Rush Orthopedics Journal





The science of healing. What causes tendinopathy to develop, and why is it so challenging to treat? See page 35 to learn how Robert W. Wysocki, MD, and Anna Plaas, PhD, are looking for answers at the cellular level.

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To view the 2019 Rush Orthopedics Journal online or to view past issues of the journal, please visit the Rush website at www.rush.edu/orthopedicsjournal.

Chairman's Letter



The Department of Orthopedic Surgery at Rush has had a decades-long commitment to research that provides a deeper understanding of musculoskeletal disorders in order to provide more effective, efficient, and precise diagnostic tools, prevention strategies, and treatment modalities. Our research is quintessentially *translational*—that is, it's focused on directly improving patient care—and it is a key component of our mission. That's why we chose to spotlight translational research in this year's *Rush Orthopedics Journal*.

Since the department was founded in 1972, our faculty investigators have developed novel surfaces for the successful long-term cementless fixation of joint replacement components to bone; improved the diagnosis and management of periprosthetic joint infection; pioneered minimally invasive and outpatient total joint replacement surgery; developed blood tests to monitor and predict the performance of joint replacements; developed new techniques and technology for minimally invasive spine surgery; expanded our understanding of the biology of disc degeneration; developed strategies to prevent overhead throwing injuries in athletes; investigated novel ways of treating cartilage injuries using regenerative medicine and biologics to promote healing and decrease inflammation; and improved the management of anterior cruciate ligament tears. And these are just some of the many accomplishments.

Of course, none of this clinical innovation could happen without our clinical faculty's ongoing collaboration with the basic science researchers in our department, as well as numerous other collaborators at Rush and beyond.

Our clinicians team up with Rush experts in biochemistry, molecular biology, cell biology, immunology, analytical chemistry, electrochemistry, tribology, materials science, biomedical engineering, and biomechanics to further our translational research. You can read about several innovative projects made possible by our department's ongoing physician-scientist partnerships in this year's journal.

We are also excited to be part of the Institute for Translational Medicine (ITM), a Chicago-wide consortium funded by a Clinical and Translational Science Award grant from the National Institutes of Health (NIH) to promote translational research throughout the Chicago area. Ultimately, this consortium will help our researchers accrue large numbers of patients to study the safety and effectiveness of the most promising research findings, so that advances in patient care can more quickly become a reality. For example, Rush is the lead institution in the ITM for a recent \$6.6 million NIH grant to identify patients at risk for chronic pain following total knee replacement (TKR). While TKRs are highly successful in the vast majority of patients, we seek to make the operation even more successful by identifying risk factors for chronic pain that can be addressed with future advancements.

Looking ahead, I'm optimistic that translational research will continue to revolutionize how we practice orthopedics. I imagine a day when my colleagues and I will be able to perform a joint replacement that will last a lifetime. Or when we will be able to regenerate damaged cartilage. Or reverse intervertebral disc degeneration.

At Rush, we believe such days are just around the corner. By leveraging both our clinical and research strengths, I am confident that we can continue to tackle the most intractable orthopedic issues and transform patient care.

Joshua J. Jacobs, MD

The William A. Hark, MD-Suzanne G. Swift Professor of Orthopedic Surgery

Chairman, Department of Orthopedic Surgery

Vice Provost for Research

Rush University Medical Center

Faculty Highlights

Lifetime achievement. Bernard R. Bach, Jr, MD, one of the first sports medicine orthopedic surgeons in Chicago and director of Rush's Division of Sports Medicine for 30 years, was elected to the American Orthopaedic Society for Sports Medicine (AOSSM) Hall of Fame in 2018.

A rising leader. Monica Kogan, MD, director of the Section of Pediatric Orthopedic Surgery and the Orthopedic Residency Program, was appointed associate chief medical officer at Rush in 2019. She was also one of two Rush physicians in 2018 to receive the Carol Emmott Fellowship, which aims to decrease the disparities in leadership by women throughout the health care field.

Adding excellence through recruitment. Shoulder surgeon Grant Garrigues, MD, and sports medicine surgeon Jorga Chahla, MD, joined the Section of Sports Medicine. Xavier C. Simcock, MD, became the fourth member of the Section of Hand and Elbow Surgery. Divya Agrawal, MD, joined the Orthopedic Physical Medicine and Rehabilitation team. And Dino Samartzis, PhD, came to Rush to head up the International Spine Research and Innovation Initiative.

Leadership on the national stage. Kern Singh, MD, was appointed chairman of the American Academy of Orthopaedic Surgeons (AAOS) spine program committee. Joshua J. Jacobs, MD, is president of the Hip Society, an elite group of academic surgeons. In 2019, Jacobs also became the vice president of the American Board of Orthopaedic Surgery. Craig J. Della Valle, MD, served as president of the American Association of Hip and Knee Surgeons. Frank Phillips, MD, is president-elect of the International Society for the Advancement of Spine Surgery and is on the board of directors of the Society for Minimally Invasive Spine Surgery. Brian J. Cole, MD, MBA, is first vice president of the Arthroscopy Association of North America (AANA) board of directors and secretary general of the International Cartilage Regeneration & Joint Preservation Society board of directors. Susan Chubinskaya, PhD, is in the presidential line for the Orthopaedic Research Society, following in the footsteps of adjunct faculty member D. Rick Sumner, PhD, who completed his presidential year in 2018. And Steven Gitelis, MD, was elected chairman of the Twentieth Century Orthopaedic Association.

New research grants. Rush received an NIH T32 Training Grant in Joint Health to support post-doctoral fellowships and short-term medical student research. Directed by **D. Rick Sumner, PhD,** and co-directed by **Markus A. Wimmer, PhD,**

and **Anne-Marie Malfait, MD, PhD,** the grant supports research training in osteoarthritis, total joint replacement, and small molecule therapeutics. **Joshua J. Jacobs, MD,** and co-PIs at Rush were awarded a \$194,000 NIH grant for their project, "Transition from Acute to Chronic Pain in TKA Patients: Identifying Resilience and Vulnerability Profiles." And **Alan T. Blank, MD, MS,** was awarded a \$50,000 cancer research grant from Swim Across America to investigate pathways in bone metastases.

Honored for excellence. Wayne G. Paprosky, MD, received the prestigious John Charnley Award in England for his contributions to the field of total joint replacement, which includes implanting the first gender-specific hip for women 15 years ago. Brian Forsythe, MD, was honored by AANA for excellence in patellofemoral research. Joel Williams, MD, received the Howard Rosen Award from the AO Foundation, a nonprofit led by an international group of surgeons specializing in the treatment of trauma and disorders of the musculoskeletal system. The award honors physicians for their teaching abilities and enthusiasm. And Markus A. Wimmer, PhD, Joshua J. Jacobs, MD, Joachim Kunze, PhD, and others, received the HAP Paul Award from the International Society for Technology in Arthroplasty for their paper titled, "Backside Wear of Tibial Polyethylene Components Is Affected by Gait Pattern: A Knee Simulator Study Using Rare Earth Tracer Technology." This notable award is given to submissions describing original contributions to the science and technology of arthroplasty.

Sharing expertise. Rush orthopedic surgeons are serving on a number of high-profile forums. Alan T. Blank, MD, MS, was selected as a member of the AAOS/Musculoskeletal Tumor Society oncology clinical practice guidelines committee. Charles A. Bush-Joseph, MD, was named chairman of the Medical Publishing Board for the American Orthopaedic Society for Sports Medicine (AOSSM), a 5-year position that oversees the American Journal of Sports Medicine, Sports Health: A Multidisciplinary Approach and The Orthopaedic Journal of Sports Medicine. He was also reappointed to the board of the OrthoForum, which represents 100 orthopedic surgery practices and more than 3,000 orthopedic surgeons nationally. And Brian Forsythe, MD, was appointed to the education committee and as director of the fellows course for the AOSSM.

Continued on page 34

Orthopedic Excellence



No. 7 in the Nation. The orthopedics program at Rush is ranked No. 7 in the nation by *U.S. News & World Report* and has been ranked in the top 10 for 7 consecutive years.



Orthopedic Building Renamed. Rush has renamed its orthopedic building the Sofija and Jorge O. Galante Orthopedic Building in recognition of Jorge Galante's leadership, his revolutionary contributions to joint replacement surgery, and the Galante family's lasting legacy of philanthropy. A dedication ceremony took place on August 9, 2019, in the building.



New Locations. Our newest locations, Rush Oak Brook and Naperville, opened in 2019. Rush Oak Brook is a state-of-the-art facility with 16 orthopedic exam rooms, a cast room, PT, OT, and imaging. It also features an outpatient surgery center, and a sports performance center designed to help patients transition from PT to more intense physical activity.



Top Doctors. Five physicians from Rush Orthopedics were named among Chicago's "Top Doctors" in the January 2019 issue of *Chicago* magazine: **Bernard R. Bach, Jr, MD,** and **Charles A. Bush-Joseph, MD** (sports medicine); **Mark S. Cohen, MD** (hand surgery); and **Steven Gitelis, MD,** and **Joshua J. Jacobs, MD** (orthopedic surgery).



Successful Summit. The 4th annual Chicago Sports Summit, hosted by Brian J. Cole, MD, MBA (2nd from left), and other Rush orthopedic physicians, including Kathleen M. Weber, MD, MS (far left), and Nikhil N. Verma, MD (center), featured sports professionals discussing a variety of topics and trends. Proceeds support local youth organizations and orthopedic research.



Team Docs for Chicago Dogs.

The Windy City's new pro baseball team selected Rush Orthopedics as their official team physicians. Our doctors also provide sports medicine and related orthopedic services to the Chicago Bulls, Chicago White Sox, Chicago Fire, Chicago Steel hockey team, Hubbard Street Dance Company, and Joffrey Ballet.

Volume and Quality Data

Surgical procedures **55,800***

Attending physicians

49

Research faculty

35

Residents and fellows

48

Advanced practice nurses and physician assistants

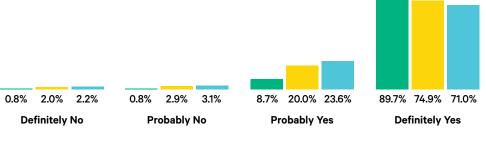
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*FY15 - FY19

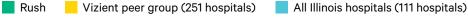




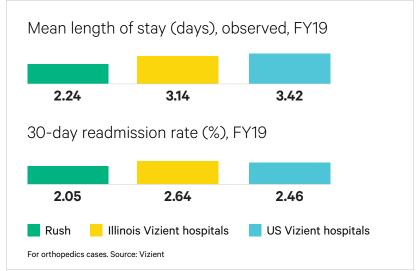
Patient satisfaction (for orthopedics providers surveyed), FY19



Recommend this hospital?



Source: Press Ganey



Mortality rates, FY19

Cases	3,709
Observed Mortality (%)	.05
Expected Mortality (%)	.15
Observed/Expected Ratio	.326

For orthopedics cases. Source: Vizient

Orthopedic Faculty and Fellows

ADULT RECONSTRUCTIVE SURGERY

Craig J. Della Valle, MD – Division Director; Director, Section of Research

Richard A. Berger, MD – Director, Section of Minimally Invasive Surgery

Tad L. Gerlinger, MD – Director, Adult Reconstructive Orthopedic Surgery Fellowship Program

Joshua J. Jacobs, MD - Chairman, Department of Orthopedic Surgery

Brett Levine, MD, MS

Denis Nam, MD

Wayne G. Paprosky, MD

Aaron G. Rosenberg, MD

Scott M. Sporer, MD, MS – Director, Section of Quality and Outcomes

Fellows (residency programs)

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Fortune Egbulefu, MD (San Antonio Military Medical Center)

Adam Olsen, MD (University of Pittsburgh Medical Center)

Michael O'Sullivan, MD (University of Connecticut Health Center)

Anas Saleh, MD (Cleveland Clinic Foundation)

Peter Shekailo, MD (Orlando Health)

ELBOW, WRIST, AND HAND SURGERY

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John J. Fernandez, MD

Xavier C. Simcock, MD

Robert W. Wysocki, MD

Hand, Upper Extremity, and Microvascular Fellow (residency program)

(residency program)

Hassan Azimi, MD (University of Colorado)

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Simon Lee, MD

Johnny L. Lin, MD

Fellow (residency program)

lan Foran, MD (University of California, San Diego)

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Matthew W. Colman, MD

ORTHOPEDIC TRAUMATOLOGY

Joel Williams, MD

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Matthew W. Colman, MD

Christopher DeWald, MD - Section Director, Spinal Deformity

Edward J. Goldberg, MD

Kim W. Hammerberg, MD

Gregory Lopez, MD

Kern Singh, MD

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Evan Sheha, MD (Hospital for Special Surgery)

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Charles A. Bush-Joseph, MD

Jorge Chahla, MD

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Brian Forsythe, MD

Grant E. Garrigues, MD

Shane J. Nho, MD, MS - Director, Section of Young Adult Hip Surgery

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Adam Yanke, MD, PhD – Associate Director, Rush Cartilage Restoration Center

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Theodore Wolfson, MD (New York University Langone Orthopedic Hospital)

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Leda A. Ghannad, MD

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David S. Cheng, MD

Madhu K. Singh, MD

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Thomas M. Turner, DVM

BIOMATERIALS LABORATORY

Nadim J. Hallab, PhD - Director

Anastasia Skipor, MS - Manager, Trace Metal Ion Laboratory

COMPUTATIONAL BIOMECHANICS LABORATORY

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THE JOAN AND PAUL RUBSCHLAGER MOTION ANALYSIS LABORATORY

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Chundo Oh, PhD

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Comparative Research Center

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Lan Zhao, PhD

Ke Zhu, PhD

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Spine biomechanics

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Anna Chee, PhD

Alejandro A. Espinoza-Orías, PhD

Phil Malloy, PT, PhD

Dino Samartzis. PhD

THE JOAN AND PAUL RUBSCHLAGER TRIBOLOGY LABORATORY

Markus A. Wimmer, PhD - Director; Associate Chairman for Research

Alfons Fischer, PhD

Joachim Kunze, PhD

Thomas M. Schmid, PhD

ASSOCIATED FACULTY AT RUSH UNIVERSITY MEDICAL CENTER

Susan Chubinskaya, PhD – Pediatrics, Orthopedic Surgery, and Medicine

Carl Maki, PhD - Cell & Molecular Medicine

Anna Plaas, PhD - Internal Medicine, Rheumatology

D. Rick Sumner, PhD – Director, Section of Bone & Cartilage Biology

Department of Orthopedic Surgery Residents

Class of 2019

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Kevin Campbell, MD

Medical school – University of Wisconsin School of Medicine and Public Health

Philip Louie, MD

Medical school - University of Washington School of Medicine

Timothy Luchetti, MD

Medical school – Columbia University College of Physicians and Surgeons

Allison Rao, MD

Medical school - Stanford University School of Medicine

Class of 2020

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Medical school - Yale University School of Medicine

Daniel D. Bohl, MD, MPH

Medical school - Yale University School of Medicine

Islam Elboghdady, MD

Medical school - Rush Medical College

Charles Hannon, MD

Medical school - Georgetown University School of Medicine

Mick Kelly, MD

Medical school – University of Wisconsin School of Medicine and Public Health

Class of 2021

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Nitin Goyal, MD

Medical school – Northwestern University Feinberg School of Medicine

lan MacLean, MD

Medical school - University of Virginia School of Medicine

Arash Sayari, MD

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David Zhu, MD

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Medical school – Virginia Commonwealth University School of Medicine

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Timothy C. Keating, MD

Medical school – Virginia Commonwealth University School of Medicine

Michael T. Nolte, MD

Medical school - University of Michigan Medical School

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Medical school - University of Michigan Medical School

Nabil Mehta, MD

Medical school – The Warren Alpert Medical School of Brown University

Elizabeth Terhune, MD

Medical school - Georgetown University School of Medicine

Class of 2024

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Medical school - Rush Medical College

Tai Holland, MD

Medical school - University of Iowa

Obianuju Obioha, MD

Medical school - University of Pittsburgh

Sarah Tepper, MD

Medical school - Washington University

Joseph Serino, MD

Medical school - Georgetown University

"These findings are important when considering graft attachment sites in patients with moderate to severe patella alta who are undergoing MPFL or MQTFL reconstruction."

