to verify the patient diagnosis. No ages were excluded,

and all cases in the included diagnostic categories were included. A full listing of the included codes and inclusion criteria is available in the appendix (Appendix Table I).

Statistical Analysis

We performed two separate statistical analyses. First, the incidence of each reported complication from the SRS M&M dataset was summarized and then compared against the incidence reported to the ACS NSQIP in a univariate analysis. Where possible, we attempted to compare pediatric and adult cases separately (defined as greater or less than 18 years of age). This was possible for patients with a diagnosis of idiopathic scoliosis because the SRS reporting requires ages for that diagnosis. However, for each of the other categories the SRS reporting does not require age information unless the patient

Table III. Univariate Comparison of Demographics and Comorbidities Amongst Patients Who Sustained a Complication

	SRS Dataset (n=2295)	NSQIP Dataset (n=364)	P Value
Age (mean, sd)	44.49(25.63)	47.39(25.45)	0.0453
Gender (%)			0.0328
Female	63.8	58.0	
Male	36.2	42.0	
ASA Grade (%)			<0.0001
1	34.0	2.5	
2	31.9	39.0	
3	29.9	53.6	
4	4.1	5.0	
5	0.1	0	
BMI (mean, sd)	26.0(7.1)	30.4(10.3)	<0.0001
Diabetic (%)	16.6	7.4	<0.0001
Smoker (%)	8.5	13.2	<0.0001
Hypertension (%)	35.5	43.7	<0.0001
Peripheral Vascular Disease (%)	8.7	0	<0.0001
History of Cancer (%)	5.1	0.3	<0.0001
Operative Time			0.529
<2 hrs	17.8	19.8	
2-6 hrs	54.7	54.4	
6-9 hrs	20.6	18.7	
9-12 hrs	5.6	6.6	
>12 hrs	1.3	0.6	

sustains a complication, and thus the other categories were not divided by patient age. Second, in an attempt to assess the impact of confounders, we compared the demographics of the patients between the SRS and the NSQIP datasets. Demographic information in the SRS dataset is only available for patients that have suffered a complication. This cohort was compared against the cohort of patients from the NSQIP dataset that also had a complication. Categorical comparisons were made with a chi-squared test and continuous variables were compared using the student’s t-test. Statistical comparisons for analyses were made using SAS (Version 9.3; SAS Institute, Cary, NC).

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The ACS NSQIP and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the

statistical validity of the data analysis or the conclusions derived by the authors.

RESULTS

In total, across all diagnostic categories, 96,875 patients were identified from the SRS dataset, of which 2,295 sustained at least one complication (2.4%). There were 15,909 patients identified from the combined adult and pediatric NSQIP dataset, of which 364 sustained at least one complication (2.3%). Small differences existed in the reported M&M incidences between the SRS and NSQIP databases in terms of overall mortality incidence (0.1% v. 0.2%), overall infection incidence (1.2% v. 2.0%), and overall neurologic injury incidence (0.8% v. 0.1%) (p<0.001 for each comparison) (Table II).

For mortality, the SRS membership reported a significantly lower incidence as compared to that recorded in the NSQIP database for both the category of idiopathic scoliosis in patients aged ≥18yrs (0.1% SRS v. 0.8% NSQIP, p=0.0018), and also for spondylolisthesis (0.04% SRS v. 0.2% NSQIP, p<0.0001). Similarly for infection, the SRS membership reported a lower incidence for every diagnostic category, and the difference reached significance for every category except neuromuscular scoliosis and other scoliosis (p<0.05 for each). In contrast to the two other categories, the SRS membership consistently reported a higher incidence of neurologic injury across every diagnostic category, and this difference reached significance for patients with idiopathic scoliosis who were aged ≥18yrs (0.8% SRS v. 0% NSQIP, p=0.032), and for spondylolisthesis (0.7% SRS v. 0.02% NSQIP, p<0.0001) (Table II).

Amongst the patients with a complication, moderate demographic and comorbidity differences existed between the two cohorts across multiple categories (Table III). The patients from the NSQIP database were slightly older (mean of 47.4 yr (sd of 25.5) v. 44.5 yr (sd of 25.6), p=0.04), were more likely to be male (42.0% v. 36.2%, p=0.03), had a higher mean body mass index (mean of 30.4 kg/m² (sd of 10.3) v. 26.0 kg/m² (sd of 7.1), p<0.0001), and tended to have a higher comorbidity burden as measured by ASA class (58.6% of NSQIP patients were ASA grade 3 or higher, as compared to 34.1% of SRS patients, p<0.0001). The range of reported operative times was similar between the two cohorts (p=0.5).

DISCUSSION

The SRS database has been widely accepted as a source of morbidity data following spinal deformity surgeries. However, few prior studies have attempted to determine the reliability of the data collection. Thus, the purpose of this study was to compare the reported incidence of short-term morbidity rates between the

NSQIP and SRS data sets. The results should provide an assessment of the validity of the SRS membership's voluntary reporting. Overall, we found that the reported incidence of complications was very similar between the two datasets, across multiple diagnostic categories. Several of our findings merit further discussion.

First, although statistically significant differences in morbidity incidence existed between the SRS and NSQIP datasets across multiple diagnostic subcategories, the magnitude of these differences was small. Specifically, nine comparisons reached statistical significance, but the magnitude of the difference was less than 1% in six of these (Table II). In addition, the composite comparisons of overall mortality incidence (0.1% v. 0.2%), overall infection incidence (1.2% v. 2.0%), and overall neurologic injury incidence (0.8% v. 0.1%) ($p < 0.001$ for each) were similar. Although the differences were statistically significant, the similarity of the two data-sets should be viewed as encouraging, providing preliminary evidence that the SRS membership has been validly reporting its complications.

Nonetheless, although the overall rates were similar, there were some notable differences. The SRS membership consistently reported lower rates of wound complications, and these differences reached significance in all except for two diagnostic sub-categories (neuromuscular scoliosis, $p=1.0$, and other scoliosis, $p=0.2$). These results are largely similar to those of Webb et al.,¹⁹ who identified a lower incidence of infection rates in the SRS database as compared the NSQIP dataset. There are several possible reasons for this discrepancy. SRS member surgeons are experts in their field, and it is possible that the SRS membership is less likely to incur an infection, as compared to non-member surgeons. Alternatively, Webb et al. suggested that SRS member surgeons might more accurately report their infections than would the NSQIP clinical reviewers, implying that the NSQIP definitions were overly inclusive, and thus not representative.¹⁹ While possible, this explanation is less likely. In our definitions, we specifically excluded simple wound dehiscence, and only included the more significant superficial and deep infection categories. It is more likely that the SRS membership might have a small bias towards under-reporting of infections. Particularly if a wound complication was minor or treated non-operatively, an SRS surgeon might be inclined not to report the issue, whereas the NSQIP reviewer is likely to document the occurrence regardless of the severity or subsequent needed treatment. Thus, SRS member surgeons might be encouraged to be extra diligent in recording this complication, to ensure the validity of the dataset. However, as noted above, the overall magnitude of difference between the SRS and NSQIP datasets was small (0.8% difference). Thus, if a bias does exist, it is

likely small, and we do not think it should detract from the overall generalizability of the SRS data.

In contrast to wound complications, the SRS membership consistently reported higher incidences of neurologic injury, and this difference reached significance for both patients with spondylolisthesis as well as for patients with idiopathic scoliosis who were over 18 years of age. The definition of neurologic injury is different between the SRS and NSQIP datasets. NSQIP defines neurologic injury as, "an injury to the nerve fibers, nerve cell body, or myelin sheath during surgery." In contrast, the SRS asks surgeons to report on any "new neurologic deficit," which is more inclusive terminology. The narrower definition from the NSQIP reviewers may lead to a relative underreporting of neurologic injuries. Furthermore, the NSQIP SCR primarily identifies complications through chart review, whereas the SRS surgical team is directly examining the patient. A significant event such as a neurologic injury might be more likely to stand out on physical exam as opposed to chart review. Indeed, prior studies of spinal surgeries from the NSQIP database have consistently reported remarkably low incidences of neurologic injury, even in complex cases.^{29,31,32} Reports from NSQIP are used by some hospitals and insurance payors as a benchmark on surgeon performance. As with each of the complication categories, the absolute magnitude of difference was small (0.7% difference). However, our study implies that NSQIP may under-represent neurologic injury to a small degree, and this finding should caution administrators against applying too low of a benchmark for neurologic complications when relying only on NSQIP data.

The last category compared between the two databases was the incidence of mortality. The overall difference was again small, 0.1%, and the difference in the sub-categories was less than 1% in each comparison. Thus, both datasets reported very similar incidences of mortality. Mortality should be an easily definable event after surgery, and thus it is encouraging that the datasets reported similar incidences. We feel that both datasets support prior studies which have shown low incidences of mortality after spine surgery,^{1,32} and this information may be useful for patient counseling and quality benchmarks.

Our study has several important limitations. Most notably, because of the limitations in the data collection methods, it was not possible to robustly adjust for differences in patient characteristics, surgical procedures, or medical comorbidities between the two cohorts. We attempted to match the patient groups based on age and their indication for surgery where possible, and reported individual differences amongst these cohorts. However, this represents a fairly limited set of matched factors, and age matching was only possible for idiopathic sco-

liosis. Thus, in an attempt to determine the magnitude of confounders present, we compared the demographics and comorbidities amongst the patients that had a complication. In this secondary analysis, multiple significant differences were identified, indicating that the two databases likely enrolled modestly different patient cohorts. In particular, the NSQIP dataset tended to capture a slightly older and more comorbid patient population, which likely affected their morbidity risk. These results highlight the need for appropriate risk-adjustment when reporting results from either dataset, and some of the differences in reported morbidity rates may be due to the fact that the patient cohorts are different. In addition, the definition of morbidity varied slightly between the two data-sets, and this also may have contributed to some of the small differences we observed. Furthermore, the SRS data is based on the retrospective recall of the surgeon, and there may be significant recall bias present in this methodology. Lastly, neither database clearly identifies the severity of the surgical intervention (for example types and numbers of three column osteotomies), and thus the cases may not be well matched in terms of surgical complexity. The overall conclusion of our manuscript is that the reported morbidity rates are similar between the two datasets. Thus, particularly in light of the modest demographic differences we identified, we do not think the reader should place too much stock in the small percentage differences we identified in some of the sub-group comparisons. Rather, the results should serve as a broad overview of the two databases.

