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INSTRUCTIONS FOR AUTHORS, 2014 EDITION


We will consider any original article relevant to orthopaedic surgery, orthopaedic science or the teaching of either for publication in The Iowa Orthopaedic Journal. Articles will be enthusiastically received from alumni, visitors to the department, members of the Iowa Orthopaedic Society, residents, and friends of The University of Iowa Department of Orthopaedics and Rehabilitation. The journal is published every June. The deadline to receive articles for the June 2014 edition is Monday, January 6, 2014.

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

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2013 IOJ EDITORS’ NOTE

It is with great pleasure that we present the 33rd edition of The Iowa Orthopaedic Journal (IOJ), corresponding with the 100-year anniversary of The University of Iowa Department of Orthopaedic Surgery.

As in previous years, submissions were received from within our department as well as from across the nation and globe. The impact of the IOJ continues to increase, as the articles are freely available via Pub Med. A recent analysis demonstrated that more than 57,000 articles from the IOJ are downloaded from Pub Med each month. We are hopeful that the Pub Med exposure will continue to increase the IOJ readership and result in ongoing growth.

We would like to recognize the departing senior residents Drs. Carlo, Compton, Ebinger, Peterson, Sullivan, and Takenaga. They have led with confidence and have inspired the younger resident classes to high achievement. We wish them all the best as they leave the department and embark on the next stage of their careers. Several will be leaving the state of Iowa to begin general practice or start fellowship training throughout the country. We hope that their Iowa Orthopaedic roots will serve them well and keep them connected to the department throughout their promising careers.

For this special 100-year anniversary, we would like to dedicate this year's journal to the Chairmen of The University of Iowa Department of Orthopaedic Surgery, both past and present, who have led our department with honesty, integrity, and a vision that has established our training program as one of the best in the world. Over the past century, our Chairmen, Drs. Steindler, Larson, Cooper, and Buckwalter, have fostered a program rich in tradition and success, and have truly reflected the essence of what it means to be a physician.

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

Finally, we would like to thank our wives, Nicole Schick and Lindsey Willey, for their tremendous support and patience throughout the creation of this journal and during residency. We could not have done it without them. In addition, we thank our children who have provided inspiration and perspective in our careers.

It has been an honor to serve as the editors for the IOJ for 2013 on the 100-year anniversary of The University of Iowa Department of Orthopaedic Surgery. This is a special place that will always be at the core of our development and lives. We are excited for the future of our department, we are thankful for the premier training we have received from our faculty, and we look forward to being connected throughout our careers.

Cameron W. Schick, MD
Michael C. Willey, MD
Co-Editors
Iowa Orthopaedic Journal
Department of Orthopedics and Rehabilitation
University of Iowa Hospitals and Clinics
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"The best people possess a feeling for beauty, the courage to take risks, the discipline to tell the truth, and the capacity for sacrifice."

-Ernest Hemingway

The University of Iowa Department of Orthopaedic Surgery has a rich history in clinical care, philanthropy, education, and research. In publishing the Iowa Orthopaedic Journal on the 100th Anniversary of the department, the editors had great difficulty in selecting one individual to honor on this occasion. After much discussion with our mentors, we elected to honor the four Chairmen of this department over its first 100 years: Arthur Steindler, Carroll Larson, Reginald Cooper, and Joseph Buckwalter.

The longevity of each Chairman’s tenure at the University of Iowa laid the groundwork for so many individuals who were associated with this department to succeed. The fact that there have been only four Chairmen is to our knowledge unique among academic orthopaedic departments with a history that extends back for a century. It is a daunting task to compile the lives of these four very influential individuals. With this dedication we will focus on the contributions of each individual to the department in the areas of philanthropy, research, and education.

ARTHUR STEINDLER

Arthur Steindler was the founding professor of orthopaedic surgery at the University of Iowa. His story began 4,800 miles away from Iowa City, when he was born in Graslitz, Czechoslovakia. Dr. Steindler later moved to Vienna with his family. His father, who was a lawyer, insisted that he develop a well rounded education that focused on literature, philosophy, language, and music. He was fluent in seven languages throughout his career, which allowed him to communicate internationally. He attended medical school at the University of Vienna and graduated in 1902.

After his training, he left Vienna for Chicago in 1907 to work at the Home for Crippled Children with Dr. John Ridlon. There was a great need in the state of Iowa for a physician experienced in the care of patients with orthopaedic problems and Dr. Ridlon encouraged him to accept the position of Professor of Orthopaedic Surgery at Drake Medical School in 1910. He was the first orthopaedic surgeon in the state of Iowa. During his years in the state capital, he developed relationships with state politicians that helped him to advocate policy decisions to help benefit citizens of the state. Dr. Stuart Weinstein has carried on this tradition of political involvement today.

In the early 1900s, the University of Iowa was under threat to transfer the state medical school from Iowa City to Des Moines. The 9th president of the University of Iowa, John Bowman, needed a hardworking and charismatic physician to serve as a magnet for patients and other physicians to practice in the small town. In 1913 Arthur Steindler joined the faculty at the University of Iowa and became the first orthopaedic surgeon at the University. He was only 35 years old at the time.

For his first 5 years of practice in Iowa City, he was the only orthopaedic surgeon at the University of Iowa and one of only three orthopaedic surgeons practicing in the state. During his time in Des Moines and Iowa City, he recognized that the residents of Iowa with crippling orthopaedic conditions had limited access to orthopaedic care. In the next stage of his career, he was involved with legislation to help these individuals. He pushed the state to pass two important pieces of legislation: the Perkins Act in 1915 and the Haskell-Klaus Act in 1919. The Perkins Act provided medical treatment to any child under sixteen years old. The Haskell-Klaus Act provided the same care to adults in the state. This coverage was similar to the current Iowa Care coverage plan that provides medical treatment for patients who do not qualify for Medicaid. These acts also established the hospital car and ambulance system that provided transportation for patients from their homes to the University Hospital.
During his early career in Iowa City, Dr. Steindler also oversaw building of the Children’s Hospital that began in 1917 and was completed in 1920. This was the first building in the complex now on the west side of the Iowa River. The hospital consisted of inpatient rooms that allowed patients to be outside during nice weather, a gymnasium for physical therapy, operating rooms, and a brace shop. In 1924 the state legislation delegated $2.5 million, matching the Rockefeller Foundation, to build the 900-bed University Hospital adjacent to the Children’s Hospital. This is equivalent to $33 million today based on inflation alone.

Dr. Steindler also dedicated a substantial amount of time to the education of upcoming orthopaedic surgeons. He established a graduate program in orthopaedic surgery that accepted ten students a year. The tuition was $50-$100 and at the end of each year he accepted two to three graduate students into a three year orthopaedic surgery residency. He had a series of didactic lectures that encouraged graduate students and residents to discuss their ideas openly. Critical thinking was an important part of his lessons and he was quoted as saying “I would rather be wrong with an impartial reason than right without one”12.

Under his leadership the University of Iowa Department of Orthopaedic Surgery was brought into fruition and in 1948 he passed on a department that was recognized internationally for clinical care and innovation.

**CARROLL LARSON**

The department was then passed into the capable hands of Carroll Larson in 1950. He was one of two chairmen native to the state of Iowa. Dr. Larson was born in Council Bluffs, IA in 1909. In high school he was an excellent student and stood out as a track and field athlete in the pole vault. He attended the University of Iowa from 1927-1933, completing his BS and medical degree. After completing medical school he traveled to Santa Clara County Hospital in San Jose, CA for an internship and residency in general surgery. In the next year, he returned to the Midwest to complete his obligation to the Army and was a locum tenens physician in Indianola and Ida Grove, Iowa. Dr. Larson then moved across the country to Boston, Massachusetts for an orthopaedic surgery residency.

At the Harvard Orthopaedic program in Boston, Dr. Marius Nygaard Smith-Peterson recognized Carroll Larson’s talents and he was recruited to help perfect the techniques and instruments for the vitallium cup arthroplasty. This early training led to his later work with clinical outcomes in hip arthroplasty completed at Iowa. Dr. Larson continued his work in Boston from 1939-1950. He remained active in the military, directing a continuing Trauma Course for Armed Forces Medical Officers, and taught orthopaedic curriculum full time at Massachusetts General Hospital.

When Dr. Larson became chairman in 1950, the three staff in the department were Dr. Ponseti, Dr. Bonfiglio, and Dr. Newman. Besides running a busy clinical practice, Dr. Larson led the department during a time of advancements in orthopaedic education and scientific pursuits. Dr. Ponseti began experiments in the biochemistry laboratory, Dr. Bonfiglio continued to lead the pathology laboratory, and Dr. Flatt later joined the department and added an upper extremity biomechanics laboratory.

Dr. Larson was a national leader in clinical outcomes research. He continued to perform the cup arthroplasty that he perfected with Dr. Smith-Peterson in Boston. Focusing on this procedure he solidified the Iowa tradition of measuring clinical outcomes with long term follow up. In 1963 Dr. Larson published a classic article describing the development of a clinical outcome score for hip disability now known as the Iowa Hip Rating9. He also published important clinical reviews with classic titles of “Fracture Dislocations of the Hip”11 and “Results of Treatment of Hip Disorders with the Cup Arthroplasty”18. Through his work in clinical research, Dr. Larson inspired new generations of orthopaedic surgeons to critically analyze patient perceived outcomes of orthopaedic procedures.

As a leader at the national level, Dr. Larson led progress in education and certification of orthopaedic surgeons. In his presidential address for the American Academy of Orthopaedic Surgery in 1967, he emphasized the importance of not only increasing the number of orthopaedic surgeons trained each year, but to increase the quality of their education. He sought to not dilute the ranks of orthopaedic surgeons as the practice expanded in the 1960s and 1970s. He summarized his presidential speech with the statement, “A mechanism in the future could be developed whereby the desires and aptitudes of trainees could be matched to programs. More young physicians will be attracted to academic orthopaedics when our training programs identify the abilities, interests, and level of maturity in the trainees and provide the flexibility and environment to accommodate their needs”10.

Dr. Larson demonstrated his dedication to caring for children with disabling orthopaedic conditions by setting aside time in his career to serve the Shriners Hospitals.
He served as Executive Medical Advisor, Director of Medical Affairs, and on the Shriners Medical Advisory Board. He also took a one-year leave of absence to critique twenty-four Shriners Hospitals to improve their efficiency and quality of care. The Shriners still to this day fund a two-day pediatric lecture series given each year at the University of Iowa in honor of Dr. Larson. In 1973 Dr. Larson turned over his leadership role at the University of Iowa Department of Orthopaedic Surgery. During his tenure, the department produced three Kappa Delta Award winners, and six residents who would go on to be chairmen of academic orthopaedic surgery departments, including the next chair of his department.

**REGINALD COOPER**

The next chairman of the University of Iowa Department of Orthopaedic Surgery has been described as "strongly opinionated" and having "powerful intellect combined with common sense," with a special talent to "combine criticism with humor". Reginald Cooper was raised in Dry Fork, West Virginia, a small town of no more than twenty-five citizens. His parents were trained as teachers and later ran the country store in Dry Fork. His grandfather was a physician caring for the citizens in the local area. He grew up working in the family country store and graduated high school with twelve classmates.

Dr. Cooper attended Potomac State College and later West Virginia University in Morgantown. He began his medical education at the Medical School in Morgantown and completed his medical degree at Medical College of Virginia in Richmond in 1955. During his medical education he developed a strong interest in the diagnosis and management of children with neuromuscular disorders. Based on this early interest, he applied and was accepted to a general surgery internship at the University of Iowa, moving to Iowa City in the summer of 1955.

After completing his general surgery internship, he was accepted to the orthopaedic surgery residency at the University of Iowa. Orthopaedic residents in 1957 were graciously offered a salary of $75 per month. In addition to the egregious salary, the orthopaedic surgery residents at that time were offered the opportunity to work with giants in the field of orthopaedics including Michael Bonfiglio, Ignacio Ponseti, Adrian Flatt, and Carroll Larson. As a resident, Dr. Cooper was expected to obtain a high level of basic scientific and clinical knowledge. After completion of his orthopaedic residency in 1960, he served in the United States Navy until 1962.

Upon completion of his service in the Navy, Dr. Cooper returned to Iowa City as an associate professor of orthopaedic surgery. During residency he had developed an interest in bone and skeletal muscle pathology, which led him to complete a National Institute of Health Research Fellowship at Johns Hopkins University. During this fellowship he completed classic studies on skeletal muscle atrophy/regeneration and cortical bone structure after immobilization. On returning to Iowa, he established the Electron Microscopy Laboratory. During his early career in 1969, he also participated in the American, British, and Canadian traveling fellowship. Dr. Larson previously participated in the first traveling fellowship in 1948.

In 1973 Dr. Cooper accepted the chairman position from his mentor, Dr. Larson. The faculty at that time consisted of Ignacio Ponseti, Michael Bonfiglio, Carroll Larson, Adrian Flatt, John Albright, and Bruce Sprague. In 1979, a small group of faculty elected to reorganize the department of orthopaedic surgery to accommodate expansion and specialization of the field. They decided to organize the faculty into orthopaedic subspecialties, in effect creating the team structure that the department and residency is organized into today.

This reorganization, as well as a focus on recruiting upcoming and influential individuals, led to an expansion in the department. By 1999 there were eighteen clinical faculty members representing every recognized subspecialty in orthopaedic surgery. Identifying and recruiting excellent talent in the field of orthopaedic surgery was a talent of Dr. Cooper and the University of Iowa is now nationally recognized for excellence in all of these subspecialties.

During his tenure many programs were expanding the roles of clinical fellows in training programs. Dr. Cooper resisted this trend at the University of Iowa turning the focus to resident education. He thoroughly evaluated each resident applicant to the program and was instrumental in improving the quality of the residency. Dr. Cooper also led the residency to be one of the first programs to accept orthopaedic residents directly from medical school. This allowed for programs to ensure that all residents had a well-rounded experience prior to entering formal orthopaedic training.

Dr. Cooper was a strong leader in the department and had many personal successes that are too numerous to thoroughly describe in this dedication. During his career he was given the Kappa Delta award in 1970, served as the president of the Orthopaedic Research Society, and president of the AAOS in 1987. He was also very involved with the Shriners Hospitals. Throughout his tenure as Chairman, his primary goal was to "teach exemplary
patient care and this philosophy lead to vast transformations in the department while maintaining excellence at the University of Iowa.

JOSEPH BUCKWALTER

You would be hard pressed to find another individual more “Hawkeye” than Joseph Buckwalter. He grew up in Iowa City while his mother completed a psychiatry residency and his father a surgical residency at the University of Iowa. He had a brief departure from the state while his father completed a fellowship in North Carolina and England, but soon returned to Iowa City in time to excel in academics and athletics at University High School. Similar to Dr. Larson, he was an outstanding track and field athlete. This success led him to the University of Wisconsin with a track and field scholarship, but after a hamstring injury, he learned his lesson and returned to Iowa City to complete a degree in Psychology.

Dr. Buckwalter entered medical school at the University of Iowa in 1969. He had an interest in pathology and took a year off in medical school to complete a masters degree in this field. During school he had chance interactions with Dr. Bonfiglio, Dr. Sprague, and Dr. Ponseti that sparked an early interest in orthopaedic surgery. In 1974 he graduated medical school. After completing an internal medicine internship, the Hawkeye State would not let him go and he entered residency in orthopaedic surgery. In 1979 he completed residency and joined the faculty at Iowa.

Dr. Buckwalter has a versatile set of skills and filled many roles according to the clinical need of the department. Soon after he joined the faculty, Dr. Flatt departed and he filled the role as the department’s hand surgeon. Later there was a need for a musculoskeletal oncologist. He adeptly filled this role after completing an accelerated fellowship with Dr. Enneking at the University of Florida. Dr. Buckwalter has maintained a busy musculoskeletal oncology practice to this day. He has also been very involved with athletics at the University of Iowa, filling the role of sports medicine physician when needed.

Dr. Buckwalter’s contributions to musculoskeletal science have been a defining part of his career. Early in his career he developed a novel method to evaluate proteoglycan molecules. This led to a wealth of information about the matrix structure of growth plates, articular cartilage, and intervertebral discs. These are major contributions to our knowledge of matrix function and pathology. He received the Kappa Delta award in recognition of these discoveries.

Dr. Buckwalter has also been instrumental in advancing our knowledge of cartilage degeneration and post-traumatic osteoarthritis at the University of Iowa. He routinely delivers lectures to the residents and at national meetings recounting advances in the field. He expertly summarizes complex advances in the field into interesting well thought out story lines. Many residents and visiting professors have felt that Dr. Buckwalter was their primary inspiration to entering the field of orthopaedics. His accomplishments in advancing musculoskeletal science are not only limited to his work at the University of Iowa, but expands to a vast network of musculoskeletal clinician-scientists.

In 1999 Dr. Buckwalter took the reins from Dr. Cooper and has maintained the national reputation of our department. During his tenure, the number of clinical faculty has increased to thirty-four, including adding five staff specializing in physiatry and four faculty with leadership roles in research laboratories. The residency program has also expanded to six residents per year. The residency program has also expanded the scope of orthopedic training by adding more orthopaedic-focused rotations during the first year compounding advances in the internship started by Dr. Cooper.

As the current Chairman of the University of Iowa Department of Orthopaedic Surgery and Rehabilitation, Dr. Buckwalter artfully manages our department as a true gentleman. He encourages a family atmosphere of cooperation and navigates the department with strong leadership. Any student, resident, or faculty who has passed through this department would list him as having a significant impact on their career.

CONCLUSION

It is a great honor for the editors of the 2013 Iowa Orthopaedic Journal 100th Anniversary Edition to dedicate this work to the Chairmen of the University of Iowa Department of Orthopaedic Surgery. These outstanding individuals are truly the pillars that have elevated this department to greatness. We are very humbled by the history of this department and have excluded many more accomplishments that could not be included in this dedication. We want to express much gratitude to the authors that compiled previous IOJ dedications and articles that served as resources for this compilation. We hope that readers of this dedication will provide others with insight to these great individuals and encourage everyone to delve into the archives of the IOJ to learn more about the history of this department.
REFERENCES

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DEPARTMENT OF ORTHOPAEDICS AND REHABILITATION
SCHEDULE OF LECTURESHIPS AND CONFERENCES

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

Carroll B. Larson Shrine Memorial Lecture
March 15-16, 2013
Kenneth Noonan, MD
Chief of Pediatric Orthopaedics
American Family Children’s Hospital
Madison, WI
Spring 2014 to be arranged. Contact Nancy Love @ (319) 356-1872

2013 Senior Resident’s Day
June 7-8, 2013
Richard Kyle, MD
Department of Orthopaedic Surgery
Hennepin County Medical Center
Minneapolis, MN

Kit Song, MD, MHA
Chief of Staff
Shriners Hospitals for Children – Los Angeles
Los Angeles, CA
Contact Gloria Yorek @ (319) 356-3523

2014 Senior Residents Day
June 13-14, 2014 (Fri/Sat)
Discussants to be arranged.

29th Annual Hawkeye
Sports Medicine Symposium
December 12-13, 2013 (Thurs/Fri)
Marriott Hotel and Conference Center
300 East 9th Street, Coralville
Guest speaker - to be arranged
Contact Kris Kriener @ (319) 353-7954

100 Year Celebration of Iowa Orthopaedics
October 10-13, 2013
http://www.uiortho.com/century

Ponseti Races
October 13, 2013 - 7am
UI Sports Medicine Center
Department of Orthopaedics

The University of Iowa
Roy J. and Lucille A. Carver College of Medicine
First Row: Ryan Ilgenfritz MD, Joseph Buckwalter MD, Charles Clark MD, John Albright, MD, James Nepola MD.

Second Row: Grant Bowman MD, Julian Carlo MD, Joseph Buckwalter MD, Cameron Schick MD, Tom Ebinger MD, Mark McCarthy MD, Shannon Cassel, Daniel Koehler MD, Tameem Yehyawi MD.

Third Row: Melissa Willenborg MD, Stephen Compton MD, Robert Westermann MD, Jeremiah Dawson MD, Kyle Duchman MD, Carolyn Hettrich MD, Nick Noiseux MD, Reginald Cooper MD, Phinit Phistikul MD, Joseph Smucker MD, Eric Ashenbrenner MD.

Fourth Row: Matt Bollier MD, Jonathan Peterson MD, Ben Miller MD, Chris Martin Md, Josh Tennant MD, Fred Dietz MD, Andrew Pugely MD, Emily Wagstrom MD, Sergio Mendoza MD, Ernie Found MD

Fifth Row: Jared Daniel MD, Michael Willey MD, Ned Amendola MD, Jaron Sullivan MD, Shane Cook MD, Matthew Hogue MD.
Julian Carlo, MD

Julian Carlo was born in Cleveland, Ohio. At the age of 10, his family moved to Birmingham, Alabama. In his youth he was active in Boy Scouts, soccer, math team, and band. During his formative years, his father, a neonatologist, instilled in him the idea that medicine was a very rewarding field. He attended college and medical school at Harvard. He credits his undergraduate studies in biological anthropology for igniting his interest in orthopaedics. He was excited to match at Iowa for residency. In his third year at Iowa, he married his long-time love, Susan. Together they have two beautiful dogs, Ignacio Jose (Nacho) and Rufus Maximus (Ruffles). In his spare time Julian enjoys drumming, traveling, and jet skiing Iowa’s lakes and rivers. He will begin a hand and upper extremity fellowship in August at the University of Florida. He is thankful to his wife for her tremendous support during residency. He feels honored to have worked with such an excellent group of fellow residents and staff at the University of Iowa and wishes them the best of luck in the future.

Stephen Compton, MD

Stephen was born in Murray, Kentucky, the third son to parents Steve and Paula. Disappointed, as they hoped to have a girl, and forced to pick a name, they somehow came up with Stephen Paul. Stephen grew up in Murray and then attended Murray State University for his undergraduate education.

While a junior in high school Stephen began dating his wife to-be, Erika and the two have been together ever since. Just as he knew that she was “the one” at age 17, he was also confident that he not only wanted to be a doctor, but specifically an orthopaedic surgeon. Stephen and Erika got married after his junior year in college. After graduating Murray State, Stephen and Erika moved to Louisville, Kentucky for him to attend medical school. While there Stephen continued on his path to become an orthopaedic surgeon.

After interviewing at Iowa, they both knew it would be a great place to train and spend five years. Iowa quickly became their second favorite state. During residency Stephen and Erika were blessed with the birth of their three amazing children Anderson, Ally Mae, and Clara Grace in Stephen’s first, third and fifth years respectively. It has been such a joy to share this exciting time in their lives with their Iowa orthopaedic family while being away from their families.

While in residency at Iowa, Stephen has enjoyed working with outstanding faculty and residents. The camaraderie, professional and personal relationships that he has built over the last 5 years are invaluable. Stephen is honored to be a part of the Iowa orthopaedic tradition.

After residency, the Compton family will return to Stephen and Erika’s hometown of Murray, Kentucky for Stephen to begin practice at Murray-Calloway County Hospital. Stephen is looking forward to not only taking his 3 Iowa born children to Kentucky, but also the world class orthopaedic training that he received as a part of the Iowa team. While excited to begin the next chapter of their lives, Stephen and the Compton family will always cherish their Iowa years and thank everyone they have encountered for making it such an incredible 5 years.
Jon Peterson, MD

Jon was born and raised in San Diego, California. He was the first of Bradley and Barbara Peterson’s three boys. Jon completed his undergraduate studies at Northwestern University in Evanston, IL where he majored in economics and molecular biology. Following college, Jon returned to San Diego for medical school at the University of California, San Diego.

During medical school, Jon did a rotation in pediatric orthopaedics with Dr. Dennis Wenger, a former Iowa orthopaedic resident. Jon was inspired to pursue a career in pediatric orthopaedics and Dr. Wenger convinced him that Iowa was the place to train. Jon was fortunate enough to match at the University of Iowa. He has enjoyed the opportunity to train under such a dedicated faculty and with such a great group of residents.

Iowa has also brought several unexpected and wonderful surprises to Jon’s life. His intern year he met and quickly fell in love with his beautiful wife Amy. Three years ago, Jon and Amy welcomed a dog, Norske, into their life. Norske has been a constant provider of loyal companionship and an occasional provider of diarrhea for the family. Last year they welcomed a son, Brock, into this world. He is a never-ending source of joy and amusement. Some of Jon’s other fond memories of Iowa will be Hawkeye football games and trout fishing near his wife’s gorgeous hometown of Decorah, Iowa. Iowa will always have a special place in Jon’s heart.

Next year Jon will be returning to San Diego to complete a fellowship in Pediatric Orthopaedics.

Thomas Ebinger, MD

Tom Ebinger was born and raised in Cedar Rapids, Iowa, the third son of Mike and Kate Ebinger. He graduated from Xavier High School in Cedar Rapids, where he was heavily involved in athletics following in his older brothers’ footsteps. After high school he played football and earned a Bachelor’s degree in Molecular Biology at Yale University. He then returned home to Iowa for his medical education. Tom married his high school sweetheart, Laura, in 2007. He graduated from the University of Iowa College of Medicine in 2008, one year after his wife graduated from the Iowa College of Law. After discovering his major interest was in orthopedics and figuring out there was a world class orthopedics department in his backyard, Tom worked to stay at his home institution for residency and was extremely fortunate to match at Iowa. During residency, Tom and Laura were blessed with the births of their two beautiful daughters Maggie and Molly.

Tom would like to thank all of the faculty at Iowa for their patience, encouragement, and teaching over the past five years. He would like to thank his co-residents and staff for their camaraderie, hard work, and enthusiasm. He would most of all like to thank his parents for giving him every opportunity in life and to his wife whose support and love drives him to succeed. Tom looks forward to staying at the University of Iowa next year to complete a fellowship in hand/upper extremity surgery.
Ryan Takenaga, MD

Ryan was born and raised in Anaheim, CA. He studied Economics at UCLA with plans for a career in business. However, his avocation for philosophy and theology led him to pursue a Masters degree in Philosophy of Religion and Ethics at Biola University in La Mirada, CA. In addition to his degree, he also ended up pursuing his eventual wife, Nancy, who was completing the same degree. With plans for a career in academic philosophy, they moved to Austin, TX, so Ryan could pursue a Ph.D. in Philosophy. During this time Ryan realized that he wanted to help and serve people in a more direct way than academia. After much soul searching, he decided on a career in medicine. This set them on an eleven year journey: pre-med studies, medical school at Johns Hopkins in Baltimore, MD, and finally residency in Iowa City. During this time they had three children: Dylan, Sophia, and Elizabeth.

Ryan thanks his parents for their consistent belief in him. He thanks his medical school mentors, fellow residents, and faculty at the University of Iowa for all they have taught him along the way. He thanks his precious children for their patience with their often tired and distracted Daddy. Most importantly, he thanks his wife Nancy for her unwavering support, encouragement, and strength during this long journey.

Upon completing residency, Ryan will practice general orthopedics in Toledo, Ohio.

Jaron Sullivan, MD

Jaron is the second of six children to his parents Paul and Marcie Sullivan and the late Shirla Wall. He was raised in Utah until the age of 17 when his family moved to Texas. While growing up he spent a substantial amount of time riding horses (and yes the rumor is true, a couple bulls), team roping, wakeboarding, enjoying the outdoors, and playing sports. His mother, the late Shirla Wall, died after a complication from a routine hysterectomy when Jaron was 17. This affected Jaron in many ways, one of which was the desire to help people that are sick and deliver the best care possible. When Jaron finished high school he served a two year mission for the Church of Jesus Christ of Latter-day Saints in San Bernardino, CA among Spanish speaking people. He then attended Brigham Young University and was fortunate enough to marry the love of his life and best friend, Emily Runyan. Emily has been an incredible support to Jaron starting with his first semester at BYU all the way through medical school at Texas A & M Health Science Center College of Medicine, and now finishing orthopedic surgery residency at the University of Iowa Hospitals and Clinics. Together they have been fortunate to have three incredible boys along this journey: Jaron Spencer (age 10), Michael Seth (age 7), and Trevor James (age 4). While the educational course has been busy and hectic at times, Jaron’s family has been a foundational cornerstone and motivation for him to be the best that he can be.

While investigating orthopedic surgery residency programs, Jaron heard rumors that Iowa was one of the few top programs in the country that had a family friendly environment. He decided to rotate at Iowa and was impressed with the strong mentors and exceptional residents. Mentors didn’t just want to know what treatment the resident would recommend for the patient, but they wanted to know why and what literature would support their decision. The mentors at Iowa were not just excellent clinicians, but in addition they were excellent teachers and some of the top researchers in the world. When the match day came around, Jaron was thrilled to have the opportunity to further his education with so many incredible individuals.

During Jaron’s residency, he developed a strong interest in Sports Medicine and was inspired by mentors to pursue a career in academics. He was fortunate enough to match at the Hospital for Special Surgery in New York to further his sports medicine training, and his family is looking forward to the education they will get moving from Iowa City to the Big Apple. Jaron is extremely appreciative to the faculty at the University of Iowa for their belief in him as a resident and dedication to help him learn to be a good doctor. He would like to thank the residents for their camaraderie and the laughs they shared that helped lighten some of the challenging experiences that occur as a part of any surgical training experience. He is indebted to his parents that taught him what it means to be a good person. He would like to thank his boys, Spence, Mikey, and Trev, for patiently awaiting daddy while he was at work, and at the same time never acting like they were missing out by him putting in long hours. Last and most important, he would like to thank Emily for her unselfish support, friendship, and love.
2013 GRADUATING FELLOWS

Marut Arunakul, MD

Marut is the University of Iowa Foot and Ankle Fellow for 2010-2012 (International Foot and Ankle fellowship program). He was born in Bangkok, Thailand. He completed medical school at Chulalongkorn University, and orthopaedic residency training at Siriraj Hospital, Mahidol University, Bangkok, Thailand. After a couple great years in Iowa, Marut looks forward to returning to Thailand to join the staff at Thammasat University Hospital.

Marut’s wife, Preeyaphan, also stayed with him in Iowa City for her Pain Research Fellowship Program. Marut would like to give special thanks to Drs. Amendola, Femino, and Phisitkul for their excellent teaching and mentorship during this past couple of years.

Grant Bowman, MD

Grant is the current orthopaedic Sports Medicine Fellow for 2012-2013. He was born and raised in Southwest Michigan. He earned his undergraduate degree in economics from the University of Michigan, and then completed his medical degree at Wayne State University School of Medicine in Detroit. He completed his residency training in orthopaedic surgery at Michigan State University’s Kalamazoo Center for Medical Studies in his hometown of Kalamazoo, MI.

After fellowship he will return to Kalamazoo to join Healthcare Midwest PC and care for athletes at Western Michigan University. Grant and his wife Emily have three sons, Isaac (3), Levi (2), and Ethan (born at UIHC this April). Grant thanks his family for their love and support. He would also like to give special thanks to Drs. Albright, Amendola, Bollier, Hettrich, Nepola, Smoot, and Wolf, as well as the Hawkeye football training staff for all they have taught him. It has been a great year and he feels blessed to have been here.
Benjamin P. Kleinhenz, MD

Ben is the University of Iowa Hand and Upper Extremity fellow for 2012-13. He was born and raised in Dayton, Ohio. He attended the University of Notre Dame and graduated cum laude with a BA in Economics. He then attended medical school at the University of Cincinnati and completed his orthopaedic surgery residency at Wright State University.

During his fifth year of residency, Ben’s wife Julie gave birth to a son, John. They will return to Ohio this summer when Ben joins Hand Surgery Specialists of Cincinnati.

Ben wishes to thank Drs. Adams, Lawler, and Shah for their generosity, patience, and commitment to teaching throughout the year.

Josh Tennant, MD

Josh is the University of Iowa Foot and Ankle Fellow for 2012-2013. Born in Tennessee and raised in North Carolina since age 3, he completed his undergraduate studies, medical school, and orthopaedic residency at the University of North Carolina at Chapel Hill. After a great year in Iowa, Josh looks forward to returning to Chapel Hill to join the staff at UNC Orthopaedics.

Josh and his wife, Melissa, a Minnesotan, have three boys: Bryce (4), Lukas (2) and Seth (born at the University of Iowa on February 4th, 2013). Josh would like to give special thanks to Drs. Amendola, Femino, Karam, Marsh, and Phisitkul for their excellent teaching and mentorship during this year.
NEW ORTHOPAEDIC FACULTY

**Eric W. Aschenbrenner, MD**

Eric Aschenbrenner was born and raised in Wisconsin. He attended Saint Mary’s University of Minnesota for undergraduate studies and went to Medical College of Wisconsin for medical school. Eric did his internship at Medical College of Wisconsin and Affiliated Hospitals in Milwaukee, Wisconsin followed by residency in Physical Medicine and Rehabilitation at Mayo Clinic in Rochester, Minnesota. After his residency he spent four years in Saint Cloud, Minnesota caring for general rehabilitation patients on both an inpatient and outpatient setting. Given his strong desire to focus more on outpatient musculoskeletal issues and after learning more about the department from his physiatry colleagues and friends within the department, he joined the University of Iowa Department of Orthopaedics & Rehabilitation in 2012. Eric’s primary interests include nonoperative conditions of the upper extremities, spine, and amputee care. He and his wife Laura have three children and are happily expecting their fourth this summer. They have enjoyed the sense of community and support within the city and the department.

**Ryan M. Ilgenfritz, MD, MS**

Ryan Ilgenfritz was born and raised in Central Florida and attended the University of Miami for undergraduate studies and medical school. Through the advice of his medical school mentor, he and his wife Lauren ventured to Iowa City where Ryan completed his residency in Orthopaedic Surgery at the University of Iowa. Within a few weeks after residency ended, Ryan and Lauren welcomed their first child Oliver, and then moved to San Diego, CA for fellowship training in Pediatric Orthopaedics and Scoliosis at Rady Children’s Hospital. The family then made a cross-country move to New Hampshire where Ryan obtained an MS in Clinical and Health Services Research at The Dartmouth Institute for Health Policy and Clinical Practice. Ryan joined the Pediatric Orthopaedics team at The University of Iowa Department of Orthopaedics & Rehabilitation in 2012. His primary interests are pediatric spinal deformity, pediatric musculoskeletal trauma, and hip disorders and reconstruction in children, adolescents, and young adults. Ryan and his family are happy to be back and settled in Iowa City, and recently celebrated the birth of their beautiful baby girl named Ivy.
Apurva Shah, MD

Apurva Shah is a hand and upper extremity surgeon who joined the University of Iowa Hospitals and Clinics in September 2012. Dr. Shah obtained an undergraduate degree in economics from Yale University in 2000 and a medical doctorate and master’s in business administration from Columbia University in 2005. He completed residency training in orthopaedic surgery at the University of Michigan and fellowship training in hand and upper extremity surgery at Brigham and Women’s Hospital and Boston Children’s Hospital. Dr. Shah joined the staff at Boston Children’s Hospital for one year prior to starting at the University of Iowa in order to gain additional experience in brachial plexus birth injuries, congenital hand differences, and pediatric upper limb reconstruction. This February, Dr. Shah launched a new adult and pediatric brachial plexus clinic at the University of Iowa Hospitals and Clinics, with plans to enroll all patients with brachial plexus birth injuries into a multicenter registry. Dr. Shah has broad research interests in orthopaedic surgery, but is particularly interested in cost analysis, cost-effectiveness, outcomes, and improving value delivery in health care. He has developed a background in time-driven activity-based costing (TDABC), and has launched several pilot investigations using this technique. This work has led to the development of a Harvard Business School teaching case currently being presented to health care executives from around the world.

Melissa Willenborg, MD

Melissa Willenborg is an adult reconstruction surgeon who joined the University of Iowa Hospitals and Clinics staff in September 2012. She is a native of Guthrie Center, Iowa. Dr. Willenborg earned a degree in biology from Luther College in 2002 and a medical doctorate from the Carver College of Medicine at the University of Iowa in 2006. She completed a residency and fellowship in adult reconstruction at the University of Virginia. Her research interests are patient factors that affect patient outcomes for hip and knee arthroplasty and how to most effectively train orthopaedic residents.
IN MEMORIUM TOM HAM

The University of Iowa Department of Orthopaedics would like to honor and celebrate the life of Tom Ham. Tom Ham worked in the department for over 40 years as an orthotist. In the early 1970s, his mentor, the late Harold E. Miller, CPO, introduced Tom to the fields of prosthetics and orthotics in Iowa City, Iowa and we are grateful for that. Working for American Prosthetics and our department Tom brought the best he had to offer for his patients who had some of the most difficult problems for which often there are no textbook answers.

Tom was a sincere, talented, warm and friendly practitioner who was the go-to person in all phases of orthotics. Since the first residents came to work for American Prosthetics from the University of Washington, in the early 1980s, he was the person all staff and physicians would ask for when there was a difficult situation. He was never too busy to listen, to instruct, or take-over any project that needed doing on a short notice.

He watched over the younger staff in an effort to maintain the fundamentals of the materials, designs, and processes, so that the quality of all products and services were sound and their fitting criteria appropriate. Tom was indeed this person.

For many years Tom made a 75 mile trek every other Tuesday to a long-term care facility for young adults with multiple, and very difficult orthopedic problems needing the services of a first class orthotist. During that time, he earned the respect and affection of every resident of the facility, and the entire staff and administration as well.

Anyone who doesn’t understand the meaning of an orthotist or the phrase clinical commitment need only to have watched Tom in action. This past year we lost Tom to his struggle with ALS or Lou Gehrig’s Disease. The University of Iowa Department of Orthopaedics wants to thank Tom and his family for the decades of service, commitment, and care he has provided. We will cherish the time we had with him.
The University of Iowa Department of Orthopaedics 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 Dr. Cassim Igram, President of the Iowa Orthopaedic Society, and Drs. Charles R. Clark, Joseph A. Buckwalter, John Femino, and Carolyn Hettrich, all members of the Department of Orthopaedics and Rehabilitation. They recommended that Dan McCabe, M4, receive the 2013 Michael Bonfiglio Student Research Award. Dan's award was based on his project, “Chondrogenic Progenitor Cells Respond to Cartilage Injury”. His advisors were Dr. Joseph A. Buckwalter and Dr. James Martin. The selection committee recommended that The Iowa Orthopaedic Society Medical Student Research Award be given to Adam Norton, M2, for his research titled “Correlation of Knee and Hindfoot Deformities in Patients with Advanced Knee Arthritis: Relevance to TKA Reconstruction in Patients with Foot and Ankle Deformity”. His advisors were Drs. John Callaghan, Phinit Phisitkul and Ned Amendola.

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
From left to right: John Callaghan, M.D., Distinguished Lawrence and Marilyn Dorr Endowed Chair for Hip Reconstruction and Research; Phinit Phisitkul, M.D.; Ned Amendola, M.D., Kim and John Callaghan Endowed Chair, Director, University of Iowa Sports Medicine; Charles R. Clark, M.D., Michael Bonfiglio Professor of Orthopaedic Surgery; Adam Norton, M2, winner of the Iowa Orthopaedic Society Medical Student Research Award; Dan McCabe, M4, winner of the 2013 Michael Bonfiglio Student Research Award; James Martin, Ph.D.; and Joseph A. Buchwalter, M.D., Professor and Head, Department of Orthopaedic Surgery and Rehabilitation, Arthur Steindler Chair of Orthopaedic Surgery.
THE GOTHIC ARCH: A RELIABLE MEASUREMENT FOR DEVELOPMENTAL DYSPLASIA OF THE HIP

Paul K. Herickhoff, MD, Megan K. O’Brien, BS, Lori A. Dolan, PhD, Jose A. Morcuende, MD, Jonathan B. Peterson, MD, Stuart L. Weinstein, MD

ABSTRACT

BACKGROUND: The “Gothic Arch” is a radiographic finding on AP pelvis x-rays postulated to be predictive of hip osteoarthritis.

PURPOSE: The purpose of this study was to determine the reliability of measurement of the Gothic Arch in patients with no known hip pathology and patients with unilateral developmental dysplasia of the hip (DDH).

PATIENTS AND METHODS: After obtaining IRB approval, nine skeletally mature patients (18 hips) with no known hip pathology were selected to serve as the control group. The AP pelvis x-rays at skeletal maturity of eight patients (16 hips) with unilateral DDH treated with closed reduction and casting comprised the comparison group. A digitizing program was designed to measure the Gothic Arch based on landmarks identified by the user. Two pediatric orthopaedic surgeons and two orthopaedic residents completed the program on two separate occasions. Intra- and interobserver reliability were determined using intraclass correlation coefficients (ICC) for continuous variables.

RESULTS: Both the unilateral DDH group and the control group demonstrated excellent intra- and interobserver reliability (ICC >0.70) for base, height, area, and orientation of the Gothic Arch, but poor reliability (ICC <0.40) for medial and lateral sharpness.

CONCLUSION: The Gothic Arch can be reliably measured on AP pelvis x-rays of patients with normal and dysplastic hips.

LEVEL OF EVIDENCE: III, Diagnostic study. See the Guidelines for Authors for a complete description of levels of evidence.

INTRODUCTION

Developmental dysplasia of the hip (DDH) is a significant risk factor for early degenerative joint disease. A natural history study has demonstrated that 30 to 48% of dysplastic hips will develop pain and/or poor function if left untreated. Cooperman et al. followed 20 adults with 32 untreated dysplastic hips for an average of 22 years, and found a 66% incidence of radiographically severe osteoarthritis, defined by 75% or more of normal joint space narrowing. Several radiologic measurements and classification systems have been described for evaluation and treatment of DDH, however, many of these have been shown to have limited reliability.

The “Gothic Arch” is a characteristic feature of anteroposterior pelvis x-rays described by Italian orthopaedic surgeon Renato Bombelli. The base of the Gothic Arch is formed by the sourcil, while the sides correspond to condensed arch-like bony trabeculae (Figure 1). The medial side of the arch represents an arc of dense cancellous bone extending from the quadrilateral plate toward the anterior superior and anterior inferior iliac spines, while the trabeculae forming the lateral side of the arch extend from the lateral acetabular ridge toward the sacroiliac joint.

Bombelli hypothesized that hips with an abnormal Gothic Arch are mechanically jeopardized and, therefore, predisposed to developing osteoarthritis. In normal hips, he argued, the apex of the Gothic Arch lies directly above the center of the femoral head on an AP pelvis x-ray, such that a line connecting these points has a perfectly vertical orientation. In abnormal hips, on the other hand, the apex of the Gothic Arch lies medial or lateral to a vertical line drawn through the center of the femoral head, resulting in craniomedial or craniolateral orientation of the Gothic Arch.

To our knowledge, there is only one investigation of the Gothic Arch by someone other than Renato Bombelli. Laforgia et al., in a retrospective case-control study, reported a direct correlation between radiographic alterations to the Gothic Arch and the development of the development of hip osteoarthritis.

Although radiographic abnormalities of the Gothic Arch may identify hips at risk for osteoarthritis, its measurement has never been subjected to reliability testing. The purpose of this study was to determine the
intra- and interobserver reliability of measurement of the Gothic Arch in patients with no known hip pathology and patients with unilateral DDH.

PATIENTS AND METHODS

Sample: Patients with No Known Hip Pathology

After approval from our Institutional Review Board, a cohort of patients with normal AP pelvis x-rays and no known hip pathology was identified to serve as a control population. A computer program was used to search through all of the x-ray reports filed at our institution from an arbitrarily chosen year (2008) for the terms “AP pelvis” AND “normal.” One hundred thirteen patients were identified using this search. The charts and radiographs of these patients were reviewed.

To be included in this patient cohort, patients were required to be skeletally mature, as defined by a closed triradiate cartilage, and the AP pelvis x-ray was required to meet the following criteria for a “perfect” AP pelvis radiograph described by Clohisy et al.: symmetric obturator foramen and 1-3 cm between the tip of the coccyx and the superior aspect of the symphysis pubis. Additionally, to minimize the chance that patients with an AP pelvis x-ray identified as “normal” actually did have hip pathology, only patients for whom the indication for the AP pelvis x-ray was “trauma” or “fall” were included. Nine patients (18 hips) met the all of the above criteria and were included in this patient cohort.

Sample: Patients with Unilateral DDH

The charts of 51 patients with 60 congenitally dislocated hips treated at the author’s institution with closed reduction between 1938 and 1969 with over 40 years of follow-up (unpublished data) were reviewed. These patients comprise a subset of patients previously reported at 30 year follow-up by Malvitz and Weinstein. Nine patients with bilateral DDH were excluded, so that the “normal” hip in the unilateral DDH patients would serve as an internal control. Supine AP pelvis radiographs at skeletal maturity were available for all patients. Patients with AP pelvis X-rays not meeting the criteria for a perfect AP pelvis x-ray described by Clohisy et al were excluded. Eight patients (8 DDH and 8 “normal” hips) with an Iowa Hip Score at 40 year follow-up ranging from 59-100 met all of the above criteria and were included in this patient cohort.

Design of a digitizing program

A digitizing program was created using MATLAB software. The program prompts the user to identify the following landmarks for each hip on an AP pelvis x-ray: center of the femoral head, lateral aspect of the sourcil, medial aspect of the sourcil, and apex of the Gothic Arch. It then draws lines connecting these points. Next, the user marks 3 points along the base of the Gothic Arch (sourcil), and 3 points each along the medial and lateral sides of the arch. Each of these sets of 3 points is then fit to a circle. Finally, the program draws a line con-
The Gothic Arch: A Reliable Measurement For Developmental Dysplasia Of The Hip

INTERCLASS CORRELATION COEFFICIENTS

Patients with no known hip pathology

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Patients with unilateral DDH

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Table 1: Intra- and interclass correlation coefficients for the base, height, lateral sharpness, medial sharpness, area and orientation of the Gothic Arch in patients with no known hip pathology and patients with unilateral DDH.

Data collection

A tutorial was created to introduce users of the digitizing program to the definition of the Gothic Arch, the purpose of the study, and instructions for how to complete the program. Two pediatric orthopaedic surgery faculty and two orthopaedic surgery residents (PGY-4 and PGY-3) completed the digitizing program twice for each patient cohort, separated in time by at least 2 weeks. The radiographs of the patients with no known hip pathology were measured during the first month of data collection, while the unilateral DDH radiographs were measured during the second month of data collection.

nnecting the medial aspect of the sourcil to the medial aspect of the arch, completing the boundaries of the Gothic Arch (Figure 2). This step was necessary to form complete boundaries for the Gothic Arch because in some radiographs the medial side of the arch never meets the acetabulum. These steps are then repeated for the other hip.

Once the Gothic Arch is complete, the computer program calculates the following descriptors: base (mm), height (mm), area (mm2), sharpness of the medial and lateral borders of the arch (base of the arch divided by the radius of the circle forming the side of the arch, therefore unitless), and orientation of the Gothic Arch (in degrees) relative to the vertical. For each AP pelvis radiograph, the vertical axis of the pelvis was determined by one of the researchers (PKH) using a separate digitizing program designed by Pedersen et al., which has previously been reported in the literature. This was standardized for all users of the computer program to eliminate this variable as a potential confounder of the data.
Statistical analysis

The descriptors of the Gothic Arch (base (mm), height (mm), area (mm2), sharpness of the medial and lateral borders of the arch, and orientation of the Gothic Arch relative to the vertical) were analyzed for reliability using intraclass correlation coefficients for continuous variables. An intraclass coefficient (ICC) of > 0.75 is considered excellent, while 0.40 to 0.75 is considered good, and < 0.4 is considered poor according to Shoukri and Pause14. Paired student’s t-test with a p value of 0.05 considered statistically significant difference was used to compare mean values for the descriptors of the Gothic Arch on the left and right hips in patients with no known hip pathology, and “normal” and dysplastic hips in patients with unilateral DDH. Statistical analysis was performed using SAS Version 9.1.3 (SAS Institute, Cary, North Carolina, USA)16.

Source of Funding

No external funding was provided for this investigation.

RESULTS

In the patients with no known hip pathology, inter- and intraobserver reliability were excellent (ICC > 0.86) for base, height, area, and orientation of the Gothic Arch, but markedly variable (ICC range 0.02 to 0.76) for the sharpness of the medial and lateral borders of the arch (Table 1). In the unilateral DDH patients, interobserver and intraobserver reliability were mostly good to excellent for base, height, area, and orientation of the Gothic Arch for both the normal and the dysplastic hips, although there were some outliers, most notably in rater 3. Similar to the patients with no known hip pathology, inter- and intraobserver reliability for the sharpness of the medial and lateral borders of both the normal and dysplastic hips, however, were not as good (Table 1).

Mean values and standard deviations of the descriptors of the Gothic Arch for each patient cohort are shown in Table 2.

DISCUSSION

The current study was designed to evaluate the reliability of measurement of the Gothic Arch, a characteristic feature of AP pelvis x-rays hypothesized to be predictive of hip osteoarthritis. Renato Bombelli, who first described the Gothic Arch, called it “the most essential feature to interpret the biomechanics of the hip”2. Given the paucity of literature on the Gothic Arch, and the potential implications for management of DDH patients, if Bombelli’s hypothesis is, in fact, correct, we designed this reliability study as our initial investigation into the clinical relevance of the Gothic Arch for patients with DDH.

One weakness of this study was the small number of patients in each cohort. The requirement that the patient have a perfect AP pelvis x-ray with normal tilt and no rotation, as defined by Clohisy et al., eliminated large number of patients in both patient cohorts. However, since the Gothic Arch is a 3-dimensional structure which is likely to change in appearance with rotated and/or tilted radiographs, we felt it was important to adhere to the strict radiographic criteria advocated by Clohisy et al3. Siebenrock and others have demonstrated the importance of pelvic tilt on two commonly used radiographic determinants of acetabular retroversion, the “cross-over sign” and “posterior wall sign.” In a study of four cadaver pelves, both of these retroversion signs appeared on all acetabula at nine degrees of inclination and disappeared at six degrees of inclination15.

Our study demonstrates that the Gothic Arch can be reliably measured in both normal and dysplastic hips. Interclass correlation coefficients for the area, width, height, and orientation of the Gothic Arch in hips with no known pathology were all greater than 0.81, while intraclass correlation coefficients were all greater than 0.86. In patients with unilateral DDH, interclass correlation coefficients for the area, width, and orientation of
the Gothic Arch were greater than 0.71 for the normal and dysplastic hips, while the height of the Gothic Arch was more reliably measured in the normal hip (ICC = 0.80) than the dysplastic hip (ICC = 0.57).

Poor interobserver reliability (ICC all less than 0.4) was noted between observers marking the medial and lateral borders of the Gothic Arch. This result likely reflects the fact that the medial and lateral borders of the Gothic Arch often are not condensed into a discreet curved line; instead they are formed by broad arcs of bony trabeculae. This introduces some variability into choosing three points among the bony trabeculae that compose the medial and lateral borders of the Gothic Arch. However, the fact that there were high ICCs for the base, width, height, and orientation measurements, indicates that our observers grossly agree on the location, size and orientation of the Gothic Arch.

Several of the radiographic measurements currently used to evaluate DDH have been shown to have limited reliability. Clohisy and others reported the inter- and intraobserver reliability of measuring several of the standard radiographic parameters used to diagnose developmental dysplasia of the hip (DDH) and femoroacetabular impingement (FAI), including acetabular version, inclination and depth, position of the femoral head center, head sphericity, head-neck offset, Tonnis grade, and joint congruency. Five hip specialists and one fellow completed the measurements on 25 control hips, 25 hips with DDH, and 27 with FAI on two separate occasions separated by 6 weeks in time. Intra-reliability was highest for femoral head center (K=0.77) and acetabular inclination (K = 0.72). Interobserver reliability was highest for acetabular inclination (K = 0.61) and Tonnis osteoarthritis grade (K = 0.59). All other measurements had kappa values less than 0.55. The interobserver reliability of measurement of the lateral center-edge angle, the most commonly used radiographic parameter to diagnose DDH, has been reported from 0.73 and 0.92.

Bombelli’s hypothesis that craniomedical or craniolateral orientation of the Gothic Arch identifies hips predisposed to develop osteoarthritis is not the focus of this study. However, it is notable that although there was a statistically significant difference between the mean orientation of the Gothic Arch in the normal and dysplastic hips in the unilateral DDH patients, there was wide variation in the orientation of the Gothic Arch (standard deviations of 4.01 and 8.73 degrees, respectively). The other statistically significant differences are likely not clinically significant. It is also noted that the hips with no known hip pathology also showed an average orientation of 6.68 degrees tilted toward the midline, which differs from Bombelli’s description of the orientation of the Gothic Arch in normal hips as vertical (0 degrees).

In conclusion, this study shows that the Gothic Arch can be reliably measured in non-tilted, non-rotated AP pelvis radiographs normal and dysplastic hips. The clinical utility of the Gothic Arch to evaluate and treat patients with DDH, however, remains unclear. Further research is warranted to determine if the Gothic Arch can be used to predict outcome and/or direct treatment in developmental dysplasia of the hip.

ACKNOWLEDGMENTS
We thank Yubo Gao, PhD, for his contribution in the statistical analysis for this study.

CONFLICTS OF INTEREST STATEMENT
Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

ETHICAL REVIEW COMMITTEE STATEMENT
This study was carried out in accordance with relevant regulations of the US Health Insurance Portability and Accountability Act (HIPAA). A copy of our Institutional Review Board approval letter is included in this submission.

LOCATION
This investigation was performed at the University of Iowa Hospitals and Clinics, Iowa City, IA.

REFERENCES


HEALING RESULTS OF PERIPROSTHETIC DISTAL FEMUR FRACTURES TREATED WITH FAR CORTICAL LOCKING TECHNOLOGY: A PRELIMINARY RETROSPECTIVE STUDY

Zachary Ries, MD, Kirk Hansen, Michael Bottlang, PhD, Steven Madey, MD, Daniel Fitzpatrick, MS, MD, J.L. Marsh, MD

ABSTRACT

Introduction: Periprosthetic distal femur fractures are severe injuries occurring in the often osteoporotic bone of the elderly. Far cortical locking (FCL) screws, which have been shown to promote increased callus formation in animal models, have recently become available for clinical use. The purpose of this study is to report preliminary healing and complication rates of periprosthetic distal femur fractures treated with FCL constructs.

Materials and Methods: A retrospective review of 20 patients who underwent open reduction and internal fixation of periprosthetic distal femur fractures using FCL constructs was performed. Healing was assessed radiographically and clinically at 6, 12 and 24 weeks post-operatively. Construct failure was defined as any hardware breakage or bone-implant dissociation leading to loss of reduction.

Results: Complete data through the 24 week study period was available for 18/20 patients. Bridging callus was identified in 16/18 patients by the 24 week follow up for a healing rate of 88.9%. In patients that healed, the average time to medial bridging callus formation was 10.7±6.7 weeks, 11.0±6.6 weeks for anterior fracture line and 13.4±7.5 weeks for the posterior fracture line. Both patients that failed to heal underwent revision surgery.

Discussion: The initial results of this study are comparable to results reported for distal femur periprosthetic fractures treated with locking plate fixation without FCL screws, although it was difficult to compare time to healing between previously published studies. It is the impression of the authors that callus appears earlier and is more robust and uniform between the three cortices in FCL cases compared to their previous experiences with traditional locking plate periprosthetic distal femur fractures. This work suggests that FCL screws may be superior to traditional locking constructs but further studies are needed to directly compare the two methods.

INTRODUCTION

Periprosthetic distal femur fractures are severe injuries occurring in approximately 0.2% to 2.5% of all total knee replacements (TKR)\(^1,2\). These numbers can be expected to increase substantially due to the rising number of total knee arthroplasties performed in our aging population. Although many of the techniques are the same as those used for other distal femur fractures, the periprosthetic distal femur fracture presents unique challenges. The orthopaedic surgeon must evaluate the pre-injury functional status, bone quality, medical co-morbidities, prosthetic bone interface and assess possible points of fixation which are limited by the presence of the femoral prosthesis. The periprosthetic distal femur fracture is often comminuted and occurs in weak osteoporotic bone, making fixation particularly challenging. Bridging callus must form early and become mechanically stable to prevent fixation failure in these difficult fractures.

Locking plates are commonly used to definitively fix periprosthetic distal femur fractures. Compared to traditional plates, locking plates provide increased fixation stability in the often osteoporotic distal femur and also allow for minimally invasive insertion techniques\(^3\). However, clinical results of distal femur fractures treated with locking plates have indicated that healing has not been improved over other techniques\(^4\). The high stiffness of locking plates may decrease micro-motion at the fracture site, limiting callus formation and secondary fracture healing\(^5\).

Far cortical locking (FCL) screws have been shown to promote callus by providing a biomechanical environment and healing response for locking plates similar to that provided by external fixators\(^6\). Symmetric motion across the fracture site combined with decreased construct stiffness has been shown to increase callus formation compared to traditional locking plates. In an ovine fracture model, Bottlang et al\(^6\). reported FCL

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screw constructs increased callus volume by 36% over traditional locking plates. The callus also contained 44% higher bone mineral content and was 54% stronger in torsion. Bone mineral content was also comparable between the near and far cortices in the FCL group, while the near cortex of the traditional locking plate group exhibited 49% less bone mineral content at the near cortex compared to the far cortex.

FCL screws are now available for clinical use but healing results and early complication rates have not been reported. It is important to carefully audit the results of new technology as it is released. The purpose of this study is to report preliminary healing and complication rates of periprosthetic distal femur fractures treated with far cortical locking constructs and compare these results to previously reported data for periprosthetic distal femur fractures fixed with traditional locking plates.

**MATERIALS AND METHODS**

This is a retrospective case series that assesses 20 consecutive patients with periprosthetic distal femur fractures above a TKR that were treated from April 2011 to July 2012 with far cortical locking screws and plates at three orthopaedic centers: The University of Iowa Hospitals and Clinics in Iowa City, IA, Slocum Orthopedics and Sports Medicine Clinic in Eugene, Oregon and Legacy Emanuel Hospital and Health Center in Portland, Oregon. During the study period the surgeons exclusively used this type of locking screw for these fractures. Occasional fractures were treated non-operatively. Inclusion criteria included non-pathological distal periprosthetic femur fractures around stable TKR which were treated with open reduction and internal fixation using locked plating with FCL screws. Operation notes and medical records were reviewed for patient characteristics (age, gender, BMI, diabetes mellitus, and smoking), fracture characteristics (side, mechanism of injury, AO/OTA classification and open vs. closed fracture), implant detail, healing and complications (implant failure and non-healing). Healing was assessed radiographically by two surgeons (SM and ZR) on anteroposterior (AP) and lateral radiographs obtained at 6, 12 and 24 week post-operative clinic visits. As initially described by Whelan et al, fractures were considered healed when bridging callus was identified separately for medial, anterior and posterior fracture lines in combination with clinical exam which demonstrated absence of pain and ability to tolerate progressive weightbearing. Construct failure was defined as any hardware breakage or bone-implant dissociation leading to loss of reduction. Serial radiographs were also reviewed for evidence of osteolysis and implant loosening.

**RESULTS**

Patient demographics and fracture characteristics are summarized in Table 1. There were 19 females and 1 male with an average age of 77.0 years and average BMI of 31.4. Eighteen of the twenty fractures occurred as a result of a ground level fall, with the remaining two fractures resulting from a motor vehicle accident and a horse accident. Three of the fractures were open. Data on healing and complications are shown in Table 2. Complete data through the 24 week post-operative study window were available for eighteen of the twenty patients. Bridging callus was identified separately for the medial, anterior and posterior fracture lines in sixteen of the eighteen patients by the 24 week follow up for a healing rate of 88.9%. In patients that healed, the average time to medial bridging callus formation was 10.7±6.7 weeks, 11.0±6.6 weeks for anterior fracture line and 13.4±7.5 weeks for the posterior fracture line. Figure 1 shows the pre-operative and 24 week post-operative radiographs of a patient who formed bridging medial, anterior and posterior callus and returned to baseline activity level.

One patient elected to follow-up locally and no follow-up data was obtained while another withdrew from the study after the 12 week follow-up. This patient had bridging callus identified both medially and anteriorly at 6 weeks, but no callus was identified posteriorly. Two patients failed to heal and both underwent revision surgery. One patient required revision with bone graft and

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**TABLE 1: Patient Demographics and Fracture Characteristics**

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<td>Left</td>
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<td>Mechanism of Injury (%)</td>
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<td>Classification (open/closed) (%)</td>
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<td>Closed</td>
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Healing Results of Periprosthetic Distal Femur Fractures Treated with Far Cortical Locking Technology

**Table 2: Healing and Complications**

<table>
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<th>Posterior Callus (wks)</th>
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<td>Continued pain with lack of bridging callus treated with revision fixation with bone grafting at 12 wks</td>
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<td>Hardware failure at 9 months requiring revision surgery</td>
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Avg±STDev 10.7±6.7 11.0±6.6 13.4±7.5

Figure 1: Pre-operative and 24 week post-operative radiographs of an 82 year old diabetic female who sustained a closed 33A1 periprosthetic distal femur fracture following a ground-level fall. She was treated with locking plate fixation with proximal FCL screws. Bridging callus is seen at the medial, anterior and posterior fracture lines. The patient was advanced to full-weightbearing at 24 weeks post-operatively and eventually returned to her baseline level of functioning.

Figure 2: Pre-operative, 24 week and 9 month post-operative radiographs of a 75 year old female who sustained a closed 33A2 periprosthetic distal femur fracture following a ground-level fall. Callus formed medially but no anterior or posterior callus is seen at 24 week post-operative films. At this visit she noted progressive pain with increasing activity. The patient presented at 9 months post-operatively with hardware failure and fracture displacement requiring revision surgery.

Additional proximal FCL screws at 12 weeks after continued pain and radiographic concern for slow progress to union. Plate failure occurred in another patient at 9 months post-operatively, which needed revision surgery with bone graft (Figure 2). Prior to hardware failure, only medial bridging callus was identified at 24 weeks post-operatively. This patient complained of persistent pain following the 12 and 24 week follow-up visits after initiation of progressive weight bearing and advancement of physical therapy.

**Discussion**

Locking plates have become one of the most common methods of operative treatment of periprosthetic fractures. However, complications such as plate failure and delayed union can occur. The use of additional proximal FCL screws at 12 weeks and continued pain and radiographic concern for slow progress to union can be beneficial in managing these complications. Revision surgery with bone grafting may be necessary in cases of hardware failure or persistent pain.

**Table 2:**

<table>
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<tr>
<th>Patient</th>
<th>Medial Callus (wks)</th>
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<td>6</td>
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</tr>
<tr>
<td>19</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

Avg±STDev 10.7±6.7 11.0±6.6 13.4±7.5
A literature review of healing of periprosthetic distal femur fractures treated with locking plates and screws identified nine studies (Table 3). The number of fractures treated, number of open fractures, rates of non-union, delayed union, revision or need for secondary bone grafting, implant failures as well as the average time to radiographic healing was included in the review. If the information was not reported, the column was left blank. The average time to radiographic healing ranged from 10 – 24 weeks. The rate of non-union and need for a revision surgery varied from 0 – 22% and the rate of implant failure was as high as 26%. Unfortunately, in the cited articles it was often impossible to know when patients were included in more than one complication category; for example it was not always clear whether a patient that developed a nonunion was the same patient undergoing revision surgery. This makes accurate calculation of the total complication rate difficult but the results in the table suggest there are difficulties with healing and fixation of these fractures.

The current study found a healing rate of 89%. The two patients that did not heal complained of persistent pain with ambulation and radiographs failed to show evidence of bridging callus. These initial results are comparable to results reported for distal femur periprosthetic fractures treated with locking plate fixation without FCL screws. Although we tried, we found it impossible to compare time to healing between studies given the wide variability in how this data is reported and the small patient numbers. It has been the impression of the authors that callus appears earlier and is more robust and uniform in all three cortices in FCL cases compared to their previous experiences with traditional locking plates for periprosthetic distal femur fractures. Additionally, we did not note any hardware complications related to the FCL screws themselves. Our lone hardware failure involved only the plate at 9 months post-operatively.

The small number of patients in the current study is a significant limitation to assessing differences in healing rates between traditional locking plates and FCL locking plates. Further patient enrollment and follow-up is necessary to adequately compare periprosthetic FCL constructs and traditional locking plate constructs. There are several additional limitations to the current study. Our method of assessing bone healing by assessing callus along the three visible fracture surfaces may not accurately determine whether or not the fracture is healed. Larger studies with longer follow up will need to employ existing validated callus extraction algorithms for objective assessment of periosteal callus formation or 3D imaging using CT. Also, patient clinical data was not included in this study. Further studies will need to combine radiographic outcomes with clinical outcomes including pain, weight-bearing status and return to pre-injury function. Lastly, accurate complication rates in the previously published literature were difficult to determine as the majority of articles did not clarify whether or not the same patients were included in multiple complication categories. This significantly limits the ability to compare these studies to current results.

Future studies will require increased patient enrollment with longer follow-up periods, objective assessment of callus formation and correlation with clinical out-

### Table 3: Healing of Distal Femur Periprosthetic Fractures Treated With Locking Plates

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Fractures (n)</th>
<th>Open (%)</th>
<th>NonUnion (%)</th>
<th>Delayed Union (%)</th>
<th>Bone Graft or Implant Revision (%)</th>
<th>Implant Failures (%)</th>
<th>Avg time to heal (wk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hou et al, 2012</td>
<td>34</td>
<td>8.8</td>
<td></td>
<td></td>
<td>8.8</td>
<td>8.8</td>
<td>12</td>
</tr>
<tr>
<td>Large et al, 2008</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td></td>
<td>4.0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Ricci et al, 2006</td>
<td>22</td>
<td>0</td>
<td>13.6</td>
<td></td>
<td>0</td>
<td>18.2</td>
<td>12</td>
</tr>
<tr>
<td>Hoffman et al, 2012</td>
<td>36</td>
<td>5.6</td>
<td>22.2</td>
<td></td>
<td>13.8</td>
<td>8.3</td>
<td></td>
</tr>
<tr>
<td>Ebraheim et al, 2012</td>
<td>27</td>
<td>3.7</td>
<td>7.4</td>
<td></td>
<td>26</td>
<td>26</td>
<td>18</td>
</tr>
<tr>
<td>Streubel et al, 2010</td>
<td>61</td>
<td>4.9</td>
<td>13.1</td>
<td></td>
<td>11.5</td>
<td>9.8</td>
<td>11.5</td>
</tr>
<tr>
<td>Kolb et al, 2010</td>
<td>23</td>
<td>0</td>
<td>0</td>
<td></td>
<td>8.7</td>
<td>4.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Fulkerson et al, 2007</td>
<td>18</td>
<td>11.1</td>
<td>11.1</td>
<td></td>
<td>22.2</td>
<td>5.6</td>
<td>24</td>
</tr>
<tr>
<td>Ehlinger et al, 2011</td>
<td>16</td>
<td>0</td>
<td>6.3</td>
<td></td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
</tbody>
</table>

Distal femur fractures above a total knee arthroplasty. However, complications associated with locking plates have remained high. Controversy exists as to whether locked plating inhibits secondary bone healing as it limits interfragmentary motion. In-vivo ovine studies have shown increased callus formation with far cortical locking plates when compared to traditional locked plating, possibly due to increased motion allowed by FCL constructs. However, no direct comparison between FCL constructs and traditional locking constructs have been reported.
comes. If this data suggests an advantage of FCL screws, a direct comparison of FCL constructs to traditional locking plate constructs in a prospective study is warranted. This study points out the difficulties of proving whether one implant leads to better healing than another in a clinical study with many uncontrolled variables.

REFERENCES


ABSTRACT

Purpose: To report radiographic, clinical, and patient-based functional outcomes following contemporary operative treatment of patients who sustained an open distal radius fracture and compare them to a similar group of patients treated operatively for closed distal radius fractures.

Methods: Over five years, 601 patients with a distal radius fracture presented to our academic medical center, including one Level 1 trauma hospital, and were prospectively enrolled in an upper extremity trauma database. Patients with open distal radius fractures underwent irrigation, debridement, and operative fixation within 24 hours of presentation. Closed distal radius fractures requiring operative fixation were treated electively. Retrospective review of the database identified eighteen open fractures of the distal radius (11 type I, 6 type II, 1 type IIIa). The open fracture patients were individually matched with eighteen closed distal radius fracture patients who underwent surgical fixation based on age, sex, injury to dominant extremity, fracture pattern, and method of fracture fixation. Clinical, radiographic, patient-based functional outcomes, and complications were recorded at routine postoperative intervals.

Results: Follow-up was greater than 77% in both groups at all time points. The open and closed groups were similar in regards to age, gender, BMI, race, tobacco use, income, employment status, hand dominance, injury to dominant extremity, mechanism of injury, fracture classification, method of fracture fixation, and presence of concomitant injury. Postoperative complications and reoperation rates were similar between the open and closed groups. Union rates and radiographic alignment one year postoperatively were similar between the open and closed fracture groups. At final follow-up, range of motion parameters, grip strengths, DASH indices, and subjective pain scores were similar between both groups.

Discussion: Open distal radius fractures treated with early debridement and fixation achieved similar outcomes to surgically treated closed fractures of the distal radius when followed for a year or more postoperatively.

INTRODUCTION

Open fractures are high-energy injuries that present with a spectrum of soft tissue and bony injury. These injuries can be complicated by infection, nonunion, and need for soft tissue coverage. While there is robust research on open long bone fractures, there is little outcome data on open distal radius fractures. Numerous studies have addressed clinical, radiographic, and functional outcomes after treatment of closed fractures of the distal radius. A better understanding of outcomes after treatment of open distal radius fractures may facilitate improvements in patient care and counseling regarding post-injury expectations.

The purpose of this study is to report radiographic, clinical, and patient-based functional outcomes following contemporary operative treatment of patients who sustained an open distal radius fracture and compare them to a similar group of patients treated operatively for closed distal radius fractures.

PATIENTS AND METHODS

Over a period of five years, six hundred and one patients presented to our academic medical center, including one Level 1 trauma hospital, with a distal radius fracture (OTA type 23), and consented to prospective enrollment in an upper extremity trauma database. Our Institutional Review Board approved retrospective review of the database to evaluate outcomes following surgical treatment of open distal radius fractures. Eighteen of these patients sustained an open fracture of the distal radius (ODRF) (Gustilo and Anderson type I, n=11; type II, n=6, type IIIa, n=1). The open fracture patients were individually matched with eighteen closed distal radius fracture patients who underwent surgical fixation (CDRF).
based on age, sex, injury to dominant extremity, fracture pattern, and method of fracture fixation.

At the time of database enrollment, baseline information including: age, gender, height, weight, ethnicity, tobacco use, employment status, income level, hand dominance, mechanism of injury, occurrence of injury to the dominant hand, OTA fracture classification, Gustilo and Anderson classification of the soft tissue injury, and presence of concomitant bony, neurologic, and vascular injury was recorded\textsuperscript{30-31}. Standard radiographs (antero-posterior, lateral, and oblique views) of the injured and contralateral wrists were obtained during initial evaluation. Contralateral wrist films were used as a reference to determine radiographic articular parameters in the coronal and sagittal plane on the uninjured side for each patient and to assess adequacy of reduction. Additional radiographs of the injured wrist were obtained following closed reduction and splinting. Direction of displacement, volar tilt, radial inclination, radial height, articular step-off, ulnar variance, and osteoarthritis grading as described by Knirk and Jupiter\textsuperscript{32} were recorded by trained researchers under the supervision of the treating attending physician using initial injury and post-reduction radiographs.

Patients who sustained an open fracture received teta
nus, intravenous antibiotics, reduction, sterile dressing application, and splinting in the emergency department. All open fractures underwent irrigation, debridement, and operative fixation within twenty-four hours of presentation (average time 8.1 hours, range 3-22 hours). Fixation in the CDRF group was performed electively for unstable fractures. Standard implants (external fixation, K-wires, volar locked plates, dorsal plates) were used for both the ODRF and CDRF groups, and the selection of the fixation construct was at the discretion of the treating surgeon (three fellowship-trained orthopaedic traumatologists, one fellowship-trained orthopaedic hand surgeon). The surgical approach (volar, dorsal, percutaneous, or combined) utilized and the performance of concurrent carpal tunnel release was recorded.

Patients were evaluated in the outpatient setting at routine postoperative intervals. At all follow-up visits, range of wrist and finger motion (flexion/extension, supination/pronation, and ulnar/radial deviation) was measured with a goniometer and grip strength was measured [in pounds (lbs)] with a dynamometer by a dedicated musculoskeletal researcher blinded to the objective of the study. Serial postoperative radiographs were obtained to assess restoration of articular parameters and fracture healing. In addition, time to radiographic union, defined as the absence or consolidation of fracture lines on wrist radiographs, was recorded. A standard Visual Analogue Scale (VAS; 0, no pain; 10, severe pain) and the DASH questionnaire\textsuperscript{33-34} were used to quantify functional outcomes based upon patients’ perceived disability. Postoperative complications and secondary surgeries were also recorded.

Descriptive statistics were compiled for all data points. Chi-square analyses were used to compare categorical variables. Independent samples students T-tests were used to compare continuous variables between two groups.

**RESULTS**

Patient characteristics including: age, gender, BMI, ethnicity, tobacco use, employment status, income level, and handedness of the patients in the ODRF and CDRF groups were compared and found to be similar between the two (Tables 1a, 1b).

Injury and treatment characteristics including: occurrence of injury to dominant hand, mechanism of injury, OTA fracture classification, presence of concomitant injury, treating surgeon, surgical approach, fracture fixation method, use of supplemental Kirschner wire fixation, acute carpal tunnel release, and occurrence of intraoperative complication were similar between the ODRF and CDRF groups (Table 2).
Follow-up data is presented for the ODRF and CDRF groups at three and twelve months postoperatively. There was no difference in rate of follow-up between the two groups at either time point and it was greater than 77.8% for both groups at each time point (Table 3).

Radiographically, there was no difference in union rates between the ODRF and CDRF groups at three and twelve months with all fractures healed by one year postoperatively (Tables 4a, 4b). Volar tilt was decreased in the ODRF group as compared to CDRF group at three months, but any coronal and sagittal plane radiographic parameter differences were diminished in both groups one year postoperatively and found to be independent of wound status at the time of injury (Tables 4a, 4b). Articular step-off and osteoarthritis grading was similar between the two groups at all follow-up time points (Tables 4a, 4b).

Range of motion, grip strength, VAS pain scores, and DASH scores were compared between the ODRF and CDRF groups (Tables 5, 6). The ODRF group had decreased supination as compared to the CDRF group three months postoperatively, but all range of motion parameters were similar at one year follow-up. There was no difference in grip strength, VAS pain scores, or DASH scores at any follow-up time point.

The ODRF and CDRF groups experienced a similar rate of postoperative complications (Table 7). There was one pin tract infection in each group, both successfully treated with oral antibiotics. In the ODRF group, three patients had postoperative neuropraxias. Two of these patients presented to the emergency room with symptoms of carpal tunnel syndrome and had acute carpal tunnel releases at time of irrigation, debridement, and fracture fixation. Both of these patients had continued

Table 2: Injury and Treatment Data: In the ODRF group, associated injuries included: eight ulnar styloid fractures, three ulnar neck fractures, one DRUJ dislocation, three median nerve neuropraxias, five additional extremity injuries (phalangeal fracture, ulnar collateral ligament rupture, thumb interphalangeal dislocation, great toe fracture), and one non-orthopaedic injury (facial fracture). There were nine ulnar styloid fractures, one scapholunate ligament tear, three additional extremity injuries (proximal humerus fracture, calcaneus fracture, patella fracture), and one non-orthopaedic injury (eye contusion) in the CDRF group.
median nerve dysfunction postoperatively which resolved without further surgical intervention. One ODRF patient had a postoperative ulnar nerve neuropraxia that resolved without surgical intervention. One ODRF patient had loosening of their ulnar Kirschner wire. Seven patients required return trips to the operating room after their index surgery (three ODRF patients: one Kirschner wire removal, one external fixator removal, one distal ulna resection for ulnar impaction; four CDRF patients: one Kirschner wire removal, two external fixator removals, one external fixator removal with concomitant locked plating). During follow-up, there were four patients that developed carpal tunnel syndrome (three ODRF patients, one CDRF patient).

### DISCUSSION

In this study, open fractures of the distal radius with lower grade soft tissue injuries treated with expedient debridement and definitive fixation were found to do as well clinically, radiographically, and functionally as closed distal radius fractures requiring open reduction and internal fixation. There is currently no other study that has compared this injury pattern with its closed counterpart using prospectively collected data.

Nyquist and Stern reviewed ten open radiocarpal dislocations treated with combinations of debridement, open reduction, casting, internal fixation, and external fixa-

<table>
<thead>
<tr>
<th>Table 3: Postoperative Follow-Up</th>
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<tbody>
<tr>
<td>Follow-up 3 months</td>
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<tr>
<td>Follow-up 1 year</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Table 4a: Radiographic Outcomes</th>
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<tbody>
<tr>
<td>Fracture Type</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Volar Tilt Postop (degrees)</td>
</tr>
<tr>
<td>Radius Inclination Postop (degrees)</td>
</tr>
<tr>
<td>Radius Length Postop (millimeters)</td>
</tr>
<tr>
<td>Articular Step-Off Postop (millimeters)</td>
</tr>
<tr>
<td>Volar Tilt 3 months (degrees)</td>
</tr>
<tr>
<td>Radius Inclination 3 months (degrees)</td>
</tr>
<tr>
<td>Radius Length 3 months (millimeters)</td>
</tr>
<tr>
<td>Articular Step-Off 3 months (millimeters)</td>
</tr>
<tr>
<td>Ulnar Variance 3 months (millimeters)</td>
</tr>
<tr>
<td>Volar Tilt 1 year (degrees)</td>
</tr>
<tr>
<td>Radius Inclination 1 year (degrees)</td>
</tr>
<tr>
<td>Radius Length 1 year (millimeters)</td>
</tr>
<tr>
<td>Articular Step-Off 1 year (millimeters)</td>
</tr>
<tr>
<td>Ulnar Variance 1 year (millimeters)</td>
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</table>

<table>
<thead>
<tr>
<th>Table 4b: Radiographic Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture Type</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Distal Radius Tilt Postoperatively</td>
</tr>
<tr>
<td>Osteoarthritis Grading Postoperatively</td>
</tr>
<tr>
<td>Distal Radius Tilt 3 months</td>
</tr>
<tr>
<td>Osteoarthritis Grading 3 months</td>
</tr>
<tr>
<td>Fracture Healed 3 months</td>
</tr>
<tr>
<td>Distal Radius Tilt 1 year</td>
</tr>
<tr>
<td>Osteoarthritis Grading 1 year</td>
</tr>
<tr>
<td>Fracture Healed 1 year</td>
</tr>
</tbody>
</table>

Osteoarthritis Grading as per Knirk and Jupiter Classification

<table>
<thead>
<tr>
<th>Table 5: Range of Motion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture Type</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Wrist Extension 3 months (degrees)</td>
</tr>
<tr>
<td>Wrist Flexion 3 months (degrees)</td>
</tr>
<tr>
<td>Supination 3 months (degrees)</td>
</tr>
<tr>
<td>Pronation 3 months (degrees)</td>
</tr>
<tr>
<td>Ulnar Deviation 3 months (degrees)</td>
</tr>
<tr>
<td>Radial Deviation 3 months (degrees)</td>
</tr>
<tr>
<td>Grip Strength 3 months (pounds)</td>
</tr>
<tr>
<td>Wrist Extension 1 year (degrees)</td>
</tr>
<tr>
<td>Wrist Flexion 1 year (degrees)</td>
</tr>
<tr>
<td>Supination 1 year (degrees)</td>
</tr>
<tr>
<td>Pronation 1 year (degrees)</td>
</tr>
<tr>
<td>Ulnar Deviation 1 year (degrees)</td>
</tr>
<tr>
<td>Radial Deviation 1 year (degrees)</td>
</tr>
<tr>
<td>Grip Strength 1 year (pounds)</td>
</tr>
</tbody>
</table>
Soft tissue injury and contamination were not specifically addressed. At variable follow-up (~15 months), they found high rates of neurologic deficit, wrist pain, and limited motion. Rozental et al. published on eighteen patients with open distal radius fractures (Gustilo and Anderson type I, n=9; type II, n=3; type IIIa, n=6). Wound severity (Gustilo and Anderson classification) was directly correlated with number of surgical procedures, number of postoperative complications, and functional deficit. They stated that there is no similarity between open and closed distal radius fractures other than the location of injury. Yang et al. found no postoperative infection in twelve Gustilo and Anderson grade I open distal radius fractures debrided greater than twelve hours after injury, suggesting that timing of debridement is not related to incidence of postoperative infection in fractures with minimal soft tissue injury. Glueck et al. presented forty-two open distal radius fractures (Gustilo and Anderson type I, n=24; type II, n=12; type III, n=8) followed for approximately fifteen months. Contamination and number of debridements, but not Gustilo and Anderson classification of soft tissue injury, time to debridement, or type of fixation, were found to be predictive of subsequent infection. Kurylo et al. retrospectively reviewed thirty-two open distal radius fractures (Gustilo and Anderson type I, n=19; type II, n=11; type IIIa, n=2). There were no postoperative infections in their series, leading to the conclusion that timing of debridement (< 6 hours after hospital admission vs > 6 hours after hospital admission) and initial type of fracture fixation (external fixation, locked plating, external fixation with planned conversion to locked plating) have no influence on occurrence of postoperative infection in Gustilo and Anderson type I and II open distal radius fractures. They found a higher rate of postoperative complication and reoperation in those patients treated with external fixation and planned conversion to locked plating as compared to those open fractures treated solely with external fixation or locked plating. Furthermore, they concluded that treatment of Gustilo and Anderson grade I and II open distal radius fractures leads to more postoperative complications than treatment of similar closed injuries.