Effect of Patella Alta on the Native Anatomometricity of the Medial Patellofemoral Complex: A Cadaveric Study

ADAM YANKE MD, PHD / HAILEY HUDDLESTON, BS / KEVIN CAMPBELL, MD / MICHAEL L. REDONDO, MA, BS ALEJANDRO ESPINOZA-ORÍAS, PHD / JORGE CHAHLA MD, PHD / BRIAN J. COLE, MD, MBA / JACK FARR, MD

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INTRODUCTION

Patellar instability is 1 of the most common orthopedic problems among young athletes, occurring at a rate of 2.29 per 100,000 person-years in the United States, with a peak incidence between 15 and 19 years of age.¹ Patellar dislocation recurrence rates can range from 10% to 70% after primary dislocation, generally in young patients who manifest with chronic instability and anterior knee pain, which can lead to apprehension.².³ Recurrence varies greatly on the basis of individual

patient risk factors, including patellar height, long leg alignment, soft-tissue laxity, and trochlear dysplasia.^{4,5,6}

The medial patellofemoral ligament (MPFL) has been well described and provides stabilization to the patella, inhibiting lateral dislocation, especially in the first 20° of flexion.7 The medial quadriceps tendon femoral ligament (MQTFL) has been described more recently and attaches proximal to the patella.8 These 2 structures form the medial patellofemoral complex (MPFC), which includes the entirety of soft-tissue restraints that prevent lateral patellar translation. The length changes, or anatomometricity, of the different aspects of the MPFC vary along the length of the complex, with the proximal aspect becoming relatively longer in early flexion compared with the lengths of the distal aspects.

Study results show that patella alta, a high-riding patella, is present in as many as 75% of patients with first-time lateral patella dislocations and

constitutes a significant risk factor for patellar instability recurrence. 9,10,11,12
Specifically, investigators in 1 study reported that patella alta was the most commonly identified risk factor that causes a statistically significant increase in instability risk when combined with 1 or more other patella dislocation risk factors. 13 Increased patellar height may predispose patients to patellar instability due to the MPFC being required to work through larger degrees of flexion before the patella engages in the trochlea.

The relationship between patella alta and its role in MPFC reconstruction complications remains poorly understood. The rate of complications after MPFC reconstruction in patients with concurrent patella alta may be higher than previously reported because patella alta may result in a more anisometric reconstruction than does MPFC reconstruction in patients with normal patellar height, potentially causing chondrosis, graft elongation, tunnel enlargement, and eventual

recurrent dislocation.¹⁴ In this regard, limited evidence exists regarding biomechanical changes, specifically anisometry, of different fixation points of the MPFC along the extensor mechanism with increasing degrees of patella alta. An understanding of these changes could affect choice of graft insertion positioning in MPFL reconstruction when patella alta is present. In addition, these surgical alterations could improve postoperative patellar tracking and patient outcomes and avoid the need to perform distalization to correct patella alta.

The purpose of this study was to evaluate anisometry of the MPFC at multiple possible reconstruction locations along the extensor mechanism in varying degrees of patella alta severity. We hypothesize that the length will differ based on the location of the insertion site on the patella and that anisometric values will be accentuated further with increasing degrees of patella alta.

METHODS

This study was exempt from institutional review at Rush University Medical Center because we used deidentified cadaveric specimens. The cadaveric specimens used in this study had been donated to a tissue bank for the purpose of medical research, and then Rush University Medical Center purchased them. We obtained 8 nonpaired, fresh frozen cadaveric knees with the following exclusion criteria: age younger than 65 years, cancer history, bedridden donor, surgical scars, and recent knee trauma. Before testing, we used fluoroscopy to evaluate the knees for gross signs of osteoarthritis and arthroscopy to evaluate the knees anatomic abnormalities. We stored the specimens at -20°C and thawed them at room temperature for 24 hours. Before dissection, we sectioned the femoral diaphysis 20 cm from the joint line and removed all soft tissues beyond 15 cm of the joint line.

Dissection Technique

We dissected the cadaveric knees to isolate the patella tendon, patella, MPFC, and quadriceps tendon (QT). We made a medial incision through skin and subcutaneous tissue. We then transected the sartorius fascia, allowing visualization of the pes anserinus tendons. We retracted the tendons and identified the superficial medial collateral ligament to its insertion on the medial femoral condyle.15 We then identified the MPFC on the femoral attachment and followed it laterally to the extensor mechanism. Next, we visualized the MPFC, QT, and patellar tendon and removed all soft tissue surrounding these structures.

Specimen Preparation

After we identified the MPFC, we used a threaded screw to mark the anatomic footprint of the MPFC at the femoral attachment point. We then marked the following attachments on the extensor mechanism: midpoint patella (MP),

center of the osseous footprint of the MPFC (FC), superior medial pole of the patella at the level of the QT insertion (SM), and 1 cm proximal to the SM point along the QT (Figure 1). After we landmarked the femoral and patellar attachments for standardized measurement, we removed the MPFC by means of clean dissection.

In each specimen, we calculated the native Caton-Deschamps index (CDI) ratio to be approximately 1.0 by obtaining a perfect lateral radiograph of the knee. To obtain these radiographs, we aligned the posterior aspects of the femoral condyles and then loaded the specimen into a custom-machined jig (Figure 2). We potted the femoral shaft in polymethyl methacrylate (PMMA) to ensure rigid fixation. We secured the QT by using a Krackow locking stitch and then modified the femoral PMMA cylinder to allow passage of the sutures (1-0 Fiberwire; Arthrex, Naples, Florida). This method allowed us to attach a 10-pound (45-N) weight, which mimicked the physiological loading of the

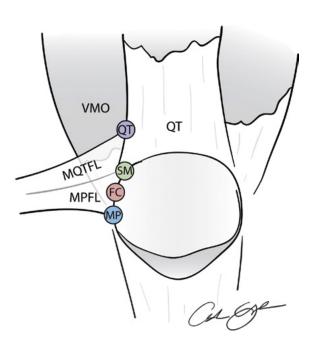


Figure 1. The circles represent MPFC attachment sites on the extensor mechanism: midpoint patella (MP), center of the osseous footprint of the MPFC (FC), superior medial pole of the patella at the level of the QT insertion (SM), and 1 cm proximal to the SM point along the QT (QT). MPFL indicates medial patellofemoral ligament; MQTFL, medial quadriceps tendon femoral ligament; VMO, vastus medialis obliquus.



Figure 2. Experimental setup. We potted the knee in PMMA and placed it in a custom-made jig that allowed for 0° to 90° of flexion.

quadriceps. ¹⁶ We measured the distance between the femoral and patellar MPFC attachment sites by using a 3-dimensional (3D) digitizer (MicroScribe MX; Solution Technologies, Oella, Maryland) at knee flexion angles of 0°, 20°, 40°, 60°, and 90°, which we confirmed during testing with a goniometer.

Specimen Testing

We standardized the CDI ratio to ratios of 1.0, 1.2, 1.4, and 1.6 by using the perfect lateral radiographs and Image J software (version 1.41; National Institutes of Health, Bethesda, Maryland). We secured suture anchors to the distal pole of the patellar tendon, passed them through the adjacent tibial tuberosity, and then brought them through the patella for fixation on the superior patellar border. We then excised the patella tendon and tied together the remaining suture anchors to specific lengths to obtain the desired CDI ratio. Finally, we measured the 3D distances of the MPFC attachment site by means of imaging analysis using OsiriX software (version 10, Pixmeo SARL; Bernex, Switzerland) and compared these distances with the data we obtained from the pretesting measurements.

Statistical Analysis

We performed statistical analyses by using SPSS Statistics software (version 25, IBM; Armonk, New York, 2012). We used 2-way repeated measures analysis of variance (ANOVA) to investigate the relationship between extensor mechanism attachment site and CDI ratio on change in MPFC length from 0° to 90° of flexion. We then analyzed pairwise comparisons to evaluate the within-subject significance of each variable. We used paired t tests to compare adjacent attachment sites and the relationship between the same sites in patella alta and the native anatomical sites at a CDI ratio of 1.0. For evaluation of the effect of CDI ratio and flexion on MPFC length, we performed a Friedman test because of the presence of outliers to determine if there was any significance between 1 location and CDI ratio at 0°, 20°, 40°, 60°, and 90°. We then performed pairwise comparisons with a Bonferroni correction for multiple comparisons. We used paired *t* tests to evaluate differences between 2 CDI ratios at 1 location at a particular degree of flexion. We then used a Spearman's

rank-order correlation to evaluate the relationship between degree of flexion (from 0° to 90°) at the QT at a CDI ratio of 1.0 and at the QT tendon at a CDI ratio of 1.6. We set significance at P < .05.

RESULTS

Effect of Location on Length Changes From 0° to 90° of Flexion

The Table shows the mean length changes occurring between 0° and 90° of knee flexion. Results of a 2-way repeated measures ANOVA indicated that extensor mechanism attachment site and CDI ratio both significantly affect changes in MPFC length from 0° to 90° (P < .0005). Point QT displayed the greatest anisometry (mean [SD], 13.90 [2.98] mm) at a CDI ratio of 1.0. In contrast, mean (SD) length change at point MP (2.72 [4.43] mm) was relatively isometric, with minimal changes in length throughout flexion at a CDI ratio of 1.0. Given the statistically significant effect shown with 2-way repeated measures ANOVA, we then conducted pairwise analysis to evaluate the relationship between attachment and MPFC change in length from 0° to 90° flexion. For each CDI ratio, the difference in MPFC length change was statistically significant when comparing each attachment site (P < .0005).

Effect of Patella Alta on Length Changes From 0° to 90° of Flexion

To evaluate the relationship between CDI ratio and MPFC change in length from 0° to 90° of flexion, we analyzed pairwise comparisons between CDI cohorts. There was a statistically significant difference in length change between a CDI ratio of 1.0 vs 1.4 (P = .038), $1.0 \text{ vs } 1.6 \ (P = .004), 1.2 \text{ vs } 1.6 \ (P = .023),$ and 1.4 vs 1.6 (P = .024). We did not find any statistically significant differences when comparing a CDI ratio of 1.0 vs 1.2 (*P* = .351) or 1.2 vs 1.4 (P = .244) (Figure 3). When we assessed the data with location as a constant, all MPFL length changes were significantly different between

CDI ratios at both the QT and SM points. At the FC site, only the means between CDI ratio 1.0 vs 1.6 (P = .014), 1.0 vs 1.4 (P = .045), and 1.4 vs 1.6 (P = .042) were statistically different. Finally, at the MP site, the only statistically significant comparison was at a CDI ratio of 1.4 vs 1.6 (P = .03).

Equivalent Extensor MPFC Attachment Points at Different Patellar Heights

We compared MPFC length changes at a CDI ratio of 1.0 with length changes under patella alta conditions from 0° to 90° flexion by using paired t tests

Table. Mean Change in MPFC Length at Each Extensor Mechanism Attachment Site Occurring Between 0° and 90° of Knee Flexion. Using 2-way repeated measures analysis of variance, we found that both CDI (P < .0005) and location (P < .0005) had a statistically significant effect on MPFC length change from 0° to 90° of flexion.

	CDI Ratio, Mean (SD), mm			
Location	1.0	1.2	1.4	1.6
QT	13.90 (2.98)	18.14 (4.23)	20.97 (3.25)	24.83 (2.92)
SM	9.00 (3.76)	11.69 (5.52)	14.30 (4.60)	18.61 (4.41)
FC	6.59 (4.24)	8.06 (5.71)	9.94 (4.76)	14.10 (5.27)
MP	2.72 (4.43)	2.84 (5.52)	3.84 (5.41)	7.69 (5.72)

Abbreviations: CDI, Caton-Deschamps index; FC, center of the osseus footprint of the MFPC on patella; MP, midpoint patella; MPFC, midpoint patellofemoral complex; QT, quadriceps tendon; SM, superior medial pole of the patella.

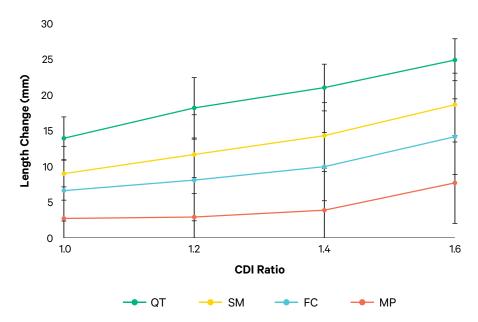


Figure 3. The length change from 0° to 90° for 4 points along the MPFC extensor mechanism (MP, FC, SM, and QT), relative to CDI ratios of 1.0, 1.2, 1.4, and 1.6. Abbreviations: CDI, Caton-Deschamps index; FC, center of the osseous footprint of the MPFC; MP, midpoint patella; MPFC, midpoint patellofemoral complex; QT, quadriceps tendon; SM, superior medial pole of the patella.

to investigate whether an adjacent attachment at a higher CDI ratio represented the anatomical location at a CDI ratio of 1.0 (Figure 4). When we investigated the QT location at a CDI ratio of 1.0, we saw no statistically significant difference compared to the SM location at a CDI ratio of 1.2 (P = .234), the SM and FC location at a CDI ratio of 1.4 (P = .89 and P = .073, respectively), and the FC location at a CDI ratio of 1.6 (P = .928). In the SM location at a CDI ratio of 1.0, we saw no differences compared with the FC location at CDI ratios of 1.2 (P = .414) and 1.4 (P = .503), and the MP location at a CDI ratio of 1.6 (P = .473). At the FC location at a CDI ratio of 1.0, we saw no differences when compared to the FC location at 1.2 (P = .157), MP location at 1.4 (P = .068), or MP location at 1.6 (P = .519). Finally, at the MP location at a CDI ratio of 1.0, we saw no differences when compared to the MP location at CDI ratios of 1.2 (P = .888) or 1.4 (P = .385).

Effect of Patella Alta on Length Changes Throughout Knee Flexion

We compared the most inferior (MP) and superior (QT) locations at CDI ratio extremes of 1.0 and 1.6 to evaluate the relationship between MPFC length and flexion (Figure 5). We observed a negative linear relationship between degree of flexion (from 0° to 90°) and MPFC length at the QT point with CDI ratios of 1.0 (r = -0.484; P = .002) and 1.6 (r = -0.692; P < .0005). We observed no differences when comparing the length at the MP location at CDI ratios of 1.0 and 1.6 at varying degrees of flexion, except at 0 of flexion (P = .017). In contrast, length difference was significant at all degrees of flexion at the QT location at a CDI ratio of 1.0 compared with 1.6. Analysis of the MP location at a CDI ratio of 1.0 showed no significant difference at different degrees of flexion. In contrast, at the MP location at a CDI ratio of 1.6, we saw significant differences only at 0° vs 90° (P = .027), 0° vs 60° (P = .044), 0° vs 40° (P = .016), and 0° vs 20° (P = .044). At the

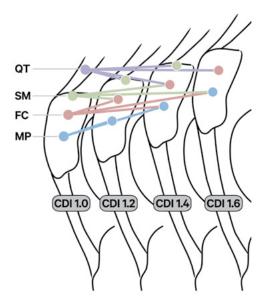


Figure 4. Relative patellar height with increased patella alta, where each attachment point is aligned with its equivalent position in each setting.

Abbreviations: CDI, Caton-Deschamps index ratio; FC, center of the osseous footprint of the MPFC; MP, midpoint patella; QT, quadriceps tendon; SM, superior medial pole of the patella.

QT location at a CDI ratio of 1.0, there were significant differences at 0° vs 60° (P = .001), 0° vs 90° (P < .0005), and 20° vs 90° (P = .005). At a CDI ratio of 1.6 at the QT location, we observed significant differences at 0° vs 60° (P < .0005), 0° vs 90° (P < .0005), and 20° vs 90° (P = .03).