Overall, the incidence of short-term morbidity was similar between the two databases, across multiple diagnostic patient categories. There were modest differences in the demographics and comorbidities of the patients enrolled in the two databases, likely reflecting differences in collection methods, and this may explain the small differences observed in morbidity. Concerns regarding possible under-reporting of M&M data by the SRS membership seem largely unfounded. Infection rates were consistently lower in the SRS database, and this may be one potential area for improvement. The incidence of neurologic injury was particularly low in the NSQIP dataset, and it is possible that NSQIP coders do not appropriately capture this complication. This study may be useful for future investigators using the NSQIP and SRS datasets.

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INCIDENCE AND RISK FACTORS FOR 30-DAY READMISSIONS AFTER HIP FRACTURE SURGERY

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ABSTRACT

Background: Unplanned hospital readmission following orthopedic procedures results in significant expenditures for the Medicare population. In order to reduce expenditures, hospital readmission has become an important quality metric for Medicare patients. The purpose of the present study is to determine the incidence and risk factors for 30-day readmissions after hip fracture surgery.

Methods: Patients over the age of 18 years who underwent hip fracture surgery, including open reduction internal fixation (ORIF), intramedullary nailing, hemi-arthroplasty, or total hip arthroplasty, between the years 2012 and 2013 were identified from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. Overall, 17,765 patients were identified. Univariate and multivariate analyses were performed in order to determine patient and surgical factors associated with 30-day readmission.

Results: There were 1503 patients (8.4%) readmitted within 30-days of their index procedure. Of the patients with a reason listed for readmission, 27.4% were for procedurally related reasons, including wound complications (16%), peri-prosthetic fractures (4.5%) and prosthetic

dislocations (6%). 72.6% of readmissions were for medical reasons, including sepsis (7%), pneumonia (14%), urinary tract infection (6.3%), myocardial infarction (2.7%), renal failure (2.7%), and stroke (2.3%). In the subsequent multivariate analysis, pre-operative dyspnea, COPD, hypertension, disseminated cancer, a bleeding disorder, pre-operative hematocrit of <36, pre-operative creatinine of >1.2, an ASA class of 3 or 4, and the operative procedure type were each independently associated with readmissions risk ($p < 0.05$ for each).

Conclusions: The overall rate of readmission following hip fracture surgery was moderate. Surgeons should consider discharge optimization in the at risk cohorts identified here, particularly patients with multiple medical comorbidities or an elevated ASA class, and should focus on wound complications and fall risks in order to minimize readmissions. Further, quality-reporting metrics should account for the risk factors identified here, in order to prevent penalties against surgeons who take on complex patients.

INTRODUCTION

Unplanned hospital readmissions represent a source of substantial expenditure for Medicare beneficiaries. During the twelve month period between 2003 and 2004, 19.6% of Medicare beneficiaries were readmitted within 30-days of their initial hospitalization, resulting in \$17.4 billion of additional expenditure.¹ This staggering expenditure triggered congressional action, and the Centers for Medicare and Medicaid services (CMS) has been authorized to initiate several cost containment measures.^{2,3} Unplanned readmissions were chosen as a key metric, and institutions with elevated readmission rates will be financially penalized.^{2,3} The CMS is collecting data, and public reporting of institutional readmission rates has already begun for total joint arthroplasty, with proposed financial penalties for underperforming institutions set to begin in 2015.^{3,5}

Many patients who sustain a hip fracture are over the age of 65 years.⁶ Thus, these Medicare quality metrics are particularly applicable to this patient population. However, few studies have examined unplanned readmissions after hip fracture surgeries,⁷⁻¹⁰ and most of these have been single center retrospective series. Therefore, the

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Ethical Review Committee Statement: This study received an exemption by the institutional review board at the University of Iowa.

Disclaimer: The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

purpose of the current study was to report the incidence and risk factors for 30-day unplanned readmissions after hip fracture surgery, from amongst a large, prospectively collected, multi-center cohort. The results should be useful in informing health policy decisions.

METHODS

Data Source

This study received an IRB exemption and was HIPAA compliant. The National Surgical Quality Improvement Program (NSQIP) consists of over 480 hospitals from around the United States, with roughly half private and half academic centers. Data collection is performed by onsite personnel called surgical clinical reviewers (SCR), who prospectively review patient progress notes, operative reports, and post-operative clinic visits in order to identify complications. If a patient has not returned for follow-up the SCR calls the patient directly to inquire about complications, and in this way readmissions that occur at outside hospitals should also be captured. Not all cases from each center are collected. However, a rolling algorithm is used for case selection in order to minimize selection bias. The dataset is routinely audited, with an inter-rater disagreement rate of only 1.56%.¹¹ Overall, NSQIP data is collected with a high fidelity, and the database has been widely accepted as a source of morbidity data across multiple surgical sub-specialties.^{4,12-16}

Patient Cohort

We retrospectively queried this database using International Classification of Diseases, 9th-edition (ICD-9) coding for patients who were admitted between 2012 and 2013 with a primary diagnosis of a hip fracture (ICD-9 820.x), and who underwent operative fixation. Operations are classified in the database by Current Procedural Terminology (CPT) codes. We included cases of hemiarthroplasty (CPT 27125), total hip arthroplasty (CPT 27130), open reduction internal fixation (ORIF) (CPT 27236), plate and screw fixation (CPT 27244), and intramedullary nailing (CPT 27245). We excluded any patient with a pre-operative infection (wound class of 2 or above), pre-operative sepsis, or patients in a coma. In total, this identified 17,765 patients.

STATISTICAL ANALYSIS

The occurrence of an unplanned readmission is specifically recorded by the NSQIP SCR's, and is categorized separately from patients with a planned readmission. The reason for readmission is recorded with an ICD-9 diagnosis code. For our statistical analysis, patients were divided into categories of those with and without an unplanned readmission within 30-days of their index procedure. First, a univariate analysis was conducted in order to identify

unadjusted differences between those two cohorts, using a student's t-test for continuous variables and a chi-squared test for categorical variables. Patients were compared across multiple demographic, surgical, and comorbidity categories (Table I). Significance in this analysis was considered to be a p-value <0.05.

Second, we performed a multivariate analysis in order to compare patient characteristics, while attempting to control for confounders. Any variable from the univariate analysis with a p<0.1 and greater than 80% data completion was included in this analysis. The multivariate model required complete patient data, and thus patients with a missing data-point were necessarily excluded. This left a total of 15,163 patients were included in the multivariate analysis. Statistical significance in this model was considered to be a p-value <0.05. All statistical calculations were conducted with using SAS 9.3 (SAS Institute, Cary, NC).

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RESULTS

Overall, 1,503 out of 17,765 patients (8.5%) were readmitted within 30-days of their index procedure. 721 (48%) of these had no reason for their readmission listed. Of the 782 patients with a reason listed for readmission, 27.4% (214 patients) were for procedurally related reasons, including wound complications (16%), peri-prosthetic fractures (4.5%) and prosthetic dislocations (6%). 72.6% of the readmissions (568 patients) were for medical reasons, including sepsis (7%), pneumonia (14%), urinary tract infection (6.3%), myocardial infarction (2.7%), renal failure (2.7%), and stroke (2.3%) (Table I).

In the univariate analysis, there were multiple differences in comorbidities, demographics, laboratory values, and surgical characteristics between the patients with and without a readmission (Table II). These differences make it difficult to draw conclusions from the univariate analysis. Thus, in an attempt to control for confounders, we subsequently performed a multivariate analysis (Table III). In this multivariate analysis, medical factors that were independently associated with readmissions risk were the

Table I. Univariate Comparison of Patient demographics and procedural characteristics between non-readmitted and readmitted patients*

Characteristic	Not Readmitted n=16262	Readmitted n= 1503	P Value
Demographics			
Age, Mean (SD), yrs	79.87(11.42)	80.52(10.66)	0.0257
Gender			
Female	71.09	66.13	<0.0001
Race			<0.0001
Black	2.87	3.73	
White	73.61	82.97	
Other	23.51	13.31	
BMI (kg/m ²)			0.0546
≤ 35.0	95.39	94.24	
>35	4.61	5.76	
Comorbidities			
Current Alcohol Abuse	4.38	3.85	0.7719
Current Smoker	11.94	13.51	0.0749
Recent Weight Loss	1.35	1.53	0.5569
Dyspnea	6.77	10.91	<0.0001
COPD	10.74	16.1	<0.0001
CHF	3.31	5.72	<0.0001
Hypertension	66.57	75.18	<0.0001
Diabetes	17.1	20.69	0.0004
PVD	2.22	5.38	0.0247
Disseminated Cancer	2.36	3.66	0.0019
Steroid Use	5.65	7.72	0.0011
Bleeding Disorder	16.01	23.55	<0.0001
Dialysis	1.76	3.26	<0.0001
Chemotherapy within 30 Days	1.32	0.77	1
Radiation Therapy w/in 90 Days	0.6	0	1
Prior Operation w/in 30 Days	0.71	2.26	0.0902
ASA Class			<0.0001
1 or 2 – No or Mild disturbance	20.82	11.56	
3 - Severe Disturbance	61.83	63.24	
4 - Life Threatening Disturbance	17.35	25.2	
Operative Variables			
Outpatient	0.31	0.2	0.6242
Emergency Case	33.54	29.74	0.0028
Operative time, hours			
> 4	0.66	1	0.1259
≤ 4	99.34	99	
Total Case Relative Value Units	18.29(2.68)	18.42(3.05)	0.1289
Length of stay, days			0.0018
> 4	61.04	65.14	
≤ 4	38.96	34.86	
Case Type			0.0004
CPT 27125 – Hemiarthroplasty	17.11	18.83	
CPT 27130 Total Hip Arthroplasty	4.24	4.86	
CPT 27236 ORIF	28.78	32.34	
CPT 27244 Plate/Screws	17.64	14.5	
CPT 27245 – IM Rod	32.23	29.47	

*All values listed as percentages except where noted.