There is no published data on radiographic outcomes after surgical fixation of open distal radius fractures. Our study showed no difference between the dorsal tilt, radial inclination, radial height, and ulnar variance of the ODRF and CDRF groups at one-year follow-up. Furthermore, the ODRF mean values for these radiographic parameters are similar to those reported in recent literature for surgical fixation of closed distal radius fractures. By objective and subjective functional measures, the ODRF patients in this study did as well as the operatively treated closed distal radius patients in numerous other studies and achieved sufficient range of motion to complete activities of daily living. Nyquist and Stern reported decreased range of motion and wrist pain with activity for all of their patients with open fractures at final follow-up. Rozental et al. found decreased range of motion (avg. flexion, extension, supination, and pronation: 37°, 40°, 47°, and 57°, respectively), decreased grip strength (50.6 lbs), and high levels of perceived disability (avg. DASH score 33) in their study patients twenty-four months post-injury. The improved performance of our open fracture patients is likely attributable to the predominance of low-grade soft tissue injuries that did not require complex or multiple reconstructive procedures.

Postoperative complications were similar in the ODRF and CDRF groups. This is not consistent with the current literature. Rozental et al. reported an overall complication rate of 66% and an infection rate of 44%. Glueck et al. noted a 7.1% infection rate in their series. Kurylo

<table>
<thead>
<tr>
<th>Table 6: Subjective Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture Type</td>
</tr>
<tr>
<td>DASH (3 month)</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>Closed</td>
</tr>
<tr>
<td>VAS (3 month)</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>Closed</td>
</tr>
<tr>
<td>DASH (1 year)</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>Closed</td>
</tr>
<tr>
<td>VAS (1 year)</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>Closed</td>
</tr>
</tbody>
</table>

DASH=Disabilities of the Arm, Shoulder, and Hand Score
VAS=Visual Analog Pain Score

<table>
<thead>
<tr>
<th>Table 7: Postoperative Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFECTION</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>P Value</td>
</tr>
<tr>
<td>LOSS OF REDUCTION</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>P Value</td>
</tr>
<tr>
<td>COMPLEX REGIONAL PAIN SYNDROME</td>
</tr>
<tr>
<td>Open</td>
</tr>
<tr>
<td>P Value</td>
</tr>
<tr>
<td>CARPAL TUNNEL SYNDROME</td>
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<tr>
<td>Open</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>P Value</td>
</tr>
<tr>
<td>NERVE DEFICIT</td>
</tr>
<tr>
<td>Open</td>
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<tr>
<td>No</td>
</tr>
<tr>
<td>P Value</td>
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<tr>
<td>HARDWARE FAILURE</td>
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<td>RETURN TO OR</td>
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<td>P Value</td>
</tr>
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<td>TENDON RUPTURE</td>
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<tr>
<td>No</td>
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<tr>
<td>P Value</td>
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</table>
et al. concluded that treatment of Gustilo and Anderson grade I and II open distal radius fractures leads to more postoperative complications than treatment of similar closed injuries. The improved outcomes of the open fractures in our series is likely related to lower grade soft tissue injuries in the current study in combination with our institution’s policy of thorough initial debridement and attempts to minimize further injury to the soft tissue with repeat manipulations/surgeries and multiple percutaneous implants.

The results should be appreciated in the context of the study’s limitations. The ODRF patients were closely matched with CDRF patients based on age, sex, injury to dominant extremity, fracture pattern, and method of fracture fixation. Baseline patient demographic and injury/treatment data was statistically compared to further validate the similarity of the groups being compared. Yet, there is still the possibility that these two groups are dissimilar with regards to some other variable that may have confounded the results, thereby introducing selection bias. Furthermore, the study is unable to comment on the treatment outcomes of Gustilo and Anderson type III injuries as only one Gustilo and Anderson type IIIa open fracture was included for analysis. Yet, our data suggests that these high-grade soft tissue injuries represent a very small percentage of an already uncommon injury pattern.

In conclusion, this study suggests that Gustilo and Anderson type I and II open distal radius fractures treated with early debridement and definitive bony fixation achieve similar outcomes to surgically treated closed distal radius fractures. This information helps guide treatment of an injury pattern that could be seen by any practicing orthopaedic surgeon and provides information necessary for counseling patients and families in the perioperative period.

The authors would like to thank Dr. David Ruchelsman, Dr. Rachel Goldstein, and Mr. Raj Karia, MPH for their assistance in preparing this manuscript.

REFERENCES

ABSTRACT

Background: One of the most catastrophic outcomes following total knee arthroplasty (TKA) is a chronic periprosthetic infection with concomitant failure of the knee extensor mechanism. This study retrospectively reviewed the clinical records of 7 patients who were treated with a 6 axis circular external fixation frame (Taylor Spatial Frame (TSF)) for this condition. Fusion was achieved in 5 of 7 patients (71%) at an average of 8.4 months after surgery. Complications occurred in the treatment of 5 of 7 patients (71%). Infection was controlled in all cases. The TSF presents another valuable tool, which the orthopaedic surgeon should consider when treating these difficult cases.

Purpose: To evaluate the use of the Taylor Spatial Frame (TSF) to achieve knee arthrodesis in patients with chronically infected total knee arthroplasties (TKAs) with concomitant failure of the knee extensor mechanism.

Methods: We retrospectively evaluated the clinical records of 7 patients who were referred to our tertiary care orthopaedic medical center with multiple failed knee arthroplasties, chronic draining infection and complete loss of the extensor mechanism. All patients were treated with a similar protocol including, debridement and bony stabilization with an adjustable, 6 axis circular external fixation frame (TSF). Hospital charts were reviewed for sociodemographic information, surgical details, hospital course and complications. Radiographs were reviewed for healing and alignment. Follow up included clinical examination and radiographs.

Results: The mean age of the patients was 70.9 years (range, 59 – 83 years) at the time of application of the TSF. There were 3 men and 4 women. The average time between TKA and diagnosis of infection was 30.7 months (range, 2.6 – 67.0 months). The 7 patients had undergone an average of 3.3 prior surgical procedures (range, 2-4 procedures) on the ipsilateral extremity. Fusion was achieved in 5 of 7 patients (71%) at an average of 8.4 months after surgery (range, 6 – 10.5 months). Complications occurred in the treatment of 5 of 7 patients (71%) and included infection at the site of the pin tracks (5 patients), antibiotic-induced acute renal failure (1 patient), wound breakdown requiring flap closure (1 patient), and femur fracture secondary to a fall after placement of the antibiotic spacer but before application of the TSF (1 patient). The 2 patients in whom failure of fusion occurred returned to ambulation with an assistive device. Infection was controlled in all cases.

Conclusion: Fusion and complication rates in this cohort are comparable to those reported in previous studies using other techniques to achieve external fixation. The TSF is a versatile external fixator that offers another tool, which the orthopaedic surgeon should consider when treating these difficult cases.

KEYWORDS: total knee arthroplasty, periprosthetic infection, Taylor Spatial Frame, knee arthrodesis

INTRODUCTION

The incidence of infection following total knee arthroplasty (TKA) is approximately 0.4-2%1-5. Despite this relatively low risk, a substantial number of patients will develop periprosthetic infections following this procedure. This is in part due to the sheer number of TKAs performed annually, and in part due to a shift in patient demographics that is projected to increase the demand for TKAs significantly over the next 20 years6. It can be expected that the prevalence of patients with periprosthetic infections after TKA will increase, even as the incidence may decrease.

Risk factors for infection after primary TKA have been well characterized5. One large retrospective study
found patients who were morbidly obese, diabetic, younger, or undergoing unilateral procedures to be at increased risk. Other groups have confirmed these findings, and also found increased risk among patients with rheumatoid arthritis, chronic corticosteroid use, use of a hinged prostheses, complications during initial wound healing, and prior ipsilateral extremity surgeries.

Standard management of early postoperative or acute hematogenous infections following TKA may begin with surgical debridement, retention of components, and administration of oral antibiotics. In their study of 104 patients, Azzam et al. found this treatment to be effective in eradicating infection in 44% of cases. In the case of more chronic infections, explantation with an antibiotic spacer for a period of time followed by reimplantation may be necessary. Definitive care in the worst cases of uncontrollable infection may consist of knee arthrodesis, particularly in patients whose leg extensor mechanisms are compromised, or for whom inadequate soft tissue coverage makes other surgical options untenable.

The results of several techniques for knee arthrodesis following infected TKA have been described. The surgical option with the most successful outcomes is intramedullary (IM) nailing, with reported fusion rates of 80-100%. However, IM nailing is contraindicated by the presence of active infection and the absence of a medullary canal. In such patients, bony fusion may be achieved through compressive external fixation, though this technique is not without its own limitations. Fusion rates are generally lower than those achieved with IM nailing, and complication rates are high. The purpose of the present study is to present the senior author’s experience with a six axis circular external fixation frame (Taylor Spatial Frame (TSF), Smith &Nephew, Memphis, TN) used for limb salvage in patients with chronically infected TKAs and either catastrophic failure of the leg extensor mechanism, or substantial loss of anterior soft tissue coverage. This construct is a unique tool, which allows bedside adjustment over time to alter the degree of compression and alignment of the knee joint during the fusion process.

**MATERIALS AND METHODS**

Our Institutional Review Board approved this study. Patients were included who met the following inclusion criteria: 1) adult patients who presented with a chronic, deep periprosthetic infection of a total knee arthroplasty, 2) failure of the knee extensor mechanism, or substantial anterior soft tissue loss and 3) use of the TSF for arthrodesis. Patients were excluded if they were under the age of 18 years at the time of surgery.

Inpatient and outpatient records were reviewed for all patients. Patient demographics, past medical histories and surgical histories were reviewed. Anteroposterior and lateral radiographs taken at regular follow-up intervals of 1, 3, 6, 12 and 24 months post-operatively were reviewed by a fellowship-trained orthopaedic traumatologist to determine time to bony fusion. Intraoperative cultures were reviewed to determine the identities of the infecting organisms.

**Surgical Technique**

The established midline knee incision was utilized to gain access to the knee. All prosthetic components and cement spacers if present were removed. Deep soft tissue and bone cultures were obtained. Non-viable soft tissues were sharply debrided and the surgical sites were irrigated with 6-9 liters of saline lavage. The medullary canals were irrigated and debrided as well. In some cases the patella was excised. Fresh flat bony cuts were made at the distal end of the femur and proximal tibia using a sagittal saw leaving two flat surfaces for compression. The soft tissue envelope was then closed with monofilament heavy sutures over large drains. Next the frame was applied to help stabilize the soft tissues and eventually to be used to gain fusion.

One full carbon fiber ring was centered over the distal end of the femur and attached using three, 6.0 mm hydroxyapatite coated half pins drilled bi-cortically through the bone and fixed to the ring with Rancho cubes. Position of the ring perpendicular to the bone was confirmed on anteroposterior and lateral intraoperative radiographs. A second ring was applied to the proximal tibia. Next the two rings were connected with 6 telescoping struts applied in a standard manner (Figure 1a,b). With the frame assembly complete, final radiographs were obtained at the end of surgery to be used for frame management post-operatively.

Following surgery, a computer-based program was used to develop a plan for compression alignment at
the arthrodesis site. Pin sites were dressed with sterile bandages initially. Following wound healing they were covered with sponges and cleaned daily with soap and water. Patients were allowed to be full weightbearing on the limb in the frame. Serial radiographs were obtained during the correction phase of treatment and then every 2-3 months following to assess healing.

The treating surgeon and an infectious disease specialist followed all patients. All patients were treated with long-term culture specific, intravenous antibiotics. Complications were defined as sequelae of the arthrodesis that required further medical or surgical treatment.

**RESULTS**

**General Demographics**

Between 2002 and 2010, 7 eligible patients were identified and constituted the study population (Table 1). There were 4 females and 3 males. The average time between TKA and diagnosis of infection was 30.7 months (range, 2.6 – 67.0 months). Average patient age at the time of application of the TSF was 70.9 years (range, 59 – 83 years). Six arthrodeses were performed on right knees and 1 on a left knee. The 7 patients had undergone an average of 3.3 prior surgical procedures (range, 2-4 procedures) on the ipsilateral extremity. The primary TKA was indicated for treatment of osteoarthritis in 6 patients and rheumatoid arthritis in 1 patient. Four of the primary TKAs were performed at the same institution as that in which the arthrodeses were performed; 3 patients underwent primary TKAs at a different institution. All patients had been diagnosed with deep, chronic peri-prosthetic infections on the basis of elevated ESR/CRP levels and clinical findings, including gross purulence. All patients had developed a non-traumatic disruption of the extensor mechanism in the affected limb. Thus in all patients, indications for arthrodesis included persistent infection and an incompetent, un-reconstructable extensor mechanism.

The average length of surgery was 222 minutes (range, 91 – 450 minutes). The average length of hospital stay was 25 days (range, 19 – 32 days). Average follow-up was 20.8 months (range, 7.9 – 64.6 months). Of the 7 patients, 6 had been treated with a surgically implanted antibiotic spacer before undergoing arthrodesis for an average time of 4.95 weeks (range, 1.4 – 7.3 weeks). In the 1 remaining patient, the prosthesis used in the primary TKA was removed during the same surgery in which the TSF was applied.

**Arthrodesis Results**

Fusion was achieved in 5 of 7 patients (71%) at an average of 8.4 months (range, 6 – 10.5 months) after application of the TSF (Figure 2a-h). The remaining 2 patients never achieved bony fusion. One of these two patients was an 83 year-old female who requested removal of the TSF at the 6-month follow-up visit, despite exhibiting no radiographic evidence of bony union. This patient was undergoing intensive treatment for metastatic cancer and refused further elective procedures. At 8 month follow-up, this patient exhibited reduced range of motion at the knee and reported ambulating in her home with the assistance of a brace. Her limb was free of infection clinically and she denied knee pain. The second patient who was considered a treatment failure was a 59-year-old female with a history of chronic osteomyelitis of the ipsilateral tibia and femur. In this patient, the TSF was removed at 7.7 months after surgery, when it was determined that further fusion was unlikely. At the most recent follow-up visit of 64.6 months after surgery, this patient continued to experience almost no knee pain. Although the knee remained unstable, the patient reported being able to ambulate in her home with the use of a brace, and even to dance slowly on occasion.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age/Sex</th>
<th>Prior Procedures (no.)</th>
<th>Antibiotic Spacer (wk.)</th>
<th>External Fixator (mo.)</th>
<th>Infection Resolved</th>
<th>Bony Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>73/M</td>
<td>4</td>
<td>7.86</td>
<td>7.93</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>59/F</td>
<td>3</td>
<td>7.29</td>
<td>7.70</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>75/F</td>
<td>3</td>
<td>5.56</td>
<td>10.40</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>82/M</td>
<td>4</td>
<td>1.43</td>
<td>6.67</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>83/F</td>
<td>3</td>
<td>n/a</td>
<td>5.97</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>62/F</td>
<td>4</td>
<td>1.57</td>
<td>9.50</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>62/M</td>
<td>2</td>
<td>6.0</td>
<td>10.5</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Avg.</strong></td>
<td>70.9 yrs.</td>
<td><strong>3.3 procedures</strong></td>
<td><strong>4.95 wk.</strong></td>
<td><strong>8.4 mo.</strong></td>
<td><strong>7/7 (100%)</strong></td>
<td><strong>5/7 (71%)</strong></td>
</tr>
</tbody>
</table>
The cause of infection was identified as a specific organism in 6 patients, and polymicrobial in 1 patient (Table 2). Infections resolved in all of the 7 patients. None of the 7 patients underwent further reconstructive surgeries or salvage procedures of the knee to date.

**Complications**

Complications associated with this surgical procedure occurred in the treatment of 5 of the 7 patients (71%). The most common of these was infection at the site of the pin track, which occurred in 4 patients (Table 3). In all cases, pin track infections resolved with local wound care or surgical debridement and pin exchange. These patients were also given supplementary oral antibiotics for coverage of gram positive bacteria if intravenous antibiotics were covering a different organism.

Table 2: Results of intraoperative cultures

<table>
<thead>
<tr>
<th>Patient</th>
<th>Infecting Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Serratia marcescens</td>
</tr>
<tr>
<td>2</td>
<td>Staphylococcus aureus</td>
</tr>
<tr>
<td>3</td>
<td>Enterobacter cloacae</td>
</tr>
<tr>
<td>4</td>
<td>Polymicrobial</td>
</tr>
<tr>
<td>5</td>
<td>Candida albicans</td>
</tr>
<tr>
<td>6</td>
<td>Staphylococcus aureus</td>
</tr>
<tr>
<td>7</td>
<td>Staphylococcus aureus</td>
</tr>
</tbody>
</table>

Table 3: Complications of treatment with the TSF

<table>
<thead>
<tr>
<th>Patient</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>Pin track infection</td>
</tr>
<tr>
<td>3</td>
<td>Pin track infection, femur fracture</td>
</tr>
<tr>
<td>4</td>
<td>Pin track infection, antibiotic-induced acute renal failure</td>
</tr>
<tr>
<td>5</td>
<td>None</td>
</tr>
<tr>
<td>6</td>
<td>Pin track infection x2, wound breakdown requiring flap closure</td>
</tr>
<tr>
<td>7</td>
<td>Wound breakdown</td>
</tr>
</tbody>
</table>

Complication Rate 5/7 (71%)

Fig 2. AP and lateral radiographs of the right knee of a 62 year old female after total knee arthroplasty (2a,b), after removal of the knee prostheses and insertion of an antibiotic spacer (2c,d), after application of the TSF (2e,f), and at 16-month follow-up (2g,h). The significant anterior defect is secondary to a previously failed knee extensor mechanism. At final follow-up, the patient had a stable, pain free extremity.
One of the 4 patients underwent additional procedures at the time of pin exchange surgery. This patient had previously sustained a fracture of the ipsilateral medial femoral condyle after falling in the shower at the rehabilitation facility prior to placement of the spatial frame. A secondary bone graft procedure at both the acute fracture and arthrodesis sites was used to aid in healing and to achieve successful fusion.

One of the 4 patients developed a wound breakdown 2 months following TSF removal. This wound was successfully treated with irrigation and debridement and closure with a local gastrocnemius muscle flap.

DISCUSSION

This series reports the use of a multiplanar circular external fixator for the purpose of gaining fusion following severe chronically infected TKAs with an absent extensor mechanism. These cases represent one of the worst case scenarios following failed TKA. In 1971, Nelson and Evarts first described knee arthrodesis as a treatment for patients with failed TKAs. This was a time when the ability to treat infections of primary TKAs was limited, leading the authors to advocate for arthrodesis so broadly. In fact, Nelson and Evarts did not differentiate between TKAs that failed due to infection from those that failed for other reasons; the treatment for either case was arthrodesis. Since then, treatment for infected TKA has evolved, and many techniques have been described to achieve such an arthrodesis. While IM nailing has produced satisfactory results, the procedure is not advisable in patients with ongoing medullary infections. In these cases, the orthopaedic surgeon must rely on external fixation in an attempt to fuse the knee and salvage the affected lower extremity.

To this end, various groups have presented their results with techniques for external fixation of the knee for arthrodesis. In 1983, Rothacker et al. reported outcomes in 29 patients whose knees were fused utilizing the Hoffmann device. In this retrospective study, 86.2% of patients achieved fusion, while the complication rate was 20.6%. Oostenbroek et al. reported a slightly improved fusion rate of 93% in their study of 15 patients whose knees were fused using the Ilizarov technique. This cohort had a surgical complication rate of 80%, though 100% of patients developed pin track infections during the study period.

Most recently, Klinger et al. presented their experience with 18 patients. The fusion rate was 89%, and 100% of patients developed pin track infections.

The knees of 5 of the 7 patients in the present study successfully fused, yielding a fusion rate of 71%. This rate is consistent with those reported in previous studies, particularly in light of the fact that 1 of the 2 patients who is considered a treatment failure elected to remove the external fixator because of discomfort incurred during oncological treatment. Given that these 7 cases all represented patients with complete loss of the extensor mechanism, several with extensive necrosis and substantial anterior soft tissue loss, this rate may represent an improvement, as these cases would have been high risk for failure using other techniques. Further, we are encouraged that neither of the patients who is considered a treatment failure has undergone subsequent above-knee amputation, a procedure to which both patients objected strongly. Both patients are functioning at a level that is acceptable to them, and neither is completely bed or wheelchair bound. The complication rate of 71% is also consistent with those seen in similar cohorts. While these sequelae are clearly undesirable, they remain an unavoidable aspect of treating patients with difficult periprosthetic infections.

An additional benefit of the TSF is its inherent versatility. The frame has been successfully used to correct complex post-traumatic and hereditary deformities of the lower extremity. While similar to a traditional external fixator, the TSF has a significant advantage in its ability to be dynamically adjusted as well. Modifying the struts individually may allow the surgeon to produce forces that would require modifying the entire frame of other constructs. Such gradual strut corrections in the TSF have been shown to be effective over time. This aspect of the implant allowed us to make adjustments and corrections during the healing phase and to add compression to the arthrodesis site as needed post operatively.

This case series has several limitations that are inherent to the retrospective review of existing clinical data. One notable example is the lack of subjective, patient-based outcome measures. While questionnaires that provide such data are an important part of orthopaedic research, it is unclear which questionnaire would be best suited for this patient population. To date, 3 groups have utilized the Short Form 36 (SF-36) questionnaire in studying patient outcomes after knee arthrodesis for infected TKAs. On the one hand, these studies have provided a useful basis for outcome comparisons to future studies. On the other hand, Benson et al. suggested that the Arthritis Impact Measurement Scale (AIMS) may be a more appropriate indicator of patient outcomes in this patient population than is the SF-36. Without further research, it is difficult to know which outcomes tool to use.

The present study presents our group’s experience with the Taylor Spatial Frame, a multi-planar external fixator used for arthrodesis and limb salvage in patients with worst case scenario, chronically infected TKAs. Patient outcomes were generally satisfactory, and all patients avoided above-knee amputation. This technique adds another viable option which orthopaedic surgeons should consider when treating patients in this difficult population.
REFERENCES


EVALUATION OF A NOVEL SILICATE SUBSTITUTED HYDROXYAPATITE BONE GRAFT SUBSTITUTE IN A RABBIT POSTEROLATERAL FUSION MODEL

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ABSTRACT:

Study Design/Setting: Randomized, Controlled study in a laboratory setting. Blinded observations/assessment of study outcomes.

Objective: The purpose of this study is to determine the performance characteristics of a novel silicate-substituted hydroxyapatite bone graft substitute (BGS), SiCaP EP (Baxter Healthcare/ApaTech, Elstree, UK), in a stand-alone mode, a stand-alone with bone marrow aspirate (BMA) mode, and an extender mode with iliac crest autograft (ICBG) in a rabbit posterolateral spine fusion model. The investigational BGS is compared to a standard iliac crest autograft (ICBG) control.

Summary of Background Data: The rabbit posterolateral fusion model is an established environment for testing of fusion efficacy. It offers the opportunity to obtain radiographic, histological, and biomechanical data on novel bone graft substitutes.

Methods: One hundred and twenty rabbits were entered into the study with 116 used for analysis. Bilateral posterolateral lumbar intertransverse fusions were performed at L5-L6. The lateral two thirds of the transverse processes were decorticated and covered with graft material in the following five groups: ICBG, SiCaP EP stand-alone, SiCaP EP with BMA (1:0.5 by volume), and SiCaP EP with ICBG (1:3 by volume). Rabbits were necropsied at 4, 8, and 12-week time points and fusion rate, quantity, and quality was evaluated based on manual palpation, mechanical stiffness testing, pqCT, and histological assessment.

Results: SiCaP EP, ICBG+SiCaP EP (3:1), and SiCaP EP+BMA (1:0.5) compare favorably to iliac crest autologous bone by multiple metrics in this rabbit posterolateral fusion model. Fusion efficacy via manual palpation and mechanical stiffness testing metrics indicate that all SiCaP EP groups had similar group-to-group performance, and were not significantly different than the ICBG control at each time period evaluated.

Conclusions: In this commonly used rabbit posterolateral fusion model, SiCaP EP utilized as a stand-alone, as a stand-alone with BMA, and as an autograft (ICBG) extender produces results that are clinically and radiographically similar to ICBG.

INTRODUCTION

Iliac crest autograft is the commonly utilized “gold standard” graft material in spine surgical techniques. A number of limitations exist with use of this osteogenic bone graft including the quantity available and known complications associated with harvest. In an effort to substitute for the use of ICBG and/or diminish the volume used, clinicians and investigators have sought alternative graft materials to extend, enhance, and/or substitute for autograft. Alternatives include: allograft bone, synthetic materials, and recombinant human bone morphogenetic proteins (rhBMPs). Among synthetic substances, silicate-substituted bone graft materials such as Actifuse® ABX (Baxter Healthcare/ApaTech, Elstree, UK) have demonstrated efficacy in human and non-human investigations. The drive to further investigate silicate-substituted materials has led to the creation of additional novel materials such as SiCaP EP.

Synthetic bone graft substitutes based on hydrated calcium phosphate hydroxyapatite (HA; Ca₁₀(PO₄)₆(OH)₂) have been used in bone repair surgery for many years¹. Numerous attempts have been made to identify the

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Funding: Portions of this study were funded by a grant to the University of Iowa from Baxter Healthcare/ApaTech Ltd. (Elstree, England, UK).

Device Status: SiCaP EP has not been approved for use in humans and has not been evaluated by the U.S. FDA.

Disclosures: The authors report no other conflicts of interest – consultancy agreements, royalties, gifts received, intellectual property with regard to the products (SiCaP EP) or company (Baxter/ApaTech) involved in this scientific investigation.
properties that promote the osteostimulatory and osteointegrative capacity of HA-based bone grafting material. For instance, partial substitution of phosphate with silicate (SiO₄) within the HA lattice results in a significant enhancement in protein adsorption and subsequent osteoblastic cell attachment and proliferation compared with that seen on stoichiometric HA.

Silicate-substituted calcium phosphate (SiCaP) may assist in the direction of differentiation of mesenchymal stem cells towards an osteogenic lineage in novel ways. These properties are believed to be partly responsible for the SiCaP matrix supporting faster repair rates and increased levels of bone ingrowth and apposition compared with stoichiometric HA. Hing et al. demonstrated that SiCaP permitted cell-mediated resorption of the scaffold itself and of new bone, which contributed to the production of a functional repair within the defect site. Optimal levels of silicon (Si) substitution appear to be in the region of 0.8 wt% Si (2.6 wt% silicate) for beneficial effects on bone formation. In this investigation, a novel bone graft comprising silicate-substituted calcium phosphate with enhanced porosity (SiCaP EP) containing 0.8 wt% silicon with 80-85% total porosity and 31-47% strut-porosity is evaluated.

**MATERIALS AND METHODS**

The rabbit fusion model is a well-accepted tool for evaluating bone graft performance. The surgical procedure involves exposure of the transverse processes of L5 and L6 and the intertransverse region between these posterolateral vertebral structures, limiting decortication to the lateral regions, and grafting with the same material bilaterally. Autograft is harvested from the bilateral iliac crests typically yielding between 2.5-3.0 cc per crest, such that approximately 3 cc of graft is placed on each posterolateral graft bed. This procedure typically results in fusion rates around 50-65%.

To evaluate SiCaP EP, three groups were compared with autograft (2.5cc side volume). Investigational groups were distributed as follows: a SiCaP EP stand-alone group (2.5 cc side volume), a SiCaP EP stand-alone group with BMA 1:0.5 by volume (2.5 cc SiCaP EP + 1.25 cc BMA), and an iliac crest autograft extender group with SiCaP EP 3:1 by volume (2.0 cc ICBG + 0.5 cc SiCaP EP). The experimental design is provided in Table 1.

**Table 1: Experimental Design**

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Animals per Time Point</th>
<th>Plain Radiograph and pqCT (n per time point)</th>
<th>Manual Palpation and Mechanical Testing (n per time point)</th>
<th>Histopathology / Histomorphometry (n per time point)</th>
<th>Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autograft (ICBG)</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>4, 8, and 12 weeks</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>4, 8, and 12 weeks</td>
</tr>
<tr>
<td>SiCaP EP</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>4, 8, and 12 weeks</td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>4, 8, and 12 weeks</td>
</tr>
</tbody>
</table>

**Surgical Procedure**

The surgical model performed was a single-level lumbar intertransverse (posterolateral) fusion at L5-L6. The surgical approach to the spine was identical in all rabbits. A dorsal midline skin incision, approximately 15 centimeters long, was made from L1 to the sacrum and bupivacaine applied to the subcutaneous fascia prior to muscle incision overlying the transverse processes (TP). The TP's were decorticated with a high-speed burr.

The bone graft materials or the combination of materials were then placed between the TP's in the paraspinal bed (2.5 cc/side). The lateral two thirds of the TP's were covered with the graft. In the ICBG control, approximately 5.5-6.0 ml of corticocancellous bone graft from the iliac crest was obtained via bilateral iliac crest harvest. Approximately 2.5 cc/side of autograft was placed in each of the paraspinal beds. In a similar fashion, with the exception of ICBG harvest, 2.5cc/side of SiCaP EP stand-alone graft was placed in the paraspinal beds. In the BMA group, bone marrow (4.0 cc) was obtained from the proximal tibia of rabbits receiving SiCaP EP+BMA (1:0.5 by volume) immediately prior to the posterolateral fusion procedure and the SiCaP EP+BMA mixture was placed in each fusion bed (2.5 cc total/side). In the extender cohort, ICBG was harvested in a fashion to allow for a 3:1 by volume of graft material to be placed in each fusion bed (2.5 cc total/side). Following placement of graft materials, the muscle and skin were closed in a routine surgical manner with 3.0 Vicryl and then the skin stapled. Animals were housed and monitored throughout the study. Animals were humanely euthanized at 4, 8, and 12 week time points post surgically.
Radiographic Assessment

Plain Films: Rabbits were radiographed preoperatively, at the time of euthanasia, and following necropsy via ventral/dorsal radiographs with a SimonDR (Quantum, Ronkonkoma, NY 11779) RAD-X High Frequency Radiographic Imaging System, (model: E7242X), and stored using WhiteCap PACs system. Radiographic images were obtained at time zero and at 4, 8, and 12 weeks post-surgery. Animals received a sedative prior to radiography. Osteolysis, fracture, and/or any other adverse events were assessed.

Necropsy

Animals were euthanized using Beuthasol solution (120 mg/kg IV). Necropsy was conducted on all study animals according to BHRL/ISRC standard operating procedures under the supervision of the PI. The entire lumbar column was removed “en-bloc”.

Macroscopic Evaluation of Paraspinal Bed

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.

Manual Palpation

Stiffness of the fused motion segment was assessed by manual palpation according to accepted practice defined in prior investigations. The fusion was graded by three independent, blinded observers as “fused” if no detectable motion at the disc space was detected in flexion and extension. The fusion was graded as “not fused” if motion was present. Final results were determined by agreement of at least two of the three observers.

Mechanical Testing

Biomechanical non-destructive stiffness testing was performed following manual palpation. 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 embedded in Bondo/Fiberglass material using 2 inch PVC piping. The specimens were mounted in a biaxial servo-hydraulic materials testing machine (858 Bionix II, MTS Corporation, Eden Prairie, MN, USA) retrofitted with two spine gimbals and a passive XZ table. Custom-made rigid body markers comprised of three infrared light emitting diodes affixed between two small aluminum plates were placed on each vertebral body and the two gimbals to track the segmental motions.

Nondestructive 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 first two cycles served as preconditioning). The displacement of each set of vertebrae was measured using an optoelectronic motion capture system (OptoTrak, Northern Digital, Waterloo, Ontario, Canada); 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 (10 normal rabbit lumbar columns, historic internal laboratory controls).

Histology

Six decalcified paraffin-embedded sections from five animals in each group and at each time point were evaluated for histopathologic changes (N=3 sections per fusion mass). Slides were stained with routine hematoxylin and eosin as well as tartrate-resistant acid phosphatase (TRAP) to specifically identify osteoclasts. Briefly, following deparaffinization and rehydration, the tissue sections were incubated at 42°C for 45 minutes in 0.1 M acetate buffer (pH 5.2), containing 1.14% tartaric acid and 2% sodium naphthol in ethylene glycol. Slides were then transferred into acetate buffer with pararosaniline dye (5%) and 4% sodium nitrite for a period of 25 minutes followed by multiple rinses with deionized water and a hematoxylin counterstain. The presence of dark red to magenta cytoplasmic staining was considered as the specific criterion for identifying TRAP positive cells. Low, medium, and high magnification images were obtained from each slide. Areas of bone tissue, soft tissue (e.g. fibrous tissue, fibrocartilage, bone marrow), and graft were labelled. Areas of inflammation, osteoconduction (e.g. centripetal bone growth through open pores), osteointegration (bone-biomaterial contact), and resorption were also identified. Histology slides were viewed by the PI and a board-certified veterinary pathologist. Semi-quantitative assessment was performed for all specimens.

Six non-decalcified resin embedded samples from five animals in each group and at each time point were evaluated for histomorphometry (N=3 sections per fusion mass). Histology slides from each fusion mass were stained with hematoxylin and eosin and evaluated with MicroSuite Pathology Edition software, Olympus, and Image J, NIH. The total area (TA) and bone area from each slide. Histology slides from each fusion mass were stained with hematoxylin and eosin and evaluated with MicroSuite Pathology Edition software, Olympus, and Image J, NIH. The total area (TA) and bone area (BA) were evaluated for each slide. The areas from six slides of each animal were averaged to obtain a single mean TA and BA value for each animal. These values were used to calculate the normalized bone area percentage ((BA/TA)*100).

Statistical Analysis

Statistical analysis was performed on the flexion-
extension flexibility data as well as the normalized histomorphometric bone 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 (α=0.05). If the data was not normal, a non-parametric Mann-Whitney test was used (α=0.05). All statistical analysis was performed using Minitab software (version 15.1.1.0: Minitab Inc., State College, PA, USA). Unless otherwise noted, data is listed as mean and one standard deviation.

RESULTS

Four rabbits were omitted from the study because of complications: one 12 week ICBG rabbit attributed to neurologic deficit due to iliac crest graft harvest, one 12 week ICBG+SiCaP EP (3:1) rabbit due to respiratory distress during surgery, one 4 week ICBG rabbit due to anesthesia complications, and one 4 week ICBG+SiCaP EP (3:1) due to a fractured L6 vertebra. These complications seemed to be randomly distributed among the groups (including the ICBG group) and were consistent with the type and rate of complications published in prior series by this and other laboratories, therefore these observations were not attributed to the graft material. The rest of the animals were evaluated by manual palpation, nondestructive flexibility testing for stiffness, histopathology, and histomorphometry.

Radiology: Density of the implanted test articles made interpretation of continuous trabecular bone formation in the test article groups challenging. Over prediction of fusion is a common occurrence with dense ceramic materials in this model10,11,12. Therefore radiographic fusion rates were not determined. No fractures, osteolysis, or other adverse reactions were evident during radiographic examination.

Figure 1: Mean Maximum Flexion/Extension Motion at 0.27Nm with Standard Deviation (Mean ± Standard Deviation)

Necropsy/Macroscopic Examination: Necropsy of the animals that completed the scheduled time courses was unremarkable regardless of treatment. Macroscopic analysis of the grafted site demonstrated healthy tissue with no apparent adverse effects such as inflamed, necrotic, or devascularized tissue surrounding the operated levels. One rabbit (12 week ICBG+SiCaP EP (3:1)) had signs of infection (an encapsulated mass containing thick, purulent material) which was later confirmed on histologic examination to be secondary to bacterial contamination of the implantation site and not due to the implant itself.

Manual Palpation Assessment of Fusion: Fusion was assessed by manual palpation of the treated motion segment (Figure 1). The fusion rate by manual palpation for ICBG in the current study (0%, 50%, and 56% at 4, 8, and 12 weeks respectively) is consistent with results from previous studies in this laboratory10,11,13,14 as well as consistent with the radiographic result in this study. At 8 and 12 weeks, all five implant groups obtained fusions in approximately half of the specimens, thus no differences between the test groups were detected.

Mechanical Testing of Stiffness: The test groups of this study were compared 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.

Motion in the flexion/extension plane was used as the primary measurement to demonstrate fusion (Figure 2) as manual palpation testing is based off of motion detected in flexion/extension. It was determined that
Table 2: Statistical Analysis of Flexion/ Extension Range of Motion Data (p values from non-parametric Mann-Whitney test)

<table>
<thead>
<tr>
<th></th>
<th>ICBG</th>
<th>ICBG + SiCaP EP (3:1)</th>
<th>SiCaP EP+BMA (1:0.5)</th>
<th>SiCaP EP</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Week Data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (Unfused)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICBG</td>
<td>0.331</td>
<td>0.153</td>
<td>0.438</td>
<td></td>
</tr>
<tr>
<td>ICBG+SiCaP EP (3:1)</td>
<td>0.903</td>
<td>0.967</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SiCaP EP+BMA (1:0.5)</td>
<td>0.850</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Week Data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (Unfused)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICBG</td>
<td>1.000</td>
<td>0.970</td>
<td>0.571</td>
<td></td>
</tr>
<tr>
<td>ICBG+SiCaP EP (3:1)</td>
<td>0.734</td>
<td>0.678</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SiCaP EP+BMA (1:0.5)</td>
<td>0.791</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 Week Data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (Unfused)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICBG</td>
<td>1.000</td>
<td>0.838</td>
<td>0.540</td>
<td></td>
</tr>
<tr>
<td>ICBG+SiCaP EP (3:1)</td>
<td>0.967</td>
<td>0.391</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SiCaP EP+BMA (1:0.5)</td>
<td>0.678</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The flexion/extension data at 4, 8, and 12 weeks was not normally distributed, thus a non-parametric Mann-Whitney test was used to determine statistically significant differences at α=0.05.

The results of the statistical analysis are provided in Table 2. General findings from the biomechanical analysis indicate that the five groups had similar performance to each other, and had statistically significantly less range of motion compared to the normal controls at each time period.

**Histopathology:** The majority of these specimens, regardless of implant type or time of implantation had low to moderate multifocal to coalescing inflammation throughout the implantation site, primarily composed of lymphocytes and plasma cells with fewer macrophages and multinucleated giant cells. The implant sites were composed of bone and fibrous connective tissue which was more mature in the 8-12 week animals as compared to the 4 week animals. Also present within implant sites were variable amounts of new cartilage. The fibrous tissue appeared to differentiate into either new cancellous bone (membranous ossification) and/or cartilage. Within the fibrous connective tissue there was moderate neovascularization. TRAP staining revealed mild to moderate osteoclastic activity near and around the residual implant indicating resorption of the graft material (Figure 3).

There was no evidence of inflammation, infection or necrosis secondary to the implants, regardless of type. One specimen (12 week ICBG+SiCaP EP (3:1)) showed signs of infection (small basophilic bacterial colonies); however, the infection appeared to be secondary to bacterial contamination of the implantation site and not due to the implant itself.

**Histomorphometry:** There were no adverse inflammatory reactions seen in any of the non-decalcified plastic embedded histology sections, regardless of graft type. The majority of sections within each group had new woven bone dorsal to the transverse processes in direct apposition or within the graft. Islands of new bone were evident within the center of the graft in all groups. Representative non-decalcified plastic embedded histology sections at 12 weeks are presented in Figures 4-7.

Normalized bone area percentages are provided in Table 3. A bar chart of the mean data with standard deviations is provided in Figures 8. It was determined that the 4 week normalized bone area data was not normally distributed, thus this data set was statistically assessed.
Table 3: Normalized Histomorphometry Area Percentages (Mean ± Standard Deviation)

<table>
<thead>
<tr>
<th></th>
<th>Time Point</th>
<th>(No. Fused/ Total No.)</th>
<th>Normalized Bone Area (BA/TA) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICBG</td>
<td>4</td>
<td>(0/5)</td>
<td>37.333 ± 5.948</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>4</td>
<td>(1/5)</td>
<td>29.056 ± 6.103</td>
</tr>
<tr>
<td>SiCaP EP</td>
<td>4</td>
<td>(1/6)</td>
<td>24.400 ± 4.519</td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td>4</td>
<td>(1/5)</td>
<td>19.533 ± 1.321</td>
</tr>
<tr>
<td>ICBG</td>
<td>8</td>
<td>(3/5)</td>
<td>34.656 ± 4.358</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>8</td>
<td>(2/5)</td>
<td>27.139 ± 4.969</td>
</tr>
<tr>
<td>SiCaP EP</td>
<td>8</td>
<td>(2/5)</td>
<td>25.400 ± 1.663</td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td>8</td>
<td>(2/5)</td>
<td>24.933 ± 5.084</td>
</tr>
<tr>
<td>ICBG</td>
<td>12</td>
<td>(2/5)</td>
<td>25.744 ± 2.904</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>12</td>
<td>(3/5)</td>
<td>26.500 ± 2.650</td>
</tr>
<tr>
<td>SiCaP EP</td>
<td>12</td>
<td>(2/5)</td>
<td>25.856 ± 4.600</td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td>12</td>
<td>(2/5)</td>
<td>24.100 ± 1.525</td>
</tr>
</tbody>
</table>

Figure 5: Non-decalcified histology section of ICBG+SiCaP EP (3:1) at 12 weeks: H&E staining (1.26x magnification)

Figure 6: Non-decalcified histology section of SiCaP EP at 12 weeks: H&E staining (1.26x magnification)

Figure 7: Non-decalcified histology section of SiCaP EP+BMA (1:0.5) at 12 weeks: H&E staining (1.26x magnification)

Figure 8: Normalized Bone Area Measured with Histomorphometry (Mean ± Standard Deviation)
Table 4: Statistical Analysis of Normalized Bone Area Measured with Histomorphometry (p value from student t-test / p value from non-parametric Mann-Whitney test)

<table>
<thead>
<tr>
<th></th>
<th>ICBG + SiCaP EP (3:1)</th>
<th>SiCaP EP + BMA (1:0.5)</th>
<th>SiCaP EP</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Week Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBG</td>
<td>[0.095]</td>
<td>[0.022]</td>
<td></td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>[0.012]</td>
<td>[0.175]</td>
<td>[0.037]</td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td>[0.012]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Week Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBG</td>
<td>0.028</td>
<td>0.014</td>
<td>0.007</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>0.490</td>
<td>0.452</td>
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<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td></td>
<td>0.855</td>
<td></td>
</tr>
<tr>
<td>12 Week Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBG</td>
<td>0.680</td>
<td>0.305</td>
<td>0.965</td>
</tr>
<tr>
<td>ICBG + SiCaP EP (3:1)</td>
<td>0.130</td>
<td>0.795</td>
<td></td>
</tr>
<tr>
<td>SiCaP EP + BMA (1:0.5)</td>
<td></td>
<td>0.463</td>
<td></td>
</tr>
</tbody>
</table>

using a non-parametric Mann-Whitney test (α=0.05). The remaining data sets were normally distributed and were assessed with a student t-test (α=0.05). Statistical analysis of the histomorphometric normalized bone area percentages is presented in Table 4.

At 4 and 8 weeks, ICBG had greater normalized bone area compared to all other groups. At 12 weeks, all groups had equivalent normalized bone area, indicating all test groups demonstrated equivalent bone healing to ICBG.

**DISCUSSION**

Bone graft technologies continue to be investigated as a method of reducing or replacing the use of iliac crest autograft over time. Other products have demonstrated efficacy as autograft enhancers or extenders, diminishing the relative need for use of large volumes of iliac crest autograft. Some of these technologies make use of ceramic materials such as calcium phosphate to create the potential for an osteoconductive environment.

This study examines the efficacy of SiCaP EP as a replacement, as an extender when in combination with autologous Iliac Crest Bone Graft (ICBG) (1:3), and in combination with Bone Marrow Aspirate (BMA) (1:0.5). The osteoconductive nature of this bone graft substitute (BGS) as an autograft extender/enhancer was tested head-to-head against a common positive control (iliac crest autograft: an osteogenic and osteoinductive bone graft material).

In this investigation, mechanical testing appeared to provide the most accurate assessment of fusion for the synthetic bone graft substitute, SiCaP EP. Density of the implanted test articles made radiographic interpretation of continuous trabecular bone formation in the test article groups challenging and over prediction of fusion is a common occurrence with the dense ceramic materials used in this model10,11,12.

Stiffness of the grafted motion segments was assessed by manual palpation and flexibility testing. In the 4 week group, no ICBG treated animals were fused and only 20% were fused in the other 4 groups tested. At 8 and 12 weeks, all grafted sites were fused in approximately half of the animals, regardless of implant, consistent with previous studies. Based on quantitative biomechanics, there were no statistically significant differences between the groups in terms of ROM in any bending modality, although all groups had statistically significantly less ROM than normal controls. The results from quantitative biomechanics support the fusion assessment by manual palpation in that animals fused by manual palpation had significantly lower ROM compared to those graded as not-fused by manual palpation.

General histologic findings demonstrated mild lymphoplasmacytic inflammation with fewer macrophages and giant cells. This would be expected in an area of implanted material. All fusion masses consisted of fibrous tissue, graft and new bone formation. The fibrous tissue appears to differentiate into new woven bone and cartilage. New blood vessels were apparent in each fusion mass regardless of implant. TRAP staining demonstrated that SiCaP EP resorbed via osteoclastic activity. Histomorphometry indicated that SiCaP EP as a standalone, as an extender (mixed with ICBG), or mixed with BMA demonstrated equivalent bone healing to ICBG at 12 weeks.

The results of this study suggest that SiCaP EP is effective in producing posterolateral fusion when employed as a bone graft substitute as evidenced through multiple metrics in this model. Though animal models cannot be directly translated to clinical application, investigation into the use of SiCaP EP as a BGS in a clinical setting may be appropriate to further characterize its efficacy.

**CONCLUSION**

SiCaP EP, ICBG+SiCaP EP (3:1), and SiCaP EP+BMA (1:0.5) compare favorably to autologous iliac crest bone graft by multiple metrics in this rabbit posterolateral fusion model.
REFERENCES


ABSTRACT:
Objective: The purpose of this study was to evaluate the BioPlex bioresorbable interbody device in a sheep lumbar fusion model and compare it to the Concorde®, a standard carbon fiber interbody cage.

Background: Lumbar interbody fusion devices are made from a variety of materials, including titanium alloys, carbon-fiber, and PEEK. The BioPlex Continuous Phase Composite (CPC) is a unique bioresorbable material comprised of ProOsteon 500R and 70:30 Poly (L/D, L-lactic acid). The BioPlex device is radiolucent, resorbable and due to its bulk nanoporosity of 8%, has a more consistent degradation profile as compared to a polymer alone.

Methods: A total of twenty five male Suffolk sheep were used in this study; nineteen of which were implanted with a BioPlex or Concorde device at the L3-L4 and L5-L6 levels using a modified transforaminal/lateral approach. A discectomy was performed and each implant (filled with autologous bone) was placed within the disc space. The sheep were sacrificed at 6, 12, 24 months post-implantation. Fusion was assessed via motion, radiographic and histological data.

Results: The BioPlex and Concorde implanted levels had significantly less motion (p<0.05) than the normal controls in flexion/extension and lateral bending at 6, 12, and 24 months. No significant difference in motion was detected between the BioPlex and Concorde implants. CT fusion scores correlated with the motion analysis in all the three cases.

Conclusion: In comparison to the Concorde device, the BioPlex implant appears to have equivalent radiographic and biomechanical fusion success.

Key Words: bioresorbable, interbody fusion, sheep model, lumbar spine, arthrodesis

INTRODUCTION
Spinal fusion is one of the most widely used modalities for treating degenerative spinal disorders, especially in the lumbar region. The ultimate goal of fusion is to obtain a solid union between two or more vertebrae. Although alternative methods to treat degenerative disc disease are increasing in popularity, the efficacy of methods such as total disc replacement are not yet fully understood, especially in the lumbar spine1.

In 2003, more than 325,000 spinal fusions were performed, of which approximately 162,000 involved the lumbar spine2. There are a number of metrics by which success may be judged with respect to fusion such as: a healed radiographic appearance, pain relief, and prevention of neurologic injury. Though there are a number of fusion approaches/techniques, an interbody fusion is the most biomechanically stable of all available fusion option; fusion rates are higher and stabilization is more effectively maintained with interbody fusion3-4.

Based on the initial experiences of Bagby with a stainless steel basket5, interbody fusion cage technologies have evolved rapidly over the past two decades. In addition to cage design, the choice of material has expanded (e.g., stainless steel, titanium, carbon fiber, PEEK, and ceramics)5-8. Although carbon fiber and PEEK cages provide an advantage over metal cages because they are radiolucent and less stiff, long-term problems such as the release of wear debris/particles and breakage of the cage have been reported5-8. The inherent limitations of current cage devices and the temporary role of fusion cages were incentives for the development of bioresorbable polyactic acid-based cages. BioPlex
Continuous Phase Composite (CPC) is one such unique bioresorbable material comprised of Pro Osteon 500R and 70:30 Poly L/D, L-lactic acid (PLDLLA).

The properties of the composite are significantly improved by filling the macroporosity of Pro Osteon 500R with PLDLLA polymer. As a base material, Pro Osteon 500R is characterized by a 100% inter-connected, porous structure that allows for polymer penetration through the entire macroporosity. The ceramic consists of a thin layer of hydroxyapatite over a calcium carbonate skeleton.

The BioPlex composite has the ability to support bone growth within the implant walls which results in more bone present at the implant site. The presence of microporosity within the BioPlex ceramic phase allows for degradation products to readily and easily be removed from within the implant preventing lactic acid build up and associated implant complications. The presence of microporosity also gives BioPlex an optimal degradation profile that allows for the gradual loading of the newly forming bone. The presence of residual Pro Osteon within the polymer during the late stages of polymer degradation allows for the remaining calcium carbonate to react with lactic acid thereby neutralizing the acid. Pro Osteon also allows the composite to be visualized on radiographs.

In this study, we compared BioPlex interbody fusion device with Concorde; a popular FDA approved carbon fiber interbody device. Motion, radiographic and histological analyses were the parameters used to compare the two devices.

**MATERIALS AND METHODS**

**Specimen Preparation**

A total of twenty-five skeletally mature male Suffolk sheep were used for this study. Six sheep served as controls, while interbody fusion devices were introduced at levels L3-L4 and L5-L6 for the remaining nineteen sheep (Figure 1). Each animal and spinal level was randomly assigned an implant (i.e., either a BioPlex or a Concorde interbody device).

For both implants, a modified transforaminal approach was used. Corticocancellous autogenous bone graft was harvested locally. A posterior midline approach was used to expose the posterior aspect of the spine. A dorsal midline skin incision was made from T10-S1. This extended incision was necessary to ensure sufficient muscle retraction. The fascia and supraspinous ligament were incised around each spinous process and on the midline between each treated motion segment. The incision was deepened to the laminae to complete the midline muscle separation. The multifidus was incised and freed from the mammillary processes. The incision was made directly on the bone to limit hemorrhage and damage to the underlying dorsal nerve root and vessels.

Lateral retraction of the muscles exposed the mammillary, cranial, caudal, and transverse processes and nerve roots and vessels. A hemifacetectomy of the cranial and caudal processes was then performed. The pars interarticularis was removed, allowing access to the lateral aspect of the disc. A near-complete discectomy was performed from this approach. The disc space was then implanted with a BioPlex or Concorde cage filled with autograft. Pedicle screws and rods were used for posterior stabilization of the spinal units in four animals to check if posterior instrumentation accelerated fusion. No instrumentation was used for the remaining animals.

The sheep were euthanized at 6, 12, or 24 months after surgery with Euthasol followed by removal of the spinal column. The spine was scanned using CT before storing them in double plastic freezer bags at -20°C. Prior to testing, the specimens were thawed overnight. The thawed specimens were carefully cleaned by tak-
ing off all the musculature while avoiding disruption of any ligaments, joints and discs. The levels of interest (L3-L4 and L5-L6) were then dissected from each spine, wrapped in saline drenched gauze and stored again in freezer bags. On the day of testing, the samples were removed from the freezer and thawed.

**Experimental Setup**

The caudal vertebra of the functional spinal unit (FSU) was secured on a custom made fixture using bolts to achieve a rigid fixation. A loading frame was attached to the cephalad vertebra. A sensor consisting of three iRed markers was rigidly attached to each vertebral body (Figure 2).

A custom designed testing rig was used to apply pure moments using dead weights and a pulley system. Maximum moments of 6.0 Nm were applied in four incremental steps of 1.5 Nm in flexion, extension, lateral bending and axial rotation. The resulting motions were recorded using an optoelectronic camera system - Optotrak 3020 (Northern Digital, Waterloo, Ontario, Canada). The angular rotations of the cephalad vertebra with respect to the caudal vertebra were calculated for each loading condition using the software Motion Monitor system (Innsport, Chicago, IL). Relative angles were calculated as Euler angles with the sequence Z (lateral bending), Y (axial rotation), X (flexion - extension).

The six intact / control specimens underwent mechanical testing first followed by the implanted specimens. Fusion was assessed by comparing the motion of the instrumented specimens with that of the control (intact) specimens.

**Radiographic Analysis**

The CT scans of each specimen were analyzed by an Orthopaedic Surgeon and the specimens were given scores on a scale of 1–5 to quantify fusion (Table 1).

**Histology**

Following the experimental investigation, histological examination was performed on each implanted specimen using parasagittal sections of the fusion mass. The slides were stained using H&E stain. The slides were then analyzed for the presence of new bone formation (NBF), quality of NBF, and inflammation and presence of residual graft.

**Data Analysis**

Student t-test with a confidence interval of 95% (p = 0.05) was used to analyze all the data.

**RESULTS**

**Control (Intact) Specimens**

Table 2 summarizes the range of motion for the 6 Nm moment (i.e., maximum moment) in flexion, extension, right & left lateral bending and right & left axial rotation. No significant differences (p>0.05) in motion were observed between the two functional levels (L3-L4 and L5-L6) tested.

**Table 2: Average range of motion observed in intact specimens at maximum moment (6Nm)**

<table>
<thead>
<tr>
<th>Range of Motion (degrees)</th>
<th>L3/L4</th>
<th>L5/L6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>4.63 ± 1.53</td>
<td>5.14 ± 2.11</td>
</tr>
<tr>
<td>Extension</td>
<td>-4.78 ± 1.07</td>
<td>-5.23 ± 2.46</td>
</tr>
<tr>
<td>Right Lateral Bending</td>
<td>5.85 ± 1.18</td>
<td>5.34 ± 0.69</td>
</tr>
<tr>
<td>Left Lateral Bending</td>
<td>-5.09 ± 0.96</td>
<td>-5.01 ± 0.42</td>
</tr>
<tr>
<td>Right Axial Rotation</td>
<td>-2.03 ± 0.57</td>
<td>-1.53 ± 0.81</td>
</tr>
<tr>
<td>Left Axial Rotation</td>
<td>1.59 ± 0.44</td>
<td>0.92 ± 0.34</td>
</tr>
</tbody>
</table>
Implanted Specimens

Figure 3 summarizes the motions for each of the 6 Nm loading modes at the various time points (6, 12, or 24 months) for both the BioPlex and Concord implanted specimens. The motion of implanted levels (both BioPlex and Concorde) decreased gradually over time. The BioPlex and Concord implanted specimens experienced a significant decrease in motion (p<0.05) at each interval of time, as compared to the control specimens. However, no significant difference (p>0.05) was observed between the two implants.

Four specimens in the six month group had posterior instrumentation. Though there was a trend for posterior instrumentation to reduce the motion in comparison to the non-instrumented specimens, the reduction in motion was not significant.

Radiographic Results

A summary of mean fusion scores and mean fusion quality scores for all implanted specimens is shown in Figure 4. In accordance with the motion analysis results, the radiographic analysis also showed an improvement in fusion over time. When BioPlex and Concorde scores were compared, there was no significant difference (p>0.05) in the scores at all time intervals. Comparing instrumented and un-instrumented specimens, BioPlex showed no significant difference which was in agreement with the motion analysis results.
Histology Results

Figure 5 shows sample histology slides for the specimens implanted with the BioPlex and Concorde cages sacrificed at 6, 12, and 24 months. At 6 months, there were clear signs of new bone formation in both cases.

At 12 months, new bone formation was extensive for both implants. Bone formation in and around the BioPlex cage was clearly visible, accompanied by implant resorption. The Concorde device, in contrast, is clearly visible with bone formation around the implant.

At 24 months, the BioPlex implant had resorbed completely and the space was filled with bone, thereby fusing the two vertebrae. The Concord implant, being composed of carbon fiber remained clearly visible with bone growth surrounding the implant.

Discussion

The aim of the present study was to evaluate the BioPlex interbody fusion device in a sheep model and compare it with the current standard, the Concorde carbon fiber cage. We were also interested whether posterior instrumentation accelerated fusion and hence four specimens had additional posterior instrumentation accompanying the interbody cages. The specimens were tested for motion in the sagittal plane (flexion-extension), coronal plane (lateral bending), and the transverse plane (axial rotation).

The six month specimens were divided into two groups depending on the use of posterior instrumentation. The instrumented group had four specimens (eight FSUs; four BioPlex and four Concorde). Although the specimens with posterior instrumentation showed a reduced motion in all directions as compared to the un-instrumented specimens, the reduction was not significant. This was observed in both the Concorde and BioPlex implanted specimens.

The total number of un-instrumented specimens for the six month group was five (nine FSUs), but four FSUs had to be excluded from mechanical testing giving us five FSUs; three of BioPlex and two of Concorde. Both the BioPlex and Concorde implanted un-instrumented specimens showed a significant reduction in flexion, extension and lateral bending when compared with control. The reduction in axial rotation was not significant. This might be due to the fact that the motion observed in axial rotation in the lumbar spine itself is low. The instrumented specimens, however, demonstrated a significant reduction in motion, not only in flexion–extension and lateral bending, but also in axial rotation. The differences in the motion observed between the BioPlex and Concorde implanted specimens were not significant for both the instrumented and un-instrumented specimens. In these specimens, most reduction was observed for lateral bending where the average reduction was more than 80% for both BioPlex and Concorde. Meanwhile the average reduction in flexion–extension and axial rotation was about 50%.

In the 12 month group, there were a total of four specimens (i.e. eight FSUs; four BioPlex and four Concorde). There was a significant reduction in motion in all directions for both the BioPlex and Concorde implanted specimen. In this group, most reduction was observed in flexion–extension (75% in BioPlex and 90% in Concorde) followed by lateral bending and axial rotation (60% in BioPlex and 75% in Concorde). In this group too, there was no statistically significant difference between BioPlex and Concorde.

There were six specimens in the 24 month group (12 FSUs; six BioPlex and six Concorde). In one BioPlex FSU, the level did not fuse due to improper placement of the implant during surgery. This sample was excluded from the analysis yielding five FSUs of BioPlex and six of Concorde. The motion observed in all of these specimens was least in comparison with the other groups giving us about 95% reduction in lateral bending, more than 90% reduction in flexion–extension, and more than 85% reduction in axial rotation. The reduction in motion was significant in all direction at a confidence interval of 99%. When compared with each other, the two implants did not differ statistically.

Considering all the un-instrumented groups together (i.e. 6 month, 12 month and 24 month), we see a gradual decrease in motion over time for flexion–extension and axial rotation. In lateral bending, the reduction was gradual for Concorde but not for BioPlex.

Other fusion related studies mostly compare stiffness as opposed to range of motion. Kanayama et al. compared to our study. When the six month results of our study were compared with 16 week results from the paper, the six month specimens (both instrumented and un-instrumented) were much stiffer.

There have been other similar fusion studies performed on various models. In a literature review by Oxland and Lund, anterior and posterior approaches for cage insertion in human cadaveric models are compared with some early animal results. Comparing the results in this paper which includes studies by Wilder et al., Brodko et al. and Butts et al. with our study, the 12 and 24 month results of our study are much better.

Radiographic results correlate to the mechanical test-
ing results in most cases. As seen in testing results, radiographic scores also showed an increase in fusion and fusion quality over time. Both fusion and fusion quality scores showed no statistically significant difference between specimens implanted with BioPlex and Concorde interbody fusion devices for all time intervals. Comparing instrumented specimens with un-instrumented ones, BioPlex showed no difference but there was a statistically significant difference in both scores for specimens implanted with Concorde cages.

Histological analysis showed that new bone formation was similar between groups with the BioPlex having slightly more in the six month group with a slight transition to Concorde by 24 months. Quality of NBF was similar at six months with generally better quality at 12 and 24 months in the Concorde group. Interestingly at 24 months, about 50% of the Bioplex group had similar quality as Concorde; however another 50% had poor quality. This also inversely corresponded to inflammation scores in which Bioplex had similar to slightly lower scores. In general the residual graft was more readily detected in the Bioplex group at all time points.

The current study serves as the first study to biomechanically, radiographically and histologically demonstrate BioPlex as an interbody device for spinal fusion. The biomechanical results demonstrated that BioPlex was equally effective in fusing the spine as the standard Concorde cage. Radiographic assessment results corroborated the biomechanical data. According to the histologic analysis, there were clear signs of bone penetration, active degradation and long term biocompatibility.

The lack of any implant complications was the result of a variety of properties unique to BioPlex. Bone in growth, residual calcium carbonate, and nanoporosity within the ceramic phase all contribute to the overall biocompatibility of BioPlex throughout the entire degradation process. The presence of bone within the implant walls makes it easier for the tissue to resorb any released lactic acid. Overall, the properties of the BioPlex composite result in a unique material that eliminates implant related complications often associated with 100% polymer devices.

**SUMMARY POINTS**

1. Specimens implanted with a BioPlex or Concorde implant showed a significant reduction in motion.
2. No significant difference in motion was observed between specimens implanted with the Bioplex and Concorde devices.
3. The BioPlex implants resorbed completely within 24 months.

**REFERENCES**


ABSTRACT

Introduction: Use of Computed Tomography (CT) to evaluate syndesmotic reduction following injury has significantly increased in recent years. The aim of this study was to compare existing clinical measurements of syndesmotic reduction to gold standard measurements of fibular motion obtained from a full 3D model.

Methods: Three common clinical measures for assessing syndesmotic congruity on axial CT slices were identified in the literature. Each measure was manually performed on 170 cadaveric ankle CT scans obtained with variable degrees of simulated syndesmotic displacement. Clinical measures were assessed for intraobserver and interobserver reliability and compared to objective measures of true medial/lateral and anterior/posterior translation and fibular rotation that were obtained from a 3D model. Pearson correlation coefficients (PCC) were computed to determine which clinical measurements were most accurate for describing syndesmotic motion obtained from the 3D model.

Results: All three clinical measurement techniques demonstrated good to excellent interobserver and intraobserver reliability. Medial/lateral displacement of the fibula was best correlated with the difference between the anterior and posterior tibiofibular joint space measurements described by Elgafy et al (PCC = 0.29 small correlation). Anterior/posterior displacement of the fibula was well correlated with the anterior/posterior measurement described by Phisitkul et al (PCC = 0.69 large correlation). Fibular rotation was best correlated with the average of the Elgafy anterior and posterior tibiofibular joint space measurements (PCC=0.33, moderate correlation). Proximal/distal displacement of the lateral malleolus was best correlated with the Elgafy posterior tibiofibular joint space measurement (PCC=0.49, moderate correlation).

Discussion: While the clinical measurements were adequately reproducible, they showed only moderate to small correlations with the 3D measurements of movement of the fibula in the longitudinal, medial/lateral or rotational directions. The only fibular translation measured by the 3D model that was well described by the three clinical measures was fibular movement in the anterior/posterior direction. This work demonstrates a need for improved clinical measurements of syndesmotic congruity on axial CT scans to serve as surrogates for the true movement of the fibula.

INTRODUCTION

Small changes in ankle joint congruity, including the syndesmosis, have been shown to have large effects on joint contact stresses\textsuperscript{12}. The ramifications of these changes in contact stresses are thought to be related to the high rate of post traumatic osteoarthritis in the ankle joint. Radiographs have been shown to have limited sensitivity in detecting subtle syndesmosis and ankle joint malalignments and are highly sensitive to positional change\textsuperscript{34}. Consequently, the use of Computed Tomography (CT) in the evaluation of ankle injury has greatly increased in recent years. The advantages of CT-based evaluation of the syndesmosis are that unlike plain radiographs, CT provides axial views of the syndesmosis and CT is substantially less dependent on ankle positioning at the time of imaging\textsuperscript{5,3}. This improved visualization has shown high rates of syndesmotic malreduction on CT following open reduction internal fixation of ankle fractures\textsuperscript{6,7}. Many of these malreductions go undetected on plain radiographs, meaning subtle malreductions may go unidentified without advanced imaging\textsuperscript{8,9}.

The manner in which the syndesmosis is evaluated using CT has been highly variable. Several different methods have been used to describe the distal tibia-fibula relationship in both injured and uninjured ankles using manual measurements between anatomic landmarks, and several studies have used only subjective criteria\textsuperscript{6,10-14}. In all cases, evaluation of the syndesmosis is made on a single axial slice through the volume, neglecting...
available 3D information. Although several methods have been shown to be reproducible in their application, their validity in assessing movement of the fibula relative to the tibia has not been shown. It is unclear if the 2D measurement methods used clinically for CT evaluation accurately represent the true deviations in the distal tibia-fibula relationship.

The purpose of this study was to evaluate existing, clinically applicable CT measurements of the syndesmosis against objective, automatically calculated gold-standard measurements taken from the calibrated 3D CT volume. While it would be ideal to always obtain fully objective 3D data about tibia and fibula position from a CT scan, this requires clinically unrealistic, time-consuming segmentation, modeling, and analysis. The goal of this work was to identify which of the commonly employed clinical measures were most indicative of true fibular motion relative to the tibia in cases of a disrupted syndesmosis.

MATERIALS AND METHODS

Ten through-the-knee lower extremity cadavers were used in the study. In order to create variability in the syndesmosis joint and relative positions of the tibia and fibula, various degrees of syndesmotic instability ranging from an isolated rupture of the anterior inferior tibiofibular ligament to a complete disruption of the syndesmosis with posterior malleolar fracture and deltoid ligament disruption were created using a scalpel under direct visualization. In each disrupted condition reduction forceps were applied to the medial and lateral malleoli at one centimeter above the joint line in three different orientations (anteromedial to posterolateral, medial to lateral, and posteromedial to anterolateral). Marking screws were placed in each specimen to ensure reproducible clamp placements and manipulations. A total of 170 CT scans (17 per specimen) were evaluated.

Manual Clinical Measurements

Common clinical measurement techniques used in this work included a metric described by Tang et al\textsuperscript{15}, intended to describe fibular rotation, measurement of anteroposterior and mediolateral fibular displacement described by Phisitkul et al\textsuperscript{16}, and a measurement of the syndesmotic joint space described by Elgafy et al\textsuperscript{13}. (Figure 1). The Tang measurement was made by finding the ratio of the vectors directed from the tibial centroid to the anterior-most point on the fibula and from the tibial centroid to the posterior-most point on the fibula. The anterior Elgafy measurement was made between the closest point on the anterior tubercle of the tibia and the point on the fibula closest to that location. The posterior Elgafy measurement was made between the point on the fibula that was midway between the medial-most and the posterior-most points, and the location on the tibia that was closest to that location. The difference and average between the anterior and posterior Elgafy measurements was calculated\textsuperscript{14}. The medial Phisitkul measurement was made between a line connecting the anterior and posterior tubercles of the tibia, and the medial-most border of the fibula. The anterior Phisitkul measurement was made between the line perpendicular to the line connecting the tubercles at the anterior tubercle, and the anterior-most point of the fibula.

These measures were performed manually on 2D axial CT slices using Vitrea® software (Vital Images, Minnetonka, MN, USA). Two observers not involved in the specimen preparation made measurements separately and in the exact manner described in the articles referenced. Measurements were repeated 12 weeks later and inter-rater reliability and intra-rater reliability was assessed.

Objective Geometric Measurements

To obtain objective measurements of fibula motion relative to the tibia, 3D models were generated from
segmantation. The tibia in the experimental case has been aligned with the intact tibia using the iterative closest point algorithm. The movement of the fibula resulting from clamping the fibula with a posteriorly directed force can be seen by the offset of the experimental fibula (red) from the intact fibula (bone). The 2D cutting plane 10mm above the articular surface for extracting the cross section from which the objective 2D measurements were made is shown for reference.

An iterative closest point algorithm was then used to match the surfaces of each experimental tibia segmentation to its anatomically aligned intact tibia segmentation. Next, a 2D cross-section through the aligned 3D volumes was selected at a level 10mm proximal to the distal tibial articular surface (Figure 2). This cross section was selected to correspond to the level above the joint that was evaluated in manual measurements on the 2D axial CT section. On each cross section extracted from the 3D model, the three clinical measurements (Tang, Elgafy, and Phisitkul measurements) and four objective 2D measurements were made using a fully automated custom Matlab algorithm.

The three clinical measurements were made by the algorithm using the same anatomic landmarks that were manually identified on the 2D axial CT slices. However, because the algorithm identified these landmarks from the 2D cross section obtained from the 3D model, these clinical measures were automated, perfectly repeatable, and user independent to serve as a gold standard. In addition to the basic clinical measurements, two derived measures were also evaluated. The difference between the anterior and posterior Elgafy measurements was calculated as a potential measure of fibular rotation, and the average of the anterior and posterior Elgafy measurements was calculated as a potential measure of medial/lateral fibular movement.

The objective measurements made by the algorithm consisted of 1) medial/lateral movement of the fibular centroid 10mm proximal to the distal tibial articular surface, 2) anterior/posterior movement of the fibular centroid 10mm proximal to the distal tibial articular surface, 3) internal/external rotation of the fibula around its own proximal/distal axis, and 4) internal/external rotation of the fibula around the tibial proximal/distal axis (Figure 3). The medial/lateral and anterior/posterior movements of the fibula were differences between the centroid of the fibula in the experimental condition relative to the location of the centroid in the intact condition. Rotation of the fibula was calculated by the angular change in a vector from the centroid of the fibula to the anterior-most point on the fibula in the intact case, to a vector from the fibula centroid to that same point in the experimental condition. Rotation around the tibia was calculated by the angular rotation of the fibula centroid around the tibial centroid.

Additionally, to investigate fibular movements out of the axial plane of the CT or cross-sectional data, movement of the distal lateral malleolus was followed in the full 3D segmentation data. First, an iterative closest point algorithm was used to determine the transformation required to move the fibula from its intact position into a given experimental position. The original lateral malleolus point was prescribed that same transformation,
and the resulting displacements of the lateral malleolus were calculated as the difference from the location of the original lateral malleolus point.

STATISTICAL ANALYSIS

The reliability of the manual clinical measurements was assessed using interclass correlation coefficients (ICC)\(^{17,16,1}\). The interclass correlation coefficient was calculated and compared between the two different observers (inter-rater reliability) and between repeated measurements by each of the two observers (intra-rater reliability) for each of the measurements. ICC was defined as poor (<0.40), good (0.41-0.75), or excellent (>0.76)\(^{17}\). The relationship between the manual clinical measurements and the objective geometric measurements made from the 3D model was assessed using Pearson Correlation Coefficients (PCC). PCCs were calculated between each manual clinical 2D measurement and each algorithm derived objective measurement. The PCC interpreted as small (0.1-0.3), moderate (0.3-0.5), large (0.5-0.7) or very large (>0.7)\(^{18}\).

RESULTS

Interclass correlation coefficients for the manual clinical 2D measurements are reported in Table 1. Both inter-rater and intra-rater reliability was found to be good to excellent for all measurements. The measurement with the highest ICC overall was the Phisitkul AP measurement. The lowest overall ICC was found with the Tang et al. rotational measurement.

Pearson correlation coefficients between the computer algorithm-generated clinical measurements and the objective 3D-based geometric measurements are shown in Table 2. Actual mediolateral displacement of the fibula was best correlated with the difference between the anterior and posterior tibiofibular joint space measurements using Elgafy method (PCC = 0.29, small correlation). Anteroposterior displacement of the fibula was best correlated with the Phisitkul anteroposterior measurement method (PCC = 0.69, large correlation). Rotational displacement of the fibula around its own axis best correlated with the average between Elgafy anterior and Elgafy posterior measurements (PCC = 0.33, moderate correlation). Longitudinal displacement of the lateral malleolus was best correlated with the Elgafy posterior tibiofibular joint space measurement (PCC=0.49, moderate correlation).

DISCUSSION

With the increasing use of CT for syndesmosis evaluation, several attempts have been made to establish techniques for describing anteroposterior, mediolateral, and rotational changes of the syndesmosis on axial CT slices. Although there is no consensus on one set of measurements that provides a gold-standard assessment of syndesmosis congruity, it is clear that previously described methods for manually measuring the syndesmosis on axial CT slices are reproducible. This reproducibility was reported in the papers originally describing the measurement techniques by Elgafy, Tang, and...
Phisitkul, and was reproduced in this work as indicated by all measurements demonstrating good to excellent interclass correlation coefficients.

Each of the clinical measurements is based on specific anatomic landmarks which are easily discernible even in cases of a malaligned syndesmosis. However, these measurements are limited to the axial plane, and changes in the measurements represent some combination of fibular translation and rotation. Obtaining pure translational and rotational information for the fibula, which were the objective measures in this work, requires development and analysis of a 3D model. While the 3D model provides the most definitive information, it is prohibitively slow for regular implementation in clinical evaluation of CT scans. Therefore it is highly desirable to know which of the clinical measures best represents the true movement of the fibula relative to the tibia.

Unfortunately, little correlation was found between many of the clinical measurements and the objective geometric measures taken from the 3D model. Anteroposterior movement of the tibia-fibula syndesmosis relationship correlated well with several of the clinical measurement techniques, most significantly with the Phisitkul A-P measurement. However, the geometric movement of the tibia-fibula relationship in the mediolateral, the longitudinal, and the rotational planes was not found to correlate significantly with any of the clinical measurement techniques. Typically, the anterior-posterior plane is the most problematic when attempting to achieve anatomic reduction of the syndesmosis. Therefore, it is encouraging that according to our work this plane can be adequately measured using one of several clinical measurements. However, syndesmotic congruity in the mediolateral, longitudinal, and rotational planes is also important and true fibular movement in these planes is inadequately assessed using clinical measurements on 2D axial CT slices.

This study does come with limitations. The cadaveric model employed to simulate the injury may not truly replicate the clinical setting because the CT scans of the ankles were obtained with reduction forceps applying a compressive force. This resulted in none of the specimens having a large diastasis of the syndesmosis. Additionally, there was no fibular fracture simulated in

Table 1. Interclass correlation coefficients for manual clinical measurements. All measurements demonstrated good to excellent correlation in inter-rater and intra-rater testing with the exception of the Elgafy posterior (C-D) measurement.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>3D Model ML</th>
<th>3D Model AP</th>
<th>3D Model Rotation</th>
<th>3D Model Longitudinal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phisitkul ML</td>
<td>-0.026</td>
<td>0.260</td>
<td>-0.282</td>
<td>-0.135</td>
</tr>
<tr>
<td>Phisitkul AP</td>
<td>0.025</td>
<td>-0.689</td>
<td>0.275</td>
<td>-0.013</td>
</tr>
<tr>
<td>Tang Rotational</td>
<td>-0.060</td>
<td>-0.361</td>
<td>0.055</td>
<td>0.152</td>
</tr>
<tr>
<td>Elgafy Anterior</td>
<td>-0.119</td>
<td>0.591</td>
<td>-0.192</td>
<td>0.037</td>
</tr>
<tr>
<td>Elgafy Posterior</td>
<td>-0.298</td>
<td>-0.095</td>
<td>0.008</td>
<td>0.499</td>
</tr>
<tr>
<td>Elgafy (A-P)</td>
<td>-0.298</td>
<td>0.611</td>
<td>-0.046</td>
<td>0.171</td>
</tr>
<tr>
<td>Elgafy A/P Avg</td>
<td>0.281</td>
<td>0.173</td>
<td>-0.332</td>
<td>-0.229</td>
</tr>
</tbody>
</table>

Table 2. Pearson correlation coefficients calculated between described measurement techniques using bony landmarks and computer generated measurements tracking centroids of the tibia and fibula. The AP measurement was well described by the Phisitkul AP, Elgafy anterior, and the Elgafy A-P measurements (bold). The remaining translations and rotations were only moderately well described by perturbations of the Elgafy measurements (bold italics).
this mode, therefore this work presumed perfect reduction of the fibula in a clinical setting. Because of the compressive force applied in the model and the lack of fibula fracture, the translational and rotational measurements obtained by all methods were small. This could have led to range restriction when assessing correlation coefficients.

A further limitation of this work relates to application of the clinical measurements used in this work. In the clinical (rather than in the research) setting, the Elgafy and Phisitkul measurements are limited to ankles without a posterior malleolus fracture. This is because in the case of the Phisitkul measurement, reference line A is dependent on an intact fibular incisura, and the Elgafy posterior measurement (CD) depends on a non-displaced posterior incisura. Advantages of the Elgafy and Phisitkul measurements are that they may be done quickly. This is not the case for the Tang measurement of rotation as finding the center of the tibia by the method described can be quite cumbersome.