DISCUSSION

We found that the location of the attachment point on the extensor mechanism affected the anisometry of the MPFC. Furthermore, an increase in the CDI ratio amplified the anisometry of the ligament. In particular, the results of this study showed that the superior aspects of the MPFC that attach to QT have a statistically significant greater change in length than do the inferior aspects that attach to the MP. Furthermore. these differences in length changes are amplified with increasing patella alta severity (increasing CDI values). In addition, our results indicate that a constant loosening at the QT point relationship exists during flexion from 0° to 90° at CDI ratios of both 1.0 and 1.6 with Spearman's rank-order correlation

tests. However, these findings were not obvious on the basis of ANOVA results, likely in part because of the large SDs at the QT points at CDI ratios of 1.0 and 1.6. In contrast, the inferior aspect of the MPFC at the MP location demonstrated loosening between 0° and 20°. Instead, the length of the MPFC at the MP point at a CDI ratio of 1.0 exhibited no significant change in length through flexion. However, with severe patella alta at a CDI ratio of 1.6, the difference in the length at 0° was statistically significant compared to the difference in length at all other measured points of flexion.

For the preceding reasons, the MPFC may be viewed more accurately as 2 entities because of the differences in anisometry and varying relationship between length and degree of flexion at the inferior and superior aspects at the MPFC. We hypothesize that the length of the inferior MPFC corresponds with the curvature of the femur (Figure 6). On the basis of this model, the superior points, such as QT, will increase linearly with length as they track along the linear aspect of

the femur. In comparison, the inferior points, such as MP, track along the radial curvature of the femur, causing its length to remain relatively constant. However, in the presence of marked patella alta, the inferior MPFC now has to track along the linear aspect of the femur, increasing its length. This model explains the statistically significant change in length seen at the MP point at a CDI ratio of 1.6 between 0° and all other degrees of measured flexion.

These findings are important when considering graft attachment sites in patients with moderate to severe patella alta who are undergoing MPFL or MQTFL reconstruction. Our results suggest that an alternative attachment site may provide superior biomechanical results. Our results suggest, as proposed with the dualentity MPFC model, that the length changes at varying CDI ratios are caused not solely by changes in translation. As we have described, the SM and FC sites at a CDI ratio of 1.2 are equivalent in anatomical location to the QT and SM points at a CDI ratio of 1.0, respectively. The SM site at a CDI ratio of 1.4 is equivalent to the QT site at a CDI ratio of 1.0, and the FC site at a CDI ratio of 1.4 is equivalent to the QT and SM sites at a CDI ratio of 1.0. Finally, the FC site at a CDI ratio of 1.6 is equivalent in location to the QT site at a CDI ratio of 1.0, and the MP site at a CDI ratio of 1.6 is equivalent to the SM and FC sites at a CDI ratio of 1.0. These relationships illustrate that it is important to understand the differing biomechanical properties of the different aspects of the MPFC and that surgeons may consider setting lengths individually when using 2 bundles for an MPFC reconstruction (MQTFL and MPFL). In addition, our results indicated that changes in length occur with increasing degrees of patella alta, suggesting that in the subset of patients with that condition, it may be more appropriate to set the length at higher degrees of flexion during MPFC reconstructions.

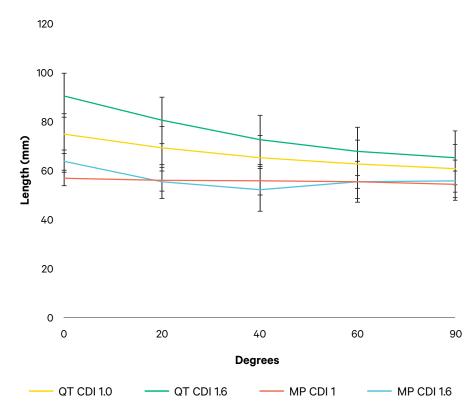


Figure 5. Absolute length of the most superior aspect (QT) and inferior aspect (MP) of the extensor mechanism presented at 2 different CDI ratios, 1.0 and 1.6.

Our results are analogous to those of prior studies whose results have shown that MPFL length changes occur when the femoral fixation location is altered. For example, in a biomechanical study, Stephen et al¹⁷ showed that shifting the attachment point of an MPFL graft distally resulted in a 9.1-mm length change and that moving the insertion proximally resulted in a 6.4-mm length change. This idea also has been investigated clinically. Matsushita et al18 analyzed 44 knees and found that nearly 30% showed unfavorable isometry patterns, defined as a large length change from 0° to 90°. Furthermore, they found that alterations in femoral positioning of the graft were the largest contributor to an unfavorable length pattern. These studies reinforce the clinical significance of the present study's findings.

A reliable clinical algorithm has not yet been defined for the treatment

of patellar instability, especially in the presence of patella alta. Results of recent studies have suggested that adjustment of the femoral fixation site may be appropriate when reconstructing knees with elevated

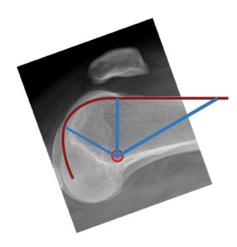


Figure 6. A representation of the proposed relationship between femoral curvature and MPFC length.

patellar heights.19 However, our results support the idea that the MPFC should be considered as 2 separate entities, proximal (MQTFL) and distal (MPFL), because of their anisometric properties and set accordingly intraoperatively. In addition, surgeons may consider an alternative graft insertion location for patients with severe patella alta that is not being corrected. An improved understanding of how patella alta affects the anisometry of the MPFC may help determine the proper surgical management of patellar instability and advance techniques in MPFL reconstruction. Future studies are needed to evaluate the clinical correlates of these findings.

There are several limitations of this study. First, this is a cadaveric model and may not perfectly reflect the load distribution of the QT in a native knee. Second, we manipulated all knees in this study to create different CDI values of patella alta, but native patella alta may have slightly dissimilar biomechanical properties not reflected in our model. Lastly, in this study, we relied heavily on the accuracy of identifying the femoral footprint, and slight inaccuracies potentially could affect our findings.

CONCLUSIONS

In conclusion, anisometry varies with the location of the patellar attachment and with patellar height within the MPFC. Specifically, the proximal aspect of the MPFC demonstrated the most anisometric behavior, with length increasing linearly with increasing flexion. In contrast, the distal aspect of the MPFC retained a relatively constant length at 20° to 90° of flexion. These findings were amplified as the CDI ratio increased. *

References and financial disclosures are available online at www.rush.edu/orthopedicsjournal.



Infinite Possibilities

Adam Yanke, MD, PhD, and Hannah Lundberg, PhD, are studying the use of advanced computer modeling to help inform surgical decisions

When you think about why a surgical procedure is used to address a specific orthopedic problem, you assume that the procedure had been rigorously tested and determined to be both medically necessary and the optimal approach for that problem. But what if that isn't the case? What if there is precedent for a procedure but not strict guidelines for its use?

That is the question at the core of a research collaboration between sports medicine surgeon Adam Yanke, MD, PhD, and scientist Hannah Lundberg, PhD. And Yanke and Lundberg are

confident that a computer simulation technique called finite element analysis can help them find the answer.

AN UNANSWERED CLINICAL QUESTION

As with much of the research conducted by the Department of Orthopedic Surgery at Rush, this project originated from a clinical observation.

To address cartilage deficiencies in the patellofemoral joint, surgeons typically employ a dual approach: They restore the cartilage surface using transplanted

tissue, including optimizing the integration of the new cartilage to the existing cartilage; they then perform a tibial-tubercal osteotomy, cutting and repositioning the bones to protect the repaired cartilage by lightening its load.

As Yanke explains, however, the reason for adding the osteotomy is not (pardon the pun) clear-cut. "We're essentially doing it now in these patients based on a historical study that shows it improves outcomes vs when you don't do it," he says. "But the osteotomy is used to correct patellar malalignment, so I started asking why we would do it

"This could turn into a long-term project where we try to optimize surgery for many different areas."

for patients with normal alignment who aren't predisposed to overloading their joints. Other osteotomies have clear pre-operative measurements that guide our surgical use; however, for offloading patellofemoral cartilage this does not exist."

Determining strict indications is particularly important for osteotomy, as it's not an easy procedure for patients to endure and there can be morbidity associated with adding it. Breaking the bone and realigning it creates a significant amount of pain; you have to limit weight bearing for the first 6 weeks post-op; and the complications associated with the osteotomy increase the overall complication rate significantly compared to not adding the osteotomy. "Even though there's

precedent for doing it, when you see that the patient-reported outcomes aren't as good as we want them to be, we need to look at how to improve what we're doing," Yanke says.

That's where Lundberg's area of expertise comes in, and why Yanke—inspired by his own scientific background, which includes a doctorate in biochemistry focused on cartilage metabolism—decided to bring this clinical issue back to the bench.

FROM COCKPITS TO CARTILAGE

Finite element analysis (FEA) is used to determine how different structures carry load—how stress is transferred throughout the structure. "You can use

it for everything from airplanes and spacecraft to human joints," Lundberg says. In fact, the aerospace industry was one of the pioneers of FEA; now, this remarkable technology has started to explode in orthopedics.

Lundberg is part of the Computational Biomechanics Laboratory, which combines novel computational and experimental modalities to better represent joint function in vivo and improve surgical outcomes. "Adam was interested in learning more about stresses in cartilage after different procedures to the patellofemoral joint, and how anatomy plays a role in that. My work lends itself well to determining stresses in different tissues," Lundberg says.

She and Yanke began to discuss creating a model of the patellofemoral joint. "I've been part of other collaborations where we're looking at computer modeling to predict total knee replacement forces and behavior during everyday life; wear of total knee replacements; and the biomechanical behavior of total hip replacement," she says. "I'm just starting to delve into natural joints through my work with Adam."

To model the patellofemoral joint, Lundberg starts with MRI images of the entire joint and separates them into individual models for cartilage and bones; she then applies the FEA technique to each of the models. "We split each model into repeating "elements"—basically, cutting the image into a lot of tiny cubes—and use software to apply physics equations to each cube to determine the stress throughout the whole model," Lundberg explains.

She and Yanke are currently developing the model. Once completed, it will allow Yanke to digitally "perform" the procedure in different cohorts without having to put the patients themselves through surgery. "The process can be repeated hundreds or thousands of times in far less time than it would take surgeons to perform that many actual



In the Computational Biomechanics Laboratory, Lundberg and postdoctoral fellows Jonathan Gustafson, PhD (left), and Steven Mell, PhD, are currently using computer modeling to predict total knee replacement forces and behavior during everyday life, wear of total knee replacements, and the biomechanical behavior of total hip replacement modular taper junctions.



Through his collaboration with the Department of Biochemistry, where he completed his PhD in 2018, Yanke is engaged in both basic science and clinical research in an effort to develop benchtop techniques that will translate directly to improved patient care.

procedures," Yanke says. "You can look at the effects of different anatomy and changing only small variables each time."

The hope is that the data gleaned from these simulations will indicate both which patients actually benefit from osteotomy, and the appropriate degree of correction for each patient who *does* need it.

LOOKING TO THE FUTURE

Over time and with additional funding, the model will enable studies of other conditions that affect the knee, such as instability and cartilage disease.

"This could turn into a long-term project where we try to optimize surgery for many different areas," Lundberg says. "That's the ultimate goal: to be able to make treatment decisions based on research findings combined with clinical experience and outcomes data. How do you know which surgery to do? You've either done so many that you have the data to show outcomes for these approaches, or you can speed up the process by creating different scenarios using computer simulation that tell you, this procedure will or won't be effective for this specific patient."

With all due respect to the pace of translational research—which can take years to unfold and yield publishable results—both Lundberg and Yanke are excited about the potential of their

partnership to drive discovery and ultimately advance treatment based on patient-specific modeling.

"Most of the collaborations we do as clinicians are for immediate patient care-related issues; we bounce cases off of each other," Yanke says. "Research collaboration does usually stem from these clinical issues, but then it becomes about two people from different fields, like Hannah and myself, working synergistically to answer a question that will positively affect patient outcomes. That's what truly inspires us." *

"Epidural steroids may reduce postoperative pain by suppressing the inflammatory cascade triggered by tissue trauma and direct manipulation of the nerve root during surgery."

Impact of Local Steroid Application in a Minimally Invasive Transforaminal Lumbar Interbody Fusion

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INTRODUCTION

Transforaminal lumbar interbody fusion (TLIF) is a common spinal procedure used to treat a variety of degenerative lumbar conditions. With the evolution of this surgical technique, the procedure now can be performed via a minimally invasive approach that requires only a 2-3 cm incision. Studies have shown that minimally invasive surgery (MIS) results in decreased postoperative complications and decreased hospital length of stay compared with the traditional open approach.²⁻⁴ However, pain immediately after surgery remains a concern and poses an obstacle for discharge.

Postoperative pain is a common concern following lumbar spine surgery. Up to 40% of lumbar spinal patients experience recurrent or persistent postoperative pain, which may lead to prolonged hospital stay, development of chronic pain, and overuse of narcotic analgesics.5-7 Therefore, providing adequate pain control early after the procedure may be advantageous for minimizing healthcare resource utilization and improving surgical and clinical outcomes. Despite the success of multimodal analgesia, however, pain control is still a major issue after lumbar fusion surgery and efforts to reduce postoperative pain are ongoing.8,9

Two studies have demonstrated improved pain control with the use of epidural steroids after lumbar spine surgery. Epidural steroids have been applied as an adjuvant therapy to lumbar spine surgery in an attempt to reduce pain, inflammatory reaction, and scar formation in the early postoperative period. The injections have resulted in notable decreases in back pain and radicular leg pain versus control, without any increase

in such complications as superficial wound infections or epidural abscesses. Epidural steroids may reduce postoperative pain by suppressing the inflammatory cascade triggered by tissue trauma and direct manipulation of the nerve root during surgery.¹¹

Given this, epidural steroids have demonstrated efficacy in improving postoperative back pain, radicular leg pain, and physical function in the early stages following lumbar discectomy. 10,12-15 Additionally, epidural steroids have been associated with decreased lengths of hospital stay and postoperative narcotic use in lumbar discectomy and laminectomy patients.6 However, few studies have investigated intraoperative local injection of corticosteroids in the epidural space in an effort to reduce the incidence and duration of postoperative pain following lumbar fusion procedures. As such, we performed a randomized, controlled trial to determine the impact of local corticosteroid application on perioperative and postoperative outcomes in patients undergoing a primary, single-level MIS TLIF.

MATERIALS AND METHODS

Patient Population

Following institutional review board approval, we performed a prospective, randomized, single-blind study at Rush University Medical Center. We included in the study patients who were scheduled to undergo a primary, single-level MIS TLIF. We excluded patients if they had a history of allergic reaction or other contraindication to the medications used in the protocol, a medical history of gastrointestinal bleeding, or a history of lumbar spine trauma. We gave patients either a local injection of methylprednisolone (Depo-Medrol; Pfizer, New York) (DEPO) or a control injection of saline (NODEPO). All patients were blinded and computer randomized to their treatment group assignment; however, the senior surgeon (K.S.) was not blinded. We enrolled a total of 105 patients between November 2015 and July 2017 (DEPO = 52, NODEPO = 53).

Power Analysis

We performed an a priori power analysis on the basis of a previous cohort that underwent a 1-level MIS TLIF by the same surgeon. The average (SD) Visual Analogue Scale (VAS) pain score on postoperative day (POD) 1 in this population was 5.17 (1.62). We set a 1-point difference in average VAS pain score between groups as the minimum needed for clinical relevance. Using a mean and standard deviation (SD) of 5.17 (1.62) for the control group, a power of 80%, and α of .05, we determined that 86 patients were needed to detect a difference of 1 point in average VAS pain score between DEPO and NODEPO groups.

Surgical Technique

We performed all MIS TLIF procedures by using a standard paramedian approach (Figure).¹⁶ After we prepared the endplate, we packed the interbody device with local bone graft and either iliac crest bone graft or bone



Figure 1. Illustration of a minimally invasive transforaminal approach using a nonexpandable tubular retractor.

morphogenetic protein-2 and placed it within the intervertebral space. Prior to surgical closure, we gave DEPO patients 1 cc of methylprednisolone (80 mg) applied at the transforaminal space by using a 10-cm² gel-foam carrier. We gave NODEPO patients 1 cc of saline applied in the same manner. We gave all patients an intravenous dose of dexamethasone (10 mg) at the beginning of the procedure. We used a multimodal analgesia protocol for standardized perioperative pain management for both cohorts.