Table II. Reasons for 30-day Readmission*

Complications	Cases (No.)	Percentage (%)
Surgical		
Wound		
Superficial SSI	23	2.9
Deep SSI	67	8.6
Wound Dehiscence	8	1.0
Hematoma/Seroma	26	3.3
Any Wound	124	16
Procedural Related		
Malunion	4	0.5
Periprosthetic Fracture	35	4.5
Prosthesis Dislocation	47	6.0
Other Hardware Complication	4	0.5
Any Surgical Related Reason	214	27.4
Medical		
Pain		
Procedural Related Pain	17	2.2
Hematologic		
Deep Vein Thrombosis	25	3.2
Pulmonary Embolism	21	2.7
Post-Operative Anemia	27	3.5
Arterial Thrombosis	2	0.3
Systemic Infection		
Sepsis	55	7.0
Septic Shock	23	2.9
UTI	49	6.3
Respiratory Infection	109	13.9
Distant Cellulitis	4	0.5
Non-specific illness	10	1.3
Neurologic		
Stroke	18	2.3
Syncope	3	0.4
Seizure	1	0.1
Delirium	14	1.8
Dementia	1	0.1
Depression	1	0.1
Intra-Cranial Hemorrhage	1	0.1

Complications	Cases (No.)	Percentage (%)
Systemic Disturbance		
Electrolyte imbalance	7	0.9
Oncology Related	1	0.1
Lymphedema	2	0.3
Hypoglycemia	4	0.5
Alcohol Withdrawal	1	0.1
Encephalopathy	7	0.9
Gastrointestinal		
Ileus/Bowel Obstruction	24	3.1
GI Bleed	21	2.7
Abdominal Pain	1	0.1
C. Diff Infection	9	1.2
Esophagitis	4	0.5
Diverticulitis	3	0.4
Cardiac		
Cardiac arrest	4	0.5
Myocardial infarction	21	2.7
Cardiac arrhythmia	10	1.3
Heart failure	15	1.9
Chest pain	4	0.5
Peripheral Vascular Disease	1	0.1
Hypotension	1	0.1
Tachycardia	1	0.1
Respiratory		
Pneumonitis	2	0.3
Pleural Effusion	1	0.1
Pulmonary Hypostasis	1	0.1
Acute Respiratory Failure	11	1.4
Dyspnea	1	0.1
Renal		
Acute Renal Failure	21	2.7
Hematuria	1	0.1
Urinary Retention	2	0.3
Trauma		
Accidental Fall	3	0.4
Pressure Ulcer	3	0.4
Any Medical Reason	568	72.6

*Overall percentage contribution excludes patients admitted for unknown reasons (n = 721). SSI = Surgical Site Infection, UTI = Urinary Tract Infection, NOS = Not Otherwise Specified, CPRS = Complex Regional Pain Syndrome, COPD = Chronic Obstructive Pulmonary Disorder, GI = Gastrointestinal

presence of pre-operative dyspnea (OR of 1.3, 95% CI of 1.1-1.6), COPD (OR of 1.3, 95% CI of 1.1-1.5), hypertension (OR of 1.2, 95% CI of 1.1-1.4), a history of disseminated cancer (OR of 1.5, 95% CI of 1.1-2.0), pre-operative renal insufficiency with a serum creatinine greater than 1.2 (OR of 1.2, 95% CI of 1.1-1.4), and a history of a bleeding disorder (OR of 1.3, 95% CI of 1.1-1.5). Laboratory values that were identified as independent risk factors included a pre-operative hematocrit of less than 36% (OR 1.2, 95% CI of 1.1-1.4). Overall medical status, as measured by the

patient's American Society of Anesthesia (ASA) score, was also independently associated with readmissions risk. Lastly, we considered intra-medullary nailing to be the least invasive procedural option. When this procedure was used as a reference, patients who underwent hemiarthroplasty (OR of 1.3, 95% CI of 1.1-1.5), total hip arthroplasty (OR of 1.4, 95% CI of 1.1-1.9), or open reduction and internal fixation (OR of 1.2, 95% CI of 1.1-1.4), were each at independently higher risk of 30-day readmissions.

Table III. Risk Factors for 30-Day Readmission As Identified By Multivariate Analysis

Variable	Odds Ratio (95% Confidence Interval)
Preoperative Dyspnea (Yes v. No)	1.3 (1.1-1.6)
COPD (Yes v. No)	1.3 (1.1-1.5)
Hypertension (Yes v. No)	1.2 (1.1-1.4)
Disseminated Cancer (Yes v. No)	1.5 (1.1-2.0)
Bleeding Disorder (Yes v. No)	1.3 (1.1-1.5)
Preoperative Anemia (Hct of ≤ 36 v. >36)	1.2 (1.1-1.4)
Renal Insufficiency (Cr of >1.2 v. ≤ 1.2)	1.2 (1.1-1.4)
ASA Class of 3 (v. 1 or 2)	1.5 (1.2-1.7)
ASA Class of 4 (v. 1 or 2)	1.7 (1.4-2.1)
Operative Procedure	
Hemiarthroplasty (v. IM Nail)	1.3 (1.1-1.5)
Total Hip Arthroplasty (v. IM Nail)	1.4 (1.1-1.9)
ORIF (v. IM Nail)	1.2 (1.1-1.4)

DISCUSSION

Overall, few prior studies have reported on 30-day re-admission risks in patients undergoing operative fixation of a hip fracture. Thus, the purpose of our study was to report the incidence and risk factors for unplanned readmissions after this common procedure, by utilizing a large, prospectively collected multi-center database. Several of our findings merit further discussion.

The first purpose of our study was to identify the incidence of unplanned 30-day readmissions after hip fracture surgery. Overall, we reported an incidence of 8.5%. This percentage is lower than those from previous reports. Kates *et al* reported on 129 30-day readmissions amongst a 1,081 patient cohort (11.9%) from a level III trauma center.⁷ French *et al.* reported on 7,579 hip fracture readmissions within 30-days, from a cohort of 41,331 patients (18.3%), identified from the Veterans Health Administration database,⁸ while Harstedt *et al.* reported on 86 patients readmitted within 30-days from a 272 patient cohort (32%). There are several possible reasons for this discrepancy. First, we have included all patients greater than 18 years of age, and the younger patients in our cohort may be less likely to be readmitted, in part because they fewer comorbidities. Overall, however, the average ages in our study were 80.5 and 79.9 years for the readmitted and not-readmitted groups, respectively. Thus, the cohort is largely composed of geriatric hip fractures, and the impact of the younger patients is likely small. More importantly, our study takes data from 2012-2013, whereas the prior reports are from the 1990's and early 2000's. Over the last 5-10 years many hospitals have focused on discharge optimization and have placed substantial emphasis on

minimizing readmissions.^{1,2} Thus, the contemporary data presented in our study may indicate that these programs have had some success, and that readmission rates have decreased over time.

The second purpose of this study was to identify risk factors for unplanned readmissions. The majority of the patients in our study were readmitted for medical reasons (72.6%). This number compares favorably with those from prior studies.

Giusti *et al* reported that higher medical comorbidity burden, and poor functional status were predictors of readmissions.¹⁷ In the Kates *et al.* study, 81.4% were readmitted for medical reasons. Similarly, French *et al.* concluded that readmissions were primarily due to comorbid medical conditions, rather than from hospital acquired or surgical complications.⁸ Sepsis (7%), pneumonia (14%), urinary tract infection (6.3%), myocardial infarction (2.7%), renal failure (2.7%), and stroke (2.3%) were among the most common medical reasons for readmission in our study.

Similarly, the majority of the independent risk factors for readmission that we identified were medical comorbidities. Patients with pre-operative dyspnea, COPD, hypertension, disseminated cancer, anemia, renal insufficiency, a bleeding disorder, or an ASA class of 3 or 4 were each found to be at higher risk. Unfortunately for surgeons and hospitals, many of these risk factors are not modifiable. Hip fracture surgery is frequently done on an urgent or semi-urgent basis, which leaves little time for optimization of chronic medical conditions. Indeed, most modern literature supports early operative intervention for minimizing morbidity risk,^{17,18} and thus operative delay for medical optimization may actually be worse for the patient. Therefore, quality metrics should take these risk factors into account when calculating expected readmissions, in order to avoid unduly penalizing surgeons who take on challenging cases.

In addition to the medical factors identified above, the type of surgical procedure was also found to be an independent risk factor for readmission. Patients treated with an intramedullary nail device had the lowest risk for readmission, and each of the other surgical options was associated with a higher risk. However, it is important to note that many hip fractures, particularly displaced fractures of the femoral neck, may not be amenable to intramedullary nailing, due to a high risk of avascular necrosis. Furthermore, our study was not designed to assess fracture healing or long-term functional outcomes, and thus this finding should not be used to dictate treatment decisions. Rather, we feel that the surgical procedure type should be one of the factors considered when assessing surgeon and hospital readmission rates. Our data indicates that the different surgical procedures have different risk profiles, and therefore should be considered separately in

statistical models of surgeon and hospital performance.

Our study does have several weaknesses. First, our outcomes data is limited to a time window of 30-days. Many medical complications that can lead to readmission, such as wound infection, non-union requiring revision surgery, or DVT/PE can occur after 30-days, and these would not be captured in our dataset. However, CMS has emphasized the 30-day target in their quality metrics, and thus we feel it is a reasonable time-point for evaluation in this study. Second, nearly half of the cohort did not have a reason for readmission listed. Thus, our analysis of the causes of readmission could potentially be biased if the remaining group was not representative of the entire cohort. However, all of the patients were included in our multivariate analysis of risk factors for readmission, and thus our primary conclusions on the incidence and risk factors for readmissions remains unaffected by this missing data. Furthermore, the causes of readmissions we identified are very similar to those reported previously in the literature, and we feel that the additional data-points would be unlikely to change the overall percentages.

Overall, the rate of 30-day readmissions following hip fracture surgery was moderate. Surgeons should consider discharge optimization in the at-risk cohorts identified here, particularly patients with multiple medical comorbidities or an elevated ASA class, and should focus on wound complications and fall risks in order to minimize readmissions. Further, quality-reporting metrics should account for the risk factors identified here, in order to prevent penalties against surgeons who take on complex patients.

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INTRUSION CHARACTERISTICS OF HIGH VISCOSITY BONE CEMENTS FOR THE TIBIAL COMPONENT OF A TOTAL KNEE ARTHROPLASTY USING NEGATIVE PRESSURE INTRUSION CEMENTING TECHNIQUE

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ABSTRACT

Background: With the advent of new bone cements with different viscosities, it is important to understand how they respond to different cementing techniques. The purpose of this study was to evaluate the high viscosity (HV) bone cement intrusion characteristics comparing negative pressure intrusion technique (NPI) and finger-packing technique in a cadaveric proximal tibial bone.