Although it would be ideal to use advanced analysis of 3D imaging techniques routinely, this is not practical in the clinical setting. Yet, based on our findings that current clinical measurements of syndesmosis congruity do not correlate strongly with mediolateral, longitudinal, and rotational movement of the fibula, we feel that improved clinical measurements are needed for useful clinical application of CT data in assessment of the syndesmosis. Future clinical measurement techniques should be validated as they arise to ensure accurate assessment of the syndesmosis. Future clinical measurement techniques should be validated as they arise to ensure accurate assessment of the syndesmosis. Future clinical measurement techniques should be validated as they arise to ensure accurate assessment of the syndesmosis. Future clinical measurement techniques should be validated as they arise to ensure accurate assessment of the syndesmosis. Future clinical measurement techniques should be validated as they arise to ensure accurate assessment of the syndesmosis.
TRIPOD INDEX: DIAGNOSTIC ACCURACY IN SYMPTOMATIC FLATFOOT AND CAVOVARUS FOOT: PART 2

Marut Arunakul, MD1,2, Annunziato Amendola, MD1, Yubo Gao, PhD1, Jessica E. Goetz, PhD1, John E. Femino, MD1, Phinit Phisitkul, MD1

ABSTRACT
Background: The Tripod Index (TI) has been created to allow assessment of complex foot deformities. It utilizes tripod relationship between center of the heel, medial/lateral borders of the forefoot, and compare it to the center of the talar head. This study aimed to verify diagnostic accuracy of the TI in symptomatic flatfoot and cavovarus foot.

Methods: Weightbearing radiographs including foot AP with a hemispherical marker around the heel, lateral, and hindfoot alignment views were obtained on 91 patients (110 feet) presenting with medial foot and ankle pain and on 89 patients (90 feet) presenting with lateral foot and ankle pain between June 2010 and May 2011. Radiographs were evaluated blindly for the TI, AP talonavicular coverage angle, lateral talo-first metatarsal angle, calcaneal pitch angle, medial cuneiform-fifth metatarsal height, and coronal plane hindfoot alignment. The sensitivity, specificity, likelihood ratios, and predictive values were calculated. Clinically diagnosed flatfoot and cavovarus foot deformity indicated for surgical reconstruction by one of our foot and ankle orthopaedic surgeons was used as the accepted standard for diagnosis.

Results: In flatfoot, sensitivity of the TI was 100%, comparable with lateral talo-first metatarsal angle (100%), and medial cuneiform-fifth metatarsal height (100%). Specificity of the TI was 93%, comparable with coronal plane hindfoot alignment (98%), but superior to other parameters. Positive likelihood ratio of the TI was 14.29, which was more than other parameters. In cavovarus foot, sensitivity of the TI was 96%, comparable with coronal plane hindfoot alignment (100%), but superior to other parameters. Specificity of the TI was 95%, comparable with lateral talo-first metatarsal angle (94%), but superior to other parameters. Positive likelihood ratio of the TI was 19.2, which was more than other parameters.

Conclusion: The Tripod Index showed high accuracy as a quantitative assessment in diagnosis of a symptomatic flatfoot and cavovarus foot.

Keywords: Tripod Index; Diagnostic test; Flatfoot; Cavovarus foot

INTRODUCTION
Flatfoot and cavovarus foot are complex foot deformities commonly seen in clinical practice. The flatfoot deformity is characterized by a combination of collapse of the medial longitudinal arch, foot abduction at the talonavicular joint, and hindfoot valgus (subtalar joint eversion)1-7. Patients with this deformity typically present with a gradual onset of medial foot and ankle pain8. In very late stage of the disease, lateral pain may occur from subfibular impingement. Cavovarus foot is characterized by hindfoot varus (subtalar joint inversion), midfoot cavus, plantarflexion of the first metatarsal, and forefoot adduction9-11. Patients with this deformity typically present with lateral foot and ankle pain, painful callosities, difficulty with shoe wear, and ankle instability9,12.

Currently, several radiographic measurements are used to assess these deformities, but none of these radiographic parameters are able to integrate deformities at multiple planes and levels of the foot into a simple measurement11. The Tripod Index (TI) has been created to allow quantitative assessment of complex foot deformities utilizing the tripod relationship between center of the heel, medial/lateral borders of the forefoot, and compare it to the center of the talar head on a standing anteroposterior radiograph. The TI has been previously developed in a study of normal feet, and it was found to be a very reliable and reproducible measure of overall foot alignment. The relationship between the foot tripod11,13 and the center of the talar head14 could theoretically demonstrate the effect of overall foot alignment on the subtalar joint. As the foot tripod is determined from landmarks on both the hindfoot and the forefoot, this measurement has the potential to appreciate the summation of deformity including hindfoot, midfoot, and forefoot in multiple planes.

The objective of this study was to verify diagnostic accuracy of the Tripod Index in symptomatic flatfoot and cavovarus foot in cohorts of patients presenting with medial or lateral
foot and ankle pain. We hypothesized that the Tripod Index has high accuracy in the diagnosis of symptomatic flatfoot and cavovarus foot.

**MATERIAL AND METHODS**

The study was approved by our hospital’s Institutional Review Board. Standard weightbearing radiographs including an AP foot view with a hemispherical marker around the heel, a lateral view, and a hindfoot alignment view were performed on two groups of patients presenting to the foot and ankle clinic over a period of 12 months (June 2010 to May 2011). The first group consisted of 110 feet in 91 consecutive patients (average age, 41.8 ± 15.1 years; range, 14 to 84; 58 females and 33 males) who presented with medial foot and ankle pain (Table 1). The second group consisted of 90 feet in 89 consecutive patients (average age, 37 ± 15.1 years; range, 14 to 70; 61 females and 28 males) who presented with lateral foot and ankle pain (Table 2).

All patients were identified and recruited from three senior fellowship-trained orthopaedic surgeons’ database (PP, JEF, and AA). Demographic data was collected from patients’ charts. With the exception of patients treated non-operatively for plantar fasciitis, all the patients either had undergone a reconstructive surgery or had been consented for it due to failure of nonoperative treatment. Patients who had a previous ipsilateral foot surgery were excluded.

**Radiographic studies**

AP and lateral weightbearing radiographs were obtained in a standardized manner. For AP images, patients were asked to stand with equal weight on both feet. Properly sized hemispherical markers, made from a metal plate padded with half-inch polyethylene foam, were put snugly on the back of both heels. The radiographic beam was positioned 40 inches

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**Table 1: Demographic data of patients with medial foot and ankle pain**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number (feet)</th>
<th>Age (year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic flatfoot</td>
<td>20</td>
<td>39 ± 19</td>
</tr>
<tr>
<td>Tarsal tunnel syndrome</td>
<td>9</td>
<td>39 ± 15</td>
</tr>
<tr>
<td>FHL tenosynovitis</td>
<td>6</td>
<td>33 ± 11</td>
</tr>
<tr>
<td>Anteromedial ankle impingement</td>
<td>15</td>
<td>32 ± 17</td>
</tr>
<tr>
<td>Plantar fasciitis</td>
<td>60</td>
<td>46 ± 14</td>
</tr>
</tbody>
</table>

Age reported as mean ± standard deviation.

**Table 2: Demographic data of patients with lateral foot and ankle pain**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number (feet)</th>
<th>Age (year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic cavovarus foot</td>
<td>26</td>
<td>47 ± 16</td>
</tr>
<tr>
<td>Peroneal tendon pathology</td>
<td>11</td>
<td>42 ± 16</td>
</tr>
<tr>
<td>Anterolateral ankle instability</td>
<td>16</td>
<td>30 ± 13</td>
</tr>
<tr>
<td>Superficial peroneal nerve entrapment</td>
<td>6</td>
<td>45 ± 8</td>
</tr>
<tr>
<td>Subtalar Impingement</td>
<td>17</td>
<td>40 ± 15</td>
</tr>
<tr>
<td>Anterolateral ankle impingement</td>
<td>14</td>
<td>32 ± 15</td>
</tr>
</tbody>
</table>

Age reported as mean ± standard deviation.
from the digital cassette and angled 15 degrees posteriorly toward the heels. Laser guides were used to align the center of the heel and second toe along the vertical axis of the cassette. For hindfoot alignment weightbearing, subjects stood on a radiolucent platform with equal weight on both feet. The platform consisted of a 0.5 inch x 20 inch x 18 inch sheet of Plexiglas mounted on a 6-inch high metal frame. The frame included a slot for holding the x-ray cassette at a 20 degree angle from vertical. A 3 mm x 2 mm x 6 cm lead strip was placed tangentially to the most posterior aspect of the heel and was oriented perpendicular to the longitudinal axis of the foot. The x-ray tube was oriented 20 degrees from horizontal, so that it was perpendicular to the plane of the film. The beam was centered at the level of the ankle, and the field of exposure was from midshaft of tibia to below the calcaneus. The source-to-film distance was 40 inches.

The AP radiographs were examined for the Tripod Index (Figure 1) and the AP talonavicular coverage angle. The lateral radiographs were examined for the lateral talo-first metatarsal angle, the calcaneal pitch, and the medial cuneiform-fifth metatarsal height. The lateral talo-first metatarsal angle; the longitudinal axis of the talus (line B1-B2) is established by placing a mark at the halfway point between the superior and inferior surfaces of the talus at the middle of the talus and the neck of the talus, and connecting these two points. A similar method is used to determine the lateral longitudinal axis of the first metatarsal (line C1-C2), with mid-diaphyseal reference points used to form this axis. The angle formed by these two lines is the lateral talo-first metatarsal angle (angle A). This angle is considered negative when there is a cavus relationship between the axis of the talus and the first metatarsal. The calcaneal pitch; it is defined as the angle (angle D) formed by the intersection of a line drawn tangentially along the inferior aspect of the calcaneus (line E1-E2) and a line drawn along the plantar aspect of the soft tissue shadow of the hindfoot when weightbearing (line F). The medial cuneiform-fifth metatarsal height; the most inferior surface of the distal aspect of the medial cuneiform is marked, and a line (line H) is extended from this point parallel to the floor. A similar line is marked (line I) on the most inferior portion of the base of the 5th metatarsal. The perpendicular distance between these two lines is measured with an electronic caliper, and is designated the medial cuneiform-fifth metatarsal height (line J).
Table 3: Radiographic parameter values for all subjects presented with medial foot and ankle pain categorized by diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Tripod Index (%)</th>
<th>Coronal plane hindfoot alignment (mm)</th>
<th>AP talonavicular coverage angle (degree)</th>
<th>Lateral talo-first MT angle (degree)</th>
<th>Calcaneal pitch angle (degree)</th>
<th>Medial cuneiform-fifth MT height (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic flatfoot</td>
<td>64 ± 17</td>
<td>13 ± 6</td>
<td>26 ± 8</td>
<td>19 ± 9</td>
<td>15 ± 3</td>
<td>1 ± 4</td>
</tr>
<tr>
<td>Tarsal tunnel syndrome</td>
<td>-7 ± 40</td>
<td>-2 ± 5</td>
<td>12 ± 11</td>
<td>3 ± 5</td>
<td>20 ± 5</td>
<td>8 ± 4</td>
</tr>
<tr>
<td>FHL tenosynovitis</td>
<td>0 ± 31</td>
<td>-3 ± 6</td>
<td>12 ± 4</td>
<td>3 ± 3</td>
<td>21 ± 2</td>
<td>9 ± 5</td>
</tr>
<tr>
<td>Anteromedial ankle impingement</td>
<td>-17 ± 31</td>
<td>-3 ± 6</td>
<td>12 ± 6</td>
<td>2 ± 5</td>
<td>22 ± 5</td>
<td>10 ± 3</td>
</tr>
<tr>
<td>Plantar fasciitis</td>
<td>-7 ± 29</td>
<td>-3 ± 5</td>
<td>13 ± 7</td>
<td>1 ± 6</td>
<td>21 ± 5</td>
<td>10 ± 4</td>
</tr>
</tbody>
</table>

Data reported as mean ± standard deviation.

Table 4: Radiographic parameter values for all subjects presented with lateral foot and ankle pain categorized by diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Tripod Index (%)</th>
<th>Coronal plane hindfoot alignment (mm)</th>
<th>AP talonavicular coverage angle (degree)</th>
<th>Lateral talo-first MT angle (degree)</th>
<th>Calcaneal pitch angle (degree)</th>
<th>Medial cuneiform-fifth MT height (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic cavovarus foot</td>
<td>-116 ± 54</td>
<td>-15 ± 4</td>
<td>-11 ± 14</td>
<td>-10 ± 5</td>
<td>27 ± 5</td>
<td>19 ± 7</td>
</tr>
<tr>
<td>Peroneal tendon pathology</td>
<td>4 ± 28</td>
<td>-2 ± 7</td>
<td>14 ± 7</td>
<td>8 ± 6</td>
<td>19 ± 3</td>
<td>8 ± 7</td>
</tr>
<tr>
<td>Anterolateral ankle instability</td>
<td>0 ± 36</td>
<td>-3 ± 7</td>
<td>9 ± 9</td>
<td>6 ± 9</td>
<td>23 ± 5</td>
<td>10 ± 6</td>
</tr>
<tr>
<td>Superficial peroneal nerve entrapment</td>
<td>20 ± 30</td>
<td>-1 ± 5</td>
<td>16 ± 7</td>
<td>12 ± 11</td>
<td>20 ± 4</td>
<td>8 ± 6</td>
</tr>
<tr>
<td>Subtalar Impingement</td>
<td>12 ± 36</td>
<td>-1 ± 6</td>
<td>14 ± 8</td>
<td>6 ± 7</td>
<td>21 ± 5</td>
<td>10 ± 3</td>
</tr>
<tr>
<td>Anterolateral ankle impingement</td>
<td>10 ± 49</td>
<td>0 ± 7</td>
<td>16 ± 12</td>
<td>8 ± 10</td>
<td>22 ± 5</td>
<td>8 ± 6</td>
</tr>
</tbody>
</table>

Data reported as mean ± standard deviation.

for the coronal plane hindfoot alignment\(^{(2)}\) (apparent moment arm) as shown in Figure 4. All radiographic measurements were performed using iSite Enterprise 3.5 image analysis software (Philips Medical Systems Nederland B.V., The Netherlands). The measurements for this study were made by an independent foot and ankle orthopaedic fellow (MA).

**Statistical analysis**

The sensitivity, specificity, likelihood ratios, and predictive values were calculated by using cut-off point for diagnosing symptomatic flatfoot and cavovarus foot from Tripod Index part 1 data. Clinically diagnosed flatfoot and cavovarus foot deformity indicated for surgical reconstruction by one of the senior foot and ankle orthopaedic surgeons was used as the accepted standard for diagnosis. Analysis of the radiographic parameter values was descriptive, using mean values and standard deviations.

**RESULTS**

Radiographic parameters for all subjects categorized by diagnosis are shown in Table 3 and 4.

In flatfoot, the sensitivity of the Tripod Index was 100%, comparable with the coronal plane hindfoot alignment (95%), the AP talonavicular coverage angle (95%), the lateral talo-first metatarsal angle (100%), and the medial cuneiform-fifth metatarsal height (100%). The specificity of the Tripod Index was 93%, comparable with the coronal plane hindfoot alignment (98%) and the lateral talo-first metatarsal angle (87%), but superior to the AP talonavicular coverage angle (64%), the calcaneal pitch angle (61%), and the medial cuneiform-fifth metatarsal height (82%). The positive likelihood ratio of the Tripod Index was 14.29, which was less than the coronal plane hindfoot alignment (47.5), but more than the AP talonavicular coverage angle (2.64), the lateral talo-first metatarsal angle (7.69), the calcaneal pitch angle (2.31), and the medial cuneiform-fifth metatarsal height (5.56). The negative likelihood ratio of the Tripod Index was 0. The positive and negative predictive values of the Tripod Index were 77% and 100%, respectively (Table 5).

In cavovarus foot, the sensitivity of the Tripod Index was 96%, comparable with the coronal plane hindfoot alignment (100%), but superior to the AP talonavicular coverage angle (88%), the lateral talo-first metatarsal angle (88%), the calcaneal pitch angle (65%), and the medial cuneiform-fifth metatarsal height (88%). The specificity of the Tripod Index was 95%, comparable with the lateral talo-first metatarsal angle (94%), but superior to the coronal plane hindfoot alignment (88%), the AP talonavicular coverage angle (91%), the calcaneal pitch angle (83%), and the medial cuneiform-fifth metatarsal height (78%). The positive likelihood ratio of the Tripod Index was 19.2, which was more than the other parameters. The negative likelihood ratio of the Tripod Index was 0.04. The positive and negative predictive values of the Tripod Index were 89% and 98%, respectively (Table 6).
Pertaining to the Tripod index, the false positive results consisted of five patients with plantar fasciitis and one patient with FHL tenosynovitis in the medial foot and ankle pain group. There was no false negative diagnosis. In the lateral foot and ankle pain group, the false positive results included one patient with anterolateral ankle impingement, one patient with subtalar impingement, and one patient with anterolateral ankle instability. The false negative result was from 1 patient indicated for cavovarus reconstruction but with the Tripod index of -38.89 %.

**DISCUSSION**

The results from this study support the hypothesis that the Tripod Index on the AP radiograph has high accuracy in the diagnosis of symptomatic flatfoot and cavovarus foot. We have confirmed that the use of 26% or more and -39% or less were the most appropriate thresholds to diagnose symptomatic flatfoot and cavovarus foot, respectively, using the Tripod Index. The Tripod Index had a high sensitivity (100% for flatfoot and 96% for cavovarus foot) and a high specificity (93% for flatfoot and 95% for cavovarus foot). The high sensitivity and specificity of the Tripod Index go along with the high positive likelihood ratio (14.29 for flatfoot and 19.2 for cavovarus foot), which indicates a high probability that patients who have a positive Tripod Index will be diagnosed as having symptomatic flatfoot or cavovarus foot. The negative likelihood ratio (0 for flatfoot and 0.04 for cavovarus foot) indicates a high probability that patients who have a negative Tripod Index will not be diagnosed as having symptomatic flatfoot or cavovarus foot. Although the Tripod Index showed high accuracy in the diagnosis of symptomatic flatfoot and cavovarus foot, there were some misdiagnoses in both groups. Most of the false positive patients in the flatfoot group were clinically diagnosed as having plantar fasciitis. Although, these patients did not present with posterior tibial tendinitis, the plantar fasciitis might represent another manifestation of flatfoot deformity. Huang et al. also reported higher incidences of plantar fasciitis in the flatfoot group than the normal arch control group. Due to the nature of retrospective studies it was impossible to delineate the co-existence of these conditions in our patient cohort.

The coronal plane hindfoot alignment was developed to characterize the mechanical alignment of the hindfoot. This method yields a value representing the apparent moment arm between the presumed weightbearing axis of the leg and point of heel-floor contact. This measurement also had a high sensitivity (95% for flatfoot and 100% for cavovarus foot) and a high specificity (98% for flatfoot and 88% for cavovarus
The high sensitivity and specificity of the coronal plane hindfoot alignment go along with the high positive likelihood ratio (47.5 for flatfoot and 8 for cavovarus foot), which indicates a high probability that patients who have a positive coronal plane hindfoot alignment will be diagnosed as having symptomatic flatfoot and a moderate shift in probability that patients who have a positive coronal plane hindfoot alignment will be diagnosed as having symptomatic cavovarus foot. The negative likelihood ratio (0.05 for flatfoot and 0 for cavovarus foot) indicates a high probability that patients who have a negative coronal plane hindfoot alignment will not be diagnosed with symptomatic flatfoot or cavovarus foot. This study has shown that both the Tripod Index and the coronal plane hindfoot alignment are the two most discriminating radiographic parameters in patients with symptomatic flatfoot and cavovarus foot. The hindfoot alignment view, however, requires an extra radiographic image taken with the patient on a specifically constructed platform while the Tripod index requires only radiographic markers on a standard AP view.

The lateral talo-first metatarsal angle was shown to be a reliable measure for determination of arch height and was suggested as the preferable measurement for the diagnosis and evaluation of operative outcomes of flatfoot according to Younger et al. and others. We found that the sensitivity, the specificity, and the negative likelihood ratio were comparable to the Tripod Index and the coronal plane hindfoot alignment but the positive likelihood ratio for diagnosis of symptomatic flatfoot was inferior to both measurements. In addition, we have found that the lateral talo-first metatarsal angle had the worst interobserver reliability compared to all other measurements in our part 1 study. This was likely due to the difficulties in finding the common osseous landmarks on lateral radiographs. However, we consider the lateral talo-first metatarsal angle an excellent radiographic parameter for diagnosing symptomatic flatfoot than can be used as an adjunct to the hindfoot alignment and the Tripod Index.

Previous studies have supported the use of linear measurement to define arch height using the medial cuneiform-fifth metatarsal height. Since Coughlin et al. found that the lowest medial cuneiform-fifth metatarsal height in their control group was 3 mm, and over 66% of their flatfoot group had a larger value, this measurement was found to be unreliable. We also found that the sensitivity, the specificity, and the positive and negative likelihood ratio of this measurement were inferior to the Tripod Index, the coronal plane hindfoot alignment, and the lateral talo-first metatarsal angle but were still high enough to evaluate flatfoot and cavovarus foot deformity. In addition, this measurement had statistically significant correlation with other accepted radiographic parameters and differences between flatfoot, cavovarus foot, and control group in our part 1 study. So, we consider the medial cuneiform-fifth metatarsal height a good radiographic parameter for evaluating symptomatic flatfoot and cavovarus foot as well.

Due to the influence of the spectrum of disease to the accuracy of diagnosis, the use of a healthy “normal” control group often overestimates the ability of most diagnostic tests. This was confirmed in our part 1 study that all six radiographic parameters, including the Tripod Index, the AP talonavicular coverage angle, the lateral talo-first metatarsal angle, the calcaneal pitch angle, the medial cuneiform-fifth metatarsal height, and the coronal plane hindfoot alignment, had very high sensitivity and specificity for diagnosing symptomatic flatfoot and cavovarus foot. In addition, Younger also reported the statistically significant differences between patients with flatfoot and a control group from the lateral talo-first metatarsal angle, the calcaneal pitch angle, and the medial cuneiform-fifth metatarsal height. These radiographic parameters were found to be highly sensitive despite a significance level of $p < 0.001$. To determine the true clinical utility of radiographic measurements, a study of diagnostic test must include a spectrum of cases that closely resembles clinical practice. As a result, we included patients that presented with medial foot and ankle pain for flatfoot group and patients presented with lateral foot and ankle pain for cavovarus group.

The limitations to this study include selection bias and the lack of gold standard for diagnosis of symptomatic flatfoot and cavovarus foot. These limitations result from the fact that there is no widely accepted definition of what constitutes a flatfoot or a cavovarus foot in an adult. However, all patients with symptomatic flatfoot deformity and cavovarus foot deformity requiring surgical correction due to failure of nonoperative treatment were included and used as the accepted standard for diagnosis. The clinical assessment of a flatfoot and a cavovarus foot was subjective, but this is a common method used by experienced foot and ankle orthopaedic surgeons in everyday practice. We also did not aim to replace clinical diagnosis of foot deformities with a single measurement, but rather hoped to create a more integrated measurement as an adjunctive tool.

Future studies may be required to evaluate the relationship between Tripod Index, plantar pressure and gait analysis, functional outcome, and the effect of foot reconstructive surgery on patients with flatfoot or cavovarus foot. The success of realignment of a planus or cavus foot, which usually includes multiple joints or planes, may be better represented with measurement of the TI versus a single measurement. Additional studies using Tripod index on other foot and ankle deformities e.g. metatarsus adductus, residual clubfoot, charcot arthropathies, and partially amputated foot may be useful.

CONCLUSION

There are several useful radiographic measures of alignment that are currently widely used in reconstructive foot and ankle surgery. The Tripod Index consists of a quantitative assessment of foot alignment that may be a more global measure. It can be made from a standard weightbearing
radiograph with a heel marker. Based on the high accuracy of the Tripod Index in the diagnosis of symptomatic flatfoot and cavovarus foot in this study, further studies to determine the usefulness of this novel measurement are warranted.

REFERENCES
SEVERE DEGENERATION OF THE MEDIAL COLLATERAL LIGAMENT IN HALLUX VALGUS: A HISTOPATHOLOGIC STUDY IN 12 CONSECUTIVE PATIENTS

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ABSTRACT

Objective: To determine the degree and location of degenerative changes of the medial collateral ligament of the first metatarsophalangeal joint, using the lateral collateral ligament as a control, in patients undergoing hallux valgus correction.

Materials and Methods: A strip of medial and lateral collateral ligaments were biopsied from 12 consecutive patients (age 45 ± 4.8 years) with symptomatic hallux valgus. A blinded analysis of histopathology was performed by an experienced pathologist.

Results: The medial collateral ligament was significantly more degenerated compared to the lateral collateral ligament ($x^2 = 23.41$, DF = 2, $p < 0.0001$). There was no significant difference in degeneration between different parts of each ligament.

Conclusion: Our study found generalized severe degeneration in the medial collateral ligament without proximal-distal predilection. This information may have implications in the management of medial soft tissue repair in hallux valgus correction.

Keywords: Hallux Valgus; collateral ligament; degeneration

The Authors received no financial support for this study.

INTRODUCTION

Hallux valgus was proposed by Carl Heuter in 1871 as a foot disorder characterized by lateral deviation of the first metatarsophalangeal joint and metatarsus primus varus (medial deviation of the first metatarsal), dislocation of the metatarsal head from the hallux sesamoids, and pronation of the first metatarsal and hallux. Hallux valgus is commonly thought to develop because of improper shoe wear; however, this does not explain all cases as some patients developed disease without ever wearing shoes. It was reported that the prevalence of hallux valgus in the adult shoe wearing population was approximately 33%. Additional risk factors such as female gender and familial genetics have also been associated with the development of hallux valgus.

At the present time, the patho-mechanical etiology leading to the development of a hallux valgus deformity remains unclear and may be multifactorial. One of the most notable causes may be due to failure of the soft tissue structure at the great toe metatarsophalangeal joint, as the hallux valgus deformity increases after a surgical release of the medial collateral ligament or after acute ligament rupture. There has been no uniform technique for the repair or reconstruction of the medial collateral ligament in hallux valgus correction. The degree of medial collateral ligament degeneration and the exact location of it may affect the surgical strategy of the medial soft tissue repair. A cadaveric study has shown both mechanical and histological deterioration of the medial capsule in specimens with hallux valgus.

Another in vivo study demonstrated the presence of extensive chronic inflammation at the medial aspect of the first metatarsal head in patients who underwent hallux valgus correction.

At present, in patients with hallux valgus, the precise anatomic location of medial collateral ligament degeneration is unknown; this site may be at the proximal insertion, mid-substance, or distal insertion. Thus we proposed a histopathological study of the medial collateral degeneration in patients who underwent hallux valgus correction using the lateral collateral ligament as a control. We hypothesized that the medial collateral ligament would be more severely degenerated than the lateral collateral ligament. In addition, the severity of degeneration was cataloged for different proximal-distal aspects of the ligaments. We hypothesized that the proximal aspect of the medial collateral ligament would be more degenerated than other areas.
Severe Degeneration of the Medial Collateral Ligament in Hallux Valgus

MATERIALS AND METHODS

Between July 2007 and May 2008, 12 women, mean age 45 ± 4.8 years, were recruited for this observational study. The study was approved by the institutional review board. All patients with symptomatic hallux valgus disease 18 years of age or older who received corrective surgery by the same surgeon (PP) at the Orthopaedic Department, Phramongkutklao Hospital and College of Medicine were included. All patients had intractable pain and failed conservative treatment for at least 6 months. Patients who had an associated underlying inflammatory disease, a history of trauma, or previous surgery were excluded from this study. All patients underwent corrective surgery using a modified Mau osteotomy technique and a lateral soft tissue release, unilaterally in 8 patients and bilaterally in 4 patients. Medial and lateral collateral ligaments were biopsied in 3mm-wide strips from the entire length of the ligament in the operating room and placed in 10% formalin solution immediately. Each capsule was divided into proximal, middle, and distal parts and randomly labeled from 1 to 3 by an orthopaedic fellow (IP) not involved in the histological evaluation. Hematoxylin and eosin stain and a light microscope was used to identify and grade the histopathology of each specimen by an experienced pathologist (TP) who was blinded to the location from which each specimen was obtained. Histopathological findings were classified into mild, moderate, and severe degeneration.

Mild degeneration was defined as increased vascularity, linear fibroblast formation, fibrosis, and collagenization. Moderate degeneration was defined as myxoid degeneration and severe degeneration was defined as chondroid metaplasia and calcium phosphate crystal deposition. Chi-square tests were used to test differences between medial and lateral collateral ligament degeneration.

RESULTS

All 12 patients had degeneration in both collateral ligaments according to our defined criteria. However, the degree of degeneration was more severe in the medial collateral ligament compared to the lateral side, as shown in Table 1 and Figure 1. There was a significant difference between medial and lateral collateral ligament degeneration (Chi-square = 23.41, DF = 2, p < 0.0001). There was no significant difference in degeneration in specimens among proximal, middle, and distal parts of medial and lateral collateral ligament (Chi-square = 1.84, Table 1: Cumulative data of the entire medial and lateral collateral ligaments

<table>
<thead>
<tr>
<th>Location</th>
<th>Degree of degeneration</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Medial</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Lateral</td>
<td>22</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 1: Cumulative data of the entire medial and lateral collateral ligaments

Figure 1. Numbers of specimens with degenerative change from medial and lateral collateral ligaments of the hallux.

Table 2: Degeneration in each part of medial and lateral collateral ligaments

<table>
<thead>
<tr>
<th>Location (part)</th>
<th>Degree of degeneration</th>
<th>Location (side)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>2 (12.5%)</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td></td>
<td>2 (12.5%)</td>
<td>8 (50.0%)</td>
</tr>
<tr>
<td></td>
<td>12 (75.0%)</td>
<td>3 (18.7%)</td>
</tr>
<tr>
<td>Middle</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>1 (6.3%)</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td></td>
<td>4 (25.0%)</td>
<td>3 (18.7%)</td>
</tr>
<tr>
<td></td>
<td>11 (68.7%)</td>
<td>3 (18.7%)</td>
</tr>
<tr>
<td>Distal</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>3 (18.7%)</td>
<td>9 (56.3%)</td>
</tr>
<tr>
<td></td>
<td>3 (18.7%)</td>
<td>3 (18.7%)</td>
</tr>
<tr>
<td></td>
<td>10 (62.5%)</td>
<td>4 (25.0%)</td>
</tr>
</tbody>
</table>

Figure 2. Numbers of specimens with degenerative change from medial and lateral collateral ligaments of the hallux divided into specific parts.

Table 2: Degeneration in each part of medial and lateral collateral ligaments
DF = 4, \( p = 0.76 \) and Chi-square = 3.75, DF = 4, \( p = 0.439 \) respectively) (Table 2 and Figure 2).

### DISCUSSION

Degenerative changes are common in medial collateral ligaments of patients who undergo hallux valgus reconstruction. The incidence of severe degeneration was more than three times as common when compared to the lateral collateral ligament in the same patients. This is in agreement with a study by Uchiyama et al. who found more type III collagen within the medial collateral ligament obtained from cadavers with hallux valgus compared to normal specimens. The degenerative change of the medial collateral ligament of the first metatarsophalangeal joint may be related to the pathomechanics of hallux valgus among other factors including osseous deformity of the first metatarsal head, instability of the first tarsometatarsal joint, genetic factors, and shoe wear. Hideji et al. found that medial soft tissues, especially the medial capsul, are crucial for maintaining stability of the first metatarsophalangeal joint from hallux valgus deformity.

In contrast to our hypothesis that the pathology of the medial collateral ligament should be more severe at the insertion on the medial aspect of the first metatarsal head, we found no difference in the degree of ligament degeneration among proximal insertion, mid-substance, or distal insertion. This information has not been described before. Wen et al. found significant degenerative change at the proximal insertion in biopsy specimens obtained from 123 patients but there was no information regarding other portions of the ligaments and there was no control group. There is no consensus in the method of medial capsulorrhaphy, which can be designed as a longitudinal cut, vertical cut at the mid-substance, Y or T, or L cut. We believed that the predilection of degeneration in certain portions of the ligament may allow for refinement in the medial soft tissue technique as the degenerated portion could be excised prior to a repair. Unfortunately, this suggestion cannot be made due to the diffuse nature of the degeneration. This is in contrast to the traumatic hallux valgus for which repair should be made at the site of injury. Douglas et al. repaired patients with traumatic collateral ligament injury through its mid-substance using end-to-end technique with two D-Ethibond sutures.

The presence of severe degeneration of the medial collateral ligament may raise some concerns regarding the feasibility of the repair. Lui et al. described a technique using the extensor hallucis brevis tendon to reconstruct the medial collateral ligament in a patient after a failed hallux valgus correction with medial capsular plication. The overall high success in the hallux valgus correction with wide varieties of soft tissue repair indicates that local tissue is adequate in the majority of cases despite the presence of degenerative changes. We believe that due to the complete correction of the hallux valgus deformity as well as the sesamoid subluxation, the medial collateral ligament may see less aberrant tension force. In addition, appropriate level of tensioning of the medial collateral ligament may promote remodeling of the degenerated collagen tissue and also provide an optimal level of corrective force against the valgus deformity. Our data suggests that repair of the medial collateral ligament should only occur as an adjunctive procedure to osseous realignment.

This study has some limitations due to small numbers of subjects and the fact that they are all female, which may limit the generalizability of the results. We also did not have normal tissue of medial collateral ligament and lateral collateral ligament in a healthy, age-matched control group to compare against. The degree of degeneration in the lateral collateral ligament in our study may be influenced by the abnormal mechanics and degenerative change that occurred due to the hallux valgus deformity causing the comparison to be less sensitive. However, a very strong statistical significance level \( p < 0.0001 \) supports our main finding regarding the degree of medial collateral ligament degeneration.

### CONCLUSION

There was generalized severe degeneration in the medial collateral ligament of the patients who underwent hallux valgus correction. There was no proximal-distal predilection of the degeneration within the ligament. Our data suggests that the surgeon should rely on the repair of the medial collateral ligament only as an adjunctive procedure to osseous realignment.

### ACKNOWLEDGEMENT

We acknowledge and extend our heartfelt gratitude to the following persons who have made the completion of this research possible:

- MVK scholarship, Phramongkutklao Hospital and College of Medicine; and Yubo Gao, PhD, for statistical support.

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2. **Sander AP, Snijders CJ, Bert VL.** Medial deviation of the first metatarsal head as a result of flexion forces in hallux valgus. Foot Ankle Int. 1992;13:515-22
ABSTRACT

Introduction: Medial Patellofemoral Ligament (MPFL) reconstruction is an accepted treatment for recurrent patellofemoral instability when patients have normal alignment and deficient proximal medial restraints. There are several reports of malpositioned femoral tunnels leading to poor outcomes. The purpose of this study was to analyze femoral tunnel placement after MPFL reconstruction and correlate this with outcomes.

Methods: We performed a retrospective review of MPFL reconstructions done at our institution from 2006-2010. We then evaluated lateral radiographs and measured the distance between the radiographic femoral MPFL isometric point and the center of the femoral tunnel. We also evaluated post-operative KOOS scores.

Results: The average distance from the femoral tunnel to the MPFL isometric point was 13.25 mm. Sixty-four percent of tunnels were placed greater than nine millimeters from our isometric point and deemed to be malpositioned. There was no statistically significant difference in outcomes scores in patients with anatomically placed MPFL tunnels when compared to those placed non-anatomically.

Conclusion: Sixty-four percent of MPFL reconstruction femoral tunnels were placed non-anatomically, but this did not correlate with a worse outcome. Graft tension, trochlear groove anatomy, patellar height, and dynamic restraints all play important roles in outcomes after MPFL reconstruction. Even though non-anatomic tunnel placement does not guarantee a poor result, we believe an anatomic tunnel placement will give the best chance to maximize graft function and outcome.

INTRODUCTION

Patellofemoral joint stability is achieved by the coordinated interaction of static, dynamic, and osseous constraints. The medial patellofemoral ligament (MPFL) has been found to be the primary soft tissue restraint to lateral patella translation and guides the patella into the groove during the first 30 degrees of knee flexion. First-time patellar dislocations can be a harbinger of future instability. Recurrent instability has been reported to occur in 15-44% of patients following the initial event, and up to 49% recurrence rate has been reported in patients with at least two prior instability events. A deficient MPFL has been described as a necessary lesion in the setting of recurrent lateral dislocations of the patella. MPFL reconstruction has become an accepted method of treating recurrent patellofemoral instability in the setting of normal alignment and deficient proximal medial restraints.

Poor outcomes after MPFL reconstruction depend on many factors including graft tension, location of patella and femoral graft fixation, underlying trochlear dysplasia, unrecognized malalignment, patella alta, hyperlaxity and associated cartilage lesions. Bollier et al. reported on five cases of medial patella overload, iatrogenic medial instability, and medial arthrosis after MPFL reconstruction in which the femoral tunnel was malpositioned (Figure 1). Elias and Cosgrea showed that short grafts and proximal malposition led to compressive forces at the medial cartilage that were twice that of normal at low flexion angles and increased the peak medial pressure by more than 50% at low flexion angles.

As the importance of femoral tunnel position has been recognized, several authors have focused on defining anatomic and radiographic MPFL femoral insertion. In a cadaveric study, the medial patellofemoral ligament (MPFL) was found to insert 1.9 mm anterior and 3.8 mm distal to the adductor tubercle (Figures 2 and 3). Schottle et al. described the MPFL anatomic insertion on the femur as the isometric point for MPFL tunnel placement in reconstruction cases. In their study, they defined a radiographic point one millimeter anterior to a line extending from the posterior cortex and 2.5 mm distal to the posterior origin of the medial femoral condyle, and proximal to the level of the posterior point of the Blumensaat line. Stephen et al., in a cadaveric study, investigated nonanatomic femoral attachment.
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Points. Proximal femoral attachment resulted in a 6.4 mm lengthening of the graft through a 0-110 degree flexion arc. Distal femoral attachments led to up to 9.1 mm of shortening through this same flexion arc16. Despite a focus on defining MPFL anatomy and function, there have been very few clinical studies looking at the femoral insertion of the MPFL graft. The purpose of this study was to analyze femoral tunnel placement after MPFL reconstruction and correlate with clinical outcomes scores.

METHODS

A retrospective review of MPFL reconstructions was performed at our institution from 2006-2010. Inclusion criteria were reconstructions that utilized a femoral tunnel, postoperative lateral knee radiographs, and recorded preoperative and postoperative KOOS scores. Patients
with an associated tibial tubercle transfer were also included. Fifteen isolated MPFL and 35 combined MPFL and tibial tubercle transfers for a total of 50 patients meeting inclusion criteria were identified (Table 1).

MPFL femoral tunnel location was evaluated on lateral radiographs using a variation of Schottle’s technique. First, we drew a vertical line extending from the inferior aspect of the posterior femoral cortex. A line perpendicular to this vertical line was drawn, extending posterior to anterior, from the intersection point of the posterior femoral cortex and metaphyseal flare. A second horizontal line was drawn, posterior to anterior, from the posterior most aspect of Blumensaat line. Finally, we defined our femoral isometric point by utilizing a point along the vertical line at the mid-point between the two horizontal lines. We measured the distance from the center of the MPFL femoral tunnel to the defined isometric point (Figure 4).

We defined anatomic position of the MPFL femoral tunnel to be within 9 mm of our defined isometric point. In a variation in a previous study on MPFL tunnel placement accuracy by Servian et al, we increased their 7-mm diameter zone described to 9-mm, given the typical 7 mm tunnel and a more posterior defined attachment point on the femur. Tunnels were accurately placed if they fell within this 9-mm diameter and considered malpositioned if the center of the tunnel fell outside. We also evaluated pre- and post-operative KOOS scores and performed a statistical analysis to see if outcomes were affected by tunnel position. We performed Pearson correlation coefficient analysis to assess for significant differences.
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RESULTS

Fifty patients were evaluated, 40 female and 10 male, with an average age of 31.3 years (range: 14-54). Of the 50 patients evaluated, 36 of them (64%) had tunnels placed outside of the defined 9-mm diameter. The average tunnel distance from the defined femoral isometric point was 13.25 mm (range: 4-28.4 mm).

The average preoperative KOOS score was 42.0. The average postoperative score was 47.65. Pearson correlation coefficient was 0.23 indicating negligible correlation between a change in KOOS score and femoral tunnel placement of the MPFL graft. There was no statistically significant difference in KOOS scores in patients who had a malpositioned tunnel compared to anatomic placement.

DISCUSSION

Anatomic placement of the MPFL femoral tunnel is ideal to maximize outcomes. Proximally placed tunnels have been shown to increase stress and contact pressure on the medial patella facet cartilage. This can lead to medial overload, arthritis, pain and significant disability. In addition, malpositioned femoral tunnels can increase stress on the non-isometric MPFL graft. This can lead to failure of the reconstruction and recurrent lateral patellofemoral instability or iatrogenic medial patella subluxation. Medial patella subluxation is commonly seen after prior patellar instability surgery (lateral release, tubercle transfer, or MPFL reconstruction) and involves a dramatic medial to lateral shift of the patella into the trochlear groove during knee flexion. Patients describe a sharp catching pain and clunk that can be quite disabling. Of note, they often report a lateral shift of the patella and this entity can easily be mistaken for lateral patellofemoral instability.

There are many MPFL reconstruction techniques with different methods to secure the graft to the patella and femur. There are several ways to determine the appropriate anatomic insertion site of the MPFL when performing the reconstruction. Medial knee anatomy and the femoral MPFL insertion have been studied extensively in recent years. The MPFL inserts in the saddle between the medial epicondyle and the adductor tubercle. This can be palpated intra-operatively. One can palpate the adductor magnus tendon insertion to help with orientation during surgery as the MPFL insertion is anterior and distal. In addition, graft isometry can be checked during surgery to determine the appropriate position of the femoral tunnel. Ideally, graft isometry should be maintained during the first 50-70 degrees of flexion and loosen in deep knee flexion. A suture can be used to connect the proposed femoral insertion site to the patella and isometry can be determined. If the suture tightens in flexion, the proposed femoral attachment site is too anterior or proximal. Based on our experience, it is easy to be fooled when only using palpation or graft isometry to determine the appropriate position of the femoral tunnel. While it is important to use several ways to check the adequacy of femoral tunnel position, we believe intra-operative fluoroscopy is the most reliable way to assess femoral tunnel position. Schottle et al. has greatly added to the understanding of radiographic MPFL insertion anatomy. Anatomic MPFL femoral guide pin location is just anterior to the intersection of the posterior femoral cortical line and Blumensaat’s line on the lateral radiograph.

Servian et al. described a method to evaluate tunnel placement. They made a line tangent to the posterior condyle and a perpendicular line to this at the posterior-most aspect of Blumensaat’s line, and then marked out a +/- 7mm zone to accommodate a typical MPFL tunnel diameter (Figure 4). They reported accurate tunnel placement in 20 of 29 MPFL reconstructions (69%), but noted no correlation between tunnel placement and clinical outcomes, as measured by IKDC scores reported by patients. Our results are similar to those of Servien et al. in that there was no correlation between tunnel position and outcome scores. It does not appear to be necessary to have an anatomic MPFL tunnel position to prevent further patellar instability episodes and achieve a good result. Both studies only report short-term outcomes and we suspect that longer follow-up may reveal an increased incidence of patellofemoral arthritic changes in patients with malpositioned grafts.

Figure 5: Servian, et al. tunnel placement, modified from Schottle’s work. Note the 5-mm Schottle’s insertion point was expanded in Servian, et al, work to accommodate the typical 7-mm tunnel used in MPFL reconstruction. (Reproduced with permission from Servien E, Frisch B, Lustig S, Demey G, Debarge R, Lapra C, et al. In vivo positioning analysis of medial patellofemoral ligament reconstruction. Am J Sports Med 2011;39(1):134-139.)
tion, we feel that anatomic graft position gives the best chance to achieve a successful short-term and long-term outcome with no recurrent instability, ability to return to sports, and prevention of medial overload and iatrogenic medial subluxation.

Regardless of the tunnel position, a key factor in MPFL reconstruction is to set the correct graft length or tension. Thaunat and Erasmus reported on two patients with pain and stiffness after over-tightened MPFL reconstructions10. Beck and colleagues showed that 2N of graft tension restored normal patellar translation11. Higher loads (10N and 40N) significantly restricted motion and increased medial patellofemoral contact pressure. It is likely that malpositioned grafts with good subjective outcomes were not over-tensioned. We believe medial patellofemoral overload and medial patella subluxation can occur when an MPFL graft has a proximal/ anterior femoral insertion and is over-tensioned. When performing MPFL reconstruction, setting appropriate graft tension or length is a key part of the procedure. There are several ways to do this. One option is to flex the knee to 60 degrees so the patella centers in the trochlea and then secure final MPFL fixation. A second method involves holding the lateral patella flush with the lateral trochlea at 30 degrees of knee flexion when securing final fixation. The MPFL is a checkrein to guide the patella into the trochlear groove during the first 30 degrees of knee flexion and is not meant to be a tight restraining ligament like others in the body. After MPFL reconstruction is finished, there should be some lateral patella translation when the knee is extended with a good endpoint. The patella should be pulled into the groove when the knee is flexed.

Several factors could have been responsible for the lack of correlation between malpositioned tunnels and poorer outcomes scores. First, our follow-up may be too short to allow the long-term effects, such as early osteoarthritic changes, to be shown. Next, while we expanded on the distance to accept a tunnel as deemed accurate, this degree of distance from the MPFL isometric point may not be far enough to reveal a significant difference. Finally, the accuracy of assessing intraoperative landmarks has not been elucidated, and it may be challenging to reliably reproduce their location despite careful surgical dissection and the use of intraoperative fluoroscopy.

Few studies have evaluated clinical outcomes in relation to femoral tunnel position. While our study showed a high rate of malpositioned tunnels, this did not correlate with outcomes scores. We propose that other factors may play a role in achieving good outcomes after this procedure including graft tension, trochlear groove anatomy, patella height, and dynamic restraints. Although results of our study suggest that it is not necessary to achieve a good result, we suggest that anatomic femoral tunnel position provides the best chance to maximize the function of the graft.

REFERENCES
ABSTRACT

Background: The medial patellofemoral ligament (MPFL) is the most frequently injured soft tissue structure following acute lateral patellar dislocation. MPFL reconstruction has become a popular option to restore patellar stability following lateral patellar dislocation due to the high incidence of recurrent instability following conservative management. Anatomic reconstruction of the MPFL minimizes graft length changes during full knee range of motion and restores patellar stability.

Materials & Methods: Four fresh frozen cadaver specimens underwent biomechanical testing in a materials testing machine. With the knee fixed in 30° of flexion, the patella was translated laterally a distance of 10 mm and continuous force-displacement data was collected with the intact MPFL and again following a newly described MPFL reconstruction technique. Lateral force-displacement and stiffness data were calculated, allowing comparison between the intact and reconstructed MPFL.

Results: The average lateral restraining force provided by the intact MPFL was 10.6 ± 5.7, 36.6 ± 2.7, and 69.0 ± 5.9 N while the lateral restraining force following MPFL reconstruction was 0.4 ± 4.3, 50.3 ± 16.3, and 110.2 ± 17.5 N at 1, 5, and 10 mm of lateral displacement, respectively.

Conclusion: Anatomic MPFL reconstruction displays similar lateral restraining force compared to the intact MPFL at low levels of lateral displacement. At higher levels of displacement, the reconstructed MPFL provides increased lateral restraining force compared to the intact MPFL, improving patellar stability in pathologic knees.

INTRODUCTION

Bony anatomy, soft tissue restraints, and the dynamic action of the quadriceps all play a role in maintaining patellar stability throughout knee motion. The medial patellofemoral ligament (MPFL) serves as the primary soft tissue restraint to lateral patellar displacement during low degrees of flexion when the patella has yet to engage the femoral trochlea. Following acute lateral patellar dislocation, the MPFL is the most frequently injured soft tissue structure, disrupting one of the key components required to maintain patellar stability. Acute lateral patellar dislocations occur most frequently in the second decade, with recurrent episodes of instability reported in 15-44% of patients treated nonoperatively. Due to the high rate of recurrent episodes of instability following conservative management of acute lateral patellar dislocation, numerous bony and soft tissue procedures have been described to restore patellar stability including MPFL repair and reconstruction.

Disruption of the MPFL has been identified as an essential lesion following acute lateral patellar dislocation, occurring in up to 96% of individuals following the injury. Early MPFL repair fails to achieve the same load to failure characteristics as the native MPFL, and clinical studies have not shown a difference between early MPFL repair and conservative management of acute lateral patellar dislocations. MPFL reconstruction aims to restore the form and function of the native MPFL, making it a popular option following acute injury.

In vivo, the native MPFL originates between the medial epicondyle and adductor tubercle of the femur and courses extracapsularly just distal to the vastus medialis obliquus (VMO) before inserting on the proximal one-third of the patella. The MPFL plays an important role in guiding the patella into the femoral trochlea during the first 20-30° of knee flexion by providing a passive checkrein to lateral patellar translation before the bony architecture of the femoral trochlea directs patellar motion in higher degrees of flexion.

During MPFL reconstruction, numerous biomechanical studies have noted the importance of anatomic graft placement, particularly on the femoral side, in order to minimize graft length changes throughout full knee range of motion. Failure to achieve anatomic graft fixation may over-constrain the patella and lead...
Biomechanical Evaluation of Medial Patellofemoral Ligament Reconstruction

...to premature osteoarthritis due to increased medial patellofemoral contact pressures or result in recurrent instability due to graft failure. Additionally, excessive tensioning with more robust auto- and allograft materials has been shown to alter normal patellar motion. In order to replicate the actions of the native MPFL while avoiding over-constraint, tensioning with as little as 2 N of force has been suggested.

While the role the native MPFL plays in maintaining patellar stability has been extensively investigated, relatively few studies have investigated patellar stability following anatomic MPFL reconstruction. The purpose of this study is to describe our preferred anatomic MPFL reconstruction technique, while also comparing patellar stability following anatomic MPFL reconstruction with patellar stability in the native knee using a cadaver model. While popular autograft and allograft tendon options undoubtedly display different biomechanical properties compared to the native MPFL, we believe that anatomic reconstruction of the MPFL can restore patellar stability by recreating the checkrein function of the native MPFL.

**MATERIALS AND METHODS**

**Specimens and Specimen Preparation**

Four fresh frozen cadaver specimens from two subjects aged 57 and 95 years (mean 76 years) were obtained for this study. The specimens included 20 cm of femur and 15 cm of tibia as well as overlying soft tissue structures. Visual inspection of all specimens failed to reveal evidence of prior surgery. Specimens were stored at -20°C prior to thawing at room temperature for a period of 24 hours. Magnetic resonance images (3.0-T MRI, Siemens Medical Solutions, Erlangen, Germany) were acquired for all specimens, and all investigators independently reviewed the images to confirm the continuity of the MPFL prior to testing. Preparation of the specimens included careful removal of the fibula and all soft tissue structures with the exception of the medial patellofemoral ligament and distal quadriceps extensor mechanism. Prior to testing, the MPFL was isolated from the surrounding medial retinacular structures which were subsequently excised. The distal quadriceps was then separated into three components including the vastus lateralis (VL), vastus medialis (VM), and combined rectus femoris/vastus intermedius (RF/VI) muscle bellies. Cloth strips were looped around the free ends of the isolated quadriceps muscle bellies and attached using sutures in standard Krakow fashion through the muscle bulk in order to allow loading of the quadriceps extensor mechanism through a pulley mechanism as described by Farahmand et al. The ends of the tibia and femur were potted in polymer resin (Bondo™, 3M Corporation, St. Paul, MN) with wood screws placed through the femoral and tibial diaphysis to enhance interdigitation.

**Experimental Setup**

Lateral displacement of the patella was achieved using a biaxial servo-hydraulic 858 Bionix II materials testing machine (MTS Corporation, Eden Prairie, MN). All four specimens were tested with the native MPFL intact and again following MPFL reconstruction. Specimens were mounted in the materials testing machine using a custom fixture that allowed the specimens to be fixed at varying degrees of knee flexion. For the purpose of this study, all knees were mounted and tested in 30° of flexion where lateral restraining forces are lowest and optimal graft fixation is achieved. The isolated quadriceps components were loaded with a total of 178 N of force taking into consideration loading direction and physiologic cross-sectional area of the muscles using previously established patellofemoral models. Briefly, the VL, VM, and RF/VI were loaded with 35, 25, and 40% of the total force, respectively. The VL was oriented 20° lateral and 0° anterior, the VM 35° medial and 0° anterior, and the RF/VI 0° lateral and 5° anterior relative to the axis of the femoral diaphysis using a custom pulley system. The loading cell was connected to the patella using a screw and a ball joint at the end of the load cell which allowed for rotation of the patella about the anterior-posterior and proximal-distal axes. The screw was placed in the center of the patella perpendicular to the coronal plane without disrupting the underlying cartilaginous surface. The experimental setup can be seen in Figure 1. Using displacement control, the patella was cyclically translated 10 mm laterally from...
a neutral position at a rate of 100mm/minute\(^\text{30}\). The patella underwent four cycles of lateral displacement, with force-displacement data collected on the fourth cycle.

**Description of MPFL Reconstruction**

After testing of the intact MPFL, the MPFL was sectioned and an anatomic MPFL reconstruction was performed. A split tibialis anterior allograft was prepared with Krakow suturing of the terminal ends.

A two incision MPFL reconstruction was then performed, with the first incision centered along the medial border of the patella. The apex of the prepared tibialis anterior allograft was secured along the proximal one-third of the patella using two SutureTak\(^\text{®}\) suture anchors (Arthrex, Inc., Naples, FL) in order to recreate the footprint of the MPFL on the patella. A second incision was centered over the medial femoral epicondyle. In the absence of superficial soft tissues in this cadaver study, the saddle between the medial femoral epicondyle and the adductor tubercle was directly visualized and palpated. This portion of the procedure is typically performed under fluoroscopic guidance as palpation and visualization of the osseous landmarks is often difficult intraoperatively\(^\text{33}\). The two free limbs of the tibialis anterior allograft were then tunneled extracapsularly between layers two and three of the medial knee. A 2.4 mm Beath pin was then placed in the previously identified saddle between the medial femoral epicondyle and adductor tubercle and driven through the femur. An 8 mm cannulated reamer was then used to create the femoral tunnel. The two free limbs of the tibialis anterior allograft were then docked into the femoral tunnel. [With the knee placed in 30° of flexion and the patella centered in the femoral trochlea, a 9 mm Bio-Tenodesis Screw\(^\text{TM}\) (Arthrex, Inc., Naples, FL) was used to secure the graft in the femoral tunnel, while ensuring that the graft was not loose nor tensioned by ensuring that the patella remained centered in the trochlear groove during gentle passive range of motion.] An example of the completed procedure can be seen in Figure 2. In all specimens, a good checkrein to lateral translation was established with less than 1 cm of lateral patellar translation with the knee in 30° of flexion.

**Graft Positioning**

Following testing in the materials testing machine, fluoroscopy was used to obtain true lateral images of the specimens in order to confirm anatomic femoral tunnel positioning. Anatomic femoral tunnel positioning was confirmed according to the method described by Servien et al., using Schöttle’s point as the anatomic center of the femoral tunnel which was expanded by 7 mm to account for the diameter of the femoral tunnel\(^\text{20,33}\). The 7 mm diameter was expanded to 8 mm for this study as this is the senior author’s preferred tunnel size for MPFL reconstruction. A tunnel was considered anatomically positioned when the center of the tunnel fell within the enhanced anatomic zone as seen in Figure 3.
Biomechanical Evaluation of Medial Patellofemoral Ligament Reconstruction

Data Analysis
Continuous force-displacement data was collected during biomechanical testing using the software provided with the 858 Bionix II materials testing machine (MTS Corporation, Eden Prairie, MN). (Raw data was organized using Microsoft Excel 2007 (Microsoft Corporation, Redmond, WA).) The mean lateral restraining force (N) with associated standard deviations was calculated in both the intact and reconstructed specimens. The slope of the force-displacement graph was calculated to determine the stiffness (N/mm) of the patella in response to lateral force displacement for both the intact and reconstructed MPFL.

RESULTS
The center of the MPFL femoral tunnel was anatomically placed in all four specimens according to the enhanced anatomic zone described by Servien et al. and displayed in Figure 3. The average lateral restraining force provided by the intact MPFL with the knee fixed in 30° of flexion was 10.6 ± 5.7, 24.6 ± 7.1, and 29.6 ± 5.4 N while the lateral restraining force following MPFL reconstruction was 0.4 ± 4.3, 16.5 ± 7.4, and 28.1 ± 11.2 N at 1, 2, and 3 mm of lateral displacement, respectively. The average lateral restraining force is displayed in one millimeter increments in Table 1 for both the intact and reconstructed specimens.

The average lateral force-displacement curves for the intact and reconstructed MPFL can be seen in Figure 4. Two linear regions were observed in both curves from 0-1.5 mm displacement and 1.5-10 mm displacement. From 0-1.5 mm of lateral displacement, the average stiffness was 24.5 ± 5.0 N/mm in the intact MPFL and 23.1 ± 4.1 N/mm following MPFL reconstruction. From 1.5-10 mm of lateral displacement, the average stiffness was 5.00 ± 1.6 N/mm in the intact MPFL and 11.2 ± 1.8 N/mm following MPFL reconstruction.

DISCUSSION
Anatomic reconstruction of the MPFL is important to restore patellar stability and prevent proposed complications including increased patellofemoral contact pressures and early graft failure. Less is known about patella contact pressures, forces, and graft biomechanics following anatomic MPFL reconstruction. Additionally, other factors, including the material properties of the graft and tensioning of the graft intraoperatively, may affect patellar biomechanics. Numerous techniques and graft options have been described for MPFL reconstruction. This study used an anatomic MPFL reconstruction technique similar to the technique described by Farr and Schepsis, with the exception that the apex of the graft was placed on the patellar side, allowing the broad-based insertion of the MPFL on the proximal one-third of the patella to be recreated. We typically prefer to use fluoroscopy intraoperatively to guide femoral tunnel placement, as we agree with Servien et al. that the sole use of palpation and visualization does not allow consistent anatomic tunnel placement. Interestingly, Servien et al. did not find any subjective differences between anatomic and nonanatomic femoral tunnel placement at minimum 2-year follow-up. Additionally, we take great care to set the appropriate graft tension by placing the knee in 30° of flexion and making sure the patella is centered in the femoral trochlea when the graft tension and length are secured.

In this study, the MPFL reconstruction technique with fluoroscopic confirmation of anatomic femoral tun-

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**Table 1. Comparison of Lateral Restraining Force in the Intact and Reconstructed MPFL**

<table>
<thead>
<tr>
<th>Displacement (mm)</th>
<th>Lateral Restraining Force (N)</th>
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<tr>
<td></td>
<td>MPFL Intact</td>
</tr>
<tr>
<td>0</td>
<td>-16.8 ± 3.6</td>
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<tr>
<td>1</td>
<td>10.6 ± 5.7</td>
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<td>2</td>
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<tr>
<td>10</td>
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**Figure 4.** Force versus displacement graph for the intact and reconstructed MPFL. The slope of the lines corresponds to the stiffness of the construct.
nel placement yielded similar biomechanical properties compared to the intact MPFL. The MPFL reconstruction produced similar lateral restraining force compared to the intact MPFL from 0-3 mm of displacement, suggesting that the reconstruction did not over constrain the patella as has been cited as a concern previously (Figure 4)\(^{20}\). At higher values of displacement, the MPFL reconstruction resulted in increased lateral restraining force compared to the intact MPFL. This could potentially be accounted for by the material properties of the tibialis anterior allograft used in this study, which has a load to failure strength of 1553 N and stiffness of 236 N/mm compared to the load to failure strength of 208 N and stiffness of 12 N/mm exhibited by the native MPFL\(^{12,14,28,29}\). Furthermore, in pathologic knees that exhibit trochlear dysplasia and vastus medialis obliquus (VMO) deficiency, which both reduce the amount of force required to displace the patella laterally\(^{34}\). increased lateral restraining force at higher values of displacement may be beneficial.

Our results are similar to those previously reported using intact MPFL specimens. The shape of the force-displacement curve (Figure 4) is similar to the curves presented by Fahramand et al. and Senavongse et al\(^{30,32}\). The average lateral restraining force of the intact MPFL in this study was 69.0 N at 10 mm of displacement, which is similar to the 75 N value reported by Senavongse et al\(^{32}\). The stiffness of the intact MPFL in the present study, 5.0 N/mm, was lower than the 17.6 N/mm value reported by Senavongse et al\(^{32}\), who tested knees in full extension as opposed to 30° of flexion in the present study, limiting comparison of these values.

Limitations of the present study include the small number of specimens, which does not allow determination of statistically significant differences between the intact MPFL and MPFL reconstruction. Additionally, the mean age of the specimens in this study, 76 years, is older than when patients typically present with acute patellar dislocation, which may affect the soft tissue properties of the specimens. The specimens in this study also failed to exhibit pathologic characteristics that often predispose to patellar instability including rotational abnormalities, VMO deficiency, and trochlear dysplasia\(^{34}\). Specimens in this study were only tested in 30° of flexion, which has been cited as the angle at which the MPFL is longest and is therefore optimal for fixation\(^{12,21,22}\). Other studies have extensively explored the way knee flexion affects lateral restraining force, with the general consensus that knees are least stable from 20-30° of flexion\(^{10,30,32}\).

Despite the assumption that anatomic reconstruction is essential to restore normal patellar motion, relatively little has been done to determine whether current reconstruction techniques actually restore the native function of the MPFL. This study describes a new technical description of MPFL reconstruction that not only restores the femoral anatomic footprint, but also restores the wide footprint of the MPFL on the proximal portion of the medial patella.

CONCLUSION

The MPFL reconstruction technique presented in this study produced similar patellar stability compared to the intact MPFL tested in the present study as well as previously reported in the literature. The similar lateral restraining forces between the intact MPFL and MPFL reconstruction during low levels of displacement suggests that the described technique also avoids the most frequent concerns associated with MPFL reconstruction, namely medial patellar overload and excessive tensioning of the graft leading to graft failure. While this study is limited by sample size, it provides a basis for future studies to explore MPFL reconstruction biomechanics while confirming that meticulous attention to detail with regard to graft position and tensioning can produce biomechanically satisfactory results.

REFERENCES


ABSTRACT

INTRODUCTION: ACL reconstructions are frequently performed following ACL injury. The most common treatment is single bundle reconstruction. While ACL reconstructions have been studied clinically and experimentally, quantitative information regarding the local biomechanics the knee following ACL reconstruction is generally lacking. Specifically, the role of graft size on joint stability and soft tissue injury propensity is currently unknown.

METHODS: Therefore, a non-linear contact finite element model was developed to systematically evaluate the relationship between ACL graft size and knee joint biomechanics following ACL reconstruction. A simulated Lachman maneuver was utilized to assess knee joint laxity, meniscal stress, in situ graft loading, and peak articular cartilage contact pressure for ACL graft sizes between 5 and 9 mm, as well as an ACL-deficient knee. The model was validated by corroboration with previously published experimental (cadaveric) data on ACL reconstruction.

RESULTS: The 5 mm graft resulted in 30% greater relative AP translation compared to the 9 mm graft; the ACL deficient knee resulted in 2.56-times greater AP translation than the average graft reconstruction. Contact pressure and peak meniscal stresses decreased monotonically for increased values of ACL graft diameter. For all graft diameters, soft tissue stress and articular contact pressure was reduced versus the ACL-deficient knee.

CONCLUSIONS: ACL reconstruction dramatically affects the local biomechanics of the knee. Stresses occurring in the soft tissues, as well as contact pressure at the articular surfaces, were found to be highly sensitive to ACL graft size. Larger grafts were associated with lower meniscal stress, decreased joint laxity, and less articular cartilage contact stress. Therefore, the current data suggests that increased graft size confers a biomechanical advantage in the ACL reconstructed knee.

INTRODUCTION

Anterior cruciate ligament (ACL) injury is common in the athletic patient population, occurring 200,000 times annually in the United States1. ACL reconstruction is a common treatment modality, with an estimated 60,000 to 175,000 surgical cases performed per year in the United States1-3. The ACL is the primary restraint to anterior tibial translation with respect to the femur, absorbing approximately 90% of the anterior displacement force during knee flexion4. The Lachman test is an important clinical exam to evaluate the soft tissue integrity of the ACL, by assessing anterior tibial translation relative to the femur at typically 20-30° of knee flexion5. It is the most reliable clinical test to assess both anterior cruciate ligament injuries and the state of reconstructions5-7. The test can be quantified in the clinical setting using KT-1000 arthrometer (MEDmetric, San Diego, California) measurements of anterior tibial translation4.

However, a reliable method to assess the mechanics associated with ACL reconstruction integrity is generally lacking. Perhaps the most frequent guide for surgical practice is the clinical study, which can give insight into apparent causality of events and outcomes. However, inherent weaknesses of clinical studies, including limited patient populations and uncontrolled confounders, often prevent systematic analysis. Therefore such studies are frequently limited in terms of their immediate clinical utility. By contrast, experimental biomechanical analyses allow for precise and controlled investigation. However, conventional biomechanical investigation, whether by simulator or cadaveric studies, is greatly resource-intensive, both in terms of labor and cost. Additionally, experimental studies must be sufficiently robust to parametrically address individual factors associated with biomechanical outcomes, further increasing their cost and complexity. Computational models – specifically finite element (FE) analyses – enable unique advantages...
is the first strain invariant, and are pseudo-invariants of the deviatoric part of the 113

deviation technique are generally unavailable9, 11-13. Therefore, biomechanics associated with variances in reconstruc-
tion from the open-source OpenKnee project14. These sur-
faces, which consisted of bony anatomy (distal femur, proximal tibia), cartilage, menisci and additional soft
tissues (lateral collateral ligament, medial collateral ligament, posterior cruciate ligament), were obtained from MRI imaging of a donor knee specimen. These surfaces were imported into the preprocessing software TrueGrid (XYZ Scientific Applications, Livermore, CA), appropriately modified, and discretized into 8-noded hexahedral continuum elements, with a mesh density based on convergence sensitivity studies.

Initial locations of the ACL graft tunnel was determined from experimental analyses of the femoral ACL footprint15 and established CT based data of arthroscopi-
cally identified loci for the tibial footprint16. To permit parametric evaluation of the effect of graft sizes up to 9.0 mm diameter, the femoral and tibial tunnels were modeled at 9.05 mm in diameter. The ACL graft was con-
struction as a single cylindrical solid (i.e., single bundle graft). The graft was manipulated within TrueGrid to penetrate approximately 1 cm into the femoral and tibial tunnel sites. The axial centroid of the graft was then aligned with a cubic spline spanning from the femoral to tibial tunnels, producing a natural strain-free anatomic geometry, permitting simulation of intraoperative tautening of the graft during reconstruction. The meshed structures were then aligned in a knee-joint coordinate orientation system17 with an approximate Q angle of 14.1°. In this orientation, the origin of the model is defined as the midpoint of the medial and femoral condyles, the x-axis is the flexion axis, the y-axis the anterior-posterior axis, and the z-axis the mechanical axial axis14.

Anisotropic (fiber direction-dependent) representation of the knee joint soft tissues were implemented using the micromechanically based hyper-
elastic constitutive model introduced by Holzapfel, Gasser and Ogden (HGO)18. In the HGO-formulation, the strain-energy potential U takes the form

\[ U = C_{10} (I_1 - 3) + \frac{1}{3} \sum_{i=1}^{N} \frac{k_i}{2} \left( (\psi_i)^2 - 1 \right) \ln J^d \]

where \( I_1 \) is the first strain invariant, and \( I_{1_{ps}} \) are pseudo-invariants of the deviatoric part of the right Cauchy-Green deformation tensor, \( \psi_i \) is the elastic volume ratio, \( N \) is the number of fiber families; \( C_{10}, D, k_1, k_2 \) are material coefficients, and \( \kappa \) is a parameter quantifying the degree of heterogeneity in the distribution of fiber directions locally within the material. A similar material model has been successfully implemented for modeling of the hip capsule following total hip arthroplasty19. The prevailing collagen fiber orientation of the ACL was assumed to run parallel to the long axis of the graft. An element-by-element continuous fiber orientation was defined for the graft (Fig. 2), allowing for appropriate material response from tensile loads acting through the soft tissue. Material coefficients for the ACL model were optimized such that the resulting load-displacement data from a simulated tensile test matched physical load-displacement20 and stiffness21 data for corresponding cadaveric native ACL specimens. The remaining cruciate and collateral ligamentous structures were similarly as-
signed prevailing fiber orientations and assigned these HGO material coefficients. The menisci were discretized such that appropriate fiber orientations in the superficial, lamellar and central layers22 could be defined (Fig. 3A). An optimization routine was used to determine the appropriate material coefficients for the HGO model of the menisci based on literature values13. Meniscal horn attachments to the tibia were approximated as a series of spring elements attaching each node on the surface.
of the meniscal horn to a node on the tibia acting approximately orthogonal to the horn face centroid. The spring constants were determined from the Young’s modulus for horn attachments. Additional spring elements, representing the meniscal coronary ligaments were similarly prescribed. Appropriate collagen fiber orientations of the articular cartilage were assigned to the deep, middle, and superficial layers (Fig. 3B), and HGO material parameters were also determined by an optimization routine to match literature cartilage mechanical behavior. Given the several-order higher stiffness of bone versus soft-tissue stiffness, the bony structures were assumed rigid.

The FE model was kinematically controlled using rigid body definitions. Reference nodes were ascribed to the tibia, the femur and the ACL graft. Attachments of the soft tissues to bones (e.g., cartilage to bone and ligaments to bone) were applied using these rigid body interfaces. Additionally, all prescribed boundary conditions (six total degrees of freedom) were applied to these reference nodes. The Lachman simulation consisted of two steps: the first step begins with the knee in full extension, and flexes the knee to 30° while an axial load of 50N is applied. To accurately represent the native ACL’s U-shaped tension curve, as well as intraoperative ACL reconstruction technique, the ACL graft is tautened (pretensioned) with 20 N tensile load at approximately 20° of knee flexion. The second step is the application of 89 N of posteriorly directed load on the flexed femur, simulating the Lachman maneuver. During both steps, all degrees of freedom at the tibia were constrained; therefore displacement of the femur relative to the tibia determined in the FE simulation is analogous to anterior displacement of the tibia during the clinical exam. To ensure the highest level of model realism, kinematic
Effect of ACL Reconstruction Graft Size on Simulated Lachman Testing: A Finite Element Analysis

Contact definitions were specified for all possible perturbations of bone, cartilage and soft-tissue engagement. The FE model was used to parametrically assess the effect of graft size on knee joint mechanics. A total of ten FE models were generated, consisting of an ACL-deficient knee, and nine variants of ACL graft diameter (5.0 mm to 9.0 mm in 0.5 mm increments). Output metrics for each simulation included: (1) anterior-posterior displacement of the femur relative to the tibia; (2) ACL reaction forces (analogous to in situ ACL load bearing during the Lachman maneuver); (3) von Mises (vM) stresses in the ACL graft and menisci; and (4) contact pressure at the articular cartilage. The FE simulations were run using Abaqus/Explicit 6.11 (SIMULIA, Providence, RI), executed on a 64-bit Suse Linux operating system with twin dual quad-core Intel Xeon platforms configured with 24 GB of RAM. Each simulation required approximately 21 processor-hrs of computation time.

RESULTS
During knee flexion and the Lachman simulation, in situ stresses developed within the ACL graft (Fig. 4). These stresses were shown to be highly dependent upon the ACL graft diameter (Fig. 5), in which increased ACL graft bundle size generated substantially less peak stress within the tissue. During the Lachman simulation, the posteriorly-directed load on the femur is taken up by the ACL graft, with summation loads (i.e., the ACL reaction force) also highly dependent upon graft diameter (Fig. 6). These in situ loads, within the range of 75-90N, agree well with experimental cadaveric data [9] with similar testing parameters.

The increased reaction forces and stresses seen with increased graft diameters also influenced the posterior translation of the femur relative to the tibia during the Lachman simulation (Fig. 7). The 5.0 mm graft resulted in nearly 30% greater relative translation compared to the 9.0 mm graft. The ACL-deficient knee resulted in substantially greater translation (12.8 mm) than that seen with the smallest graft simulated (5.75 mm with the 5.0 mm graft). The magnitude of relative translation reported here also agrees favorably with that seen experimentally.9
Owing to the considerably altered local mechanics resulting from ACL graft size variance, discrepancies in peak meniscal stress (Fig. 8) and articular cartilage contact pressure (Fig. 9) were also observed. In general, both peak meniscal stress and peak articular cartilage contact pressure decreased with increased graft diameter.

**DISCUSSION**

ACL reconstructions are common procedures in orthopaedics and are generally associated with good results. Although several techniques exist, single bundle ACL reconstructions remain the mainstay of treatment. However, objective evidence regarding the influence of patient- and surgical-specific variables on outcomes following ACL reconstruction is very limited. Therefore, the ability to perform efficient systematic and parametric biomechanical analysis of ACL reconstructed knees is a desirable goal. Toward objectively analyzing knee joint mechanics following ACL reconstruction, a three-dimensional contact FE model of single-bundle reconstruction was developed, and utilized to investigate the role of graft size on joint stability and soft tissue stresses. Model validation was conducted by corroboration of the FE model with published studies of ACL reconstructions. In a cadaveric study, Kato et al. found anterior tibial translation at 30° with 89 N of force to be 5.9-6.1 ± 2mm for intact ACLs and anatomic single bundle reconstructions. Prophy and Pearle reported anterior tibial translations of 4 ± 1 mm with conventional ACL graft placement. Under similar conditions in the present investigation, translations of 4.6-5.7 mm were observed with similarly-sized graphs. In situ forces from the present study also agree well with the established literature. Yagi et al. demonstrated 2.67-times greater AP translation of an ACL deficient knee compared to a single bundle reconstruction. This compares favorably with the 2.56-times greater AP translation observed in the present FE study. After single bundle ACL reconstructions under similar loading conditions, in situ forces have been reported between 65 N and 110 N. In situ ACL graft forces of 75-90N were observed in the present investigation. The excellent agreement achieved between the computational and experimental results reinforces the validity of the current FE model.
The present data indicate that even small changes to ACL graft size used for reconstruction can result in large variation in the local biomechanics of the knee. Increased ACL integrity, as simulated with increased ACL graft diameter, resulted in substantially less joint laxity during Lachman simulation by increasing the load burden of the ACL. Owing to decreased translation across the articular surface and concomitant compressive loads on the menisci, increased ACL graft integrity was found to decrease the stresses generated in the lateral and medial meniscal structures. Contact pressures generated at the articular surface demonstrated a similar dependence upon ACL graft size. Additionally, in all cases, the soft-tissue stresses generated during the simulation of ACL-deficient knees were substantially greater than that observed for any simulation involving reconstructed ACLs. Given the well-established clinical association of the development of osteoarthritis in ACL-deficient and in some reconstructed ACLs, the ability association of the development of osteoarthritis in ACL-reconstructed ACLs. Given the well-established clinical association of the development of osteoarthritis in ACL-deficient and in some reconstructed ACLs, the ability to systematically evaluate the effects of surgical variables on the local- and whole-joint mechanics of the ACL-injured knee deserve further attention. The present study, which to the authors’ knowledge represents the first computational model of Lachman testing in ACL-reconstructed knees, provides the first quantitative data in this regard. Of course, numerous other surgical variables – such as tunnel location, tunnel angle, graft pretensioning, graft choice, etc. – can similarly affect the biomechanics of the ACL-reconstructed knee. Parametric investigation of these variables is an attractive avenue for further investigation with the present FE model.

Despite every effort to attain the highest level of realism with the computational formulation, several modeling limitations merit attention. First, the present study evaluated joint mechanics only for a Lachman-type maneuver. Several clinical examinations are available for evaluation of joint laxity prior to, and following, ACL-reconstruction. However, the Lachman test was chosen owing to the availability of experimental data for model corroboration. Additionally, while alterations in cartilage, meniscal and ligament stresses were reported for Lachman testing, it is perhaps more clinically relevant to determine the effect of ACL-reconstruction variables on potentially deleterious soft tissue engagements for more clinically relevant joint motions, such as gait, stair descent, etc. While the relative complexities of these additional maneuvers would plausibly increase the complexity associated with computational simulation, a distinct advantage of the present FE model is its relative robustness, permitting the systematic computational evaluation of complex kinematic and kinetic challenges. This represents another attractive area for further investigation. Finally, while the anisotropic fiber-dominated material models used in the present model were attentively defined – and consequently represents one of the more sophisticated knee FE models in the orthopaedic literature – several simplifications were necessarily involved with model development. Defining the material response of the articular cartilage as a three-layer fibril-reinforced hyperelastic material may be an over-simplification, as the mechanobiology of articular cartilage is often represented as a biphasic poroelastic viscous (time-dependent) material. Additionally, all ligaments in the present study were assumed to have the same material model coefficients. While the effect of these simplifications at the whole-joint level is unknown, given the excellent agreement of the current model with experimental data, their influences are assumed negligible.

In summary, the present investigation has quantified the effects of ACL graft size on knee joint stability and soft-tissue stresses. Increased graft size was associated with substantially greater joint stability, and considerably lower meniscal stress and articular cartilage contact pressures. Given the high costs and technical complexities involved with cadaveric biomechanical investigations, the present study offers an attractive alternative modality for systematic evaluation of ACL-reconstructed knees.

ACKNOWLEDGEMENTS

The authors would like to express their sincerest gratitude to Dr. Ahmet Erdemir for his generosity in developing the freely-available OpenKnee project (available from https://simtk.org/home/openknee). Finite element model development is a laborious process, often prohibitively so. OpenKnee was a potent springboard for this investigation, greatly facilitating initial model development. The authors would also like to thank Dr. Austin Ramme for his assistance during model development. We would also like to thank The National Center for Research Resources (UL1 RR024979) for research support.

REFERENCES


ABSTRACT

Purpose: The goal is to introduce a reproducible exam technique that allows clinical diagnosis of symptomatic plical bands and associated synovium about the knee. We then aimed to assess the accuracy of the exam technique through arthroscopic confirmation of these tissues. Lastly, we hope to determine whether arthroscopic plicectomy and partial synovectomy is an effective treatment for alleviating the pain associated with symptomatic plica.

Methods: This retrospective study evaluated 80 consecutive symptomatic knees under the care of a single physician diagnosed with symptomatic plica and associated painful synovium from 2001-2011. These patients underwent diagnostic and therapeutic arthroscopy to verify the presence of a plica and painful synovium with plicectomy and partial synovectomy if necessary. Statistical analysis was performed to determine the sensitivity and positive predictive value of the exam.

Results: The medial parapatellar region was the most common location for symptomatic plica and associated synovial tissue. The exam technique described in this study had a sensitivity of 83.8% with a positive predictive value of 98.6% in the specific patient population described.

