



# ORTHOPAEDIC INSIGHTS

WINTER 2020

NEWS AND INSIGHTS FROM  
THE DEPARTMENT OF ORTHOPAEDIC SURGERY

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# DEAR COLLEAGUES



I am eager to share our newest edition of *Orthopaedic Insights*, which comprises highlights from Cleveland Clinic's Department of Orthopaedic Surgery. Our dedicated team of physicians and researchers works tirelessly every day

to improve patient care, lead research investigations and train the next generation of physician leaders. This publication is full of news and insights that reflect our mission to put patients first — from new surgical approaches and research innovations to a large, multicenter grant and data-driven strategies to personalize orthopaedic care. Here is a snapshot of the articles in this issue:

- Our cover story is a case review of an anterior vertebral body tethering nonfusion technique in a 13-year-old with progressive scoliosis. The surgeon discusses his approach and the promising outcomes (p. 3).
- In a case review of a 67-year-old patient with severe hip osteoarthritis, joint destruction and bone loss, an orthopaedic surgeon shares his decision to use robot-assisted total hip arthroplasty (p. 5).
- Cleveland Clinic osteoarthritis (OA) researchers receive a \$3 million NIH grant award that aims to identify long-term risk factors for OA after an anterior cruciate ligament tear and reconstruction (p. 7).

- Researchers discuss the implications of developing a clinically relevant animal model to better understand the etiology of periprosthetic joint infection (p. 8).
- A new patient data program aims to improve orthopaedic care and drive down healthcare costs associated with musculoskeletal conditions (p. 10).
- A resident-authored article describes a feasibility trial that validates a new remote patient monitoring system for patients who were discharged home following total knee arthroplasty (p. 12).
- Two orthopaedic surgeons discuss a viable technique to salvage the ankle joint in the reconstruction of a distal tibia fracture nonunion (p. 14).
- A new orthopaedics informatics initiative is leveraging artificial intelligence to improve patient experience (p. 17).
- A recent proof-of-concept study shows promising outcomes in a bone-preserving shoulder technique that is more anatomically accurate (p. 18).

Respectfully,

BRENDAN M. PATTERSON, MD

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## ORTHOPAEDIC INSIGHTS | WINTER 2020

*Orthopaedic Insights* is published by Cleveland Clinic's Department of Orthopaedic Surgery to inform musculoskeletal specialists about advances in diagnosis, medical and surgical management, and research.

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# ANTERIOR VERTEBRAL BODY TETHERING: A NONFUSION TECHNIQUE FOR IDIOPATHIC SCOLIOSIS IN GROWING CHILDREN