Methods: Soft tissues were removed from twenty-four fresh frozen cadaver proximal tibiae, and standard arthroplasty tibial cuts were performed. Palacos-R (Zimmer, Warsaw, IN) and Simplex-HV (Stryker Howmedica Osteonics, Mahwah, NJ) bone cement were used. Each tibia was randomly assigned to receive one of the two bone cements with finger-packing technique and NPI technique. Forty-five Newton weight was applied along the long axis of the tibia during cement-setting phase. Once the cement had cured, sagittal sections were prepared and analyzed for cement penetration depth using digital photography and stereoscopic micrographs. Area of interest (AOI) for each specimen was also used to quantitatively evaluate the area of cement penetration.

Results: When using Palacos-R, significant differences were detected in cement penetration between the two cementing techniques. On the other hand, when using Simplex-HV, cement penetration was not significantly increased with finger-packing technique when compared to NPI technique. When comparing the two high-viscosity bone cements when using NPI cementing technique, significant differences were detected at Zone 4, where Simplex-HV penetrated deeper than the Palacos-R. When finger-packing technique was used with Simplex-HV, significant differences were detected in bone cement penetration at Zones 3-5. When looking at AOI, no significant differences were found between the Palacos-R and Simplex-HV bone cements in terms of penetration depths with NPI technique. Higher penetration depths were achieved with Simplex-HV bone cement compared to Palacos-R cement in finger packing technique.

Conclusions: The data demonstrated that the combination of different bone cement formulations and the cementing technique has a significant effect on cement penetration into the cut bone surface.

INTRODUCTION

Numerous studies have investigated a wide range of techniques to improve cementation of the tibial base plate during total knee arthroplasty (TKA).¹⁻¹⁴ These methods include modification of the implant design, different cementing techniques, carefully preparing the bone cut surface, vacuum mixing bone cement, and using different cement viscosities. Several investigators have shown that some of these methods improve cement intrusion characteristics.^{1,2,6,11,12.}

The intrusion depth of bone cement is thought to be a combined function of bone permeability, cement viscosity, and pressure gradient applied to the curing of methylmethacrylate. During any TKA, the bone permeability is predetermined based on the porosity of the native bone. Methods such as washing the cut surface with pulsatile lavage to remove bone marrow and bone debris may further improve bone permeability. With the advent of new bone cements, the combination of controlling different cement viscosities and using

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different cementing techniques is thought to increase cement penetration depth and thus improve the bone-cement interface.

Negative pressure intrusion (NPI) is an alternative cementing technique for the tibial base plate in TKA. In this technique, after standard pulsatile lavage and drying of the cut tibial surface, suction is applied from within the bone to remove residual fat and fluid while drawing bone cement into the cancellous bone of the proximal tibia. Together with the impaction of the tibial baseplate, which acts to provide external positive pressure, it has been shown that this allows more low viscosity bone cement to flow around the trabeculae.¹

Currently, several cements with different viscosities are available. Popular high viscosity (HV) bone cements such as Palacos-R (Zimmer, Warsaw, IN) typically have faster time to “dough” than other bone cements with lower viscosities, and this factor might reduce operating time significantly. Studies, however, have shown that some HV bone cements have reduced cement penetration depth compared to the medium viscosity bone cements.^{2,4} Simplex-HV (Stryker Howmedica Osteonics, Mahwah, NJ) is a newly developed HV bone cement with a short mixing time while also maintaining adequate cement intrusion. The purpose of this study was to evaluate the HV bone cement intrusion characteristics using NPI and finger-packing techniques in cadaveric proximal tibial bone.

MATERIALS AND METHODS

Two types of HV polymethylmethacrylate (PMMA) bone cements were used in this study: Palacos-R (Zimmer, Warsaw, IN) and Simplex-HV (Stryker Howmedica Osteonics, Mahwah, NJ). Each contains 40 g PMMA powder and 20 ml liquid monomer (Stryker Orthopaedics, Mahwah NJ). A total of 24 fresh frozen lower extremities cadavers (15 left and 9 right) were harvested above the knee and thawed at room temperature for 24 hours prior to testing. No other demographic information was available for the specimens. None of the specimens had previous knee surgery, obvious deformities, or skeletal abnormalities that could confound the study. The Stryker Triathlon[®] tibial base plate (Stryker Howmedica Osteonics, Mahwah, NJ) was used in all implantations, and the procedures were performed by the same surgeon to eliminate individual variation.

After thawing each specimen to room temperature, soft tissues were removed and standard arthroplasty tibial cuts were made 2 ± 1 mm below the most compromised articular cartilage of the medial tibial plateau with 0° tibial slope using standard TKA instrumentation. The cut surfaces were prepared in standard fashion for the Triathlon[®] tibial base plate, and the bone was sectioned at the mid-shaft. Before bone cement application, the cut

surfaces were washed using pulsatile lavage with normal saline solution to remove marrow and other bone debris. The surface of the tibial base plate was coated with a thin layer of petroleum jelly to facilitate the removal of component after the cement had cured. This method was used in a previously published study.¹¹

Both the Palacos-R and the Simplex-HV bone cements were prepared according to the manufacturer’s protocol at standard operating room temperature (18 to 19° C) and humidity. Both PMMA bone cements were prepared by mixing for 30 seconds in a standard Stryker Revolution Cement Mixing System (Stryker Instruments, Kalamazoo, MI) under a vacuum of 559 mm Hg. Each tibia was randomly assigned to one of the bone cements for implantation using either NPI cementing technique or finger packing technique. The NPI technique was performed by placing a Medi-Vac[®] Frazier suction tip (Cardinal Health, McGaw Park, IL) into one of the 1/8-inch drill holes, which were used to hold the tibial base plate template.¹ A negative pressure of 559 mm Hg was then applied to create suction. The cut surface was then dried with surgical lap sponges. Bone cement was then applied onto the tibial bone cut surface and the tibial base plate was impacted until seated fully.

For the finger-packing technique, bone cement was applied onto the cut surface using digital pressure. The tibial base plate was then impacted until seated fully as the previous step. The finger-packing technique was used as a baseline for comparison to the NPI cementing technique. Six samples of each bone cement type for each cementing technique were tested.

In all cases, excess cement was removed. A 45 N force was applied along the long axis of the tibia during the cement-setting phase. After complete polymerization of the cement (20 minutes), the base plate was then removed by a gentle tap. Each proximal tibia was then fixed into a custom-designed jig using dental cement (Garreco; Heber Springs, AR) to hold the tibia in the correct orientation while cutting. Seven sagittal sections were made using a table saw with a thin kerf cutting blade at 5, 15, and 25 mm from the center of defect created by the removal of tibial base plate (Figure 1). The cut surfaces were subsequently cleaned with pressurized air to remove cut debris. The depth of cement intrusion was measured at equal spacing along the anteroposterior plane of each specimen at 5 mm intervals.

Cement penetration into the cancellous bone was measured using an image analysis technique for each high resolution digital photographic image (1,000 dpi) of the sagittal section that included a standardized measurement scale (Figure 2). The image analysis measurement tool was calibrated to measure millimeters using the reference marks, and the measurements of cement depth penetra-

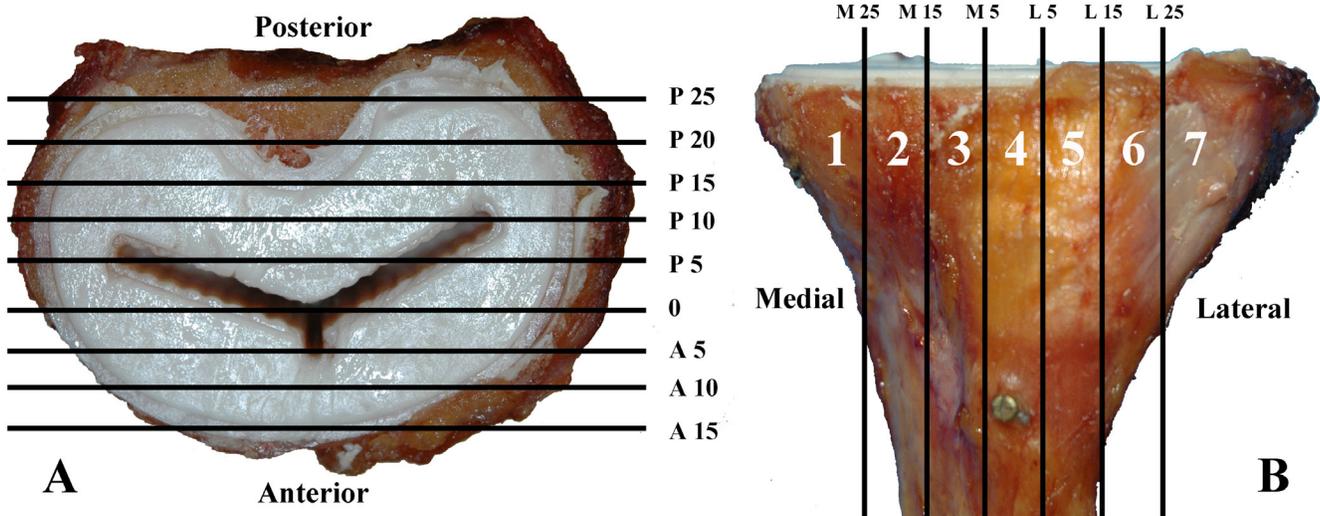


Figure 1. Example of the proximal tibia showing the levels of sectioning for the sagittal sections. (A) Top view, and (B) Anterior view.

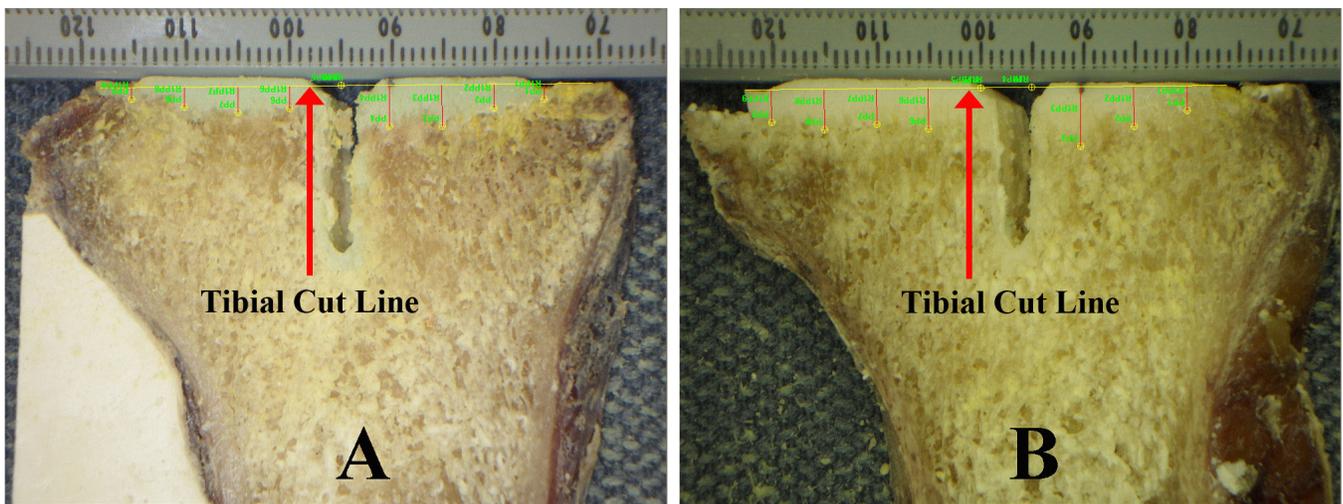


Figure 2. Image analysis of cement penetration measurement. (A) Simplex-P, (B) Palacos-R, and (C) Simplex-HV.

tion was made at the desired grid points as previously described.¹ Image analysis was performed using Image Pro Plus analysis software (Media Cybernetics, Inc. Rockville, MD, Version 4.5.1.22). The cement penetration depth was measured from the tibial bone cut surface.