Conclusions: This study suggests that while the medial plical band is the most common, there is frequently sensitive synovial tissue found in multiple locations about the knee. This study also suggests that a thorough exam technique can accurately diagnose both the plical bands as well as the sensitive synovial tissue.

Level of Evidence: Level II, Diagnostic Study. See the Guidelines for Authors for a complete description of levels of evidence.

INTRODUCTION

Symptomatic synovial plicae about the knee have been a topic of discussion in the medical literature for quite some time, with much debate about the incidence of the synovial plicae in the population today. A common scenario fifteen years ago was to discover a plica at the time of arthroscopic evaluation for knee pain and remove it, without determining causality between the plica and a patient’s clinical presentation of pain. This often resulted in less than optimal post-operative success rates and failure to relieve the knee pain. The actual incidence of plical tissue in normal knees has also been called into question. Ogata and Uhthoff studied the incidence and location of plicae during embryologic development of the knee. At 8-20 weeks gestation, the infrapatellar plica was found in 50%, the suprapatellar was found in 33%, the mediopatellar was found in 37%, and the lateral plica was found in only one embryo. However, a review of the more recent literature shows high variability from arthroscopic and cadaveric studies: suprapatellar 55.5% to 87.0%, medial 24.5% to 72%, infrapatellar 65.5% to 86.0%, and the lateral 0% - 1.3%.

There is no consensus on the incidence of symptomatic synovial plica of the knee. Normally, plicae of the knee are pliable in nature. However, when they become thick and fibrotic, plicae can cause significant pain as they impinge on the femoral condyles or patellar facets during movement. It is hypothesized that one cause of significant chronic and acute-on-chronic knee pain is a mechanically based synovitis that can occur in a patient with congenitally present synovial plicae. During Scott Dye’s arthroscopic inspection of his own knee joint without intraarticular anesthesia, he noted that even light touch to the unanesthetized synovium resulted in
exquisite and substantial pain, whereas direct probing to his Grade III chondromalacia was asymptomatic. It is still not fully understood what causes the synovial-plical complex to become symptomatic. Trauma to the knee or repetitive movements may cause inflammation of the synovial tissue surrounding the plica, leading to increased fibrocity, loss of elasticity, and varying degrees of synovitis. It has been shown that trauma and overuse can increase the number of nerve endings within plicae, causing a decreased pain threshold.

Unfortunately, the literature has focused primarily on the diagnosis and treatment of medial synovial plica. Many patients have more widespread synovial involvement due to plicae in other areas about the patella rather than the medial parapatellar plicae most frequently reported in the literature. The presence of this sensitive tissue can be detected on clinical exam, and for patients who fail conservative measures, surgical excision can be highly effective.

The aims of this study are to: (1) demonstrate a unique physical exam that is reproducible for diagnosis of the symptomatic synovial-plical complex, (2) provide statistical evidence that the physical exam is accurate, as verified by arthroscopy, which is considered to be the gold standard for symptomatic plica diagnosis, (3) show that synovial plicectomy and partial synovectomy is an effective treatment for alleviating the chronic pain syndrome, and (4) provide an updated clinical picture of the patient with the symptomatic synovial-plical complex.

It is our observation that many people may have congenitally present plical band(s) and associated excessive, sensitive synovial tissue found incidentally at the time of routine clinical exam. Occasionally these individuals will develop severe anterior knee pain requiring treatment but few will require surgical intervention to alleviate symptoms. Contrary to the history of plical discovery and excision at the time of arthroscopy, it is our hypothesis the diagnosis can be made in the clinical setting. Most often these will respond to non-operative measures such as nonsteroidal anti-inflammatory medications, physical therapy, and rest. However, in this study we report a group of patients who have failed conservative measures and required surgery. It is also our observation that the plica and excessive, sensitive synovial tissue are often found together in varying relationships. In our work we have referred to the pain syndrome associated with a symptomatic plica and its sensitive synovial tissue as the Synovial-Plical Complex.

Hypothesis: The diagnosis of a symptomatic synovial-plical complex can be made in the clinical setting.

METHODS

This retrospective study reviewed consecutive surgically managed patients with the diagnosis of synovial-plical complex from 2001-2011 under the care of a single physician at a single institution who did not respond to conservative treatment modalities. The electronic medical record was queried in order to identify all patients under the care of a single physician whose primary pre- or postoperative diagnosis was symptomatic synovial plica. Preoperative diagnosis of symptomatic plica was made using a unique physical exam described in this study. These patients subsequently underwent diagnostic and therapeutic arthroscopy to verify the diagnosis. Patients with coexisting, advanced chondromalacia, osteoarthritis, and patellofemoral instability were excluded. Also, workman’s compensation and those with pending legal action were also excluded. The query produced 73 patients with 80 symptomatic knees with suspected synovial-plical complex. Of the 80 knees surgically managed, 78 were seen in follow-up (97.5%). Of the two knees that did not return to follow up, one knee was correctly diagnosed by clinical exam and underwent plicectomy, while the other was pre-operatively diagnosed with a lateral meniscus tear but instead a medial plica was found and excised at surgery. The average age at surgery was 24 years. The causal relationship of the plica to the pain-syndrome was confirmed by the post-operative relief of pain.

Plica diagnosis was made arthroscopically by looking for impingement of tissue between the patella and the femur, as well as associated excessive or thickened synovial tissue. This was viewed from the standard infra-patellar portals as well as the superior patellar portals with a 70-degree arthroscope. The tissue inferior to the patella was resected through the arthroscope. The tissue in the supra-patellar pouch was resected either arthroscopically or through a mini-lateral incision.

Exam Findings

The initial step in the workup of anterior knee pain was to determine the existence of patellofemoral surface pathology by performing a patellar compression test with the patient’s leg relaxed in 30, 60, and 90 degrees...
A of chondromalacia will typically have palpable crepitus during active range of motion of the knee in addition to subpatellar pain. Parapatellar pain during flexion of the knee is distinct from subpatellar pain and may indicate a plica trapped between the patella and femur. However, the finding of pain alone is neither sensitive nor specific for synovial-plical complex. Further examination requires methodical palpation of the parapatellar region in order to palpate a soft, popping plica during active flexion and extension of the knee as described below.

Medial Synovial-Plical complex

With the patient’s leg relaxed in extension, force the patella laterally while palpating for a thickened band along the medial edge of the widest portion of the patella. Once palpated, press the band toward the patella. Passively moving the leg into flexion often produces a palpable pop along the medial edge of the patella. Active flexion will also produce a palpable pop and is often accompanied by appreciable pain recreating the patient’s symptoms (Figure 2) (Figure 3).

Lateral Synovial-Plical complex

With the patient’s leg relaxed in extension, force the patella medially while palpating for a thickened band along the lateral edge of the widest portion of the patella. Once palpated, press the band toward the patella. Passive and active range of motion produce findings similar to the medial synovial-plical complex as described previously.

Suprapatellar Synovial-Plical complex

Deeply palpate the tender suprapatellar region while having the patient actively flex his or her quadriceps (Figure 4). If pain decreases or resolves completely

of flexion. If pain was present, the patient was asked to distinguish whether the pain was directly beneath the patella or around the periphery. Mild patellar chondromalacia may have subpatellar pain with provocative testing as the only finding, whereas more severe grades of chondromalacia will typically have palpable crepitus during active range of motion of the knee in addition to subpatellar pain. Parapatellar pain during flexion of the knee is distinct from subpatellar pain and may indicate a plica trapped between the patella and femur. However, the finding of pain alone is neither sensitive nor specific for synovial-plical complex. Further examination requires methodical palpation of the parapatellar region in order to palpate a soft, popping plica during active flexion and extension of the knee as described below.

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With the patient’s leg relaxed in extension, force the patella medially while palpating for a thickened band along the lateral edge of the widest portion of the patella. Once palpated, press the band toward the patella. Passive and active range of motion produce findings similar to the medial synovial-plical complex as described previously.

Suprapatellar Synovial-Plical complex

Deeply palpate the tender suprapatellar region while having the patient actively flex his or her quadriceps (Figure 4). If pain decreases or resolves completely
with activation of the muscle, suspect a suprapatellar synovial-plical complex.

**Superolateral Synovial-Plical complex**

The synovial-plical complex in this location often occurs concomitantly with medial or lateral synovial-plical complexes and are often so large that they are frequently missed. Palpate along the superolateral edge of the patella with an index finger to locate the band while the patient’s leg is relaxed in extension (Figure 5). While palpating the band ask the patient to slowly contract the quadriceps. Doing so helps distinguish a large synovial-plical complex from the overlying vastus lateralis. Once again, palpation often results in pain that reproduces the patient’s symptoms.

**Central Infrapatellar Synovial-Plical complex**

The central infrapatellar synovial-plical complex may be palpated directly beneath the patellar tendon. Much like the palpation for the suprapatellar plica, if the pain decreases or resolves completely with activation of the quadriceps muscle, suspect the infrapatellar synovial-plical complex as the origin of the patient’s pain.

**Medial Infrapatellar Synovial-Plical Complex**

Begin with the patient in 90 degrees of flexion. Palpate the edge of the patellar tendon located medial to the inferior pole of the patella while having the patient actively move their leg into full extension. As they move into extension, you will be able to feel the medial synovial-plical complex emerging from the infrapatellar fat pad and this palpation will recreate the pain that the patient with the symptomatic medial synovial-plical complex would experience.

**Lateral Infrapatellar Synovial-Plical Complex**

Repeat the exam for a medial infrapatellar synovial-plical, focusing on the lateral edge of the patellar tendon. Existence and location of the synovial-plical complex was always verified by at least two physicians.

### RESULTS

In the 70 knees that were verified at time of surgery for a symptomatic synovial-plical complex, 20 had medial bands, 15 had lateral bands, 3 had superior bands, and 14 had superolateral bands. Multiple bands were found in 15 knees. Three knees did not have palpable bands using the described physical exam technique but were still scheduled for diagnostic arthroscopy based on a combination of nonspecific symptoms including popping, catching, locking, and crepitus suggestive of symptomatic synovial-plical complex (Table 1).

Females accounted for 57 of the 80 (71.2%) symptomatic knees evaluated in this study. Males accounted for the remaining 23 (28.8%) of symptomatic knees. Trauma was the inciting event for anterior knee pain in 27 of the knees. Sports or repetitive activities were responsible for symptoms in 25 knees, and an insidious onset was described in 28 knees. Other associated subjective findings on physical exam were as follows: popping noted in 47 knees, catching in 20 knees, locking in 19 knees, and crepitus in 19 knees.

Sixty-seven of the 80 knees were diagnosed with

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**Table 1. Suspected synovial-plical complex location based on physical exam and verified with arthroscopy**

<table>
<thead>
<tr>
<th>Location of plica(e)</th>
<th>Number</th>
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<tbody>
<tr>
<td>Medial</td>
<td>20</td>
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<tr>
<td>Lateral</td>
<td>15</td>
</tr>
<tr>
<td>Superolateral</td>
<td>14</td>
</tr>
<tr>
<td>Superior</td>
<td>3</td>
</tr>
<tr>
<td>Multiple Locations:</td>
<td></td>
</tr>
<tr>
<td>Medial + Lateral</td>
<td>7</td>
</tr>
<tr>
<td>Medial + Superolateral</td>
<td>2</td>
</tr>
<tr>
<td>Medial + Superior</td>
<td>2</td>
</tr>
<tr>
<td>Lateral + Superior</td>
<td>2</td>
</tr>
<tr>
<td>Medial + Superior + Lateral</td>
<td>1</td>
</tr>
<tr>
<td>Medial + Superior + Lateral + Inferomedial</td>
<td>1</td>
</tr>
<tr>
<td>None</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>70</strong></td>
</tr>
</tbody>
</table>
symptomatic synovial-plical complex preoperatively by the physical and were subsequently confirmed by arthroscopy. Nine knees carried a false negative diagnosis in that the synovial-plical complex was not identified until arthroscopy but plicectomy and partial synovectomy led to symptomatic relief. One of the false negative patients was lost to follow-up. One patient carried a false positive diagnosis in that the clinical exam indicated the existence of a synovial-plical complex but none was found. The clinical exam carries a sensitivity of 83.8% and a positive predictive value of 98.6%. Specificity was not calculated because the exam technique was not performed on asymptomatic individuals and no asymptomatic individuals underwent arthroscopy.

Of the 78 patients that returned for follow-up, all reported symptomatic relief in the short-term with average follow-up of seven weeks (range 2-36 weeks). Four patients required manipulation under anesthesia after the plicectomy and partial synovectomy in order to regain their motion, with an average time of nine weeks after the original procedure.

**DISCUSSION**

There is a paucity of literature describing symptomatic plicae that are not located in the medial parapatellar region. Our results suggest that while the symptomatic medial parapatellar plica plays a role in the majority of patients with symptomatic synovial-plical complex, the associated sensitive synovial tissue that often accompanies these plical bands are often found in multiple parapatellar locations which lead to the development of the symptomatic synovial-plical complex.

One of the most important steps in correctly diagnosing a symptomatic synovial plica is receiving a thorough and accurate history of the patient’s anterior knee pain. Patients may note a traumatic episode at which point they began to notice pain, others may describe a history of athletic activity or repetitive flexion/extension of the knee, and some may not be able to note any particular event. Our cohort of patients showed an even distribution of inciting events among these three categories that were used. Past surgical treatments, including arthroscopic procedures, in the knee joint have been shown to increase the risk of a symptomatic plica. Twenty-five of our 79 knees with verified synovial-plical complex (32%) had at least one previous knee operation prior to their plicectomy and partial synovectomy.

Patients often describe chronic pain that progressively worsens over time and is worse with activity or after long periods of sitting or standing. The majority of our patients experienced subtle, painful popping in the parapatellar region suspected to be caused by the symptomatic synovial-plical complex snapping over the respective femoral epicondyle. Painful catching and locking of the knee joint are also commonly noted by the symptomatic synovial-plical complex patient and confirmed by our study. Upon physical examination of the knee, there may be mild swelling, along with quadriceps wasting. The patient will have tenderness where the synovial-plical complex is located in the parapatellar region. The frequency and location of complex described in this study and previous studies can be seen in Table 2.

Patients will often gain relief from symptoms by eliminating the activity that aggravates the plica, whether this is their sport, running, walking, or any other repetitive flexion/extension of the knee joint. Medications such as NSAIDS and other pain relievers are of limited help to the symptomatic-plical complex patient. However, intraarticular cortisone and lidocaine injections often produce immediate relief and can be used as a diagnostic tool. Injections and physical therapy serve as the primary conservative treatment modality for symptomatic plicae. However, conservative treatment has yielded poor results, with success rates between 0%-16% reported in the literature. It was noted that those patients who did well with conservative measures were younger (21.5 years) than the other patients (28.5 years).

Previous literature suggests that while the physical exam may place symptomatic plica in the differential, arthroscopy is required for definitive diagnosis. On the contrary, the clinical exam used in this study demonstrated a sensitivity of 88.6% and a positive-predictive value of 98.6%. The nine incorrect preoperative diagnoses were subsequently identified arthroscopically as follows: six medial meniscus tears, two lateral meniscus tears, and one focal chondral defect on the femur. The single false positive was diagnosed as symptomatic synovial-plical complex prior to surgery but intraoperatively chondromalacia of the patellofemoral joint was the only identifiable pathology. Following arthroscopic plicectomy

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**Table 2. Study comparison of frequency and location of plica(e)**

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Mediapatellar</th>
<th>Suprapatellar</th>
<th>Lateral</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>McCunniff et al.</td>
<td>2013</td>
<td>20 (29%)</td>
<td>17 (24%)</td>
<td>15 (21%)</td>
<td>15 (21%)</td>
</tr>
<tr>
<td>Dorchak et al.</td>
<td>1991</td>
<td>43 (84%)</td>
<td>3 (6%)</td>
<td>4 (8%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Johnson et al.</td>
<td>1993</td>
<td>12 (27%)</td>
<td>42 (48%)</td>
<td>7 (16%)</td>
<td>32 (69%)</td>
</tr>
</tbody>
</table>
and partial synovectomy, relief of preoperative symptoms are typically noted 2 to 4 weeks postoperatively. Because of this, our analysis did not use follow-up data from patients within two weeks of surgery. For the two patients lost to follow-up, relief of preoperative symptoms cannot be assumed. Although they were correctly diagnosed with symptomatic synovial-plical complex prior to arthroscopic confirmation, we cannot assume that the excision of the complex led to the relief of their symptoms. In this case, the sensitivity of the clinical exam would be 89.6% with a positive predictive value of 98.5%.

We excluded patients with secondary synovitis from chondromalacia, osteoarthritis, and others where one can envision the debris causing a reaction from the normal synovium, creating false positive findings on clinical exam for our synovial-plical complex.

LIMITATIONS

True negative patients in this report were not investigated because we did not prospectively record arthroscopic findings in patients with a history and physical suggestive of an etiology other than the synovial-plical complex. Such etiologies including rheumatoid arthritis, severe chondromalacia, or patellofemoral osteoarthritis. While our focus was providing immediate relief of clinical symptoms post-operatively, a limitation of this study is the short-term follow-up, with a mean postoperative follow-up at 7 weeks. Dorchak et al. addressed long-term results following plicectomy of plica limited to the medial shelf, describing 51 patients, 38 (75%) with excellent or good results at an average follow-up of 47 months. All patients in this cohort had improved clinical outcome scores postoperatively compared to preoperatively. Hardaker et al. reviewed the results of plicectomy of plica in all locations and reported excellent or good results in 97% of 61 patients at an average follow-up of 19 months.

While videos are available for the complete findings on physical exam, this journal does not have the online capability at this time.

CONCLUSION

Our findings suggest that a careful physical exam can correctly identify the presence of the symptomatic synovial-plical complex. Several authors have suggested that the clinical diagnosis of a pathological plica is one of exclusion and arthroscopy is the only way to verify or disprove a symptomatic synovial-plical complex. However, we have demonstrated a unique physical exam that is reproducible and can accurately diagnose the congenitally present, symptomatic synovial-plical complex. We have also demonstrated causality because the surgical removal of the synovial-plical complex in recalcitrant cases brings immediate relief of the pain syndrome. The existence of the symptomatic synovial-plical complex should always be made preoperatively in order to avoid the errors of the past.

REFERENCES

ABSTRACT:

Background: The tibial tubercle-trochlear groove measurement (TT-TG), which measures the lateral offset of the tibial tubercle relative to the trochlear groove of the femur, has been utilized as an intraoperative tool to help establish maximum patellofemoral congruency in patients who suffer from patellar instability. We have previously published our approach of establishing how far to transfer the tibial tubercle using intraoperative femoral nerve stimulation in order to achieve congruency from 0-30° of flexion. The technique and clinical outcomes have previously been published in this journal and elsewhere. Here we describe the use of the TT-TG distance to determine how far to transfer the tibial tubercle to achieve our goals and have found that it varies according to the clinical exam features.

Purpose: We intended to determine the effectiveness of using the preoperatively established TT-TG to predict the degree of intraoperative medialization of the tibial tubercle to achieve our goal of establishing dynamic congruency of the patella in the trochlear groove when using the previously described femoral nerve stimulation method of estimating dynamic tracking of the patella.

Methods: From the study group of patients used in other publications, we examined 20 knees in 18 patients who had a history of recurrent lateral dislocations and underwent a Fulkerson tibial tubercle transfer. Each knee was dynamically assessed preoperatively by obtaining an MRI at 30° of flexion and complete hyperextension while voluntarily contracting their quadriceps. These were then compared to the intraoperative transfer of the tibial tubercle required to achieve maximum congruency when the femoral nerve was stimulated. We then looked at the preoperative TT-TG measurement to determine its role in predicting what was required at achieving congruency in the context of the quad active MRI findings.

Results: Thirteen knees preoperatively demonstrated a positive J-sign defined as the patella subluxated greater than or equal to 5mm lateral in full extension compared to 30° of flexion. In these patients, the TT-TG was accurate if the distance medialized was 1:1 with the measured TT-TG. In 7 out of the 20 knees, the patella demonstrated a false negative J-sign where the patella was radiographically subluxated at 30° of flexion as well as at hyperextension. In this group, the TT-TG underestimated the transfer required for congruency on average 5mm even when using the 1:1 ratio.

Conclusions: The preoperative use of the J-sign is of value when determining the role of the TT-TG measurement and estimating the distance required to intraoperatively achieve congruency when using the femoral nerve stimulation technique. Those that demonstrated a positive J-sign of 5mm or greater, a 1:1 ratio of TT-TG to medialization is most reliable at establishing congruency of the patellofemoral joint. Whereas, those that demonstrated a false negative J-sign even the 1:1 ratio remains inadequate at producing congruency and more medialization is required.

Level of evidence: Level III, Retrospective Observational/Comparative Study

INTRODUCTION

Patellar maltracking and instability are largely thought to be the result of an imbalance between bone morphology, soft tissue, and muscular action. In order to surgically correct patellar instability and recurrent dislocations there are numerous options including soft tissue balancing, tibial tubercle transfer, trochleoplasty, as well as rotational osteotomy of the femur14. At our institution, the most common procedure performed to treat severe maltracking is an anteromedialization of
the tibial tubercle to align the extensor mechanism of the knee thus allowing the patella to glide smoothly within the confines of the trochlear groove. The senior author has previously employed the use of femoral nerve stimulation to intraoperatively estimate the amount of correction required to achieve complete congruency of the patella tracking in the trochlear boundaries of the femur from 0° to 30° of flexion.

Currently, as a preoperative assessment of how far to transfer the tibial tubercle intraoperatively, most surgeons order a preoperative CT scan or an MRI to determine the lateral offset of the tibial tubercle relative to the trochlear groove (TT-TG distance). Intraoperatively, we consider the TT-TG distance to help guide placement of the tibial tubercle, even though our final placement of the tibial tubercle is based on maximal patellofemoral congruency during active quadriceps extension when the femoral nerve is stimulated. It is our goal to reach complete congruency in this dynamic condition.

The purpose of our study was to determine the effectiveness of using the preoperatively established TT-TG to predict the degree of intraoperative medialization of the tibial tubercle to achieve our goal of establishing dynamic congruency of the patella in the trochlear groove when using the previously described femoral nerve stimulation method of estimating dynamic tracking of the patella.

The goal of our analysis included: 1) To compare our preoperative TT-TG calculations to the actual medialization required for congruency when nerve stimulation of the quadriceps was employed between 30° of flexion and hyperextension and 2) To establish the role of the J-sign in the application of the TT-TG value.

Our hypothesis is that the preoperative quad active MRI-based J-sign assessment plays a significant role in the use of the TT-TG measurement for our purposes of establishing intraoperative femoral nerve-based congruency of the patellofemoral joint.

**MATERIALS AND METHODS**

*Imaging*

We retrospectively identified 20 knees in 18 patients who had a history of recurrent lateral dislocations and obvious patellofemoral maltracking who had undergone Fulkerson tibial tubercle medializations between 2008 and 2011. The average age in the patient population was 23 years with a range of 13-41 years, 11 of which were females and 9 were males. In order to be considered for the study, the patients had to provide consent and must have had all MRI scans prior to surgery that were required for the study (quad active 30° of flexion and full extension as well as full length axial MRI scans from hip to ankle).

Preoperatively, the patients were examined clinically for congruency of the patella in relation to the trochlea of the femur at 30° of flexion and complete hyperextension of the knee. This was objectively quantified by obtaining an MRI with the quadriceps contracted and the leg held at 30° of flexion and at complete extension and measuring the relationship of the lateral aspect of the patella to the lateral aspect of the trochlea of the femur, known as the lateral patellar edge (LPE). Duchman and colleagues described the LPE as the most reliable measurement for quantifying the clinical finding of the J-sign.

We also obtained a full length lower extremity scan from the hip down to the ankle joint. With this scan, the femoral torsion, tibial torsion, and overall alignment of the lower extremity were measured to look for other potential causes of maltracking.

**Measurements**

*TT-TG:* The TT-TG measurement measures the lateral offset of the tibial tubercle relative to the trochlear groove of the femur. An MRI scan was done of the entire lower extremity from the hip to the ankle joint with the leg lying on the table passively positioned in full extension. A reference line was drawn on the posterior aspect of the condyles. A second line was drawn perpendicular to the reference line and through the deepest part of the trochlear groove. A third line was drawn parallel to the second line but through the most anterior aspect of the tibial tubercle. The distance between the second line and the third line along the reference line is the measured TT-TG. Our TT-TG was accurately measured according to Dejour et al. but instead of using CT as they described we used axial MRI images. Schoettle et al. demonstrated that there is no difference between CT and MRI in determining TT-TG distance accurately.

*J-Sign:* The J-sign is a clinical finding that describes the route the patella takes as the knee goes from 30° of flexion to full extension during quadriceps contraction. As described by Duchman et al., we quantified the clinical finding of the J-sign based off of the preoperative quad active MRI images that were taken with the quadriceps isometrically contracted and the leg held at full extension and 30° of flexion. First, a horizontal reference line was drawn along the most posterior aspect of the condyles. A second line was drawn perpendicular to the posterior condyle reference line intersecting the most superior aspect of the lateral condyle. A third line was drawn parallel to the second line; however, instead of intersecting the outer edge of the trochlear groove, this line touches the lateral aspect of the patella. The distance between these lines is the lateral patellar edge (LPE) distance. We modified the LPE slightly by taking into consideration the patellar tilt. This modified LPE measurement as depicted in Figures 1 and 2 was done.
at the 30° flexion angle and full extension to assess the lateral movement of the patella as the leg moves from 30° of flexion to full extension.

If the patella was subluxated by 5mm or more in full extension compared to 30° of flexion, then those were categorized as a “positive” J-sign as shown in Figure 1. On the other hand, there were others that were subluxated throughout 30° of flexion and full extension as shown in Figure 2. In these knees, the patella never medializes as the leg goes from full extension to 30° of flexion. On clinical exam of the J-sign, this would be found to be a “false negative” J-sign. In this study, this group was classified based on if the patella was displaced laterally by less than 5mm in full extension compared to 30° of flexion. For the purpose of our study, rather than being concerned with the congruency of the patella with the trochlea at 30° of flexion and full extension, we concentrated on the trajectory of the patella from 30° of flexion to full extension so that we could correlate the clinical exam features of the J-sign. Table 1 shows the measured LPE in full extension, 30° of flexion, and whether the knee demonstrated a positive or false negative J-sign.

**Surgical Technique**

As described by Lavery et al., prior to surgery all of the patients received a stimulating femoral catheter which was placed near the femoral nerve at the location...
A Clinical and Radiographic Approach for Establishing Proper Tibial Tubercle Transfer

of the inguinal crease. With the patient awake, adequate placement was determined by observing that complete quadriceps contraction had been achieved through stimulation of the nerve. Under anesthesia, a preliminary assessment of patellar tracking was again made by stimulation of the nerve. A medial parapatellar approach was made to expose the tibial tubercle and patella so that tracking of the patella could be directly assessed. In order to allow for a “free body” analysis of the distance required to obtain congruency with quadriceps activated, the medial patellofemoral ligament (MPFL) and lateral patellofemoral ligament (LPFL) were severed from the patella and an anteromedialization of the tibial tubercle was performed. The tubercle was then transferred according to three measurements: 1) a 2:1 TT-TG to medialization ratio, 2) a 1:1 ratio of the TT-TG measurement, and finally 3) the point of maximum congruency during active quadriceps contraction through stimulation of the nerve and direct observation of the relationship of the patella to the trochlear edges throughout the 30° of flexion to complete extension motion. The 2:1 and 1:1 TT-TG to medialization ratios are illustrated in Figure 3.

Table 1 shows the lateral patellar edge (LPE) distance during full extension and in 30° flexion for each knee. The second to last column is the difference between column 2 and 3 and is used to define which group each knee belongs; it is either a false negative J-sign (any value 5mm or less) or shows a positive J-sign (any value greater than 5mm).

<table>
<thead>
<tr>
<th>Knee Number</th>
<th>Full Ext LPE (mm)</th>
<th>30deg Fxnn LPE (mm)</th>
<th>Full Ext - 30deg Fxnn LPE (mm)</th>
<th>Positive or False Negative J-sign</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>False Negative</td>
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<tr>
<td>20</td>
<td>17</td>
<td>8</td>
<td>9</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Figure 3 illustrates the measured TT-TG distance of 20mm (left), the 1:1 TT-TG to medialization ratio so medialization is 20mm or the same distance as the measured TT-TG (middle), and the 2:1 TT-TG to medialization value so medialization is 10mm or half the distance of the measured TT-TG (right).
RESULTS

In 13 out of the 20 knees, the patella was subluxated at full extension, but retracted toward the trochlear groove at 30° of flexion with the quadriceps contracted before and during surgery demonstrating a positive J-sign. In this group, the TT-TG was accurate at predicting the medialization if the distance medialized was a 1:1 ratio. In using the 2:1 ratio as the transfer distance, 100% of the time it did not correct or eliminate the J-sign. The success rate of achieving complete intraoperative dynamic congruency was increased from 0% to 92% when a 1:1 ratio was used when accepting less than a 5mm error. Table 2 shows the measured TT-TG for each knee, the 2:1 ratio, the 1:1 ratio, and the actual distance that the tubercle was transferred at surgery when obtaining maximum congruency during quadriceps contraction.

In the other 7 knees, the patella was subluxated at both 30° of flexion and in complete extension demonstrating a false negative J-sign. In this group, the TT-TG underestimated the transfer required for congruency at 0 and 30° of flexion on average 5mm with a range of 0mm to 12mm even when using the 1:1 ratio. This group required even further medialization of the tubercle to establish congruency using our method.

DISCUSSION

One of the weakest points of any corrective surgery for patellofemoral instability related to maltracking is how much correction is needed. The senior author has developed an approach based on the dynamics of the extensor mechanism of the knee in establishing congruency of the patella tracking within the boundaries of the femoral trochlea as the knee traverses from extension to early flexion5-8. The distance required for our intraoperative goal is based on the TT-TG measurement; however, it has been our experience that this measurement is not always sufficient for our purposes. We utilized the preoperatively measured TT-TG and modified LPE to determine the amount of medialization required at surgery. It is our belief that this gives consideration to the bony anatomy as well as muscular action. In addition, we give consideration to these factors during surgery by utilizing intraoperative femoral nerve stimulation to activate the quad muscle with the patient under anesthesia. We believe that by considering the active properties of the joint that the tibial tubercle transfer placement is better than if we considered only passive properties of the joint without femoral nerve stimulation. By examining the dynamic properties of the joint both preoperatively and intraoperatively, it is reasonable to think that the tibial tubercle placement would be best at maximizing patellofemoral congruency in the postoperative knee as indicated in the articles by Duchman et al. and Mellecker et al5,8.

In this study, the transfer of the tubercle is greater than is commonly performed; however, the intent of this article is solely to describe the use of the TT-TG to achieve our goal of dynamic congruency. Given the TT-TG values for the normal population, Dejour et al. recommends that the goal of tibial tubercle transfer is to reduce the TT-TG to between 10 to 15mm10. In our study, we found that this was not adequate to achieve complete congruency with femoral nerve stimulation. Our findings suggest in the population with a positive

Table 2 shows the preoperative measured TT-TG for all 20 knees, the 2:1 ratio predicted medialization value, the 1:1 ratio predicted medialization value, and the actual value medialized when finding maximum congruency intraoperatively during femoral nerve stimulation. The values in parentheses correspond to the amount in which the prediction was off of the intraoperative medialized value (negative=underestimates, positive=overestimates). Knees 1-7 demonstrate the false negative J-sign, whereas knees 8-20 are knees that show a positive J-sign. The 2:1 ratio underrepresented the medialization on average by -12.8mm, whereas the 1:1 ratio underrepresented the medialization on average by 1.9mm. Overall, trends show that the 1:1 ratio is best when patients show a positive J-sign preoperatively (knees 8-12); however, in patients that show a negative J-sign the 1:1 ratio consistently underrepresents the actual medialization (knees 1-7).

Table 2 shows the preoperative measured TT-TG for all 20 knees, the 2:1 ratio predicted medialization value, the 1:1 ratio predicted medialization value, and the actual value medialized when finding maximum congruency intraoperatively during femoral nerve stimulation. The values in parentheses correspond to the amount in which the prediction was off of the intraoperative medialized value (negative=underestimates, positive=overestimates). Knees 1-7 demonstrate the false negative J-sign, whereas knees 8-20 are knees that show a positive J-sign. The 2:1 ratio underrepresented the medialization on average by -12.8mm, whereas the 1:1 ratio underrepresented the medialization on average by 1.9mm. Overall, trends show that the 1:1 ratio is best when patients show a positive J-sign preoperatively (knees 8-12); however, in patients that show a negative J-sign the 1:1 ratio consistently underrepresents the actual medialization (knees 1-7).

<table>
<thead>
<tr>
<th>Knee</th>
<th>Measured TT-TG (mm)</th>
<th>2:1 Ratio (mm)</th>
<th>1:1 Ratio (mm)</th>
<th>Nerve Stimulation (mm)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>20</td>
<td>10 (-18)</td>
<td>20 (8)</td>
<td>28</td>
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J-sign of greater than or equal to 5mm measured by quad active MRIs that one should medialize the tubercle the entire measured TT-TG (1:1 ratio). If the J-sign measurement is <5mm then even the 1:1 ratio was inadequate and an additional medialization to achieve complete congruency was needed.

From our results, we made the conclusion that in the false negative J-sign group, the 1:1 TT-TG to medialization ratio remains inadequate to reliably produce congruency when the muscle is stimulated. We tried to hypothesize what makes the patella track in this way, and why when it does that it requires further medialization than when the patella shows a positive J-sign. It is our belief that the false negative J-sign group suffers from more severe maltracking because the patella does not appear to engage into the confines of the groove. Given the more severe tracking, the requirement for further medialization is needed to realign the extensor mechanism of the knee to maximize congruency. It was to no surprise that we did not find any specific bony anatomic differences between those that demonstrated a positive J-sign or false negative J-sign. The only conclusion we could make was that those that demonstrated a false negative J-sign needed more medialization of the tubercle. Interestingly, when reading through the intraoperative notes on each of the knees, in the false negative J-sign group, notes were made by the attending surgeon that many of these knees had an oblique takeoff angle of the quadriceps tendon compared to those that showed a positive J-sign. We understand that this was mentioned subjectively and that no objective data was obtained in regards to this finding, but it is a future goal of ours to analyze the takeoff angle of the quadriceps tendon with respects to the femur to objectively verify these intraoperative findings.

CONCLUSION

Given our goal of achieving complete congruency, we made three general conclusions: 1) The 2:1 ratio of TT-TG to medialization is always inadequate regardless of the group to create maximum patellofemoral congruency at both 30° of flexion and extension with the quadriceps contracted, 2) In the group that demonstrated a positive J-sign, a 1:1 ratio of TT-TG to medialization is more reliable, and 3) In the population of patients where the patella remains subluxated at 30° of flexion and full extension (false negative J-sign), even the 1:1 ratio remains inadequate to reliably produce congruency when the muscle is stimulated. Typically, these knees required more significant medialization than the 1:1 ratio.

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REFERENCES:

ABSTRACT

Background: Patellofemoral instability is a complex problem with most previous treatment plans addressing static alignment and static stabilizers. Although the quadriceps muscles are known to affect the tracking of the patella, they are rarely taken into account during a surgical procedure.

Purpose: The purpose of this study is to determine the two year minimum results of 37 knees which received a Southwick-Fulkerson Osteotomy and MPFL repair or reconstruction both under the guidance of femoral nerve stimulation.

Methods: Patients underwent a Southwick-Fulkerson Osteotomy and either medial patellofemoral ligament (MPFL) repair or reconstruction using femoral nerve stimulation as a means of dynamic intraoperative evaluation of patello-femoral congruity in terminal extension. Two year minimum outcomes of 26 patients, 31 knees (84% return rate) were evaluated using KOOS and IKDC scores, and physical exam features of apprehension and assessment of dynamic tracking in the last 30 degrees of knee extension. Variables were evaluated with t-tests and ANOVA.

Results: 29/31 knees reported they were happy with the procedure and reported they would do it again. One knee (3%) reportedly “redislocated”, but did not return for verification by exam. 30/31 had non-pathologic tracking. One knee displayed a small but residual J sign. 4/16 knees with MPFL repair only and 0/15 with MPFL repair and reconstruction exhibited a positive apprehension sign. Increased age and apprehension were correlated with lower outcome scores.

Conclusions: Intraoperative femoral nerve stimulation is an effective way of evaluating patellar tracking intraoperatively that leads to 97% stable patellae with near congruent patello-femoral tracking. MPFL reconstruction is superior to MPFL repair in eliminating the persistence of the apprehension sign.

Key terms: patellofemoral instability, intraoperative femoral nerve stimulation, MPFL reconstruction, dovetail.

INTRODUCTION

The Southwick-Fulkerson Osteotomy is a novel surgical procedure designed to fully correct patellofemoral incongruity in a manner that is sufficiently stable to withstand quadriceps contraction under anesthesia. Chronic recurrent patellofemoral instability is a pathologic condition often involving maltracking of the patella in the groove of the femur (trochlea) that leads to subluxation or frank dislocation episodes. Patellofemoral instability can stem from a multitude of problems which usually include a variety of anatomical defects of the lower extremity. These defects may involve dynamic and passive forces.

The mix of issues causing this problem often makes patellofemoral instability difficult to treat. Over 100 different surgical procedures have been devised and used to treat this single issue of patellar instability. The primary problem with obtaining success with any one treatment method stems from the multi-factorial nature of each patient’s pathology. Not only are the contributing factors of each patient’s instability different, but current clinical evaluation techniques focus on static restraints of the patellofemoral joint and do not take into account the role of the dynamic muscle-tendon anatomy. Based on our review of the English speaking literature, other than VMO advancements, the role of dynamic movement associated with muscle contraction has never been a major focus.

The procedure introduced in this case series combines the advantage of anterior-medialization of the tibial tubercle (Fulkerson) with the added tubercle stability realized by the (Southwick) proximal dovetail shelf architecture. To correct for high incidence of apprehension associated with isolated distal transfer techniques, in this study the tubercle transfer was done in combination with either a medial patellofemoral ligament (MPFL) repair alone or reconstruction to supplement the repair.
Currently, transfer distance is calculated preoperatively through the tibial tubercle – trochlear groove (TT-TG) measurement of the bony alignment on CT or MRI or intraoperatively with passive attempts to force the patella to escape the trochlear groove through various combinations of varus and valgus and internal and external rotation. Interestingly, proponents of this technique are hesitant to fully correct the tracking of the patella in the trochlear groove for fear of overcorrection and medial dislocation. However, we have hypothesized that for many patients, residual post-operative maltracking stems from dynamic forces created by the muscle which cannot be evaluated through these methods. To avoid this problem, we teamed with the anesthesia department in developing a method of intraoperative femoral nerve stimulation that allows for dynamic tracking to be assessed throughout the case. Using this approach, it is the intraoperative goal to achieve complete congruity of the patella in the confines of the trochlear borders in the initial phases of flexion of the knee. We also hypothesize that reconstruction of the MPFL will eliminate the sensation of apprehension often found in patients where congruity is established but only repair of the compromised static stabilizer is attempted.

The purpose of this study is to retrospectively evaluate the two year minimum results of 37 knees which received a Southwick-Fulkerson Osteotomy and MPFL repair or reconstruction under the guidance of femoral nerve stimulation in order to evaluate the effectiveness of this technique in determining tubercle transfer distance.

METHODS

I. Patient Population

This study received institutional IRB approval. Thirty-seven knees (17 right and 20 left) in twenty-six patients underwent a Southwick-Fulkerson Osteotomy between November 2002 and April 2007. This included all patients who underwent a Southwick-Fulkerson Osteotomy and MPFL repair or reconstruction under the guidance of femoral nerve stimulation and were at least two years post-operative. The decision to repair or reconstruct the MPFL was made on a chronological basis, creating a prospective randomized study. In total, the first 16 patients received an isolated MPFL repair and the next 21 patients received an MPFL repair augmented with an allograft reconstruction. All patients received the same post-operative instructions and rehabilitation.

Inclusion criteria included a history of recurrent dislocations with evidence of maltracking through patellar subluxation in the merchant view and/or a grossly positive J-sign. TT-TG measurements were consistent with lateral malalignment and ranged from 12-24 mm on CT imaging. This study only included patients undergoing the combination of Southwick-Fulkerson Osteotomy and MPFL repair or reconstruction under the guidance of femoral nerve stimulation. Exclusion criterion included: no patient requiring rotational femoral osteotomy, independent Fulkerson-Southwick osteotomy, independent MPFL reconstruction or repair, and no patient with a previous diagnosis of a generalized soft tissue hyperlaxity syndrome.

II. Catheter Placement

As previously described by Lavery et al., under local anesthesia, a femoral nerve catheter is placed directly on the nerve through a needle and attached to a small stimulator. Ultrasound guidance is used at the discretion of the anesthesia team. The catheter is adjusted until the extensor muscles twitch with stimulation between 0.3-0.5 mA. The femoral nerve catheter is not dosed prior to surgery in order to be able to stimulate the nerve during the procedure. With the frequency set to 50 Hertz, the intensity is slowly increased until a tetanic stimulation was obtained. The intensity is increased slowly to prevent post-operative neuropathy, which can be inflicted with high intensities.

III. Surgical Correction

An incision is made extending from the proximal portion of the medial femoral condyle to the distal end of the tibial tubercle. The patellar tendon is identified and clearly defined. At this point, lateral structures up to the mid-portion of the patella and medial structures up to the vastus medialis are released and the femoral nerve is stimulated. This exposure is necessary to directly assess the tracking of the patella in relationship to the trochlear borders while not under the influence of soft tissue structures. Tracking is dynamically assessed with the quadriceps muscle extending the knee from 30 degrees of flexion to full extension. A pin is placed through the frontal plane of the tibial tubercle at an angle varying between 0 and 30 degrees in order for the tubercle to move anteriorly as it is medialized. The pin is used as a guide for the oscillating saw. The osteotomy separates the bone into approximate anterior one third and posterior two thirds, see figure 1. This cut begins at the proximal portion of the patellar tendon insertion and extends to the distal portion of the tubercle. The cut narrows as it extends distally, but is never completed in order to have a distal hinge bridging the tibial crest with the osteotomy. A small sagittal saw is then used to create a dovetail at the proximal portion of the initial cut. This overhanging ledge provides an additional point of stabilization. A bone tamp is used to transfer the tubercle anteriomedially to the TT-TG measurement previously measured on CT. Three temporary pins are placed to hold the tubercle in position and manual pressure is applied while the femoral nerve is being stimulated.
IV. Nerve Stimulation

Prior to the osteotomy, the nerve is stimulated in order to evaluate the corrected tracking of the patella. Stimulation is begun with the knee flexed 90 degrees and the leg is guided through the contraction to full extension. This replicates the force of the quadriceps as if the patient were extending their knee while awake. Throughout range of motion, the surgeon directly visualizes the patella in relation to the lateral and medial trochlear edges in an effort to determine the ideal tubercle position. Once the osteotomy has been made, the action of the quadriceps is only tested through the terminal 30 degrees of extension to closely assess the achievement of congruity in this critical range.

V. Secure Tendon Fixation

Once appropriate placement has been determined, two or three bicortical screws are placed through the osteotomy fragment and into intact bone. Fluoroscopy is used to evaluate the adequacy of screw purchase on the tibia.

VI. Medial Patellofemoral Ligament Reconstruction

Prior to beginning reconstruction of the MPFL in a two-tailed manner as described by Fithian\(^\text{8}\), the original medial and lateral ligaments and capsule are plicated to allow for tissue balancing adjustments to be made that take into account the new tracking of the extensor mechanism. This completes the repair of the lateral structures. For MPFL reconstruction, the isometric anchor point on the distal medial femoral condyle is first identified. It is located distal to the adductor tubercle at the border of the vastus medialis and the anterior margin of the MCL. A pin is passed through the femur for placement of the ligament. If pin placement is acceptable, a suture is looped around the pin with the ends extending onto the medial patellar edge at a) its midportion and b) the junction between the middle and superior thirds. The knee is passively moved to test for the adequacy of tissue balancing and also evaluated dynamically through nerve stimulation. If these are satisfactory, a 6-7 mm tunnel for the hamstring allograft is drilled and it is fixed in place with an endobutton on the lateral side of the femur. Suture anchors are then drilled into the patella. The stimulator is again used to validate the balanced points for attachment of the allograft tendon and to confirm the patella is not over-constrained. When these points have been determined, the ends of the allograft are sutured to the top of the patella using Krakow stitches.

If a repair is elected, the medial capsule including the original MPFL is imbricated.

VI. Post-operative Protocol

Patients are able to partial weight bear immediately following the procedure. Crutch use is recommended for two weeks and brace use for six weeks. Range of motion from 0 to 90 degrees is allowed immediately postoperatively. A safe, rapid return to full weight bearing is allowed for two structural reasons. First, the osteotomy is not as deep in this procedure as originally described by Fulkerson. Second, superior fixation achieved by the five point fixation proven intraoperatively to be able to withstand the forces of the quadriceps activation assures security of the construct in the early post surgical period. This allows the patient to be ambulatory in the early post-operative period compared to the six week delay reported with the Fulkerson technique of fixation.

As a precaution, patients are cautioned to remain within the envelope of comfort and evaluated radiographically at 2 and 6 weeks post-operative to assure they are not developing a fatigue fracture and to ensure proper healing of the tibia. Physical therapy, consisting of range of motion exercises and gradual muscle strengthening, is recommended for six weeks with at home continuation.
VII. Assessment of Results

These patients were asked to return to clinic for follow-up and to complete functional evaluation forms, including the International Knee Documentation Committee functional evaluation form (IKDC) and Knee Injury and Osteoarthritis Outcome Score (KOOS).

The more aggressive fixation used in this procedure has been observed to lead to a dramatically more comfortable early post-operative course including earlier return to weight bearing and everyday activities such as work and driving. We therefore included questions to reflect these outcome measures in our evaluation.

Patients also received a physical exam to determine clinical outcomes by both the primary surgeon (JPA) and a member of the research team (CJM). If disagreements occurred, the patient was re-evaluated by both to determine an agreed upon result. Patellar tracking was observed in a sitting and supine position, and while walking. The "J-sign", which was invariably present before the surgery was evaluated as a sign of corrected tracking. The "J-sign" is the movement of the patella past the lateral femoral condyle when the knee is in full extension. Patients were also evaluated for an "S-sign", which we defined as the movement of the patella medially prior to moving laterally past the lateral femoral condyle. With the patient relaxed and with their knee flexed slightly, the examiner looks for apprehension when attempting to displace the kneecap laterally. This was done with maximum effort, placing 15-20 pounds of force directly lateral at both 20 degrees of flexion and full extension. Range of motion and the presence of crepitus were also recorded.

STATISTICAL ANALYSIS

All information was analyzed through independent variable t-tests. Multi-variable analysis was done with the use of Chi squares. A p-value of less than .005 was determined to be significant.

RESULTS

Six knees were lost to follow-up, leaving thirty one included in the study (84% return). Sixteen received MPFL repair and fifteen were supplemented with an MPFL reconstruction. The patient group consisted of seven males and nineteen females. Average time of follow-up was 3.72 years, ranging from 2 years to 5.95 years. The average age at the time of surgery was 24.06 years old (range 14-47). Twenty-four patients returned to clinic. The remaining seven completed the survey through mail correspondence with clinical exam findings taken from our most recent clinic note and confirmed through phone interviews.

I. Patient Satisfaction:

Twenty-nine knees (93.5%) reported they considered the surgery successful and would repeat it.

II. Transfer distance:

In 8 of the 31 cases, the pre-operatively determined distance was altered due to intraoperative tracking. This added distance varied from up to 5mm in this study group. None were decreased.

III. Exam findings:

One patient, or 3.22%, reported a subsequent dislocation. She did not return for evaluation, but was seen by an outside orthopedic surgeon who reported her patella to be adequately stabilized. None reported subluxation. Thirty patients had correction of their J-sign to the point of being grossly described as having “relatively normal” tracking, 96.78% of the 31 followed-up. “Perfect tracking” (total absence of J-sign) was present in 14 of the 31 patients, 45.16%. A slight J-sign, lateralization of only a few millimeters with hyperextension, was noted in eight patients, 25.8%, and an “S” sign (where the patella was observed to move medially from 30 to 10 degrees of flexion and then laterally to neutral in complete extension) was noted in another eight patients, 25.8%. This left one patient, 3.22%, demonstrating an obvious J sign of more than five millimeters. The existence of the obvious J sign was present only after suffering a post-operative trauma.

IV. Functional Outcome Scores:

Postoperative scores were obtained for all 31 knees. Overall, the mean KOOS scores were: symptom 52.4 (sd ±13.9), pain 79.9 (sd±20.28), ADL 85.34 (sd±18.24), sport 61.61 (sd±31.36) and QOL 64.11(sd±24.68). For the entire group, the mean postoperative IKDC score was 68.4 (sd±22.78). Unfortunately, preoperative KOOS and IKDC scores were available in only 13 of our 31 knees.

For the 13 knees with pre-operative scores, pre-operative averages were symptom 55.65, pain 55.69, ADL 62.53, sport 27.66 and QOL 36.64. Post-operative averages improved to symptom 52.64, pain 84.85, ADL 60.35, sport 64.6 and QOL 68.4.
V. MPFL repair vs. MPFL reconstruction:
An MPFL ligament reconstruction was found to be statistically superior to an MPFL repair in every section of KOOS except quality of life and IKDC outcomes (table I). MPFL reconstruction also correlated with decreased patient apprehension. Apprehension was associated with a decreased KOOS symptom score (p=.0284).

VI. Recovery time milestones:
Recovery periods were measured in days. Patients continued to use their crutches, at least part time, for an average of 35.72 (sd±24.98) days and also continued brace use for an average of 59.24 (sd±39.15) days. Patients returned to driving and work an average 52 (sd±67.65) and 73.44 (sd±72.15) days after surgery, respectively. Patients reached their self-declared full recovery at an average 190.03 (sd±122.33) days.

All recovery time milestones were biased to two patients who reported far outlying results as a consequence of neuropathy as a result of the femoral nerve block. Both patients reached a full recovery within a year.

DISCUSSION
In the modern literature, aside from outcome scores, the results of reporting any one technique for patellofemoral maltracking have been limited to a) re-dislocation and b) need for re-operation. There have been no studies in which visually determined, subjective assessment of patellar tracking or apprehension have been reported. When these classic criteria are applied to our study, our results are equal to or superior to most current literature on the treatment of patellofemoral instability at 96.68%, due to one patient reporting a dislocation. However, given our focus on the dynamics of the extensor mechanism, a broader criterion for success was necessary which includes the direct assessment of patellar tracking and the existence of apprehension. Our study has a success rate of 80.6%, when success is defined as near normal tracking, no apprehension, no subluxations or dislocations and did not require a repeat operation. When only the patients receiving the MPFL reconstruction are evaluated, this success rate raises to 93.75%.

Patients were generally pleased with the outcome of their surgery with 93.5% reporting that they both considered the surgery successful and would undergo the procedure again. While the same number of patients were unhappy with one of these outcomes, it is important to note that there was one patient who considered their surgery successful, but would not do it again as well as one patient who did not consider their surgery successful, but would choose to have the procedure again. While this is not a common outcome measure, Morshuis et al. found only 80% of patients subjectively satisfied at first evaluation, with this number dropping to 65% at an average follow-up of 30.4 months.

Only one patient in our study, 3.22%, experienced an episode of dislocation post-operatively. This matches outcomes of MPFL repair and improves upon the instability reportedly found in patients who received the Elmslie-Tillat procedure. Post-operative KOOS and IKDC scores were improved to a significant level, however, comparison to other studies is difficult due to the difference in outcome measures. Additionally, this procedure was only performed on patients who experienced repeated patellar dislocations and did not include patients who experienced only patellofemoral pain or were one time dislocators, as many MPFL studies include. The closest patient cohort is described in Ebinger et al. In their small pilot study of seven cases, the same criterion of success was used and one dislocation was present. Although this matches the number of dislocations present in this study, it represents a higher percentage of their cohort at 14.28%.

An important finding in the study was the improved outcome of MPFL reconstruction over repair. While most studies agree that attention should be paid to the MPFL, the difference between reconstruction and repair has not been effectively evaluated. MPFL reconstruction has been proven alone to be an effective method of patellar stabilization, however, due to the tendency of the MPFL to tear near its insertion into the femur, repair of the ligament near the patella has been questioned as an effective treatment. Although there is discussion of the downfalls of MPFL reconstruction through over tensioning of the ligament causing increased stress rates on the medial femoral condyle and medial facet of the patella, our results show the superiority in stability and outcome scores. We believe we eliminate this problem through the additional use of the femoral nerve stimulator as an evaluation of ligament placement and graft tensioning on the already transferred extensor mechanism by observing that there is no added tension on the reconstruction imposed by the contracting quadriceps. In addition to post-operative outcome scores, apprehension was decreased with MPFL reconstruction, a sign of more severe malalignment. A previous study of dovetail procedures reported by the senior author found a 20% incidence of retained apprehension signs despite no history of redislocation. The elimination of apprehension found in this study is an important outcome of the procedure as it allows patients to experience more everyday activities without the fear of subluxation or dislocation. A decrease in apprehension also improved KOOS symptom scores. Although these statistics could be interpreted as an
MPFL reconstruction being sufficient for realignment without the additional osteotomy, the authors of this paper continue to believe static repairs will not last if the dynamics behind them remain unchanged14.

While early weight-bearing can have negative effects16, patients included in this study were able to return to successive milestones at equal or improved time than patients undergoing other realignment procedures without complication. While these patients averaged about five weeks (range less than one to 13 weeks) on crutches, most studies describe a protocol of six to eight weeks9. Return to everyday activities, such as driving, were not evaluated in other studies despite their impact on the patients’ perception of the surgery. This study reports an average 190 days, or about six months to a self-reported full recovery. At six months post-operatively in other studies, patients would only be starting to return to running with return to sports occurring at nine to twelve months13. Other recovery milestones could not be found in existing literature, but are provided here as a basis of comparison for future studies. While it is agreed that over-ambitious post-operative protocol can lead to further complications, it is believed that this procedure’s improved placement of the tubercle, in addition to dovetail and double screw fixation led to an improved recovery time. Only a review of MPFL reconstruction without distal realignment matched the post-operative recovery times of this study15.

In conclusion, we feel the intra-operative evaluation of the dynamic knee extensor mechanism during tibial tubercle realignment and MPFL repair/reconstruction provides important information to supplement existing techniques in this difficult patient population. This study has several limitations. These include, but are not limited to: lack of a control group which had the same procedure without the femoral nerve catheter and lack of pre-operative objective scoring measures for all patients included in this study. Further study into the soft tissue anatomy of this cohort is needed to improve upon the understanding of patellar maltracking and instability.

REFERENCES

SINGLE-BUNDLE VERSUS DOUBLE-BUNDLE ACL RECONSTRUCTIONS IN ISOLATION AND IN CONJUNCTION WITH EXTRA-ARTICULAR ILIOTIBIAL BAND TENODESIS

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ABSTRACT

Background: Intra-articular anterior cruciate ligament (ACL) reconstruction has been the primary treatment option for isolated ACL injuries for many years. An anatomic double-bundle reconstruction has been devised in an effort to improve rotational control. The role of the extra-articular iliotibial band tenodesis in ACL injuries has evolved from primary treatment, to an adjuvant secondary procedure, to being used more selectively in revision ACL reconstructions.

Hypotheses: 1) Single-bundle and double-bundle intra-articular ACL reconstructions will both restore pre-injury laxity measurements in an isolated ACL injury cadaver model. 2) The deep iliotibial band structures contribute to rotational control and in a dual ACL + ITB injury cadaver model, ACL reconstruction alone cannot restore rotational control.

Study Design: Controlled Laboratory Design

Methods: 17 fresh frozen cadavers received intra-articular reconstructions, seven single-bundle and ten double-bundle; laxity was measured with the ACL intact/ITB intact, ACL reconstructed/ITB intact, after cutting the ITB, and after an ITB tenodesis procedure; laxity measurements of anterior tibial translation (ATT) and internal rotation (IR) were measured following applications of an anterior shear force, an internal torque and a coupled anterior shear force-internal torque at 30 and 90 degrees of flexion.

Results: Single-bundle and double-bundle ACL reconstructions both restored IR to a native knee state under isolated internal torques and under coupled forces. Both reconstruction techniques also re-established anterior tibial translation to at least the pre-ACL injury level, with over-constraint in the double-bundle subgroup [5.00 (+2.11) to 3.50(+1.18), p-value 0.026] under coupled loads at 30 degrees of flexion. With the individual ACL reconstructions held constant, under coupled forces mean IR increased in the single-bundle subgroup [13.7(+1.1) to 17.6(+1.2), p-value 0.004] and the double-bundle subgroup [9.5(+1.0) to 12.4(+1.0), p-value 0.009] with the cutting of the ITB at 30 degrees. Under internal torque, mean IR increased in the single-bundle subgroup [14.0(+1.0) to 18.4(+1.6), p-value 0.016] with the cutting of the ITB at 30 degrees, while IR increased in the double-bundle subgroup [10.0(+1.3) to 13.4(+1.5), p-value 0.002] under the same internal torque at 90 degrees. With the ACL reconstruction held constant, ATT did not significantly change when the ITB was cut or when it was tenodesed under any specific loading condition.

Conclusion: Single-bundle and double-bundle intra-articular reconstructions were both able to restore internal rotation and anterior tibial translation to at least native knee laxity levels after an isolated laboratory ACL injury. When the ACL reconstructions were held constant, internal rotation statistically increased with the cutting of the ITB under multiple testing conditions in both the single-bundle and double-bundle subgroups.

Key terms: Iliotibial band reconstruction, ACL reconstruction, computer assisted kinematic analysis, ACL+iliotibial band injury

INTRODUCTION

The treatment of ACL injuries has been researched and debated extensively in the literature amongst orthopedic surgeons since ACLs were first repaired in the 1950's. As technology facilitated improvements in surgical technique, ACL treatment options focused on intra-articular variables of graft type, tunnel location, method for drilling tunnels, and number of bundles. The treatment goals of restored knee function and prevention of long-term consequences have remained
The focus of ACL reconstruction has become the restoration of native ACL anatomy. The native ACL is comprised of three bundles, the anteromedial, the posterolateral, and the intermediate bundle. Collectively, the bundles function to act as the primary static stabilizer of anterior tibial translation and internal rotation of the tibia throughout knee range of motion. However, each bundle restricts rotation and translation differently as the knee flexes and extends.

Historically, single bundle graft placement has more closely resembled the anatomical position of the anterior bundle and has not reproduced the position and rotational control of the posterolateral bundle. Rotational stability has always been the most difficult motion to restrict with intra-articular reconstruction because of the intrinsically short biomechanical lever arm of the ACL graft.

Extra-articular reconstructions have the biomechanical advantage for rotational control and have been used in varying degrees to treat ACL injuries for decades. Terry et al. demonstrated that during an injury that resulted in a clinically deficient ACL, 93% of IT bands were also torn. The magnitude of iliobibial band compromise is difficult to assess at the time of injury and its role in long-term success or failure of intra-articular reconstruction is even more unknown.

An in vivo study designed to assess the prevalence and impact of ITB injuries in clinically deficient ACL knees would be difficult to perform. Thus, a laboratory cadaver-based model was made. Within this model, two hypotheses focused on ACL reconstruction were tested. 1) Single-bundle and double-bundle intra-articular reconstructions will both restore pre-injury laxity measurements in an isolated ACL injury cadaver model. 2) The deep iliobibial band structures contribute to rotational control in a dual ACL + ITB injury cadaver model and thus, ACL reconstruction alone cannot restore rotational control.

**METHODS**

Twenty paired fresh-frozen cadaveric knees (63-87 years old) were thawed in a lukewarm water bath 12-18 hours prior to use. Three knees were removed from the testing protocol. Two were removed secondary to computer error resulting in data loss and one for intra-articular tunnel misplacement (Figure 1). All specimens contained at minimum 18 cm of bone and soft tissue proximal and distal to the tibio-femoral joint line. Testing apparatus (Figure 2) rigidly secured cadavers proximally with a clamp around the femur. Poly (methyl methacralate) (PMMA) and a wooden dowel were placed within the intramedullary space of the femur to prevent femur fracture during testing. Flexion and extension was controlled distally by placing PMMA and a wooden dowel with a perpendicularly oriented K-wire within the tibial intramedullary space. Ropes that could be adjusted were secured to the K-wire and anchored to an external structure to allow testing at variable angles of flexion.

Soft tissues covering the tibial shaft were stripped to eight cm distal to the joint line. Exposure of the tibia was performed to allow a specially designed metal ring.

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**Figure 1 - Flow Diagram. Sequence of procedures and kinematic testing.**

**Figure 2 - A) Lateral and B) AP drawing of biomechanical apparatus. C) Oblique photograph of specimen during testing in lab.**
to be anchored to the tibia ten cm distal to the joint line. The center of the ring was aligned with the longitudinal axis of the tibia and the three fixation screws were equally spaced on the ring and tightened to the bone. The 4.15 cm fixed external radius of the ring provided a consistent moment arm for torque application. Tibial torsion was applied via two ropes, which were secured to the outside of the ring. The first rope rotated from the ring anteriorly, while the second rope rotated from the ring posteriorly. Each rope was run over freely rotating metal bars, medially and laterally, and connected to 6.1 kg weights respectively (5Nm torque). The heights of the metal bars were adjusted based upon the specimen and the flexion angle to maintain perpendicular alignment of the rotational moments to the longitudinal axis of the tibia. During torque application, both 6.1 kg weights were released simultaneously to equally load the tibial ring.

The anteriorly directed load on the tibia was produced via a 2.5 cm wide cloth strap that was wrapped superficially around the skin and soft tissues of the proximal tibia. The center of the strap was aligned parallel with the joint line three to four cm distal to the tibial plateau. A rope was tied to the front of the strap directly anterior to the joint line. The rope was strung over a freely rotating metal bar whose height was adjusted to maintain an anteriorly directed moment that was perpendicular to the longitudinal axis of the tibia. The distal end of the rope was tied to a 0.2 kg metal hook that held a 9.1 kg sandbag. The 5 Nm torque and 91.2 N anterior shear force were applied to the proximal tibia strap. The 5 Nm torque and 91.2 N anterior shear force were oriented perpendicular to the tibia and were designed to coincide with previously performed ACL biomechanical literature.

Prior to kinematic testing all knees were examined and determined to be stable to varus-valgus stress with no corresponding joint space opening. Lachman and pivot shift tests were also negative. OrthoPilot 2.0 (B/Braun AESCULAP, Tuttingen, Germany) computer-assisted-surgery system was used for obtaining of kinematic data, confirmation of ACL tunnel location, and verification of knee flexion angles. The accuracy of the OrthoPilot system has been documented as 0-1 degree and 0-1 mm19. The use of the OrthoPilot system has been documented as able to reproducibly measure laxity and position of ACL graft tunnels.

OrthoPilot references the knee through rigidly fixed femoral and tibial markers. The femoral marker was placed just proximal to the medial femoral epicondyle and the tibial marker was fixed to the anterior medial surface of the tibia 15-20 cm distal to the joint line. The joint line is assessed by repeatedly cycling the knee through flexion and extension. Additional required intra-articular anatomic reference points were tagged by the laboratory investigator using the OrthoPilot stylus.

Testing Protocol

Four different testing conditions were assessed for each specimen (Figure 1).

1. ACL intact/ITB intact - represents the native knee before injury and reconstructive surgery.
2. ACL reconstruction/ITB intact – represents an ACL reconstructed knee (either single or double bundle) with an uninjured ITB.
3. ACL reconstruction/ITB deficient – represents a combination ACL+ITB injury where only the ACL is reconstructed.
4. ACL reconstruction/ITB tenodesis – represents a combination ACL+ITB injury where both the ACL and ITB were reconstructed.

Assessment of Laxity

Each specimen was evaluated at 30 and 90 degrees of flexion. The OrthoPilot 2.0 CAS system measured anterior tibial translation (ATT) and rotational change of the tibia in reference to the rigidly fixed femur at each testing point. Measurements were based on a zero point made with the femur rigidly fixed proximally and the tibia secured in the desired angle of flexion by distal rope attachment to the tibial intramedullary dowel.

1. Neutral drawer - anterior 91.2 N shear force was applied to the proximal tibia strap.
2. Internal torque - 5 Nm torque was applied to the tibial ring.
3. Coupled anterior drawer-internal torque – anterior 91.2 N shear force was applied in combination with the 5 Nm internal torque.

Intra-articular ACL Reconstruction

Single bundle

The ACL was cut and debrided. A centrally located guide pin in the tibial footprint was used to coincide with the suggested seven to eight mm of distance between the PCL and the guide pin, one knee had six mm of distance22. A ten mm drill was used to create the tunnel. The femoral guide pin was placed trans-tibially by manipulating the flexed knee to accommodate a corresponding ten o'clock or two o'clock position. Tunnel position was confirmed by arthroscopic visualization and supported by the CAS system. A ten mm drill was also used for this tunnel. After drilling, a posterior wall of one to four mm was visualized in all specimens.

In order to eliminate cadaveric tendon inconsistencies as a possible source of error, synthetic rope was used. Elongation of several samples of ten mm diameter synthetic rope were tested. These ropes were secured at one end and weight was hung from the other end. No time related graft elongation was measured. A 15
The femoral guide pin was positioned with the footprints and avoided potential complications noted by Giron et al. In an effort to reproduce the native AM and PL femoral tunnel was drilled through a medial joint line to the tibial plateau and ten mm anterior to the PCL. The tibial footprint centered at 45-52% of the medial width of the tibial plateau and ten mm anterior to the PCL. This tunnel was always re-visualized to confirm placement and its ability to resist deformation. Once the graft was placed, the knee was flexed and extended in external rotation three times to assess graft isometry before securing. The graft was tightened and secured at 30 degrees of flexion using two perpendicularly oriented hemostats clamped directly against both the tibia and the femur. Graft tension was arthroscopically visualized and palpated with a curved probe after fixation and periodically during kinematic testing to monitor for fixation slippage.

Double bundle

The ACL was cut and debrided. The anteromedial bundle was first made by drilling a guide pin to exit the tibial footprint centered at 45-52% of the medial width of the tibial plateau and ten mm anterior to the PCL. The femoral tunnel was drilled through a medial joint line incision in an effort to reproduce the native AM and PL footprints and avoid potential complications noted by Giron et al. The femoral guide pin was positioned with the use of OrthoPilot between the 1:30 and 2:30 or 9:30 and 10:30 position and was visualized to be within the native footprint. The guide pin was located approximately six to seven mm from the “over-the-top” position.

Both tibial and femoral tunnels were drilled with a five mm drill bit. (Figure 3)

The posterolateral bundle was made by positioning a guide pin within the tibial footprint centered on the tibia at 50-55% of the medial width of the tibial plateau and three to four mm anterior to the PCL. This tunnel was kept lateral to ensure that the tunnels did not converge on one another. A visible bony bridge between the tunnels was always intact before graft placement. The tunnel was always re-visualized to confirm placement within the ACL footprint. The femoral guide pin was placed between the 2:30 and 3:30 or 8:30 and 9:30 position and was approximately eight to nine mm from the “over-the-top” position. A visible bony bridge between the tunnels was always confirmed to be intact before graft placement.

Five mm grafts made of polyester that demonstrated no time dependent elongation were used as the double bundle grafts. These grafts were also secured with two perpendicular hemostats clamped directly against the bone and were tightened in the same dynamic fashion as the single bundle graft. The grafts were tightened in a sequence consistent with Cuomo et al, the posterolateral graft tightened first at 30 degrees and the anteromedial graft tightened second at 75 degrees.

Extra-articular Release and ITB Tenodesis

The deep layers and capsule-osseous fibers of the ITB were released with a sharp knife. These layers were targeted for release because of their high co-injury rate in ACL deficient knees. First, the skin was incised longitudinally over the ITB at the level of the joint line. The anterior border of the ITB was visualized and palpated. A blunt hemostat was used to dissect a plane between the superficial ITB fibers and the deep structures. A scalpel released deep ITB layers parallel to the joint line and capsule-osseous fibers from the femur without compromising posterolateral capsule, anterolateral capsule, lateral collateral ligament or popliteus tendon. Distally, the deep ITB fibers were released from the tibia down to, but not including Gerdy’s tubercle. Tubercle insertion remained intact.

The superficial ITB that had been left intact until this point was used as the graft material for the extra-articular tenodesis, originally described by Losee et al. A 15 mm wide by 120 mm long ITB graft was incised from the most anterior distal aspect of the ITB, with its insertion on Gerdy’s tubercle left intact. Fiberwire was tied with a Krachow stitch to the free proximal end of the dissected graft. A Steinman pin was used to identify the proper anchor point of the tenodesis. This pin was located at the junction of the anterior border of the LCL and the superior edge of the popliteal tendon. The pin location was tested by placing the leg in external rotation, wrapping the graft around the pin, and then ranging the knee from 0 to 90 degrees of flexion. Acceptable pin placement was defined as no shortening of the graft greater than 2 mm during sagittal plane motion. The graft was anchored with a unicortical bone screw to the lateral femoral condyle under maximum tension.

Maximum tension during fixation of the extra-articular reconstruction was used to avoid variations between specimens related to graft tension. Overconstraint was not a concern in this study because the hypothesis was
that the increased laxity observed with ITB compromise would be corrected with a lateral extra-articular procedure. Although clinically, overconstraint is problematic, other studies have shown overconstraint can be avoided by decreasing tension on the graft during in vivo fixation.

Statistical Analysis
Multivariate linear mixed model analysis was used to test the effect on displacement and rotation of varying ITB states in an ACL reconstructed knee. From the fitted model, test of mean contrast was performed to test for mean change in displacement and rotation on ACL reconstructed specimens with ITB intact, ITB deficient, and ITB tenodesis. To account for the multiple tests performed (i.e. four pairwise comparisons), p-value was adjusted using Bonferroni’s method. These comparisons were done separately for single bundle and double bundle ACL reconstructions. The results of the statistical analyses are summarized in Tables 1-3.

**RESULTS**

Isolated ACL Reconstruction (Table 1)

**Single Bundle**
Under all of the variable loading conditions at 30 and 90 degrees of flexion, no anterior translational or internal rotational laxity measurement was statistically different when comparing the native ACL with single-bundle ACL reconstruction results. When assessing for laxity changes from the native ACL state to the ACL deficient state, all laxity measurements statistically increased except for the anterior tibial translation data at 90 degrees of flexion. These results demonstrated that knee laxity measurements increased with the cutting of the ACL in isolation and single-bundle reconstruction restored knee laxity to the level of the native ACL.

**Double Bundle**
The laxity measurements under the ACL deficient state were all statistically larger than the native ACL measurements. Following double-bundle reconstruction, all laxity measurements, under all loading conditions, were restored to non-statistically different levels as the native ACL. The only significant finding was overconstraint under the coupled anterior shear force-internal torque...
Kinematic Effects of Varying the ITB State in Single Bundle ACL Reconstruction Knees

<table>
<thead>
<tr>
<th>Testing Condition</th>
<th>Knee Flexion</th>
<th>Displacement Measurement</th>
<th>ACL Graft/ITB Deficient</th>
<th>ACL Graft/ITB Tenodesis</th>
<th>ITB Def - ITB Intact</th>
<th>ITB Tenodesis - ITB Def</th>
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<td>Change due to ITB state</td>
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<td>Bon adj p-value</td>
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<td>6.4 (0.6)</td>
<td>0.4 (-1.3, 2.1)</td>
<td>&gt;0.99</td>
<td>-0.7 (-2.2, 0.8)</td>
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<td>3.3 (0.3)</td>
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<td>&gt;0.99</td>
<td>0.0 (-1.2, 1.2)</td>
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<tr>
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<td>10.9 (1.3)</td>
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<tr>
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<td>3.4 (0.5)</td>
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<td>&gt;0.99</td>
<td>-1.1 (-2.8, 0.5)</td>
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<tr>
<td>90 degrees</td>
<td>IR</td>
<td>13.3 (1.3)</td>
<td>14.7 (1.4)</td>
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<td>1.4 (-0.9, 3.8)</td>
<td>0.866</td>
<td>-5.1 (-8.3, -1.9)</td>
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</table>

Table 2: Single Bundle ACL reconstruction was held constant and the ITB state was varied. (ATT = Anterior tibial translation (mm), IR = internal rotation (degrees), ACL = anterior cruciate ligament, ITB = iliotibial band, SD = standard deviation, CI = confidence interval, Bon adj = Bonferroni’s adjustment, statistically significant p-value <0.05)

at 30 and 90 degrees of flexion. The double-bundle reconstruction was able to restore anterior tibial translation and internal rotation regardless of simulated load to at least the level of laxity of the native ACL.

ACL Reconstructed/ ITB state variable

Single Bundle Reconstructions Constant (Table 2)

**Internal Torque**

Under isolated internal torque, internal rotational laxity increased within the single bundle reconstruction subgroup from 14.0 degrees to 18.4 degrees (P=0.016) at 30 degrees of flexion when the ITB was released. Upon ITB tenodesis, internal rotation decreased to 10.9 degrees. The decreased rotation with tenodesis was significant when compared to when the ITB was intact (P=0.036) and when the ITB was deficient (P=0.003). At 90 degrees of flexion, ITB tenodesis demonstrated less internal rotation, 8.1 degrees, than when the ITB was deficient, 14.9 degrees, or when the ITB was intact 13.6 degrees (P=0.007 and P=0.002 respectively).

**Coupled Anterior Drawer – Internal Torque**

At 30 degrees of flexion, internal rotational laxity increased from 13.7 degrees to 17.6 degrees (P=0.004) with the release of the deep and capsule-osseous fibers of the ITB. The increase in internal rotation with the cutting of the ITB was not significant after the placement of the ITB tenodesis. Status-post ITB tenodesis, internal rotation decreased to 10.1 degrees, which was significant when compared to the ITB deficient state (P=0.001). At 90 degrees of flexion, an additional significant decrease from the ITB deficient state to the ITB tenodesis state was measured, 14.7 degrees to 9.6 degrees (P=0.01).

Double Bundle (Table 3)

**Internal Torque**

Internal rotation in the double bundle reconstruction model increased from 10.0 degrees to 13.4 degrees (P=0.002) at 90 degrees of flexion when the select fibers of the ITB were cut. This increase in rotation was significantly decreased to 7.5 degrees of internal rotation (P=0.002) with the ITB tenodesis.

**Coupled Anterior Drawer – Internal Torque**

The double bundle reconstruction subgroup demonstrated a similar laxity pattern under coupled anterior drawer-internal rotation as the single bundle subgroup under coupled anterior drawer-internal rotation at 30 degrees of flexion. The double bundle ACL reconstruction was not able to maintain internal rotational control when the ITB was compromised either. Internal rotation increased from 9.5 degrees to 12.4 degrees (P=0.009). The increase in rotation was decreased to 8.9 degrees (P=0.044) with ITB tenodesis.

**DISCUSSION**

The role of the ACL as the primary rotational and anterior translational restraint of the knee is well proven\(^{25}\). However, the ability to restore native stability to the knee following ACL injury has been more complicated. Continued instability, most specifically rotational laxity, and high long-term osteoarthritis rates in ACL reconstructed knees have led the push for more anatomic reconstructions\(^{12,17,28}\). Single-bundle reconstructions historically imitate the function of the anteromedial bundle, while intra-articular double-bundle reconstructions attempt to restore the static rotational control of the posterolateral bundle\(^{6,7}\).
Double bundle reconstruction has been documented to decrease the rate of the clinically important pivot shift\(^{30,39}\). While the pivot shift, a dynamic assessment of laxity that can be reproduced in the office, correlates more closely with a patient’s perceived stability\(^{31}\). Not all studies support the claim of double bundle superiority\(^{22,33}\). Some biomechanical laboratory assessments have shown a difference in rotational control, but large clinical follow-ups have not shown a functional difference\(^{27,34}\).

The results found within this cadaver model show that both single-bundle and double-bundle reconstruction techniques are able to restore static laxity under variable loading conditions to those of an uninjured native knee. The argument against single-bundle reconstruction is the inability to reconstruct the posterolateral bundle fibers. A single-bundle footprint of a ten mm diameter tunnel covers approximately 82% of the native femoral footprint, as observed by Harner et al\(^ {30}\). The femoral tunnel may be placed further lateral in an attempt to simulate the function of both native ACL bundles. Tsuda et al showed that a laterally based single tunnel could replicate both rotational and translational knee laxity measurements of double bundle reconstructions\(^{37,36}\).

Single-bundle and double-bundle reconstructions are successful procedures with low rates of failure\(^{12,37}\). The most common modes of failure, in order of occurrence, are traumatic re-injury, technical mal-position of the tunnels or fixation, and biologic failure of the graft\(^ {38}\). Misplaced tunnels during an ACL revision can be easily addressed, but fixation failure and failure of graft incorporation are more difficult to define as a specific cause. Although the ACL is the primary restraint to anterior tibial translation and internal rotation, secondary structures decrease the strain on the remodeling ACL, which is most important during the first six months after surgery when the graft is remodeling\(^ {39,40}\).

An extra-articular tenodesis functions as a secondary restraint. Engbretsen et al. showed that by adding an extra-articular ITB tenodesis, ACL forces could be reduced by up to 43%\(^ {41}\). However, biomechanical data has been mixed about its role in restoring knee stability after ACL injury\(^ {25,42}\). Historical literature has shown that extra-articular tenodesis in addition to intra-articular ACL reconstructions for chronic ACL tears have improved return to level of activity, improved anterior laxity, and improved overall functional scores\(^ {43}\).

Recent clinical five year follow-up has demonstrated faster return to sport, less kneeing pain, and high capacity to return to normal muscle trophism with coupled intra- and extra-articular procedures\(^ {30}\). While long term concerns of lateral compartment arthritis secondary to overload with overtightening of an extra-articular tenodesis exist, this was not observed in a 10-13 year follow-up by Marcucci et al.\(^ {12}\). Pernin et al., at mean 24.5 year follow-up of intra-articular ACL reconstruction and extra-articular tenodesis, noted that radiographic joint space narrowing was directly attributed to meniscal and chondral damage observed at the time of original surgery. If meniscus and cartilage surfaces appeared uninjured at the time of ACL injury, only 38% of patients demonstrated radiographic signs of osteoarthritis at long-term follow-up\(^ {37}\).

Assuming the laboratory data showing that ITB deficiency leads to increased rotational laxity in the ACL reconstructed knee can be extrapolated to a clinical application, these results still do not mean that all ACL

### Table 3: Double bundle reconstruction was held constant, while the ITB state was varied. (ATT = Anterior tibial translation (mm), IR = internal rotation (degrees), ACL = anterior cruciate ligament, ITB = iliotibial band, SD = standard deviation, CI = confidence interval, Bon adj = Bonferroni’s adjustment, statistically significant p-value <0.05)

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<th>Change due to ITB state</th>
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<td></td>
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<td>2.1 (0.5)</td>
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<td>ITB Tenodesis - ITB Def</td>
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injuries need an adjunctive ITB reconstruction. Rather, it shows that the ITB may have a greater role in postoperative ACL reconstruction kinematics than previously thought. When these conclusions are applied to Terry et al.'s findings that 93% of clinically damaged ACLs also have ITB injury it presents a potential frequently overlooked point.