NEW NONFUSION TECHNIQUE DEMONSTRATES EARLY PROMISE



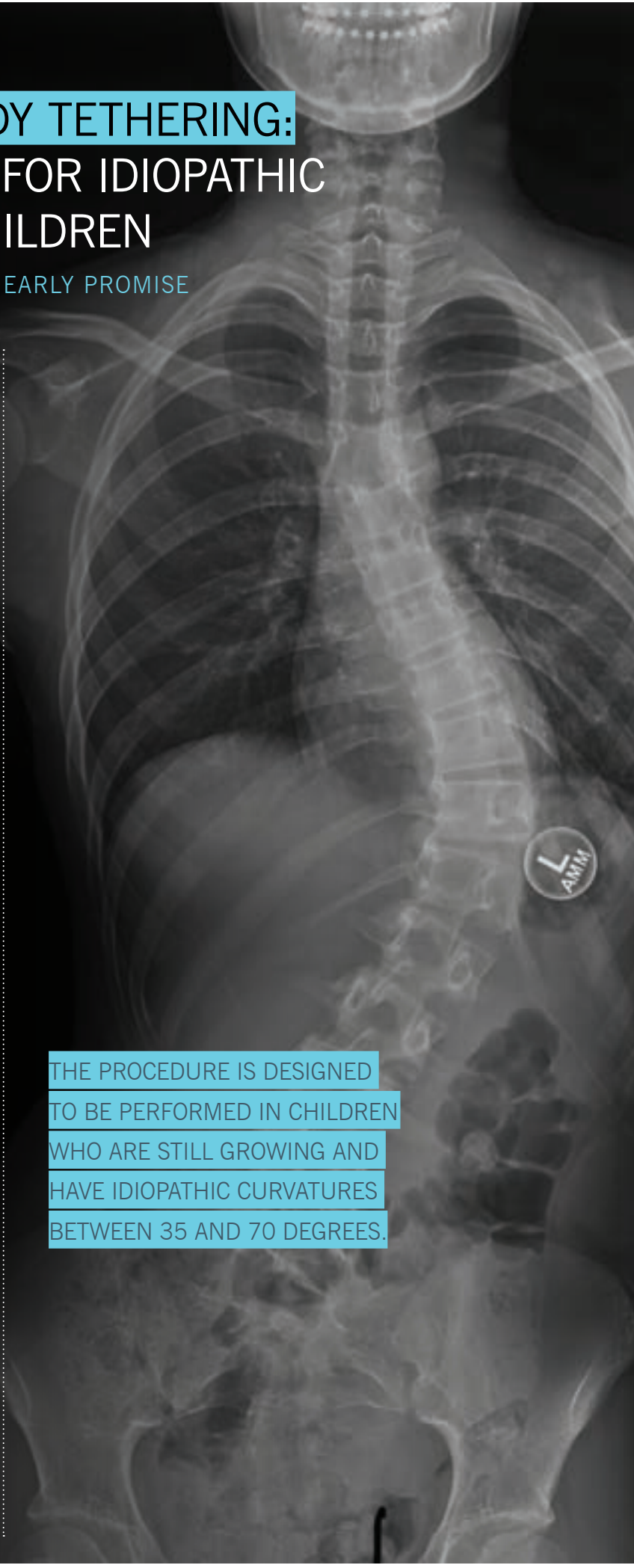
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Thousands of children undergo surgery for progressive scoliosis each year. Since the advent of modern medicine, the gold-standard surgical technique has been fusion of the involved vertebral elements, which limits spinal motion and stresses adjacent segments. Although good long-term data demonstrate the success of this procedure, modern instrumentation has markedly changed our surgical techniques, improving our ability to realign and stabilize the spine.

Newer techniques permit guided growth for young patients with progressive scoliosis. These techniques were developed to stabilize the spine and allow remaining growth to occur. During the postsurgical growth period, the deformity can correct slowly over time. This technique is similar to growth modulation techniques used in the lower extremities of children, which have been commonplace for years (e.g., stapling, physeal plating, epiphysiodesis). Vertebral body tethering is one such technique that permits continued growth without fusion and so preserves motion.

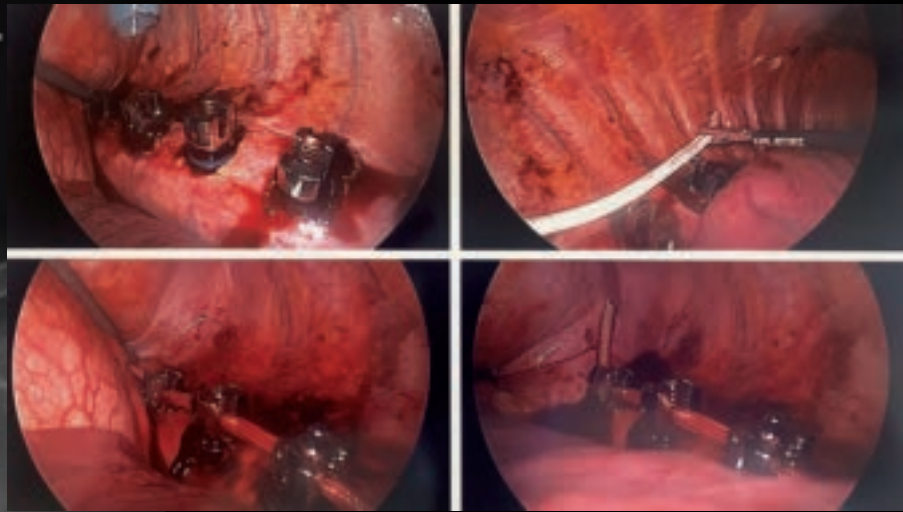
As this is a relatively new procedure, indications continue to evolve. The procedure is designed to be performed in children who are still growing and have idiopathic curvatures between 35 and 70 degrees. Children who are near skeletal maturity based on a bone age film or iliac crest apophysis are not candidates for this procedure. Goals of the procedure include stabilization of the convex portion of the curve with nonfusion instrumentation, modest correction in the operating room and completion of the deformity correction with future growth.