Two zones (5 mm medial and lateral from the center of defect created by removal of tibial base plate, M5 & L5) were partitioned to create an area of interest (AOI) approximately 7 mm wide (from the center line) and 7 mm deep from the top of the cement mantle (Figure 3). The purpose of defining the AOI is to provide an accurate way to quantify the total area of cement intrusion in a representative region. The selected zones were examined under the magnification of 50X with a stereoscopic microscope (Olympus BX51M microscope), equipped

with a mechanical stage, to measure the ratio of cement area to bone area. Multiple photomicrographic images of the AOI were taken and merged together using the automatic mechanical stage with auto-stitching software for every specimen. The AOI analysis of the selected regions was conducted using the Image Pro Plus analysis software with assigned imaged based pixel identity to correlate with the presence of bone cement to determine the ratio of cement area to bone area.

Statistical analysis

The mean bone cement penetration depths were calculated for each section at every point of measurement, and these values were used to determine statistical differences between cement penetrations into cancellous

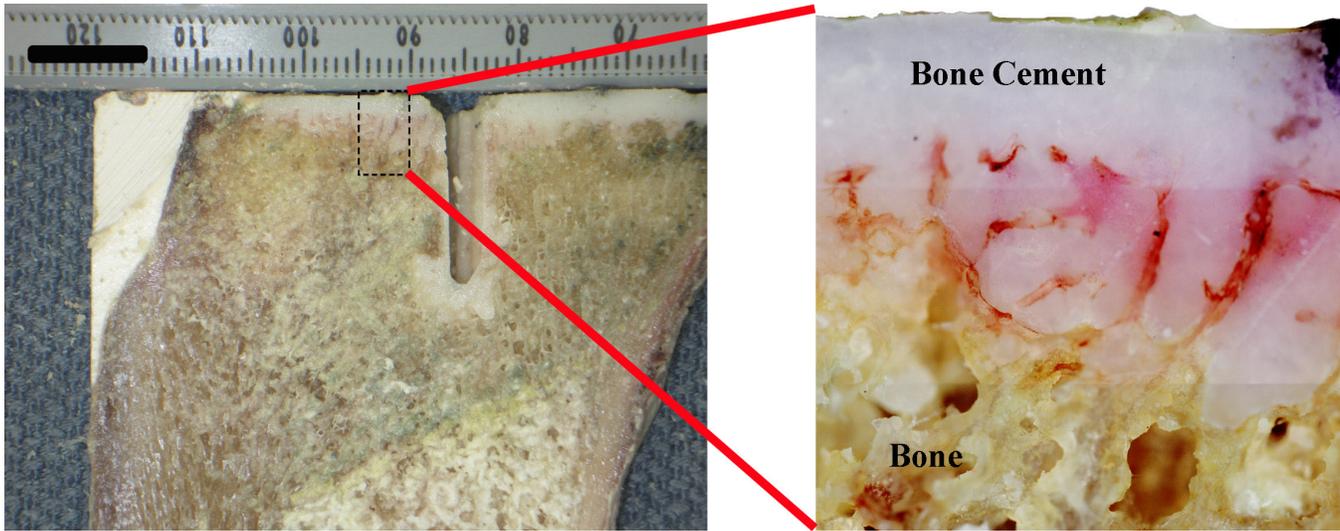


Figure 3. Ratio of cement volume to bone volume analysis in an area of interest (AOI).

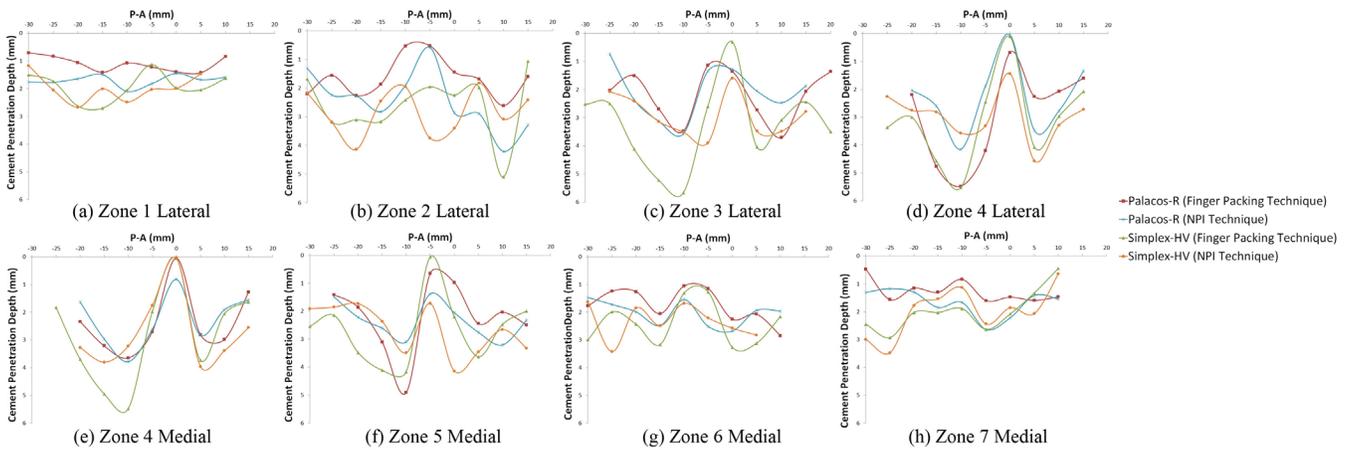


Figure 4. Cement penetration depth measurement results.

bone for each type of bone cement. To analyze the AOI, the depths of cement penetration were also calculated by the mean and standard deviation of the cement area to bone area ratio in percentage of the two selected zones. A one-way analysis of variance (ANOVA) using SPSS software (Version 19.0; SPSS Inc, Chicago, IL) with the Least Significant Difference (LSD) multiple comparisons post hoc analysis used to determine significant differences in cement mantle depth between the different bone cements at each point of measurement. The level of significant difference was defined as $p < 0.05$.

RESULTS

When using Palacos-R, significant differences were detected in cement penetration into the proximal tibial zones between the two cementing techniques, NPI and

finger-packing (Figure 4) (average: 2.1 ± 0.4 mm vs 1.8 ± 0.6 mm, $p = 0.004$). On the other hand, when using the Simplex-HV, cement penetration into the tibial plateau was not significantly increased with finger-packing technique when compared to the NPI technique (average: 2.7 ± 0.3 mm vs 2.7 ± 0.5 mm, $p = 0.144$).

When comparing the two high-viscosity bone cements using the NPI cementing technique, significant differences were detected at Zone 4 where Simplex-HV bone cement penetrated deeper than Palacos-R bone cement (average: 2.0 ± 1.6 mm vs 1.5 ± 1.4 mm, $p = 0.003$). When finger-packing technique was used, Simplex-HV also showed a significant difference in bone cement penetration at Zones 3 – 5 compared to Palacos-R bone cement (Zone 3: 2.9 ± 1.8 mm vs 1.6 ± 1.1 mm, $p = 0.000$; Zone 4: 2.2 ± 1.9 mm vs 1.8 ± 1.7 mm, $p = 0.02$; Zone 5: 2.2 ± 1.4 mm vs 1.7 ± 1.4 mm, $p = 0.015$).

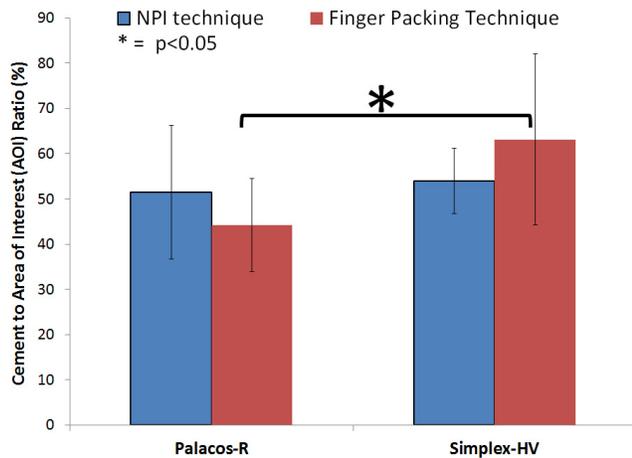


Figure 5. Cement area to bone area ratio within an area of interest (AOI).

Simplex-HV had an average cement penetration depth from the tibial bone cut surface of 2.7 ± 0.3 mm (range 2.4 - 3.2 mm) for NPI technique and also 2.7 ± 0.5 mm (range 2.0 - 3.0 mm) for finger-packing cementing technique. Penetration depths for Palacos-R were 2.1 ± 0.4 mm (range: 1.6 - 2.7 mm) for NPI cementing technique and 1.8 ± 0.6 mm (range: 1.1 - 2.6 mm) for finger-packing cementing technique. When the cement mantle thickness was included, the total cement penetrations were approximately 3.7 ± 0.3 mm (NPI technique) and 3.7 ± 0.5 mm (finger-packing technique) for Simplex-HV ($p = 0.144$), 3.1 ± 0.4 mm (NPI technique) and 2.8 ± 0.6 mm (finger-packing technique) for Palacos-R ($p = 0.004$).