Data Collection

We collected baseline and perioperative characteristics for each patient. Patient characteristics included age, sex, body mass index, smoking status, preoperative diagnosis, and comorbidity burden, as measured by Charlson Comorbidity Index (CCI). We used a modified CCI with the age component removed to allow for the testing of comorbidity burden and age separately during statistical analysis. We recorded perioperative variables such as operative time, estimated intraoperative blood loss, length of postoperative stay, and day of discharge. Via scheduled clinic visits, we also recorded any complications or reoperations during the perioperative period and during the postoperative period for at least 2 years following the procedure. Further, we recorded acute postoperative VAS pain scores during

the inpatient period according to standard nursing protocols and averaged them over each postoperative day. We converted narcotics utilization for the duration of the inpatient stay to oral morphine equivalents (OME), and then reported them as a total and average per hour for each postoperative day.

We administered patient-reported outcomes (PRO) questionnaires preoperatively and at 6-week, 12-week, and 6-month postoperative time points. PRO measures included Oswestry Disability Index (ODI), VAS back pain, and VAS leg pain scores. We then determined achievement of minimum clinically important difference (MCID) in PRO at 6-month follow-up by using values proposed by Copay et al.¹⁷ The MCID values for VAS back, VAS leg, and ODI were -1.2, -1.6, and -12.8, respectively.

Statistical Analysis

We performed statistical analysis by using Stata/MP 13.0 (StataCorp LLC; College Station, Texas). We assessed differences between DEPO and NODEPO cohorts in patient demographics and perioperative characteristics by using independent t tests for continuous variables and χ^2 analysis for categorical variables. We then determined the association between local corticosteroid use and inpatient pain or narcotics consumption by using linear regression controlled for sex. Next, we compared improvements in PROs between groups by using linear regression controlled for sex. Lastly, we tested differences in rates of MCID achievement between cohorts by using Poisson regression with robust error variance controlled for sex. We used P < .05 to determine statistical significance.

RESULTS

We enrolled and randomized a total of 105 patients to the DEPO (n=52) or NODEPO cohorts (n=53). We excluded from our analysis 4 patients in the DEPO cohort who inadvertently

received only a 40-mg injection of methylprednisolone. We excluded an additional 8 patients from final analysis due to incomplete postoperative survey completion (DEPO = 3, NODEPO = 5). As such, 93 patients were included in the final analysis, of which 45 (48.4%) and 48 (51.6%) were in DEPO and NODEPO groups, respectively. A greater percentage of DEPO patients were female (53.3% vs 27.1%, P = .010) compared to the NODEPO group. However, we identified no significant differences in other preoperative characteristics between groups (P > .05; Table 1).

Table 2 describes perioperative characteristics and complication rates. We determined that patients in the DEPO and NODEPO cohort had similar surgical times and intraoperative blood loss. Likewise, length of stay and postoperative day of discharge were also similar between groups. There was 1 patient in the DEPO cohort who exhibited postoperative urinary retention, requiring a urinary catheter upon discharge and follow-up with the urology service. Additionally, 2 patients in the DEPO group developed superficial wound infections in the first 6 postoperative weeks that resolved with

oral antibiotic therapy. Finally, 1 patient in the DEPO cohort developed symptomatic pseudarthrosis, which required an anterior lumbar interbody fusion at the index level approximately 18 months postoperatively. We observed no complications in the NODEPO cohort.

Table 3 describes inpatient pain scores and narcotics consumption. We observed no differences in acute postoperative VAS pain scores or total narcotics consumption between DEPO and NODEPO groups (*P* > .05). DEPO patients consumed fewer hourly narcotics on POD 0 (5.3 vs 6.3 OME/h,

Table 1. Baseline Characteristics

	NODEPO (n = 48)	DEPO (n = 45)	P value ^a
Age, mean (SD), y	52.4 (10.8)	51.8 (11.2)	.826
Sex, No. (%)			.010
Female	13 (27.1)	24 (53.3)	
Male	35 (72.9)	21 (46.7)	
BMI, No. (%)			.349
Nonobese (BMI < 30 kg/m²)	22 (45.8)	25 (55.6)	
Obese (BMI ≥ 30 kg/m²)	26 (54.2)	20 (44.4)	
Smoking status, No. (%)			.161
Nonsmoker	44 (91.7)	37 (82.2)	
Smoker	4 (8.3)	8 (17.8)	
Ageless comorbidity burden, CCI, mean (SD)	0.8 (0.9)	1.1 (1.1)	.091
Preoperative diagnosis, No. (%) ^b			
Degenerative spondylolisthesis	30 (62.5)	29 (64.4)	.846
Isthmic spondylolisthesis	8 (16.7)	6 (13.3)	.653
Recurrent herniated nucleus pulposus	9 (18.8)	9 (20.0)	.879
Degenerative disc disease	26 (54.2)	22 (48.9)	.611
Spinal stenosis	45 (93.8)	39 (86.7)	.248

Abbreviations: BMI, body mass index; CCI, Charlson Comorbidity Index; DEPO, patients receiving a local injection of methylprednisolone; NODEPO, patients receiving a control injection of saline.

Boldface indicates statistical significance.

 $^{^{}a}P$ values were calculated using χ^{2} analysis for categorical and independent t test for continuous variables.

^bPatients may have multiple diagnoses.

Table 2. Surgical Characteristics and Complications

	NODEPO (n = 48)	DEPO (n = 45)	P valueª
Surgical time, mean (SD), min	112.6 (24.2)	111.2 (29.8)	.806
Estimated blood loss, mean (SD), mL	60.8 (69.7)	61.3 (71.9)	.973
Length of hospital stay, mean (SD), h	32.3 (23.9)	32.4 (14.4)	.979
Discharge day, No. (%)			.196
POD 0	9 (18.7)	3 (6.7)	
POD 1	27 (56.3)	32 (71.1)	
POD 2	7 (14.6)	8 (17.8)	
POD 3+	5 (10.4)	2 (4.4)	
Complications, No. (%)			
Postoperative urinary retention	0 (0.0)	1 (2.2)	.299
Superficial wound infection	0 (0.0)	2 (4.4)	.140
Repeat surgeries ^b	0 (0.0)	1 (2.2)	.299

Abbreviations: DEPO, patients receiving a local injection of methylprednisolone; NODEPO, patients receiving a control injection of saline; POD, postoperative day.

P = .034). However, we found no differences between groups in hourly narcotics on POD 1 or 2 (P > .05).

Table 4 illustrates postoperative PRO improvements from preoperative scores. Preoperative VAS leg scores were significantly greater in the NODEPO cohort (6.5 vs 5.4; P = .027); however, preoperative ODI and VAS back scores did not differ between groups (P > .05). Additionally, DEPO and NODEPO groups experienced similar improvements in PROs at all postoperative timepoints. Further, patients in both cohorts achieved MCID for ODI, VAS back, and VAS leg at similar rates (P > .05; Table 5).

DISCUSSION

In this randomized, controlled, singleblind trial, we investigated the effect of local intraoperative steroid application

on perioperative and postoperative clinical outcomes in MIS TLIF patients. Although DEPO patients consumed fewer average narcotics per hour on POD 0, total narcotic consumption over time was not different between groups. We established no association between the use of DEPO and reductions in length of stay or acute postoperative pain. Additionally, DEPO patients experienced similar PROs to NODEPO patients; however, the DEPO patients also had more complications than the NODEPO group had. These results suggest that the administration of local intraoperative steroids does not provide additional benefits with regard to surgical or clinical outcomes after MIS TLIF.

The similar acute postoperative pain and narcotics use between DEPO and NODEPO cohorts is in contrast to previous reports in the spine literature. Akinduro et al¹⁸ performed a metaanalysis of 17 studies on the association between intraoperative epidural steroid use and outcomes in lumbar discectomy. The authors reported that, of the 12 studies reporting acute postoperative pain, 8 (66.7%) indicated that steroid use was associated with significantly decreased pain. Additionally, 10 of 11 (90.9%) studies reporting narcotic use demonstrated decreased consumption among those receiving steroids. These results have been supported by additional systematic reviews in the literature.^{5,10}

Although the majority of studies on local intraoperative steroids exists in the lumbar decompression literature, their utility in lumbar fusion populations has not been thoroughly investigated. Jirarattanaphochai et al¹⁹ performed a randomized, double-blind, controlled trial on 103 patients

 $^{^{9}}P$ values were calculated using χ^{2} analysis for categorical and independent t test for continuous variables.

^bPatient underwent anterior lumbar interbody fusion at index level 18 months postoperatively for symptomatic pseudarthrosis.

Table 3. Inpatient Pain Scores and Narcotics Consumption

	NODEPO (n = 48)	DEPO (n = 45)	<i>P</i> value ^a
Inpatient VAS pain scores, mean (SD)			
POD 0	5.5 (1.8)	5.0 (2.0)	.089
POD 1	4.7 (1.6)	4.5 (2.0)	.542
POD 2	5.6 (1.5)	6.1 (1.7)	.950
Total daily OME consumption, mean (SD)			
POD 0	62.4 (20.2)	59.5 (22.3)	.251
POD 1	58.5 (26.0)	52.9 (25.1)	.360
POD 2	50.6 (16.2)	49.3 (28.2)	.431
Hourly OME consumption, mean (SD)			
POD 0	6.3 (2.5)	5.3 (2.0)	.034
POD 1	3.4 (1.5)	3.0 (1.1)	.084
POD 2	3.3 (1.8)	3.0 (1.4)	.134

Abbreviations: DEPO, patients receiving a local injection of methylprednisolone; NODEPO, patients receiving a control injection of saline; OME, oral morphine equivalent; POD, postoperative day; VAS, Visual Analog Scale.

Boldface indicates statistical significance.

undergoing lumbar discectomy, laminectomy, and/or spine fusion. They randomized patients to receive either methylprednisolone and bupivacaine or a saline injection applied to the surgical site prior to closure. They administered methylprednisolone as an epidural injection, whereas they infiltrated the bupivacaine into the paraspinal muscles and subcutaneous tissues. Patients in the methylprednisolonebupivacaine group reported that their postoperative pain at rest was significantly lower than did those in the control group (mean difference, -4.58; P = .001). Additionally, the cumulative morphine dose during the first 48 postoperative hours was significantly lower in the treatment group than in the placebo group (mean difference, -8.24 mg; P = .01). However, when the authors stratified the data by procedure type, they did not identify

any difference in morphine use between groups for patients who underwent a lumbar fusion (P = .06). These results may suggest that local steroid application may not afford the same benefits in decreasing acute pain or narcotics use for more invasive procedures such as lumbar fusions. The intraoperative steroids may have diminished analgesic effects in patients undergoing a lumbar fusion due to a relatively more invasive procedure compared to a discectomy or laminectomy. This may explain why patients receiving intraoperative steroids had similar pain profiles and narcotic consumption to the control group.

Complications related to administration remain a consideration with routine use of local intraoperative steroids. The most common complications with epidural steroid injections are superficial wound infections and

epidural abscesses; however, these are rare occurrences.10 In the present study, a greater number of complications occurred in the DEPO cohort. These complications included 1 patient with postoperative urinary retention, 2 patients with superficial wound infections, and 1 patient who required a repeat surgery for symptomatic pseudarthrosis. However, this was not a statistically significant association. The aforementioned study by Akinduro et al¹⁸ also investigated complication rates with intraoperative steroid use. Upon meta-analysis, the authors identified a trend toward rates of higher infection (0.94% vs 0.08%, P = .10) and total complication (2.69% vs 1.18%, P = .19) among those receiving intraoperative steroids, although these were not statistically significant. The authors initially thought that this finding was due to a low overall complication rate associated with

^aP values calculated using linear regression controlled for sex.

Table 4. Change in Patient-Reported Outcomes

	NODEPO (n = 48)	DEPO (n = 45)	P value ^a
VAS back change, mean (SD)			
Preoperative	6.5 (2.5)	6.4 (2.6)	.999
6 weeks	-2.5 (2.8)	-3.0 (2.9)	.399
12 weeks	-2.7 (2.9)	-2.9 (3.1)	.807
6 months	-3.6 (3.3)	-2.9 (3.3)	.317
VAS leg change, mean (SD)			
Preoperative	6.5 (2.6)	5.4 (3.1)	.027
6 weeks	-3.4 (2.7)	-3.1 (3.0)	.588
12 weeks	-3.7 (2.6)	-3.5 (3.2)	.518
6 months	-4.3 (2.8)	-3.3 (3.9)	.079
ODI change, mean (SD)			
Preoperative	44.8 (17.2)	40.8 (16.4)	.158
6 weeks	-8.5 (15.0)	-6.5 (20.4)	.550
12 weeks	-11.4 (17.6)	-13.6 (16.0)	.810
6 months	-20.9 (20.2)	-18.7 (17.3)	.422

Abbreviations: DEPO, patients receiving a local injection of methylprednisolone; NODEPO, patients receiving a control injection of saline; ODI, Oswestry Disability Index; VAS, Visual Analog Scale.

Boldface indicates statistical significance.

lumbar discectomy that prevented statistically significant differences. These results, in combination with those of the present study, indicate the need for further investigation to better characterize the relationship between intraoperative steroid use and complication rates for MIS TLIF. Hospital readmission data and closer surveillance of patients following discharge would better capture complications related to epidural steroid injections. Nevertheless, as the current literature is inconclusive, it would be prudent for surgeons to assess the potential risk for complications when considering the use of local intraoperative steroids for MIS TLIF.

In the present study, local corticosteroid injection did not lead to differences in patient reported pain or disability up to 6 months postoperatively. Variable results regarding the association between steroid use and postoperative PROs have been reported in the literature. Ranguis et al⁵ performed a systematic review of 12 randomized controlled trials to evaluate the efficacy of epidural steroids in lumbar spine surgery. Upon meta-analysis, they found that steroid use was associated with decreased radicular pain at 1-2 months postoperatively (mean difference -2.14, P = .002). However, the authors did not identify any differences in back pain at 1-2 months postoperatively between treatment and control groups.

Jirarattanphochai et al19 also investigated postoperative pain and ODI scores among patients undergoing lumbar spine surgery with either local intraoperative steroids or a placebo. Although back pain, leg pain, and ODI scores at 3-month follow-up were reported to be lower in the steroid group, this difference did not reach statistical significance. In relation to our investigation, intraoperative steroid injection did not lead to a more favorable long-term recovery in pain and disability. This may be due to the relatively short period in which steroids have clinical effect. However, further study will elucidate the long-term effects of intraoperative steroid injection as there is conflicting evidence in the literature. This study has several limitations. First,

 $^{{}^{\}mathrm{a}}P$ values calculated using linear regression controlled for sex.

Table 5. Patients Who Achieved Minimum Clinically Important Difference

	No, (%)		
	NODEPO (n = 48)	DEPO (n = 45)	P valueª
ODI	30 (62.5)	25 (55.6)	.413
VAS back	35 (72.9)	28 (62.2)	.280
VAS leg	35 (72.9)	27 (60.0)	.111

Abbreviations: DEPO, patients receiving a local injection of methylprednisolone; NODEPO, patients receiving a control injection of saline; ODI, Oswestry Disability Index; VAS, Visual Analog Scale.

all patients were treated by a single surgeon at our solo institution, which may limit its generalizability. Second, although all patients received a standardized pain regimen on discharge, we were unable to assess acute postoperative pain and narcotics use after the inpatient hospital period. Therefore, we were unable to evaluate differences in pain or narcotics consumption between groups in the immediate postoperative period after hospital discharge. Third, complications occurring between hospital discharge and the 6-week postoperative clinic visit depended on patient reports. However, we asked patients if they experienced any complications during the early convalescent period at their 6-week appointment. This study population reported few complications overall, which may have prevented our ability to detect differences in complication

rates between cohorts. Fourth, although VAS has been proven to be a valid measure of pain,20-22 it does involve potential subjectivity and variability in its application, which may have limited our ability to detect small differences in pain experience between groups. Finally, we were unable to assess long-term outcomes due to limited compliance with PRO survey completion at 1- and 2-year postoperative time points. However, we are engaging in ongoing follow-up to assess for complications after the use of local steroid injections. Further investigation will help to evaluate long-term outcomes associated with local steroid use. Despite these limitations, this study was the first of its kind to assess the efficacy of the local intraoperative steroid use specifically in MIS TLIF through a randomized controlled trial.