*continued next page* ➤

An anteroposterior (AP) X-ray of a child's spine. The spine shows a clear lateral curvature (scoliosis). A circular marker with the letter 'L' and 'AMM' is visible on the right side of the image. The ribs and pelvis are also visible.

THE PROCEDURE IS DESIGNED  
TO BE PERFORMED IN CHILDREN  
WHO ARE STILL GROWING AND  
HAVE IDIOPATHIC CURVATURES  
BETWEEN 35 AND 70 DEGREES.





**Figure 1:** Intraoperative photo of video assisted thoracoscopy anterior vertebral body tethering.

### Surgical technique

The procedure is performed under general anesthesia in the lateral decubitus position with the convexity up, most typically the right side. A dual lumen endotracheal tube is preferred so that the lung can be collapsed for visualization. Standard neurologic monitoring is used in all cases. Video-assisted thoracoscopy is performed through four to five portals in the hemithorax. Under camera visualization, as well as fluoroscopic guidance, anterior screws are placed in the vertebral bodies on the convexity along with a staple at each level. This instrumentation is then connected with a tether device that is flexible yet secures the instrumentation under tension that is controlled by the surgeon (Figure 1).

### Postoperative care

Postoperative care typically consists of two to three days in the hospital with a chest tube. Activity restrictions are in place for only six weeks, after which patients can resume all activities as tolerated. Patients are seen in follow-up at six-month intervals to monitor their radiographic changes as they grow. Complications are infrequent but may include pulmonary complications, screw failure, tether failure, overcorrection and, rarely, neurologic injury.

As this technique is in its infancy, no long-term studies are yet available. Short-to midterm data suggest the procedure is safe and can produce good correction both in the operating room and over time, eliminating the need for fusion. Future studies are warranted as the use of this technique becomes more widespread. ■

***Dr. Goodwin** is Director of the Center for Pediatric and Adolescent Orthopaedics.*

# ROBOTIC TOTAL HIP REPLACEMENT: WHEN IS IT RIGHT FOR YOUR PATIENT?

## ORTHOPAEDIC SURGEON DISCUSSES AN INNOVATIVE ROBOTIC TECHNIQUE FOR TOTAL HIP ARTHROPLASTY

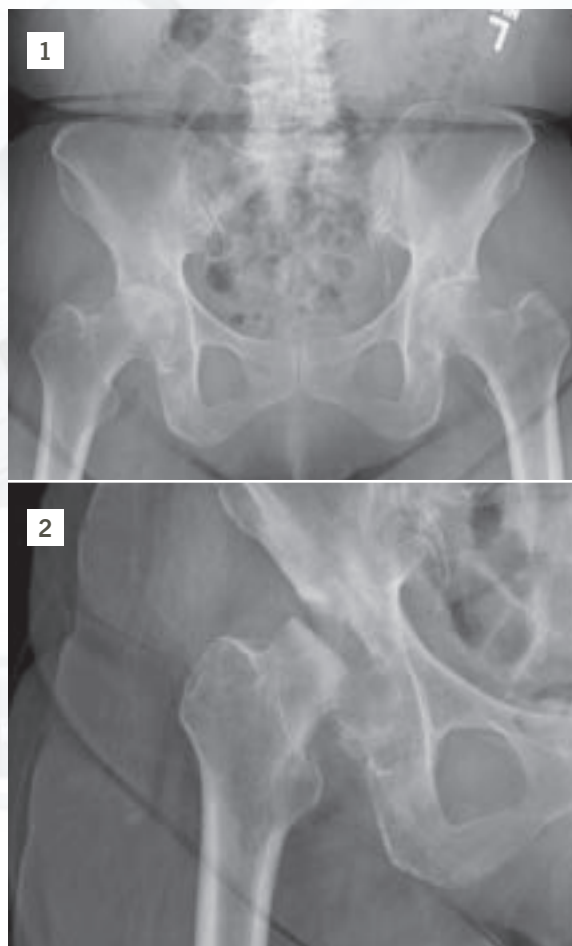
Robotic-assisted total hip arthroplasty (THA) is an exciting technology that can benefit patients in routine and complex cases alike. The system (Mako®, Stryker Orthopaedics) is compatible with all common hip approaches and can be incorporated into a busy adult reconstruction practice.