If ITB injuries occur at Terry et al.'s reported rate and the ITB plays a significant role in rotational control following ACL-ITB injuries, why are there not more obvious problems with instability after ACL reconstruction? The answer is more likely multi-factorial. First, the natural healing process of the ITB following injury is not completely understood. If the immobilization period following ACL reconstruction is enough time for the ITB to naturally heal, then increased rotational laxity would not be appreciated when the patient is allowed to return to activity. Second, the ITB injury in this laboratory study was extensive. The degree of ITB injury in most ACL patients might not be as severe, thus lessening the frequency of increased rotational laxity seen clinically. Third, the rotational changes measured in the lab, despite statistical significance, may not be clinically significant. The significant increases in internal rotation were only three to four degrees. This might be too small of an increase in laxity for a patient to note a problem. Additionally, the patient's perception of instability does not always align with its mechanical function considering laxity is a quantitative outcome, while instability is a patient's perceived qualitative outcome.

While anterolateral reconstructions are not performed on a regular basis in conjunction with an intra-articular ACL reconstruction, the procedure does have its place. McGuire et al. describes three specific indications: failed ACL reconstruction with proper technique and follow-up, persistent laxity in a knee with prior lateral reconstruction in conjunction with intra-articular ACL reconstruction, and knee dislocation13. The first indication is the one that pertains most to this discussion. ITB injury does not appear to have a large impact on the majority of ACL reconstruction patients, despite reported high co-injury rate. This is seen in the high success rate of primary ACL reconstruction. However, when patients have complications status post ACL reconstruction and the intra-articular procedure appears to be well performed, other sources of injury need to be evaluated. In these circumstances, it would be appropriate to evaluate the ITB more thoroughly and consider an extra-articular procedure.

The design of this cadaver-based laboratory model lent itself to numerous limitations. One issue being what is a significant ITB injury? The capsule-osseous fibers and the deep layer of the ITB were released in this study. These are the two most common layers injured per Terry et al., however, how often clinically are both of these layers completely torn19? If the ITB was over released in comparison to what occurs clinically, this study's results would underestimate the potential laxity following ITB injury. Another limitation to this study was it being an in vitro cadaver model. Potential inconsistencies of cadaver tissue, lack of active knee restraints, and drying of tissues during the lengthy protocol present possible sources of error. The synthetic rope used for the ACL grafts, both single and double-bundle, provided consistency, yet synthetic grafts are not used clinically44. Obtaining autograft for each specimen would have added additional variability secondary to tissue obtained, technique used for acquisition, and length of time added to procedure. Another potential issue with the chosen graft technique was that it could potentially slip since it was not rigidly fixed to the tibia or femur. However, double clamping with clamps perpendicular to each other, clamping directly against bone, as well as repeated graft tension evaluation decreased this risk.

Computer assisted surgery has been well documented as a reliable option for reproducible tunnel placement and laxity measurements45-47. Also, in a prospective randomized control trial, there was no measurable functional difference between ACL reconstructions done with navigation or manual tunnel placement by the surgeon48.

CONCLUSION

In a cadaver-based laboratory model, single-bundle and double-bundle intra-articular reconstructions were both able to restore internal rotation and anterior tibial translation to at least native knee laxity levels after an isolated ACL injury. When the ACL reconstructions were held constant and the ITB deep capsule-osseous fibers and deep fibers connecting to the proximal tibia were released, internal rotation significantly increased under multiple testing conditions in both the single-bundle and double-bundle subgroups. The increase in laxity demonstrated with ITB release was eliminated with ITB tenodesis.

REFERENCES


SURVEY OF HIGH SCHOOL ATHLETIC PROGRAMS IN IOWA REGARDING INFECTIONS AND INFECTION PREVENTION POLICIES AND PRACTICES

Mark Pedersen, MS1,8, Matthew R. Doyle, MS, ATC3, Alan Beste, MS, ATC4, Daniel J. Diekema, MD, MS6,7, M. Bridget Zimmerman, PhD2, Loreen A. Herwaldt, MD1,5,7

ABSTRACT

Objective: To assess high school athletic programs’ infection prevention policies and procedures and to estimate the frequency of skin and soft tissue infections (SSTIs) among Iowa’s high school athletes.

Methods: An on-line survey of high school athletic programs.

Results: Nearly 60% of programs responded. Schools in higher classifications were more likely to have a certified athletic trainer (AT; \( P < 0.0001 \)) and to report that they had a policy preventing athletes with SSTIs from participating in athletic events than were schools in lower classifications \( (P = 0.0002) \). Programs that had an AT reported that athletic training equipment \( (P = 0.01) \) and tables \( (P = 0.02) \) were cleaned more frequently than did programs without ATs. Programs were significantly more likely to provide training equipment than to provide soap or towels. About 57% of programs reported that at least one athlete acquired an SSTI during the prior school year, including methicillin-resistant Staphylococcus aureus \( (N = 14; 10.8\%) \). Programs that had an AT \( (P = 0.02) \) were in higher classifications \( (P < 0.0001) \), educated athletes about SSTIs \( (P < 0.0001) \), or had policies regarding athletes with SSTIs \( (P = 0.01) \) were more likely than other programs to report having at least one athlete with an SSTI. The estimated SSTI rate per 1000 athletes ranged from 22.0 in 1A to 5.9 in 4A programs.

Conclusions: SSTIs are common among Iowa’s high school athletes. Staff should review and update their infection prevention policies. Athletic programs need resources to support infection prevention efforts.

INTRODUCTION

Community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA) often causes skin and soft tissue infections (SSTIs) in young people, including athletes. This organism has caused numerous outbreaks on athletic teams and many of the investigations identified infection prevention deficits1-8. Given that many of the reports in the literature affected high school athletes3-5,8, we wanted to assess infection prevention policies and practices used by high school athletic programs in Iowa, to determine whether specific resources, such as certified athletic trainers (ATs), affected practices and rates of SSTIs reported by respondents, and to estimate the frequency of SSTIs, including those caused by CA-MRSA, among high school athletes in Iowa.

METHODS

We developed a web-based survey and a cover letter that included a link to the survey and was signed by the Assistant Executive Director of the Iowa High School Athletic Association (AB; IHSAA) and the senior author (LAH). We distributed the letter by email to the athletic department at each high school in Iowa \( (N = 394) \). Each school was identified by a code number previously assigned by the IHSAA. The survey was available online between 09/05/2007 and 02/28/2008. We sent two emails reminding athletic programs to submit surveys.

We used the Pearson chi-square test to test the association between two categorical variables (e.g., does having policy on SSTI differ between schools with and without AT), and the Wilcoxon rank-sum test was used to test the association between a categorical variable and an ordinal variable (e.g., compare the frequency of cleaning in schools between those with and without AT). For the analysis that involved school classifica-
tion by school size (1A, 2A, 3A, and 4A), we used the Cochran-Armitage trend test for the binary variables to test whether proportions increased (or decreased) with school classification, and the Jonkheere-Terpstra test to assess the rank-ordered responses. We performed logistic regression analysis, where the model was fitted using the method of generalized estimating equations (GEE), to test whether athletes participating in different sports had a significantly different likelihood of being educated about preventing SSTIs. The GEE method to account for the correlation of responses from a school (i.e., a school responded for each of the four sports). We did pairwise comparisons among the sports using Holm's Bonferroni stepdown method. We used the negative binomial regression, with the model fitted using the GEE method to account for the correlation of a school's responses for different sports, to determine whether the number of athletes with skin infections during the prior season varied among the four sports.

**RESULTS**

**Response Rate and Demographic Data**

Three hundred ninety-two of 394 high schools had athletic departments; 320 surveys were submitted online but 85 school codes were entered into more than one survey. We assumed that surveys with the same internet protocol (IP) address and the same school code were from the same school. For each IP address, we analyzed the survey with the latest submission date and we excluded the 49 earlier submissions. Thirty-six surveys were submitted from separate IP addresses but had the same school code; we excluded these surveys because we could not determine whether they were duplicates or submissions from different schools. After excluding these 85 surveys, we had 235 surveys for a response rate of 59.9%.

Nearly 70% of the surveys were from 1A schools or 2A schools (Table 1) and athletic directors completed 221 (94.0%) surveys. The number of athletes increased significantly by school classification ($P < 0.0001$; Table 1). We estimated the total number of athletes in these schools to be 48,030. Of 227 responding schools, 111 (48.9%) did not have an AT, 107 (47.1%) schools had 1 AT, 1 (0.4%) school had 1.5 ATs, 7 (3.1%) schools had 2 ATs, and 1 (0.4%) school had 4 ATs. Schools in higher classifications were significantly more likely than schools in lower classifications to have at least one AT ($P < 0.0001$; Table 1).

**Reported Education Practices**

Overall, 189 (83.6%) respondents reported that they educated athletes about SSTIs. This practice varied significantly: 69.7% among respondents from 1A programs, 87.5% in 4A programs, 91.3% in 2A programs, and 92.1% in 3A programs ($P = 0.004$; Cochran-Armitage trend test). In addition, programs were most likely to educate wrestlers (N = 162, 68.9%; 95% confidence interval [CI], 63.0-74.8) about SSTIs compared with football players (N = 146, 62.3%; 95% CI, 55.9-68.3; $P = 0.035$), male basketball players (N = 110, 46.8%; 95% CI, 40.4-53.2; $P < 0.0001$), and female basketball players (N = 103, 43.8%; 95% CI, 37.5-50.2; $P < 0.0001$) (logistic regression with p-values adjusted using Holm's Bonferroni stepdown method).

Schools that had an AT were somewhat more likely to report that they educated athletes about preventing SSTIs (87.9%) than schools that did not have ATs (79.5%; $P = 0.8$; Pearson chi-square test). We should state that there was a trend, but that it did not reach statistical significance.

**Reported Policies and Practices**

Eighty-one (35.8%) of 226 respondents reported that they had a policy preventing athletes who had SSTIs from participating in athletic events. Programs in higher classifications were significantly more likely than programs in lower classifications to report that they had such a policy (range from 23.4% in 1A to 59.4% in 4A; $P < 0.0001$).
Table 2: Frequency of Cleaning Items Daily by School Classification

<table>
<thead>
<tr>
<th>School classification</th>
<th>Locker rooms</th>
<th>Showers</th>
<th>Training equipment</th>
<th>Practice uniforms</th>
<th>Training tables</th>
<th>Patient care areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>35/58 (60.3%)</td>
<td>26/58 (46.6%)</td>
<td>8/49 (16.3%)</td>
<td>12/38 (31.6%)</td>
<td>6/55 (19.4%)</td>
<td>9/38 (25.7%)</td>
</tr>
<tr>
<td>2A</td>
<td>46/61 (75.4%)</td>
<td>39/56 (69.6%)</td>
<td>14/55 (25.3%)</td>
<td>14/39 (35.9%)</td>
<td>15/62 (33.3%)</td>
<td>19/47 (45.2%)</td>
</tr>
<tr>
<td>3A</td>
<td>25/30 (83.3%)</td>
<td>15/28 (55.6%)</td>
<td>8/27 (29.6%)</td>
<td>8/17 (47.1%)</td>
<td>13/25 (52.0%)</td>
<td>11/22 (45.8%)</td>
</tr>
<tr>
<td>4A</td>
<td>22/26 (84.6%)</td>
<td>18/23 (78.3%)</td>
<td>9/21 (42.9%)</td>
<td>6/17 (35.3%)</td>
<td>15/22 (62.5%)</td>
<td>17/21 (70.8%)</td>
</tr>
</tbody>
</table>

* P-values were calculated by the Jonckheere-Terpstra test for the distribution across the different frequencies for cleaning (other, never, when soiled, weekly, daily, after each use) and the different school classifications.

Programs in higher classifications were significantly more likely than programs in lower classifications to report that the showers, locker rooms, patient care areas, and athletic training equipment were cleaned frequently (Table 2; Jonckheere-Terpstra test). In contrast, the frequency of cleaning game uniforms (8.0%-13.6% daily; 69.1%-84.0% after each use), protective equipment (14.0%-23.8% daily; 4.5%-16.7% after each use), and wrestling mats before practice (67.7%-78.8% daily; 15.3%-23.8% after each use) or during tournaments (28.0%-57.7% daily; 38.5%-57.6% after each use) did not vary with school classification. Programs that had at least one AT were more likely to report that athletic training equipment (P = 0.01; Wilcoxon rank-sum test) and athletic training tables (P = 0.02; Wilcoxon rank-sum test) were cleaned more frequently than did programs without an AT. The frequency of cleaning other items did not vary significantly with the presence of an AT.

Programs were significantly more likely to report that they provide weights than to provide cardio equipment, and they were more likely to provide training equipment than to provide soap, towels, and laundry services (Table 3, logistic regression with p-values adjusted using Holm’s Bonferroni stepdown method). Programs in class 3A and 4A schools were significantly more likely to provide soap for showering, practice uniforms, and laundry services than were programs in 1A or 2A schools (Cochran-Armitage trend test).
Table 4: Infections Identified among High School Athletes by Sport

<table>
<thead>
<tr>
<th>Program</th>
<th>Number of Infections Identified</th>
<th>Number of Programs Reporting (N = 203)</th>
<th>Mean Infections/School (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrestling†</td>
<td>0</td>
<td>101 (49.8%)</td>
<td>1.45 (1.19-1.77)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>25 (12.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>36 (17.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>16 (7.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4-10</td>
<td>24 (11.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 10</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Total Athletes with Infections: 294</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Football†</td>
<td>0</td>
<td>146 (71.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>24 (11.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>18 (8.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4 (2.0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4-10</td>
<td>9 (4.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 10</td>
<td>2 (1.0%)</td>
<td></td>
</tr>
<tr>
<td>Total Athletes with Infections: 160</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys’ basketball†</td>
<td>0</td>
<td>190 (93.6%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>12 (5.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Total Athletes with Infections: 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Infections/School (95% CI)</td>
<td>0.07 (0.04-0.12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Girls’ basketball†</td>
<td>0</td>
<td>193 (95.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>7 (3.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2 (1.0%)</td>
<td></td>
</tr>
<tr>
<td>Total Athletes with Infections: 15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Infections/School (95% CI)</td>
<td>0.07 (0.04-0.15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other sports</td>
<td>Total Athletes with Infections: 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: To determine whether the number of athletes with skin infections during the prior season varied among the four sports, we used negative binomial regression, with the model fitted using the GEE method, to account for the correlation of a school’s responses for different sports.

† Wrestlers had significantly more infections than football players (P = 0.030). Wrestlers and football players had significantly more infections than female basketball players (both comparisons P < 0.0001) and male basketball players (both comparisons P > 0.0001).

Table 3: Supplies, Equipment, and Services Provided by High School Athletic Programs

<table>
<thead>
<tr>
<th>Items/Service</th>
<th>Number of schools providing the item or service/Number of school responding</th>
<th>95% confidence intervals</th>
<th>Pairwise comparisons (P-value)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weights</td>
<td>226/227 (99.6%)</td>
<td>97.6-100.0</td>
<td>(&lt; 0.0007)†</td>
</tr>
<tr>
<td>Cardio equipment</td>
<td>181/226 (80.1%)</td>
<td>74.9-85.3</td>
<td>(&lt; 0.0007)†</td>
</tr>
<tr>
<td>Towels for practices and games</td>
<td>140/226 (62.0%)</td>
<td>55.6-68.3</td>
<td>(&lt; 0.0009)†</td>
</tr>
<tr>
<td>Soap for showering</td>
<td>140/227 (61.7%)</td>
<td>55.4-68.0</td>
<td>(&lt; 0.0006)†</td>
</tr>
<tr>
<td>Uniforms for practices and games</td>
<td>135/226 (59.7%)</td>
<td>53.3-66.1</td>
<td>(&lt; 0.0001)†</td>
</tr>
<tr>
<td>Whirlpool</td>
<td>121/223 (44.3%)</td>
<td>47.7-60.8</td>
<td>(&lt; 0.0053)†</td>
</tr>
<tr>
<td>Laundry services for towels</td>
<td>113/225 (50.2%)</td>
<td>43.7-56.8</td>
<td>(&lt; 0.0009)†</td>
</tr>
<tr>
<td>Towels for showering</td>
<td>87/226 (38.2%)</td>
<td>31.8-44.8</td>
<td>(&lt; 0.0053)†</td>
</tr>
<tr>
<td>Laundry services for uniforms</td>
<td>78/226 (34.5%)</td>
<td>28.3-40.7</td>
<td>(&lt; 0.0008)†</td>
</tr>
</tbody>
</table>

* We used logistic regression to assess whether the percentage of schools providing specific equipment, supplies, and services varied significantly by item or service. Items with different letters are significantly different, with P-values as specified (e.g., c is significantly different from a, b, d, and e but not from c, d).

Reported Injuries and Infections

Among the 235 respondents, 90 (38.3%) reported that athletes managed their own turf, floor, or mat burns, 65 (27.7%) reported that ATs managed them, and 21 (8.9%) reported that managers did. Respondents reported that most athletes with SSTIs went to their own physicians or to clinics/hospitals for diagnosis (213; 90.6%) and treatment (221; 94.0%). Athletes also saw a team physician, student health, or an AT for diagnosis (103; 43.8%) and for treatment (120; 51.1%) of SSTIs.

Of the 130 (56.8%) programs that reported at least one athlete with SSTIs, 119 programs provided information on the number of athletes that acquired SSTIs by sport (Tables 4 and 5). As expected, wrestling programs reported more infections than did other programs. For the sports reported, we estimated at least 493 SSTIs occurred during the prior season, for an SSTI rate of at least 12.2/1000 (95% CI, 9.8-15.2 per 1000 athletes; N = 203, which includes respondents that reported SSTIs and those that did not report SSTIs). Respondents reported a total of 56 (43.1%) tinea infections, 31 (23.9%) S. aureus infections, 14 (10.8% or 7.9% of all schools) MRSA, 27 (20.8%) Herpes simplex infections, and 16 (12.3%) streptococcal infections.
**DISCUSSION**

This study is one of the first to assess infection prevention policies and procedures among a state’s high school athletic programs and to estimate the frequency of SSTIs among the athletes. Nearly 60% of the responding athletic programs reported that they identified athletes with SSTIs during the 2006-2007 seasons but less than 10% reported identifying MRSA SSTIs. Buss et al. surveyed high schools in Nebraska and found that the percent of schools reporting one or more athletes with MRSA infections increased from 4.4% during 2006-2007 to 14.4% during 2007-2008⁹. These investigators estimated that the incidence of MRSA infections increased from 19.6/10,000 to 60/10,000 among wrestlers and from 5.0/10,000 to 25.1/10,000 among football players. In contrast, about 32% of licensed ATs working in 4A and 5A high school athletic programs in Texas reported MRSA infections among their athletes and about 17% reported that they identified two or more MRSA infections during the 2003 fall athletic season⁵. One program reported an outbreak affecting 23 football players⁵. Barr et al. queried ATs at schools in the highest classifications and in our study these programs were the ones most likely to report that they had identified athletes with MSRA SSTIs. In addition, we previously found that the most common CA-MRSA strains (USA300 and USA400) began causing invasive infections in Iowa later than in more populated areas¹⁰. Thus, a lower percentage of programs in Iowa than in Texas may have had athletes with MRSA SSTIs.

However, we suspect that our results may underestimate the percentage of programs that had athletes with MRSA SSTIs, in part, because most student-athletes...

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**Table 5: High School Athletic Programs Reporting that Athletes Acquired Skin Infections during the prior School Year by whether or not the School had a Certified Athletic Trainer**

<table>
<thead>
<tr>
<th>Event</th>
<th>All schools</th>
<th>With AT</th>
<th>Without AT</th>
<th>Pearson chi-square P-value</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any athletes acquired skin infection*</td>
<td>130 (56.8%)</td>
<td>75 (64.7%)</td>
<td>55 (48.7%)</td>
<td>0.02</td>
<td>1.93 (1.14, 3.28)</td>
</tr>
<tr>
<td>Any athletes acquired MRSA skin infections*</td>
<td>14 (6.1%)</td>
<td>12 (10.3%)</td>
<td>2 (1.8%)</td>
<td>0.007</td>
<td>6.40 (1.40, 29.30)</td>
</tr>
<tr>
<td>Know of presence/absence of MRSA</td>
<td>174† (73.6%)</td>
<td>90‡ (77.6%)</td>
<td>83§ (69.7%)</td>
<td>0.17</td>
<td>--</td>
</tr>
</tbody>
</table>

* Unknowns were grouped with “no” for the analysis and N = 229 for all schools, 116 for “with AT,” and 113 for “without AT.”
† N = 235. ‡ N = 116. § N = 119.
Abbreviation: MRSA = methicillin-resistant S. aureus.

**Table 6: High School Athletic Programs Reporting Athletes that Acquired Skin Infections during the prior School Year by School Classification**

<table>
<thead>
<tr>
<th>Event</th>
<th>1A</th>
<th>2A</th>
<th>3A</th>
<th>4A</th>
<th>Cochran-Armitage trend test P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any athletes acquired skin infections*</td>
<td>25 (32.9%)</td>
<td>51 (63.8%)</td>
<td>27 (71.0%)</td>
<td>26 (81.3%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Any athletes acquired MRSA skin infections*</td>
<td>2 (2.6%)</td>
<td>3 (3.8%)</td>
<td>2 (5.3%)</td>
<td>7 (21.9%)</td>
<td>0.0009</td>
</tr>
<tr>
<td>Know whether or not athletes acquired MRSA skin infections</td>
<td>62† (79.5%)</td>
<td>55 (68.8%)</td>
<td>28‡ (71.8%)</td>
<td>25 (78.1%)</td>
<td>0.71</td>
</tr>
</tbody>
</table>

* Unknowns were grouped with “no” for the analysis and N = 76 for 1A, N = 80 for 2A, N = 38 for 3A, and N = 32 for 4A.
† N = 78. ‡ N = 39.
Abbreviation: MRSA = methicillin-resistant S. aureus.
with SSTIs were seen by their own physicians and many physicians do not obtain cultures before treating SSTIs. Also students might not report culture results to their athletic programs and athletic directors (the primary respondents to our survey) are less likely than ATs to know whether athletes have had infections. Furthermore, MRSA has been the most common cause of SSTIs among patients seen in emergency departments, with MRSA causing 15% to 74% of these infections11,12.

The percentage of programs reporting that athletes had SSTIs in the prior season increased with school classification. Moreover, programs in higher classifications were also more likely to have ATs, to educate athletes about SSTIs, and to have policies excluding athletes with SSTIs from participating in practices or games/meets and these three variables were positively associated with programs that reported SSTIs among their athletes. Programs in higher classifications most likely had more resources (e.g., ATs) for education, prevention, and surveillance than programs in lower classifications and their staff members may have had more educational opportunities. However, the estimated rate of SSTIs was higher in 1A and 2A programs than in 3A and 4A programs. Anderson recently reported that 299 (4.2%) wrestlers participating in Minnesota's high school wrestling state tournament had SSTIs. In contrast to our results, larger schools (i.e., higher classification) had significantly more wrestlers with SSTIs than did smaller schools13.

A high percentage of athletic programs reported that they educated athletes about preventing SSTIs. As expected, education was most common for wrestlers and football players, whose risk of infection was higher than that of other athletes. However, less than 25% of the programs reported having policies on hand hygiene and only one third reported having policies about other practices to limit spread of infectious agents such as restricting athletes with SSTIs from participating in practices or games/meets or from using whirlpools. Data from outbreaks suggest that such policies may be important preventive measures1,3,14. Moreover, Sosin et al. found that skin injuries and contact with other athletes who had furuncles increased the risk for furuncles among male high school athletes3. Begier et al. noted that the risk of infections at covered sites increased significantly as use of the cold whirlpool increased1.

Hall et al. demonstrated that MRSA could be eliminated from a football locker room by implementing infection control interventions and educating athletes and custodial staff17. Thus, ATs and other athletic department staff should develop procedures for cleaning and disinfecting their areas, to prevent infections in athletes.

The frequency of cleaning the environment increased with the school classification, suggesting that larger schools had more resources for cleaning. Thus, while the wrestling mats and locker rooms were cleaned frequently, other areas were cleaned less frequently and could serve as reservoirs for pathogenic organisms.

Athletic programs were significantly more likely to provide weights and cardio equipment than they were to provide soap for showers and other supplies or services that would improve infection prevention. Among collegiate football players, one outbreak of MRSA SSTIs occurred in a setting where soap was not provided in the showers1 and another was associated with sharing bars of soap3. Given the economic situation, high schools in rural Iowa might not be able to hire ATs or to provide soap, towels, and laundry services. Program staff, athletes, athletes’ parents, and local communities may need to identify creative ways to provide these supplies and services so that the risk of SSTIs can be minimized.

Although this survey was conducted before the current economic crisis, less than half of the high schools in our survey reported having an AT, which may help explain why ATs were not significantly associated with either having policies and procedures that would help prevent SSTIs or with educating athletes about preventing SSTIs. ATs are trained to prevent, diagnose, and treat conditions that can impair athletes’ performance, including MRSA SSTIs. Thus, ATs could help athletic programs implement policies and practices that would prevent SSTIs among athletes15.

Our study had several limitations. We did not validate the answers the respondents submitted, culture the environment, or observe the efficacy of cleaning. We also did not ask the programs how many MRSA infections their staff identified. Thus, we could not estimate the incidence of these infections. Moreover, athletic directors were the most frequent respondents but ATs, coaches, or school nurses might know more about athletes’ practices and infections than do athletic directors.

SSTI were identified commonly among high school athletes in Iowa but athletic directors believe that MRSA SSTIs are not common. Staff members of most athletic programs are aware of MRSA SSTIs and are using some measures to reduce the risk of SSTIs but many programs have not implemented policies on hand hygiene and glove use or on excluding athletes with SSTIs from participating in sports. Such policies could improve athletes’
and caregivers’ (e.g., ATs) safety. CDC, the National Athletic Trainers’ Association (NATA), and the National Collegiate Athletic Association (NCAA) have developed guidelines that can help prevent SSTIs, including those caused by MRSA\(^ {18-21}\). ATs, physicians, athletic directors, school nurses, and coaches should work together to develop and implement policies to address infection control practices that could prevent SSTIs. Many high school athletic programs need additional resources so that they can implement current guidelines and improve their infection prevention practices.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the staff members of Iowa’s high school athletic programs who took time to answer the survey and Ms. Martha Freeman who entered the survey into WebSurveyor. This study was funded by a CDC Prevention Epicenter, grant number 5 R18 CI000583. None of the authors has any conflicts of interest that are relevant to this manuscript.

REFERENCES

ABSTRACT
Serum protein electrophoresis (SPEP) is often obtained at the initial evaluation of a radiolucent bone lesion of unknown etiology. The results are considered convincing evidence of the presence or absence of a plasma cell neoplasm. The sensitivity and specificity of the SPEP have not been reported in this clinical scenario. Our purpose is to assess the diagnostic value of the SPEP in the initial work-up of the radiolucent bone lesion. We identified 182 patients undergoing evaluation of a radiolucent bone lesion that included tissue biopsy and an SPEP value. We then calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SPEP as a diagnostic test for a plasma cell neoplasm in this clinical scenario. Forty-six of 182 (25.3%) patients in our series were diagnosed with a plasma cell neoplasm by histopathologic analysis. The sensitivity of SPEP was 71% and the specificity was 83%. PPV was 47% and NPV was 94%. When analyzing only those presenting with multiple lesions, the percentage of patients diagnosed with multiple myeloma increased to 44.7% (34 of 76 patients). The SPEP, however, did not have a substantially increased diagnostic accuracy with sensitivity of 71%, specificity 79%, PPV 40% and NPV 93%. SPEP lacks sensitivity and positive predictive value to provide a definitive diagnosis of myeloma in radiolucent bone lesions, but has a high negative predictive value which may make it useful in ruling out the disease. We recommend that this test either be performed in conjunction with urine electrophoresis, immunofixation electrophoresis and free light chain assay, or after biopsy confirming the diagnosis of myeloma.

INTRODUCTION
Patients presenting with a radiolucent bone lesion and no known primary malignancy present a diagnostic challenge. Previous studies suggest a protocol for evaluating such lesions which involves history and exam focusing on thyroid, breast and prostate, advanced imaging including computed tomography (CT) scan of the chest, abdomen and pelvis and laboratory analysis including complete blood count (CBC) with differential, electrolyte and renal function panel, liver function panel, alkaline phosphatase, erythrocyte sedimentation rate (ESR), and serum protein electrophoresis (SPEP)1-4. Using this algorithm in a prospective manner for patients with metastatic disease, Rougraff et al. were able to identify a primary site of malignancy in 85% of patients2.

The aforementioned study, however, excluded patients with SPEP levels suggestive of myeloma as they were presumed to have a lesion due to this disease. There are no studies that we are aware of looking at the clinical utility of the SPEP in this exact setting. It has been our general impression that the eventual histologic diagnosis does not necessarily correlate with the interpretation of the SPEP done at the initial work up of a lytic lesion. Further, it has been suggested that a plasma cell neoplasm can be accurately diagnosed by histologic and immunophenotyping analysis in isolation, and previous knowledge of the SPEP value is not required.5 As nearly all patients being evaluated for a radiolucent bone lesion of unknown etiology require a confirmatory biopsy, the value of the SPEP in the initial work-up is uncertain.

Our primary question in designing this study was: what is the diagnostic performance of the SPEP in the setting of a lytic lesion of unknown origin? As a secondary outcome we were interested in the diagnostic performance of the SPEP in patients presenting with multiple lytic lesions.
MATERIALS AND METHODS

This study was designed as a retrospective chart review. After obtaining approval from our institutional review board, patients were identified by searching our electronic database for all those who had both an SPEP as well as a biopsy performed between the years of 2001 and 2010. Inclusion criteria were patients with a pathology report of the bone biopsy and an SPEP value obtained prior to the biopsy. Exclusion criteria were patients with incomplete records and those younger than 40 years old, as they lie outside the common age range for metastatic disease and multiple myeloma.

After identification of the patients, a limited chart review was performed to identify the location of the lesion, whether it was solitary or if there were multiple, the histopathologic diagnosis, and the presence of a monoclonal spike. An SPEP value was deemed to be positive, and therefore indicative of a plasma cell neoplasm (monoclonal gammopathy of undetermined significance, plasmacytomas, multiple myeloma, plasma cell leukemia), if there was a detectable monoclonal spike in the gamma region of the electrophoresis.

Two by two tables were then constructed to determine the diagnostic performance of the SPEP in the diagnosis of plasma cell neoplasm. From these tables the sensitivity and specificity were calculated. We estimated the prevalence of multiple myeloma in this clinical scenario (lytic lesion of unknown origin) at 17% from previously reported studies. We then calculated the positive predictive value and negative predictive value. A second analysis was performed looking at only the group presenting with multiple lytic lesions (patients presumed to be more likely due to multiple myeloma) to see if the diagnostic performance of the SPEP was enhanced in this group. For patients with a positive SPEP value, we calculated average levels of the monoclonal spike (in g/dL) to compare the value between those who were eventually diagnosed with a plasma cell neoplasm, and those who were not. A two-tailed student’s t-test was used to compare the means to determine statistical significance.

RESULTS

Our retrospective review identified 182 patients who met criteria for the study. Anatomic locations for the lesions are located in Figure 1. Sixty one percent of the lesions were encountered in the axial skeleton (skull, spine, and pelvis) with the remainder being found in the appendicular skeleton. The femur was the most common long bone affected. Of the 182 patients analyzed, 46 patients were diagnosed with a plasma cell neoplasm (38 with multiple myeloma, six plasmacytomas, one plasma cell leukemia and one monoclonal gammopathy of undetermined significance). This indicates a prevalence of 25% in our series (Figure 2), which is larger than the estimated population prevalence of 17% that was used in our calculations.

When evaluating all patients presenting with a lytic...
A lesion the sensitivity and specificity of the SPEP was 71% and 83%, respectively (Table 1). This indicated a positive predictive value (PPV) and negative predictive value (NPV) of 47% and 94%, respectively. Seventy six of the 182 patients presented with greater than one lytic lesion. In this patient subgroup there were 34 patients who were ultimately diagnosed with a plasma cell neoplasm, representing an increase in series prevalence to 45%. The sensitivity and specificity in this subgroup were 71% and 79% (Table 2). The PPV and NPV were 40% and 93%, respectively, and were calculated using a prevalence of 17%.

For a sensitivity analysis, we substituted our literature-based prevalence estimation with those found in our series (Table 3) to determine the effect of this estimation on PPV and NPV.

For those patients with a positive SPEP who were eventually diagnosed with a plasma cell neoplasm (n = 33), the average IgG value was 1.6 g/dL (range 0 – 7.2 g/dL). For those patients with a positive SPEP who were not diagnosed with a plasma cell neoplasm (n = 23), the average value was 0.6 g/dL (0 – 6.1 g/dL). The p value comparing these means was 0.07.

**DISCUSSION**

The diagnostic algorithm proposed in the classic 1993 study by Rougraff et al. excluded patients with SPEP levels suggestive of myeloma. The implication is that a positive SPEP indicates a high likelihood of a plasma cell neoplasm and a negative value insinuates absence of this disease. It has been our general impression that this is not the cause. Our goal was to calculate the sensitivity, specificity, positive predictive value, and negative predictive value of serum protein electrophoresis in the population of patients presenting for evaluation of a radiolucent bone lesion of unknown etiology. Determination of the inherent characteristics of this test allows for further discussion regarding the necessity and timing of the SPEP in these patients.
The main limitation of this study is that it is a retrospective review. This is problematic because it is dependent upon accurate data entry at the time of patient presentation. Another weakness is the possibility that some selection bias has been incorporated into our patient group. An overall prevalence of a plasma cell neoplasm of 25% is quite high, as previous studies have indicated a prevalence of 17%7,8. It is possible that patients were selected to have an SPEP lab drawn by the practitioner only if there were radiographic and clinical history characteristics consistent with multiple myeloma. Although this would undoubtedly introduce a selection bias, it should theoretically bias our results towards an improved diagnostic performance of the SPEP (i.e. improved PPV).

Our primary goal was to evaluate the diagnostic performance of the SPEP in the setting of a lytic lesion of unknown origin. It has been suggested that the SPEP alone is not a definitive test for myeloma, as a review of 1027 patients from the Mayo Clinic noted a positive SPEP in only 83% of the new diagnoses9. We found a sensitivity of 73% and a specificity of 81% when analyzing patients presenting with a lytic bone lesion who were eventually diagnosed with a plasma cell neoplasm. That same study from the Mayo Clinic, however, did note an improved diagnostic accuracy when incorporating the urine protein electrophoresis (UPEP), immunofixation electrophoresis (IFE) and free-light chain (FLC) assay10. Although there are no defined “acceptable” values for a diagnostic test, obviously the goal is to optimize both the sensitivity and specificity to prove that the test is reliable, reproducible, and accurate. For example, a widely used diagnostic tool, computed tomography (CT) scanning, has been shown in some studies to have 100% sensitivity and 98.9% specificity in the diagnosis of acute appendicitis11. Our results indicate that the SPEP has suboptimal performance as a definitive diagnostic test in isolation.

However, when compared to screening tests (studies performed in an asymptomatic population at risk of a disease), it performed similarly. For example, a prostate specific antigen (PSA) value of greater than 4 ng/mL has a sensitivity of 21% and specificity of 91% in the screening of prostate cancer12,13. PPV and NPV are reported at 30% and 85%, respectively. Mammography for breast cancer screening has been shown to have a sensitivity of 70% and specificity of 92% with a PPV of 5%. For a screening test to be a good one, it should have a high specificity, or very low false positive rate. Although the SPEP is not truly a screening test, as it is being performed because a clinical finding prompted further work-up, it is helpful to consider its performance in this context. When viewed as such, it performs reasonably well to “rule out” multiple myeloma. A negative predictive value of 94% shows that, when negative, the SPEP reliably indicates a low likelihood of the diagnosis of myeloma in patients presenting with at least one lytic bone lesion.

As a secondary outcome we were interested in the diagnostic performance of the SPEP in patients presenting with multiple lytic lesions. It would seem logical that this would enhance the diagnostic performance of the SPEP as those with multiple lytic lesions would be more likely to have a diagnosis of myeloma; however, our data indicates that this was not the case. The performance was essentially unchanged, with sensitivity and specificity of 71% and 79%, respectively.

Additionally, we found that there was a trend towards larger absolute values of monoclonal spikes in the patients with a “positive” SPEP in the patients with a diagnosis of a plasma cell neoplasm compared to those with a false positive (p=0.07). Although the total numbers are relatively small, the wide range in values for the SPEP for each group (true and false positives) and the presence of several histologically confirmed cases of a plasma cell neoplasm with no measurable SPEP further supports the notion that this test is lacking substantially in terms of diagnostic performance.

It is interesting to note that our comparison screening tests (PSA and mammography) are quite controversial in their clinical utility. Both have both been publicly criticized as unhelpful in the overall care of patients, even though their inherent characteristics may be acceptably accurate14,15. One may make a similar argument in this example, as an SPEP value at the initial evaluation of these patients means little by itself. Our data indicate that SPEP lacks the sensitivity, specificity, PPV, and NPV characteristic of a good diagnostic test; however, it may have some utility in ruling out myeloma at initial presentation. Given that plasma cell neoplasms are readily characterized on histopathologic exam without knowledge of the SPEP result, our findings raise the question of whether this test should be used at all prior to a histologically confirmed diagnosis of a plasma cell neoplasm. This test may be best utilized as a baseline, after a confirmatory biopsy, by which to measure the response to therapy16. Alternatively, if the SPEP is to be used in the work-up of a patient with a lytic bone lesion, it should be combined with UPEP, IFE and FLC assay so as to avoid the diagnostic errors that our data indicates would ensue from reliance upon SPEP alone.
REFERENCES


FACTORS AFFECTING OUTCOMES IN PATIENTS TREATED SURGICALLY FOR UPPER EXTREMITY TUMORS AND TUMOR-LIKE LESIONS

Jesse E. Otero, MD, PhD, Christopher M. Graves, MD, Ashley TeKippe, BS, Joseph A. Buckwalter, MD, MS, Benjamin J. Miller, MD

ABSTRACT

There is little data available regarding outcomes of patients who have undergone surgery for tumors of the upper extremity. Functional data after surgery for upper extremity tumors would aid in guiding patient expectations in the peri-operative period. The purpose of this study was to identify patient, tumor, and surgery-related characteristics associated with patient-reported physical and emotional function before and after surgery for tumors of the upper extremity.

Pre- and post-operative mental and physical Medical Outcomes Study Short Form 36 (SF-36) scores were collected from 79 patients with benign and malignant neoplasms of the upper extremity. A retrospective chart review was performed to ascertain whether tumor behavior, type, location, patient sex, age, surgical specimen size, or type of surgery were correlated with differing outcomes. Our outcome measure was patient-reported physical and mental score (SF-36) at less than one year, one to two years, and greater than two years post-operatively.

We found that patients with tumors proximal to the elbow and patients with right-sided tumors had statistically significantly lower post-operative physical scores at minimum two-year follow-up (p=0.02). Additionally, lower physical scores were associated with age greater than 50 (p=0.03) and tumor resection rather than curettage (p=0.01). The subset of patients with hereditary multiple exostoses had significantly lower post-operative physical scores than other patient sub-populations. There was no difference in physical function after surgery between patients with benign and malignant tumors, patients with tumors larger than 5 cm and less than 5 cm in greatest dimension, and patients with bone versus soft tissue tumors. Interestingly, we found that there was no difference in mental function scores between any comparisons.

Our results suggest that patient age, tumor location, and type of surgery are correlated with patient-reported physical function following surgery. These findings could be helpful in counseling patients undergoing surgery for tumors of the upper extremity.

INTRODUCTION

Surgical and medical care for patients with bone and soft tissue tumors of the extremities continues to improve with advancement of chemotherapeutic strategies, surgical techniques, and understanding of pathogenesis1-4. The long-term functional and psychosocial disability reported by survivors of bone cancer is among the highest of all cancer survivors, comparable to that reported by survivors of brain cancer5,6. Clearly, more research is needed to understand the factors which contribute to patient outcomes after treatment of cancer of the extremities. This information could guide physician and patient discussions in the perioperative period.

Goals in treatment differ depending on whether a patient’s tumor is benign or malignant. For malignant tumors of the extremities, treatment goals focus on both local oncologic control and optimizing function of the affected limb. Surgery, often aided by adjuvant therapy, is the cornerstone in treatment for these patients. Limb-salvage (LS) surgery for malignant extremity tumors7 show rates of local disease control and disease-free survival which are comparable to those observed after limb amputation (LA)811. Limb-salvage surgery has a potential advantage over amputation in allowing the patient to retain a functional native limb.

Treatment goals for benign extremity tumors are to reduce pain, optimize function, and prevent local recurrence1213. Since benign bone and soft-tissue tumors are relatively rare, research involving surgery for benign extremity neoplasms is largely limited to case series on focused patient populations1415.
Because of the diversity of conditions treated by the musculoskeletal oncologist, treatment is individualized in every case. Therefore, little information is available in the literature to aid in appropriately counseling individual patients regarding expected functional outcomes after surgery. The current study was undertaken to analyze patient-reported mental and physical function before and after surgery for benign and malignant tumors of the upper extremity. Specifically, we sought to identify particular patient, tumor, and surgery-related characteristics that are significantly associated with differences in patient-reported mental and physical function post-operatively.

METHODS

All patients in the study underwent surgery for a benign or malignant tumor of bone or soft tissue of the upper extremity between January, 2000 and December, 2010. For the purposes of the study, upper extremity was defined as the shoulder girdle (scapula, clavicle, and axilla) distally to the phalanges, and the overlying soft tissue. The surgical procedure was performed by an orthopaedic musculoskeletal tumor specialist. Anatomic pathology reports confirming the diagnosis of tumor was confirmed for all included cases. Patients were only included in the study if they filled out a Short Form-36 (SF-36) survey post-operatively. Patients were excluded from the study if they had surgery performed for a reason other than a tumor or if pathology reports did not confirm the diagnosis of tumor. This study was approved by The University of Iowa Institutional Review Board.

Seventy-nine patients met inclusion criteria. Thirty-seven patients (47%) were male, and 42 (53%) were female. Average age at the time of surgery was 38 years (range 1 to 85 years). There was a bimodal distribution of age at time of surgery with one peak occurring in the second decade and another occurring in the fifth decade of life.

Table 1: Diagnoses in Patients Treated Surgically for Upper Extremity Lesions

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>Benign</th>
<th>Malignant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipoma</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Osteochondroma</td>
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<td>4</td>
</tr>
<tr>
<td>Unicameral Bone Cyst</td>
<td>6</td>
<td>4</td>
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<td>3</td>
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<td>Hemangioma</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Enchondroma</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Chondromyxoid Fibroma</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Desmoid Tumor</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Giant Cell Tumor</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Chondroblastoma</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lymphangioma</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Osteoblastoma</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Schwannoma</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Synovial Chondromatosis</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>46</td>
<td>34</td>
</tr>
</tbody>
</table>

*one pt with both lipo and lymphangioma

Table 1: Tumor diagnosis
Tumor types were ascertained after surgery through surgical pathological analysis. There were 46 benign tumors and 34 malignant tumors. One patient had co-existing primary lipoma and lymphangioma resected during a single procedure.
Factors Affecting Outcomes in Patients Treated Surgically for Upper Extremity Tumors and Tumor-like Lesions

Outcomes Measured:
Post-operative Medical Outcomes Study (MOS) Short Form-36 (SF-36) data were collected from all patients in the study, and pre-operative SF-36 scores were available for 50 of the 79 patients in our study. Mental component scores (MCS) and physical component scores (PCS) were tabulated. Post-operative data were divided into three periods for statistical analysis: less than one year follow-up (31 surveys available in 26 patients), one to 2 years follow-up (35 surveys available in 31 patients), and greater than two years follow-up (76 surveys available in 71 patients). Variables were analyzed in each time period in the study: male versus female patients; patients 50 years of age and younger versus patients older than 50; tumors on the right versus the left upper extremity; patients with tumors proximal versus distal to the elbow joint; bone versus soft tissue tumors; benign versus malignant tumors; surgical specimens whose largest dimension was 5 cm or less versus greater than 5 cm. Resection specimen size was gleaned from pathology reports. Within the group of patients who underwent surgery for a soft tissue tumor, we compared outcomes between those who had resection of mass alone versus those who had resection of mass including muscle and/or nerve tissue. Time periods were separated into less than two years and greater than two years post-operatively.

Statistical Analysis:
SF-36 MCS and PCS scores were compared pre-operatively and at each post-operative time period between each of the demographic, pathologic, and surgical variables. The differences in scores were analyzed with the Student’s t-test in Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA). P values less than 0.05 were considered statistically significant. When patients submitted more than one survey in one of the analyzed time periods, their MCS and PCS scores were averaged and tabulated as one score to avoid inappropriate influence of one patient on the average score for a group.

RESULTS
The mean post-operative physical component score (PCS) of the SF-36 in all patients was 45.8 (standard deviation 9.9). There was no statistical difference in pre-operative SF-36 PCS scores between any of the groups compared. The PCS was compared between multiple groups at less than one year (early), 1-2 years (intermediate), and greater than two years follow-up (long-term). Statistically significant differences in outcome were detected in the following comparisons: Patients 50 years of age and younger had higher PCS in the long-term follow-up period (47.5 versus 42.8, p=0.03). Patients with right upper extremity tumors had a lower PCS than did patients with left-sided tumors in the long-term follow-up period (43.8 versus 49.0, p=0.02). Additionally, patients with tumors proximal to the elbow had a lower PCS than did patients with tumors distal to the elbow at long-term follow-up (45.1 versus 49.8, p=0.02). We did not detect a significant difference in post-operative PCS between patients undergoing surgery for soft-tissue versus bone tumors (Figure 2, Table S1). Within the group of patients undergoing surgery for bone tumors, those treated with resection of tumor had statistically significantly lower post-operative PCS than those undergoing curettage at long-term follow-up (38.9 versus 49.9, p=0.01) (Figure 2, Table S2).

The mean post-operative mental component score (MCS) of the SF-36 in all patients was 53.9 (standard deviation 8.5). The MCS was also compared between multiple groups at less than one year (early), 1-2 years (intermediate), and greater than two years (long-term) follow-up. The MCS was not significantly different between groups in any comparison (Table S1 and S2).
<table>
<thead>
<tr>
<th>Age at Surgery</th>
<th>Sex</th>
<th>Diagnosis</th>
<th>Location</th>
<th>Greatest Dimension (cm)</th>
<th>Surgery</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>F</td>
<td>Aneurysmal Bone Cyst</td>
<td>Left Scapula</td>
<td>2.7</td>
<td>Rsx</td>
<td>Two surgeries ending with Resection and Grafting</td>
</tr>
<tr>
<td>40</td>
<td>F</td>
<td>Aneurysmal Bone Cyst</td>
<td>Left Olecranon</td>
<td>2.4</td>
<td>Curettage</td>
<td>Curettage with Cancellous Allograft</td>
</tr>
<tr>
<td>48</td>
<td>F</td>
<td>Aneurysmal Bone Cyst</td>
<td>Left Proximal Humerus</td>
<td>5.2</td>
<td>Curettage</td>
<td>Curettage with Cancellous Allograft</td>
</tr>
<tr>
<td>21</td>
<td>F</td>
<td>Aneurysmal Bone Cyst</td>
<td>Right Distal Humerus</td>
<td>1</td>
<td>Rsx</td>
<td>Curettage with Cancellous Allograft</td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>Chondroblastoma</td>
<td>Left Proximal Humerus</td>
<td>2</td>
<td>Curettage</td>
<td>Curettage with Cancellous Allograft</td>
</tr>
<tr>
<td>47</td>
<td>M</td>
<td>Chondromyxoid Fibroma</td>
<td>Left Distal Humerus</td>
<td>3</td>
<td>Curettage</td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>F</td>
<td>Chondromyxoid Fibroma</td>
<td>Left Distal Humerus</td>
<td>2.5</td>
<td>Curettage</td>
<td>Curettage and Cancellous Allograft</td>
</tr>
<tr>
<td>56</td>
<td>F</td>
<td>Chondrosarcoma - Grade I</td>
<td>Right Humerus</td>
<td>2.2</td>
<td>Curettage</td>
<td>Two surgeries ending with Curettage and Cancellous Allograft</td>
</tr>
<tr>
<td>59</td>
<td>F</td>
<td>Chondrosarcoma - Grade II</td>
<td>Right Scapula</td>
<td>17</td>
<td>Rsx</td>
<td>Four total surgeries for local recurrence</td>
</tr>
<tr>
<td>54</td>
<td>F</td>
<td>Chondrosarcoma - Grade II</td>
<td>Right Proximal Humerus</td>
<td>10</td>
<td>Rsx + Jt</td>
<td>Modular Hemiarthroplasty</td>
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<tr>
<td>19</td>
<td>M</td>
<td>Dermatofibrosarcoma protuberans</td>
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<td>4.1</td>
<td>Exc</td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>F</td>
<td>Desmoid Tumor</td>
<td>Left Anterior Shoulder</td>
<td>7</td>
<td>Exc + Muscle</td>
<td>Two total surgeries for local recurrence</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>Enchondroma</td>
<td>Right Index Finger</td>
<td>2.5</td>
<td>Curettage</td>
<td>Curettage and Cancellous Allograft</td>
</tr>
<tr>
<td>57</td>
<td>M</td>
<td>Enchondroma</td>
<td>Left Proximal Humerus</td>
<td>2.5</td>
<td>Curettage</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>F</td>
<td>Enchondroma</td>
<td>Right Second Finger</td>
<td>2</td>
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<td></td>
</tr>
<tr>
<td>48</td>
<td>F</td>
<td>Enchondroma</td>
<td>Left Second Finger Middle Phalanx</td>
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<td>Curettage</td>
<td>Curettage and Grafting</td>
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<td>2</td>
<td>F</td>
<td>Ewing’s Sarcoma</td>
<td>Left Ring Finger</td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>Ewing’s Sarcoma</td>
<td>Left Dorsal Forearm</td>
<td>3.4</td>
<td>Rsx + Jt</td>
<td></td>
</tr>
<tr>
<td>63</td>
<td>M</td>
<td>Extraskeletal Myxoid Chondrosarcoma</td>
<td>Left Forearm</td>
<td>8</td>
<td>Exc + Muscle</td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>M</td>
<td>Giant Cell Tumor</td>
<td>Left Proximal Humerus</td>
<td>4</td>
<td>Curettage</td>
<td>Two separate surgeries</td>
</tr>
<tr>
<td>76</td>
<td>M</td>
<td>Giant Cell Tumor</td>
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<td>4.5</td>
<td>Rsx + Jt</td>
<td>Proximal Fibular Autograft</td>
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<tr>
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<td>F</td>
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<td>Right Posterior Elbow</td>
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<td>Exc + Muscle</td>
<td></td>
</tr>
<tr>
<td>34</td>
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<td>Hemangioma (Intramuscular)</td>
<td>Right Forearm</td>
<td>3.9</td>
<td>Exc + Muscle</td>
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</tr>
<tr>
<td>31</td>
<td>M</td>
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<td></td>
</tr>
<tr>
<td>17</td>
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<td>Hemangioma and Lipoma</td>
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<td>2</td>
<td>Exc + Muscle</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>Hereditary Multiple Exostosis</td>
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<td></td>
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<td>11</td>
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<td>2</td>
<td>Rsx</td>
<td></td>
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<td>Rsx</td>
<td>Three surgeries involving shoulder girdle</td>
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<td>44</td>
<td>M</td>
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<td>Right Proximal Humerus</td>
<td>2.5</td>
<td>Rsx</td>
<td></td>
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</table>
# Factors Affecting Outcomes in Patients Treated Surgically for Upper Extremity Tumors and Tumor-like Lesions

<table>
<thead>
<tr>
<th>68</th>
<th>M</th>
<th>High Grade Sarcoma</th>
<th>Right Posterior Arm</th>
<th>13</th>
<th>Exc</th>
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<tr>
<td>68</td>
<td>M</td>
<td>High Grade Sarcoma</td>
<td>Left Dorsal Forearm</td>
<td>7.6</td>
<td>Exc + Muscle</td>
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<tr>
<td>11</td>
<td>F</td>
<td>High Grade Sarcoma</td>
<td>Left Dorsal Forearm</td>
<td>7</td>
<td>Exc + Nerve + Musc</td>
</tr>
<tr>
<td>44</td>
<td>F</td>
<td>High Grade Sarcoma</td>
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<td>14.5</td>
<td>Exc + Musc + Nerve</td>
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<td>M</td>
<td>Leiomyosarcoma</td>
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<td>4</td>
<td>Exc + Muscle</td>
</tr>
<tr>
<td>38</td>
<td>F</td>
<td>Leiomyosarcoma</td>
<td>Right Medial Forearm</td>
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<td>Exc + Muscle</td>
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<td>45</td>
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<td>Lipoma</td>
<td>Right Lateral Deltoid</td>
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<td>Right Shoulder Subdeltoid</td>
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<tr>
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<td>Left Forearm</td>
<td>11</td>
<td>Exc + Muscle</td>
</tr>
<tr>
<td>67</td>
<td>M</td>
<td>Lipoma</td>
<td>Right Antecubital Region</td>
<td>11.5</td>
<td>Exc</td>
</tr>
<tr>
<td>39</td>
<td>F</td>
<td>Lipoma</td>
<td>Right Antecubital Region</td>
<td>3</td>
<td>Exc</td>
</tr>
<tr>
<td>40</td>
<td>F</td>
<td>Lipoma</td>
<td>Right Shoulder</td>
<td>14</td>
<td>Exc</td>
</tr>
<tr>
<td>60</td>
<td>F</td>
<td>Lipoma</td>
<td>Left Proximal Arm and Shoulder</td>
<td>15</td>
<td>Exc</td>
</tr>
<tr>
<td>17</td>
<td>F</td>
<td>Lipoma</td>
<td>Right Arm</td>
<td>6.7</td>
<td>Exc</td>
</tr>
<tr>
<td>43</td>
<td>F</td>
<td>Lipoma</td>
<td>Right Shoulder</td>
<td>6.8</td>
<td>Exc</td>
</tr>
<tr>
<td>49</td>
<td>F</td>
<td>Lipoma</td>
<td>Left Shoulder</td>
<td>9.5</td>
<td>Exc</td>
</tr>
<tr>
<td>67</td>
<td>F</td>
<td>Lipoma</td>
<td>Right Shoulder</td>
<td>5</td>
<td>Exc</td>
</tr>
<tr>
<td>61</td>
<td>M</td>
<td>Liposarcoma (High-grade)</td>
<td>Right Forearm</td>
<td>5</td>
<td>Exc + Muscle</td>
</tr>
<tr>
<td>65</td>
<td>F</td>
<td>Liposarcoma</td>
<td>Right Deltoid</td>
<td>5.5</td>
<td>Exc + Muscle</td>
</tr>
<tr>
<td>29</td>
<td>M</td>
<td>Liposarcoma</td>
<td>Right Shoulder</td>
<td>12</td>
<td>Exc</td>
</tr>
<tr>
<td>57</td>
<td>F</td>
<td>Liposarcoma (Well-differentiated)</td>
<td>Right Shoulder</td>
<td>14</td>
<td>Exc</td>
</tr>
<tr>
<td>47</td>
<td>M</td>
<td>Liposarcoma (Well-differentiated)</td>
<td>Right Shoulder</td>
<td>14.5</td>
<td>Exc</td>
</tr>
<tr>
<td>37</td>
<td>F</td>
<td>Lymphangiomia</td>
<td>Right Dorsal Wrist, Right Lateral Forearm</td>
<td>4.5</td>
<td>Exc</td>
</tr>
</tbody>
</table>
| 66 | M | Metastatic clear cell carcinoma | Left Humerus Diaphysis | 2.6 | Rsx | Resection with Interca-
lary Graft |
| 67 | M | Metastatic clear cell carcinoma (renal primary) | Left Glenoid | 2 | Curettage | Curettage and Cancel-
lous Autograft |
| 46 | M | Metastatic Esophageal Adenocarcinoma | Left Proximal Humerus | 6.3 | Rsx + Jt | Modular Hemiarthro-
plasty |
| 55 | M | Multiple Myeloma | Right Distal Humerus | 2.5 | Curettage | Curettage and Cancel-
lous Allograft |
| 77 | F | Myxofibrosarcoma - High Grade | Right Posterior Arm - Triceps | 7.2 | Exc + Muscle | Involved Triceps |
| 51 | F | Myxofibrosarcoma | Right Shoulder | 10.5 | Rsx |
| 43 | M | Myxofibrosarcoma Intermediate Grade | Right Shoulder Rotator Mass | 6.2 | Exc + Muscle |
| 0 | M | Neurocristic Hamartoma | Left Shoulder | 5.5 | Exc |
| 21 | M | Osteoblastoma | Left Proximal Humerus | 1.1 | Curettage | Curettage and Graft |
| 25 | M | Osteochondroma | Right Scapula | 7.1 | Rsx |
| 11 | M | Osteochondroma | Left Ring Finger | 0.9 | Rsx |
| 23 | M | Osteosarcoma | Proximal Left humerus | 18 | Rsx + Jt | Modular Hemiarthro-
plasty |
| 24 | M | Osteosarcoma | Left Proximal Humerus | 11.8 | Rsx + Jt | Modular Hemiarthro-
plasty |
DISCUSSION

Our study is unique in its attempt to analyze patient-reported functional scores in a diverse patient population with tumors and tumor-like lesions of the upper extremity. We included all patients with tumors and tumor-like lesions of the upper extremity, benign and malignant, treated by an orthopaedic oncologist at our institution. We collected data to determine whether particular patient-, tumor-, or surgery-related factors exist which may affect patient reported outcomes. The theoretical benefit of such research is to offer evidence-based information to guide patient expectations regarding their long-term function after surgery.

The MOS SF-36 is used to ascertain patient-reported outcomes. This simple test was developed to provide a global assessment of patients’ perspective on their physical and mental health. We simplified our analysis by using the physical and mental component scores of the SF-36. The use of the SF-36 in global health assessment has been validated previously for the assessment of orthopaedic surgery outcomes. The SF-36 has been shown to reliably correlate with the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire with Pearson coefficients reaching -0.62. The SF-36 has also been shown to correlate with the Enneking scale, a musculoskeletal tumor-specific outcome measurement tool.

Table 2: Patient, Tumor, and Surgical Characteristics

<table>
<thead>
<tr>
<th>#</th>
<th>Age</th>
<th>Sex</th>
<th>Tumor Type</th>
<th>Location</th>
<th>Size</th>
<th>Treatment</th>
<th>Method of Surgical Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>F</td>
<td>Parosteal Osteosarcoma</td>
<td>Left Proximal Humerus</td>
<td>12.5</td>
<td>Rsx + Jt</td>
<td>Hemiartroplasty</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>M</td>
<td>Parosteal Osteosarcoma</td>
<td>Right First Metacarpal</td>
<td>6</td>
<td>Rsx + Jt</td>
<td>Fibular Autograft</td>
<td></td>
</tr>
<tr>
<td>54</td>
<td>M</td>
<td>Recurrent Malignant Peripheral Nerve Sheath Tumor</td>
<td>Right Humerus Diaphysis</td>
<td>3.5</td>
<td>Exc + Nerve</td>
<td>Two surgeries for local recurrence. Radial Nerve sacrificed</td>
<td></td>
</tr>
<tr>
<td>85</td>
<td>M</td>
<td>Recurrent Malignant Peripheral Nerve Sheath Tumor</td>
<td>Left Proximal Humerus</td>
<td>11.6</td>
<td>Rsx + Jt</td>
<td>Two surgeries because of Metastasis to proximal humerus treated with Modular Hemiarthroplasty</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>F</td>
<td>Schwannoma</td>
<td>Right 2nd Metacarpal Head</td>
<td>2</td>
<td>Curettage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>M</td>
<td>Spindle Cell Sarcoma - Low Grade</td>
<td>Right Medial Arm</td>
<td>1.2</td>
<td>Exc</td>
<td>Two total surgeries for local recurrence</td>
<td></td>
</tr>
<tr>
<td>52</td>
<td>F</td>
<td>Synovial Chondromatosis</td>
<td>Left Elbow</td>
<td>5.1</td>
<td>Exc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>Synovial Sarcoma</td>
<td>Left Forearm</td>
<td>3.1</td>
<td>Exc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>Unicameral Bone Cyst</td>
<td>Right Proximal Humerus</td>
<td>1</td>
<td>Curettage</td>
<td>Curettage and Graft</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>Unicameral Bone Cyst</td>
<td>Right Proximal Humerus</td>
<td>5.5</td>
<td>Curettage</td>
<td>Curettage and Graft</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>Unicameral Bone Cyst</td>
<td>Right Midshaft Humerus</td>
<td>1</td>
<td>Curettage</td>
<td>Curettage and Graft</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>Unicameral Bone Cyst</td>
<td>Right Clavicle</td>
<td>3.5</td>
<td>Curettage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>F</td>
<td>Unicameral Bone Cyst</td>
<td>Left Distal Humerus</td>
<td>2</td>
<td>Curettage</td>
<td>Curettage and Graft</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>Unicameral Bone Cyst</td>
<td>Left Midshaft Humerus</td>
<td>Not given</td>
<td>Curettage</td>
<td>Curettage and Graft</td>
<td></td>
</tr>
</tbody>
</table>

This study analyzed patient, tumor, and surgery-related characteristics to determine which factors affect patient-reported physical and mental scores, including patient sex and age, tumor behavior and location, along with type of surgery and resection specimen size. We detected no pre-operative (baseline) difference in PCS between any of the groups defined by the demographic, surgical, or pathological characteristics compared. Furthermore, there were no differences in MCS for any of the comparisons performed pre-operatively or post-operatively. This has clinical importance because a patient’s sense of emotional well-being may affect how he or she perceives his or her physical capabilities, which would confound detected differences in patient-reported physical function.

This study found no difference in physical outcomes between patients in our study with benign and malignant tumors. We observed uncharacteristically low post-operative scores for the subset of patients with hereditary multiple exostoses (HME). When the scores of these patients were removed from the analysis, a significantly higher PCS was seen in patients with benign tumors at early followup compared to patients with malignant tumors (Benign, 49.1 versus Malignant, 42.6; p=0.04). This effect was not seen at intermediate or long-term follow-up. We did not perform a survival analysis in our study. The low post-operative PCS scores in patients with HME may be related to the effect of their multiple
Factors Affecting Outcomes in Patients Treated Surgically for Upper Extremity Tumors and Tumor-like Lesions

We found significantly lower post-operative PCS scores for patients older than 50. Pre-operative scores in older patients did not differ significantly, arguing that the difference in post-operative scores is not a result of co-morbidities in elderly patients, but rather, the effect of recovery from surgery in older individuals. In this regard, a study that analyzed factors affecting function after limb-salvage surgery for tumors of the lower extremity found age to be an independent predictor of pre-operative SF-36 score\textsuperscript{21}. The reason pre-operative SF-36 score was not different between age groups in our study most likely relates to specific characteristics of the populations which we did not analyze.

Figure 2: SF-36 Physical Component Scores comparing patient, tumor, and surgical parameters

Average MOS SF-36 physical component scores (PCS) in patients treated by an orthopaedic surgeon for upper extremity malignancy at baseline (Pre-operative) and at early (0-1 yr) follow-up, intermediate (1-2yr) follow-up, and long-term (> 2 yr) follow-up. Patients were divided into separate groups for comparing the effect of (A) sex, (B) age, (C) malignancy, (D) laterality, (E) size, (F) location in relation to the elbow, and (G) Tissue-type involved. (H) A separate analysis compared outcomes within soft tissue tumors comparing those excised alone, or those whose excision involved muscle or nerve. Followup was divided into less than two years and greater than two years. (I) Likewise, bone tumors were divided into those treated with curettage, Resection (Rx), and Resection involving joint (Rx + Joint). Statistically significant results denoted by asterisks: *, p=0.03; **, p=0.02; ***, p=0.01.
In comparing patients with right upper extremity tumors to those with left-sided tumors, we found no difference in pre-operative SF-36 score. Interestingly, those with right-sided tumors had lower PCS scores in all follow-up periods. These scores were significantly lower than patients with left-sided tumors at long-term follow-up. We assume that the majority of patients in our study were right-hand dominant, although we were unable to confirm this in our retrospective chart review. This data suggests that recovery from surgery involving the dominant limb poses greater physical difficulty, given post-operative limitations in function.

In comparison of outcomes between patients with tumors located proximal and distal to the elbow, we found a significantly lower post-operative PCS at long-term follow-up in patients with tumors proximal to the elbow than distal to the elbow. Pre-operative scores were not different. In a recent analysis of patients with aggressive tumors of the upper extremity reconstructed with vascularized fibular grafts, Rashid and colleagues also found that patients with tumors proximal to the elbow had lower functional scores. The authors postulated that this discrepancy was related to compromised function of the elbow or shoulder after surgery. Motion at these joints is essential for activities such as eating and personal hygiene, which are accounted for by the SF-36 PCS. We also sought to determine whether there was an effect of tissue origin (bone versus soft tissue) of tumor on PCS and MCS post-operatively. We did not detect a difference in post-operative scores at early, intermediate, or long-term follow-up. The heterogeneity of surgical treatments within the groups may have affected our results. We attempted to address this concern by subdividing patients as follows: We separated patients with soft tissue tumors into those whose tumors were excised alone versus those whose tumor excisions involved nerve or muscle tissue. For bone tumors, we subdivided into those treated with curettage, resection, or resection involving a joint surface. Among the different subgroups, we detected significantly lower post-operative scores at long-term follow-up in those with bone tumors treated with surgical resection compared with curettage.

Our study was limited by several important factors. First, the retrospective nature of the study limited our data to that available on chart review. All data were gathered in the context of patient care, and therefore, scheduled follow-ups for uniform data collection were not available. Additionally, the number of patients who filled out the survey was low compared to the total number of patients with upper extremity tumors treated between 2000-2010, so a significant amount of data were missing in our study. Related to low patient numbers, the study may have been inadequately powered to detect differences in some comparisons. Furthermore, the population analyzed was heterogenous with regard to age, diagnosis, and type of surgery, so fine differences in outcomes may have been missed. Finally, our data were incomplete in that many of our patients did not submit surveys during all of the time periods analyzed, so each individual in the study did not necessarily contribute to every statistical comparison made.

The research presented provides an analysis of mental and physical function in patients after surgery for upper extremity tumors and tumor-like lesions. We found that patient age, tumor relation to the elbow joint, and tumor laterality were significantly associated with physical function after surgery. The data, although limited by study population size, may be helpful in counseling patients regarding functional outcomes after surgery for upper extremity tumors.
### Table S1: Numerical PCS and MCS Data

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Pre-operative</th>
<th>0-1 yr</th>
<th>1-2 yr</th>
<th>&gt;2 yr</th>
<th>Pre-operative</th>
<th>0-1 yr</th>
<th>1-2 yr</th>
<th>&gt;2 yr</th>
<th>Pre-operative</th>
<th>0-1 yr</th>
<th>1-2 yr</th>
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<th>Pre-operative</th>
<th>0-1 yr</th>
<th>1-2 yr</th>
<th>&gt;2 yr</th>
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<tr>
<td>Physical Component Score (PCS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Benign v Malignant</td>
<td>46.42</td>
<td>50.94</td>
<td>0.07</td>
<td></td>
<td>53.01</td>
<td>53.06</td>
<td>0.98</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Age &lt;=50 &gt; 50</td>
<td>49.30</td>
<td>47.11</td>
<td>0.16</td>
<td>0.11</td>
<td>52.40</td>
<td>52.70</td>
<td>0.59</td>
<td>0.74</td>
<td>53.13</td>
<td>54.92</td>
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<tr>
<td>Right v Left</td>
<td>48.70</td>
<td>46.23</td>
<td>0.43</td>
<td>0.17</td>
<td>52.14</td>
<td>52.27</td>
<td>0.70</td>
<td>0.42</td>
<td>53.48</td>
<td>53.09</td>
<td>0.31</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size of Specimen</td>
<td>48.40</td>
<td>41.72</td>
<td>0.75</td>
<td>0.17</td>
<td>53.94</td>
<td>53.09</td>
<td>0.37</td>
<td>0.70</td>
<td>53.97</td>
<td>53.20</td>
<td>0.60</td>
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<tr>
<td>Proximal v Distal</td>
<td>47.50</td>
<td>44.45</td>
<td>0.36</td>
<td>0.57</td>
<td>52.40</td>
<td>50.25</td>
<td>0.31</td>
<td>0.42</td>
<td>52.90</td>
<td>54.37</td>
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<tr>
<td>Bone v Soft Tissue</td>
<td>46.86</td>
<td>43.78</td>
<td>0.27</td>
<td>0.49</td>
<td>51.59</td>
<td>50.40</td>
<td>0.37</td>
<td>0.37</td>
<td>53.20</td>
<td>53.67</td>
<td>0.36</td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

Average PCS and MCS score at early (0-1 yr), intermediate (1-2 yr) and long-term (>2 yr) followup are listed for all comparisons. Student's t-test with two tailed null-hypothesis for non-paired means was used to compare average scores between groups. Italics denote statistically significant p-values. Prox, Proximal to elbow joint; Dist, Distal to elbow joint; ST, Soft Tissue Tumor.
Table S2: Numerical PCS and MCS Data Comparing Method of Surgical Treatment

<table>
<thead>
<tr>
<th></th>
<th>Soft Tissue</th>
<th>Bone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-operative</td>
<td>Pre-operative</td>
</tr>
<tr>
<td>Phys. Comp.</td>
<td>46.53</td>
<td>44.28</td>
</tr>
<tr>
<td>Ment. Comp.</td>
<td>52.45</td>
<td>52.88</td>
</tr>
<tr>
<td>&lt; 2 yr</td>
<td>46.38</td>
<td>50.33</td>
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<td>48.38</td>
<td>41.10</td>
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<tr>
<td>&gt; 2 yr</td>
<td>45.73</td>
<td>46.19</td>
</tr>
<tr>
<td></td>
<td>49.37</td>
<td>45.21</td>
</tr>
</tbody>
</table>

Table S2: Numerical PCS and MCS Data Comparing Method of Surgical Treatment

We compared method of surgical treatment of soft tissue tumors, separating treatment into surgeries which required excision alone versus excision in which muscle or nerve was sacrificed (Exc+M/N). We also compared method of surgical treatment of bone tumors, separating treatment into curettage, resection, or resection involving a joint surface (Resx + Joint). Upper table lists PCS with p-values for multiple comparisons: C, Curettage; R, Resection; RJt, Resection involving a joint surface; E, Excision; E+M/N, Excision in which muscle and nerve was sacrificed. Statistically significant p-values are italicized.

REFERENCES

ABSTRACT

OBJECTIVE: Proximal femur fractures cause significant pain and economic cost among pediatric patients. The purposes of this study were (a) to evaluate the distribution by hospital type (teaching hospital vs non-teaching hospital) of U.S. pediatric patients aged 1–20 years who were hospitalized with a closed hip fracture and (b) to discern the mean hospital charge and hospital length of stay after employing propensity score to reduce selection bias.

METHODS: The 2006 Healthcare Cost and Utilization Project (HCUP) Kids’ Inpatient Database (KID) was queried for children aged up to 20 years that had principle diagnosis of hip fracture injury. Hip fractures were defined by International Classification of Diseases, 9th Revision, Clinical Modification codes 820.0, 820.2 and 820.8 under Section “Injury and Poisoning (800-999)” with principle internal fixation procedure codes 78.55, 79.15 and 79.35. Patient demographics and hospital status were presented and analyzed. Differences in mean hospital charge and hospital length of stay by hospital teaching status were assessed via two propensity score based methods.

RESULTS: In total, 1,827 patients were nationally included for analysis: 1,392 (76.2%) were treated at a teaching hospital and 435 (23.8%) were treated at a non-teaching hospital. The average age of the patients was 12.88 years old in teaching hospitals vs 14.33 years old in non-teaching hospitals. The propensity score based adjustment method showed mean hospital charge was $34,779 in teaching hospitals and $32,891 in the non-teaching hospitals, but these differences were not significant (p=0.2940). Likewise, mean length of hospital stay was 4.1 days in teaching hospitals and 3.89 days in non-teaching hospitals, but these differences were also not significant (p=0.4220).

CONCLUSIONS: Hospital teaching status did not affect length of stay or total hospital costs in children treated surgically for proximal femur fractures. Future research should be directed at identifying factors associated with variations in hospital charge and length of stay.

INTRODUCTION

Pediatric hip fractures are frequent injuries1. They pose a serious threat to the health and well-being of young people, and can have profound negative consequences for young people in terms of their physical, mental, and emotional health2–4. Treatment of these fractures places a burden on the patient’s family, the health care system, and society as a whole5.

Much of the previous research on children fractures focused on injury treatments or patterns1,6-11. Few studies have used national data to compare the hospital charges and length of stay (LOS) by hospital teaching status for closed hip fractures in children and adolescents. A recent paper12 describing the impact of comorbidities on hospitalization costs following hip fracture, discussed the impact of hospital teaching status on cost, but only with patients greater than 55-years old. Another paper13 discussed hospital charge differences by hospital teaching status, but the patient population was asthma-related. Given that pediatric hip fractures are often complex injuries, understanding the impact of hospital teaching status on inpatient costs and length of stay may elucidate the optimal treatment location for these patients.

Thus in this study, we sought to examine length of stay and cost patterns according to teaching status. We hypothesized that mean hospital charge is higher and hospital length of stay is longer in teaching hospitals compared with non-teaching hospitals.

METHODS

Data Source

This study used data from the 2006 Healthcare Cost and Utilization Project (HCUP) Kids’ Inpatient Database (KID)14 produced by the Agency for Healthcare Research and Quality (AHRQ), which is the only national dataset on hospital use, outcomes, and charges designed to study children’s use of hospital services in the United States.
This KID database includes a sampling of all hospital discharges where the patient was age 20 or less at admission during the year 2006. It contains approximately 3.1 million pediatric discharges from 3,739 communities, non-rehabilitation hospitals in 38 states representing all 4 geographic census regions (Northeast, Midwest, West, and South). The database also allows for extrapolation to a national estimation of 7.6 million pediatric hospital discharges. Patient demographic variables include age at time of admission, sex, race, and median household income quartiles based on the ZIP code of the family’s residence. Hospitalization variables include admission month and source, diagnostic and procedure codes, duration of stay, total charges, expected payer, waiting days from admission to procedure and discharge disposition. Hospitals included in this database are divided into strata using 6 characteristics: ownership/control, bed size, teaching status (teaching vs non-teaching), rural/urban location, US region, and hospital type (pediatric vs other). Bed capacity is categorized into small, medium, or large, and varied in specific bed capacity depending on whether the hospital was located in a rural area or was an urban non-teaching or urban teaching hospital.

Study of Population

Patients in the 2006 KID were selected by principal ICD-9-CM$^{15}$ (International Classification of Diseases, Ninth Revision, Clinical Modification) diagnosis code for a closed fracture of the hip, 820.0 (closed transverse fracture), 820.2 (closed lateral fracture), and 820.8 (unspecified closed fracture of femoral neck). Open fractures were not included in this analysis. Also patients received principal ICD-9-CM internal fixation procedure codes of 79.15, 79.35 and 78.55 designating treatment type.

After strict inclusion criteria, 1,107 discharges records were obtained. After applying sampling weights provided by HCUP to extrapolate national estimate, the final data represented 1,827 discharges nationwide.

Data Analysis

Descriptive statistics including numbers, means, standard error, and percentages were used to characterize the study population by hospital teaching status. Continuous variables were compared via least squares means, while proportional comparisons were conducted via Rao-Scott $\chi^2$ analysis. For comparing hospital charge and LOS between teaching hospital and non-teaching hospital, multiple statistical techniques were used. First, a simple univariate analysis in terms of least square means was used. Next, in order to reduce potential patient selection bias between teaching hospital and non-teaching hospital in this retrospective observational study, propensity scores$^{16}$ were used to make adjustment. Propensity scores allow for analysis of observational data on a level comparable to randomized control trials$^{17-19}$, and their use has been widely accepted$^{20-23}$. The propensity score here is defined as the conditional probability (ranging from 0 to 1) of receiving treatment in teaching hospital based on observed co-variants, and estimated from the most popular multivariate logistic regression.

In this study, the co-variants are the patients, hospitals, and hospitalization variables. Specifically, patients variables include: 1) known comorbidities, including alcohol abuse, deficiency anemias, rheumatoid arthritis/collagen, chronic blood loss anemia, chronic pulmonary disease, coagulopathy, depression, uncomplicated diabetes, diabetes with chronic complications, drug abuse, uncomplicated hypertension, hypothyroidism, liver disease, fluid and electrolyte disorders, metastatic cancer, other neurological disorders, obesity, paralysis, psychoses, pulmonary circulation disorders, solid tumor without metastasis, valvular disease, and weight loss, and 2) others, such as age, gender, payer type$^{24}$ (public-Medicaid vs private-others), and median household income quartiles for patient’s ZIP Code. One variable, race, was excluded due to high missing rate (27.5%). Hospital variables include hospital bed size (small, medium, large), hospital region (northeast, midwest, south, west), and hospital location (rural, urban). Hospitalization variables include treatment (Transcervical-ICD 820.0, Pertrochanteric-ICD 820.2, Unspecified part of neck of femur-ICD 820.8), discharge quarter, number of diagnoses, number of procedures, and number of days from admission to procedure. According to a previous study, delay in operation directly relates to hospital charge and LOS$^{25}$.

After obtaining propensity scores, a common support test comparing propensity scores distributions between hospital types revealed considerable overlap indicating they were comparable. Then, from among three available propensity score analysis methods$^{26}$ (regression, stratification, and matching), two of them, regression and stratification, were used to compare hospital charge and LOS between hospital types. We chose to use two separate statistical models because a positive result using two separate statistical methods holds greater validity than a single method alone.

In the first model, propensity scores were used as a continuous variable to make adjustment in comparing hospital charge and LOS between hospital types in the regression model. In the second model, patients from each cohort (teaching vs non-teaching) were matched into five equal strata based on their propensity scores. Propensity matching into quintiles alone has been shown to reduce bias by 90%$^{27}$. Differences between hospital types for each stratum on hospital charge or LOS were calculated, then averaged across strata using stratum-
specific weights, that is, the square of the standard error of the difference between means, and finally the overall effects of hospital teaching status on hospital charge and LOS were derived from the averaged difference divided by the variance of the estimated mean differences. Statistical analyses, after incorporating complex sample designs, were conducted using SAS (Cary, NC) version 9.2. The level of significance for all statistical tests was set at \( P<0.05 \).

### RESULTS

Characteristics of the 1,827 hospital discharges for hip fractured children and adolescents are presented in Table 1(A) and (B). Table 1(A) displays categorical variables, while Table 1(B) shows continuous variables. It can be seen from Table 1(A) that most patients were treated in teaching hospitals (76.2%), located at urban with large bed sizes. Patients were predominantly male (71.47%) and about two-thirds were white. Seventy-one percent of the sample reported a private payer as the primary source of insurance coverage, with 29% having a public payer. Family income level was nearly evenly distributed.
Is Hospital Teaching Status a Key Factor in Hospital Charge for Children with Hip Fractures?