CONCLUSIONS

We observed that local corticosteroid application did not lead to decreases in acute postoperative pain or narcotics consumption after MIS TLIF. Additionally, we determined that there was no association between local corticosteroid administration and postoperative improvements in PROs. The findings of this randomized trial suggest that the utilization of local intraoperative steroids may not provide additional benefit in surgical and clinical outcomes following a MIS TLIF. However, additional studies are needed to further assess long-term outcomes and complication risks related to the use of local intraoperative steroids in lumbar fusion procedures. *

References and financial disclosures are available online at www.rush.edu/orthopedicsjournal.

^aP values calculated using Poisson regression with robust error variance controlled for sex.

"One surgical advancement that may offer a solution to some of the complications associated with STS wide resection is the use of a hybrid plasma scalpel rather than traditional Bovie electrocautery."

Reduced Blood Loss With Use of Canady Hybrid Plasma Scalpel Compared With Bovie Electrocautery in the Resection of Soft-Tissue Sarcomas

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INTRODUCTION

As medicine continues to seek increasingly improved outcomes, many fields have developed novel and innovative treatments. The field of orthopedic oncology is no exception to this effort and as a result has seen notable changes in guidelines and research discoveries within the past 10 years, particularly in the treatment of softtissue tumors. Improvements in

multidisciplinary care at large institutions over the years have paved the way for improved surgical treatment options that aim to conserve limb function through an improved understanding of the various histologic subtypes of musculoskeletal tumors.^{1,2}

One of the more common malignancies orthopedic oncologists treat is soft-tissue sarcoma (STS). These tumors are a heterogeneous group that represent a small percentage of cancer diagnoses in the United States, with an incidence of 5 per 100 000 people per year.^{2,3} STS comprises numerous different histopathologic subtypes with varying degrees of aggressiveness. These tumors can vary from low to high grade and are identified most commonly in the extremities and less commonly in axial distribution.3 For many patients with STS, wide resection techniques offer curative treatment, often with adjuvant or neoadjuvant radiation treatment, depending on initial biopsy findings.3 With current advances in the surgical

resection of STS, improved radiation techniques, and the increasing use of limb salvage surgery, many patients have had improved functional outcomes.⁴

Despite these great advances, wide resection of STS still presents marked secondary causes of morbidity. The main complications associated with surgical treatment of STS are blood loss and wound complications, especially in cases with preoperative and/or postoperative radiotherapy.5 Study results have shown that wound complications, including wound dehiscence, surgical site infections, hematomas, seromas, and necrosis, can occur in 16% to 56% of cases.6,7 Furthermore, wide resection is associated with notably more blood loss than are marginal resections in the removal of malignant musculoskeletal tumors.8

One surgical advancement that may offer a solution to some of the complications associated with STS wide resection is the use of a hybrid plasma

Table 1. Patient Demographic Characteristics and Baseline Operative Information Compared Across Cohorts

Parameter	Bovie (n = 97)	Plasma (n = 40)	P Value
Female, No. (%)	53 (54.6)	18 (45)	.350°
Age at primary operation, y (SD)	54.86 (19.71)	55.95 (19.35)	.768 ^b
Tumor location, No. (%)			
Lower extremity	68 (70.1)	29 (72.5)	1.000°
Upper extremity	24 (24.7)	10 (25.0)	
Axial	4 (4.1)	1 (2.5)	
Upper extremity/axial	1 (1.0)	0 (0)	
Procedure type, No. (%)			
Wide/limb salvage	81 (83.5)	32 (80.0)	.865ª
Other	8 (8.3)	4 (10.0)	
Amputation	7 (7.2)	4 (10.0)	
Marginal resection	1 (1.0)	0 (0)	
Superficial lesion (vs deep), No. (%)	25 (25.8)	9 (22.5)	.829ª
Lesion size, cm (SD)	14.64 (6.88)	15.92 (8.15)	.383⁵
Primary closure, No. (%)	79 (84.4)	32 (80.0)	.814ª

^aResults from Fisher exact test.

scalpel rather than traditional Bovie electrocautery. The Canady Hybrid Plasma Scalpel (CHPS) is a unique surgical tool that is capable of cutting and coagulating tissue simultaneously through its application of combined electrocautery and inert argon plasma.9 Because of these features, the CHPS may offer hemostasis during surgery that is superior to that of traditional electrocautery and other perioperative methods, including bipolar sealer, antifibrinolytics, and hemostatic agents. For example, in patients who underwent direct anterior total hip arthroplasty, those whose operation included the CHPS demonstrated significantly smaller decreases in postoperative blood hemoglobin levels and measured blood loss than those in which the surgeon used bipolar sealer.9 Other applications of the CHPS demonstrated thermal properties of sterilization and coagulation that were the same as or

superior to that of Bovie electrocautery but without the damage to normal healthy tissue.¹⁰

In addition, surgeons have expressed interest in using the CHPS for its therapeutic anticancer properties in the resection of solid tumor masses. The CHPS can apply inert argon gas as cold atmospheric plasma (CAP), now considered a major therapeutic option for the treatment of solid tumor masses. Specifically, CAP selectively eradicates various types of cancer cells, including lung, bladder, and hepatocellular carcinomas, as well as brain and other head and neck cancers, both in vitro and in vivo, without damaging nearby healthy cells.11,12 CAP may be able to eradicate cancer cells selectively by preferentially targeting rapidly dividing cells by deregulating genes responsible for reactive oxygen species (ROS) metabolism and oxidative stress response.13 Although some study results

have demonstrated that the CHPS offers a therapeutic advantage over traditional electrocautery in the resection of various solid tumors, whether these advantages apply to the outcomes of patients with STS is currently unknown.

The primary purpose of this retrospective study was to compare the outcomes of patients with STS who underwent resection with either Bovie electrocautery or the CHPS. We hypothesized that patients who undergo STS wide resection with the CHPS would have less blood loss, shorter operative time, and lower rates of wound complications and local recurrence than would patients who underwent STS wide resection with Bovie electrocautery. Our secondary outcomes were to review the diseaserelated outcomes in both groups, including local recurrence, metastases, and overall survival.

^bResults from *t* test.

METHODS

The Rush Institutional Review Board approved this study before commencement. We obtained data obtained retrospectively through the medical charts of 137 patients who underwent resection of an STS during 2010 through 2018. The patient population consisted of 2 cohorts—97 patients who underwent resection by means of Bovie electrocautery during the period from 2010 through 2015 and 40 patients who underwent resection by means of the CHPS after 2015. We examined multiple data points for every patient at the time of surgery, including baseline demographic characteristics, procedure type, duration of operation, type of scalpel used, intraoperative blood loss, amounts and types of blood products transfused, size of lesion, depth of lesion, type of wound closure, and histopathologic findings. Secondary outcome measures included development of local recurrence, development of metastasis, need for adjuvant therapy after primary surgery, duration of operation, hematoma formation, seroma formation, surgical

site infection, fatality, negative margins, blood products transfused, adjuvant therapy after primary surgery, and development of wound complications. The primary outcome measure was intraoperative blood loss.

For the univariate analysis, we used the Fisher exact test for categorical variables and a t test for continuous variables. We used regression analysis to evaluate the primary outcome measure, intraoperative blood loss. We had considered logistic and linear regression analyses for the secondary outcome measures, but they were not fruitful, so we used univariate analysis. We performed all analyses using Stata/IC 14.2 (StataCorp LLC; College Station, Texas) and set significance at α of .05.

RESULTS

We compared patient demographic characteristics and baseline operative information across the CHPS and Bovie cohorts; the 2 cohorts were equivalent on all noted baseline variables, as shown in Table 1. Therefore, we consider the 2 cohorts to be comparable.

We compared the secondary outcome measures by using univariate analysis; we found that the 2 cohorts were not statistically different according to any of these measures, as shown in Table 2. Specifically, the length of surgery was not statistically different, with the average Bovie cohort operation lasting almost 91 minutes and the average plasma cohort operation lasting more than 95 minutes (P = .74). Also, 9 (9.4%) of 96 patients in the Bovie cohort and 1 (2.5%) of 40 patients in the plasma cohort (P = .28) had surgical site infection; 8 (8.3%) patients in the Bovie cohort and 1 (2.5%) in the plasma cohort (P = .28) had seroma formation; 11 (12.1%) patients in the Bovie cohort and 5 (12.5%) in the plasma group developed a local recurrence (P = 1.00); and 30 (34.1%) patients in the Bovie cohort and 9 (22.5%) in the plasma group developed metastasis (P = .22).

For the primary outcome measure, intraoperative blood loss, we used a linear regression, as shown in Table 3; we used the length of the operation and the size of the lesion as confounding factors. We also incorporated a second-

Table 2. Secondary Outcome Measures Compared Across Cohorts

Outcome Measure	Bovie (n = 97)	Plasma (n = 40)	P Value
Wound complications, No. (%)	22 (22.9)	7 (17.5)	.646ª
Seroma formation, No. (%)	8 (8.3)	1 (2.5)	.282ª
Hematoma formation, No. (%)	4 (4.2)	3 (7.5)	.419ª
Surgical site infection, No. (%)	9 (9.4)	1 (2.5)	.280ª
Metastasis, No. (%)	30 (34.1)	9 (22.5)	.218ª
Local recurrence, No. (%)	11 (12.1)	5 (12.5)	1.000°
Fatality, No. (%)	9 (9.8)	5 (12.5)	0.759ª
Negative margins, No. (%)	92 (94.8)	38 (95.0)	1.000°
Blood products received, No. (%)	22 (22.7)	8 (20.0)	.823ª
Adjuvant therapy after primary surgery, No. (%)	60 (61.9)	22 (55.0)	.151°
Duration of operation, min (SD)	90.98 (68.85)	95.18 (62.41)	.740 ^b

^aResults from Fisher exact test.

 $^{{}^{\}mathrm{b}}\mathsf{Results}$ from t test.

Table 3. Regression Analysis of Primary Outcome (Intraoperative Blood Loss)^a

Variable in Regression	Coefficient	P Value	95% CI
Duration of operation	1.05	< .001	0.58-1.53
Duration of operation squared (second-order term)	-0.17	.006	-0.200.03
Use of CHPS	-0.75	< .001	-1.120.38
Size of lesion	0.08	< .001	0.05-0.11
Constant	2.69	< .001	2.13-3.24

^aThis regression was log-transformed so the dependent response variable was the natural logarithm of blood less (Inblood loss). Abbreviations: CHPS, Canady Hybrid Plasma Scalpel; CI, confidence interval.

order factor for length of surgery because of the nonlinear relationship between operation duration and blood loss. The assumption of normality of residuals was not valid; therefore, we used a logarithmic transformation, and the resulting logarithmic-linear model is valid. From this model, we can conclude that the use of the CHPS reduced blood loss by 52.9% (95% CI: 31.8%-67.4%; P < .001) (Figure). Assuming the average operation duration and lesion size, this difference equates to an approximately 95-mL reduction in operations with the CHPS in our data set.

DISCUSSION

With an incidence of 5 per 100 000 people per year, STS account for only 1% of all cancer diagnoses yearly.^{3,14} Overall, STS comprises more than 50 different histologic subtypes and can vary from low to high grade.1 High-grade lesions can be associated with a mortality rate of 40% to 60%.15 Most patients have tumors diagnosed in the extremities and less frequently in the trunk, retroperitoneum, and head and neck areas, and most have a clinical presentation of a painless, gradually enlarging mass.3 With better understanding of the various histologic subtypes and their natural history, the recognized consensus for treatment of these musculoskeletal tumors is first to biopsy the tumor and, if histopathologic diagnosis does not demonstrate the tumor to

be high grade, the recommendation is to proceed to with wide surgical resection.³ Over the years, the trend toward limb salvage surgery in the treatment of STS has led to increased functional outcomes in many patients. Although many patients have been successfully treated, some patients who undergo wide surgical resection still experience significant morbidity in the form of blood loss, prolonged hospital stays, and wound complications.

Many medical disciplines, including orthopedics, have turned to newer methods to improve intraoperative hemostasis; in some instances, the CHPS was superior for the control of blood loss⁹. When compared with bipolar sealer and traditional Bovie electrocautery, the CHPS significantly reduced blood loss intraoperatively when measured through both hemoglobin and hematocrit levels and actual counted blood loss. Furthermore, the authors found that the CHPS significantly reduced the length of operations when compared with the other hemostatic methods measured, which may mirror any intraoperative complications, including hemostasis control.

Patients in this study who underwent STS wide resection with the CHPS lost significantly less blood than did those who underwent resection with Bovie electrocautery, as measured by estimated intraoperative blood loss. Increased perioperative blood loss in

orthopedic and oncologic surgery is well known to increase mortality and morbidity.16 Perioperative blood transfusion in cancer resection also has been associated with worse outcomes and increased risk of disease recurrence because of the immunosuppressive nature of allogeneic products.^{17,18} Therefore, the ability of the CHPS to significantly reduce perioperative blood loss in patients undergoing STS wide resection should translate to improvements in some secondary outcomes, including length of stay and mortality from major noncardiac operations; however, we did not confirm this finding in our study, possibly because of the limited sample size.

Although our study's results did not show any statistically significant difference in overall complication rates, we saw a decreased percentage of wound complications, seromas, and surgical site infections in the CHPS group.

The CHPS can offer many other benefits besides improved hemostasis in patients undergoing surgery for musculoskeletal tumors. The application of inert argon gas from the CHPS (ie, CAP) can induce preferential malignant necrotic cell death, leading to the recently recognized field of plasma oncology. Pesults from 1 study showed that CAP can both target cancer cells and reduce tumor size in various cancer cell

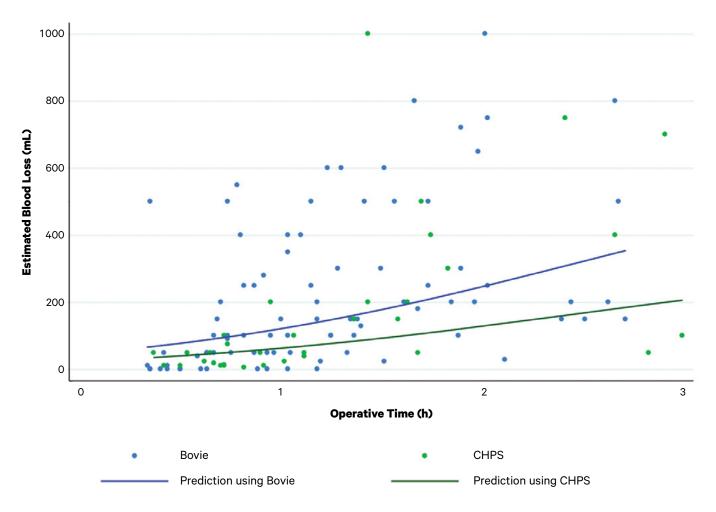


Figure. Estimated Intraoperative Blood Loss Comparison Between Bovie Electrocautery and Canady Hybrid Plasma Scalpel (CHPS)

lines, including lung, bladder, skin, and brain and other head and neck cancers, suggesting that application of CAP offers a major paradigm shift in the surgical treatment of cancer.12 Volotskova et al¹³ hypothesized that CAP is able to eradicate cancer cells selectively by preferentially targeting rapidly dividing cells and deregulating key genes in malignant cells that are responsible for ROS metabolism and the oxidative stress response. Tumor cells at baseline are under increased oxidative stress because of the increased gene activation and cell division; investigators in 2 studies19,21 have hypothesized that this characteristic makes them more

vulnerable to the additional exposure to oxidants, in this case CAP-induced increase of ROS. Although our study's results did not show any statistically significant difference between the rates of local recurrence, metastases, or survival in the comparison of the Bovie electrocautery cohort and the CHPS cohort, the CHPS group had a decreased percentage of metastases.