Image analysis of photomicrographs of the AOI in each selected zone revealed no significant differences of cement penetration depth between the Palacos-R and Simplex-HV for NPI technique ($p = 0.722$). Palacos-R had an average of 51 ± 7 % cement area within an AOI while Simplex-HV had 54 ± 4 % of cement area. In contrast, higher penetration depths were achieved with Simplex-HV compared to Palacos-R in finger-packing technique, and the result was statistically significant ($p = 0.020$). Simplex-HV had an average of 63 ± 7 % cement area while Palacos-R was measured at 44 ± 19 % (Figure 5).

DISCUSSION

Aseptic loosening of the tibial component still remains one of the most common long-term complications in TKA, and numerous studies have demonstrated that cement penetration of between 3 to 4 mm below the tibial component seems to be the ideal cement penetration depth.⁵⁻⁹ It also has been shown that better cement intrusion increases tensile and shear strength at the cement-bone interface.¹⁰ There are several techniques

that have been used to improve the cementation of the tibial base plate during TKA. Methods such as negative pressure intrusion,¹ modified cementing techniques,¹¹ lift leg technique,⁵ high-pressure pulsatile lavage,^{6,12} and cement gun application¹³⁻¹⁵ all proved to have increased benefits. However, none of these reports investigated the effect of cement viscosity and cementing techniques on the level of cement penetration depth. To our knowledge, this is the first in vitro study comparing two HV bone cements using two different cementing techniques.

Previous literature has demonstrated that HV bone cements typically provide a shorter mixing and setting time than medium viscosity bone cements, such as Palacos-R bone cement, but this occurs at the expense of reduced cement penetration.^{2,15} Our results indicate that a combination of different HV formulations with different cementing techniques may lead to variable cement penetration depth. The new formulation of bone cement (Simplex-HV) is a newly developed HV bone cement that has a short mixing time while maintain similar setting time as medium viscosity bone cement. Although both Palacos-R and Simplex-HV are characterized as HV bone cements, we speculate that the longer curing time for Simplex-HV may allow deeper cement penetration prior to the polymerization of cement. Our results did not show any significant cement penetration depth difference when using either finger-packing technique or NPI technique. This study also shows that cement with HV may not be suitable for the negative pressure technique. This could be due to the inability to create a pressure gradient necessary to overcome the viscosity of the materials with current negative pressure techniques. A study by Banwart et al.¹ showed that there was increased cement penetration depth at the region proximal to the Frazier suction tip that was used to apply the negative pressure, and a low viscosity cement was tested at that time. In our experiment, significant difference in cement penetration was noticed at zone 4 when using the NPI technique. However, the difference was not observed at other zones.

Our experiment also shows that Simplex-HV responds well to finger packing technique compared to Palacos-R. Although both are characterized as HV cements, this study indicates that the different formulation of Simplex-HV may lead to a viscosity that is not as high as Palacos-R, and the time from “dough” stage to “set” stage is also much slower when compared to Palacos-R but similar to medium viscosity bone cement. The lower force that is generated with finger pressure to overcome the viscosity of Palacos-R leads to reduced cement penetration, whereas Simplex-HV has a different viscosity and, therefore, is more suited for the lower pressure generated using finger packing.

Several limitations exist in our model. We recognize that our study was performed on cadaveric specimens, which had been frozen and then thawed prior to the study. This could have compromised the structure of the cancellous bone. In addition there is a possibility that marrow elements had been compromised leading to inaccurate cement penetration. Another potential confounding variable is the bone quality of the specimens. We recognize that bone mineral density was not performed in current study, and could be considered in future studies.. Another weakness of the current study is that the majority of the specimens had normal articular surface. This might not accurately represents knees in patients with existing arthritis and sclerosis. We also recognize that the sagittal section cutting or cleaning of the bone could widen the existing gap. Given the available research models, we feel that the data is valid for the current investigation, although because it is an in vitro evaluation, further evaluation in patients is required to support the conclusions of this study.

In conclusion, this study compared two HV bone cements with two different cementing techniques and demonstrated that the combination of different bone cement formulations and the cementing technique has a significant effect on cement penetration into the cut bone surface.

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COMPARISON OF TWO SYNTHETIC BONE GRAFT PRODUCTS IN A RABBIT POSTEROLATERAL FUSION MODEL

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ABSTRACT

Background: The drawbacks of iliac crest autograft as graft material for spine fusion are well reported. Despite continued modifications to improve bone healing capacity, the efficacy of synthetic graft materials as stand-alone replacements remains uncertain. The rabbit posterolateral fusion model is an established environment for testing of fusion concepts. It offers the opportunity to obtain radiographic, biomechanical and histological data on novel fusion materials. The objective of this study was to compare the spine fusion capability of two synthetic bone graft products in an established rabbit posterolateral spine fusion (PLF) model: Signafuse® Bioactive Bone Graft Putty and Actifuse® ABX.

Methods: Bilateral intertransverse spine fusion was performed at the L5-L6 transverse processes (TPs) of New Zealand White rabbits using either Signafuse or Actifuse ABX as the bone graft material. Bone remodeling and spine fusion were assessed at 6 and 12 weeks using radiographic, biomechanical and histological endpoints.

Results: Fusion rate by manual palpation at 6 weeks was greater for Signafuse (33%) compared to Actifuse ABX (0%), and equivalent in both groups at 12 weeks (50%). Biomechanical fusion rate based on flexion-extension data was 80% in Signafuse group and 44% for Actifuse ABX. Histology revealed a normal healing response in both groups. MicroCT and histomorphometric data at 6 weeks showed greater new bone formation in

the Signafuse group compared to Actifuse ABX ($p < 0.05$), with no differences detected at 12 weeks. Histological fusion scores were greater in the Signafuse group at 6 and 12 weeks, indicated by higher degree structural remodeling and tendency towards complete bridging of the fusion bed compared to the Actifuse ABX group.

Conclusion: Confirmed by several metrics, Signafuse outperformed Actifuse ABX as a standalone synthetic bone graft in an established PLF model, demonstrating greater rates of bone remodeling and spine fusion. The combination of 45S5 bioactive glass and biphasic HA/ β TCP granules of Signafuse appear to provide greater bone healing capability in comparison to the 0.8% silicate-substituted hydroxyapatite material of Actifuse ABX.

BACKGROUND

Iliac crest autograft (ICBG) has been used for many years as a bone graft in spinal fusion procedures despite issues associated with donor site morbidity¹⁻¹¹. Synthetic alternatives to autograft are commercially available in a number of forms and have been shown to support bone healing used as stand-alone, extender, or enhancer type products. Calcium phosphate materials have been used clinically as the foundation of synthetic bone void fillers for several decades. Such products have been demonstrated to be osteoconductive, providing a scaffold for cell. Calcium phosphate grafts are similar in composition and crystalline structure to human bone and generally comprise some form of hydroxyapatite (HA), beta tricalcium phosphate (β TCP), or a blend of the two (HA/ β TCP), referred to as biphasic calcium phosphate (BCP). Depending on specific composition, these biomaterials differ in terms of resorption rate, osteoconductivity, and remodeling capability¹².

In an attempt to enhance the bone healing capabilities of calcium phosphate materials, certain modifications have been incorporated into several products with claims that these changes bestow “bioactive” or “stimulative” properties. More recently, products have been introduced that contain synthetic granules with collagen or resorbable polymers to render the graft moldable to improve delivery and retention of the granular materials at the surgical site.

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The authors declare no relevant conflict of interest

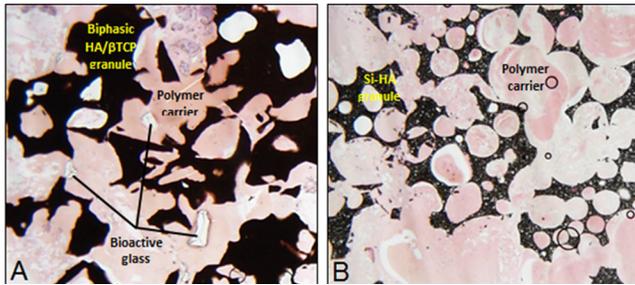


Figure 1. Time 0 histology showing the granulate and polymer carrier components of the Signafuse (A) and Actifuse ABX (B) graft materials.

TABLE I. Experimental Design

Endpoint	Animals per Time Point (n)	
	6 weeks	12 weeks
Radiographic	6	10
Macroscopic Evaluation	6	10
MicroCT	6	10
Manual Palpation	6	10
Biomechanical Testing	-	10
Histopathology	3	5
Histomorphometry	3	5
Histological Fusion	3	5

In this investigation, Signafuse® Bioactive Bone Graft Putty (BioStructures, LLC, New Port Beach, CA, USA), comprised of biphasic calcium phosphate granules (1-2 mm) and 45S5 bioactive glass (212-420 µm) suspended in a resorbable alkylene oxide polymer (AOP) matrix, was compared to Actifuse ABX (Baxter Healthcare, Deerfield IL, USA), a phase-pure, silicate-substituted hydroxyapatite granules (1-2 mm) suspended in a resorbable alkylene oxide copolymer (AOC) matrix (Figure 1), using an established posterolateral spine fusion (PLF) rabbit model¹³⁻¹⁹. The aims of the study were to directly compare the fusion performance of two synthetic bone graft products as well as determine potential correlations between the “claimed” biological properties of each material and the actual bone healing and fusion capability observed in vivo.

METHODS

Bilateral intertransverse spine fusion was performed at the L5-L6 transverse processes (TPs) of New Zealand White rabbits using either Signafuse or Actifuse ABX as the bone graft material. All surgeries were performed following IACUC approval (1208187). Animals were sacrificed at 6 weeks (n=6) and 12 weeks (n=10) for each treatment group. The experimental design is shown in Table I.

Surgical Procedure

A dorsal midline skin incision, approximately 15 centimeters long, was made from L1 to the sacrum. Overlying fascia and muscle were incised over the L5-L6 TPs. The TPs were then decorticated with a high-speed burr. Approximately 2.5-3.0 cc per side of test article was placed in the paraspinal bed between the TPs. The fascia and skin were closed in the routine manner consistent with good surgical practice. Post-operative care of the animals was performed in accordance with good husbandry practices as understood in the art.

Necropsy/ Macroscopic Evaluation

Animals were euthanized using Euthasol solution (120 mg/kg IV). Necropsy was conducted on all study animals according to standard operating procedures under the supervision of the principal investigator (PI). The entire lumbar column was removed “en-bloc”. Soft tissues were immediately removed from the surgically treated spinal unit after the spine was dissected out of the body. The grafted site was examined for graft migration, infection, and soft tissue abnormalities. Spines from the 6 week animals were placed in 10% neutral buffered formalin. Spines from the 12 week animals were immediately biomechanically tested.