The patients treated in teaching hospitals had a mean age 12.88 years, compared to the rest treated in non-teaching hospitals with a higher mean age 14.33 years. See Table 1(B). Also, the mean number of diagnoses, the mean number of procedures, and the mean waiting days from admission to principle procedure were larger at teaching hospitals, and those differences were significantly different.

Proportional comparisons in the distributions of the most frequently mentioned comorbidities (chronic pulmonary disease, deficiency anemias, fluid and electrolyte disorders, other neurological disorders, and obesity) revealed no difference by hospital teaching status. Seventy-three percent had no comorbidity, 20% had a single one, and only 0.1% had maximum six comorbidities. Treatment procedures proportions showed no differences.

Unadjusted hospital charges were significantly higher (17.36% more) in teaching vs non-teaching hospitals (p=0.0085). After propensity adjustment, however, these differences narrowed to 5.74% and were no longer statistically significant (p = 0.2940). From another perspective, the averaged across strata mean hospital charge difference between teaching and non-teaching hospitals was $5586, but not significant (95% CI [-$1486 - $12657]). These results are detailed in Table 2. With regard to hospital LOS (Table 3), unadjusted rates were 17.03% longer at teaching hospitals (p=0.0198). After adjustment, however, this difference was only 6.22% and not significant (p=0.4220). Likewise, the averaged across strata mean LOS difference between teaching and non-teaching hospitals was 0.44 days, but this also was not significant (95% CI [-0.16, 1.03]).

DISCUSSIONS

In this study, we have analyzed the impact hospital type had on total hospital charge and hospital length of stay after closed hip fracture treatment in 1827 pediatric patients using the 2006 KID data. Treatment of these injuries is costly, with annual US charges exceeding $60 million. After propensity score adjustment, we have shown that hospital type had minimal influence on hospital length of stay and hospital costs. We also observed some interesting demographic and geographic trends.

Several of these results merit further discussion. The present study showed clear gender disparity, namely

| Table 1(B): Characteristics of U.S. hospital discharges for hip fractured children and adolescents by hospital teaching status in 2006—for continuous variables |
|---------------------------------|-----------------|-----------------|---------|
|                                | Teaching Hospital (n=1392) | Non-Teaching Hospital (n=435) | P value |
|                                | Mean (S.E.) | Mean (S.E.) |         |
| Age                            | 12.88(0.15) | 14.33(0.25) | <0.0001 |
| No. of diagnoses               | 3.31(0.11)  | 2.86 (0.15)  | 0.0157  |
| No. of procedures              | 2.03(0.07)  | 1.77(0.11)   | 0.0402  |
| No. of days from admission to principal procedure | 0.70(0.04)  | 0.46(0.04)   | 0.0001  |

| Table 2: Comparisons of hospital charge for hip fractured children and adolescents by hospital teaching status in 2006 |
|---------------------------------|-----------------|-----------------|---------|
|                                | Teaching Hospital mean (S.E.), (US$) | Non-Teaching Hospital mean (S.E.), (US$) | P value |
| Unadjusted                     | 34662(1234)      | 29534(1490)     | 0.0085  |
| Propensity score adjusted      | 34779(1303)      | 32891(1512)     | 0.2940  |

| Table 3: Comparisons of length of stay for hip fractured children and adolescents by hospital teaching status in 2006 |
|---------------------------------|-----------------|-----------------|---------|
|                                | Teaching Hospital mean (S.E.), days | Non-Teaching Hospital mean (S.E.), days | P value |
| Unadjusted                     | 4.26(0.17)      | 3.64(0.21)      | 0.0198  |
| Propensity score adjusted      | 4.10(0.14)      | 3.89(0.23)      | 0.4220  |
males were more likely to sustain hip fracture injuries than females, and that children were more likely to be admitted to large, urban, teaching hospitals. Also, there were more patients from the southern region than any other region, and more fractures occurred in summer than any other seasons, likely reflecting climate variation. These results are consistent with previous studies which demonstrate seasonal and climate variations within pediatric trauma patterns. The results in Table 1(B) probably imply that teaching hospitals treated more serious patients (more diagnoses and procedures) and higher volume (longer waiting time).

Understanding the relationship between hospital teaching status and costs of care is particularly relevant in locales in which teaching and children’s hospitals compete with more efficient community hospitals. After using propensity scores to reduce potential selection bias here, we found that hospital charge was not significantly different between hospital types, and the same was true for LOS. These findings were consistent with findings seen in children with asthma. This is particularly important given the increasingly competitive health care markets in which many teaching hospitals operate with functions of education, research, and care. Due to the limitations of the present database, it is unclear whether the observed differences in LOS and hospital charge are the results of enhancement of care or fulfillments of more functions by teaching hospitals.

There are several limitations within our study. Aside from the retrospective nature of our study, the KID is missing detailed, clinically important perioperative information such as blood loss and type of anesthetic used, which may have relationship to LOS and hospital charges. Since data capture ends at discharge, individuals who were hospitalized multiple times might have multiple records in the KID. The cost information provided by the KID is based on hospital charges, not actual costs; these are not always the same. Therefore, our estimation of total hospital charges may not reflect fully the financial impact on the patients and their families. In addition, not all hospitals in the United States were included in the KID.

CONCLUSIONS

This study analyzed characteristics of hip fractures that resulted in hospitalization in children by hospital teaching status, and suggested that teaching hospitals do not have higher charges or longer stay. Future research should be directed towards understanding the referral patterns after pediatric fractures, injuries appropriate for hospital transfer, and the economic impact of these patterns.

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MANAGEMENT OF IDIOPATHIC CLUBFOOT AFTER FORMAL TRAINING IN THE PONSETI METHOD: A MULTI-YEAR, INTERNATIONAL SURVEY

Asitha Jayawardena, BA1, Lewis E. Zionts, MD2, Jose A. Morcuende, MD, PhD1

ABSTRACT

Background: Over the past decade, the Ponseti method has become the standard of care to treat clubfoot amongst orthopaedic surgeons around the world. Since 2001, the University of Iowa, under the guidance of the late Dr. Ignacio Ponseti, has been teaching the Ponseti method through a standardized training course. This study examines the current clubfoot management practices of those who have participated in the course and the effectiveness of formal Ponseti Training Courses.

Methods: An online survey was administered to practitioners who participated in the University of Iowa Ponseti Training Course from 2001-2011.

Results: One hundred and thirty-one practitioners responded to the survey representing 33 different countries and 70 different orthopaedic societies. Ninety-seven percent of practitioners reported currently using the Ponseti method as the preferred treatment for clubfoot. The respondents reported the average duration of each cast was 9.21 days (SD=9.04 d) and the average cast phase of treatment lasted 7.62 weeks (SD=2.43 w). Physicians were responsible for applying the cast 79% of the time. Braces were utilized following casting by 96% of physicians. The average age of brace use was 41 months (SD=16 m). The reported relapse rate was 21% (SD=17%).

Ninety-seven percent of practitioners changed their practice after completion of the course. The preferred method prior to the course was surgical release (48%). Sixty-one percent of practitioners preferred review articles as an additional educational support; 49% preferred training videos. Sixty-seven percent believed an ‘on-site’ visit to their hospital by an expert in the Ponseti method would be very beneficial. Seventy-three percent suggested improving the course by providing more ‘hands on’ experience. Ninety-five percent of practitioners were satisfied with the course.

Conclusion: The Ponseti Training Course is an effective way to educate physicians on how to treat clubfoot with the Ponseti method. However, improvements should include more hands-on learning as well as an ‘on-site’ visit with an expert Ponseti practitioner.

INTRODUCTION

Over the past decade, the Ponseti method has become the standard of clubfoot care around the world14-17. Surveys of the Pediatric Orthopaedic Society of North America (POSNA) membership from 2001 and 2012 suggest that the use of the Ponseti method has increased among their members18,19. Of those surveyed in 2010, nearly 83% reported receiving formal training in the Ponseti method19. The majority of those respondents reportedly received their training directly from Dr. Ignacio Ponseti19.

The University of Iowa’s Department of Orthopaedics has been conducting a formal CME course on the Ponseti method each year since 2001. This course attracts a more international attendance than the previously characterized clubfoot management surveys, which have a high North American prevalence18,19.

The purpose of this study is to assess the clubfoot management practices of those who attended Dr. Ponseti’s formal Ponseti Training Course at the University of Iowa (which typically is taught in weekend-long workshops). Furthermore, this study analyzes the pedagogical effectiveness of these courses and solicits specific improvements for this educational approach.

METHODS

Population

An international survey of health care practitioners who attended the University of Iowa CME Ponseti Training Courses was conducted. Those who attended these
courses are presumed to be practitioners of the Ponseti method in their respective practice settings.

**Survey Design and Testing**

The study investigators designed the survey instrument by utilizing both information reported in the existing literature and investigator hypotheses. The survey was divided into three main segments: respondent characteristics, clubfoot management, and course feedback. An online survey program (Qualtrics, Inc., Provo, UT) was used to administer the survey. The instrument underwent trial by two high-level clubfoot practitioners for functionality and quality. This study was granted exemption from consent by the Institutional Review Board of the University of Iowa.

**Data Collection**

The initial request for survey participation was sent by email (via Qualtrics, Inc.) from the medical director of the Ponseti International Association. A follow-up reminder was sent to the same list three weeks later. The survey was open for three months from December 2011 to February 2012.

**Measures and variables**

Questions with free response answers that were categorical variables were organized and tabulated with the most common answers being reported. Questions with free response answers that were numerical (i.e., days before casting) were organized and reported as a mean, standard deviation (SD), and median. When a large amount of participants responded ‘other’ and reported similar answers, the similar answer was reported as a ‘write-in’ and included in the reported responses.

**RESULTS**

**Respondent characteristics**

Responses were received from 131 participants (32%). The responses are summarized in Tables 1-3. The majority of respondents were MDs or DOs (65%). The next most common type of practitioner was physical therapists (10%). The respondents were mostly from the United States (53%), however, 32 other countries were also represented. Seventy orthopaedic societies were represented with AAOS (43 respondents), POSNA (35 respondents), and AOA (11 respondents) being the societies most commonly represented. The most common type of practice was academic (43%), followed by multi-disciplinary group practice (28%). The number of respondents ranged from 13 to 35 depending on the year of the training course (mean = 19.9 respondents).

**Current clubfoot management**

An overwhelming majority of respondents currently use the Ponseti method (97%) to treat clubfoot, while only 5% use the physical therapy/French method. Providers reported that they initially treated approximately 95% (SD = 20%, median = 100%) of their clubfoot patients with the Ponseti method. The preferred method of casting was the long leg cast (98%). Practitioners preferred plaster of paris (81%) to synthetic cast material (12%) while 7% reported using both materials. The casts are most often molded by the physicians (79%), while residents, physical therapists, and cast technicians each mold about 11% of the casts.

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<th>Table 1. Respondent Characteristics</th>
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The preferred age to initiate cast treatment was 7.51 days (SD = 7.25 d, median = 7 d). The average duration of each cast was 9.21 days (SD = 9.04 d, median = 7 d). The average duration of the casting phase of treatment was 7.62 weeks (SD = 2.43 w, median = 8 w). Eighty-one percent of patients required an Achilles tenotomy (SD = 21%, median = 90%). Providers preferred the percutaneous Achilles tenotomy (94%) versus the mini-open (4%) and open (0%) tenotomies. Fifty-seven percent of respondents reported use of local anesthesia for the Achilles tenotomy while 44% utilized general anesthesia and 18% used conscious sedation.

Ancillary treatments included stretching exercises by parents (81%), formal physical therapy (42%), and Botox injections (7%). A brace was used following the cast treatment by 96% of practitioners. The most common types of braces included the Dennis-Brown FAO (54%), the Mitchell FAO (43%), the Dobbs Dynamic Bar (14%), and other orthopaedic FAOs not listed (14%). The brace was discontinued on average at 41 months (SD = 16 m, median = 48 m). Twenty-one percent of patients treated using the Ponseti method had a relapsed deformity (SD = 17%, median = 20%) and 4.52% (SD = 6.71%, median = 2%) required an extensive soft tissue release.

Training course impact

Prior to attending the clubfoot treatment course, the preferred method of treatment was surgical release (48%). The Ponseti method was only used 42% of all cases while 10% of practitioners used another method to treat clubfoot. After attending the course, 97% of practitioners changed their practices. Fifty-three percent increased the amount of patients who were treated with the Ponseti method, 41% practiced less surgery and 39% did not specifically change their practice but reported a better understanding of the method. Of the three respondents who did not change their practice, one reported that the program was not relevant to their practice, the other cited a lack of support from the hospital, and one practitioner stated that the proper clinical setting was not available.

**COURSE EVALUATION**

Additional review articles were the preferred form of educational support (61%), followed by training videos (49%), quarterly updates (37%), the University of Iowa website (33%), and webinars/virtual forums (28%). The majority of physicians (67%) believed that an ‘on-site’ visit would compliment their training. Suggestions for improvement to the program included more hands on experience (73%), more patient demonstration (45%), more lectures on technique (36%), a section on billing (11%), and more patient testimonials (9%).
Most providers (70%) felt comfortable with the technique after seeing between 0 – 20 patients. However, only 45% felt comfortable teaching the technique after seeing 0 – 20 patients.

Ninety-six percent of practitioners were satisfied, very satisfied or extremely satisfied with the course.

**DISCUSSION**

The current study documented a response rate from course participants of 32%, which is comparable to the rate of response from recent studies of the POSNA membership. As expected, the rates of adherence to standard Ponseti method protocol after attending the CME Ponseti Training Courses were quite high (97%). This is similar to the reported use of Ponseti method in a recent survey of the POSNA membership. The high rate of utilization of the Ponseti method among the Ponseti Training Course participants mirrors the well-documented decline in surgery and the rise of the Ponseti method as the standard of care in clubfoot management.

When compared to the work of Zionts et al. and Heilig et al. in POSNA membership surveys, the present study supports the various trends documented by those authors. Specifically, both this study and that by Zionts et al. suggest that current management of clubfoot deformity reflects increased adherence to the principles of the Ponseti method as indicated by the increase use of long leg casts, foot abduction orthoses, an increased duration of brace use, and a decrease in extensive release surgery than when compared to Heilig’s survey of POSNA membership in 2001.

Additionally, this study reveals that when compared to the clubfoot membership of the POSNA membership in 2010, participants in the CME Ponseti Training Courses prefer local anesthesia at a higher rate than the POSNA membership (57% vs 39%). This may be attributable to differences in access to an operating room between the mostly North American POSNA respondents and the more international respondents in the present study. Ponseti Training Course participants also utilize the brace for an average duration of 8 weeks longer (41 weeks vs 33 weeks) than the 2010 POSNA membership. This may be attributable to differences in access to an operating room between the mostly North American POSNA respondents and the more international respondents in the present study. Ponseti Training Course participants also utilize the brace for an average duration of 8 weeks longer (41 weeks vs 33 weeks) than the 2010 POSNA membership.

Ultimately, there is an inherent bias in comparing those who participated in a CME Ponseti Training Course to the general POSNA membership. Those who sought out participation in a workshop likely have a higher interest in clubfoot than the general POSNA membership. However, the results of this study provide further support to two major concepts: the use of the...
Ponseti method is increasing compared to a decade ago, and that this increase is likely correlated to a decrease in the rate of patients who require extensive release surgery.

Furthermore, this study provides insight on the effectiveness of the CME Ponseti Training Course conducted at the University of Iowa. Ninety-six percent were satisfied, very satisfied or extremely satisfied with the course and 97% changed their clubfoot management after the program. However, despite the perceived satisfaction with the two-day workshop format, several suggestions were solicited. First, most participants felt comfortable with their own technique after about 17.8 patients. However, they did not feel comfortable teaching their technique until after about 26.7 patients. This suggests that a two-day workshop is not satisfactory to train practitioners to comfortably teach their peers. Additionally, the majority of participants (67%) believed an on-site visit would greatly compliment their training. These results support an alternate Ponseti teaching pedagogy, which may include on-site visits from expert practitioners as a means to enhance Ponseti method teaching in the future.

**CONCLUSION**

The CME Ponseti Training Course is an adequate means to educate practitioners in the Ponseti method. However, in order to train practitioners comfortable in training other practitioners in the method, more than a weekend-long workshop may be necessary. Specific suggestions include an on-site visit with an expert practitioner.

**REFERENCES**


MANAGING UNCERTAINTY IN THE CONTEXT OF CLUBFOOT CARE:
EXPLORING THE VALUE OF UNCERTAINTY MANAGEMENT THEORY
AND THE SENSE OF VIRTUAL COMMUNITY

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Julie Andsager, PhD2, Jose A Morcuende, MD, PhD2

ABSTRACT
Serious health conditions, such as clubfoot, could be a major source of uncertainty and stress for parents of children affected. How parents deal with uncertainty and stress as related to their child’s health condition is of interest for medical professionals and health communicators alike. Until the 1990s, health professionals were the major source of information related to health conditions, and close family and friends the major source of support for parents of children affected by rare diseases. The development of information technologies in general and of the Internet in particular, provides new ways for parents to search for and find information, as well as to request and receive support from individuals facing similar challenges41.

While physicians remain a preferred source of health information (during medical encounters or via phone and email communication) many individuals seek out health information on the Internet likely because they can access large quantities of information quickly and on their own schedule8-11. Parents of children with health conditions may use the Internet in a number of ways; the most important being information seeking and social support, two constructs of the Uncertainty Management Theory (UMT)12. UMT states that individuals employ various behaviors to decrease, maintain or increase their uncertainty. Uncertainty management behaviors include seeking, acquiring, and exchanging information in addition to other types of social support13,14.

The diagnosis of a birth defect and the process of caring for a child with such a condition may result in high levels of stress for parents7,15. Evidence indicates that mothers report more psychological stress than fathers7,15,16. Stress can add additional burden on the parent, decrease their quality of life, and may have a negative effect on early childhood development. Considerable effort needs to be exerted to cope with the stress generated, not only with the normal anxiety of having a newborn, but with a newborn with a health condition10,16. Some parents may turn to online support communities (OSCs) to manage their stress and uncertainty.

Studies focusing on the underlying processes in OSCs remain scarce despite the increasing interest in understanding online support communities. There have been relatively few studies addressing online support communities that are initiated and managed without input from health institutions27. In the context of online support communities, Eysenbach4 suggested that information seeking (websites, online groups and direct communication), social support, knowledge, uncertainty (confusion) and stress may be inter-related.
Managing Uncertainty in the Context Of Clubfoot Care

METHODS

This research explored the connections between Uncertainty Management Theory (UMT) constructs and the potential contribution of the sense of virtual community (SOVC) to the UMT framework. The PATH model proposed in Figure 1 indicates how the constructs under study may be related to each other according to UMT. The research question and hypothesis addressed in this study are listed next.

RQ1: Is UMT applicable to interactions in online environments in the context of clubfoot?

H1.1: There is a negative relationship between knowledge and information seeking

H1.2: There is a positive relationship between information seeking and perceived social support

H1.3: There is a negative relationship between information seeking and uncertainty

H1.4: There is a negative relationship between perceived social support and uncertainty

H1.5: There is a positive relationship between uncertainty and stress

Because the Uncertainty Management Theory (UMT) was not created specifically to explore online communities, new constructs (such as Sense of Virtual Community or SOVC) may be a necessary addition. Sense of Virtual Community represents an important feature of virtual communities. It is defined as “members’ feelings of membership, identity, belonging, and attachment to a group that interacts primarily through electronic communication.”18 SOVC has been used to analyze various online groups including groups related to infertility and pregnancy.19,20 It is hypothesized that SOVC would be a valid construct in the case of online communities for caregivers of children with clubfoot. Adding the SOVC in the equation as proposed in the Path model illustrated in Figure 2 allowed us to explore the following research question and hypothesis.

RQ2: Does adding SOVC improve the UMT PATH/SEM analysis? (Figure 2)

H2.1: There is a positive relationship between perceived social support and SOVC

H2.2: There is a negative relationship between SOVC and uncertainty

Sample and procedure

The study participants were parents of children with clubfoot. Participants were recruited using a snowballing technique by posting an invitation in an online support community managed and used by parents of children with clubfoot. Potential participants were invited to complete an anonymous survey concerning their uncertainty related to clubfoot and their use of Internet for information seeking and social support. The invitation to participate in the study was posted by the administrator/moderator of online support group. The text of the invitation encouraged parents to share the link to the survey with other parents caring for children with clubfeet. The study methodology was approved by the University of Iowa’s Institutional Review Board. Data was collected using an Internet-based survey, developed and administered via WebSurveyor. The survey was pilot tested before administration.

The following measures were collected as part of the survey: uncertainty, stress, knowledge, information seeking behavior, perceived social support and sense of virtual community. Three items adapted from the Hilton Uncertainty Stress Scale were used for assessing current global uncertainty, stress, and knowledge. Uncertainty was defined overall as the anxiety the parent feels because of clubfoot related issues. Global uncertainty was measured using a score ranging from 0 (no uncertainty) to 100 (very high uncertainty). Stress was defined as the overall stress the parent feels as a result of clubfoot related issues. Global stress was measured using a score ranging from 0 (no stress) to 100 (very
Knowledge about clubfoot was assessed using a self-report measure asking the parent to rate his or her general knowledge level about clubfoot related issues on a scale from 0 (no knowledge) to 100 (very high knowledge). To measure information seeking behavior, respondents were asked to indicate how often they used various information sources related to clubfoot over the last twelve months. The responses were averaged to generate an information seeking score. Seventeen items adapted from Blanchard’s SOVC scale were used to measure the sense of virtual community in the online group. Nine items were adapted from Cutrona and Russell’s Source Specific Social Provisions Scale to measure perceived social support.

**Data analysis**

The Statistical Package for the Social Sciences (SPSS) was used to conduct descriptive analyses and correlations. The AMOS software was used to conduct Path analysis (structural equation modeling - SEM) and to test direct and indirect relationships. The analysis aim was to explore the application of UMT to caregiver online behaviors and interactions in the context of clubfoot. As suggested by the UMT theory, it was believed that knowledge, information seeking, social support, uncertainty and stress are inter-related. The aforementioned constructs were treated as observed variables.

To address RQ1 & RQ2, two SEM analyses were conducted. The first Path model (without SOVC) was tested for goodness of fit in the first phase. The second Path model (with SOVC) was tested for goodness of fit in the second phase. Maximum likelihood imputation was used to handle missing data as recommended by Byrne. There are several goodness-of-fit indexes computed by AMOS to evaluate the fit of the model such as root mean squared error of approximation (RMSEA), Bentler’s Comparative Fit Index (CFI), and the incremental index of fit. RMSEA takes population error into consideration, while CFI compares the hypothesized model with the independence model. A RMSEA value of 0.05 is indicative of a good fit, a value of 0.08 is a reasonable fit and values greater than 0.10 are a poor fit. Bentler suggested CFI as the index of choice with a cutoff value around 0.95 or more. The incremental index of fit (IFI) indicates a good fit over 0.95 and accounts for issues of parsimony and sample size that may influence CFI. Fifteen cases per predictor in a standard ordinary least squares multiple regression analysis is reasonable according to James Stevens’ Applied Multivariate Statistics for the Social Sciences. A minimum of 15 cases per measured variable in SEM was also considered reasonable since SEM is closely related to multiple regression in some respects. In addition, Mitchell indicates that having at least twenty times as many cases as variables is recommended for SEM. The study sample size (N=203) exceeded the aforementioned limits for both Path analysis models proposed.

**RESULTS**

The mean age of the respondents was 33.4 years (SD=5). Ninety-four percent of the respondents were women. Ninety percent of the respondents had college level education and 87% had an income level of over $35,000. Eighty-one percent of the respondents identified themselves as non-Hispanic White, 6% Hispanic/Latino, 6.5% Asian and 6.5% mixed ethnicity. Table 1 illustrates the correlations among constructs under investigation.

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<td>Uncertainty</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Stress</td>
<td>0.646**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td>-0.056</td>
<td>-0.208**</td>
<td></td>
<td></td>
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<tr>
<td>Information seeking</td>
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<td>0.13</td>
<td>0.139*</td>
<td>0.216**</td>
<td></td>
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<tr>
<td>SOVC</td>
<td>0.014</td>
<td>0.002</td>
<td>0.142</td>
<td>0.175*</td>
<td>0.692**</td>
</tr>
<tr>
<td>Social support</td>
<td>-0.024</td>
<td>-0.06</td>
<td>0.113</td>
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</tr>
</tbody>
</table>

**Correlation is significant at the 0.01 level (2-tailed).  *Correlation is significant at the 0.05 level (2-tailed).**
comparative fit index (CFI) = 0.904 and the incremental index of fit (IFI) = 0.91 were both under 0.95 supporting the above conclusion. 

The SEM analysis results did not support H1.1 as there was a positive relationship between knowledge and information seeking at the 0.05 significance level (estimated regression weight = 0.14, p=0.049). The results provided support for H1.2 as there was a positive relationship between information seeking and perceived social support (estimated regression weight = 0.185, p=0.013). The results did not support H1.3 because there was a non-significant relationship between information seeking and uncertainty (estimated regression weight = 0.124, p = 0.083). The results did not support H1.4 because there was a non-significant relationship between perceived social support and uncertainty (estimated regression weight = -0.05, p=0.511). The results supported H1.5 as there was a statistically significant positive relationship between uncertainty and stress (estimated regression weight = 0.646, p<0.001). The results did not support H2.2 because there was a non-significant relationship between SOVC and uncertainty (estimated regression weight = -0.014, p=0.851).

**DISCUSSION**

Although considerable research attention has been devoted to studying illness-related uncertainty, less has been done on researching uncertainty management in online contexts. One way we might help caregivers deal with uncertainty is by better understanding their uncertainty management processes. Toward that effort, this study offers an initial empirical test of Uncertainty Management Theory. The results contribute to current understandings of the uncertainty management processes in three primary ways: a) lending insight into the relationships between constructs, b) exploring the applicability of the Uncertainty Management Theory to the population and context of interest and, c) identifying the need for constructs and theoretical models adapted to online contexts. The outcomes also uncover new directions for future research focused on uncertainty management in online contexts.

The results of this research suggest that the UMT needs to be adapted for use in online contexts. One way is to include theoretical constructs (i.e. sense of virtual community) specifically developed to measure online interactions. This study demonstrated that such an addition may result in a more appropriate theoretical model.

Analysis revealed statistically significant relationships between knowledge and information seeking, information seeking and perceived social support, perceived social support and sense of virtual community, as well as between uncertainty and stress. The results indicated that knowledge, information seeking, perceived social support, and sense of virtual community are closely interconnected, judging by the relationships between variables in the second proposed structural model.
Knowledge was positively related to information seeking behavior. This supports the idea that for some parents the acquisition of information leads to more information seeking\textsuperscript{31}. There may be an underlying need to validate one’s body of knowledge as a way to deal with uncertainty\textsuperscript{32}.

Information seeking behavior was positively related to perceived social support. A potential explanation is that the more parents seek for information related to the health condition of their children, the more likely they are to come across an online support community and become members of such a community. Evidence indicates that online support communities are an important source of information for parents\textsuperscript{4,10-14}. Of the survey respondents, over 60% visit an online support community a few times a week or even daily. Over 98% of the survey respondents indicated that they used a search engine in their information seeking.

The study results provided support for a strong relationship between illness-related uncertainty and stress\textsuperscript{15-18}. Identifying and addressing uncertainty causes before, during, and after medical encounters may allow caregivers to better cope with stress\textsuperscript{3,19}. Furthermore, such an approach may also increase compliance with treatment by increasing the trust between parents and medical care providers\textsuperscript{3,18}.

Perceived social support was positively related to the sense of virtual community. The strong relationship between perceived social support and sense of virtual community indicates that both of them may need to be considered in theory and in practice. This study shows that a theoretical model including SOVC may fit the data better than one without SOVC. Developers and administrators of online communities may need to pay attention not only to the support exchanged in a community, but also to the sense of belonging to the community. This may be particularly important especially because members with a low SOVC may be more likely to leave the community as soon as their support needs have been fulfilled, instead of becoming active contributors. The active involvement of long-term members in an online community of support represents a critical factor in the success of such a community\textsuperscript{20}.

Some limitations of the study are noted next. First, the results did not indicate a statistically significant relationship between perceived social support and uncertainty, nor between information seeking behavior and uncertainty, nor between SOVC and uncertainty. A potential explanation is that other constructs that have not been captured in the present study may influence uncertainty and stress. Second, data collected is self-reported and thus may be subject to response bias and other limitations of surveys as noted in other caregiver studies\textsuperscript{21}. Third, most of the respondents were reportedly white, suggesting that other ethnicities may not use the online support resources as much because of reasons that require further inquiry such as income and education status, access to a computer and so forth.

Despite the above, this research uncovered some important relationships between constructs that have both theoretical and practical applications. One of the major critiques of research related to online support communities is the lack of theoretical frameworks\textsuperscript{22}. This study specifically explored the applicability of a theoretical framework (UMT) to analyzing individual and interpersonal constructs in the context of online behaviors of caregivers of children with clubfoot. The study findings recommend adding the sense of virtual community to the uncertainty management theoretical framework.

It is generally held that information seeking and social support are crucial constructs in uncertainty management for confronting the diversity of challenges that a caregiver may face. Yet much remains to be learned about the internal organizational functioning of an online community. Understanding individual level variables (i.e., information seeking), interpersonal level variables (i.e., social support), and community level variables (i.e., sense of virtual community) is a valuable endeavor from both theoretical and practical perspectives with respect to online communities. The joint consideration of information seeking, social support, and a sense of virtual community have the potential to increase understanding of all three constructs\textsuperscript{23-25}. It is clear that securing information and social support in order to deal with illness related uncertainty is a complex process\textsuperscript{26}. The results suggest that, with some additions, Uncertainty Management Theory could be a valuable framework in exploring caregivers’ experiences and that online communities of caregivers of children with health conditions provide an appropriate setting for this type of research\textsuperscript{27}.

CONCLUSION

Health communication efforts designed to support parents of children with serious health conditions may need to expand in parallel with the Internet. Treatment of clubfoot remains critically important, yet much more emphasis is needed on communication efforts designed to reduce the stress experienced by parents. Future advances in health communication could be achieved through a combination of research and practice involving partnerships between parents, health professionals and scholars interested in clubfoot. A modified Uncertainty Management Theory could potentially be used to explore, analyze, and understand various online behaviors related to health conditions such as clubfoot and thus contribute substantially to what we know about caregivers in their role as uncertainty managers.
ACKNOWLEDGMENTS

We would like to acknowledge the parents of children with clubfoot for their dedication and continued support to each other and for their contributions to the study, the Ponseti International Association and its members for their sustained efforts to promote the conservative treatment of clubfoot, and the Engage Research Lab at the University of the Sunshine Coast for editing support. The authors are supported in their work by one or more of the following: the Research Cluster for Health Improvement and the Inflammation and Healing Research Cluster at the University of the Sunshine Coast; Ponseti International Association, the Center for International Rural and Environmental Health and the Center for Health Communication and Social Marketing at the University of Iowa.

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ABSTRACT

This paper explores local knowledge and perceptions about clubfoot in the Indus Hospital’s catchment population in Karachi, Pakistan. Data was collected through seven focus group discussions with community members and Lady Health Workers, nine in-depth interviews with parents of children with treated or untreated clubfoot, and one interview with an adult with untreated clubfoot.

We found that participants were unable to distinguish clubfoot from other disabilities. Moreover, participants had a number of beliefs about the causes of clubfoot, which included lunar and solar eclipses, religious explanations, the health status and behaviours of parents, and genetics. While participants were aware of surgery and other allopathic treatments for clubfoot, many also believed in traditional and religious treatments or were unaware that clubfoot is a treatable condition.

This study is the first of its kind in Pakistan and provides important insights that clubfoot programs need comprehensive strategies to raise awareness about clubfoot amongst community members, health providers, and religious leaders in order to be successful.

INTRODUCTION

Idiopathic clubfoot, or congenital talipes equinovarus, is a congenital orthopedic anomaly of the foot. If left untreated, the condition becomes increasingly fixed and pronounced, and can severely hamper physical mobility. Studies in Uganda, Malawi, and Latin America (Chile, Guatemala, and Peru) have found that community knowledge and perceptions about clubfoot impact treatment-seeking behaviours. In Uganda and Malawi, there were a number of misconceptions about the causes of clubfoot and people often did not seek treatment because they were unaware about its availability and did not consider clubfoot to be a correctible condition. In Uganda, where a higher power was considered responsible for clubfoot, people turned to traditional spiritual healers for help instead of allopathic caregivers. Fear of corrective surgery also prevented some from seeking treatment. Similarly, a number of physicians in Guatemala and some in Peru believed that the culture and beliefs of patients were strong barriers to treatment.

In 2011, the Indus Hospital in Karachi, Pakistan initiated the Pehla Qadam program to treat clubfoot using the Ponseti method. Although there is some literature available on clubfoot treatment options in Pakistan, there is no literature about local beliefs about clubfoot. Given the links between beliefs and treatment-seeking behaviours, we conducted a preliminary qualitative study to understand perceptions and knowledge about clubfoot in Pakistan. This paper presents the findings of this study.

METHODS

The data was collected during September and October 2011 in the Indus Hospital catchment community in Karachi, Pakistan. The Indus Hospital is a free-of-charge 150 bed facility located in a low-income industrial area of Karachi. The hospital’s direct catchment population includes Korangi town, Landhi town, and parts of Bin Qasim town and consists of a multi-ethnic population of approximately 2.5 million people. The population comprises of various migrant settlements adjacent to historical fishing villages along the south-eastern coast of Karachi.

Seven focus group discussions (FGDs) were held, which included three groups of female community members, two groups of male community members, and two groups of Lady Health Workers (LHWs) who are community-based primary health workers in rural areas and urban slums in Pakistan. Each FGD had six to 15 participants, for a total of 65 participants (22 male community members, 22 female community members, and 21 LHWs). Additionally, eight in-depth interviews (IDIs) were conducted with parents of children with clubfoot.

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one interview with an adult with untreated clubfoot, and one interview with the mother of two children with untreated clubfoot.

FGD participants and the IDI participants with untreated clubfoot were recruited through social workers from Non Governmental Organizations (NGOs) and (Community-Based Organizations (CBOs) working in the Indus Hospital catchment community. We identified parents of children with treated clubfoot using the medical records at the Indus Hospital to identify children with clubfoot who had recently received surgery to correct their condition.

A semi-structured interview guide was developed for data collection which focused on understanding community knowledge, perceptions, and experiences related to clubfoot. Interviews were primarily conducted in Urdu, the national language of Pakistan. A few interviews conducted in Sindhi, a regional language, and were translated into Urdu for analysis. Purposive sampling was used to ensure diversity in gender, age, geographic location, and ethnicity.

Thematic analyses of interviews was conducted using open coding in Weft QDA 1.01. Oral consent was taken from all participants of the study. Ethical clearance for the research was granted by the Interactive Research and Development Institutional Review Board (IRD-IRB).

RESULTS

Familiarity with clubfoot
Most FGD participants were unable to differentiate clubfoot from other disabilities and were unaware about it as a separate condition. When shown photographs of clubfoot, the majority of the FGD participants described it as having twisted feet, being crippled, or being disabled. Some participants described the condition as a birth disability. A few participants confused clubfoot with deformities resulting from polio.

Without knowledge about clubfoot, parents of children with clubfoot often did not immediately realize that their newborn’s feet were affected. Most participants of the in-depth interviews said that they noticed the condition after a few days or after a relative or someone else pointed out the condition.

Causes
Participants ascribed clubfoot to a variety of causes such as lunar or solar eclipses, religious explanations, the health status and behaviours of parents, and genetics.

Lunar and Solar Eclipses
The most common belief held by community members about the cause of clubfoot was related to lunar and solar eclipses. In fact, some people referred to the condition itself as “chand girhan” or lunar eclipse. Most participants believed that any movement by a pregnant woman during an eclipse can lead to clubfoot and other disabilities in the unborn child. As a result, participants said that women are advised to lie flat on their backs for the duration of an eclipse to prevent any harm to their unborn child. Many participants believed that the disability in the child is related to the activity carried out by the mother during the eclipse. For example, a focus group participant said, “A woman I know was cutting vegetables during a lunar eclipse and so her child was born without ears.” While the majority of participants believed that only the pregnant mother’s movements could result in clubfoot, a few participants also believed that movement by the father during the eclipse could have an impact on the physical condition of the child. One participant felt that a lightning storm during pregnancy could also result in this disability.

While the link between clubfoot and disability was a very commonly held belief by participants, not all community members subscribed to this. One focus group participant said, “We used to hear [that a woman shouldn’t move during an eclipse] when we were younger but that thinking has now changed...They say that education is becoming more common and, based on that, the thinking is changing. Previously, women used to say that the lunar eclipse [caused disability] but we don’t think that.”

Some parents of children with clubfoot also believed that the movement of the mother during an eclipse was the cause of their child’s disability. A mother with two children with clubfoot said, “Women[tell me] that you must have bent your legs during the lunar eclipse and, because of that, [your children have clubfoot.]” Some mothers said that they were not aware of the eclipse and therefore did not restrict their movement. One mother said that during her pregnancy there was a lunar eclipse that she did not know about. “I was asleep. It happened at night. I didn’t know about it, otherwise I would have taken precautions.” Another woman said, “[During my pregnancy], there was a lunar eclipse during [the month of] Ramadan. I read the Qur’an during that time...People say that I must have done something, some work, or cut something. I tell them that I didn’t do anything. It was evening time and I never do any work during that time...I just read the Qur’an...[Still,] it must have happened because of the lunar eclipse.”.

Religious Explanations
A number of participants of both the FGDs and in-depth interviews attributed the cause of clubfoot to the will of God. It was seen as God-given and natural, which can make the acceptance of the condition easier. An FGD participant said, “[People with children with clubfoot think] that God did this to us. This is also the will of God. This will also have some benefit for us.”
One mother with a child with clubfoot was told by a religious leader that the clubfoot was a sign of the prayers that he had conducted to help her take her pregnancy to term after a number of miscarriages. He said that even if she were to try to treat the condition, it would not be successful as the clubfoot was a mark of his prayers.

Other participants saw clubfoot as a punishment from God. Some felt that it was a punishment for behaviours such as greed, dishonesty, denying people their rights, or using intoxicants. Others thought that it was a retribution from God for making fun of someone with a disability. The interview participant living with untreated clubfoot said, “In our neighbourhood, there is a boy...When his mother was pregnant I used to go there to get milk. My friend told me that this woman used to laugh at my feet....When she gave birth, she had a child just like that...I told my friend that I wasn’t offended by what she said and nor did I wish her ill. [However,] this is a natural thing. It could be that God got angry at her.”

A few participants, including the mother of a child with clubfoot, believed that clubfoot was caused by djinns or spirits.

Health status and behaviours of the parents

Some FGD participants said that not enough nutrition for the mother or a shortage of specific nutrients such as proteins, calcium, iron, and vitamins, in mothers caused clubfoot in the unborn child. A FGD participant said, “If a mother has a shortage in vitamins or calcium or anything, this causes the unborn child’s feet to become bent. Clearly, bones are made of calcium and so I think this must be the cause of clubfoot.” A mother with a child born with clubfoot said, “In our extended family there is a calcium deficiency. As far as I can tell, [my child’s clubfoot] was caused by a shortage in calcium.” Participants linked these nutritional deficiencies with poverty, which prevented mothers getting adequate nutrition.

Some participants also believed that clubfoot could be caused by the consumption of intoxicants such as paan, cigarettes, tobacco, betel nut, or even drugs such as heroine by the mother during pregnancy. A few participants also believed that clubfoot could be caused in a child through drug consumption by either parent. An FGD participant said, “If the father consumes drugs, this too will affect the unborn child and if the mother does then this will have affect the child’s development even more. Drugs get absorbed in the mother’s blood.”

Finally, a few participants linked clubfoot to a variety of causes such as poor hygiene, anaemia, insufficient vaccinations, family planning, getting x-rays during pregnancy, high blood pressure, medication used during pregnancy, not taking care of self during pregnancy, or stress.

Genetics

Genetics were also considered a contributor to clubfoot by a majority of participants, including parents of children with clubfoot. They cited examples of children with clubfoot that have relatives, such as grandparents, uncles, and siblings, who have clubfoot. Furthermore, a few participants thought that clubfoot could also be caused by marriage between cousins or marriage between people of the same blood group.

Treatment

Participants cited a number of allopathic remedies for clubfoot including surgery, special shoes, and plaster casts. Of these, surgery was the most commonly cited. Participants also cited a number of traditional or home remedies for the treatment of clubfoot. The most commonly cited traditional remedies were oil massages or warm bandages. The father of a child with clubfoot took his son to a woman who was famous for her bandaging technique. “My friend said that a lot of people’s broken feet have been healed with her massage and bandage so if you go there, [you child’s foot] will also become alright.” However, he did not feel like it made much of a difference to his son’s foot. Another mother took her child to the doctor when he was a couple days old and was told that she just needed to put oil and massage the foot and that the child would eventually outgrow it.

Another traditional belief that was cited was burying the child in sand, either up to their neck or just completely immersing their legs in the sand. A variation of their belief was that it had to be near the sea or during an eclipse. An LHW said, “My aunt’s [six-year-old] daughter’s feet were okay but she couldn’t walk. We took her to the seaside, dug a hole and put her inside so that only her head was outside. We did this every day and she became okay. She was able to walk.” Two parents of children with clubfoot said that they were advised to do this with their children but they were too scared.

Some participants also said that treatment could come through visits to religious healers or to the shrines of saints for healing. A mother of a child with clubfoot said that she visited a number of shrines and healers to no avail because relatives told her this was the way to find a cure for her child’s clubfoot.

Finally, some participants believed that there was no cure for clubfoot or they believed that a child would eventually outgrow the condition. Parents of children with clubfoot said that they were often told by friends and relatives that that there was no need to treat it as it would correct itself with age or that it was untreatable. One mother said that a family member told her, “This is a very dangerous disease. This child will stay this way. He will either grow up and move around in a wheelchair or not be able to move around at all.”
DISCUSSION

This study provides unique and important insight into the knowledge and perceptions about clubfoot at the community level in Karachi that have key implications for clubfoot programs in Pakistan. There was a great deal of incorrect information and misconceptions about clubfoot that were common across ethnicities and educational levels of participants.

The study found that participants were unable to distinguish clubfoot from other disabilities, even confusing it with polio. This emphasizes the need for clubfoot programs to create awareness about the unique condition of clubfoot and how it is presented in order to promote early identification and appropriate treatment for this condition.

The study also found that, like in Malawi and Uganda, there are numerous misconceptions about the causes of clubfoot in Pakistan, many of which placed blame for the condition on the mother. These may lead to the stigmatization of families of children with clubfoot and could have a detrimental impact on mothers of children with clubfoot.

Similarly, there were also a number of misconceptions about treatment that could not only lead to the incorrect treatment of the condition, but can also lead to treatment delays. Thus, it is also important to raise awareness about effective treatment methods and their availability.

Finally, the study also found that these misconceptions were held not only by the general community members, but also by LHWs participating in the study, indicating the need for awareness at both the community and health provider level. Moreover, due to the belief in religious explanations for clubfoot and the practice of approaching religious leaders and healers for treatment, the findings indicate it is imperative to educate religious leaders about this condition and its treatment.

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ABSTRACT

Background: The Ponseti method has been established as the standard of care for the treatment of clubfoot in many developed countries for its utility, cost-effectiveness, and efficiency. However, despite its being described as the gold-standard for clubfoot treatment, there are still many areas of the world bereft in formal training in the Ponseti method. This is especially important since 80% of patients with clubfoot are born in developing countries where the need is the greater for experienced providers. This study analyzes a ‘Train the Trainer’ approach, specifically in the island nation of Sri Lanka, as a model for future dissemination of the Ponseti method throughout the developing world.

Methods: A rapid ethnographic study design that included interviews, focus groups, and direct observation of 162 patients and healthcare practitioners directly involved with clubfoot care was conducted.

Results: The average age of the patients at the time of the interview was 75.4 weeks old (SD = 149.2), traveled 45.2 kilometers (SD = 49.8) to receive their care, and received 4 casts (SD = 2.2) for correction of the deformity. Since the initiation of the ‘Train the Trainer’ educational program, clubfoot clinics reportedly grew from 6-7 patients per week to over 60 patients per week. The majority of this patient population growth was attributed to word of mouth. Major barriers to the method included casting materials, bracing materials, and a lack of a dedicated area of the clinic to conduct tenotomies under local anesthesia. Of note, cost was not cited as a major barrier.

Conclusion: Early evaluation suggests great utility of the ‘Train the Trainer’ method – especially regarding an increased patient demand for treatment. However, further studies are necessary to understand the long-term utility of this training methodology.

INTRODUCTION

The Ponseti method is a well-established clubfoot treatment in both developed and developing countries due to its efficacy and cost-effectiveness1-16. Clubfoot, which is most often found in the developing world, is a deformity that can cause debilitating disability if left untreated17,22. Furthermore, the economic impact of untreated clubfoot on a nation’s economy and labor force is profound21,24. Although many barriers exist to enhancing global healthcare delivery, appropriate education of healthcare providers is repeatedly cited as a major barrier2,13,25.

To date, educational programs have been successfully implemented in over 50 countries, but despite these efforts, there are still areas bereft of appropriate clubfoot care1-16,26. The Ponseti method has traditionally been taught in weekend-long hands-on workshops2,4,7,13. However, this method of teaching leaves the country without a dedicated Ponseti ‘expert’ despite many practitioners being capable of providing the treatment13.

A ‘Train the Trainer’ approach has been used in several countries (Brazil, Hungary, Croatia, Bosnia, Armenia, Nigeria, Cameroon, Sri Lanka, and Pakistan amongst others) as part of an effort to train more Ponseti practitioners. This approach also utilizes a country’s existing healthcare infrastructure to establish dedicated clubfoot clinics.

Here, we analyze the country of Sri Lanka, and its progress since its participation in the ‘Train the Trainer’ Ponseti program. Several factors make Sri Lanka a model nation to study the effects of the ‘Train the Trainer’
program. Sri Lanka has a GDP per capita of $5700, currently 146th in the world, making it an adequate representative of a low-resourced country. Sri Lanka also has a high population density as the most recent census revealed a population of 21.5 million people who inhabit an island slightly larger than West Virginia. To date, no formal clubfoot training has been documented in Sri Lanka prior to the current “Train the Trainer” program – likely secondary to the recent conclusion of the island’s 26-year civil war. In addition to the detrimental developmental effects of the civil war, the nation was devastated by the Boxing Day Tsunami of 2004. Interestingly, post-tsunami orthopaedic reports revealed a high need for clubfoot practitioners due to high rates of untreated clubfoot.

In July 2012, two Sri Lankan physicians participated in a 3-week fellowship visit at the University of Iowa Department of Orthopaedics. These physicians mastered the Ponseti method through direct observation of trained practitioners, case discussions, lectures and practice on clubfoot models. The progress of their work after their participation in the training was evaluated after 5 months in order to give practitioners adequate time to initiate changes in their practices.

This paper is a qualitative study that describes the successes and barriers to the ‘Train the Trainer’ approach using Sri Lanka as a model country.

METHODS

A rapid ethnographic study design was conducted. Data collection utilized a variety of qualitative methods including interviews, focus group discussions, and direct observation (Table 1). Multiple data collection tools were used to gather and verify data in order to increase the validity of the study through data triangulation. Participants included staff and patients from: Lady Ridgeway Hospital for Children (LRH), the largest pediatric hospital in the nation; Colombo North Teaching Hospital (CNTH), a large teaching hospital for Colombo’s north district; and a private orthopaedic clinic at Leesons Private Hospital (LPH). Interviews with additional key informants included the project director of Sri Lankan School of Prosthetics and Orthotics (SLSPO), and the manager of the Lady Ridgeway Hospital Orthotics program.

Direct observation of clubfoot clinics occurred at each of the sites. Observation of the initial clinical visit by the physician, Ponseti manipulation, cast application, tenotomy procedures, and bracing follow-up appointment including the construction of the brace itself were observed.

Brief parent interviews were conducted of each patient observed. These interviews collected the patient’s age, distance traveled from home to the hospital, number of casts applied, and relapse history. In-depth interviews were conducted with select parents. In-depth interviews collected information on the current and past treatment plans of the patients, challenges and barriers faced with clubfoot treatment, parent satisfaction with the correction, and experience with the brace. Effort was made to include interviews from patients at each stage of the treatment including casting, bracing, and relapses.

Interviews were also conducted of the consultant orthopaedic surgeons, medical officers, and nursing staff at the clubfoot clinics. Interviews with medical practitioners solicited information on the state of clubfoot management in Sri Lanka, training methods used, perceived barriers from the patient’s perspective, changes in clinics post-Ponseti training course, and barriers to further development of Sri Lanka’s clubfoot treatment program. Interviews began with open-ended questions and the interviewer guided the interview if further questioning was needed.

Two different focus groups were conducted. One focus group consisted of the two medical officers who run the clubfoot clinics at LRH and the other consisted of two nursing staff who apply the casts at LRH and CNTH. The interview questions were open ended and the interviewer probed for more information when necessary. The focus group interview for each the medical officers and nursing staff solicited information on the set-up of the clubfoot clinics, how they were trained, and the change in clubfoot clinics over time.

Interviews and focus groups were conducted in English when possible, however, when required, a Sinhala translator was used. The Sinhala translator was a native of Sri Lanka whose mother tongue is Sinhala, but was also fluent in English. No interviews were conducted in Tamil, a language spoken by 18% of the population, most notably in the north of the country. Notes from focus groups and interviews were immediately recorded in English and transcribed to an electronic record on Microsoft Excel within 24 hours. Notes were reviewed between authors AJ, SW, and DT to ensure validity and accuracy. Electronic notes were then organized into themes based on the similarities of responses. A team approach was used to draw conclusions about the organized data.

This study was granted exemption from consent by the Institutional Review Board of the University of Iowa. No patient or parent names were collected and the data was stored in a secured location.

RESULTS

Sri Lankan Healthcare System

In order to provide context to this report, a brief overview of the Sri Lanka healthcare system and or-
orthopaedic surgeon training program will be outlined. Healthcare in Sri Lanka is provided by the government free of charge to the people. In addition to the government-run healthcare system, there also exists a private system which supplements the public system for those with financial means.

There are seven different medical schools in Sri Lanka, which each produce about 150 graduates per year. The MBBS degree, equivalent to the MD degree, is awarded after 5 years of medical school. After the MBBS, a one-year internship is required. If the graduate chooses to pursue practice at this point, he or she can practice as a medical officer, however, to become a consultant specialist, he or she must pursue postgraduate medical education. Post-graduate orthopaedic training is 6 years of advanced training followed by a required international training period of 1-2 years.

Upon their return to Sri Lanka and obtaining board certification from the Post-graduate Institute of Medicine, most graduates are placed by the government for 4 year posts at hospitals around the country if they do not choose to resign from the government system. There are a limited number of ‘end posts,’ which allow the applicant to remain at that post until they retire without having to re-apply. ‘End posts’ are highly competitive and generally only received near the end of a career.

Currently, Sri Lanka has 44 practicing orthopaedic surgeons.28 With a population of 21.5 million, there are nearly 500,000 patients per orthopaedic surgeon. The Sri Lankan Orthopaedic Association (SLOA), the official orthopaedic association of Sri Lanka, meets annually every October for their scientific session.

The unique healthcare system in Sri Lanka poses some interesting challenges to clubfoot management in Sri Lanka. The rotating government posts around the country every four years have made it a challenge to set up a consistent clubfoot clinic. However, this limitation is also an asset. Eventually, far more areas of the island will be exposed to formal Ponseti clubfoot clinics. The consultant orthopaedic surgeon currently stationed in CNTH will be moving to a large hospital in Kurunagela in January 2013 where he is planning to establish a new Ponseti clubfoot clinic.

**Current Clubfoot Management in Sri Lanka**

**Lady Ridgeway Hospital:**

Lady Ridgeway Hospital (LRH), located in Colombo, Sri Lanka, is one of the largest children’s hospitals in the world. It currently has 901 pediatric beds and serves 2500-3000 children per day. It functions as Sri Lanka’s national referral center for all pediatric care on the island. LRH has been running a clubfoot clinic for eight years since 2004. The clinical model now used by LRH ensures each child is seen directly by the consultant orthopaedic surgeon. The surgeon manipulates the child’s foot using the Ponseti method and determines the child’s current treatment plan (ie. more casting, tenotomy, surgery, etc.). If the child is due for casting, he or she is taken to the cast room where two teams of three nurses place Ponseti casts on the children. If the child is being treated for a relapse, a medical officer with post-graduate medical training (equivalent to an MD degree) will place the cast. Several posters with information on the Ponseti method are displayed in the cast room. The cast room is large, with room for several beds and allows a team of health professionals to place the casts.

At LRH, each child is also seen every month for a follow-up bracing appointment. At this appointment, the medical officer observes the child wearing the brace. The patient’s clubfoot correction is also observed and appropriate clinical action is taken if necessary. The patient and parent are asked if they have any problems with the bracing and further brace education is provided at this point.

**Colombo North Teaching Hospital:**

The Colombo North Teaching Hospital (CNTH), located in North Colombo, is one of the largest hospitals in Sri Lanka. The hospital’s catchment area includes the districts of Gampaha, Puttalam, and Kurunagala; a population of over 6.5 million people. CNTH serves both adults and pediatrics and is in the process of building a dedicated orthopaedic’s building.

The clubfoot clinic in Colombo North is a recent addition to the orthopaedic services at CNTH. Similar to LRH, the CNTH model allows each child to be seen directly by the consultant orthopaedic surgeon who manipulates the child’s foot and determines the treatment plan. A separate room is available for casting, which is placed by nursing staff, medical officers, and the consultant orthopaedic surgeon – all of which have been trained in the Ponseti method. A poster, printed from the internet, describing the Ponseti method is displayed in the cast room. The cast room is a very small private room.

**Leesons Private Hospital:**

Leesons Private Hospital (LPH) is located in Ragama, Sri Lanka less than a mile away from the Colombo North Teaching Hospital. The same consultant orthopaedic surgeon who runs the Colombo North Teaching Hospital holds a private clinic at the LPH. Practicing in both a public and private setting is common for Sri Lankan physicians.

There is no formal clubfoot clinic at LPH, however, clubfoot patients are seen and casted during the general clinic hours. Casts are placed by the consultant physician with the help of the nurse. No posters of visual
representation of the Ponseti technique are observed in the clinic. The clinic is a small, one room unit, with a physician desk, cast cart, and patient bed.

**Participant Characteristics**

162 total patients were observed during their clubfoot care (Table 1). 152 (94%) of the patients consented to interview and 45 (28%) consented to an in-depth interview. The majority of the interviews and observations came from Lady Ridgeway Hospital (82%), which treats the highest pediatric population of the hospitals surveyed.

The average age of the children surveyed was 75 weeks (SD = 149 weeks). On average, each had received about 4 casts (SD = 2.6 casts) at the time of the interview (Table 2). Most patients traveled about 45 km (SD = 50 km) to receive their clubfoot care. The majority of the patients observed were in the casting stage (66%).

**Barriers to clubfoot care**

**Casting:**

Casting materials were repeatedly cited as a barrier by consultant orthopaedic surgeons, medical officers and nurses. The casting material provided by the government is not a fast-drying plaster of paris. The slower drying time of the casts made it more difficult to achieve the appropriate manipulation with the cast due to the baby’s movement during the casting process. Furthermore, no 2-inch casting material is available. Four-inch plaster of paris were cut in half to achieve the 2 inch length appropriate for casting infants. However, the act of cutting the 4-inch material in half degraded the interior structure of the plaster of paris making it more difficult to handle the casting material. This further exacerbated the difficulties encountered with the slow drying casts. The lack of appropriate casting materials increased the amount of clinical time necessary to spend with each patient and decreased the likelihood of achieving an appropriate correction with the cast.

Additionally, the quality of the cotton padding provided by the government was reported to be very poor, especially at CNTH. The cotton was irregular in thickness making appropriate padding difficult. Furthermore, the cotton did not tear very easily making its application more difficult and cumbersome. Several children presented with skin abrasions and pressure sores from the casting application.

Some patients required synthetic casting if they were older or had broken previous plaster of paris casts due to excessive movement. However, synthetic casts are not provided by the government, which required parents to purchase these materials themselves. Most pharmacies that offered the synthetic casting material were located near the hospital ensuring that a patient could purchase the cast and have it placed the same day. However, occasionally a patient will be sent to the pharmacy to purchase cotton padding, synthetic casting material, or stockings and will return with the wrong supplies provided by the pharmacy.

The stockings placed underneath the cotton and plaster of paris are also not provided by the government. At CNTH, the consultant physicians purchased the stockings themselves. Many of the patients who were treated initially with the Ponseti method reported being satisfied with the casting and correction.

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**Table 1. Participant information**

<table>
<thead>
<tr>
<th></th>
<th>Public Pediatric Hospital</th>
<th>Public Hospital</th>
<th>Private Clinic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brief Parent Interviews</strong></td>
<td>126</td>
<td>24</td>
<td>4</td>
<td>154</td>
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<tr>
<td><strong>In-depth interview</strong></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Parents</td>
<td>18</td>
<td>24</td>
<td>3</td>
<td>45</td>
</tr>
<tr>
<td>Consultant Physicians</td>
<td>1</td>
<td>1*</td>
<td>1*</td>
<td>2</td>
</tr>
<tr>
<td>Medical Officers</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Nursing Staff</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td><strong>Focus Group</strong></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Nursing Staff</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Medical Officers</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Direct Observations</strong></td>
<td>83</td>
<td>21</td>
<td>3</td>
<td>107</td>
</tr>
<tr>
<td>Casting</td>
<td>43</td>
<td>3</td>
<td>1</td>
<td>47</td>
</tr>
<tr>
<td>Bracing</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Tenotomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>132</td>
<td>26</td>
<td>4</td>
<td>162</td>
</tr>
</tbody>
</table>

*Same orthopaedic practitioner interviewed in each location.*
Tenotomy:
In all LRH, CNTH, and LPH, the tenotomy procedure was done under general anesthesia in the operating theater. A cataract blade and percutaneous tenotomy is used for small children. Larger children receive a mini-open tenotomy and a regular scalpel blade. Roughly 60-65% of children receive tenotomies. At CNTH, the number of children receiving tenotomy would be higher if not for various barriers to completing the procedure.

Utilization of general anesthesia was a barrier to the administration of the tenotomy. In LRH, each child is given their own operating room, however, in CNTH, the OR space is limited and two patients share the same room. In LRH, a dedicated pediatric unit, anesthetists had no trouble inducing children into general anesthesia, however, the same could not be said at CNTH. At CNTH, in fact, anesthesiologists were reluctant to induce infant children under general anesthesia for the tenotomy. Also, the OR time is limited. Orthopaedic surgeons are only given one day in the OR for non-emergent procedures. In Sri Lanka, similar to many developing countries, the OR time of orthopaedic surgeons is vastly consumed by trauma. The tenotomy, although itself is a very quick procedure, took roughly 30 minutes of OR time with the majority of this time being used to anesthetize the child.

Some physicians revealed a preference for general anesthesia versus local anesthesia for the tenotomies for various reasons. First, no sterile area exists during clubfoot clinics, which at CNTH are performed on the wards. Furthermore, there is no time during clinics to conduct the tenotomies at LRH due to the high patient caseload. Furthermore, due to the lack of fast-drying casting material, there is a preference for a sedated child post-tenotomy to achieve adequate casting.

However, despite the perceived advantages of general anesthesia, there is an effort to pursue local anesthesia. The barrier to achieving this goal is the convincing of upper level management to clear a clean space during clubfoot clinics. The dedicated orthopaedic building currently being constructed at CNTH may alleviate this barrier.

Bracing:
A child is measured for the brace about 3-4 weeks before the consultant orthopaedic surgeon believes the child’s casting treatment will conclude. Braces take about 3-4 weeks to be made. Braces for children who attend the public hospital are provided free of charge. Additionally, when a brace no longer fits a child, they can have another one made for free. Braces for patients who attended a private clinic were available for 3000 rupees (~$25). An average of 3-4 braces are used throughout the child’s treatment.

Bracing materials were repeatedly identified as a barrier to clubfoot care. Several parents reported difficulty with brace compliance due to children being uncomfortable while wearing the braces. The government has reportedly struggled to find a balance between providing free braces that are also comfortable for the child.

Also, a few patients reported being confused about the bracing protocol. At LRH, their questions were easily answered during their one month follow-up, however no follow-up appointment was offered at CNTH. Some patients believed they needed to wear the brace for 23 hours as long as 6 months after casting was complete. The confusion about the bracing protocol reduced brace compliance. At the follow-up appointment the parents were instructed that they could reduce the duration the child was in the brace.

The clinical time necessary to fit the child for the brace was deemed unnecessary by one healthcare provider. If the braces could be made with adjustable width and shoe sizes, this could be avoided. Furthermore, this would prevent children who graduated from the casting phase earlier than expected not to have to wait for their brace to be made before wearing it. An alternate method suggested was to have pre-made braces of various sizes for hospitals to offer patients during the clinic. However, this is unlikely due to limited resources by the government providing the brace.

The Orthotics and Prosthetics Department at LRH is the largest producer of the Ponseti brace in the country. They currently produce 30-35 braces for the LRH hospital and 15-20 which are sent to other areas in the country. The unit manager revealed difficulties obtaining the raw materials for the brace. Currently, leather and aluminum are used to construct the brace. Subtle adjustments can be made for the children with special needs. One child was allergic to leather and was made a unique brace to help them with this ailment. A grant from USAID and Handicap International support the brace-constructing operation at LRH. An additional barrier was workshop
space. Despite a recent renovation of the workshop, it has struggled to keep up with the increased demand for the Ponseti braces.

A discussion with the project director of the Sri Lankan School of Prosthetics and Orthotics (SLSPO) revealed additional barriers to brace production. Although SLSPO has not yet started to produce the brace, they plan to do so in the near future. However, because SLSPO primarily functions as an orthotics and prosthetics school, they have various other priorities that take precedence over the Ponseti brace. They have been in contact with a local manufacturer who can create the leather shoes and a different local manufacturer who can create the steel bars. The braces made by SLSPO would be modeled after a brace donated from the United States and would include adjustable foot abduction, shoe size, and width between the shoes. The brace also would include a small pad along the heel which would help make the brace more comfortable. One issue the program director cited to successful manufacturing of the braces was a lack of uniformity amongst orthopaedic providers. They believe an endorsement from the Ministry of Health for the Ponseti protocol as well as a national training program would be a very useful step for SLSPO to make the braces.

Cost:
Cost of treatment is a negligible barrier for optimal clubfoot treatment in Sri Lanka. Despite the low GDP per capita in Sri Lanka, the government provides all healthcare free of charge. Additional materials that need to be purchased include stocking materials, cast padding, and synthetic casting (if necessary). Synthetic cast material cost 1700 rupees (~$13) and cast padding costs 300 rupees ($2.40). Patients who can afford private healthcare are asked to pay 4000 rupees ($31.50) for bilateral clubfeet and 2000 rupees ($15.60) for unilateral clubfeet per clinic visit. Braces cost 3000 rupees ($23.30) if purchased through the private clinic. However, no patient interviewed directly cited cost as the major barrier to clubfoot care.

Distance traveled:
Patients reported traveling up to 280km to receive their clubfoot care. Currently, only two practitioners have been formally trained in the Ponseti method. In the small medical community of Sri Lanka, physicians are knowledgeable of the two trained Ponseti practitioners and have begun to refer patients to them from all parts of the island.

The LRH in Colombo serves as the tertiary care pediatric hospital for the entire island. Therefore, it is not uncommon for patients to travel to LRH for their treatment from various parts of the country. In fact, many mothers receive their obstetric care from one of the major obstetric hospitals in Colombo and establish care at a Colombo hospital for their child. Many parents inherently believe that treatment in the capital is better than in their local provinces despite entirely adequate regional hospitals. Often, families then create ‘medical homes’ with friends and family in Colombo, which allows them to stay locally while receiving their healthcare. One family described having parents in Colombo, who they visited once per month. They coordinated their medical visits with these trips; however, this did not allow them to achieve the once/week Ponseti care necessary for optimal correction. The hospital does not provide any housing assistance for those who have traveled long distances.

Ponseti educational program
Prior to the training program undertaken by two Sri Lankan physicians, each physician reported previous use of the ‘Ponseti’ method. However, reports from patients and physicians alike reveal a number of different methods of casting and surgery that did not fit the Ponseti protocol. Patients treated with these alternate methods were often seen in the clinic during the duration of this study as relapsed patients. Furthermore, the clubfoot clinic at LRH prior to the Ponseti training program reportedly averaged about 6-7 patients per week.

Since two Sri Lankan physicians were trained in the Ponseti method, the clubfoot clinics have changed drastically. The nursing staff and medical officers report being given hands on casting training with clubfoot foot and bone models. Supplemental videos were also watched. Additionally, the structure of the clinics changed allowing one practitioner to see all of the patients and make their treatment decisions. Prior to this, the nursing staff collectively decided the outcomes of the child leading to high observer variance in the child’s management. Other changes include the casting of relapse patients, an area where surgery was the previously preferred alternative.

Clubfoot clinics at LRH currently exceed 60 patients per week (casting and bracing), a drastic increase from the previously reported 6-7 cases. Parents reported several methods of learning about the clubfoot clinics, which included recommendations from other physicians and conversations with and observations of children treated at these clinics.

**DISCUSSION**
This is the first study to describe the early successes and failures of the ‘Train the Trainer’ strategy in the dissemination of the Ponseti method. Successes include a drastic increase in patient demand and thorough modification of the clinic set-up after physicians return from their three-week training. However, various barri-
ers continue to exist including casting materials, brace discomfort, and a great distance traveled by several patients to achieve adequate care.

The 'Train the Trainer' approach utilizes a country's existing orthopaedic staff, nursing staff, and clinic/hospital capital. The only cost to the utilization of this program is the cost of the plane flight and lodging for the practitioners during their stay at the University of Iowa. This model not only demonstrates early positive results, but also does so in a financially efficient manner. The results of this study should serve as a model for other nations as they plan to undertake similar training programs of their own.

Sri Lanka can continue to improve their clubfoot management by increasing the number of practitioners with a thorough understanding of the Ponseti method, continuing to train their house officers, residents, and nursing staff in the importance of the method, and working to improve the resources available for casting and bracing.

A one-year follow-up visit by an expert Ponseti practitioner from the University of Iowa is planned to continue the assessment of Sri Lanka's clubfoot management and also to train more physicians in the method in conjunction with the two existing practitioners. As the success of the Ponseti clinics continues spread, one would anticipate a further increase in the patients who attend the clinics. However, until the one-year follow-up training program commences, it is likely that patients will continue traveling long distances to attend the Ponseti clinics.

This study is limited in that it only interviewed Sinhala-speaking patients in Colombo and its surroundings. No interviews were conducted with the Tamil-speaking northern districts of Sri Lanka. However, clubfoot care in this area has previously been documented as poor.[6]

An effort should be made to include this group in follow-up training.

Follow-up studies should be conducted at 1- and 5-year time periods to appropriately document the utility of the 'Train the Trainer' method of physician education in Sri Lanka. Although this study thoroughly describes the early successes and barriers to the program, long-term conclusions cannot be drawn from a study conducted five months after the Sri Lanka Ponseti program was established.

In conclusion, Sri Lanka has greatly benefited from the 'Train the Trainer' approach to their clubfoot management. Clubfoot clinics run much more efficiently and patient attendance has drastically increased. Remaining barriers include resource allocation and a great distance traveled by some patients. Planned follow-up training, as well as an inevitable integration of the Ponseti method into the Sri Lanka healthcare system over time, should alleviate these problems.

ACKNOWLEDGEMENTS

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REFERENCES


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THE PONSETI METHOD OF TREATMENT FOR CLUBFOOT IN BRAZIL: BARRIERS TO BRACING COMPLIANCE

Monica Paschoal Nogueira MD, PhD¹, Mark Fox², Kathleen Miller², Jose Morcuende, MD, PhD³

ABSTRACT

Background: Clubfoot is the most common extremity birth defect. It causes the feet of affected individuals to point inward and downward, preventing them from walking normally. Neglected clubfoot causes disabilities that result in a lack of social integration, creating a psychological and financial burden for the family and community. Clubfoot has been effectively treated through the Ponseti method, a treatment utilizing serial casts to correct the deformity followed by use of an abduction brace for approximately 2-4 years. Sustained use of the brace is necessary to prevent relapse and ensure a successful outcome. Brace compliance in the setting of limited resources in the developing world can be challenging. The purpose of this study was to identify the barriers to bracing compliance in southeastern Brazil. In addition to socioeconomic and cultural barriers, this study also looked at improper prescribing practices by physicians as a potential cause of noncompliance. The study sought to identify the role of physician education in the use of the Ponseti method and physicians’ knowledge of the bracing process.

Purpose of the study: Identify the barriers to bracing adherence that could negatively impact the treatment of children with clubfoot.

Methods: Forty-five orthopedists from several centers in southeastern Brazil were interviewed. Physicians were asked about their training in the Ponseti method, their protocol when prescribing the brace, their evaluation of its importance, and a series of open-ended questions designed to identify the positive and negative qualities of local braces. They were also asked what they perceived to be the biggest challenges to sustained brace use.

Results: Sixteen of the physicians interviewed were orthopedic residents, and 29 had completed their residencies. Of these two groups, only 25% and 65%, respectively, appropriately prescribe the abduction brace for patients, with the majority recommending use of the brace for an inadequate period of time. The high costs and delays in acquisition of the brace and a lack of orthopedic stores able to adequately construct the orthotic, also present considerable barriers to sustained brace use.

Conclusions: Many of the causes of noncompliance with bracing protocol stem from systemic inequities and challenges, rather than a lack of collaboration from the families themselves. Furthermore, insufficient prescription of the brace by physicians may represent a major barrier to bracing compliance in southeastern Brazil. This research indicates a need to evaluate physician training and continuing medical education in order to ensure that physicians are adequately utilizing the brace.

INTRODUCTION

Clubfoot is a congenital birth defect that causes the feet of affected infants to point inward and downward, forcing the child to walk on the sides of his or her feet. It often results in significant disability for affected individuals by limiting mobility, increasing the risk of skin and bone infections, and decreasing opportunities to pursue education and employment¹,². It can also be a source of psychological harm when the child is subjected to ostracism or derision.

Historically, clubfoot has been treated with extensive and invasive surgeries. However, since the 1990s, the Ponseti method of treatment has repeatedly been proven to effectively treat clubfoot with only minimally invasive surgery¹,³,⁸. This technique, which involves a series of manipulations and castings followed by an office-based Achilles tenotomy, is especially groundbreaking in developing countries, where extensive surgery is often prohibitively expensive and where 80% of children with clubfeet are born¹,². Rates of success with the Ponseti method have been reported to be as high as

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95%¹; however, relapse rates are also high and present a significant problem in treatment⁸. Relapses occur in 14-41% of patients⁹, with some patients experiencing multiple relapses or treatment failure. The single factor most frequently associated with relapse is inadequate use of an abduction brace following the casting phase of treatment⁵⁹. According to Ponseti protocol, the brace should be prescribed for 23 hours a day for 3 months, followed by approximately 4 years of nocturnal use⁹. A lack of adherence to the bracing protocol increases the risk of relapse by 17-fold⁴. It is thus critically important that physicians trained in the Ponseti method are aware of the importance of the brace, and correctly prescribe the use of the abduction brace in order to prevent relapses. Invasive surgery can be performed in the case of multiple relapses or treatment failure; however, it is associated with long-term pain and impaired quality of life¹⁰-¹⁴. In addition to the role of physicians in the use of the abduction brace, barriers to bracing compliance on behalf of the parents of treated children must be adequately addressed and resolved in order to ensure the best possible outcome for patients treated with the Ponseti method. Various studies have estimated rates of noncompliance regarding use of the brace from 32-61%⁹. While a number of papers have described a range of causes of noncompliance⁹,¹⁶-¹⁸, there have been no studies that are culturally specific to Brazil.

The first widespread use of the Ponseti method in Brazil took place in 2001, when the first large Ponseti clinic was introduced at Universidade Estadual Julio de Mesquita Filho (UNESP) in the state of São Paulo. Since that time, a number of conferences have offered formal training in the Ponseti Method. In 2004, the Brazilian handbook of treatment guidelines according to the Society of Brazilian Orthopedists and Traumatologists cited the Ponseti method as the preferred treatment for clubfoot¹⁵. At that time, the Ponseti method was introduced into a number of orthopedic residency programs in Brazil, and has since become increasingly incorporated into curriculums across the country. However, the training varies greatly depending on the residency, and the physicians teaching the technique have not necessarily had formal training in the Ponseti method. As a result, physicians may or may not be familiar with appropriate bracing protocol.

As the Ponseti method becomes more widely dispersed throughout Brazil, a need has developed to evaluate whether or not physicians are appropriately prescribing the abduction brace, as well as the need to identify barriers to bracing compliance on behalf of families of children with clubfoot. As Brazil was the first country in South America to begin a national Ponseti initiative, its successes and challenges may be applicable to other countries in earlier stages of developing their own national initiatives.

**METHODS**

Forty-five physicians completed surveys that were followed by interviews over a 10-week period regarding their use of the abduction brace following treatment for clubfoot with the Ponseti method. Participating physicians were either residents in orthopedic surgery or orthopedic specialists who had completed their residencies. Participants were recruited from two large hospitals in São Paulo, Brazil and included residents and fellows from other institutions who were participating in rotations or continuing education at the primary hospitals. All physicians had been trained in the Ponseti method at the time of the survey or interview. Participants were divided into three groups: residents, physicians who had completed their residencies, and physicians who had completed their residencies and additionally participated in post-residency Ponseti training. Responses regarding their use of the abduction brace were divided into four categories and assigned a grade ranging from A – D according to how well their use of the brace was in accordance with Ponseti protocol (see Table 1). Physicians were also asked about the costs of braces, difficulties in acquiring the brace, time spent educating patients regarding brace use, the positive and negative qualities of the brace they use, and what they considered to be the biggest barrier to bracing compliance. Informed consent was obtained by having participants review a consent letter in Portuguese. IRB approval was obtained from the University of Iowa for the project, and local standards of ethical research were strictly adhered to.

<table>
<thead>
<tr>
<th>Classification of physician responses regarding prescription of the abduction brace in Ponseti treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
</tr>
<tr>
<td><strong>B</strong></td>
</tr>
<tr>
<td><strong>C</strong></td>
</tr>
<tr>
<td><strong>D</strong></td>
</tr>
</tbody>
</table>

*Table 1*
The Ponseti Method of Treatment for Clubfoot in Brazil: Barriers to Bracing Compliance

Forty-five orthopedic surgeons were surveyed or interviewed regarding their use of the abduction brace as part of the Ponseti method of treatment. Sixteen residents participated, as well as 29 physicians who had completed their orthopedic residencies. All participants, including residents, had been formally trained in the Ponseti method at the time of the surveys. Of the physicians who had completed their residencies, 23 of the 29 had participated in post-residency training in the Ponseti method, and the remaining six had learned the Ponseti method during residency. All participants were asked their standard prescription protocol for the use of the abduction brace following serial castings. They were graded on a scale of A to D regarding their prescription of the brace (see Table 1). Their responses to semi-structured questions regarding perceived difficulties to bracing were divided into ten categories (see Table 2).

**Physician training and prescription of the brace**

Of the residents, 25% appropriately prescribe the abduction brace and received an A classification. Thirteen percent received a classification of B, 19% a C, and 25% a D (see Figure 1). Nineteen percent of residents did not know how to answer the question.

Of physicians who had completed their residencies, 65% appropriately prescribe the brace. Of these, 74% of physicians who had attended post-residency Ponseti training correctly prescribed the brace, compared to 40% of physicians who did not have post-residency training. All physicians who had completed their residencies were able to answer all the questions. Five physicians had completed their additional Ponseti training in Europe or the United States; these five physicians all received scores of “A.”

**RESULTS**

Parent education regarding the brace

The physicians and residents interviewed estimated that a total of approximately 3,000 patients had been treated since they began practicing the Ponseti method. In all but two cases, physicians are responsible for educating parents about the appropriate use of the brace. In one hospital, physical therapists are responsible for parent education and bracing follow-up; in another, psychiatrists are accountable. Physicians reported that they spend an average of 17 minutes explaining the brace to parents, ranging from 5 to 60 minutes. Thirty-four percent of physicians have educational or written materials regarding the brace available for parents and families.

Brace acquisition

Physicians reported that it takes an average of 30 days to acquire the brace once it is ordered, ranging from 7 days to 6 months. Patients dependent on social services to acquire the brace face significantly longer wait times, and occasionally the brace cannot be obtained due to cost or the delay in acquisition. While the brace is provided at no cost to patients at some public hospitals, other public hospitals require patients to purchase the brace. Of the private stores where the braces can be acquired, physicians reported that the average cost of the brace is 249 Brazilian reais, or approximately 160 American dollars. One physician uses a philanthropic organization to help pay for braces, and 58% of physicians recycle braces in order to assist families who may have difficulty purchasing them.

**Table 2**

<table>
<thead>
<tr>
<th>Number of physicians attributing bracing noncompliance to the following causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents think correction has been achieved and the brace is no longer necessary</td>
</tr>
<tr>
<td>Lack of education / information</td>
</tr>
<tr>
<td>Parents believe the brace is uncomfortable</td>
</tr>
<tr>
<td>Child cries or complains</td>
</tr>
<tr>
<td>Difficult to use / put on</td>
</tr>
<tr>
<td>Parents believe the brace is painful</td>
</tr>
<tr>
<td>Cultural reasons / stigma</td>
</tr>
<tr>
<td>Cost / financial difficulties</td>
</tr>
<tr>
<td>Aesthetic reasons</td>
</tr>
<tr>
<td>Childcare difficulties</td>
</tr>
</tbody>
</table>
Physicians perceived barriers to compliance

Physicians were also asked what they believed were the most significant causes of parental noncompliance with regard to the abduction brace. The attributed causes of compliance were divided into ten categories, outlined in Table 2.

All but six physicians use what were described as Dennis-Brown braces, also called a foot abduction orthosis (FAO). This brace is the most commonly used orthotic in Brazil for the treatment of clubfoot. It consists of an aluminum bar attached to shoes that hold the feet in a dorsiflexed position with 60-70° of external rotation. The majority of physicians expressed satisfaction with the brace, primarily because it effectively maintains the correction. Seven physicians added that the brace is easy for parents to use. However, several physicians also emphasized that they had no experience working with other braces, and as a result couldn't compare the Dennis-Brown brace to other varieties. Complaints about the Dennis-Brown brace included the fact that it's very heavy, and has a lack of flexibility for nocturnal use. Additionally, a number of doctors reported that the screws responsible for holding the feet in 70° of external rotation frequently come loose due to poor construction of the brace, which causes the feet to be rotated at an incorrect angle from the time the screws loosen until the patient returns for a follow-up visit.