CONCLUSION

The purpose of this study was to investigate whether the CHPS improves outcomes in patients undergoing resection of STS. Overall, we showed that the CHPS was associated

significantly with reduced blood loss intraoperatively. Both groups had similar rates of transfused blood products and postoperative complications, including wound infections, seromas, and metastases. Future studies with increased sample sizes are needed to determine whether there are beneficial effects of the CHPS in the treatment of STS. Future studies of CAP treatment of sarcoma at the molecular level also may be beneficial to understanding the potential benefits of treatment with the CHPS. *

References and financial disclosures are available online at www.rush.edu/orthopedicsjournal.

"...each class [of surgery] needs to be assessed for the presence of the July effect to understand its influence on those procedures."

The July Effect in Hand Surgery

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INTRODUCTION

At teaching hospitals throughout the nation, July marks the start of the new academic year. This period often involves a sharp transition of trainee roles: medical students to interns, junior residents to senior residents, and senior residents to fellows. The so-called July effect is the popularized theory that patients in teaching hospitals have inferior outcomes in July due to the transition of trainee roles. Studies have found evidence of the July effect within internal medicine with regard to myocardial infarction in high-risk patients,1 medication error,2 mortality,3 and diagnostic and pharmaceutical charges.4 No July effect has been found for the intensive care unit⁵ or for neonatal mortality.⁶

Within the surgical field, Anderson et al⁷ demonstrated a 12% greater relative risk of mortality for elderly patients with hip fractures who were treated in teaching hospitals compared

with those treated in nonteaching hospitals, suggesting the presence of a July effect. However, this study did not look at month-to-month variation to adequately control for more patients with more complex cases in teaching hospitals. Nandylaya et al⁸ demonstrated that, for anterior cervical fusion, patients undergoing surgery in July at teaching institutions had a greater length of stay and demonstrated increased rates of postoperative thromboses, surgical site infection, and dysphagia. Other studies have refuted the July effect, specifically for cardiac and abdominal surgery,9 elective spine surgery, 10 surgery for adjacent idiopathic scoliosis,11 total shoulder arthroplasty,12 total knee and hip arthroplasty,13 and pediatric neurosurgery.14

The variability in the literature with regard to the existence of the July effect in the surgical field suggests that this effect may be procedure dependent. There are no published data reporting on the existence of a July effect in hand surgery. Such an effect, if present, would be important to identify so as to bridge educational gaps that may be affecting outcomes. Additionally, an understanding of the presence or lack of a July effect in hand surgery would help surgeons counsel patients who inquire about the influence of trainee involvement. The purpose of this study was to determine

if there is an increased risk of adverse events for patients undergoing hand surgery with trainee (resident/fellow) involvement within the early part of the academic year.

MATERIALS AND METHODS

We used the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database for this study. This database contains multicenter, prospectively collected data that track surgical outcomes and adverse events during the first 30 postoperative days, from more than 600 hospitals.15 We identified patients who underwent hand or wrist surgical procedures between 2005 and 2016 on the basis of 208 Current Procedural Technology (CPT) codes that have previously been determined as representative of hand, wrist, and forearm surgeries in the NSQIP database.16 This study was granted an exemption by our institutional review board as all data were deidentified.

We stratified cases on the basis of whether or not a trainee was involved in the treatment of the patient, according to standard NSQIP documentation. We also categorized patients as presenting in the first academic quarter (July, August, or September) or in the rest of the academic year, in accordance with multiple prior studies investigating

the July effect.5,10,12,13 We characterized preoperative demographics and comorbidities, including age, body mass index, American Society of Anesthesiologists (ASA) class, gender, functional dependence vs independence, diabetes, dyspnea on exertion, hypertension, chronic obstructive pulmonary disease, smoking, and anemia. Additionally, we looked at and characterized individual adverse event rates, including death, surgical site infection, wound dehiscence, pneumonia, deep vein thrombosis, pulmonary embolism, unplanned intubation, acute kidney injury, urinary tract infection, stroke, coma, peripheral nerve injury, cardiac arrest, myocardial infarction, anemia requiring transfusion, sepsis, and return to the operating room. We then evaluated the total adverse rate.

We performed statistical analysis with Stata MP 14.1 (StataCorp LLC; College Station, Texas). We used t tests and Pearson χ^2 tests for continuous and categorical variables, respectively, to compare patient demographics

and comorbidities between trainee cases and nontrainee cases, as well as between first academic quarter cases and cases performed during the remainder of the academic year. We also used *t* tests to compare total adverse event rates between trainee and nontrainee cases, as well as between cases occurring in the first academic quarter and the remainder of the academic year to detect any differences in total adverse event rates when not controlling for patient characteristics and surgical procedure. We used multivariate Poisson regressions¹⁷ with robust error variance, controlling for baseline patient characteristics and surgical procedure, to generate relative risks in comparing total and individual adverse event rates between trainee and nontrainee cases, as well as between cases performed in the first academic quarter and those performed during the rest of the academic year.

We assessed the July effect on the basis of the significance of the relative risk of an interaction term between trainee involvement and first academic quarter variables within the regression, while also including trainee involvement and first academic quarter variables within the regression individually. Thus, the interaction term represents the interaction between trainee involvement and the first academic quarter, controlling for the effects of both trainee involvement and first academic quarter. The rationale behind this is that if a July effect exists for a given adverse event, the effect of trainee involvement within the first academic quarter would be notable over and above the effect of trainee involvement and first academic quarter alone. In other words, a true July effect exists if the adverse event rate is higher for trainees in the first academic quarter than the adverse rate for trainees or the first academic quarter alone.

RESULTS

A total of 3613 patients met inclusion criteria for this study. Of these, 38.2% of cases had trainee involvement, 26.5% cases were performed in the first academic quarter, and 11.5% of cases

Table 1. Patient demographics and comorbidities among cases with and without trainee (resident/fellow) involvement

	Trainees (n = 2233)	No trainees (n = 1380)	P value
Age, mean (SD), y	53.9 (17.8)	54.4 (16.8)	.332
Body mass index, mean (SD), kg/m²	28.5 (6.5)	28.8 (7.4)	.140
ASA Class, points	2.2 (0.7)	2.3 (0.7)	.002
Female, No. (%)	1286 (57.6)	746 (54.1)	.040
Functional dependence, No. (%)	118 (5.3)	100 (7.3)	.013
Diabetes mellitus, No. (%)	180 (8.1)	136 (9.9)	.071
Dyspnea on exertion, No. (%)	118 (5.3)	85 (6.2)	.254
Hypertension, No. (%)	877 (39.3)	545 (39.5)	.017
Chronic obstructive pulmonary disease, No. (%)	80 (3.6)	48 (3.5)	.055
Current smoker, No. (%)	558 (25.0)	430 (31.2)	.010
Anemia, No. (%)	451 (20.2)	357 (25.9)	<.001

Abbreviation: ASA, American Society of Anesthesiologists.

Table 2. Patient demographics and comorbidities among cases performed during the first academic quarter vs cases performed during the rest of the year

	Rest of the academic year (n = 2654)	First academic quarter (n = 959)	P value
Age, mean (SD), y	54.2 (17.5)	53.9 (17.3)	.629
Body mass index, mean (SD), kg/m²	28.6 (6.8)	28.8 (7.1)	.432
ASA Class, points	2.2 (0.7)	2.2 (0.7)	.720
Female, No. (%)	1491 (56.2)	539 (56.3)	.945
Functional dependence, No. (%)	153 (5.8)	64 (6.7)	.354
Diabetes mellitus, No. (%)	244 (9.2)	72 (7.6)	.138
Dyspnea on exertion, No. (%)	153 (5.8)	50 (5.3)	.578
Hypertension, No. (%)	1043 (39.3)	378 (39.5)	.904
Chronic obstructive pulmonary disease, No. (%)	98 (3.7)	29 (3.1)	.389
Current smoker, No. (%)	639 (24.1)	213 (22.3)	.271
Anemia, No. (%)	602 (22.7)	206 (21.5)	.430

Abbreviation: ASA, American Society of Anesthesiologists.

both had trainee involvement and were performed in the first academic quarter.

Cases with trainee involvement had a higher ASA class (2.3 vs 2.2; P = .002), a higher proportion of patients who were functionally dependent (7.3% vs 5.3%; P = .013), a higher proportion of patients with hypertension (39.5% vs 39.3%; P = .017), a higher proportion of patients with anemia (25.9% vs 20.2%; P < .001), a lower proportion of females (54.1% vs 57.6%; P = .040), and a lower proportion of current smokers (21.3% vs 25.0%; P < .001) (Table 1). There were no differences in patient demographics or comorbidities between patients whose surgeries were performed in the first academic quarter and those whose surgeries were performed during the rest of the academic year (Table 2).

The interaction term in the multivariate model had no statistically significant association with the occurrence of adverse events (relative risk, 0.83; 95% confidence interval, 0.43-1.61; P = .590), suggesting that there was no effect on adverse event incidence from trainee involvement within the first

academic quarter over and above the effect of trainee involvement and first academic quarter alone. Similarly, the interaction term had no statistically significant association with each individual adverse event (P > .05) (Table 3). When we did not control for baseline patient characteristics and surgical procedure, trainee cases compared to nontrainee cases were associated with a statistically significantly increased total adverse event rate (6.09% vs 2.82%, P < .001). In the multivariate model, when we adjusted for baseline patient characteristics and surgical procedure without the interaction term or first academic quarter variable, trainee involvement had no statistically significant association with the total adverse event rate, suggesting no difference in adverse event incidence when trainee were involved than when they were not (relative risk, 1.38; 95% confidence interval, 0.99-1.94; P = .059). When we did not control for baseline patient characteristics and surgical procedure, there was no statistically significant difference in total adverse

event rate between cases performed in the first academic quarter compared with those performed during the rest of the academic year (4.80% vs 3.81%, respectively; P = .183). In the multivariate model, when we adjusted for baseline patient characteristics and surgical procedure without the interaction term or trainee variable, there was no statistically significant association between first academic quarter and total adverse event rate (relative risk, 1.38; 95% confidence interval, 0.99-1.92; P = .055).

DISCUSSION

The July effect has been shown to exist in various aspects of both medical and surgical specialties. ^{1,4,7,8} This effect has at the same time been refuted for several different types of surgical procedures. ⁹⁻¹⁴ The variable presence of this effect in the literature suggests its specificity to certain classes of surgery; each class therefore needs to be assessed for the presence of the July effect to understand its influence on those procedures.

In this study of nationwide data, we could not support the presence of the July effect in hand, wrist, and forearm surgery. This finding is based on the lack of statistical significance of the interaction terms between academic quarter and trainee involvement in the multivariate analyses.

The lack of July effect found in our study was similar to prior studies investigating cardiac and abdominal surgery, 9 elective spine surgery, 10

surgery for adjacent idiopathic scoliosis,¹¹ total shoulder arthroplasty,¹² total knee and hip arthroplasty,¹³ and pediatric neurosurgery.¹⁴ This may be explained by attending hand surgeons having a sense of expected trainee capabilities that are based on training level. Attending surgeons are likely to be effective at supervising the trainees and allowing appropriate autonomy.

For cases in which there was trainee involvement, there was an overall

statistically significant higher proportion of medical comorbidities compared with those without trainee involvement. This trend possibly contributes to the increased overall adverse event rate for cases with trainee involvement throughout the year compared with cases without trainee involvement, a finding also seen in similar studies. 10,13 When we did not control for patient characteristics and surgical procedure, there was a statistically significant increase in

Table 3. The July effect in hand, wrist, and forearm surgery

	Adverse event rate, No. (%)									
	Rest of year (N = 2654)		First academic quarter (N = 959)		Interaction term ^{a,b}					
	No trainees (n = 1688)	Trainees (n = 966)	No trainees (n = 545)	Trainees (n = 414)	RR	95% CI	<i>P</i> value			
Total adverse event rate	42 (2.49)	59 (6.11)	21 (3.85)	25 (6.04)	0.83	0.43-1.61	.590			
Individual adverse event rates										
Death	5 (0.3)	9 (0.93)	5 (0.92)	4 (0.97)	0.49	0.05-4.75	.539			
Surgical site infection	18 (1.07)	20 (2.07)	7 (1.28)	8 (1.93)	0.97	0.28-3.39	.968			
Wound dehiscence	4 (0.24)	2 (0.21)	3 (0.55)	1 (0.24)	0.45	0.04-4.46	.492			
Pneumonia	3 (0.18)	4 (0.41)	4 (0.73)	2 (0.48)	1.06	0.09-12.86	.964			
Deep vein thrombosis	4 (0.24)	3 (0.31)	0 (0)	0 (0)	-	-	-			
Pulmonary embolism	0 (0)	2 (0.21)	0 (0)	0 (0)	-	-	-			
Unplanned intubation	4 (0.24)	10 (1.04)	6 (1.1)	8 (1.93)	0.98	0.16-6.15	.983			
Acute kidney injury	2 (0.12)	2 (0.21)	1 (0.18)	1 (0.24)	2.99	0.06-149.40	.584			
Urinary tract infection	5 (0.3)	4 (0.41)	2 (0.37)	2 (0.48)	1.95	0.19-20.18	.575			
Stroke	0 (0)	0 (0)	0 (0)	3 (0.72)	-	-	-			
Coma	0 (0)	0 (0)	1 (0.18)	1 (0.24)	-	-	_			
Peripheral nerve injury	2 (0.12)	0 (0)	0 (0)	0 (0)	-	-	_			
Cardiac arrest	1 (0.06)	3 (0.31)	0 (0)	2 (0.48)	-	-	-			
Myocardial infarction	2 (0.12)	0 (0)	0 (0)	0 (0)	-	-	-			
Anemia requiring transfusion	3 (0.18)	13 (1.35)	0 (0)	4 (0.97)	-	-	-			
Sepsis	6 (0.36)	6 (0.62)	4 (0.73)	3 (0.72)	0.89	0.16-4.99	.894			
Return to operating room	0 (0)	8 (0.83)	0 (0)	1 (0.24)	_	_	_			

Abbreviations: CI, confidence interval; RR, risk ratio.

^aStatistical significance of the interaction term within the multivariate analysis represents the presence of a July effect, the additional effect of trainee involvement within the first academic quarter over and above the effect of trainee involvement or first academic quarter alone.

bStatistical analysis could not be performed when there were no adverse events occurring in 1 or more of the 4 groups.

total adverse event rate in trainee cases. However, in the multivariate analysis, when we controlled for patient demographics, comorbidities, and surgical procedure, trainee involvement had no statistically significant effect on adverse event rate, although the *P* value did approach .05. This finding supports the theory that teaching hospitals tend to have sicker, more complex patients than do nonteaching hospitals, which contributes to the increased adverse event rate.

Moreover, patients at teaching hospitals may have additional complexities that are not accounted for by the demographic variables and comorbidities included in this study. For example, for a given CPT code, patients referred to an academic center may have a more complex variant of a given condition (eg, a more intricate fracture pattern, a more advanced stage of a disease with deformity) that can lead to a more difficult surgery and higher complication/repeat surgery rate.

This pattern supports the need for studies of the July effect or the impact of trainee involvement on patient outcomes to control for medical comorbidities and demographic

variables, because there may be a powerful selection bias favoring cases with trainees. However, if in fact trainee involvement does lead independently to a greater risk of adverse events, further studies also should be directed at identifying which clinical scenarios pose the greatest risk. This would allow educators and trainees alike to be aware of the risks and to be able to minimize them. It is important to recall that a true July effect does not imply worse outcomes when trainees are present; rather, it implies worse outcomes when trainees are present at the start of the year.

A limitation of this study involves the postoperative duration of tracking complications for 30 days. It is possible that certain important postoperative complications would not be captured in this period, such as malunion, nonunion, range of motion, postoperative function, and repeat surgery. Another limitation involves the inability to determine the level of trainee participation within a case, because having a trainee perform key portions of the procedure may have a different effect compared with having a trainee retract for the majority of the

procedure. Further study prospectively following patients undergoing hand, wrist, and forearm surgery at a single institution where trainee involvement and postoperative function are better characterized may help elucidate further whether the July effect actually exists. For any surgical discipline, it is also critical to monitor the effects of trainees on not only postoperative outcomes but also on intraoperative metrics. Further study that reports data on intraoperative complications would also be very useful for learning the full effect of trainees on patient care.