Radiographic Assessment

Ventral/dorsal radiographs were obtained with a Simon DR (Quantum) RAD-X High Frequency Radiographic Imaging System, (model: E7242X), and stored using Whitecap PACs system. Radiographic images were obtained immediately postoperatively and at 6 and 12 weeks post-surgery. Animals received sedation prior to radiography and images were assessed for osteolysis, fracture, and/or any other adverse radiographic events including infection and graft migration. Radiographic assessment of fusion was not performed as calcium phosphate-based materials, such as those contained in the test articles, look similar to bone preventing adequate radiographic evaluation^{13,20}.

MicroCT Assessment

Microcomputed tomography (microCT) scans of the fusion defects were obtained at 6 and 12 weeks post-operatively. Bilateral morphometric analysis of sagittal scans was performed using a rectangular region of interest (ROI) of 250 mm² placed across the fusion site inclusive of the TPs. Bone area was determined based on validated contrast parameters and reported as a percentage of the ROI.

Manual Palpation

Following spine removal at 12 weeks, three blinded independent observers graded the fusion mass as fused

TABLE II. Histological Fusion Scoring Parameters

Fusion Status	Score
Union of TPs by mature bone; complete bridge	10
Union of TPs by immature bone and cartilage; complete bridge	9
Union of TPs by cartilage with little fibrocartilage	8
Partial union with more bone (>75%) than cartilage and fibrocartilage	7
Partial union with more (56%-75%) than other tissues (i.e., cartilage, fibrocartilage and fibrous tissue)	6
Partial bridge; equal amounts of bone (45%-55%) and other tissues	5
Minimal bridge with less bone (25%-44%) than other tissues	4
Minimal bone (<25%) with predominantly other tissues	3
Little new bone with predominantly fibrous tissue	2
Fibrous tissue only between TP; full (across the defect)	1

or not fused. Fused meant that there was no noticeable movement of the fusion mass in flexion and extension, while not fused meant movement of the fusion mass. Consensus among 2 of the 3 observers decided final results¹³⁻¹⁹.

Biomechanical Testing & Fusion Analysis

Non-destructive biomechanical stiffness testing was performed following manual palpation of the 12 week animals. Testing consisted of flexion/extension, lateral bending, and torsion to a pre-determined, sub-failure load. The vertebral bodies cranial and caudal to the fused motion segment were mounted in a biaxial servohydraulic materials testing machine (858 Bionix II, MTS Corporation, Eden Prairie, MN) retrofitted with two spine gimbals and a passive XZ table. Custom-made rigid body markers were placed on each vertebral body and both gimbals to track segmental motion. Non-destructive flexibility tests were performed about each axis of rotation (i.e., flexion-extension, right-left lateral bending, and right-left axial rotation) by applying an isolated ± 0.27 Nm moment about each of the primary axes. Each test initiated and concluded in the neutral position with zero load. Three loading and unloading cycles were performed with motion data collected on the third cycle. The displacement of each vertebrae was measured using an optoelectronic motion capture system, the output of which was synchronized with that of the MTS. During testing, the specimens were kept moist with saline solution spray. Stiffness was determined and compared to normal controls. Range of motion (ROM) data was compared between test groups and to historical internal laboratory data of normal unfused rabbit spines. Normal motion of the rabbit lumbar spine was determined by testing 10 normal (untreated/unfused) rabbit lumbar spinal columns using the same

testing methods as described above. Biomechanical determination of spine fusion was based on the flexion-extension ROM data, which provides a direct correlation to the manual palpation evaluation¹⁶. Specimens showing a total ROM of less than 5 degrees were deemed to be fused. This threshold has been previously reported in the PLF rabbit model using ICBG, where Elruker and colleagues demonstrated that solid fusion, as initially determined by manual palpation, correlates to ROM of less than 5° in flexion-extension²³.

Histologic Processing

Fusion sites were sectioned in the sagittal plane to obtain a total of 6 sections per animal (3 per side of the vertebral body). For each side, sections were created adjacent to the vertebral body, through the center of the fusion mass, and through the lateral aspect of the fusion mass, spaced approximately 3 mm apart. A total of six rabbits per test group were processed at 6 weeks and ten rabbits per test group at 12 weeks. At each time point, animals were evenly allocated for either decalcified paraffin embedded or non-decalcified plastic embedded processing. Routine hematoxylin and eosin (H&E) staining was applied to all slides.

Histopathology

Decalcified, paraffin-embedded sections were evaluated for histopathologic changes at 6 and 12 weeks using low and high magnification fields from each slide. Slides were viewed by the PI and a board certified veterinary pathologist. Areas of bone tissue, soft tissue (e.g. fibrous tissue, fibrocartilage, bone marrow), and graft were labelled on representative images from each group and time period. Areas of inflammation, osteoconduction (e.g. centripetal bone growth through open pores), osteointegration (bone-biomaterial contact), and resorption were also identified. The host biological response was scored and semiquantitatively assessed based on ISO 10993-6²⁰.

Histomorphometry

Non-decalcified plastic embedded sections were subject to bilateral histomorphometry analysis at 6 and 12 weeks. A rectangular ROI of 85.8 mm² placed across the middle of the fusion bed between but not inclusive of the TPs was analyzed for each slide. Bone area was determined based on validated color pixel parameters and reported as a percentage of the ROI.

Histologic Fusion Analysis

Non-decalcified plastic embedded histology sections for each test group were semiquantitatively assessed for fusion at 6 and 12 weeks by 3 blinded observers according to the scale scoring shown in Table II¹⁹. Scores for each slide from the 3 observers were averaged to obtain

TABLE III. MicroCT Morphometric Results

Test Group	Normalized Bone Area (%)	
	6 weeks	12 weeks
Signafuse®	19.7 ±6.2	23.2 ±7.7
Actifuse ABX	12.3 ±3.4	21.4 ±7.6
p-value	0.002	0.478

TABLE IV. Biomechanical Range of Motion Results

Test Group	Flex-Ext (°)	Lat Bend (°)	Axial Rot (°)
Normal Unfused*	14.57	13.43	2.92
Signafuse	4.19	2.04	0.93
Actifuse ABX	5.35	3.42	0.99

*Obtained from historical internal laboratory data of normal unfused rabbits.

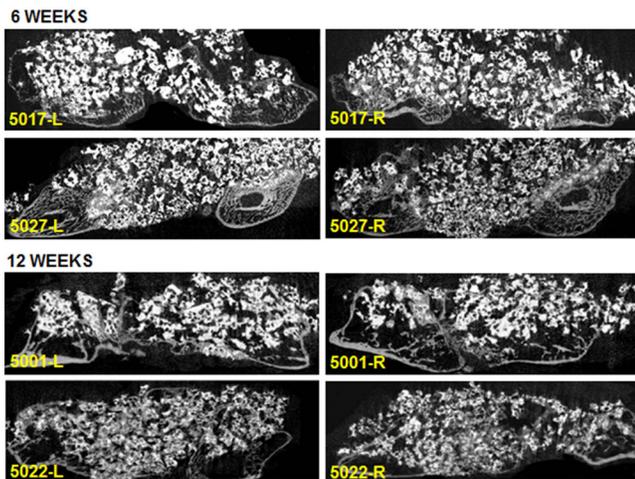


Figure 2. Representative bilateral microCT sagittal images of the fusion defects at 6 and 12 weeks for Signafuse (5017, 5001) and Actifuse ABX (5027, 5022).

a fusion score for each animal. The final fusion scores were determined as the mean of the animal fusion scores for each test group and time point.

Statistical Analysis

Statistical analysis was performed on the biomechanical flexibility data as well as the normalized microCT and histomorphometric area percentages. First, a normality test was performed on each data set from each time point. If the data was normal, a student’s t-test was conducted ($\alpha=0.05$). If the data was not normal, a non-parametric Mann-Whitney test was used ($\alpha=0.05$). All statistical analysis was performed using Minitab software (version 15.1.1.0: Minitab Inc., State College, PA, USA). All morphometry data was analyzed to a 95% confidence level ($p<0.05$) with a 2-tailed Student’s t-test, assuming unequal variance using Microsoft Excel.

RESULTS

Necropsy/ Macroscopic Evaluation

Necropsy of the animals was unremarkable regardless of test group. Macroscopic analysis of the implant sites demonstrated healthy tissue with no apparent adverse effects such as inflammation, tissue necrosis, or devascularized tissue surrounding the defect sites.

Radiography

Radiographic observations at 6 and 12 weeks indicated a normal healing response over time in both test groups, with no evidence of fractures, osteolysis, or other adverse reactions.

MicroCT Assessment

The 6 week morphometric data showed significantly greater bone area in the Signafuse group compared to Actifuse ABX (19.7% vs. 12.3%; $p < 0.05$), while the 12 week data showed no statistical differences between groups (Table III). Although the area-based morphometric bone data was similar at 12 weeks, distinctions in the alignment and structural development of new bone across the fusion bed were observed between groups. The Signafuse group generally demonstrated a more developed fusion structure compared to Actifuse ABX, characterized by a higher tendency of mature bone spanning the fusion bed. The Actifuse ABX group generally demonstrated a lesser degree of mature bone formation and structural development across the fusion defect (Figure 2).

Manual Palpation

At 6 weeks, the fusion rate by manual palpation was 33% (2/6 animals) for Signafuse and 0% (0/6 animals) for Actifuse ABX. At 12 weeks, the fusion rate was 50% (5/10 animals) in both test groups, and thus no differences were detected between groups.

Biomechanical Testing & Fusion Analysis

At 12 weeks, both groups had statistically significant less ROM in all motion planes compared to the normal controls ($p < 0.001$), and no differences were detected between test groups in any motion plain (Table IV). However, the mean flexion-extension ROM for the Signafuse group (4.19°) met the fusion criteria ($< 5^\circ$) while Actifuse ABX did not (5.35°). Analysis of individual specimens based on this flexion-extension fusion criteria revealed a biomechanical fusion rate of 80% (8/10 animals) in the Signafuse group and 44% (4/9 animals) for Actifuse ABX (Table V).

Histopathology

Histopathology analysis of decalcified paraffin sections generally revealed minimal inflammation and a normal healing response regardless of implant type or

TABLE V. Biomechanical Fusion Analysis

Treatment Group	Biomechanical Fusion Rate (< 5° ROM, Flexion-Extension)	
Signafuse®	8/10 rabbits	80%
Actifuse ABX	4/9 rabbits*	44%

*One of the fusion masses broke before biomechanical testing.