Potential advantages include:

- Three-dimensional computer tomography (CT)-based preoperative planning.
- Haptic guidance of the robotic arm to decrease errors in acetabular reaming and preserve bone stock.
- Improved accuracy of acetabular component positioning, with fewer outliers, compared with manual instrumentation (as noted in several clinical and cadaveric studies).
- Possibly lower dislocation rates compared with manual THA, perhaps because of better accuracy relative to manual techniques and the ability to compensate for intraoperative pelvis position.
- Ability to precisely change the desired abduction and anteversion targets based on the patient's specific spinal-pelvic alignment.
- Greater surgical efficiency with use of one reamer for acetabular preparation.
- Decreased need for intraoperative fluoroscopy with on-table direct anterior approach.

### A clinical case and the decision to use robotic assistance

In a recent clinical case, a 67-year-old female presented with complaints of severe pain and grinding in her right hip, inability to ambulate, and shortening of the leg. She had no significant medical history aside from being a current smoker. She had received a corticosteroid injection three months previously for treatment of hip osteoarthritis. A radiograph taken before the injection (Figure 1) shows severe hip osteoarthritis, and a current radiograph (Figure 2) indicates rapidly progressive arthritis with joint destruction, severe acetabular and femoral bone loss. Preoperative aspiration was negative for infection. She was indicated for complex primary THA, and was counselled preoperatively about smoking cessation. Given the complexity of the acetabular reconstruction, I elected to do the case with robotic assistance to allow for accurate bone preparation and implant placement.

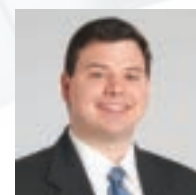


**Figure 1:** Radiographs of the patient's hip before corticosteroid injection. **Figure 2:** Radiographs three months later upon presentation, showing rapidly progressive arthritis with joint destruction and severe acetabular bone deficiency.

### The approach

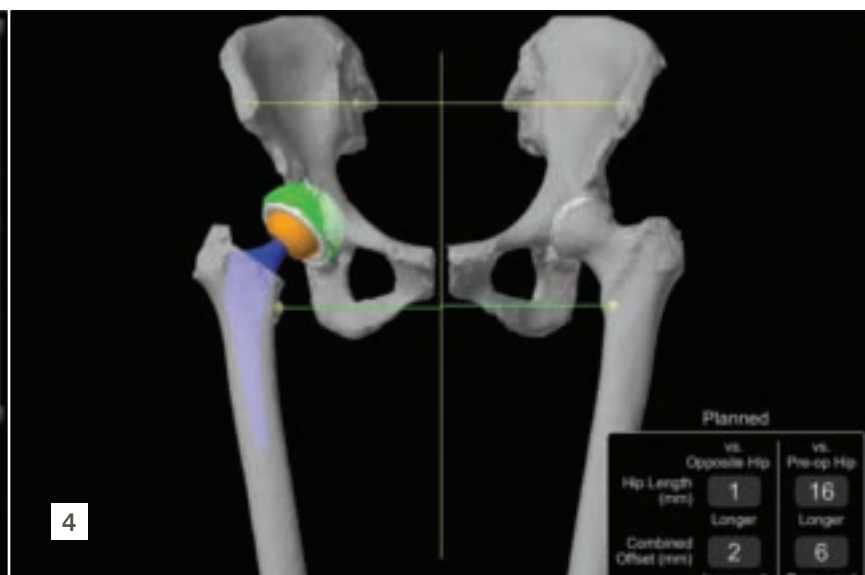
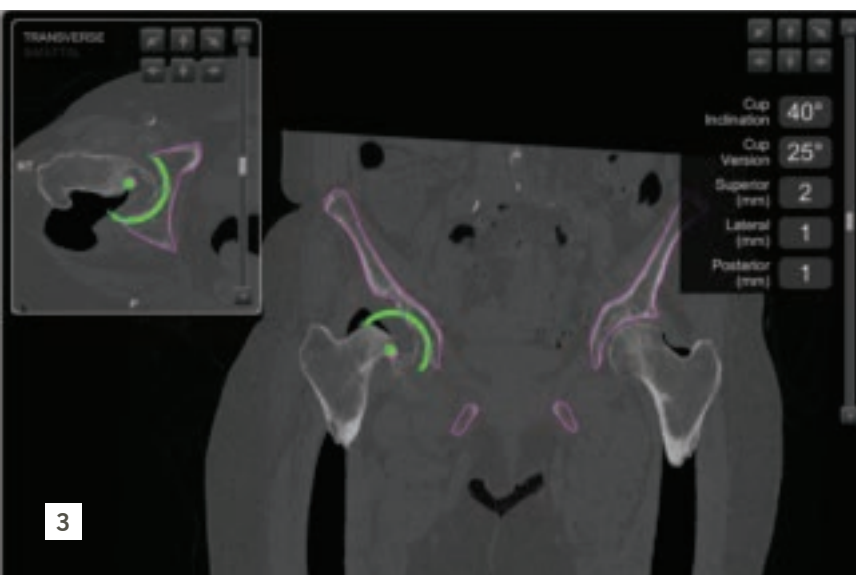
A preoperative CT scan was obtained and the reconstruction was planned using the software. Once the desired inclination and version are selected, the acetabular component is sized and placement is chosen in all three planes relative to the host bone, in quarter-millimeter increments. I planned the reconstruction near the native hip center, which allowed for fit between the remaining anterior and posterior walls (Figure 3). There was a large segmental acetabular defect of the superior dome with uncoverage of the implant (Figure 4), and a superior acetabular augment was planned. After planning the femoral reconstruction, the approximate leg length and offset are restored.