In conclusion, the present study could not produce evidence of a July effect in hand, wrist, or forearm surgery. Attending surgeons hold ultimate responsibility for the safety and quality of any procedure, regardless of the month in which it is performed. Patients can schedule elective hand, wrist, or forearm surgery at teaching hospitals during the first academic quarter with reassurance that there is no evidence of a July effect. *

References and financial disclosures are available online at www.rush.edu/orthopedicsjournal.

Continued from page 3

New treatment for stiff necks.

Frank Phillips, MD, served as a principal investigator for a trial on the new M6-C artificial cervical disc, which was recently approved by the U.S. Food and Drug Administration as an alternative to spinal fusion. The disc can help ease neck or arm pain due to cervical disc degeneration.

Leading conferences in 2019. Kern

Singh, MD, was chair of the Society for Minimally Invasive Spine Surgery national meeting. **Grant E. Garrigues, MD,** served as co-chair of the shoulder section for the International Consensus Meeting on Periprosthetic Joint Infection. **Frank Phillips, MD,** was the keynote speaker at the Japanese Orthopaedic Association annual meeting. And **Bernard R. Bach, Jr, MD,** was selected as The Ohio State University College of Medicine Michael J. Patzakis Lecturer.

Tackling the opioid crisis. Two recent studies by **Denis Nam, MD, Tad Gerlinger, MD, Craig J. Della Valle, MD,** and others explored opioid prescribing for patients undergoing a hip or knee replacement. One study published in

Journal of Arthroplasty found many patients did not report their opioid use to their surgeons prior to surgery. A second study found that many patients receive more opioid pills than they need after surgery and can receive the same pain relief with fewer pills. *



Of Equines and Elbows

Robert W. Wysocki, MD, and Anna Plaas, PhD, are building on discoveries about a crippling disease in horses to unlock the mysteries of tendinopathy in humans

Shortly after connective tissue researcher Anna Plaas, PhD, arrived at Rush in 2007, she was presented with an unusual request. Jorge O. Galante, MD, DMSc, world-renowned joint replacement surgeon and founding father of the Department of Orthopedic Surgery, expressed a desire to generate basic research on tendinopathy—but not on human disease.

"Jorge mentioned his interest in degenerative suspensory ligament desmitis (DSLD), a severely debilitating connective tissue disease in horses," Plaas explains. "Jorge owned a stable of Peruvian Paso horses, and DSLD is highly prevalent in that breed." Galante, who passed away in 2017, brought tissue samples to Rush; Plaas, together with her husband and longtime collaborator John Sandy, PhD, bioengineer Vincent Wang, PhD, and their graduate students, evaluated the tissues using histological, biochemical, and molecular biological technologies.

"We discovered that as part of the degeneration of the tendons and ligaments in those horses, plaques with fibrocartilage-like appearance had infiltrated those tissues. We called them 'chondroid deposit' and hypothesized that they were generated by progenitor cells (stem-cells in adult tissues) that were wrongly activated during the

normal wear and tear of the limbs during the horses' lifetimes," Plaas says.

At that same time, she and Sandy were working on skin wound-healing with a knockout mouse that lacked a protein that regulates the formation and removal of such chondroid matrices during the wound-closing stages.

They had noticed that this strain of mice did not repair the wounds, but instead developed chronic retention of chondroid deposits not only in their skin wounds, but also spontaneously in their tendons and ligaments. At all levels, these deposits were identical to those seen in the DSLD-affected horses; clearly, it was not a coincidence.

From a functional perspective, both the horses and mice had difficulty using the affected limbs due to stiffness and pain. "These symptoms are obviously what you see in human tendon disease as well, so we wondered whether chronic accumulation of chondroid deposits also occurred in people with chronic tendinopathies," Plaas says. "That's when Jorge said we needed to get an orthopedic surgeon involved in our research." And he knew exactly which one would be interested in delving deeper into the science of tendon healing.

A CLINICAL ISSUE WITH NO ANSWERS

Hand, wrist, and elbow surgeon Robert W. Wysocki, MD, sees a lot of patients with lateral epicondylitis (LE), a tendinopathy injury that causes pain and tenderness at the prominence on the outer part of the elbow. A poorly misunderstood condition—it does not appear to be an overuse injury and many patients experience spontaneous onset—it often strikes adults in their prime.

"For patients I sometimes liken it to a stress fracture of the tendon. You get these microscopic tears at the origin of the tendon," Wysocki says. Unfortunately, there are no good solutions. Surgical outcomes are mixed and unpredictable. Conservative modalities—including cortisone injections, ultrasound, transcutaneous electrical therapy, iontophoresis, and physical and occupational therapy—have proven ineffective. Even over-the-counter remedies such as NSAIDs have no proven efficacy in reversing or stopping the progression of the tendon degeneration. In fact, a published research study carried out in collaboration with a Rush orthopedic fellow, Adam Bitterman, DO, showed that administering oral ibuprofen in mice with Achilles tendinopathy was actually detrimental to healing.

That's not surprising, given that tendinopathy—including LE—is not a chronic inflammatory condition. So what *does* cause LE, and which treatments *can* help? The answers, it seemed, might be found at the bench. With Wysocki on board, bringing clinical observations and tissue samples, the team submitted a grant application and received funding to do more research on this problem.



In her lab, Plaas, Jun Li, MD (left), and Eric Quan Sheng, PhD, have been studying the mechanism of soft tissue repair after injuries.

WHEN GOOD CELLS GO BAD

"We found that with human LE, instead of the normal fibrogenic response of reconstituting normal tendon tissue, you get an abnormal metaplastic response of chondrogenesis—similar to what we observed in the equine and mouse models," Wysocki says.

The reason for this abnormal response may be as simple as the air we breathe.

Progenitor cells aid in the healing of all connective tissue in adults; following an injury or overuse of the tissue, they are activated by inflammatory signals to migrate to the site of damage and then become different types of cell—tendon, bone, cartilage, skin—based on the type of tissue that needs repair.

But the signals can go awry. The issue in tendinopathy appears to be that a low-oxygen environment (also known as "hypoxia") in injured tendons fools the progenitor cells into thinking they are supposed to generate cartilage rather than tendon tissue. "Repair is an energy-consuming process, and this is largely derived from intake of glucose by the repair cells, and with the help of oxygen converted into the needed metabolic energy supply. Our data suggest that persistent hypoxia in the tendons may be responsible for converting the high glucose load into abnormally high amounts of chondroid matrix by the progenitor cells, and ultimately tricking them into maintaining a stiff fibrocartilagelike environment instead of regenerating the collagen-rich elastic tendon tissue with lots of tensile strength," Plaas explains.

Over time, the chondroid deposits disrupt the tendons' mechanical properties, making them prone to more injury, inflammation, and repair attempts—each leading to further chondroid formation during healing attempts. "Eventually, the original tendon becomes overgrown by this poor-quality tissue and can no longer

function in keeping the joint moving without pain," Wysocki says. "We see this in many different joints, including the hip, shoulder, heel, knee, and of course elbow."

TARGETING THERAPIES

The team postulated that stopping chronic chondroid deposition with early intervention can help the tendon to properly heal. They have been studying an approach that targets hyaluronan—one of the first molecules progenitor cells secrete at the injury sites. Hyaluronan is also used by cells to provide the scaffold into which they deposit chondroid and eventually form cartilage, so disrupting the scaffold to prevent chondroid deposition should signal the repair cells toward regenerating tendon. The team is utilizing an injectable protein, rHuPH20, a recombinantly produced enzyme that destroys hyaluronan in the tissue, and which is already FDAapproved for aiding chemotherapy in cancer patients.

"We have developed a model of Achilles tendinopathy in mice, and we can stage our model to early inflammation, the repair attempt phase, and then the point at which it either heals or becomes chronically defective," Plaas says. "We found that injecting recombinant hyaluronidase at the site of damage shortly after the first inflammatory phase recedes was very effective in preventing chronic chondroid accumulation. Furthermore, after the injection, swelling in the tendon was reversed, and its mechanical properties were restored very quickly, leading to more rapid and complete healing." The results of that study will be published in a special issue of the Journal of Orthopedic Research on Novel Therapies for Tendon Diseases.

Ongoing studies include injections of FDA-approved hyaluronan formulations, alone or in combination



Wysocki's research partnership with Plaas will potentially lead to better treatments for patients with lateral epicondylitis and other conditions.

with platelet-rich plasma (PRP), to induce better vascularization and enhanced oxygen supply to promote fibrogenic (tendon) instead of chondrogenic (chondroid) repair tissue formation. Due to promising results in the early stages of this work, it can be speculated that other therapies that stimulate oxygen supply, and/or normalize glucose-derived energy metabolism in the progenitor cells during the early healing phases, might improve tissue repair and prevent future injuries.

"As Anna and her group continue to expand basic mechanistic and therapeutic studies on tendinopathy in the mouse model, this is a ripe area for translatability from bench to bedside to determine the optimal interventions in progressive tendon diseases," Wysocki says. "Especially with our work showing that hypoxia may even play a role in epigenetic modifications that affect gene activity, it makes sense to refine treatments that can improve blood supply and oxygenation before tendon progenitor cells become locked into a chondrogenesis mode."

THE FRUITS OF COLLABORATION

While it's still too early to say which specific biologic therapies may help LE patients, and at which stages of injury and healing they should be used, both Wysocki and Plaas are confident that they're on the right path. And they believe their research has the potential to be a game-changer not just for tendinopathy, but for other soft tissue pathologies that affect the joints, like post-trauma heterotopic ossification at the elbow and shoulders; or the calcinosis of tendons and ligaments often seen in diabetic patients and those affected by scleroderma.

"What's exciting about the Department of Orthopedic Surgery in particular, and this goes back to Jorge Galante, is the sincere appreciation for the value of basic research in advancing clinical treatment," Plaas says. "Jorge knew that where there's good science, and clinicians like Rob who are interested in embracing and exploring the new knowledge generated through basic research, you open the door to all kinds of remarkable discoveries." *

"These results are particularly important in projecting anticipated timelines of recovery and informing shared decision-making tools."

When Do Patients Perceive Clinical Benefits After Knee and Shoulder Sports Surgery?

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INTRODUCTION

Advances in clinical registry databases, together with new value-based care approaches, have revolutionized patient-reported outcome measure (PROM) research over the past decade.1-5 Traditional PROM research is limited by variability in PROM selection across studies, with the need for continued validation of new PROMs.6-8 Another equally important limitation is methodological because the majority of investigators use statistical significance to define outcome differences without specifying the minimum difference in score necessary for patients to perceive clinical benefits (ie, the minimally clinically important difference).9,10

Clinically significant outcomes (CSOs) address the latter methodological limitation by defining score thresholds that indicate meaningful change in clinical status.11 Investigators in orthopedic studies increasingly cite 3 specific measures: the minimal clinically important difference (MCID), or the minimum score difference for patients to perceive a clinical benefit; the substantial clinical benefit (SCB), representing patient benefit greater than that of MCID; and the patient acceptable symptomatic state (PASS), or the absolute value above which patients perceive their clinical status as passable.9,12-15 Investigators have begun to define threshold values for MCID, SCB, and PASS for various PROMs in arthroscopic partial meniscectomy (APM), anterior cruciate ligament reconstruction (ACLR), arthroscopic rotator cuff repair (RCR), and biceps tenodesis (BT).¹⁶⁻¹⁸ However, few investigators have examined the achievement of CSOs as a function of time or examined the time-dependent nature of CSO in APM, ACLR, RCR, or BT. 19,20

In this study, we conduct a comparative analysis of CSO achievement across 4 common sports medicine procedures:

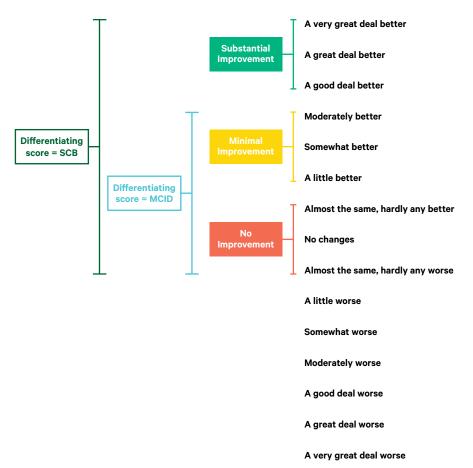
APM, ACLR, RCR, and BT. We hypothesize that (1) across cohorts, patients will continue to attain CSOs for up to and including 2 years; (2) most patients will achieve MCID, SCB, and PASS between 4 and 9 months, suggesting favorability toward earlier outcome achievement; (3) progressively fewer patients will achieve CSO over time, and (4) the smallest change in percentage will be observed between 12 and 24 months.

MATERIALS AND METHODS

Study Design, Outcome Measures, and Patient Selection

We queried a prospectively maintained institutional registry kept by OBRED for patients treated for primary APM, ACLR, RCR, or BT between January 2014 and January 2017 with serial PROM completion at 6, 12, and 24 months. Exclusion criteria were revision procedures, concomitant ligament and cartilage procedures, biological augmentation, or a lack of consecutive follow-ups, that allowed for the determination of MCID, SCB, and PASS. We collected knee-based PROMs compromised of the International Knee Documentation Committee (IDKC) score

A) Anchor Question: Since your surgery, has there been any change in your pain?



B) Anchor Question: Taking into account all activities you have done during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?

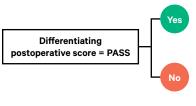


Figure. Anchor Questions: MCID, SCB, and PASS. Abbreviations: MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; SCB, substantial clinical benefit.

and all Knee Injury and Osteoarthritis Outcome Score (KOOS) subscores, including Joint Replacement (JR), Physical Function Shortform (PS), Symptom, Pain, Activities of Daily Living (ADLs), Sport and Recreation (Sport/Rec), and Quality of Life (QoL). We also included patient-reported outcome measures examining the upper extremity: the American Shoulder and Elbow Score (ASES), Single Assessment Numerical Evaluation (SANE), and Constant-Murley.

Statistical Analyses

The CSOs included MCID, SCB, and PASS values, which we derived from the cohort data with an anchor-based

methodology using the Global Assessment Scale (Figure). ²¹⁻²³ We used receiver-operating curves with area under the curve (AUC) to establish threshold values based on anchor questions, with AUC > 0.7 deemed as acceptable. If we found that AUC < 0.7, we used distribution-based methods. ²¹⁻²³

Table 1 summarizes reference MCID, SCB, and PASS threshold values. We calculated cumulative probabilities of outcome achievement on the basis of survival analysis. We reported them by using the true follow-up time data in days and calculated for each time by subtracting the follow-up survey completion date from the preoperative

survey completion date. We used software (RStudio, version 1.0.143; R Foundation for Statistical Computing, Boston, Massachusetts) for all statistical analyses.