TABLE VI. Histopathology Analysis

Test Group	Semiquantitative Analysis (ISO 10993-6)	
	6 weeks	12 weeks
Signafuse®	25.60	68.27
Actifuse ABX	24.00	52.40

TABLE VII. Histomorphometry Analysis

Test Group	Normalized Bone Area (%)	
	6 weeks	12 weeks
Signafuse®	29.4 ±6.0	22.9 ±6.8
Actifuse ABX	24.4 ±6.4	20.9 ±7.7
p-value	0.019	0.288

TABLE VIII. Histological Fusion Scores

Test Group	Fusion Score	
	6 weeks	12 weeks
Signafuse®	5.46 ±0.79	6.76 ±0.67
Actifuse ABX	3.83 ±0.62	4.13 ±0.65
p-value	0.156	0.047

time point, largely characterized by very low numbers of macrophages and multinucleated giant cells (which in some cases could be osteoclasts) with some scattered, often rare lymphocytes and plasma cells. All fusion sections demonstrated moderate neovascularization, fibroconnective tissue and new bone formation, which was more mature in the 12 weeks animals compared to the 6 weeks animals. New bone formation was not specifically scored but at both 6 and 12 weeks points it appeared that Signafuse had more abundant new bone formation and remodeling as compared to Actifuse ABX. Semiquantitative histology analysis at 6 weeks indicated a similar biological response in both groups (Table VI). The scoring at 12 weeks indicated an increased response in both groups, due to an increase in macrophages and giant cells likely associated bone and/or tissue remodeling. There were more giant cells associated with new bone and/or implant material suggestive of osteoclast remodeling. In lieu of this, there were, as expected, an increased number of macrophages to clean up associated cellular debris. Neovascularization and fibrosis were similar to that at 6 weeks in both groups. The increased

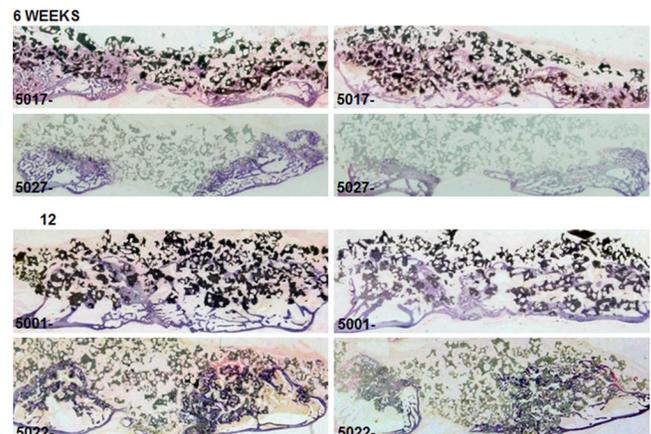


Figure 3. Representative bilateral non-decalcified histology of the fusion defects at 6 and 12 weeks for Signafuse (5017, 5001) and Actifuse ABX (5027, 5022).

response of the Signafuse treated defects compared to Actifuse ABX at 12 weeks correlates with the observation of more abundant new bone formation and remodeling in the Signafuse sections.

Histomorphometry

Histomorphometry analysis of the nondecalcified sections revealed significantly greater bone area in the Signafuse group at 6 weeks compared to Actifuse ABX (29.4% vs. 24.4%; p <0.05), while the 12 week data showed no statistical differences between groups (Table VII).

Histological Fusion Analysis

Although the area-based bone histomorphometry data was similar at 12 weeks, distinctions in the structural development of new bone across the fusion bed were observed between groups, as demonstrated by the histological fusion scores (Table VIII). The scoring suggests more advanced remodeling of the fusion defects in the Signafuse group at both 6 and 12 weeks, characterized by a greater presence of mature bone and tendency toward complete bridging of the transverse processes, which was less apparent in the Actifuse ABX group (Figure 3). The bioactive glass component of Signafuse was appreciably resorbed at 6 weeks and completely replaced by host bone at 12 weeks. The ceramic component in both groups showed new bone formation in direct apposition to and bridging between granules. The biphasic granules of Signafuse demonstrated a loss of distinction at the new bone interface indicating a normal resorption process, which was less apparent for the silicate-substituted HA granules of Actifuse ABX (Figure 4). The greater structural development of the fusion masses observed over time in the Signafuse group also supports the microCT assessment and biomechanical fusion data.

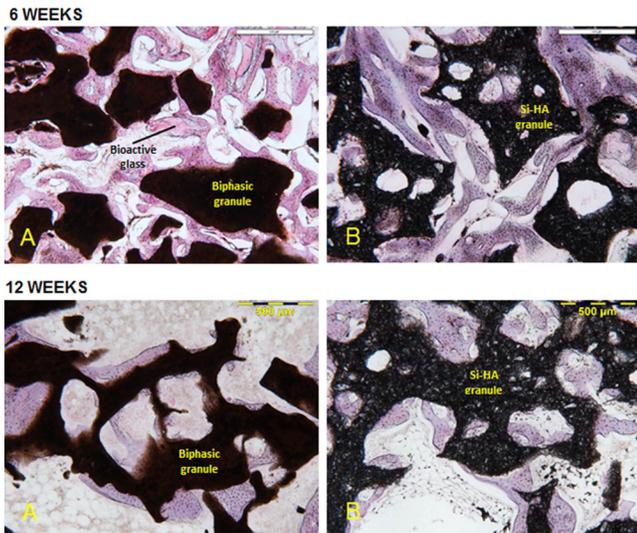


Figure 4. Representative high-magnification non-decalcified histology at 6 and 12 weeks showing the remodeling progression of the graft materials for Signafuse (A) and Actifuse ABX (B).

DISCUSSION

Synthetic bone graft materials continue to be developed as alternatives to ICBG, with the ultimate goal of optimizing implant resorption and bone substitution such that solid bony fusion can be reliably achieved¹². This study evaluated the fusion performance of two synthetic bone graft products for which the base materials have been reported to influence the biologic healing response in bony defects, namely Signafuse and Actifuse ABX. Confirmed by multiple metrics, Signafuse outperformed Actifuse ABX as a standalone synthetic bone graft in an established PLF rabbit model, demonstrating greater rates of bone remodeling and spine fusion. The distinctions in performance between the grafts were observed in all endpoints including radiographic, biomechanical and histological evaluations.

The 50% fusion rate by manual palpation observed in both test groups at 12 weeks is typical of this animal model. The majority of reported PLF rabbit studies have used ICBG as the standard of care control, as it best mirrors in situ fusions in humans. Published meta-analyses of these studies have revealed manual palpation fusion rates of 56.8% and 58.3%¹⁴⁻¹⁵. Manual palpation has historically been considered an accurate indicator of solid fusion in this animal model because it allows direct functional assessment, as would be performed during surgical exploration in the clinical setting. However, manual palpation is a subjective evaluation dependent on perceived relative rigidity of the fusion segments, and therefore comprehensive evaluation of additional endpoints is often required to judge actual fusion status.

In this study, biomechanical ROM of the fused segments in flexion-extension was used as an objective determinant of solid fusion, based on previously reported ROM data for ICBG in the rabbit PLF model. Eruker and colleagues, using almost identical method as employed in this study, demonstrated that solid fusion, as initially determined by manual palpation, correlates to total ROM in flexion-extension of less than five degrees ($< 5^\circ$) in ICBG treated fusions¹⁶. Due to the established efficacy of ICBG in the rabbit PLF model, this value was used as the determinant of biomechanical fusion in the current study. This measurement is also relevant in the clinical setting, where less than 5° ROM, as observed in lateral flexion-extension radiographs, has been used as a criterion for successful fusion²¹.

Of significant note is that the 80% (8/10 animals) fusion rate in the Signafuse group is higher than the 63% (5/8 animals) fusion rate reported in the referenced ICBG study¹⁸. Although this data represents fusion at 5 weeks, it has been reported that ICBG fusion rates do not significantly increase past this time point, and therefore a casual comparison of Signafuse fusion rates to ICBG may be warranted.

The greater bone area across the fusion bed measured in the Signafuse group at 6 weeks was likely due to the presence of the bioactive glass inter-dispersed among the BCP granules. Aside from the potential biologic effects previously reported²²⁻²⁵, the rapid dissolution and apatite layer formation may have produced a viable osteoconductive substrate for cellular attachment earlier in healing process. The biphasic HA/ β TCP granules demonstrated intimate surface bonding with host bone and indicated an active remodeling process based on changes in granular appearance and loss of distinction at the new bone interface. The silicate-substituted hydroxyapatite (Si-HA) material of Actifuse ABX did demonstrate sufficient bone bonding capability, however new bone formation was largely associated with the decorticated transverse processes, with limited formation across the defect. In addition, a more distinct surface demarcation was evident at the host bone interface, indicating low solubility and a limited resorption profile.

Although the morphometric data at 12 weeks was similar in both groups, appreciable differences in the maturity and structure of new bone formation was observed between groups in the histological fusion scoring. As remodeling of the fusion mass progresses, new bone will condense and align directionally according to anatomical constraints and physiological stress, which can result in minimal change or a reduction in morphometric bone area in successfully fused specimens. The progression in bone remodeling toward a structurally

mature fusion mass at 12 weeks, evidenced by mature bone and developed marrow spaces bridging across the defect, may be attributed to the continued dissolution and complete remodeling of bioactive glass, in addition to the gradual resorption properties of the BCP granules, which appeared to be compatible with the host remodeling process. The Si-HA granules of Actifuse ABX did support a progression in new bone formation and remodeling over time, but the fusion structures were relatively underdeveloped, evidenced by a lesser degree of mature bone and bridging between TPs and apparent minimal resorption of the Si-HA granules.

In conclusion, this study has demonstrated the efficacy of Signafuse as a viable standalone replacement for ICBG in spinal fusion procedures based on performance outcomes in an established rabbit spine fusion model. Fusion defects treated with Signafuse demonstrated greater levels of bone remodeling and higher fusion rates compared to Actifuse ABX, as confirmed across several endpoints. The combination of biphasic calcium phosphate and bioactive glass appears to elicit a greater bone healing response than the 0.8% silicate-substituted hydroxyapatite. The prevalence of structurally mature fusion development in the 12 week Signafuse animals, observed both biomechanically and histologically, is uncommon for a synthetic bone graft and compares favorably to historical ICBG data in this animal model.

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