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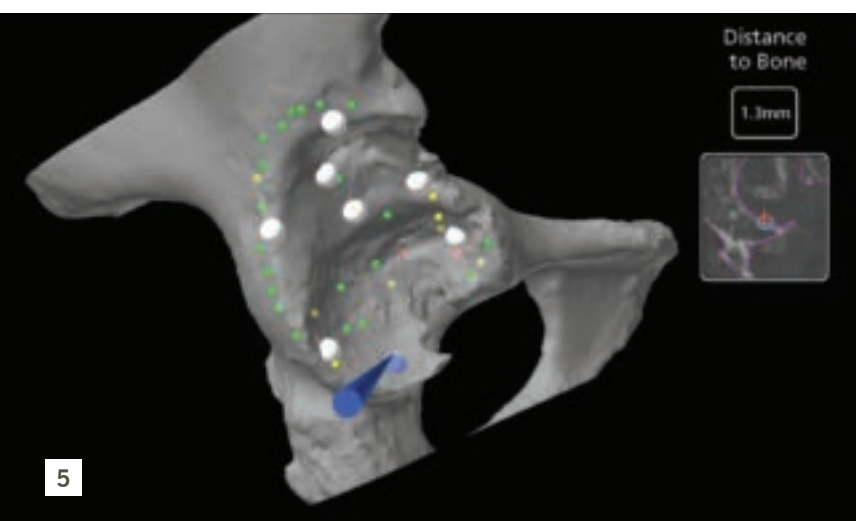
**Figure 3:** Using the planning software, the acetabular component is sized and placement is chosen relative to the remaining host bone.

**Figure 4:** The construct is planned to approximate the desired leg length and offset. Note the significant uncoverage of the cup from the bone deficiency, for which an acetabular augment was planned.

**Figure 5:** Successful intraoperative verification of the bone registration.

This case was done through a posterior approach, and wide acetabular exposure around the defect was accomplished. The acetabular bone was registered with the optical navigation, and the registration was verified to ensure accuracy (Figure 5). The robotic arm was then brought in and used to ream the bone according to the preoperative plan. With good bone preparation, the final implant was inserted with the robotic arm locking the impactor into the chosen orientation. A multihole revision cup was used in this case for enhanced screw options. Although the cup was significantly uncovered superiorly as expected, the press-fit between the walls was very good, and four screws were placed into the remaining acetabular bone to augment initial fixation. We trialed and selected a superior acetabular augment, which was then fixed to the pelvis with three additional screws. The construct was unitized by placing cement between the augment and cup, and a dual mobility articulation was chosen due to elevated risk of instability.

The femur was broached and the hip trialed, with excellent stability and re-creation of clinically equal leg lengths. After placement of the final implants, the leg length and offset were verified using the computer.