DISCUSSION

Barriers related to physician education

This study was limited by the fact that only a small number of physicians clustered at two primary hospitals were interviewed, which may mean that the results are not representative of the nation as a whole. However, the results indicate that many children are being prescribed braces for an inadequate period of time. Only 25% of residents (all of whom had been formally trained in the Ponseti method) appropriately utilize the abduction brace. Many of these residents are not pediatric orthopedists and the Ponseti method is less likely to be an area of expertise for them. Physicians who had completed their orthopedic residencies and practice the Ponseti method in their clinical practice only prescribe the brace appropriately 65% of the time. Seven percent of physicians prescribe the brace for less than six months of use; only one eighth of the time it should be utilized.

Orthopedic surgeons who had attended any form of post-residency training in the Ponseti method were significantly more likely to follow appropriate bracing protocol. Seventy-four percent of physicians with post-residency training complied with Ponseti bracing protocol, compared to 40% of physicians who completed their Ponseti training during their orthopedic residency. This has significant implications for the administration of continuing education in Brazil: at this moment, residency programs may not be sufficient to adequately prepare physicians to treat patients with the Ponseti method.

Moreover, when physicians fail to appropriately prescribe the brace, it indicates a decreased level of comprehension regarding the Ponseti method itself, and further exemplifies the need for additional training. Considering that the bracing protocol is an integral part of the Ponseti treatment, failure to adequately prescribe the brace may indicate that physicians are not practicing the method as described by Dr. Ponseti, but rather a modified, and less effective, version.

The lack of adequate understanding of bracing protocol on the part of physicians may represent an important barrier to the use of the abduction brace in Ponseti treatment. Other barriers to compliance become irrelevant if patients are provided inaccurate information regarding the brace. Additionally, physicians need to recognize that they are frequently the only healthcare professionals involved in prescribing and explaining the brace to their patients; as such, it is essential that they take a degree of responsibility in ensuring parental compliance and comprehension of the importance of bracing. Parents are unlikely to be compliant if the physician has a laissez-faire attitude towards the abduction brace: rather, physicians must be the driving force behind parental compliance and understanding of the importance of the brace in maintaining the correction.

Barriers related to cost and acquisition of the brace

A problem that was frequently brought up in the interviews was the difficulty in acquiring braces. Braces are provided by certain, but not all, public hospitals, and many institutions in southern Brazil have arrangements to provide braces for families who can't afford them. However, even when the brace is free or partially subsidized, there is often a considerable delay in acquiring it. When this is the case, physicians are either forced to prescribe the brace extremely early, without knowing the appropriate size of the brace they are ordering, or apply additional casts until the brace arrives. Some physicians reported that parents went without the brace due to the delay or expense of acquiring it. Additionally, multiple braces must be purchased as the child outgrows each brace, adding to the financial burden of the brace. Up to two pairs of orthotic shoes may be required in the first year of bracing, followed by one new pair of shoes for each following year; as a result, families may have to purchase up to five pairs of orthotic shoes, which is a considerable cost for low-income families. Previous studies have consistently identified costs as one of the most significant barriers to bracing adherence in developing countries2,10, making it a difficulty worth addressing.
The difficulties in acquiring the brace were substantially greater for families dependent on public social services. This two-tiered health care system increases the health disparities between social classes, and presents a challenge and a great deal of frustration for practitioners working in the Brazilian setting. However, only three physicians considered cost to be a potential cause of bracing noncompliance. The failure of physicians to recognize the economic considerations that may result in noncompliance represents a lack of understanding of the significance of these financial barriers. While 58% of the physicians in the survey recycle braces, only one hospital reported having a program designed to facilitate this type of initiative. A unified program throughout the major cities of southeastern Brazil could potentially help remedy this dilemma. Additionally, another form of sustainable program – such as governmental assistance to public hospitals who do not currently provide the brace for free – may be one way to improve bracing adherence in southeastern Brazil.

Physicians outside of major metropolitan areas also expressed frustration due to an inability to find orthopedic stores able to adequately construct the brace. Information about brace construction in low-income settings is widely available through non-profit organizations, including booklets available in Portuguese. Dissemination of this information may be one way to promote the utilization of a low-cost and easy-to-construct brace.

**Barriers related to family perceptions and utilization of the brace**

There appear to be discrepancies between what physicians consider the primary causes of bracing noncompliance and what families believe to be the most difficult aspects of the bracing process. The majority of physicians interviewed attributed patient noncompliance with regard to the abduction brace to either lack of education or the parents’ belief that the deformity had been corrected and would not recur. Previous studies have identified a number of considerations as barriers to bracing compliance, including a child that cries or fusses, skin irritations, incorporating the brace into the to bracing compliance, including a child that cries or

The Ponseti Method of Treatment for Clubfoot in Brazil: Barriers to Bracing Compliance
CONCLUSIONS
Many of the causes of noncompliance with bracing protocol stem from systemic inequities and challenges, rather than a lack of collaboration from the families themselves. One of the biggest barriers to bracing compliance in southeastern Brazil is the acquisition of the brace itself. Its high cost and long delays in the time it takes to acquire the brace create noteworthy obstacles that must be overcome by patients, thus making the already difficult process of following the bracing protocol even more challenging. The fact that long waits are faced only by patients dependent on social services is also indicative of the economic discrepancies between Brazil’s social classes. A unified system of recycling braces and sustainable program for purchasing new braces may be helpful towards increasing bracing compliance. Promoting the use of a low-cost brace may be one way to increase the availability of braces in rural areas.

Furthermore, insufficient prescription of the brace by physicians may represent a major barrier to bracing compliance in southeastern Brazil. Encouraging Ponseti practitioners to undertake further training following their residencies may be one way to promote better adherence to the bracing protocol in Brazil. Physicians who were most familiar with appropriate bracing protocol had frequently attended additional trainings outside of their residencies, either in the form of travel abroad or Brazilian orthopedic conferences and workshops. Physicians who were trained only during their residencies were less likely to know the appropriate protocol. Given that patients can only be compliant to the extent that they are given appropriate instructions, this represents an important barrier to use of the abduction brace in southern Brazil.

REFERENCES
ABSTRACT

Congenital clubfoot is the most common birth defect of the musculoskeletal system and affects 1 in every 1000 live births each year. Although there have been numerous studies of investigation, the etiology and pathogenesis of clubfoot remains unknown. To date, no epidemiological studies have been conducted in Peru to assess possible genetic and environmental risk factors associated with this deformity. The purpose of this study was to evaluate specific environmental and socioeconomic factors that may increase the risk of clubfoot.

A descriptive clinic-based study was conducted using structured questionnaires given to biological mothers of clinically confirmed clubfoot patients (n=72) and biological mothers of children between ages 0-18 with no first or second degree family history of clubfoot as controls (n=103). Phenotypic data from clubfoot subjects were also collected. We found that males were twice as likely to have clubfoot as females, and half of all clubfoot patients had bilateral clubfoot. There was no significant difference in the rate of left vs. right clubfoot.

Infant birth in the winter months correlated with an increased risk of clubfoot (p=0.01476). Maternal characteristics found to be significantly associated with increased risk of clubfoot were young maternal age at conception (p=0.04369) and low maternal education (p=0.003245). Young paternal age also had a correlation with increased risk of clubfoot in the child (p=0.0371). Both paternal smoking (p=0.00001) and the presence of any household smoking (p=0.00003) were strongly associated with an increased risk of clubfoot.

INTRODUCTION

Congenital talipes equinovarus, more commonly known as clubfoot, is a leading cause of disability worldwide. This birth defect is characterized by equinus of the ankle, varus of the hindfoot, as well as cavus and adductus of the forefoot with an associated atrophy of the calf muscles. The most common presentation of clubfoot is idiopathic; however, it may also be associated with other medical syndromes such as myelomeningocele or arthrogryposis. The incidence of clubfoot is approximately 1 in 1000 live births per year, with the global burden of this birth defect affecting more than 150,000 infants each year. Over 80% of cases occur in developing nations, where clubfoot is a major disease burden in low-resource areas. Despite many previous research studies and investigations, the etiology and pathogenesis of clubfoot has not been fully elucidated.

Prevalent studies have proposed several risk factors that are associated with clubfoot, including male gender, maternal smoking, maternal age, maternal marital status, parity, maternal education, and maternal diabetes. Currently, no epidemiological studies have been produced examining the risk factors associated with clubfoot in Peru. This study was designed to describe specific risk factors that may be associated with an increased risk of idiopathic clubfoot in Peru. Determining these risk factors will assist further understanding of the etiology of this deformity as well as providing information for further educational programming for parents.

MATERIALS AND METHODS

The University of Iowa Institutional Review Board approved this study before implementation. A Spanish-
The cohort for this case-control study included patients from two major children's hospitals located in the capital city of Lima. Questionnaires were given to the biological mothers of children between the ages of 0-18 from live, singleton births. The population of cases included patients with a physician-confirmed diagnosis of idiopathic clubfoot who received treatment in pediatric orthopedic outpatient clinics. The population of controls included patients receiving treatment in the pediatric orthopedic outpatient clinics who did not have a diagnosis of idiopathic clubfoot. Additionally, the controls did not have a first- or second-degree family history of clubfoot or any other congenital abnormalities.

The anonymous questionnaire described data about the child, biological mother, and biological father. Information collected about the patient included gender, gestational age, birth weight, birth month, exposure to smoking, and location of birth. Information collected about the maternal pregnancy included age at conception, mode of delivery, presence of breech presentation, smoking history, education, marital status, and diabetes. Information collected about the biological father included age at the time of conception and smoking history. The data were recorded in Spanish, translated into English, and analyzed with EpiInfo version 7 using a student's t-test. A p-value of < 0.05 indicated a statistically significant association.

RESULTS

At the completion of the study, 72 cases of clubfoot and 103 control patients were enrolled in the study to respond to risk factor questionnaires.

Phenotypic characteristics of the clubfoot cases are located in Table 1. Of all clubfoot cases, 61% were male and 39% were female. Forty-two percent of the cases presented with bilateral clubfoot, while 53% of the cases presented with unilateral clubfoot. Of the 38 cases with unilateral clubfoot, 53% had an affected right foot and 47% had an affected right foot. Of the 72 families, 11% of the cases reported a known family history of clubfoot.

Descriptive statistics of possible risk factors associated with clubfoot are shown in Table 2. There was no significant association between gestational age or birth weight of the infant and clubfoot. Twenty-two percent of clubfoot cases were born before full term (< 37 weeks gestation) compared to 20% of controls. Fourteen per-

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<th>Table 1: Descriptive Statistics of Cases</th>
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<td>Phenotypic Characteristics</td>
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<tr>
<td>Gender</td>
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<td>Laterality</td>
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<td>Maternal Age at Conception</td>
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<td>Breech Presentation</td>
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<td>Maternal smoking during pregnancy</td>
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<td>Maternal diabetes</td>
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<td>Known Family History</td>
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<th>Table 2: Descriptive Statistics of Clubfoot Cases and Controls</th>
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<td>Demographic Characteristics</td>
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</tr>
<tr>
<td>Gestational Age</td>
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<td>Birth Weight (grams)</td>
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<td>Breech Presentation</td>
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cent of clubfoot cases were born with birth weights less than 2500 grams compared to 11% of controls. We did find a significant association between season of birth and clubfoot; 63% of clubfoot patients were born in the winter months of March to August while 45% of control patients were born in winter months, corresponding to a $p$ value of 0.01476. We did not find a significant association between clubfoot and method of birth, including breech presentation or Cesarean delivery. Four percent of clubfoot cases were born in breech presentation compared to 2% of controls. Thirty-five percent of clubfoot cases were delivered by Cesarean compared to 34% of controls.

Of the social and demographic maternal characteristics measured by the study, maternal age at conception and level of maternal education were statistically associated with clubfoot. While 32% of mothers of clubfoot patients were under the age of 23 at conception, 19% of control mothers were of young maternal age, corresponding to a $p$ value of 0.04369. Thirty-two percent of mothers of clubfoot cases did not complete high school compared to 14% of control mothers, corresponding with a $p$ value of 0.003245. Three percent of mothers of clubfoot cases smoked during the pregnancy compared to 3% of the control mothers. None of the mothers in either the clubfoot cases or the controls reported presence of maternal diabetes. Twenty-nine percent of mothers of clubfoot cases were married compared to 34% of control mothers.

Of the social and demographic paternal characteristics measured by the study, both paternal age at conception and paternal smoking were statistically associated with clubfoot. While 29% percent of fathers of clubfoot patients were under the age of 23 at conception, 9% of fathers of control patients were of young paternal age, corresponding to a $p$ value of 0.0371. Thirty-one percent of fathers of clubfoot patients reported smoking during pregnancy compared to 13% of fathers of controls, corresponding with a $p$ value of 0.003359.

Other characteristics of the child’s family found to be statistically significantly associated with clubfoot were presence of any smoking in the household and location of residence. Forty-seven percent of parents of clubfoot patients reported presence of any smoking in the household during the child’s pregnancy compared to 17% of control parents corresponding with a $p$ value of 0.00001192. Forty-two percent of clubfoot patients resided in Lima and the surrounding area compared to 73% of control patients, corresponding with a $p$ value of 0.000033.

**DISCUSSION**

The results of this study support previously reported data in the literature indicating that males are twice as likely as females to be affected by clubfoot (61% of males and 39% of females, $n=72$), indicating that there is a genetic influence for male sex as a strong risk factor for clubfoot$^{12,13}$. Also, in concordance with the literature, approximately 50% of children were affected with bilateral clubfoot. In our study, there was no significant difference between cases of left or right unilateral clubfoot (53% left and 47% right, $n=38$), although previous studies have found an increased prevalence of right-sided clubfoot$^{19-21}$.

We did not find significant associations between clubfoot and low birth weight (<2500 g) or pre-term birth (<37 weeks), both of which have been shown to have associations with clubfoot in previous studies$^{22-24}$. Our study did not find an association between breech presentation and clubfoot, which has been shown in previous studies$^{14}$. Both the cases and controls had a high non-response rate to the question regarding breech presentation, possibly related to the high prevalence of birth by Cesarean section in both the case and control groups.

Our findings did show an association between seasonal variation and clubfoot$^{22-25}$. Previous studies have reported an increased prevalence of infants with clubfoot born in the winter season. In the southern hemisphere, the winter season lasts from March until August, and our data shows an increased prevalence of clubfoot during this time. Other studies have not found this seasonal variation$^{26}$.

The literature also reports several sociodemographic characteristics associated with increased risk of clubfoot that vary among populations, specifically maternal smoking$^{12,18}$. In Peru, female smoking habits have declined from 17.8% in 1999 to a 9% prevalence in 2009$^{27}$. Only 3% of case and 3% control mothers indicated smoking habits; however, there was a significant association between clubfoot and maternal smoking (31% cases, $n=72$ and 13% controls, $n=103$) as well as any household smoking present (47% cases, $n=72$ and 17% controls, $n=103$). Thus, these data support previous indications that second-hand smoke is a risk factor for clubfoot$^{28}$.

In our study, young maternal age (<23 years old) was found to have a significant association with increased risk of clubfoot (32% case mothers, $n=72$ and 19% control mothers, $n=103$) in concordance with many other epidemiologic surveys$^{14,29}$. Similarly, we also found that young paternal age (<23 years old) was significantly associated with increased risk of clubfoot (29% of case fathers, $n=71$ and 9% of control fathers, $n=103$). Mothers with an education level less than high school was also found to be a risk factor with a significant association with increased clubfoot prevalence, supporting previous data$^{12,14,15}$. Maternal diabetes and maternal marital status were not found to have significant association with clubfoot in our study population.
The project described was supported by Grant Number T37MD001453 from the National Institute On Minority Health And Health Disparities. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Minority Health And Health Disparities or the National Institutes of Health.

CONCLUSIONS

This study supports previously reported data stating that males are twice as likely to be affected by clubfoot and approximately 50% of clubfoot patients are affected bilaterally. In our study, there was no significant difference between left and right clubfoot in patients that are unilaterally affected. Many of these findings are universally reported by numerous studies, suggesting a strong genetic association with clubfoot. Our findings also confirm previous studies reporting associations with young maternal age, maternal education, young paternal age, paternal smoking habits, and household smoking habits. The absence of the association between maternal smoking and clubfoot in our study contradicts numerous studies that have shown a strong association. Differences in culture may have led to this disagreement. These preliminary findings provide the foundation for future epidemiologic studies in the Peruvian population as well as studies in the general South-American population in the future.

REFERENCES

ABSTRACT

Idiopathic clubfoot affects approximately 100,000 children each year and is one of the leading causes of disability worldwide. The Ponseti method is an inexpensive, non-surgical treatment that, when executed correctly, is more than 95% effective; however, in Peru, a developing country where a low-cost alternative is greatly needed, physicians report up to 30% of patients do not complete treatment. This study involved semi-structured interviews with 25 physicians who practice the Ponseti Method in Peru to discuss obstacles for the method in their country. The most frequent obstacles to the Ponseti method in Peru reported by physicians included lack of physicians trained in the Ponseti method in the country, patient transportation and distance to treatment centers, and lack of parental knowledge of the Ponseti method. These data suggest the need to train more physicians in Peru, particularly in the provinces. Increasing access to trained physicians in provincial areas may reduce the financial and travel burden of parents to help increase compliance with treatment.

INTRODUCTION

Clubfoot, or congenital taipes equinovarus, is the most common musculoskeletal birth defect in the world with an incidence of approximately 1:1000 births and affecting more than 150,000 infants born each year. The deformity, identified as a downward and inward turning of the foot, can present idiopathically or associated with other diseases such as myelomeningocele and arthrogryposis.

Surgical intervention was the conventional treatment for clubfoot in many parts of the world during the last century, commonly posteriomedial soft-tissue release or Achilles tendon release, but long-term longitudinal studies have demonstrated adverse effects including pain and rigidity several decades following surgery. Especially in low income, developing nations, the high cost and resources required for surgery can be prohibitive to further treatment, leading to lasting disability and social stigma for the patient.

In the past ten years, the Ponseti method has been gaining acceptance worldwide as the gold standard for treating clubfoot. This low-cost, non-surgical treatment is more than 95% effective when executed correctly and begins with specific manipulation of the clubbed foot with weekly serial casting. In approximately 85% of cases an Achilles tenotomy is required, which can be performed in an outpatient clinic under minimal local anesthesia. The final phase of the Ponseti method is an abduction brace worn for four years after completion of treatment to prevent relapse.

While our previous study focused on the initial impact of the Ponseti method in several countries in Central and South America, this study focuses exclusively on the country of Peru. Located on the western Pacific coast of South America, Peru is an upper middle-income nation with a population of 29.4 million people, a GDP per capita of approximately $10,600, and a poverty rate of 27.8%. This study evaluated how the barriers to using the Ponseti method have changed and evolved in the past 2 years, as well as providing insight into implementing country-wide initiative in the Ponseti method in Peru.

MATERIALS AND METHODS

In-person semi-structured interviews with physicians, physical therapists, and nurses trained in the Ponseti method in Peru were conducted at several public and
private hospitals in the capital city of Lima. Thirty-seven health care professionals were interviewed for this study. Five professionals who had not treated any patients with the Ponseti method were not included in the final study. Thirty-one physicians and one physical therapist were included in the final study for a total of thirty-two Ponseti method practitioners in Peru.

A Spanish-speaking medical student conducted the interviews over a period of ten weeks. Medical professionals trained in the Ponseti method were contacted either by phone or through email prior to observation and interview. The interviews were recorded in Spanish, translated into English, and sorted into themes. Participants' names were removed after data collection and the data were kept in a secure location. Medical professionals were provided a consent letter to read prior to the interview. The University of Iowa Institutional Review Board approved this study before implementation.

Ponseti method practitioners were interviewed in the following hospitals: Instituto Nacional de Salud del Niños, Instituto Nacional de Rehabilitación, Hogar Clínica San Juan de Dios, Hospital de Emergencias Pediátricas, Hospital Rebagliati, and Clínica Ricardo Palma. Twenty-three out of 32 (72%) of the providers interviewed were located in public institutions in Lima, which included Instituto Nacional de Salud del Niños, Instituto Nacional de Rehabilitación, Hospital de Emergencias Pediátricas, Hospital Rebagliati, and Clínica Ricardo Palma. Nine out of thirty-two (28%) providers interviewed were located in private institutions including at Hogar Clínica San Juan de Dios, Hospital de Emergencias Pediátricas, and Clínica Ricardo Palma in Lima, Peru and Medical Ministry International in Arequipa, Peru.

Based on the data collection from our previous study, physicians were asked to identify which of the following were obstacles to using the Ponseti method in Peru: physician education, the health care system of Peru, knowledge of the parents about the Ponseti method, distance and transport to treatment centers, financial barriers for patients, and financial barriers for hospitals.

### RESULTS

Official Ponseti International Association courses were held in Lima, Peru in 2007, 2011, and 2012. The workshops incorporated both theory-based lectures and case discussion, as well as guided practice in applying casts to both models and patients. The PIA estimates that it has trained approximately 45 physicians in Peru through official two-day workshops. Twenty-five out of 32 (78%) providers were trained in an official PIA course, six out of 32 (19%) had attended a non-PIA affiliated course with theory and practice, and five out of 32 (16%) indicated they had read books or watched videos on the internet to learn the method.

### PHYSICIAN EDUCATION

Thirty-one out of 32 (97%) of physicians in Peru identified physician education as an obstacle to the use of the Ponseti method in their country. Twenty-five out of 32 (78%) practitioners had attended an official PIA course, six out of 32 (19%) had attended a non-PIA affiliated course with theory and practice, and five out of 32 (16%) indicated they had read books or watched videos to learn the method. As reported in our previous study, the curriculum in Peruvian medical schools still does not teach the Ponseti method as an alternative to the traditional surgical treatment of clubfoot, and practicing physicians must take time away from treating patients at work to attend training sessions. However, in contrast to our previous study, physicians who trained after 2011 did not have to pay a fee (previously $200) to attend the PIA workshops because the cost was covered by the Ministry of Health.

Although the defrayed cost of training workshops through the Ministry of Health and the greater availability of training workshops through national specialty organizations will make diffusion of the Ponseti method more accessible, several barriers still remain. The experience of the physicians is greatly varied. Twenty-one out of 32 (65%) had fewer than five years of experience practicing the method, 11 out of 32 (34%) have five or more years, and three out of 32 (9%) have had ten or more years of experience. The number of patients treated each year also varies. Fourteen out of 32 (44%) see 12 or fewer patients a year (1 a month or fewer), 15 out of 32 (45%) see between 13 and 119 patients a year (between two and nine per month), and three out of 32 (9%) see more than 120 patients a year (ten or more per month).

This discrepancy of experience with the method can help explain the continued prevalence of surgical treatment amongst physicians who have been trained in the

### Table 1: Descriptive statistics of providers

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<th>Provider characteristics</th>
<th>N=32</th>
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<tr>
<td>Provider type</td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td>31 (97%)</td>
</tr>
<tr>
<td>Non-physician</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>Provider training</td>
<td></td>
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<tr>
<td>PIA Course</td>
<td>25 (78%)</td>
</tr>
<tr>
<td>Other Course</td>
<td>6 (19%)</td>
</tr>
<tr>
<td>Reading or videos</td>
<td>5 (16%)</td>
</tr>
<tr>
<td>Treatment method</td>
<td></td>
</tr>
<tr>
<td>Only Ponseti</td>
<td>24 (75%)</td>
</tr>
<tr>
<td>Surgery</td>
<td>8 (25%)</td>
</tr>
<tr>
<td>Patient populations</td>
<td></td>
</tr>
<tr>
<td>Lima</td>
<td>9 (28%)</td>
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<tr>
<td>Provinces</td>
<td>23 (72%)</td>
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Ponseti method in Peru. While in the past, physicians in Peru would commonly treat clubfoot with the Kite method or surgical procedures, the formal introduction of the Ponseti method into the country in 2007 has greatly reduced the numbers of patients treated with other methods. When asked to report the number of clubfoot cases treated since training in the Ponseti method, the physicians reported approximately 93% cases treated with the Ponseti method versus 7% of patients treated with surgical procedures, specifically posteriomedial soft-tissue release.

Health Care System

Twenty-four out of 32 (75%) physicians indicated that the health care system in Peru was an obstacle to the Ponseti method. Since our previous study, the Ministry of Health in Peru now endorses the Ponseti method as the treatment of choice for clubfoot in the country, as evidenced by the funding of the 2011 PIA course that trained 26 medical professionals. The Ministry of Health sponsors two types of public medical insurance. Seguro Integral de Salud (SIS) provides coverage for citizens in poverty (currently covering 18% of the population), while Es Salud is an employee-based insurance plan (covering about 20% of the population). Another 4% have private insurance, while the remaining 58% do not have any access to health insurance coverage whatsoever\(^5\).

The main observation by physicians regarding the health care system in Peru is that SIS, which covers the nation’s poorest citizens, does not cover the costs of congenital diseases. Especially at public institutions, the lack of coverage for clubfoot treatments for patients in poverty is a great barrier. Another observation is that the Ministry of Health does not permit extra scheduled appointment time to apply casts. The cast is applied in approximately 20 to 30 minutes and doctors must apply the casting treatment in their ‘free time’ while also meeting a quota for the number of patients seen each day.

Before the casting begins, the patient must purchase the cotton and casting materials from the hospital pharmacy or SIS pharmacy. Sometimes, the hospital runs out of the higher quality brand of plaster preferred by the physicians who use the Ponseti method, and the patient must wait another day until a new shipment of casting materials arrives. If the patient bought the lower quality brand, with a longer setting time and weaker construction, it is harder for the physician to properly mold the cast and is prone to disintegration.

Some participants also lamented the lack of communication between specialists in Lima and the general hospitals in the provinces where a majority of the patients originated. One interviewee indicated the need for a national protocol for treatment and management to detect the birth of a child with clubfoot born in the provinces. By training nurses, pediatricians, and other medical professionals, they could refer clubfoot patients for proper and timely treatment in a center close to their place of birth.

Parental Knowledge

Twenty-seven out of 32 (75%) believed that lack of parental knowledge about the Ponseti method was a barrier to its success in Peru, specifically in patients from the provinces. Parents in Lima, who are oftentimes more affluent, may have greater access to the internet and can access resources clearly explaining the method and treatment course. In contrast, parents from the provinces often receive word-of-mouth information regarding an ambiguous cure for their child’s clubfoot. The parents, especially those with low education levels, come to Lima thinking the treatment will only last a single visit. After the casting phase is over and the parents see a corrected foot, it is common to ‘lose patients’ who do not come in for follow-up and are not properly monitored for abductor bracing use. While many of the physicians indicated continual follow-up clinic visits to monitor the child for relapse during the bracing stage, of the 72 patients observed in clinic during this study, 67 (93%) were in the casting phase, while only 5 (7%) came for appointments during the bracing stage.

Physical Distance and Transport

Thirty out of 32 (94%) of providers indicated that physical distance and transport to treatment centers were barriers to the Ponseti method in Peru. All but one of the providers interviewed practice in the capital city of Lima, which is inhabited by 8 million of the 29.5 million of the country’s population; however, twenty-three out of thirty-two (72%) of physicians reported that a majority of their clubfoot patients come from the provinces outside of Lima.

For example, patients who come from the mountainous northern province of Cajamarca must travel approximately a ten hours by bus through treacherous mountain passes to reach Lima every week during the casting phase of treatment. From Piuria, another mountainous northern province, patients must travel 16 hours by bus.

<table>
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<tr>
<th>Table 2: Descriptive statistics of barriers</th>
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<tr>
<td>Perceived barriers</td>
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<tr>
<td>Lack of trained professionals</td>
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<tr>
<td>Distance and transport</td>
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<td>Lack of parental knowledge</td>
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<td>Parental finances</td>
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<td>Hospital finances</td>
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<td>Ponseti Method</td>
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through the Andes. During the casting period, patients must return to the clinic every 7-15 days to change casts. While in the US the casts are usually changed every 5 days, one physician remarked that when patients come from far away, it is nearly impossible to come every week. When bringing a child in for treatment, the parents will either stay in Lima during this period or make the long commute, incurring high costs via transit or housing and missing days from work to support the other members of their family.

While previous anecdotal reports have reported a handful of physicians who practice “the Ponseti method” outside of Lima, it is unknown whether or not they are instead using an altered and therefore less effective form. Children born to parents in Lima often receive treatment within the first few months of life, while those from the provinces have an average age of two to three years. Because of this age discrepancy, children from the provinces are more likely to be treated with surgical procedures. Eight out of eight (100%) physicians who still perform surgery to treat clubfoot cited presentation of case older than two years of age as a contraindication for their use of the Ponseti method while two out of eight (25%) physicians using surgical treatment for clubfoot cited presence of associated diseases such as arthrogryposis or myelomeningocele as a contraindication for their use of the Ponseti method.

Taken from an interview with one physician, “People from provinces don’t tolerate follow up visits very well. We lose these patients in consult and it is very difficult. Distance and transportation is the most important factor. This is the principal reason. We lose the patients because they have to travel every 15 days. After the tenomy, they don’t return.”

Financial Barriers for Patients

Twenty-five out of 32 (78%) of physicians believed there are financial barriers for patients to access the Ponseti method. Each child will use approximately 6-10 casts over the treatment period, which cost approximately $3-5 for the cotton and casting supplies per cast. If the child is fitted with an abduction brace, the cost can be as much as $200. While some physicians believed the financial cost of the Ponseti method was less prohibitive than the financial cost of surgical operations, these physicians were less likely to mention the costs incurred for transportation and housing for families who live in the provinces during the weekly trips during the casting phase as mentioned in the section above.

Financial Barriers for Hospitals

Fourteen out of 32 (44%) of providers felt that financial barriers for hospitals were obstacles preventing the use of the Ponseti method in Peru. Many physicians emphasized that the relative cost of the Ponseti method supplies were much less expensive than the cost of supplies for operations. Other practitioners commented that every time a patient had an appointment to apply a cast in the Ponseti method, it required 20 to 30 minutes of casting. During that time the physician could have seen 2 to 3 other patients. In many hospitals, a doctor’s performance and salary are based on the number of patients seen in a day, and so the financial incentives may prevent some hospitals from promoting the Ponseti method.

DISCUSSION

With the insight gained from experience of previous studies examining the medical, institutional, and cultural barriers for the Ponseti Method in over 35 different countries all over the world, the Ponseti International Association has created the PIA approach for developing effective national clubfoot programs. This approach utilizes a public health model, which focuses on essential elements sorted into three streams: training and supply, treatment process, and policy and awareness. All three elements of the model are crucial to institute a national program that exemplifies quality, local ownership, and sustainability.

To achieve these goals, two Peruvian champions and stakeholders were chosen to lead the efforts implement-

<table>
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<th>Table 3: Public Health Model for Effective National Clubfoot Programs</th>
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<td><strong>Through Support of Local Champions/Stakeholders</strong></td>
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<tr>
<td><strong>Children Effectively Treated</strong></td>
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<tr>
<td>Frontline Health Workers</td>
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<td>Materials and Supplies</td>
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<td>Clinical Staff/Facilities Providers</td>
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<td>Follow-up</td>
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<td>Diagnosis &amp; Treatment</td>
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<tr>
<td>Referral</td>
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<td>Identification</td>
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<td>Community Groups/Media</td>
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<td>Training Institutionalization</td>
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<td>Ministry of Health</td>
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<td>Local Hospital Administration</td>
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<td>Health Professional Societies</td>
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<td><strong>Training &amp; Supply</strong></td>
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<td><strong>Treatment Process</strong></td>
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<td><strong>Policy &amp; Awareness</strong></td>
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<tr>
<td><strong>Core Values:</strong> Quality - Local Ownership - Sustainability</td>
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ing the essential elements of developing a national clubfoot program. Dr. Liliana Mayo is the General Director and founder of Centro Ann Sullivan del Peru (CASP), a non-profit school in Lima, Peru for children with “different abilities”, including developmental disabilities. Dr. Julio Segura is a pediatric orthopedic surgeon and former president of the Peruvian Pediatric Orthopedic society. Through their influence and organizations, PIA was able to meet with and receive the endorsement of senior advisors to the Minister of Health.

Developing the treatment process stream to provide access to effective Ponseti method treatment will rely on addressing several areas identified in our study as well as previous studies10-14. For children to be effectively treated, the program must develop identification of children born with clubfoot, referral to a Ponseti method provider, diagnosis and treatment by a skilled professional, as well as adequate follow-up. Currently the lack of trained professionals and burden imposed by great distance and transport hinder his process in Peru.

In addition to the lack of trained professionals, our study identified several resource-driven barriers including burdens on parental and hospital finances that are congruent with previous studies in low- and middle-income nations10-14. To address these issues, elements of the training and supply stream must be met, including training of frontline health workers to identify clubfoot, assuring proper clinical and staff facilities for Ponseti method treatment, training skilled Ponseti method providers, and assuring appropriate quality and quantities of clubfoot treatment casting, bracing, and tenotomy materials and supplies.

In order to influence parental and public knowledge about the Ponseti method as well as address the health system of Peru, the national program must also develop the policy and awareness stream. Through the influence of Dr. Segura and other local experts, the Ponseti method can gain support from local hospital administrations, health professional societies, and the Ministry of Health. To ensure the long-term sustainability of a new treatment method, support from the Ministry of Health is crucial to institutionalize curricular training of new providers and front-line health professionals including midwives, nurses, obstetricians, and pediatricians. Collaborating with Dr. Mayo and CASP, who have educated over 10,000 people over the last four years how to care for individuals with disabilities through low-bandwidth web conferencing15, PIA will develop the role of community groups and media to educate the public that “clubfoot is treatable” and a treatment is attainable for every child who needs it.

The project described was supported by Grant Number T37MD001453 from the National Institute On Minority Health And Health Disparities. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Minority Health And Health Disparities or the National Institutes of Health.

CONCLUSIONS
This study identified several potential barriers to the implementation of the Ponseti method in Peru. The results of this study may help to guide the development of high-quality, locally-directed, and sustainable Ponseti Method treatment in Peru that employs a coordinated public health approach at the national level to achieve their ultimate vision: a world free of clubfoot disability.

REFERENCES


ABSTRACT
Orthopaedic surgery requires a high degree of technical skill. Current orthopaedic surgical education is based largely on an apprenticeship model. In addition to mounting evidence of the value of simulation, recent mandated requirements will undoubtedly lead to increased emphasis on surgical skills and simulation training. The University of Iowa’s Department of Orthopaedic Surgery has created and implemented a month long surgical skills training program for PGY-1 residents. The goal of the program was to improve the basic surgical skills of six PGY-1 orthopaedic surgery residents and prepare them for future operative experiences. A modular curriculum was created by members of the orthopaedic faculty which encompassed basic skills felt to be important to the general orthopaedic surgeon. For each module multiple assessment techniques were utilized to provide constructive critique, identify errors and enhance the performance intensity of trainees. Based on feedback and debriefing surveys, the resident trainees were unanimously satisfied with the content of the surgical skills month, and felt it should remain a permanent part of our educational program. This manuscript will describe the development of the curriculum, the execution of the actual skills sessions and analysis of feedback from the residents and share valuable lessons learned and insights for future skills programs.

BACKGROUND
Acquiring procedural skills is a critically important area in surgical residency training. Currently, the progress of orthopaedic residents in acquiring surgical skills is assessed through faculty evaluations and case logs. Despite the imminent addition of trainee surgical skills assessment in the form of patient care milestones, skills training predominantly occurs in a live operating room by virtue of an apprenticeship method.

There is growing momentum to incorporate structured surgical skill education, including surgical simulation, into surgical residency training. Often cited reasons include resident work hours restricting surgical experience, an increased demand for surgical efficiency in the setting of busy academic faculty practice, an elevated concern for patient safety, and the availability of better surgical simulations. Studies have shown that structured surgical skill programs which include surgical simulation, can be used to train, assess, and improve operative performance.

The results of a recent survey indicate strong agreement amongst both orthopaedic residency program directors and residents that a surgical skills curriculum, skills training and simulation technology should be a component of an orthopaedic resident’s training. Orthopaedic resident educators cite the lack of a formalized curriculum as one of the most substantial barriers to wide spread adoption of surgical skills training. The Residency Review Committee (RRC) for Orthopaedic Surgery, a review committee of the Accreditation Council for Graduate Medical Education (ACGME), and the American Board of Orthopaedic Surgery (ABOS), have for the first time mandated a laboratory- and curriculum-based training for orthopedic residents at the PGY-1 level. These new requirements will be in effect as of July 2013.

In anticipation of these new requirements, The University of Iowa orthopedic residency program received special consideration from the ABOS to develop and pilot a month-long laboratory based skills rotation aimed at teaching basic surgical skills to PGY-1 residents. This article will describe the experience of this month, from creation of the curriculum to execution of the actual skills sessions, while sharing lessons learned and the potential for future years.

GOALS AND OBJECTIVES
The overall goal of the surgical skills program was to improve the basic skills of PGY-1 residents in areas fundamental to the practice of orthopedic surgery and to prepare them for actual operating room experiences.
This goal was achieved by a) designing a modular curriculum, b) incorporating background cognitive knowledge, c) allowing protected time for practice of basic skills, d) providing expert instruction, and e) incorporating assessment metrics with pre and post testing. The comprehensive curriculum was designed specifically for a single month where all six PGY-1s were together and free of other clinical responsibilities.

OVERVIEW OF FORMAT

The curriculum was designed to be a series of skills modules that followed a logical and sequential progression of difficulty level. Phase 1 of the American College of Surgeons and the Association of Program Directors in Surgery (ACS/APDS) basic surgical skills program template, which consists of an online syllabus and video tutorials, was incorporated into several modules, and served as a guideline for the curriculum design. The template that was used (Table 1) for each individual module was based on the ACS/APDS template and was similar to a template accepted by an ABOS skills task force to develop a national orthopedic PGY-1 curriculum.

The development of the curriculum and its individual modules required effort and engagement from multiple faculty members in various orthopaedic subspecialties. The central focus of the month-long course was surgical skill development. Carefully chosen supplementary didactic materials were provided as needed to support each surgical skill. The curriculum focused on those skills that were felt to be appropriate for entry level orthopaedic residents. The plan allotted time for dedicated practice of the specific surgical skills to promote retention of basic skills and improve subsequent operating room performance.

Repeated assessment of resident skills played an important role in the curriculum. Assessment started with basic tests of aptitude in spatial reasoning and dexterity that were administered at the beginning of the month.

A variety of assessment metrics and approaches were utilized throughout the month in the various modules, allowing learners to demonstrate improvement, while enhancing performance intensity.

MODULE DEVELOPMENT

Once the department committed to a protected, month-long orthopaedic surgical skills rotation for PGY-1s, a core group of contributing faculty were identified. At an initial meeting, approximately nine months prior to the surgical skills month, faculty began the process of selecting skills modules that were felt to be relevant to the entry-level orthopaedic surgery resident. As modules were selected and agreed upon by the group, individual or pairs of faculty with particular interests took ownership in the development of the content for individual modules. The module template provided a development plan. During this development period, some faculty chose to use existing media for instruction, while others chose to create new written and video content. In parallel with the development of module content, the anticipated required equipment and potential budgetary considerations were catalogued and incorporated into the planning process. Faculty engagement and interest in this process was high.

MODULES

During the six months leading up to the designated month long rotation, consensus was obtained between the participating faculty members regarding the specific
The titles of the modules that were chosen are presented in Table 2. Within the constraints of a busy academic and clinical practice, individual dates were scheduled during the skills month for each module with some flexibility (to meet faculty needs) and to promote a sequential learning process. Days during the month were typically filled with one, and at most two, individual modules (Figure 1). The course syllabus and supporting background materials and reading (including video examples) were provided to the residents prior to the commencement of the month. The month began with an orientation on the objectives, goals, and context of the month. The final schedule was agreed upon three months prior to the skills month, and faculty members responsible for individual modules set aside time to participate and instruct residents on the day of their module (average three hours per day).

**DESCRIPTION OF A REPRESENTATIVE MODULE – BASIC TECHNIQUES IN OPEN REDUCTION AND INTERNAL FIXATION (ORIF)**

Most modules occupied the residents for around six hours. Residents spent additional time reading or, when cadavers were available, performing dissections relevant to surgical approaches and anatomy. A detailed description of the entire curriculum is beyond the scope of this paper. Instead, the description of a single illustrative module (Module 8: Basic Techniques of Internal Fixation) is briefly presented here to convey the basic approach incorporated in each of the individual modules (Figure 2).

In this module, residents read background material and watched educational videos (Figure 2 VIII) that had been produced prior to beginning the day’s activities. Trainees were then individually assessed by an experienced surgeon as a reviewer using an Objec-

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**Table 2: University of Iowa Surgical Skills Month**

<table>
<thead>
<tr>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
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<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>Offices Closed</td>
<td>Orientation</td>
<td>Module 1</td>
<td>Module 2</td>
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<td></td>
<td></td>
<td>Sterile Technique/OR Setup</td>
<td>Techniques of Fluoroscopy</td>
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<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
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<tr>
<td>Module 3/4</td>
<td>Module 5</td>
<td>Module 6</td>
<td>Module 7</td>
<td>Module 8</td>
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<tr>
<td>Musculoskeletal Traction</td>
<td>Soft-Tissue Handling Techniques</td>
<td>Techniques in Hand Trauma</td>
<td>Knot Tying/ Suturing Techniques</td>
<td>Basic Techniques in ORIF</td>
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<tr>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Module 9</td>
<td>Module 10</td>
<td>Module RM1</td>
<td>Module 11</td>
<td>Module 12</td>
</tr>
<tr>
<td>Bone Handling Techniques</td>
<td>Joint Aspiration/ Ultrasound Techniques</td>
<td>Research Methods</td>
<td>Fracture Reduction Techniques</td>
<td>External Fixation Techniques</td>
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<td>21</td>
<td>22</td>
<td>23</td>
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<td>25</td>
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<tr>
<td>Off (Holiday)</td>
<td>Module 13</td>
<td>Module 14</td>
<td>Module 15</td>
<td>Module 16</td>
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<tr>
<td></td>
<td>UE Arthroscopy</td>
<td>Splinting/Casting Techniques</td>
<td>Basic Hip Arthroplasty Techniques</td>
<td>Basic Knee Arthroplasty Techniques</td>
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<tr>
<td>28</td>
<td>29</td>
<td>30</td>
<td>31</td>
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<tr>
<td>Module 17</td>
<td>Module 18</td>
<td>Module RM2</td>
<td>Debriefing</td>
<td></td>
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<tr>
<td>Basic Spine Surgical Techniques</td>
<td>LE Arthroscopy</td>
<td>Research Methods</td>
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Figure 1: University of Iowa Surgical Skills Month
Development of an Orthopaedic Surgical Skills Curriculum

While they performed a fluoroscopy guided exposure, drill, tap, and screw placement on a cadaveric ankle, video recordings with multiple cameras for instructional purposes were also captured. Residents then performed skills exercises on PVC pipe both with and without a foam covering. They practiced basic techniques of drilling, depth gauging and placing screws and achieved proficiency on each of these skills. In the afternoon, the residents had a final assessment while performing the same screw placement task (described above) on a different cadaver ankle, again recorded and assessed via an OSATS. The eight hour module was designed to run with limited faculty involvement other than assessments and periodic instruction.

**FACILITIES**

The majority of the skills sessions took place in the Joseph Buckwalter Surgical Skills Laboratory (Figure 3) within the orthopaedics department. This laboratory is 500 square feet in size, and it is equipped with multiple arthroscopy towers, deep freezers for cadaveric specimen storage, a radio-opaque and radiolucent table, sinks, and miscellaneous surgical instruments. Dedicated fluoroscopy was not available, and when utilized as part of a module, it had to be scheduled well in advance with hospital radiology. The PGY-1 residents spent one half day in a vacant operating room learning sterile technique, patient positioning, operating room table set up, and techniques of prepping and draping. Didactic portions of modules were held in the Arthur Steindler Orthopedic Library adjacent to the skills lab.

**FACULTY/STAFF TIME COMMITMENT**

The coordination of planning and execution of the surgical skills month required dedicated faculty and support personnel time. The planning of the surgical skills month required five 45-minute meetings, at increasing frequency as the month approached. Each meeting was attended by 5-7 faculty members. While variable, individual faculty effort for module development required between 6-8 hours. This preparation time was greater for faculty choosing to create supporting media. On the day of their module faculty spent between one and four hours assisting and teaching during the module.

Support staff members were critical to the success of the month. One laboratory and one research assistant played an integral role in the preparation and execution of the month. They were tasked with ensuring the required supplies and materials were available on each designated day. They worked closely with individual faculty members in the coordination of this effort. In addition, they were invaluable during the inevitable occasions of trouble-shooting. The laboratory assistant worked in the lab full time during the month, and the research assistant was involved with the project about one third time.

**MATERIALS PLANNED AND UTILIZED**

The provision of essential materials required careful planning. Each individual faculty member responsible for a specified module was tasked with providing a detailed and itemized checklist of desired equipment and materials. This equipment database required continuous modification with foresight as to the timing of modules and the most efficient use of materials and equipment. The most commonly requested items were cadaveric specimens, surrogate bone models (Sawbones Inc.), suture materials, surgical instruments, and C-arm fluoroscopy.
RESEARCH/ASSESSMENT PROJECTS

Two research projects were incorporated into the skills month, laying the foundation for future refinement of intervention strategies aimed at improving skills acquisition. Through careful planning, grant funding from a variety of sources was obtained to support this research. [The research results will be reported later elsewhere.] The two specific modules that incorporated research objectives involved (1) the use of fluoroscopy to navigate guide wire placement and (2) articular fracture reduction through a limited incision. Prior to and after the use of alternative radiation-free simulations for basic skills training, a fluoroscopy guided bone surrogate simulation of a surgical procedure was accomplished in the skills lab for both modules.

The first research project focused on the fact that fluoroscopy guided wire navigation is fundamental to a number of orthopedic procedures. Directing and advancing the wire in the correct plane relies on both visual-spatial and psychomotor dexterity skills. In order to reduce radiation exposure in training, an augmented reality wire-navigation simulator was used, combining a real drill, wires, and surrogate bone models with virtually generated, radiation-free fluoroscopic images. During this simulation, trainees navigated a wire from the lateral femoral cortex, through the femoral neck, attempting placement within 5mm of the femoral head articular surface. The simulator promoted drilling dexterity, interpreting fluoroscopy images, and visual-spatial wire navigation skills.

The second research project used simulation of the surgical reduction of a three-fragment tibial plafond fracture that has previously been described\(^3\)\(^,\)\(^7\) to compare the performance of the first-year orthopaedic residents before and after the use of a box skills trainer. This task simulator gives residents a 15 minute window to reduce and fix fracture fragments using a standard set of surgical tools and K-wires. The residents also made use of a fluoroscopy unit to help determine the current position of the fragments. The fracture fragments are housed in a surrogate soft tissue foot and ankle model (Sawbones Inc.). Data collected and analyzed following the fracture reduction simulation include: the number of discrete hand motions and cumulative hand distance traveled, average final articular step-off measured by CT, the number of fluoroscopy images taken (radiation exposure), and an OSATS from an expert surgeon. Multiple angles of video were recorded, including a head-mounted camera (Go Pro Hero3 silver edition) to better assess the process of thought of the trainees from their point of view.

The box skills trainer consisted of two video cameras mounted on an aluminum frame. The cameras view the workspace from orthogonal positions: one from 1.5 feet above, while the second is directed towards the participant from approximately 1.5 feet behind the workspace. In order to obstruct the view of hand motions in the workspace, a screen between the workspace and the participant is present. Thus the box skills trainer requires the participant to rely solely on the two camera views visible on a monitor placed conveniently nearby to navigate the 3D environment. Several tasks performed in the workspace were used to exercise the trainees’ skills, developing the learners’ three dimensional spatial navigation using only two dimensional images.

COSTS

A recent survey reported that one of the most substantial barriers to the adoption of dedicated orthopedic surgical skills programs is the lack of available funding\(^4\). The cost of the one month simulation course is a complex variable which requires careful assessment both for the month as a whole, as well as for each of the individual modules. We categorized expenses into the following classes: Consumables, Rental, Personnel, and Donated. Consumables including cadaveric specimens, surrogate bone models and miscellaneous equipment accounted for the majority of the tangible expenses. Cadaver specimens, including shipping charges, were the largest single expense at approximately 8500 USD. Surrogate bone models represented the second largest expense at approximately 5000 USD. Other consumable supplies (e.g. suture material, PVC pipe, foam insulation) were significantly less expensive, totalling approximately 1000 USD altogether. The largest rental expense during the month was the use of C-Arm Fluoroscopy, at 12 USD/hour this accounted for between 200-300 USD for the month. At our institution, securing use of a C-Arm required substantial coordination which created difficulty with some of the modules.

Throughout the month, two laboratory personnel were available to assist in the logistics of lab set-up and take-down. In addition, these two individuals were critical to the success of photo and video archival of the month. An undergraduate student who services our laboratory on an hourly rate during the year worked full time for this month. Additional support was provided by a research-assistant who was funded by grants. The estimated cost of their time was 2500 USD. The estimated total cost for the month was approximately 22,500 USD. By virtue of including research as a part of the program, the work was able to be funded (in part) by grants from the OMeGA Medical Grants Association, the National Board of Medical Examiners\(^\text{®}\) (NBME\(^\text{®}\)) Edward J. Stemmler grant, MD Medical Education Research Fund, the Orthopaedic Trauma Association, the Orthopaedic...
Development of an Orthopaedic Surgical Skills Curriculum

Research and Education Foundation, a private donor and a Medtronic Resident Education Grant. The remaining costs were assumed by the department.

In addition to the tangible costs enumerated, significant time, effort, energy and equipment were donated by local industry representatives. They were involved in the planning and execution of several modules, primarily adult reconstruction, trauma, and spine. Perhaps the largest cost, although not explicitly accounted for in the budget, was that of faculty time and effort. Each of the 15 faculty members that participated in various levels of planning and execution of the modules, contributed on average about 8 hours of their time between the planning and preparation of the month, as well as the planning and execution of their individual module(s).

SURVEY OF RESIDENT'S EXPERIENCE

Upon completion of the month, the resident participants were given an inclusive questionnaire to survey their experience. The residents reported 100% satisfaction with the format of our modules, as well as the month as a whole (Figure 4a). While they ranked their skill set as similar to that of their peers at other institutions, the residents acknowledged that the program improved their surgical skill set (83%). There was an 83% consensus among the residents that they felt prepared for the month, and that the experience would enhance their operating room safety (83%). The residents unanimously agreed that this curriculum enhanced their orthopaedic training, and that it should become a permanent part of the resident education program.

All of the residents agreed that a dedicated month of skills training was preferred to a longitudinal course during the year. One resident noted that it was helpful to have had some experience in rotations prior to the curriculum. While only half of the residents thought the amount of cognitive knowledge supporting the exercises was ideal, they unanimously felt that the modules were at exactly the right level, and that they were given adequate practice time. 71% of participants believed they had the ideal amount of faculty instruction and 83% thought that the course had the ideal number of modules and amount of assessment (Figure 4b).

SUMMARY, CONCLUSIONS AND FUTURE PLANS

This novel one month laboratory-based surgical skills curriculum for orthopedic PGY-1 residents was developed de novo and executed by the faculty of the Department of Orthopaedics at the University of Iowa. The curriculum’s modules were directed to provide PGY-1 residents with the basic surgical skills needed for future operative experiences. Despite considerable time invested in the planning and execution of the month, the faculty members were very engaged and eager to contribute to the process. Other than this faculty time commitment, the single greatest expense was for cadaveric specimens. With better planning and with different and more cost effective simulations, this expense could be reduced. The video content produced from this year’s course will be beneficial, as it should allow residents to learn more independently, and decrease the faculty time commitment in the future.

Resident satisfaction after participating in the curriculum was high. We plan to repeat this rotation again next year, with distinct goals to develop better assessment metrics as well as an assessment of the relative value of each of the modules. As we move forward, alternative sources of funding will be sought. This experience demonstrates that a dedicated one month rotation of surgical skill training aimed at educating residents at the PGY-1 level is both a viable and beneficial tool for developing the technically competent orthopaedic surgeons of the future.

REFERENCES


HOW ORTHOPAEDIC RESIDENTS PERCEIVE EDUCATIONAL RESOURCES

Brian R. Wolf, MD, MS¹, Carla L. Britton, PhD¹

ABSTRACT

Introduction: The educational paradigm for orthopaedic surgeons is shifting from a strictly Operating Room based approach to the addition of simulator- and lab-based models. This study aims to assess resident views on the relative value of orthopaedic educational resources and the value of a cadaver-based arthroscopy skills laboratory.

Method: A questionnaire assessing beliefs about various orthopaedic educational resources for overall orthopaedic education and surgical skills education was given to all residents in one orthopaedic residency program with a new arthroscopic skills laboratory during a three year period. Forty-one orthopaedic residents from years PGY1 through PGY5 participated.

Results: Observation and participation in the OR was the highest ranked learning activity for both overall and surgical skills education. Sessions in the skills lab ranked second for surgical skills education and fourth for overall orthopaedic education. The arthroscopic skills lab was most highly valued for practicing 3-D use of instruments and developing familiarity with equipment.

Conclusions: Orthopaedic trainees highly value operating room experience as the primary resource for education during residency. Orthopaedic trainees have found the addition of a surgical skills training lab for teaching arthroscopic skills a significant benefit to both their overall education and to surgical skills training.

INTRODUCTION

There are currently approximately 150 orthopaedic training programs in the United States producing approximately 620 graduates annually¹. Orthopaedic training programs have been guided by the American Board of Orthopaedic Surgery (ABOS) since 1934². However, the educational curriculum for orthopaedic training is not standardized and varies considerably among programs. There are three main goals of orthopaedic training: 1) education in the diseases and conditions that are common to the field of orthopaedic surgery, 2) education in the pertinent basic and clinical sciences, and 3) education in the procedural skills and operative techniques of orthopaedics. The third goal encompasses knowledge of the operation details, equipment utilized, and the practice of technical skills. All three goals are integrated in the process of developing surgical judgment in orthopaedic residents.

Educational resources in orthopaedics include didactic lectures, experience in the operating room, and experience in the clinical setting while caring for patients. Additional knowledge is gained from reading orthopaedic texts and journals, and from web-based resources. Recently, other skills-based learning opportunities have become more prevalent within orthopaedic surgery. Residency programs have opted to develop surgical skills labs where techniques and skills are taught and practiced on simulators, plastic models or cadaveric specimens. In addition, orthopaedic organizations, societies, and industry-funded education and surgical training courses using cadaveric specimens are prevalent and are frequently used by residents either as a formal part of a residency program’s curriculum, or to supplement existing program activities. The potential benefit these labs offer is increased opportunities for residents to gain familiarity with surgical equipment, procedures, and techniques in a low-risk, low-cost environment.

Paradigm shifts in surgical education have encouraged orthopaedic residency programs across the country to invest in surgical skill laboratories to provide relatively low-cost opportunities for residents to develop familiarity with equipment and techniques³. The residents at the investigator’s program spend approximately 90 minutes per week practicing arthroscopic procedures on cadaveric knee, shoulder, ankle and elbow specimens as a formal part of the curriculum. Residents are required to attend

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Instruction during these teaching sessions is directed by a faculty member or a current sports medicine fellow. Senior [Post graduate year (PGY) 4 and 5] residents also instruct more junior residents (PGY2). At the time of this study residents spent 4 months as a PGY2, 4 months as a PGY4, and 2 months as a PGY5 on rotations where arthroscopy was routinely performed and a significant part of the surgical experience.

Despite the variety of educational resources and curricula, little is known regarding the value of the individual components to orthopaedic education. The author’s department recently invested in building and equipping a surgical skills and arthroscopy laboratory to enhance the teaching of surgical anatomy and surgical skills with an emphasis on arthroscopy. However, the relative value of a surgical skills lab in the realm of resident and fellow education has not previously been evaluated. Hence, the purpose of this study was twofold. First, the study was to gauge the subjective importance of various educational resources available to orthopaedic surgery residents. Secondly, the subjective benefits of using an arthroscopic skills lab utilizing cadaveric specimens in an orthopaedic training curriculum were assessed. We hypothesized that the use of a surgical skills laboratory would be favorably received by orthopaedic residents at all levels.

### Methods

All orthopaedic residents and trainees were asked to complete a survey at the end of three academic training years regardless of their participation in formal skills lab teaching sessions that year or not. The surveys were administered in 2005, 2006, and 2009. The survey was composed of questions related to the relative value of several common orthopaedic educational resources. The resources included: didactic lectures and conferences, case-based lectures and conferences, textbooks, teaching videos, observation and participation in the operating room, surgical skills teaching lab sessions, clinic teaching, teaching from senior residents / fellows / colleague trainees, and journal articles. These survey questions required the trainee to rank order the available educational resources from most to least important. The resources were separately rank ordered in terms of their importance for overall orthopaedic education and importance for surgical skills education. The nine rankings were categorized into three groups: upper third (ranks 1-3), middle third (ranks 4-6) and lower third (ranks 7-9).

Multiple potential benefits of using a cadaveric specimen for learning and practicing arthroscopic surgical skills were queried. The questions and responses applicable to this part of the study are included in Table 1.

For the purposes of this study, only the first response for each question was recorded as the typical response for a resident or fellow.
How Orthopaedic Residents Perceive Educational Resources

A resident with more than one response was included.

Pearson’s chi-square tests of independence were conducted to assess differences in frequency distribution of trainee responses by year in training.

RESULTS

A total of 56 surveys were completed at the end of three academic years. Forty-one different trainees completed surveys during this time and these were included in this analysis. The demographic data and post graduate levels of the trainees completing the surveys are summarized in Table 2.

The educational resources that orthopaedic trainees found most useful for both overall orthopaedic training and surgical skills training are listed in the Table 3. For both overall and surgical skills training, observation and participation in the OR was considered most valuable with 85% (34/40) of respondents ranking it in the top third for overall training and 95% (38/40) ranking it in the top third for surgical skills training. 95% (38/40) of residents ranked skills lab sessions in the first third for surgical skills training but only 35% (14/40) ranked skills lab sessions in the top third for overall orthopaedic education. Residents perceived observation/participation in the OR, teaching from fellows and colleagues,

### Table 2. Gender and year in training of respondents

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>37 (80.4)</td>
</tr>
<tr>
<td>Female</td>
<td>4 (19.6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year in Training</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGY1</td>
<td>7 (17.1)</td>
</tr>
<tr>
<td>PGY2</td>
<td>5 (12.2)</td>
</tr>
<tr>
<td>PGY3</td>
<td>12 (29.3)</td>
</tr>
<tr>
<td>PGY4</td>
<td>2 (4.9)</td>
</tr>
<tr>
<td>PGY5</td>
<td>14 (34.1)</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (2.4)</td>
</tr>
</tbody>
</table>

### Table 3. Elements of orthopaedic training and their perceived value to orthopaedic residents (n = 41)

<table>
<thead>
<tr>
<th></th>
<th>Value to overall orthopaedic education</th>
<th>Value to surgical skills education</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rank 1 – 3</td>
<td>Rank 4 – 6</td>
</tr>
<tr>
<td>Observation/participation in OR</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Skills lab sessions</td>
<td>34 (85.0)</td>
<td>6 (15.0)</td>
</tr>
<tr>
<td>Teaching: clinic</td>
<td>14 (35.0)</td>
<td>18 (45.0)</td>
</tr>
<tr>
<td>Teaching: sr. residents/fellows/colleagues</td>
<td>19 (47.5)</td>
<td>12 (30.0)</td>
</tr>
<tr>
<td>Teaching: videos</td>
<td>26 (65.0)</td>
<td>10 (25.0)</td>
</tr>
<tr>
<td>Case-based lectures and conferences</td>
<td>5 (12.5)</td>
<td>7 (17.5)</td>
</tr>
<tr>
<td>Didactic lectures and conferences</td>
<td>10 (25.0)</td>
<td>24 (60.0)</td>
</tr>
<tr>
<td>Textbook readings</td>
<td>5 (12.5)</td>
<td>12 (30.0)</td>
</tr>
<tr>
<td>Journal articles</td>
<td>2 (5.0)</td>
<td>12 (30.0)</td>
</tr>
</tbody>
</table>

Note: Number of respondents varies due to missing data.

### Table 4. Perceived benefits of skills laboratory sessions (n = 37)

<table>
<thead>
<tr>
<th></th>
<th>Not/Slightly Beneficial</th>
<th>Somewhat Beneficial</th>
<th>Very Beneficial</th>
<th>Extremely Beneficial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Familiarity with basic arthroscopy equipment</td>
<td>2 (5.4)</td>
<td>5 (13.5)</td>
<td>21 (56.8)</td>
<td>9 (24.3)</td>
</tr>
<tr>
<td>Familiarity with arthroscopic instruments</td>
<td>4 (10.8)</td>
<td>7 (18.9)</td>
<td>19 (51.4)</td>
<td>7 (18.9)</td>
</tr>
<tr>
<td>Familiarity with arthroscopic anatomy</td>
<td>6 (16.2)</td>
<td>8 (21.6)</td>
<td>13 (35.2)</td>
<td>10 (27.0)</td>
</tr>
<tr>
<td>Practicing 3D use of instruments</td>
<td>--</td>
<td>5 (13.5)</td>
<td>14 (37.8)</td>
<td>18 (48.7)</td>
</tr>
<tr>
<td>Learning procedure techniques</td>
<td>3 (8.3)</td>
<td>7 (19.4)</td>
<td>14 (39.0)</td>
<td>12 (33.3)</td>
</tr>
<tr>
<td>Teaching by faculty/fellows</td>
<td>4 (10.8)</td>
<td>14 (37.9)</td>
<td>13 (35.1)</td>
<td>6 (16.2)</td>
</tr>
</tbody>
</table>

Note: Number of respondents varies due to missing data.
teaching in the clinic and skills lab sessions as most important to overall orthopaedic education. Observation/participation in the OR, skills lab sessions, teaching from fellows and colleagues and teaching videos were perceived as most valuable to surgical skills education. Journal articles were perceived as having the least value for learning in both educational areas.

Skills laboratory sessions were perceived by the majority of respondents as being beneficial (Table 4). Almost half (48.7%) of the respondents considered skills lab sessions to be extremely beneficial for practicing three-dimensional (3-D) use of instruments. All respondents considered the skills lab sessions to be at least somewhat beneficial for practicing 3-D instrument use. Over 80% (30/37) of respondents perceived skills lab sessions to be very to extremely beneficial for developing basic familiarity with arthroscopic equipment. Teaching by faculty/fellows was considered to be least beneficial with close to half (48.7%) of respondents perceiving it to be no more than somewhat beneficial.

Table 5 summarizes resident perception of the value of skills lab sessions to the OR experience. Over half the respondents reported a moderate increase in confidence, speed and efficiency, and participation in OR cases as a result of skills lab sessions. Amount of participation in the OR was perceived as the domain least affected by practice in the arthroscopy skills lab with 30% (10/33) of respondents reporting no or only a slight increase. Over 80% (27/33) of the respondents reported that confidence in the OR increased at least moderately as a result of practice in the arthroscopy skills lab.

No significant differences in resident responses relative to year in training were observed.

**DISCUSSION**

Orthopaedic education has evolved into a multi-faceted activity, integrating established teaching methods with new technologies. These changes are, in part, the result of recently implemented restrictions in resident work hours, increased pressure for clinical productivity at academic teaching institutions and technological advances. Despite these changes, little research has been done to evaluate either the subjective value of learning experiences or objective measures of learning success in orthopaedic residents. To develop a better understanding of what educational activities residents value for learning orthopaedic surgery, we conducted a survey of residents in one program at an academic medical center.

Survey respondents in this orthopaedic program identified operating or assisting in the operating room as by far the most important educational resource for both overall orthopaedic learning and surgical skills learning. This is not surprising in that most orthopaedic residents choose this field based on interest in the surgical aspect of orthopaedics and most residents enjoy time in the operating room. Even the best models outside the OR cannot duplicate the full OR experience.

Education from peers was also valued highly for both overall orthopaedic education and for surgical skills education. This may reflect the educational model of the investigating institution where residents primarily work in teams of 2-4 residents of varying seniority. Teaching by senior residents may benefit both junior and senior residents in an extension of the traditional “see one, do one, teach one” paradigm of surgical education. This finding could potentially lend support to allocating residents into teams with senior and junior resident components although it needs further formal study.

Residents subjectively valued the addition of a surgical skills lab based on a cadaveric model highly relative to other resources, especially in gaining surgical skills. Residents perceived the lab to have value for learning and practicing the basics of arthroscopy and they perceived the skills practiced in the lab to translate to the OR through increased confidence, speed and efficiency and participation in the OR. These benefits are very important given the increasing pressure on academic training programs to be efficient and more productive in the operating room. These outside pressures can result in less time for resident participation and teaching in the formal operating room setting. If it is true that practice in the lab translates to more efficient performance in the OR, then patients also stand to benefit through decreased anesthesia and OR time and perhaps through decreased risk of iatrogenic injury.
O’Neill reported that over half of all orthopaedic training programs had cadaveric wet labs in 2002. The provision of the opportunity for repetitive practice of arthroscopic skills over the course of an orthopaedic residency is appealing as it has been shown that procedural skills are not retained without repetitive exposure, suggesting that repetition and multiple training episodes are preferable. Surveys of teaching faculty at training programs also suggest numerous exposures are needed for trainees to gain proficiency in common orthopaedic arthroscopic procedures. A significant learning curve exists with exposure to new arthroscopic procedures, even for practicing surgeons, suggesting that repetitive practice is essential for residents where all aspects of arthroscopy are new. (Snow and Stanish KSSTA 2010) A skills lab is a way to enable residents to practice surgical skills without the time constraints associated with the OR. Residents can use the lab at their convenience and can repeat a procedure as often as desired.

The cost-benefit ratio of skills lab utilization in a training program has not been evaluated. Initial development and start-up, maintenance, cadaveric specimen purchase and other costs are incurred. However, there is literature to suggest that simulation training can transfer to increased competency and skill in the operating room. In a 2008 study of the effect of laboratory-based simulator training on resident ability to perform knee diagnostic arthroscopy, Howells et al. demonstrated improved skills in trainees that underwent repetitive instruction using a bench-top knee simulator. Transfer of skills after training using a cadaveric model has not been evaluated to our knowledge. However, use of cadaveric specimens is common and a preferred method of learning surgical skills in orthopaedics. Vitale et al. surveyed more than 2400 members of the American Academy of Orthopaedic Surgeons and found that practice on cadaveric specimens ranked third relative to sports medicine fellowship and hands-on courses in importance for learning arthroscopic rotator cuff repair. In addition, skills assessment systems are being developed for use in simulated learning situations.

Our survey results show that the skills lab was highly regarded by our residents for learning arthroscopic techniques. Substantial benefit was noted for becoming familiar with equipment, instruments, procedures, anatomy and especially with practicing the 3-dimensional aspect of arthroscopy. Our residents felt that skills lab sessions resulted in increased confidence, efficiency and participation in the operating room.

Teaching in the clinic and in didactic settings will continue to have places in orthopaedic education. Trainees in our program still valued teaching in the clinic setting highly. This is an important finding in light of reduced work hours and increasing surgical burdens on teaching programs. As training programs move residents to the operating room for a larger majority of their weekly schedule, the educational benefit of seeing outpatients in the clinic setting may be overlooked. Our residency program has six residents per year, and residents spend varying amounts of time in outpatient clinics and the operating room depending on which of the nine different services they are rotating through. The formal educational curriculum with didactic lectures, case-based conferences, morbidity and mortality, fracture conference and grand rounds are incorporated into two 90-minute conference sessions during the week. Each subspecialty team additionally has team conferences with subspecialty education and case review components.

There are several limitations to this study. We collected information from only one orthopaedic residency program, thus our conclusions may not be generalizable to other residency programs. Also, our sample size was small and the data available from our study is limited and not amenable to detailed statistical analysis. Small sample size may limit the power required to detect differences between different PGY levels. Whereas PGY1s may rank cadaver-based training higher due to their limited experience with “real world” arthroscopy, PGY5s may consider cadaver-based training unrealistic compared to their experiences.

In conclusion, orthopaedic trainees highly value operating room experience as the primary resource for education during residency. Orthopaedic trainees have found the addition of a surgical skills training lab for teaching arthroscopic skills a significant benefit to both their overall education and to surgical skills training.

REFERENCES


INTRODUCTION

Calcaneal slide osteotomy is a commonly performed surgical hindfoot procedure typically associated with mechanical weight-bearing axis realignment with medial or lateral displacement of the posterior calcaneus. An oblique lateral heel incision, in line with the planned osteotomy, is the standard open approach to the calcaneus for the procedure. The oblique incision crosses directly over the arborization of the sural nerve on the lateral hindfoot, even if the main branch of the nerve may be avoided by careful dissection. The medial neurovascular structures in the tarsal tunnel are also at risk using a saw blade directed from lateral to medial, as over-penetration of the medial cortex with the saw could cause unintentional injury.

We describe a three incision, percutaneous endoscopically-assisted calcaneal osteotomy (PECO) technique that minimizes potential injury to both the sural nerve laterally and the plantar and medial neurovascular structures.

MATERIALS AND METHODS

The patient is positioned supine on the operating table with the feet at the end of the bed, with a bump placed behind the ipsilateral hip so that the foot rolls to a slightly internally rotated position (Figure 1). A thigh tourniquet is placed, and standard sterile prep and draping proximal to the knee is performed. The PECO technique may be done in addition to other procedures for planovalgus or cavovarus deformity reconstruction as a part of the planned surgical treatment.

The proximal-posterior aspect of the osteotomy should start at approximately midway between the posterior aspect of the calcaneal tuberosity and the posterior aspect of the lateral malleolus, and aimed approximately 45 degrees anterior toward the plantar cortex (Figures 2A and B). Fluoroscopy may be used to identify these landmarks on the skin.

Two small (five millimeter) lateral heel skin-only incisions are made with a 15 blade, one at the proximal-posterior aspect and the other and the distal-plantar aspect of the planned 45 degree calcaneal osteotomy,
J. N. Tennant, A. Veljkovic, P. Phisikkul

with the incisions made parallel to the orientation of osteotomy. A blunt curved hemostat is used to dissect percutaneously down to the lateral wall of the calcaneus through each incision. The hemostat is then used to create a tunnel along and directly over the lateral calcaneal cortex between the two incisions, deep to the plane of the sural nerve.

Through the lateral proximal-posterior incision, the same curved hemostat is used to dissect directly medially, anterior to the distal Achilles tendon, and posterior to the medial neurovascular bundle, until it is prominent under the medial skin. A 15 blade is used to make a longitudinal five millimeter skin incision, exposing the tip of the hemostat. Through this single medial incision, the medial and plantar medial subcutaneous tunnel is developed with the hemostat, in a similar fashion to the lateral tunnel, in line with the planned osteotomy and directly adjacent to the medial periosteum. The hemostat, directed laterally, is passed deep to the medial head of the quadratus plantae and the neurovascular structures.

Through the lateral distal-plantar incision, the plantar tunnel directly against the plantar calcaneal cortex is developed with the hemostat, completing the deep circumferential tunnel around the calcaneal tuberosity.

Suture shuttling begins with passing a No. 2 suture from medial to lateral using a hemostat passed through the lateral proximal-posterior incision into the medial incision. This suture is left in place (Figure 3). Next, an empty, closed right-angled clamp is passed through the medial incision plantarward and distalward along the medial calcaneal periosteum until the plantar medial curvature of the calcaneus is palpable with the tip of the instrument (Figure 4). To avoid an injury to the neurovascular structures, the suture previously placed in the medial incision can be used to guide the tip of the clamp down towards the calcaneus. This is performed by capturing the suture with the tip of the clamp, pulling the suture from the lateral incision allowing the clamp to make contact with the bone, and partially opening the clamp to release the suture, and redirecting the clamp towards the medial and plantar cortices respectively. A 4 millimeter dry scope cannula with an inserted blunt trochar and a No. 2 suture threaded through its distal eyelet (Figure 5) is passed into the lateral distal-plantar incision along the plantar calcaneal cortex until the tip of the right angle clamp is palpated with the cannula at the medial plantar curvature of the calcaneus. The blunt trochar is removed, and the tip of the right angle clamp is maneuvered so that it rests...
Technique Tip: Percutaneous Endoscopically-Assisted Calcaneal Slide Osteotomy

within the bore of the cannula (Figure 6). Position is confirmed with a gentle toggle of either instrument, resulting in movement of the other instrument. The arthroscopic camera is placed in the cannula to either assist the engagement of the instruments or to confirm the intra-cannula position of the clamp, and the grasping of the suture loop by the clamp is directly visualized (Figure 7). The loop is pulled by the clamp medially, out of the medial incision. The initially shuttled suture (from the lateral proximal-posterior incision to medial) is then placed in the suture loop. The suture is pulled around the medial and plantar cortex, out through the lateral distal-plantar incision. The result is a single suture touching the periosteum of the dorsal, medial, and plantar calcaneus, with each end exiting through the two small lateral incisions.

A Gigli saw is shuttled using the suture into the same position (Figure 8). Soft tissue-protecting retractors are placed over the Gigli saw to protect the skin incisions during sawing (Figure 9). Gigli saw osteotomy is performed with care to avoid injury to the lateral soft tissue and the sural nerve. When the osteotomy is nearly complete, the sawing is performed carefully as it is held at almost a straight line by the surgeon’s fingers. Completion of the osteotomy is confirmed by an easily mobile posterior calcaneus. A ¼ inch osteotome is inserted through the distal-plantar incision and is gently rotated within the osteotomized calcaneus to distract and translate the tuberosity medially or laterally (Figure 10). Fluoroscopy is used to check displacement and alignment.
Two percutaneous cannulated 6.5 millimeter screws are placed under fluoroscopic guidance across the osteotomy site from posterior to anterior, with start points proximal to the weight-bearing portion of the calcaneus and distal to the Achilles tendon insertion (Figures 11A-D).

A single nylon skin suture is used to close each of the five small incisions, three for the osteotomy (two lateral and one medial), and two posteriorly for the two screws.

RESULTS

Twenty-five patients have undergone PECO by a single surgeon at our institution, in all cases with additional procedures performed at the same setting for hindfoot alignment reconstruction. Institutional review board approval through practice surveillance was obtained. Preoperative and postoperative radiographic hindfoot alignment was assessed, as well as displacement of the osteotomy achieved intraoperatively. Clinical postoperative neurovascular complications were assessed in follow-up. Twenty-five patients underwent twenty-five displacement osteotomies (20 lateral displacement, 5 medial displacement; 13 men, 12 women; 14 left, 11 right) by the PECO technique. Average follow-up was 8 months. Mean correction based on intraoperative axial heel view was 7.3 +/- 2.0 mm of displacement. Mean correction on comparison of preoperative and postoperative hindfoot alignment radiographs relative to the axis of the tibial shaft was 13.9 +/- 7.5 mm. No patients had vascular or wound complications. One patient (1/25, 4%) had persistent post-operative numbness in the sural nerve distribution.

DISCUSSION

Despite an early learning curve, the lead author has found this technique to be both safe and efficient, particularly for soft tissue management about the hindfoot. Although arthroscopy about the calcaneus has been described previously, few similar descriptions to our PECO technique exist. A four-incision percutaneous technique without endoscopic assistance has been noted previously, but the technique description raises concerns for potential injury to medial plantar neurovascular structures by the Gigli saw. The previous technique included a plantar medial incision, did not use suture as an initial shuttling tool (instead primary passage of the Gigli saw), and did not use an endoscope to confirm position of the saw’s path as it went under the plantar calcaneus. Moreover, the Gigli saw was pulled through the plantar lateral and plantar medial incisions, which would place the plantar structures and medial neurovascular bundle at greater risk. In contrast, we recommend passing a non-absorbable suture initially and shuttling the Gigli saw thereafter to improve the procedure’s safety. The endoscope confirms the location of the suture’s path under the plantar medial heel, obviating the need for a fourth, plantar medial incision. Lastly, our preference is to have the Gigli saw exit from the proximal lateral and plantar lateral incisions to minimize injury potential to more critical plantar and medial structures, while protecting the skin with percutaneous skin retractors.

The perils of the open technique for calcaneal osteotomy have been noted in the literature. Previous reports and studies have shown risk to neurovascular structures, particularly on the medial side of the hindfoot, during
Technique Tip: Percutaneous Endoscopically-Assisted Calcaneal Slide Osteotomy

calcaneal osteotomy procedures using a power saw1,5,7. Branches of the lateral calcaneal nerve are directly in the path of the oblique incision commonly used in open techniques2. The presently described PECO technique is clinically effective, minimally invasive, and maximally protective of neurovascular structures about the calcaneus during osteotomy.

REFERENCES
TOWARD IMPROVED CLINICAL RELEVANCE OF CARTILAGE INSULT MODELS IN THE RABBIT KNEE: SURGICAL ACCESS TO THE HABITUAL WEIGHT-BEARING REGION

Yuki Tochigi, MD, PhD1, Joseph A. Buckwalter, MD, MS2, Thomas D. Brown, PhD3

ABSTRACT
Objective: This article addresses considerations for using a posterior (popliteal) instead of anterior (para-patellar) approach for experimental insult to the rabbit knee medial femoral condyle (MFC) surface in vivo. The posterior approach is particularly advantageous when intending to address the pathomechanisms of OA associated with habitual cartilage loading, or the efficacy of a cartilage repair method, in a clinically relevant experimental setting.

Design: Studies using anterior versus posterior approaches for such purposes in survival rabbit models of the MFC articular surface insults were systematically surveyed. The anterior-posterior span of the primary weight-bearing region of that surface was demonstrated cadaverically.

Results: Of a total of 31 papers identified in 2007-2012, an anterior approach was utilized in 28 studies (> 90%). More than half (17/28) explicitly regarded the cranial half (inferior aspect) of the MFC surface as being a “weight-bearing” region. The insult site through anterior approach (identified in figures) was located in the cranial half region in all cases. Cadaverically, however, the center of habitual tibio-femoral contact locations on the MFC surface was located in the caudal half region (posterior aspect) of the MFC surface. The majority of the habitual contact region was accessible only by a posterior surgical approach.

Conclusion: For the above-noted purposes, use of a posterior (popliteal) approach, rather than an anterior approach, is highly recommended.

Keywords: animal models; rabbit knee; medial femoral condyle; cartilage; weight-bearing region.

INTRODUCTION
The rabbit knee is one of the most commonly utilized joints in survival animal studies of osteoarthritis (OA) and cartilage repair4. The relatively large physical size of the rabbit knee is well suited for creating chondral or osteochondral defects or for acute cartilage injury (blunt impactions). The articular surface of the medial femoral condyle (MFC) is often chosen as a site of interest, because it is presumed to be a high weight-bearing surface. Given that osteochondral lesions in corresponding regions in the human knee present a substantial challenge for cartilage repair24, testing new treatment methods in a clinically relevant experimental setting in vivo is crucial for obtaining valid pre-clinical information.