RESULTS

APM

We included 126 surgical patients in the APM analysis, of whom 72 (57.1%) were male, with an average (SD) age of 46.9 (13.6) years and average (SD) body mass index (BMI) of 25.9 (6.1) kg/m². MCID achievement rates ranged from 43.6% to 56.3% at 6 months, improving to 70.6% to 84.1% at 12 months and 73.0% to 89.7% at 24 months. SCB achievement rates ranged from 23.8%

Table 1a. MCID, SCB, and PASS Threshold Values for ACLR and APM

		IKDC	KOOS JR	KOOS PS	KOOS Pain	KOOS Symptom	KOOS ADL	KOOS Sport/Rec	KOOS QoL
ACLR	MCID	18.9	8.87	-14.9	11.9	15.7	13.3	27.0	25.9
	SCB	29.6	13.4	-29.8	15.5	25.3	19.9	43.0	35.8
	PASS	75.0	76.3	18.6	80.6	78.6	92.3	70.0	50.0
АРМ	MCID	10.6	10.7	-8.2	9.7	8.9	11.0	12.5	15.6
	SCB	25.3	13.2	-11.3	22.2	7.1	16.9	27.5	34.4
	PASS	57.9	68.3	26.2	76.4	71.4	89.0	55.6	46.9

Table 1b. MCID, SCB, and PASS Threshold Values for RCR and BT

		ASES	SANE	Constant-Murley
	MCID	11.1	16.9	4.6
RCR	SCB	17.5	29.8	5.5
	PASS	86.7	82.5	23.3
	MCID	16.3	3.5	6.8
ВТ	SCB	16.8	5.8	11.0
	PASS	59.6	65.5	19.5

Abbreviations: ACLR, anterior cruciate ligament reconstruction; ADL, activities of daily living; APM, arthroscopic partial meniscectomy; ASES, American Shoulder and Elbow Score; BT, biceps tenodesis; IKDC, International Knee Documentation Committee Score; JR, Joint Replacement; KOOS, Knee Injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; PS, Physical Function Shortform; QoL, quality of life; RCR, rotator cuff repair; SANE, Single Assessment Numerical Evaluation; SCB, substantial clinical benefit.

to 42.1% at 6 months, from 39.7% to 65.1% at 12 months, and from 43.7% to 71.4% at 24 months. PASS achievement rates ranged from 30.5% to 69.8% across PROMs. Across MCID, SCB, and PASS estimates, mean achievement time for MCID was 6.39 to 8.37 months; SCB, 6.48 to 8.37 months; and PASS, 6.54 to 7.72 months; and median achievement time occurred between 5.67 and 6.05 months (Table 2).

ACLR

The ACLR cohort comprised 144 patients who underwent surgery, of whom 59 (41.0%) were male, with an average (SD) age of 30.86 (12.78) years and BMI of 25.51 (4.64) kg/m². Achievement of MCID ranged from 52.0% to 73.5% at 6 months and from 82.1% to 97.5% at 12 and 24 months. SCB achievement rates ranged from 40.0%

to 65.5% at 6 months and 74.9% to 93.3% at 12 months. PASS achievement rates improved from 50.0% to 76.6% at 6 months and to greater than 95.1% across PROMs at 24 months. Mean MCID, SCB, and PASS ranged from 6.40 (PASS, KOOS Pain) to 9.66 (SCB, KOOS PS). Median achievement rates were 6.11 to 8.98 months across PROMs (Table 3).

RCR

We included 203 surgical patients in the RCR cohort, of whom 124 (61.1%) were male, with an average (SD) age of 56.19 (9.96) years, BMI of 30.29 (6.49) kg/m², and symptom duration of 10.04 (14.20) months. MCID achievement rates ranged from 54.2% to 75.9% at 6 months to 72.9% to 94.6% at 12 and 24 months. SCB achievement improved from 43.8% to 52.7% at 6 months to 67.0% to 89.2% at 24 months. PASS achievement

ranged from 48.8% to 66.0% at 24 months, with SANE having the lowest PASS achievement (26.1%) and the longest PASS mean achievement time (9.13 months). Mean achievement times ranged from 5.69 to 9.13 months, and median achievement times ranged from 5.19 to 5.82 months (Table 4).

BT

We included 191 surgical BT patients, of whom 120 (62.8%) were male, with an average (SD) age of 46.9 (13.0). MCID achievement at 6 to 12 months was 71.3% to 83.2%. We found large differences in SCB improvement when comparing ASES (59.4%-64.1%) and Constant-Murley (35.9%-42.2%) to SANE (80.0%-80.2%). PASS achievement rates improved marginally from 6 months (58.3%-69.5%) to 12 months (59.7%-70.8%). Mean achievement time ranged from

Table 2. CSO Achievement After APM

	Percer	ntage Achieved at Fol					
PROM	6 Months	12 Months	24 Months	Mean (mo)	Median (mo)		
MCID							
IKDC	52.4	80.9	86.5	6.91	5.72		
KOOS JR	49.2	71.4	73.0	6.40	5.67		
KOOS PS	48.4	70.6	76.2	6.39	5.72		
KOOS Pain	54.8	84.1	88.1	6.53	5.72		
KOOS Symptoms	46.8	70.6	74.6	6.54	5.77		
KOOS ADL	56.3	83.3	86.5	6.39	5.68		
KOOS Sport/Rec	43.6	71.4	74.6	6.68	5.78		
KOOS QoL	52.3	83.3	89.7	6.76	5.78		
		S	СВ				
IKDC	26.1	46.0	52.4	8.16	6.01		
KOOS JR	40.5	63.5	65.9	6.98	5.76		
KOOS PS	42.1	64.2	71.4	6.48	5.82		
KOOS Pain	23.8	39.7	43.7	7.50	5.88		
KOOS Symptoms	42.1	65.1	68.2	6.66	5.73		
KOOS ADL	34.9	54.8	62.7	7.26	5.86		
KOOS Sport/Rec	30.2	54.0	61.1	8.37	6.01		
KOOS QoL	29.2	51.6	51.6	7.72	6.05		
		P/	ASS				
IKDC	38.8	61.9	68.3	7.35	5.85		
KOOS JR	39.7	64.2	65.1	6.54	5.75		
KOOS PS	33.3	54.8	61.1	7.15	5.82		
KOOS Pain	30.2	46.0	50.8	7.53	5.82		
KOOS Symptoms	40.5	68.2	69.8	6.60	5.86		
KOOS ADL	35.7	54.8	61.9	6.74	5.78		
KOOS Sport/Rec	32.5	55.6	62.7	7.72	5.95		
KOOS QoL	31.7	61.1	66.7	7.27	6.05		

Abbreviations: ADL, activities of daily living; APM, arthroscopic partial meniscectomy; CSO, clinically significant outcome; IKDC, International Knee Documentation Committee Score; JR, Joint Replacement; KOOS, Knee Injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; PROM, patient-reported outcome measure; PS, Physical Function Shortform; QoL, quality of life; SCB, substantial clinical benefit.

7.30 to 8.10 months, whereas median achievement time ranged from 5.90 to 6.40 months (Table 5).

DISCUSSION

The primary findings in our study include evidence of clinically significant outcome achievement for

patients undergoing APM, ACLR, and RCR until 2 years after surgery and for those undergoing BT until 1 year after surgery. Achievement rates decreased sharply after 6 months, with right-tailed distributions suggesting that the majority of patients achieved outcomes before 6 months postoperatively. Across cohorts, mean CSO achievement times

occurred between 5 and 10 months, with the median achievement time being less than the mean achievement time for each PROM. Lastly, when we excluded SANE for PASS in the RCR cohort, the majority of patients achieved each given CSO across PROMs for each individual cohort. These results are particularly important

Table 3. CSO Achievement After ACLR

	Percei	ntage Achieved at Fol					
PROM	6 Months	12 Months	24 Months	Mean (mo)	Median (mo)		
MCID							
IKDC	63.0	95.8	97.3	8.05	7.77		
KOOS JR	73.5	92.2	93.1	7.59	7.01		
KOOS PS	52.0	82.1	96.1	8.88	7.79		
KOOS Pain	66.2	88.7	91.0	6.68	6.41		
KOOS Symptoms	62.9	90.3	93.5	7.83	7.38		
KOOS ADL	67.3	88.5	90.2	6.58	6.11		
KOOS Sport/Rec	70.7	93.3	94.7	7.28	6.95		
KOOS QoL	53.1	95.1	97.5	8.81	7.94		
		S	СВ				
IKDC	44.2	86.5	88.4	8.19	7.89		
KOOS JR	63.3	83.1	84.8	8.20	7.98		
KOOS PS	40.0	74.9	89.7	9.66	8.98		
KOOS Pain	65.5	84.4	86.2	6.81	6.60		
KOOS Symptoms	48.8	75.6	78.0	7.88	7.46		
KOOS ADL	65.1	86.0	87.4	6.88	6.72		
KOOS Sport/Rec	44.4	85.2	88.1	7.62	7.40		
KOOS QoL	46.7	93.3	96.7	9.20	8.71		
		P	ASS				
IKDC	50.0	95.1	95.1	8.70	8.21		
KOOS JR	76.6	94.1	96.4	7.40	6.94		
KOOS PS	64.1	87.5	98.1	8.15	7.72		
KOOS Pain	72.6	88.7	96.8	6.40	6.32		
KOOS Symptoms	74.2	97.9	98.1	7.29	7.01		
KOOS ADL	79.4	97.1	97.1	6.88	6.38		
KOOS Sport/Rec	65.2	96.8	97.9	7.96	7.80		
KOOS QoL	70.1	93.8	98.2	8.04	7.58		

Abbreviations: ACLR, anterior cruciate ligament reconstruction; ADL, activities of daily living; CSO, clinically significant outcome; IKDC, International Knee Documentation Committee Score; JR, Joint Replacement; KOOS, Knee Injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; PROM, patient-reported outcome measure; PS, Physical Function Shortform; QoL, quality of life; SCB, substantial clinical benefit.

in projecting anticipated timelines of recovery and informing shared decision-making tools.

Important differences emerged when comparing achievement rates according to PROM across ACLR and APM cohorts. Patients who underwent ACLR had superior achievement of

PASS across IKDC score and KOOS subscales than did those who underwent APM (ACLR, > 95.1%; APM, 50.8%-69.8%). The large discrepancy in PASS achievement rates suggests there may be clinically significant differences in perceived benefit between the 2 patient cohorts postoperatively. Although study investigators have established

that outcomes after ACLR are beneficial with respect to PROM data and return to play, there are few long-term clinical results after APM. 24-26 In addition, results from studies in which the investigators examined outcomes after APM have been inconsistent with respect to the benefits of APM for confirmed meniscal tears. 27,28 Although

Table 4. CSO Achievement After RCR

	Percer							
PROM	6 Months	12 Months	24 Months	Mean (mo)	Median (mo)			
MCID								
ASES	75.9	94.1	94.6	5.69	5.21			
SANE	59.1	76.8	77.8	6.16	5.19			
Constant-Murley	54.2	72.9	76.4	6.85	5.23			
SCB								
ASES	43.8	63.1	89.2	6.13	5.23			
SANE	47.3	64.0	67.0	6.95	5.23			
Constant-Murley	52.7	70.9	74.9	7.03	5.24			
PASS								
ASES	40.2	65.5	66.0	7.13	5.36			
SANE	26.1	40.9	48.8	9.13	5.82			
Constant-Murley	36.5	54.7	63.1	8.54	5.44			

Abbreviations: ASES, American Shoulder and Elbow Score; CSO, clinically significant outcome; MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; PROM, patient-reported outcome measure; RCR, rotator cuff repair; SANE, Single Assessment Numerical Evaluation; SCB, substantial clinical benefit.

Table 5. CSO Achievement After BT

	Percentage Achie	eved at Follow-Up						
PROM	6 Months	12 Months	Mean (mo)	Median (mo)				
MCID								
ASES	71.3	77.9	7.30	5.90				
SANE	83.1	83.2	8.00	5.90				
Constant-Murley	76.4	78.7	8.00	6.10				
SCB								
ASES	59.4	64.1	7.30	6.05				
SANE	80	80.2	8.10	6.00				
Constant-Murley	35.9	42.2	8.10	6.40				
PASS								
ASES	69.5	70.8	7.50	6.10				
SANE	61.1	62.9	7.40	6.07				
Constant-Murley	58.3	59.7	7.70	6.10				

Abbreviations: ASES, American Shoulder and Elbow Score; BT, biceps tenodesis; CSO, clinically significant outcome; MCID, minimal clinically important difference; PASS, patient acceptable symptomatic state; PROM, patient-reported outcome measure; SANE, Single Assessment Numerical Evaluation; SCB, substantial clinical benefit.

investigators in some studies report a lack of statistically significant PROM score improvement, investigators in other studies report statistically significant patient benefits at particular postoperative times.²⁹⁻⁴⁸ The ACLR cohort also tended to achieve PASS at later times (ACLR median, 6.11-8.98 months; APM median, 5.67-6.05 months), aligning with results from a recent systematic review suggesting interval subjective improvement until 1 year postoperatively.49 Our data further demonstrated that, despite a lack of statistically significant difference in mean PROM scores between 1 and 2 years postoperatively, patients continued to attain MCID, SCB, and PASS across PROMs until 2 years postoperatively (Table 3).

With respect to the RCR and BT cohorts, mean achievement rates in the RCR cohort in our study were generally longer for PASS (7.13-9.13 months) than in the MCID (5.69-6.85 months) and SCB (6.13-7.03 months) cohorts. This finding suggests that certain patients may perceive either small or large benefits early in the postoperative period but require further improvement to deem their state acceptable. However, this finding contrasts with the findings in the BT cohort, in which PASS mean achievement rates were comparable among MCID (7.30-8.00 months), SCB (7.30-8.10 months), and PASS (7.40-7.70 months).

Despite these differences in mean achievement rates, median achievement rates were fairly comparable overall between the RCR (5.19-5.82 months) and BT (5.90-6.40 months) cohorts. In addition, with respect to the BT cohort, although patients continued to achieve clinically significant outcomes from 6 to 12 months postoperatively, the difference in cumulative outcome achievement was no greater than 6.6% for a single PROM, suggesting marginal gains in total achievement when compared with those from the date of surgery to 6 months postoperatively.

Our study has important limitations. First, we report differences in MCID, SCB, and PASS thresholds that depend on the patient population studied. We developed these threshold values by either anchor- or distributionbased methods, depending on the cohort in question. Although methodological consistency would be ideal in preventing bias, we purposely calculated distribution-based measures for the scenario in which area under the curve values limited the appropriate outcome capturing. Furthermore, anchor-based methodologies are limited in part by decreased patient compliance at long-term follow-up. In addition, we specifically chose our selection criteria for primary surgical cases with full completion of PROM data. As a result, they may not be

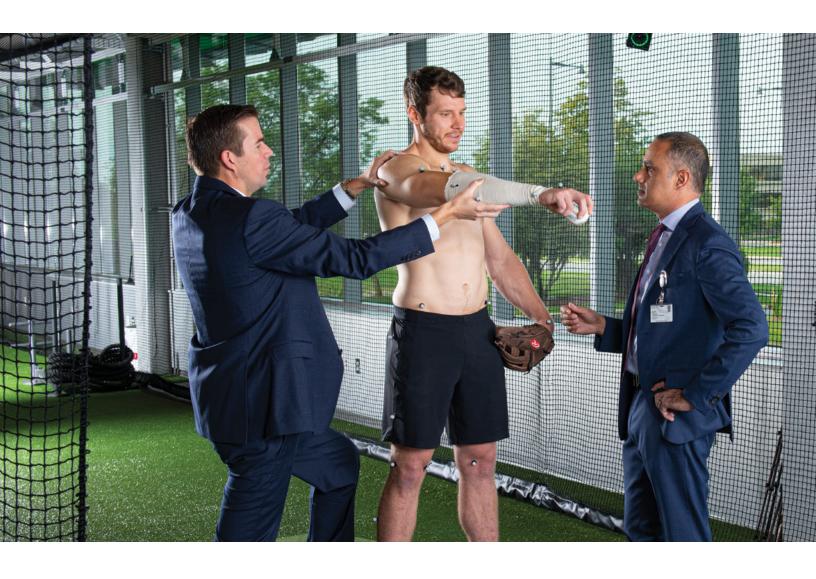
appropriate to generalize to revision cases or to those with elaborate concomitant procedures, such as biological augmentation. Inclusion of cases with only full completion of PROM data also may create selection bias on the basis of differences between those who complete patient-reported outcome questionnaires and those who do not.

CONCLUSIONS

Clinically significant outcome achievement occurs for patients undergoing APM, ACLR, and RCR until 2 years and for patients undergoing BT until 1 year. Achievement rates decreased sharply after 6 months, with right-tailed distributions suggesting that the majority of patients achieved outcomes before 6 months postoperatively for each procedure. Across cohorts, mean CSO achievement times occurred between 5 and 10 months postoperatively. These results are particularly important in projecting anticipated timelines of recovery and informing shared decisionmaking tools. *

References and financial disclosures are available online at www.rush.edu/orthopedicsjournal.

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