**Figure 6:** Radiographs of the reconstruction three months postoperatively.

At the most recent follow-up three months postoperatively, radiographs (Figure 6) showed the final reconstruction, and the patient was recovering appropriately with no hip pain. ■

*Dr. Bloomfield is an orthopaedic surgeon subspecializing in adult reconstruction.*

# MULTICENTER OSTEOARTHRITIS STUDY RECEIVES \$3M GRANT FROM THE NIH

THE LONGITUDINAL STUDY WILL EXAMINE LONG-TERM RISK FACTORS  
FOR OSTEOARTHRITIS AFTER ACL INJURY

A multicenter team of researchers led by Xiaojuan Li, PhD, Department of Biomedical Engineering, Lerner Research Institute, and Kurt Spindler, MD, Orthopaedic & Rheumatologic Institute, has received a five-year, \$3.1 million grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (part of the National Institutes of Health) to help identify long-term risk factors for osteoarthritis after an anterior cruciate ligament (ACL) tear and reconstruction.

WHILE EARLIER STUDIES HAVE  
FOCUSED ON SHORT- AND MIDTERM  
MAGNETIC RESONANCE IMAGING  
(MRI) FOLLOW-UP, LONG-TERM SOFT  
TISSUE DEGENERATION OF THE KNEE  
FOLLOWING ACL SURGERY HAS NOT  
BEEN EVALUATED.

ACL injuries are one of the most common, and severe, knee injuries and are usually reconstructed with surgery. Even after surgery, however, patients are at greater risk for post-traumatic osteoarthritis (PTOA). At this time, it is difficult to accurately predict which patients will develop PTOA several years after the surgery. While earlier studies have focused on short- and midterm magnetic resonance imaging (MRI) follow-up, long-term soft tissue degeneration of the knee following ACL surgery has not been evaluated.

## Advanced imaging to understand and prevent PTOA

This multicenter study will add to the Multicenter Orthopaedic Outcomes Network Study, which followed for 10 years patients who had an ACL reconstruction in order to determine their risk for PTOA. The new study will utilize an advanced type of MRI known as quantitative MRI, or qMRI, to see damage to the knee earlier than would be possible with a regular MRI, while PTOA can still be prevented. Nancy Obuchowski, PhD, Department of Quantitative Health Sciences, helped design this new study.

The qMRI studies will evaluate the cartilage, bone, muscle and other lesions in the surgically reconstructed knees that may be related to osteoarthritis. The goal of the study is to illustrate long-term structural damage and degeneration of the cartilage after the ACL reconstruction to help identify the risk factors for PTOA, as well as ways to mediate them.

The study will take place at three sites, including Cleveland Clinic, Vanderbilt University and The Ohio State University. "Our ultimate goal is to use quantitative radiology to provide guidance for personalized, optimized interventions to reduce the prevalence of PTOA after ACL injury and reconstruction," says Dr. Li. "This study has the potential to improve patient management of this young and active population with an evidence-based approach." ■

*Dr. Li is Director of the Program for Advanced Musculoskeletal Imaging and holds the Bonutti Family Endowed Chair for Musculoskeletal Research.*

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# TREATING PJI: THE CASE FOR CLINICALLY RELEVANT ANIMAL MODELS

BY ANABELLE VISPERAS, PHD; NICOLAS PIUZZI, MD; ALISON KLIKA, MS; ANNA C.S. SAMIA, PHD; Wael Barsoum, MD; AND CARLOS HIGUERA-RUEDA, MD

Periprosthetic joint infection (PJI) is a catastrophic complication of total joint arthroplasty,<sup>1-3</sup> which accounts for 18%-30% of revision hip<sup>4,5</sup> and 19% of revision knee<sup>6</sup> replacements in the United States. Projections have estimated it will cost over \$1.6 billion with a caseload of 70,000 revisions per year by 2020.<sup>7</sup> The five-year mortality rate is close to 26%, which is as high as that for many common cancers.<sup>8</sup> While treatment options, including a combination of irrigation and debridement (I&D), intravenous antibiotics, and one- and two-stage revisions, are commonly utilized, failure rates are still high at around 30% to 50%. This is mainly related to the formation of bacterial biofilms and the reduced capabilities of antibiotics to have a significant effect on them. Thus, there is a dire need to improve treatment options and create innovative alternatives.

## Bacterial biofilm makes it difficult to diagnose and treat PJI

Both diagnosis and treatment are difficult due to the impenetrable biofilm produced by many bacterial species responsible for PJI.<sup>9,10</sup> This biofilm decreases the metabolism of bacteria and protects it from antibiotic therapies and the immune system. Therefore, both diagnosis and treatment strategies can benefit from disrupting biofilm formation. Bacterial biofilm has become a hot topic in recent years in the microbiology field, where novel treatment strategies are being developed. Nevertheless, an animal model that is clinically representative of human PJI needs to be developed to test these treatment modalities.