Among the many survival rabbit model studies in the literature, anterior (typically medial para-patellar) approaches are commonly utilized to apply experimental insults to the MFC surface. From a functional and anatomical perspective, however, it is questionable whether or not the habitual weight-bearing region in this surface is truly accessible anteriorly. The rabbit’s habitual posture is one of squatting, in which the knees are deeply flexed. Even during hopping (Figure 1), the rabbit knee appears to remain flexed throughout the majority of the motion event. Based on this consideration, Hurtig et al. reasoned that the posterior region of the rabbit knee MFC surface was responsible for habitual weight-bearing, leading them to adopt a posterior (popliteal) approach to create osteochondral defects there. Nevertheless, most investigators before and since have used an anterior approach for such purposes. There appears to be insufficient awareness about the relatively predominant posterior location of weight-bearing in this species, and about accessibility of this location when using an anterior surgical approach. The purpose of the present article is to draw attention to this issue, which

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Toward Improved Clinical Relevance of Cartilage Insult Models in the Rabbit Knee

Figure 1. Successive instances during rabbit hopping. Note that the knee is kept in flexion except for a very short duration at the instant of “taking off.”

1. Early stance  2. Mid stance  3. Late stance


will improve the human clinical relevance of rabbit knee models addressing the pathogenesis of OA, and hopefully improve the efficacy of treatment methods in high weight-bearing articular surfaces.

METHODS

Literature Survey

A systematic survey was performed of the English language literature regarding survival rabbit model studies, in which articular surface defects or blunt impaction cartilage injuries were created in the MFC surface. The PubMed database from 2007 was searched using a combination of keywords [“rabbit” AND “knee” AND “cartilage” AND (“defect” OR “impact”)]. Next, the searched articles were screened by the journal’s impact factor (1.0 or higher). These candidates (a total of 110 papers) were subjected to quick review of the abstract (or main text as needed) to select the papers that satisfied the above-noted (underlined) criteria. Finally, these selected papers were carefully reviewed to assess the methodological details. The points of interest included: 1) research interest, 2) insult modality, 3) surgical approach, 4) statement that regarded the insult site as a weight-bearing region, and 5) the insult site location identified in figures.

Cadaver Demonstration

The anterior-posterior span of the primary weight-bearing region in the rabbit knee MFC surface was explored in a normal whole-leg cadaver specimen harvested from an adult New Zealand White rabbit. The specimen was dissected free from soft tissue from the femoral head through the ankle, except for the major passive knee stabilizing structures (including the cruciate and collateral ligaments and the menisci). The femur was secured horizontally to a plastic-foam baseplate using two perpendicular Kirshner wires (diameter: 1.6 mm), one proximally through the femoral head, and the other distally across the medial and lateral distal femoral epicondyles. Another perpendicular K-wire was placed at the ankle (through the talar dome), so that the leg could be stabilized at predetermined knee flexion positions. The K-wire insertion points on the baseplate were regarded as reference points for the sagittal-plane positions of the hip, knee, and ankle, respectively. The angle between the hip-knee and knee-ankle axes (Figure 2A) was measured using an analog goniometer, and then defined as the knee flexion angle (where 0° indicated full extension).

Information regarding the physiologic range of motion of the rabbit knee was searched in the literature. Belozerova et al. reported that the rabbit knee’s flexion angle at rest ranged from 90° to 120°, while Mansour et al. reported that the range of motion during hopping was from 120° to 160°. (Note: In the original reference papers, knee flexion positions were expressed as “extension angles,” where 0° indicated full extension. Therefore, the above-noted ranges were reported as 60° to 90° and 20° to 60°, respectively.) Accordingly, flexion angles of 90°, 135°, and 160° were selected as representative habitual weight-bearing positions for the rabbit knee.

For each of these three positions, the center of the tibio-femoral contact location in the MFC was marked using a 1.25-mm K-wires, which was pierced in a retrograde fashion through the proximal tibia (Figure 2A).
For accurate pin positioning, a double trocar-tipped K-wire was pierced from proximal to distal into the center of the medial plateau (at which the tibial surface was uncovered by the meniscus, Figure 2C) while visualizing the insertion point by internally rotating the tibia. In addition, perpendicular access to the medial femoral condyle surface, both anteriorly and posteriorly to the proximal tibia, was simulated using a 2-mm dermal biopsy punch (Figures 2D and 2E), and medio-to-lateral digital photographs were taken at the most posterior position accessible from anteriorly and the most anterior position accessible from posteriorly. The joint was then disarticulated by transecting all knee ligaments, and the tibia was removed. Finally, the anterior-posterior distribution of the three above-noted bone holes (marked by inserting K-wires) was recorded, again by means of digital photographs (Figure 2B).

RESULTS

In the literature review (Table 1), a total of 31 papers\textsuperscript{7,37} were found to meet the above-noted criteria. Of these, the vast majority (28 of 31, > 90%)\textsuperscript{7,11,13,15,20,30,37} utilized anterior approaches to access the MFC surface. More than half (17 of 28) of these anterior approach studies\textsuperscript{7,8,10,11,16-19,21,23,25,27,32,34,36,37} regarded the site of the experimental insult as being in the weight-bearing region. The insult site through anterior approach (when identified in figures) was located in the cranial half region of the MFC surface (Figure 2B) in all cases\textsuperscript{7,11,13,15,20,26,28,30,32,36}. Posterior approaches were utilized in only three studies\textsuperscript{12,14,29}, one of which was from our group.

Figure 2. A) Definition of knee flexion angle in the present cadaver demonstration setting. B) Mediolateral view of the rabbit medial femoral condyle, on which the center-of-contact locations at 160°, 135°, and at 90° of knee flexion were indicated using metallic pins. C) Superior view of the proximal tibia after disarticulation. The opening of the tibial tunnel (white arrow) is accurately positioned at the center of the medial tibial plateau (at which articular cartilage is uncovered by the meniscus). D) Anterior limit of posterior perpendicular access. E) Posterior limit of posterior perpendicular access.
In the cadaver demonstration, the tibio-femoral contact locations on the MFC surface at the representative habitual weight-bearing knee flexion positions (indicated by the pins in Figure 2B) were distributed only within the caudal half region. When using a dermal punch to access the MFC surface from posteriorly to the tibia (Figure 2D), perpendicular apposition was feasible across almost the entire habitual contact region. By contrast, using anterior access, the dermal punch could only reach the boundary between the cranial and caudal halves (Figure 2E).

**DISCUSSION**

The literature review documents that the cranial half region (inferior aspect) of the rabbit MFC surface has most commonly been regarded as a high weight-bearing region. However, cadaverically, it is evident that the primary (habitual) weight-bearing region lies mostly within the condyle’s caudal half region (posterior aspect). Presumably, investigators tend to regard the cranial half region as the “primary weight-bearing” because this is the corresponding region in the human knee MFC during bipedal gait. However, given the substantial difference in posture during gait, it is reasonable that the tibio-femoral contact characteristics in the rabbit knee are very different from those in the human knee. It is also evident that the center of contact in the rabbit MFC surface is accessible only from posteriorly. These facts need to be recognized when designing studies that involve perpendicular-access survival insults to weight-bearing cartilage in the rabbit knee. And, these same factors should be considered when interpreting results from studies which used anterior access.

The above cadaveric demonstration is intended only for illustrative purposes, rather than to provide formal quantitative information as to whether or not a specific insult technique would permit reproducible experimental insult to the primary weight-bearing region of the rabbit MFC surface. However, it is obvious that the posterior approach provides better accessibility to the center of primary weight-bearing region\(^1\),\(^4\),\(^8\), while leaving all major joint stabilizing structures (including the extensor mechanisms) uninjured. For future survival rabbit knee model studies that involve surgical insult to the MFC surface to study the pathomechanisms of OA associated with habitual cartilage loading, or to address the efficacy of cartilage repair methods in a clinically relevant experimental setting, using a posterior approach rather than an anterior approach is highly recommended.

**ACKNOWLEDGEMENT**

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**REFERENCES**


NERVE INJURY AND PAIN AFTER OPERATIVE REPAIR OF CALCANEAL FRACTURES: A LITERATURE REVIEW

Jaclyn Haugsdal, Jeremiah Dawson, MD, Phinit Phisitkul, MD

ABSTRACT

Peripheral nerve injury is a common problem in foot and ankle surgery. We look at evidence of nerve injury as it relates to different operative approaches to the fractured calcaneus. The direct lateral, extended lateral, smile, sinus tarsi, and percutaneous approaches are discussed and the reported incidence of nerve injury in each is identified. We expect to identify divergent rates of injury between approaches and stimulate further investigation into prevention and treatment.

INTRODUCTION

Peripheral nerve injury is a common clinical problem associated with foot and ankle surgery that may lead to severe pain, serious disability, and poor outcomes\(^1\,2\). This condition is especially concerning following operative repair of calcaneal fractures. The calcaneus is a subcutaneous bone that sustains repetitive and maximum impact loads from ground reaction forces as well as irritation from shoe wear\(^3\,4\). Thus, heel pain and hypersensitivity following surgery can be unrelenting and difficult to manage. The literature has not adequately focused on nerve injuries related to the surgical treatment of calcaneal fractures despite the large impact of this unfortunate complication. While wound complications have greatly improved with modification of incisions and concern for vascular injury, nerve injury remains a prominent clinical problem\(^5\). The goal of this review is to highlight the current literature on nerve injury-related pain after repair of calcaneal fractures to prompt future research in the topic.

Although it is suspected that this condition has been underreported, studies have nonetheless revealed multiple different types of nerve injury following various surgical approaches to repair calcaneal fractures\(^6\,11\). Whether resulting from direct injury, traction injury, or idiopathic mechanisms such as reflex sympathetic dystrophy/complex regional pain syndrome, nerve pain results in significant morbidity and distress for affected patients. As there is no uniform definition or diagnosis to describe postsurgical nerve pain, such conditions may appear in the literature as neuropraxia, post-surgical neuroma, unexplained heel pain, hypersensitive scar, or complex regional pain syndrome (CRPS). Neuromas can result from traumatic mechanisms including direct injury (transection or unintentional suturing), excessive retraction, or entrapment within scar tissue\(^12\). They typically cause pain, burning, paresthesias, dysesthesias, and hyperesthesia\(^1,12\). CRPS can be caused by any type of surgery or trauma and results in unremitting and prolonged pain that is out of proportion to injury\(^8\). CRPS type I is similar to idiopathic reflex sympathetic dystrophy and not related to a specific nerve. CRPS type II is defined as causalgia from direct injury to a named nerve\(^9\). Neuropraxia, defined as irritation to a nerve resulting in a transient loss of function through conduction block without axonal degeneration, is most commonly caused by traction\(^13,14\). It is typically diagnosed by pain at the site of lesion with radiation in the anatomic path of the nerve and carries a relatively good prognosis\(^13,14\).

INCIDENCE OF NERVE INJURY RELATED TO VARIOUS SURGICAL APPROACHES

Direct lateral approach

Palmer\(^15\) originally described the direct lateral approach in 1948 for treatment of displaced intra-articular calcaneal fractures. The incision is initiated proximal and posterior to the tip of the fibula, curves around the lateral malleolus at the level of the sinus tarsi, and extends to the calcaneocuboid joint (Figure 1, A)\(^15,17\). Depth of the incision is made down to the sheath of the peroneal tendons, which can then be retracted anteriorly\(^15,17\). In addition, the sural nerve is dissected posteriorly and retracted\(^17\). Early studies by Stephenson\(^17\) and Leung et al\(^18\) reported 1 out of 22 (5%) and 5 out of 64 (8%) calcaneal fractures developed post-operative sural nerve lesions along the sural nerve distribution. All the cases spontaneously resolved without treatment\(^17,18\). In 1992, Buckley and Meek\(^19\) reported 5 of 17 feet that had post-operative sural nerve lesions following the
direct lateral approach. Four resolved spontaneously, but one resulted in an unsuccessful neuroma resection\textsuperscript{19}. Eastwood and Atkins\textsuperscript{16} found 11 sural nerve problems out of 20 cases, of which four continued to have permanent pain and dysfunction. Fernandez and Koella\textsuperscript{20} reported one case of a painful sural nerve neuroma out of 41 patients (2%). Chan\textsuperscript{21} in 1995, described 3 of 40 patients (7.5%) with sural nerve damage while another three patients (7.5%) were diagnosed with reflex sympathetic dystrophy.

**Extended lateral approach**

This approach is described as a full thickness ‘L-shaped’ incision on the lateral heel raised without direct exposure of sural nerve unless it is encountered at the proximal or distal end of the incision (Figure 1, B)\textsuperscript{22}. In comparison to the direct lateral approach, the extended lateral approach has been shown to reduce damage to the sural nerve and preserve blood supply to the flap from minimizing the dissection\textsuperscript{22,23}. Sanders et al.\textsuperscript{24} reported four cases (3.3%) of permanent paresthesias

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**Table 1. Summary of nerve injury complications reported in the literature by various approaches for operative repair of calcaneal fractures**

<table>
<thead>
<tr>
<th>Article</th>
<th>Number of calcaneal fractures repaired operatively</th>
<th>Number of nerve injury symptoms (% of total)</th>
<th>Number of CRPS cases (% of total)</th>
<th>Incidence of spontaneous recovery (% of nerve injuries)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Lateral Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eastwood and Atkins (1992)</td>
<td>20</td>
<td>11 (55%)</td>
<td></td>
<td>7 (63%)</td>
</tr>
<tr>
<td>Buckley and Meek (1992)</td>
<td>17</td>
<td>5 (29%)</td>
<td></td>
<td>4 (80%)</td>
</tr>
<tr>
<td>Stephenson (1987)</td>
<td>22</td>
<td>1 (5%)</td>
<td></td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Leung et al. (1989)</td>
<td>64</td>
<td>5 (8%)</td>
<td></td>
<td>5 (100%)</td>
</tr>
<tr>
<td>Fernandez and Koella (1993)</td>
<td>41</td>
<td>1 (2%)</td>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Chan (1995)</td>
<td>40</td>
<td>3 (8%)</td>
<td>3 (8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Extended Lateral Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eastwood and Atkins (1992)</td>
<td>20</td>
<td>2 (10%)</td>
<td></td>
<td>2 (100%)</td>
</tr>
<tr>
<td>Sanders et al. (1993)</td>
<td>132</td>
<td>12 (9%)</td>
<td></td>
<td>8 (66%)</td>
</tr>
<tr>
<td>Harvey et al. (2001)</td>
<td>218</td>
<td>6 (3%)</td>
<td></td>
<td>5 (83%)</td>
</tr>
<tr>
<td>Weber et al. (2008)</td>
<td>26</td>
<td>2 (8%)</td>
<td>4 (15%)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>Freeman et al. (1998)</td>
<td>150</td>
<td>4 (3%)</td>
<td></td>
<td>4 (100%)</td>
</tr>
<tr>
<td>Smile Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wiley et al. (2005)</td>
<td>73</td>
<td>6 (8%)</td>
<td>3 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Sinus Tarsi Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ebraheim et al. (2000)</td>
<td>106</td>
<td>3 (3%)</td>
<td>(2T; 1S)</td>
<td>1 (33%)</td>
</tr>
<tr>
<td>Geel and Flemister (2001)</td>
<td>32</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weber et al. (2008)</td>
<td>24</td>
<td>1 (4%)</td>
<td>(1T)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Mostafa et al. (2010)</td>
<td>18</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spagnolo et al. (2011)</td>
<td>39</td>
<td>0 (0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nosewicz et al. (2012)</td>
<td>21</td>
<td>1 (5%)</td>
<td>(1T)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Percutaneous Approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tomesen et al (2011)</td>
<td>39</td>
<td>4 (10%)</td>
<td>1 (3%)</td>
<td>4 (100%)</td>
</tr>
<tr>
<td>Wang et al (2010)</td>
<td>210</td>
<td>12 (6%)</td>
<td>(6T; 6S)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

T: Tibial nerve injury; S: Sural nerve injury; All reported injuries are based on sural nerve unless specified.
from the original 12 patients with sural nerve symptoms (10%) following 120 repaired calcaneal fractures using this approach. Harvey et al. reported post-operative sural nerve dysfunction in 6 of 218 patients (2.8%), one of which was treated with transposition of a neuroma, while the others resolved spontaneously. Four of 26 patients (15%) studied by Weber et al. in 2008 were diagnosed with complex regional pain syndrome following extended lateral incision with 2 additional cases (8%) having injury to the sural nerve. Eastwood and Atkins described 2/20 (10%) of patients that had altered sensation in the sural nerve distribution following the extended lateral approach, both of which resolved spontaneously. Additionally, Freeman et al. reviewed 150 cases of open reduction and internal fixation of calcaneal fractures using the extensile lateral approach and found four cases of paresthesias that resolved spontaneously without major sural nerve injuries. Overall, up to 23% of patients with the extended lateral approach have some sort of nerve pain following operative repair, if sural nerve injury and CRPS cases are combined.

**Smile Approach**

The “smile” approach, as described by Wiley et al. in 2005, was developed to reduce wound healing issues, but sural nerve injury is still a concern as the incision and nerve cross at right angles. The three main landmarks of the incision include the posterior superior apex of the calcaneus (1), the inferior border of the calcaneus below the fibula (2), and the superior extent of the anterior process of the calcaneus (3) (Figure 1, C). From landmarks 1 and 2 the incision is taken directly down to bone, but from landmarks 2 to 3 only skin is incised initially. The sural nerve is then carefully dissected out with a blunt instrument and mobilized. Six out of the 73 patients (8%) followed by Wiley reported numbness or pain in the sural nerve distribution following the “smile” approach. In addition, three patients developed reflex sympathetic dystrophy, but there were no neuromas reported. They concluded that the “smile” approach does not cause any more nerve injuries compared to those in the extended lateral incision.

**Sinus Tarsi Approach**

The sinus tarsi approach is more recently described and growing in popularity as a limited incision for fractures of the os calcis. As described by Weber et al. in 2008, the incision is made from the tip of the lateral malleolus to the calcaneocuboid joint in line with the 4th metatarsal (Figure 1, D). The incision continues deep between the peroneal tendons and the sinus fat pad but only to the fascia of the extensor digitorum brevis muscle located more distally. Out of 24 cases, Weber et al. reported one case of plantar nerve injury but no sural nerve injuries and no cases of complex regional pain syndrome (CRPS). Nosewicz et al. reported one case of tarsal tunnel syndrome (tibial nerve) out of 21 patients following the sinus tarsi approach that improved following a tarsal tunnel release without additional cases of nerve injuries. Of 106 surgically repaired calcaneal fractures using the sinus tarsi technique, Ebraheim et al. described two patients with symptoms of tarsal tunnel syndrome and improvement following a tarsal tunnel release. In addition, there was one case of sural nerve injury that recovered spontaneously at four months. There were no reported cases of nerve injury, entrapment, or CRPS in studies by Geel and Flemister, Mostafa et al., and Spagnolo et al. evaluating 32, 18, and 39 cases, respectively. An anatomic study done by Lawrence highlighted a concern for incisions placed in the sinus tarsi area causing potential injury to the communicating branch connecting the sural and superficial peroneal nerves, but no specific injuries to this branch have been reported. The relatively more common tibial nerve symptoms related to this approach are poorly understood. Overall, there are less reported nerve injuries with the sinus tarsi incision compared to both the direct lateral and the extensile lateral incision.
Percutaneous Approach

Many newer approaches for operative repair of calcaneal fractures, including the percutaneous approaches, are becoming more popular in foot and ankle surgery. However, a limited number of studies report nerve injury complications following the percutaneous approaches. Percutaneous reduction of calcaneal fractures typically involves posterior superior placement of K wires or Steinmann pins to aid in reduction followed by screw placement, followed often, in various techniques, by a lateral to medial screw into the sustentaculum tali. Screw placement is ultimately variable based on fracture lines and different methods are employed for distraction and reduction between studies. Tomesen et al. reported four out of 39 patients developed transient paresthesias and one patient that developed CRPS following percutaneous calcaneal fracture repair. Of the 210 fractures reported by Wang et al., four patients developed medial plantar nerve injuries, two had tibial nerve injuries (calcaneal branch), and six patients had sural nerve injuries. This approach involved a small posterolateral incision for insertion of a plate. All of these patients improved following hardware removal and/or neurolysis. Schepers et al. described a 10% risk of injury to the lateral dorsal cutaneous nerve, the continuation of the sural nerve, using the percutaneous approach with most cases improving spontaneously. Specific data was not reported, however, in that description. Overall, additional studies reporting the incidence of nerve injury complications are needed to accurately assess the risk using the percutaneous approach. Much of the existing literature focuses on wound complications and maintenance of reduction when comparing percutaneous approaches to more standard described approaches.

PREVENTION AND AVAILABLE TREATMENT

Nerve pain is a difficult problem to treat and the best management is prevention of nerve injury. Knowledge of peripheral neuroanatomy and potential pattern variations, in addition to choosing an incision that is less likely to cross the main nerve, are the foundations to prevent nerve pain. Minimizing the degree of nerve retraction should also be considered when choosing the best incision; but when necessary, gentle and brief retraction should be implemented. In some cases nerve sacrifice is unavoidable and may be preferable to excessive nerve retraction. In addition, careful wound closure with awareness of stitch placement is needed to avoid entrapment. It is unknown the exact mechanism and cause of complex regional pain syndrome; however some have proposed potential preventative measures to reduce its likelihood postoperatively. Overall, identification and protection of the nerve throughout surgery is imperative to reduce the incidence of nerve pain.

Even if the above measures are taken to prevent nerve injury, injuries will still occur. The presence of pain post-operatively is difficult to treat, as some pain resolves spontaneously while others may only improve surgically, even with experienced clinical judgement, it may be hard to discern initially which patients will get better non-operatively. Nerve pain is first managed medically with steroid injections, local or peripheral nerve blocks, and neuropathic pain medications such as amitriptyline, gabapentin, and carbamazepine in addition to physical therapy and continued activity of the affected limb. Narcotics should only be used during acute pain episodes. Some patients may find pain improvement with transcutaneous electrical nerve stimulation (TENS). Patients with continued intractable pain who fail non-surgical treatments may benefit from a surgical treatment. For neurectomies, proximal resection and embedding into nearby muscle or silicone capping has been proposed. Neuromas are difficult to treat as cut ends can form new neuromas. Therefore, embedding into the nearby muscle or capping is thought to protect the nerve and, hopefully, any neuroma that may form is minimized. If there is not an obvious nerve lesion intraoperatively, decompression or neurolysis may be beneficial, or occasionally nerve resection with repair or grafting may be an option. These surgical procedures should only be reserved for those with intractable pain as they put the patient at risk of having increased pain postoperatively.

CONCLUSION

Nerve pain is a common complaint in foot and ankle surgery, especially following operative repair of calcaneal fractures. Current research demonstrates rates of nerve injuries in the direct and extended lateral approach, but research is lacking for the newer and more limited incisions, such as percutaneous approach. Additional research should be focused on the incidence of nerve complications using these newer incisions and other methods to reduce future nerve injuries.

REFERENCES


ABSTRACT
The optimal route (oral versus intravenous) of antibiotic administration for pediatric acute osteomyelitis is not well established. Seventy-eight children from our university hospital and 17 children at our county hospital were treated for acute osteomyelitis. The rates of intravenous antibiotics upon discharge were 95% versus 65% (P=0.002), respectively. The recurrence rate and line complication rates were 10% and 24% at the university hospital, compared to 0% (P=0.34) and 6% (P=0.29) at the county hospital. Based on this data, a prospective comparison between intravenous and early oral antibiotic therapy for pediatric acute osteomyelitis is recommended.

Keywords: pediatric acute osteomyelitis, intravenous antibiotics, oral antibiotics

INTRODUCTION
Pediatric osteomyelitis is a common disease treated by the orthopaedic surgeon. Treatment includes antibiotic therapy and immobilization, with or without surgical drainage and decompression. Both the route and duration of antibiotic therapy can have significant impact on a child’s clinical course, as these factors determine whether the child will require a central venous catheter. Despite this, a recent review of the literature found no clear data on the optimal route and duration of antibiotic therapy, and recommended continuation of the gold standard of 4-6 weeks of intravenous antibiotics pending further evidence1.

Historically, early conversion to oral antibiotic therapy was associated with a high failure rate23. With the advent of high dose oral antibiotic dosing and serum assays for antibiotic titers, multiple studies have suggested that oral antibiotic regimens can treat acute osteomyelitis with similar low failure rates4-21. However, most of these studies do not address the pediatric population, and many of the comparative studies are retrospective and within the same institution, which can lead to bias.

Intravenous antibiotic therapy is often viewed as a relatively benign treatment. However, in the pediatric population complication rates can be high, ranging from 29-41% in previous studies22-24. Although the majority of these complications are simple line malfunctions, a line sepsis rate of 11% was reported in one study22. Intravenous antibiotics are also associated with adverse drug events in children undergoing prolonged outpatient treatment for osteomyelitis, with a rate of 32% in one recent study25.

We have noticed a difference in treatment philosophy at two of our hospitals. At our university hospital, pediatric patients are routinely treated with approximately six weeks of intravenous antibiotics for acute osteomyelitis. At our county hospital, one of the infectious diseases staff prefers oral antibiotics, and converts patients to oral antibiotics prior to discharge as a first-line treatment unless there is a concern for noncompliance, reaction to the oral antibiotics or lack of an oral antibiotic option. The purpose of this study was to compare the rates of intravenous antibiotic use, line complications and recurrence of infection at our two institutions.

METHODS
Patient Selection
This retrospective study was approved by both the University and the County hospital’s Institutional Review Boards. Inclusion criteria included all pediatric patients, ages 17 years and younger, admitted to our institution between January 2000 and December 2006 with ICD-9 codes 711.00-711.09 (septic arthritis) and 730.00-730.29 (osteomyelitis, acute and chronic). Diagnosis of septic arthritis was used to allow inclusion of patients with both septic arthritis and osteomyelitis. Patients were excluded if they were treated at an outside hospital for their impa-
Antibiotics for Osteomyelitis

...tient stay, did not carry a diagnosis of osteomyelitis, or did not have a complete inpatient chart establishing the diagnosis and detailing antibiotic treatment. We defined acute osteomyelitis as the initial presentation, and thus patients who had already been treated for a previous episode were excluded. Finally, we excluded children with significant medical comorbidities that could potentially lead to higher rates of recurrence. These comorbidities included: cerebral palsy, trisomy 21, myelodysplasia, osteosarcoma, premature birth, and Crohn’s disease. These exclusion criteria were utilized in an attempt to equalize the populations between our university and county hospitals.

The same pediatric orthopaedic group covered both hospitals. Surgical drainage was performed for subperiosteal abscess, extension into the joint and clinical deterioration despite antibiotic therapy.

Chart Review
Charts were reviewed for patient demographics (age, gender, medical comorbidities), presentation (duration of symptoms, preceding illness, fever on presentation, ESR and CRP on admission or within first day), site of infection, culture results, treatment (surgery, duration of inpatient stay, intravenous versus oral antibiotics upon discharge, duration of antibiotics), recurrence, line complications (accidental removal, malfunction, infection) and date of last follow up either with orthopaedics, infectious diseases or their primary care practitioner. Recurrence was defined by the need for a repeat course of antibiotics therapy, with or without a repeat surgical debridement.

Statistical Analysis
Age, duration of symptoms, presenting laboratory values, duration of antibiotic treatment, duration of inpatient stay, and duration of follow up were compared with two-tailed t-tests. Gender, preceding illness, fever on admission, rate of exclusions, patients undergoing surgery, intravenous antibiotics upon discharge, recurrence and line complications were compared with Fisher exact tests.

RESULTS
Our review included 78 patients from the university hospital and 17 patients from the county hospital. Demographic data is provided in Table 1. There were no significant differences between the baseline characteristics of the two populations.

Table 1 – Patient Demographics by Hospital

<table>
<thead>
<tr>
<th></th>
<th>University Hospital</th>
<th>County Hospital</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>78</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>7.5 ± 4.9</td>
<td>7.8 ± 4.6</td>
<td>0.82</td>
</tr>
<tr>
<td>Female</td>
<td>33 (42%)</td>
<td>3 (18%)</td>
<td>0.10</td>
</tr>
<tr>
<td>Male</td>
<td>45 (58%)</td>
<td>14 (82%)</td>
<td></td>
</tr>
<tr>
<td>Duration of symptoms (days)</td>
<td>13 ± 23</td>
<td>11 ± 11</td>
<td>0.65</td>
</tr>
<tr>
<td>Preceding Illness</td>
<td>12 (15%)</td>
<td>1 (6%)</td>
<td>0.45</td>
</tr>
<tr>
<td>Fever on Admission</td>
<td>56%</td>
<td>44%</td>
<td>0.72</td>
</tr>
<tr>
<td>ESR</td>
<td>54 ± 30</td>
<td>55 ± 32</td>
<td>0.93</td>
</tr>
<tr>
<td>CRP</td>
<td>7.0 ± 7.9</td>
<td>4.6 ± 4.6</td>
<td>0.23</td>
</tr>
<tr>
<td>Medically excluded</td>
<td>16 (17%)</td>
<td>3 (15%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Table 2 – Patient Results by Hospital

<table>
<thead>
<tr>
<th></th>
<th>University Hospital</th>
<th>County Hospital</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>78</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>36 (46%)</td>
<td>7 (41%)</td>
<td>0.79</td>
</tr>
<tr>
<td>IV on discharge</td>
<td>74 (95%)</td>
<td>11 (65%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Duration IV (days)</td>
<td>36</td>
<td>42</td>
<td>0.22</td>
</tr>
<tr>
<td>Total duration (days)</td>
<td>54</td>
<td>53</td>
<td>0.68</td>
</tr>
<tr>
<td>PO on discharge</td>
<td>4 (5%)</td>
<td>6 (35%)</td>
<td></td>
</tr>
<tr>
<td>Duration IV (days)</td>
<td>2.5</td>
<td>4.5</td>
<td>0.20</td>
</tr>
<tr>
<td>Total duration (days)</td>
<td>21</td>
<td>44</td>
<td>0.04</td>
</tr>
<tr>
<td>Inpatient stay (days)</td>
<td>6.0 ± 5.2</td>
<td>6.5 ± 3.3</td>
<td>0.65</td>
</tr>
<tr>
<td>Recurrence</td>
<td>8 (10%)</td>
<td>0 (0%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Line complications</td>
<td>16 (24%)</td>
<td>1 (6%)</td>
<td>0.29</td>
</tr>
<tr>
<td>Follow up (months)</td>
<td>6.0 ± 14.1</td>
<td>32 ± 35</td>
<td>0.009</td>
</tr>
</tbody>
</table>

At the university hospital, two of 16 patients (13%) with line complications developed recurrence, which was not notably different than the rate of recurrence in children without line complication. There was a significantly longer duration of follow up at the county hospital (32 versus 6 months, P=0.009).
Tables 3 and 4 show demographic and treatment data when comparing all patients treated with intravenous versus oral antibiotics at discharge. The intravenous group presented with an increased duration of symptoms (13.5 versus 5.2 days, P=0.007), and a trend towards a higher initial CRP (6.9 versus 3.5, P=0.11).

Table 5 lists the sites of infection at the two hospitals. Table 6 lists the culture results from peripheral blood, bone aspiration and direct culture either from a wound or within the operating room. The majority of the infections at both hospitals were either culture positive for *Staphylococcus aureus* or culture negative.

We retrospectively studied patients from two different institutions with different treatment philosophies to obtain a less biased comparison of intravenous versus oral antibiotics. Our analysis showed no significant difference in recurrence, despite the increased rate of intravenous antibiotics at the university hospital. Although one might expect a lower duration of follow up at a county hospital, ours had longer follow up which was attributed to the centralized electronic medical record used at the county hospital. The longer follow up at the county hospital increases our confidence in the lower rate of recurrence despite the higher rate of oral antibiotic usage.

We also found a relatively high rate of line complications, which fits well with the literature range of 29-41%. Like previous reports, we did not find an increased rate of recurrence in children who had line complications. Nevertheless, these complications represent a significant number of visits to the emergency room or clinic, as well as hospital admissions.

When we analyzed our results based on treatment modality, we did find a shorter duration of symptoms, and a trend towards a lower initial CRP, suggesting baseline differences between the intravenous and oral treatment groups. It is possible that these differences were due to the inclusion of the small percentage of patients who received oral antibiotics upon discharge at the university hospital. The patients at the university hospitals had a significantly shorter total duration of antibiotics, suggesting that they were equivocal cases of infection.

Older studies in the literature reported fairly high rates of recurrence with shorter courses of intravenous antibiotics, with one noting a 19% failure rate with three or less weeks of intravenous treatment versus a 2% failure rate with longer durations. Notably, these studies either did not use oral antibiotics after intravenous treatment or use modern dosages of oral antibiotics. Multiple studies have since reported the importance of high dose oral antibiotics and measurement of serum titers to ensure adequate antibiotics levels in the bloodstream. One study found that in 8 of 75 children the antibiotic dosage was changed based on titers. Notably, it is routine at our county hospital to check serum titers after converting to oral antibiotics, and prior to discharge.

Recent comparison studies in adults have not found differences in recurrence rates when comparing shorter versus longer durations of intravenous antibiotic therapy. One randomized prospective study in children found similar rates of recurrence when comparing an
average of 6 versus 28 days of intravenous antibiotics, but only enrolled 23 patients in the study. A recent database study of 29 pediatric hospitals compared 1,021 children discharged on intravenous antibiotics and 948 children discharged on oral antibiotics for acute osteomyelitis and found similar recurrence rates of 5% and 4%, respectively.

By comparing two hospitals with different treatment philosophies, rather than separating the treatment groups within a single hospital, we feel that our study reduces the treatment bias of oral antibiotics for more mild cases and offers a useful comparison between the two routes of antibiotic treatment. While a rate of 65% at our county hospital still seems relatively high, this rate was attributed to the fact the only one of the pediatric infectious diseases staff favored oral antibiotics, while the other staff preferred intravenous. The general practice of that staff member was oral antibiotics for all patients unless there were issues with patient noncompliance, or a lack of any available oral antibiotics due to allergies, reactions and susceptibilities.

Our study has important limitations. It is a retrospective study, and it was not possible to create two equal treatment groups, though we attempted to minimize this bias by excluding patients with significant medical comorbidities. As noted above, the significantly increased length of patient symptoms and trend towards a larger CRP indicates that the intravenous group may have had a more significant disease burden than the oral group. In addition, our total number of patients treated with oral antibiotics is relatively small, and our study is not powered to definitively state that intravenous and oral antibiotic treatments are equivalent in terms of recurrence. With our small patient numbers we also did not separate our results by organism, which may be significant in cases where the oral antibiotics available are not as effective as the parental antibiotics. Finally, we did not review patient compliance, which could have a significant impact on our results.

In conclusion, this study supports the growing body of evidence that early transition to oral antibiotic therapy may offer a similar recurrence rate to intravenous therapy, while avoiding the relative high rate of complications seen with central venous catheters. Like many others, we support the use of serum titers to ensure adequate oral dosing. In the future, prospective comparative studies are necessary to determine the optimal route and duration of antibiotic treatment in pediatric acute osteomyelitis.


SECONDARY CHONDROSARCOMA OF THE PELVIS ARISING FROM A SOLITARY EXOSTOSIS IN AN 11-YEAR-OLD PATIENT

A Case Report with 5-Year Follow-Up

Lukas M. Nystrom, MD, Barry R. DeYoung, MD, Jose A. Morcuende, MD, PhD

ABSTRACT
Although conversion of an osteochondroma to chondrosarcoma is a well-described rare occurrence, it is usually associated with syndromes such as multiple hereditary exostoses and is much more common after maturity. We present here a rare case of secondary pelvic chondrosarcoma arising from a solitary exostosis in a pediatric patient. An 11-year-old, otherwise healthy, female was referred to our clinic for evaluation of a pelvic mass detected on a radiograph. The radiographs obtained by the referring physician demonstrated a large lesion arising from the right superior pubic ramus, which was visible but not identified on an abdominal radiograph several years prior. Histopathologic analysis showed chondrosarcoma which was supported by an additional opinion to rule out chondroblastic osteosarcoma. The patient was treated with wide resection without adjuvant therapy and is doing well with no evidence of recurrence five years post-operatively. There have been only a few small case series describing chondrosarcoma in the pediatric patient. Even rarer are descriptions of secondary chondrosarcoma with only occasional cases reported as part of larger case series. Chondrosarcoma is a rare and difficult diagnosis in the pediatric patient. There is often considerable debate between chondrosarcoma and chondroblastic osteosarcoma, and the treatment implications of differentiating these diagnoses are of paramount importance.

INTRODUCTION
Although a relatively common primary malignant tumor of bone in the adult population, it is exceedingly rare for a chondrosarcoma to affect a pediatric patient, and to our knowledge there are only a few small series reported in the literature.

Conversion of an osteochondroma to chondrosarcoma is a well-described, albeit rare, occurrence. The conversion typically results in a low-grade chondrosarcoma, although higher grade tumors are also possible. It is usually associated with syndromes such as multiple hereditary exostoses (MHE) and is far more common after maturity, with only occasional reports of this occurring in the pediatric patient. The purpose of this report is to present a rare case of secondary pelvic chondrosarcoma in a pediatric patient. The patient and her family were informed of our intention to submit de-identified case information for publication, and verbal consent was obtained.

We aim to highlight the characteristics of the tumor and the issues and implications associated with making this difficult diagnosis in this age group.

CASE REPORT
An 11-year-old otherwise healthy female presented to our office for evaluation of a pelvic mass. She had symptoms including a limp and activity-related pain in the right groin for one month. On examination there was a firm, fixed mass in the right groin.

Radiographs demonstrated a large lesion arising from the right superior pubic ramus (Figure 1). An abdominal radiograph (Figure 2) obtained four years prior for an evaluation of abdominal pain, although read as negative, clearly demonstrates an abnormal lesion in the same location. The lesion is not entirely visualized such that comparisons of a size differential across the four year time span are not possible. We obtained a plain radiographic skeletal survey to evaluate for other potential osteochondromatous lesions. This study was unremarkable, essentially ruling out the diagnosis of MHE.

A computed tomography (CT) scan of the chest, abdomen and pelvis, and magnetic resonance imaging (MRI) scan of the pelvis were obtained (Figures 3 and 4). The imaging of the pelvis demonstrated a large lesion arising from the superior pubic ramus with a large
associated soft-tissue mass. The soft tissue component showed stippled areas of calcification on the CT scan and a high signal on T2 weighted imaging throughout the mass on MRI with peripheral enhancement on the T1 post-contrast films. The radiographic differential diagnosis favored chondrosarcoma; however, also included were chondroblastic osteosarcoma and Ewing’s sarcoma. Staging studies demonstrated no evidence of pulmonary metastatic lesions and no other bony lesions.

An incisional biopsy was performed shortly thereafter and showed the tissue had a grossly cartilaginous appearance. Microscopic exam (Figure 5) demonstrated a hypercellular field of disorganized chondrocytes and moderate nuclear atypia. A diagnosis of low-grade
Secondary Chondrosarcoma of the Pelvis Arising from a Solitary Exostosis in an 11-year-old Patient

A chondrosarcoma was made. The patient was therefore indicated for a wide resection, which we felt could be safely accomplished in the form of a type III limb-sparing pelvic resection.

Microscopic inspection of the wide resection showed two foci of osteoid which initially appeared to be scaffolding onto normal host bone, raising the concern for a chondroblastic variant of osteosarcoma (Figure 6). However, after further review with our musculoskeletal pathologist (BRD) regarding the patient’s history, the diagnosis was upheld as chondrosarcoma, grade II/III. This diagnosis was further corroborated by an independent review from another academic institution in the region. Based on this diagnosis no adjuvant treatment was administered. The patient has since been monitored with routine pulmonary surveillance with CT scans and local surveillance with radiographs and physical exam. She is now five years out from the surgical resection and is doing well with no obvious or reported functional limitations.

DISCUSSION

The first point of interest in this case is the rarity of encountering this lesion in a pediatric patient. Chondrosarcoma is an uncommon malignancy in general, and when encountered is most often in the adult population. The overall annual incidence in the United States is approximately 1 in 200,000. The National Cancer Data Base (NCDB) has identified only 9606 cases over an 18-year time period and the Surveillance, Epidemiology and End Results (SEER) Program database of the National Cancer Institute has identified a total of 2890 cases over a 30-year time period. Based on the SEER data, this is a disease primarily affecting adults with an average age 51. There have, however, been several small series from major referral centers reporting on chondrosarcoma in young patients. The Children’s Hospital Medical Center in Boston revealed the diagnosis in only 12 pediatric patients (ages 6-20) over a 23 year time period. The Mayo Clinic database revealed chondrosarcoma in only 14 pediatric patients (under age 17) among 634 total cases. The largest series in the orthopaedic literature is from Memorial Sloan-Kettering and included 79 patients under the age of 21. This group was collected over a 54 year period.

Even more rare is the likelihood that this patient’s lesion was a malignant transformation of a solitary exostosis. As stated in the case report, there is a visible lesion in an abdominal radiograph performed four years prior to the diagnosis of chondrosarcoma. How long that lesion had been present is unknown, as this was the first radiograph visualizing this patient’s pelvis. This initial lesion, seen in Figure 2, certainly has the appearance of an osteochondroma arising from the pubis. This lesion was believed to be solitary based on the skeletal survey demonstrating no other lesions. The available imaging supports that this patient had a solitary osteochondroma with malignant degeneration to a secondary chondrosarcoma. This malignant transformation is a well-described phenomenon, but is exceedingly rare in the pediatric population. In one large series, Ahmed et al., reported that most cases of degeneration of osteochondromas to chondrosarcomas occurred in patients with multiple exostoses, and even then the average age was 34.9 years. Young et al. reported seven of their 47 cases (15%) of adult chondrosarcoma appeared to be malignant degeneration of a solitary osteochondroma. Huvos et al. reported the same finding in ten of their 79 cases (13%). The risk of malignant degeneration of a solitary osteochondroma in any age is estimated at less than one percent, although there are reports of rates as high as 7.3% in large referral centers. Due to the difficulty in studying a disorder that is frequently asymptomatic and often goes undiagnosed, the true incidence of malignant transformation of solitary osteochondromas is unknown. As noted previously, this patient had no evidence of that condition on her skeletal survey.

Lastly, there was considerable debate as to the diagnosis of the tumor: chondrosarcoma versus chondroblastic osteosarcoma. The difference between these diagnoses has significant treatment implications with the former typically treated surgically with wide resection and the latter also with a neo-adjuvant and adjuvant chemotherapy regimen. Given the extremely low incidence of chondrosarcoma in the pediatric population, a high index of suspicion must be maintained to make the diagnosis and more common tumors (i.e. osteosarcoma, Ewing’s
sarcoma) must be ruled out. The diagnosis can be extremely difficult from a histopathologic standpoint. Chondrosarcoma is diagnosed by visualizing malignant cartilage producing cells along with infiltration of the marrow cavity and entrapment of preexisting bone trabeculae. Due to the appearance of what was eventually deemed enchondral ossification of the tumor in some fields, significant consideration was given towards a diagnosis of chondroblastic osteosarcoma. Osteosarcoma, chondroblastic variant, is more common in the pediatric patient. This lesion is specifically characterized by sheets of spindle cells around lobules of chondroid with interposition of lacy osteoid. The explanation for the osteoid seen in this case is that this represents so-called “normalization” of the chondrosarcoma (enchondral ossification of the tumor matrix onto entrapped pre-existing bone trabeculae). The diagnosis becomes difficult when there is this “normalization” of the chondrosarcoma, leaving patches of osteoid visible in portions of the tumor. An accurate diagnosis depends entirely upon pathologist interpretation of the slides. There are no known immunohistochemistry or genetic translocations that are believed to be helpful in differentiating chondroblastic osteosarcoma from chondrosarcoma. The Mayo Clinic authors noted that two of their initial 53 diagnoses of chondrosarcoma were changed on second review to chondroblastic variant of osteosarcoma. This is a vital diagnostic consideration as these two diagnoses have very significant treatment implications. Treating a chondrosarcoma with chemotherapy would subject the patient to a 10 month course of extremely toxic and unnecessary therapy. However, treating a high-grade osteosarcoma without chemotherapy would be considered substandard care. The patient in our case was treated without a chemotherapy regimen. She has been followed regularly and is now doing well with no evidence of local recurrence or metastases at five year follow-up, further lending support to the diagnosis of chondrosarcoma.

In summary, chondrosarcoma is a rare and difficult diagnosis in the pediatric patient. There is often considerable debate between chondrosarcoma and chondroblastic osteosarcoma. The diagnosis should be made based on history, imaging, and in consultation with a pathologist specializing in sarcoma and supplemented with additional opinions as necessary. The treatment implications of an accurate diagnosis are of paramount importance.

REFERENCES
ABSTRACT

Bone bruise patterns are commonly seen after acute anterior cruciate ligament injuries; they represent a subchondral impaction injury that occurs in the lateral knee joint between the mid-lateral femoral condyle and the posterior lateral tibial plateau. These contusion patterns are present in the majority of noncontact ACL injuries. These injury patterns vary significantly in severity and this aspect is poorly understood. Edema patterns have gained increased interest in the literature of late; they may indicate the severity of the initial injury. They also may be correlated with the development of subsequent osteochondral defects and osteoarthritis. Given the location of this subchondral injury, it is plausible to assume that the geometry of the lateral femorotibial joint may play a role in ACL injury mechanism and severity of injury. We are reporting two cases of clinically identical ACL injuries. A patient with a flat lateral tibial plateau was noted to have a much larger bone edema pattern than a second patient with the highly convex lateral tibial plateau. This may shed light on the pathomechanics of ACL injury and suggests that an individual with a relatively flat tibial plateau has a stable lateral knee joint. Therefore, we hypothesize that much greater force is required to dislocate a flat and stable lateral femorotibial joint in a pivot shift pattern to produce an ACL injury. The greater force required results in a large bone edema pattern. Conversely, the individual with a relatively short and convex tibial plateau has an inherently unstable lateral joint and relatively smaller amounts of force would be needed to produce the identical injury to the ACL. As less force is required, smaller bone edema patterns result.

INTRODUCTION

Bone bruises are commonly identified on Magnetic Resonance Imaging (MRI) following acute Anterior Cruciate Ligament (ACL) injury. These “footprints” of injury are likely the result of femoral and tibial impaction or traction forces that occur at the time of or shortly following ligament rupture\(^1\)\(^-\)\(^3\). Non-contact ACL injury is thought to occur via a pivot shift mechanism characterized by anterior tibial translation, internal tibial rotation and subluxation of the lateral compartment of the knee in a rotational nature about the axis of the MCL\(^4\). Once the ACL is disrupted by this mechanism, anterior subluxation and internal rotation of the tibia occurs relative to the femur; the endpoint of this translation results in an impaction injury of the anterolateral femoral condyle against the posterolateral margin of the tibial plateau\(^1\),\(^5\),\(^6\).

There has been increased attention in the literature to ACL associated bone bruises and associated findings. It is suggested that the prevalence of MCL and medial meniscus injuries are higher in the presence of larger bone bruise patterns\(^7\). It has also been suggested that there is a greater disability associated with large bone bruise patterns\(^8\). Furthermore, large bone bruise patterns have been associated with accelerated cartilage degeneration at 5 to 7 years follow-up\(^9\). Given the heightened attention in recent literature, relatively little investigation has aimed at determining anatomic factors that may predispose patients to extensive cartilage injury following acute ACL disruption.

Based on our understanding of the pivot-shift mechanism, the magnitude of the dislocation associated with ACL injury is seen most in the lateral compartment\(^4\),\(^6\). It is plausible to suggest that the anatomic configuration of the lateral femorotibial joint may influence the amount of translation and the degree of impaction following acute ACL rupture. This would suggest that variability in lateral knee geometry may influence the volume and location of bone bruises associated with ACL injury.

Recent studies display a correlation of lateral knee articular geometry with ACL injury\(^10\). It was observed that there was significant heterogeneity in male lateral...
knee geometry; an anatomic phenotype characterized by highly convex distal femoral condyle and convex lateral tibial plateau had a strong correlation with ACL injury. A phenotype with highly convex opposing surfaces may take less energy to dislocate during a pivot shift, while two opposing flat surfaces may provide significant stability only overcome by a large amount of force. In this paper, we are reporting two clinically similar cases of acute ACL injury: one with a flat lateral tibial plateau and one with a highly convex lateral tibial plateau.

We hypothesize more extensive bone contusions will be observed in the patient with a relatively flat lateral tibial plateau (larger radius of curvature) than the highly convex lateral tibial plateau (smaller radius of curvature). We propose this may be due to the increased force required to produce a pivoting ACL injury in a flat/stable lateral joint. The footprint of this high-force injury mechanism can be observed visually by larger bone edema patterns; conversely, the patient with the highly convex and unstable lateral tibial plateau may be susceptible to ACL injury at lower forces and therefore display smaller lateral bone edema patterns.

CASE REPORTS

Case 1
A 29-year-old male was playing recreational soccer when he suffered a pivot-shift injury (during deceleration) to his right knee. He had immediate swelling. Advanced imaging revealed a complete ACL disruption along with a medial meniscus tear. He had a positive preoperative pivot shift. He underwent physical therapy for 5.4 months then underwent successful ACL reconstruction with hamstring autograft. He had no postoperative instability, and was able to return to the same level of athletics as he did prior to his injury. [Figure 1]

Case 2
A 30-year-old male injured his left knee while playing recreational basketball. He had an immediate knee effusion, and a positive pivot shift on exam. His MRI was notable for complete ACL disruption and medial meniscus tear. He underwent preoperative physical therapy, and 8.5 months after his injury underwent successful ACL reconstruction with hamstring autograft. He had no postoperative instability symptoms, and when last seen 6 months postoperatively, was doing straight line aerobic activities but had not yet returned to basketball. [Figure 2]

METHODS
The patients had MRI scans of the injured knee at 7 and 10 days post-injury. Images were obtained on a 1.5-T magnet. Fat suppressed sequenced were used to assess the intensity of the bone marrow signal. The representative sections along the center of the weight-bearing axis were identified as previously described10. The representative sagittal images correlating with the mid-portion of the coronal weight bearing axis were imported into OsiriX imaging software (version 3.6.1, OsiriX Foundation, Geneva, Switzerland). A best-fit circle was then digitally superimposed to the articular surface of the tibial plateau similar to previously described techniques 10.
Does Lateral Knee Geometry Influence Bone Bruise Patterns after Anterior Cruciate Ligament Injury?

RESULTS

Case 1
Lateral tibial plateau radius of curvature measures 53.5mm. The bone bruise can be classified as extensive/severe according to Brittberg and Winalski.11 [Figure 1]

Case 2
Lateral tibial plateau radius of curvature measures 32.1mm. The bone bruise pattern is classified as superficial/mild according to Brittberg and Winalski.11 [Figure 2]

DISCUSSION
We have presented two clinically identical patients with acute rupture of the ACL. They are similar in age, activity, concurrent meniscus injury and time from injury to MRI. While these factors are similar, they have very different bone bruise patterns noted. The patient with the extensive bone contusions is noted to have a relatively flat tibial plateau. The patient with only trace bone bruise patterns is noted to have a relatively highly convex tibial plateau. Given that noncontact ACL injuries occur via a pivot-shift mechanism, there is a translation of the lateral femorotibial joint where the lateral tibial plateau undergoes anterior translation and internal rotation relative to the femur. The bone edema patterns are from femorotibial impaction of the anterolateral femoral condyle against the posterolateral margin of the tibial plateau. Recent studies have correlated injury severity with magnitude of bone edema patterns.

Given recent studies correlating lateral knee geometry with ACL injury10, these two distinct cases may shed light on the importance of the lateral femorotibial joint with regard to ACL pathomechanics. A highly convex lateral joint has been suggested to correlate clinical and biomechanical instability. Kujala et al observed that convexity of the lateral tibial plateau positively correlated with a clinical history of instability and the pivot shift test in patients with chronic ACL deficiency12. In the patient with the highly convex lateral tibial plateau, there is only trace bone edema patterns noted. Therefore, if highly convex lateral joint may be inherently unstable, relatively smaller amounts of force would be required to produce a pivot. This relatively lower force may be displayed visually by absence of bone edema patterns after ACL disruption.

Conversely, a relatively flat femorotibial joint may be inherently stable. A cadaveric study by Matsumoto et al examined knees with ACL division who did not display a positive pivot shift were thought to have a flat or less convex lateral tibial plateau. Given suggestions of stability with relatively flat lateral joint surfaces, we are postulating that it takes much greater force for this phenotype to pivot. The increased force required to produce a pivot shift and therefore ACL disruption results in a more extensive bone edema pattern.

The lateral tibial plateau has been overlooked in the literature as a key structure in understanding ACL pathomechanics. In order to understand the importance of lateral plateau geometry, we first must understand gross ACL pathomechanics. Observational video analysis studies correlate a valgus collapse mechanism with ACL injury13-17. It has been demonstrated that low valgus torques can elicit tibial subluxation in the ACL deficient knee that resembles a positive pivot shift test18, and therefore been postulated that the pivot shift reproduces the lateral joint subluxation that occurs during ACL injury19. This valgus moment opposes and loads the convex surfaces of the lateral femoral condyle and the lateral tibial plateau. In ACL injuries, there is increased load in the lateral joint as well as a rotatory subluxation. These two cases may suggest that when a highly convex and therefore unstable joint surface is opposed, relatively smaller amounts of energy are required to pivot. This relatively smaller amount of energy may be demonstrated by a small bone edema pattern. Conversely, a flat and stable lateral femorotibial surface may require relatively increased forces to pivot, and this is displayed visually by large bone edema pattern.

REFERENCES


SPONTANEOUS REDUCTION OF A CHRONIC RADIAL HEAD SUBLUXATION AFTER OPEN REDUCTION AND PERCUTANEOUS PIN FIXATION OF A RADIAL NECK FRACTURE: A CASE REPORT AND REVIEW OF THE LITERATURE

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ABSTRACT

Background: Fractures of the radial neck in children have shown to account for 5-10% of traumatic elbow injuries in the pediatric population. Chronic dislocation of the radial head with concomitant fracture has been shown to result in progressive deformity and unacceptable loss of motion.

Methods: In this case report, we describe a patient who sustained a type 2 radial neck fracture with 100% displacement. The patient's clinical and surgical management will be discussed and a review of the literature is provided as it relates to this particular case.

Results: The patient underwent open reduction and percutaneous pin fixation of her displaced, dislocated left radial neck fracture in the operating room after multiple failed attempts at closed reduction due to interposition of the annular ligament. Three months after her operation radiographs revealed a well-healed radial neck with no signs of avascular necrosis with an anterior dislocation of her radial head, which was a new finding from her previous radiographs. Fourteen months after her initial injury and operation, radiographs taken at this visit revealed a radial neck fracture that was completely remodeled and had spontaneous relocated and was now aligned with the capitellum without any reduction attempt.

Conclusion: Closed reduction of displaced radial neck fractures may be unsuccessful and open reduction may be warranted. Excess callus formation post-operatively may have resulted in the radial head subluxation; however there was spontaneous reduction with conservative treatment without a reduction attempt, most likely related to remodeling of the excel callus formation.

CASE

A 6-year-old right-hand-dominant female presented to the emergency room with pain and swelling of her left elbow. Earlier that day she sustained a fall from a swing onto an outstretched left elbow. The patient had immediate onset of pain and tenderness over her left lateral elbow. There were no other complaints or concerns by the patient or the patient's family at the time of injury. The patient's medical history and review of systems was otherwise non-contributory. On physical examination the patient had pain to palpation over the lateral aspect of her elbow directly over her radial head. There was mild swelling and the patient would not move her elbow secondary to pain. No abrasions or signs of open wounds were noted. She was neurovascularly intact with no deficits noted in the emergency room. The remainder of the physical examination was non-contributory. Plain radiographs demonstrated a type 2¹ radial neck fracture with 100% displacement which was consistent with the physical exam findings and the mechanism of injury. No other musculoskeletal injuries were noted on imaging, including no injury to the ulna (Figure 1A, B).

The patient was taken to the operating room that night for closed versus open reduction of the left radial neck fracture and placed under general anesthesia. The Patterson, Israeli, and Esmarch techniques of closed reduction all failed to provide adequate reduction as assessed on fluoroscopy. The arm was prepped and draped and two 0.062 inch K-wires were used to attempt percutaneous reduction. Multiple attempts failed to relocate the radial head and the decision was made to proceed with open reduction. A Kocher (ECU-Anconeus) approach was utilized. The radial head was found to be displaced out of the joint capsule, and the annular ligament was found to be interposed in the fracture site. The radial head was reduced and pinned into place with a 0.045 inch K-wire. The capsule and fascia were closed with 2-0 Vicryl and skin closed with 4-0 Monocryl. The K-wire was bent, cut and the arm was placed in a posterior splint with the elbow in 90 degrees of flexion. The patient was observed in the hospital overnight and discharged the next day.

At her two week follow-up, the patient was grossly intact to light touch sensation in the radial, ulnar and median distributions and capillary refill was adequate and
less than 2 seconds for all digits. She had intact anterior interosseous, posterior interosseous, and ulnar motor function. Plain radiographs demonstrated a well-reduced radial neck fracture that was completely located with no migration of the pin (Figure 1C, D). Three weeks later the patient was seen for removal of her percutaneous pin. Her physical examination at that time was unchanged from her previous appointment and the patient was doing well. Radiographs at that visit revealed good callus formation, with some excess anterior callus formation, with alignment of the radial head in line with the capitellum on both the anterior to posterior and lateral views. The parents were thoroughly counseled on the risk of avascular necrosis and elbow stiffness associated with this injury and advised to follow-up in 6 weeks time.

Three months after her operation she was seen in clinic for a standard follow up evaluation. She had left elbow range of motion from 0-130 degrees of flexion, which was 10 degrees less flexion than her uninjured right side. She had full symmetric supination of 90 degrees in both forearms and had 70 degrees of pronation in the left forearm compared to 80 degrees in the right. She had no pain with range of motion. Radiographs revealed a well healed radial neck with no signs of avascular necrosis. However, the patient had an anterior dislocation of her radial head, which was a new finding from her previous radiographs postoperatively (Figure 2A). Functionally the patient was doing quite well and there were concerns that a reoperation at this time could cause heterotopic ossification and possibly cause more complications. The decision was made to wait for the callus formation to resolve before making a reduction attempt.

Fourteen months after her initial injury and operation, and 11 months after being diagnosed with an anterior radial dislocation which was treated conservatively, the patient returned to clinic for follow-up. The patient stated she was doing extremely well and had no complaints or concerns related to her previous elbow injury. She had regained full range motion, including full extension, flexion, pronation and supination and was neurovascularly intact. Radiographs taken at this visit revealed a radial neck fracture that was completely remodeled, spontaneously relocated, and aligned with the capitellum without further reduction attempt (Figure 2B). As of 14 months postoperatively, the patient was doing well with no pain or functional complaints and was able to play piano.

**REVIEW OF THE LITERATURE**

**Introduction**

Diagnosis and treatment of radial head fractures with subluxation in children has not been discussed widely in the literature. Of the small number of case studies and retrospective clinical trials conducted, most studies address Monteggia and Galeazzi fractures with associated radial dislocation. Fractures of the radial head and/or neck in children have shown to account for 5-10% of traumatic elbow injuries in the pediatric population\(^5\). Despite the relatively high frequency of the injury, treatment guidelines and prognosis vary considerably\(^2\). Chronic dislocation of the radial head with concomitant fracture has been shown to result in progressive deformity and unacceptable loss of motion, which leads to a need for timely fixation and reduction\(^4\). Some authors have proposed that closed reduction with casting should be attempted in all cases of radial head fractures, while other orthopaedic specialists maintain that open reduction and internal fixation should be the
preferred approach in cases of joint instability. Delayed or inadequate treatment can result in complications such as pain, loss of full range of motion, nonunion, avascular necrosis of the radial head, enlargement of the proximal end of the radius, and periarticular ossification have been described by multiple authors.

Role of the radial head in the stability of the elbow
Resection of the radial head has been shown to be associated with gross instability of the elbow and recurrent dislocation. The radial head is proposed to stabilize the elbow by resisting valgus forces to prevent chronic radial head dislocation and by stabilizing the wrist and forearm when forces are transferred from the wrist to the radiocapitellar joint. Studies have shown that between 40-60% of the load transferred across the elbow is borne by the radiocapitellar joint. Follow-up studies in cases of radial head resection have shown a tendency for the radius to displace proximally, leading to restricted supination and progressive deformity.

Radiographic and Clinical Evaluation
The majority of radial head fracture-dislocations are posttraumatic, with a child falling on an outstretched arm. The child may present with point tenderness in the elbow that may or may not be localized to the radial head, depending on other affected structures in the elbow. Anteroposterior and lateral radiographs should be obtained and inspected for associated injuries such as Monteggia type fracture patterns. A Greenspan view or a modified radial head-capitellum view may also be obtained to avoid coronoid overlap. A Greenspan view is obtained with the shoulder abducted 90 degrees, the elbow flexed 90 degrees and the thumb pointing up. The x-ray beam is centered 2-3 cm distal to the lateral epicondyle at a 45 degree angle. An alternative imaging technique is the modified radial head-capitellum view described by Tomas and Proubasta. In this view the arm is kept at the side, the elbow is flexed between 70 and 90 degrees, and the forearm is kept in a supinated position. The x-ray is oriented at 45 degrees medio-laterally and centered on the elbow. Location of the radial head in relation to the capitellum should be assessed on the lateral radiograph, with the radial head aligning with the capitellum in the case of well located joint (Figure 2B). CT scans can be used to further assess the fracture and other injuries that may be present as well. Additionally, range of motion testing, including pronation, supination, flexion, and extension, as well as varus-valgus testing should be performed for comparison post-op.

Types of Interventions
The management of posttraumatic radial head dislocation has been studied by a number of different authors. Although once considered the favored approach, radial head resection with or without prosthetic replacement is not recommended for pediatric patients due to the large number of possible consequences related to the growing skeleton. Fractures of the radial head with less than 45° angulation and/or less than 2 mm displacement may be treated with plaster fixation following closed reduction, although authors disagree as to the maximum allowable degree of angulation and displacement that can effectively be treated with closed reduction. Multiple methods for achieving closed reduction have been described. In cases with an angulation greater than 45°, displacement more than 2 mm, or in cases of dislocation/subluxation; closed reduction and percutaneous pinning or open reduction and internal fixation (ORIF) are the treatment of choice. In cases of displaced radial head fracture with greater than three fragments, radial head resection is warranted, because ORIF has shown to have less reliable results. In addition to resection and ORIF, several types of percutaneous interventions have been successful for mildly displaced fractures. The current recommendation is that ORIF be used in children with fractures that are severely displaced or when closed or percutaneous reduction has failed.

Outcome of Intervention
Open reduction with fixation is the treatment of choice for severely displaced radial head fractures in children that cannot be closed reduced. In a study by Merchant, he found that 50% of patients with such an injury were found to have a good result (full mobility, range of motion with no pain), with 27.8% having a poor result (loss of >20 degrees of mobility in any direction and the presence of pain) following open reduction and axial transarticular internal fixation with a K-wire. In another study of chronic radial head dislocation in children by Kim et al., ORIF produced excellent results in posttraumatic radial head dislocations (based on pain, deformity, range of motion and function) with only one fair and one poor result. In an article by Gonzalez-Herranz et al., it was reported that closed intramedullary pinning (Metaizeau technique) produced excellent results in 16 of 17 pediatric patients with displaced radial head fracture. The only fair result was in a patient with a radial head fracture with concomitant partial dislocation, and noted that closed reduction with intramedullary pinning may not be adequate in many cases of radial head fracture with subluxation or dislocation. Kim et al., as well as Merchant, found that in posttraumatic radial head dislocations, a longer latency to treatment resulted in more profound deformities and limitations to range of motion. Due to the development of cubitus valgus and radial deviation at the wrist, the practice of radial head resection following fracture and dislocation should be completely abandoned except in cases where the radial...
head cannot be salvaged. Different studies used different methods for evaluating the outcome of corrective surgical interventions for treating radial head fracture with displacement. However, the literature suggests that success should be judged with respect to loss of range of motion and pain, with some authors also using deformity and function as a measure of operative success. 

DISCUSSION

Our patient was a 6-year-old female with a 100% displaced radial neck fracture that had a non-traumatic, asymptomatic radial head dislocation observed at her three month follow-up that spontaneously relocated by the time of her next follow-up at 14 months post-injury. It is important to note that she did not have a fracture of the ulna, nor did she have any post-traumatic greenstick bowing of the ulna and therefore this fracture was not a Monteggia equivalent. Late dislocations have been described after Monteggia equivalent fractures. In all of these cases the late radial head dislocation did not spontaneously reduce and required surgical intervention for reduction. To our knowledge no case has been reported of a spontaneous reduction after a radial neck fracture that had been treated with open reduction and internal fixation and later developed a dislocation. It is possible that the dislocation that was noted at three months postoperatively was due to the abundant callus which may have dislocated the radial head by the “cam” effect described by Wedge and Robertson. It is also possible that as the radial neck remodeled, allowing the radial head to reduce spontaneously. Even after careful questioning, the patient never admitted to feeling anything that would have suggested a dislocation or a reduction event. This case illustrates that mild cases of radial head subluxation that are associated with fracture may spontaneously improve as the fracture callus remodels. Close clinical and radiographic follow-up is essential.

ACKNOWLEDGEMENT

The authors would like to thank Brooke Robinson for her assistance with this manuscript.

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ABSTRACT

Human dirofilariasis is a rare zoonotic infection caused by the bite of a blood-feeding mosquito infected with a filarial nematode (roundworm). These infections can manifest as stationary or migratory subcutaneous or conjunctival nodules. We report an unusual case of Dirofilaria tenuis (D. tenuis) infection that developed into a space-occupying lesion in the wrist leading to median nerve compression pathology in an otherwise healthy young woman. We also comment on the natural history of the disease and report the outcome after surgical excision. To our knowledge, we are the first to report a case of median nerve compression caused by a growing subcutaneous nodule from a D. tenuis infection.

Key words: median nerve compression, parasite, dirofilaria

INTRODUCTION

Dirofiliriasis is a zoonotic infection caused by nematodes (roundworms). Various species of the Dirofilaria genus are known to infect domestic and wild carnivores and can infect humans who can serve as an accidental host. *D. immitis*, the dog heartworm, and *D. repens* are well documented for causing human pulmonary and subcutaneous nodules, respectively. The *D. tenuis* species, a parasitic heartworm of the American raccoons, less commonly accounts for subcutaneous dirofilariasis in humans. Human *Dirofilaria* infections lead to formation of subcutaneous nodules that are mostly stationary but can be migratory, erythematous, pruritic and variably tender. Nodules are commonly found in the head, neck, breasts, arms and legs, and even in the conjunctiva of the eyes.

CASE

FC is a healthy 15 year-old right hand-dominant female softball player who presented for evaluation of right wrist pain. She had been complaining of wrist pain, intermittent numbness, and difficulty writing for approximately four months. She attributed the pain to increased text messaging after acquiring a new cellular phone. The patient was evaluated by an orthopaedic surgeon who diagnosed her with flexor tendonitis and prescribed a wrist splint and NSAIDs.

The patient tried splinting and NSAIDs for approximately two months; however she had little relief of her symptoms. She subsequently sought a second opinion. The second provider agreed with the diagnosis of flexor tendonitis, but given her lack of response to conservative management, an MRI was ordered. MRI showed a mass in the carpal tunnel compressing the median nerve (Figure 1). A diagnosis of ganglion cyst was made and patient was referred to our office for definitive surgical management.

On physical exam at our office, the patient had no visible masses, erythema or swelling of the right wrist or forearm. The patient had significant pain and paresthesias with Phalen’s test. There was no thenar atrophy. There was crepitation and fullness at the carpal tunnel with finger flexion and extension. The MRI was reviewed, which showed a definite mass in the carpal tunnel compressing the median nerve and the working diagnosis was modified to giant cell tumor of the tendon sheath compressing the median nerve.

The findings were discussed with the patient and family and we recommended surgical excision of the mass. Patient was taken to the operating room for excision of the mass and nerve decompression. A large, extended carpal tunnel incision was made from the middle of the palm to approximately 4 cm above the wrist crease. Incision was carried through the transverse carpal ligament to the level of the flexor tendons. A large mass was seen originating from the flexor tendon sheath compressing the median nerve. The sheath was incised and a thick yellow fluid was expressed. The fluid was not malodorous and no purulence was observed. Tissue samples were sent to pathology. The wound was thoroughly irrigated and skin was closed in standard fashion. Given the benign appearance of the fluid, no antibiotics were prescribed.
The patient was seen in clinic two weeks post-operatively. The incision was well-healed and sutures were removed. The results from pathology showed inflammatory tissue with no bacterial or fungal organisms. Infectious disease consultation was obtained who reviewed the histological features of the specimen and a diagnosis of *D.tenuis* infection was made (Figure 2). Further investigation by the infectious disease physician revealed that the patient played softball at a field adjacent to a swamp containing many mosquitoes, one of which was the likely vector of this infection. The consultant went on to explain that although the nematodes may live temporarily in human hosts where they are unable to reproduce, and eventually die. As a result, no specific anti-microbial treatment was recommended.

The patient was seen at five weeks post-operatively and denied any pain or paresthesias. There was no palpable mass. She had full wrist and hand range of motion and excellent strength. She had started playing softball with no difficulties. She was released to full activity without restrictions.

**DISCUSSION**

*Dirofilariasis*, an infection known to occur in both wild and domestic animals, can lead to accidental human infection⁵. In human infection, the filarial larvae of various species of *Dirofilaria* enter the human body following a bite from a vector mosquito (Anopheles, Aedes, or Culex). Once in the human body, the larvae can complete several molts, and can range in size from 40-130 mm in length to 150-330 µm in diameter⁶. In humans, the worms die before reaching sexual maturity and are unable to produce the microfilaria that would normally be taken up by the mosquito during a blood meal to perpetuate the life cycle by infecting a definitive host (dog, raccoon, bear, etc). Therefore, humans cannot transmit the infection to other hosts. However, adult worms are able to wander in human subcutaneous tissues for weeks to months before they die causing vasculitis and a granulomatous reaction⁴. The nodules are mostly stationary but can be migratory, erythematous, itchy and variably tender. Nodules are commonly found in the head, neck, breasts, arms and legs, and even in the eye¹.

Geographically, *D.tenuis* is most commonly found in south Florida, Texas, and Georgia due to higher populations of the infected raccoons⁵. One study which analyzed raccoon blood samples from southeast Georgia revealed that 65% of samples contained the *D.tenuis* organism⁶. The risk of *Dirofilaria* infection increases with increased density of the vector mosquito in a given area and the abundance of the definitive host in a particular area³.

Clinically, the nodules that characterize the *Dirofilaria* infection should be differentiated from sarcoidosis, ruptured dermoid cyst, infectious abscesses, neoplasms and idiopathic pseudotumors if they are present in deeper layers of tissue⁷. In this case, the pre-operative diagnosis made from MRI showing enhancement within the carpal tunnel was that of giant cell tumor. As is typical, the diagnosis of *Dirofilaria* infection was made after histological analysis of the excised tissue demonstrating the morphological features of the parasite as well as the characteristic inflammatory response comprised of lymphocytes, histiocytes and abundant eosinophils⁸⁻⁹. Less commonly, the diagnosis is made by extraction of the live adult worm from the lesion⁹. There is presently no serologic test for *Dirofilaria* infection¹⁰. However, although not seen in *D.tenuis* infection, esinophilia and elevations in immunoglobulins G, M and E has been reported in other *Dirofilaria* infections⁵.

Surgical excision of the mass is the definitive treatment for human *Dirofilaria* infection and the prognosis in most cases is excellent without the need for anti-microbial therapy.
CONCLUSION

The rare diagnosis presented in this report should be considered in cases of suspected median nerve compression. In particular, it should be considered in patients with a history of exposure to vector organisms or travel to endemic areas.

REFERENCES:
SUBUNGUAL EXOSTOSIS OF THE FINGER: CASE REPORT AND REVIEW OF THE LITERATURE

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ABSTRACT
Although common in the toes, subungual exostoses of the fingers are relatively rare. We describe the case of a 65-year-old woman who presented with a subungual mass of her left long finger. The lesion was excised and pathologic examination confirmed the diagnosis of subungual exostosis. We also review the previously reported cases of subungual exostoses of the finger.

INTRODUCTION
Subungual exostosis (SE) is a benign solitary lesion that grows from the terminal tuft of the distal phalanx. The mass itself is typically painless, but pressure on the nail plate can result in pain and deformity of the involved digit. Subungual exostosis can be correctly diagnosed based on clinical and radiographic appearance alone. Surgical resection of SE in the fingers is typically curative, with only two previous reports of recurrence.

Dupuytren first described a subungual exostosis in 1847 in a case involving the great toe. In fact, the vast majority of SE occur on the foot with 70-80% occurring on the hallux. Involvement of the fingers is much less common, with less than 60 reported cases in the English language literature. Here we describe a SE of the left long finger.

CASE REPORT
A 65-year-old right hand dominant female presented with an eight year history of a slowly growing mass on the tip of the left long finger. She denied any significant trauma to the digit. The mass was painful when bumped, and occasionally bled. She also noticed that the distal end of the nail had an abnormal appearance.

On exam, she had an 8 mm mass extending from beneath the distal aspect of the nail plate of the left long finger. There was poor adherence of the last 5 mm of nail plate to the underlying nail matrix, but the proximal nail plate and matrix were normal in appearance. The mass was firm and covered with dry, scaly skin. The proximal interphalangeal and distal interphalangeal joints exhibited full range of motion. Fluoroscopic images revealed a bony growth off of the tip of the distal phalanx (Figure 1). We performed a punch biopsy in clinic, which revealed “bone with fibrocartilagenous tissue in dermis, consistent with exostosis.”

The patient underwent excision of the mass in the operating room. After performing a digital block, the distal 8 mm of the nail plate was elevated from the underlying matrix. The sterile matrix was divided longitudinally and carefully lifted off of the mass. An osteotome was used to divide the base of the mass at its juncture with the distal phalanx. The nail matrix was repaired with absorbable suture and the nail plate was replaced. Pathologic analysis of the lesion revealed “skin with bone and soft tissue, consistent with exostosis.”

Six weeks following resection, the patient had no pain in the finger and had resumed her usual activities. The surgical wound appeared well healed. The distal 2 mm of nail plate remained poorly adherent to the underlying matrix, but there was evidence of normal nail growth proximally. One year following treatment, there was no evidence of recurrent SE and the nail plate appeared completely normal.

DISCUSSION
Our patient had a rare case of subungal exostosis (SE) in the hand. Exostoses of the finger are most commonly reported on the thumb of the dominant hand. In contrast, our patient’s growth was found on the non-dominant long finger. Finger SE are about 1.5 times more common in women than men. Unlike exostoses elsewhere in the body, SE often appear and continue to grow after skeletal maturity. About 50% present during the second or third decade of life, with the other half presenting in patients over age forty.

The etiology of SE is unknown. Authors have hypothesized their growth is related to trauma, chronic infection, or irritation. Our patient reported slow growth over...
Subungual Exostosis of the Finger: Case Report and Review of the Literature

eight years with no history of trauma. Starnes reported a genetic correlation involving a t(X;6) balanced translocation in a small number of patients. In an analysis of the histology of SE, Ippolito et al reported that growth could occur via two different mechanisms: enchondral ossification, or more commonly, intramembranous/mixed ossification.

The rarity of SE of the finger has led to initial misdiagnosis in many cases. In previous reports, 44-80% of SE were initially misdiagnosed as other types of neoplasms. Other diagnoses in the differential include subungual verruca, squamous cell carcinoma, onychocryptosis, inclusion cysts, glomus tumor, and malignant melanoma. Unlike these lesions, SE contain an osseous component that is readily visualized on plain radiographs.

Radiologic imaging of SE reveals an osteocartilaginous exophytic mass extending from the distal tuft of the phalanx. Like exostoses found elsewhere, the medullary canal of the the lesion is continuous with the medullary canal of the distal phalanx. Notably, Hoehn et al reported one case where insufficient calcification of the cartilage in the lesion led to inability to identify the growth as an exostosis by radiographic imaging alone. Advanced imaging such as magnetic resonance imaging also reveals bone with a cartilaginous cap, but is typically not necessary for diagnosis or treatment of these lesions.

Malignant degeneration of SE has never been reported in the literature and recurrence of the lesion after resection is rare. Although Suga et al reported 13% incidence of recurrence (2 of 16 cases), most studies report complete resolution after resection. In contrast, recurrence of SE in the toes occurs in 6-11% of cases. Recurrence may be related to incomplete initial excision. Other complications of resection are also rare, but postoperative nail deformity can occur.

CONCLUSION

SE of the fingers are not common, but their diagnosis and treatment can be straightforward. With few exceptions, resection of the lesions is curative and not associated with complications.

REFERENCES

ABSTRACT

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

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

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

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

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

INTRODUCTION

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

Although there are numerous fracture classification systems available for specific fracture locations, the OTA Fracture and Dislocation Classification Compendium is the most comprehensive. It applies consistent fracture classification principles to the entire axial and appendicular skeleton. It has incorporated the most useful concepts...
Under-Utilization of the OTA Fracture Classification in the Orthopaedic Trauma Literature

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<th>Table 1: Mention of OTA Classification System in Text</th>
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METHODS

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

RESULTS

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

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

Overall, 16 of 100 (16%) articles cited an OTA Classification. Sixteen of the 38 (42%) articles that mentioned the OTA Classification cited some version of the OTA Classification as a reference. Six of 16 (38%) articles cited the older 1996 OTA Coding and Classification reference17 even though the newer classification had been published four years previously3. Ten of 16 (63%)
articles cited the 2007 reference of the OTA Fracture Classification. Two of these 10 (20%) articles cited the 2007 reference with some error and eight of 10 (80%) or eight out of 100 (8%) articles correctly cited the 2007 OTA Fracture Classification reference [Table 4].

Forty-seven of 100 (47%) articles cited another classification system as a reference. Forty-eight of 100 (92%) that mentioned another classification cited a reference. We did not investigate the accuracy of the citations of other classification systems. In comparison, 38 of 100 (38%) articles mentioned the OTA Classification but only 16 of 38 (42%) cited a reference [Tables 4 and 5].

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

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

DISCUSSION

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

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

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

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

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

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

The choice of terminology such as “distal radius” and “radius and ulna shaft” that is built into the OTA Classification is of some importance. Authors may still choose “Colles fracture” instead of “distal radius fracture” or “both bone forearm fractures” instead of “radius and ulna shaft fractures”. One consequence of using non-standard terminology would be a lack of precision of the inclusion criteria. A “Colles fracture” is not specifically defined anywhere. Additionally, a computer search of all articles relating to “radius and ulna shaft” fractures will not capture all pertinent articles. For example, articles with titles including “both bone forearm, BBFA, forearm, Piedmont, fracture of necessity” or any other colloquial or eponym-derived fracture ter-
The Current classification of fractures in compliance will hopefully lead to an expansion of future submissions will grow. This resulting increase will be utilized and cited, the more the level of expectation for the increasing utilization of the classification in the literature to be seen. The more frequently the OTA Fracture Classification is referenced, the more the presence of this requirement, accompanied by the increase in publication of this article will help remind authors and reviewers of the Journal of Orthopaedic Trauma that routine and consistent utilization of the classification is so despite the fact that it is “required” according to the instructions to authors. We feel that authors should utilize and correctly reference the 2007 OTA Fracture Classification so that the benefits of a common language and improved interpretability of treatment outcomes in published orthopaedic trauma research can be realized. Routine and consistent utilization of the classification may ultimately lead to more consistency and improved interpretability of treatment outcomes in published orthopaedic trauma research.

REFERENCES