## PJI animal model considerations

Many groups have begun developing various PJI animal models, utilizing rodents (mice and rats), rabbits, dogs and goats. Each animal model has its own set of advantages and disadvantages.<sup>11</sup> While rodents are relatively cheap and are appealing for high-throughput testing, their joint space volume, bone physiology and size can be a hindrance. Larger animals have several advantages. They are able to handle multiple surgeries, as is commonly the case in PJI treatment in humans; relative to rodents, they have musculoskeletal and immunologi-

cal systems similar to human ones; and larger animals have sufficient joint space volume for potential future treatment applications. However, their exorbitant costs compared with that of rodents and the ethical concerns associated with large animal research need to be considered.

## Developing standardized criteria

Carli et al.<sup>12</sup> suggested four standardized criteria that future models need to include to be clinically representative of PJI:

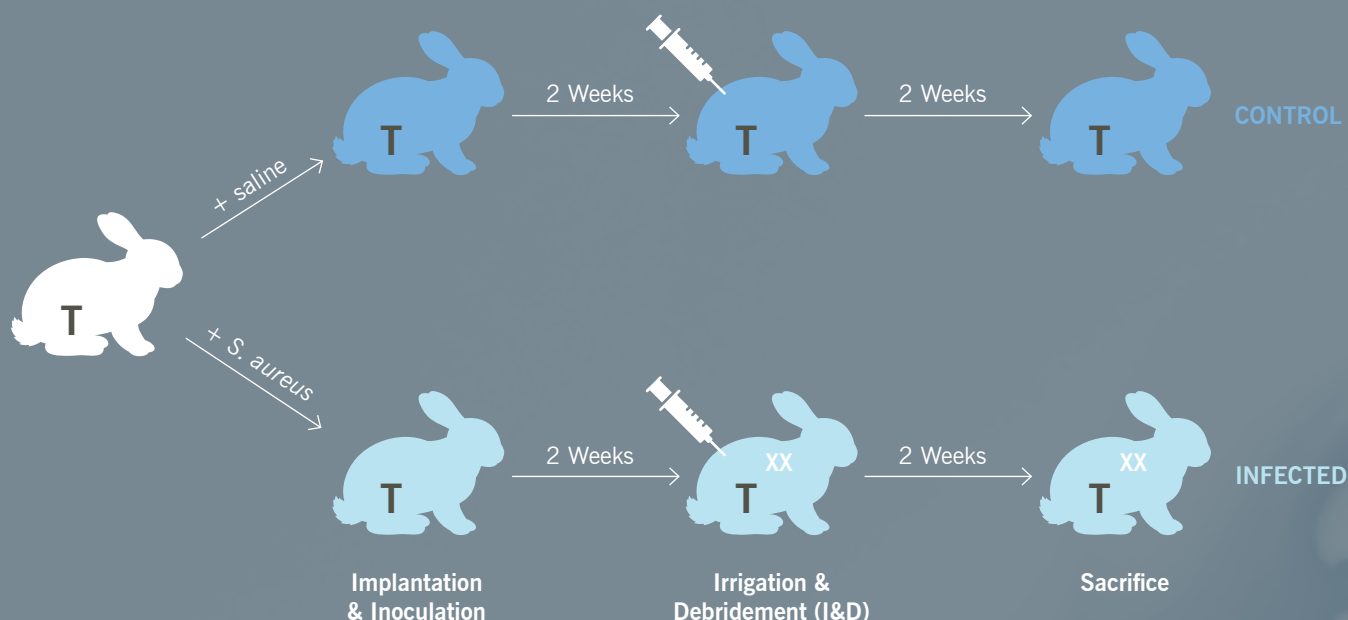
1. The animal must have musculoskeletal and immunological properties similar to those of humans.
2. The implant should be made of relevant material, bear weight and reproduce the periprosthetic environment.
3. The study should use clinically relevant bacteria that can reliably produce biofilm on implant.
4. The study should employ a methodology to measure biofilm, bacterial burden and immunological response.

## What is our approach?

Our group has built on existing models and the recommendations of peers to develop a clinically relevant rabbit model of knee PJI (Figure 1). We used rabbits as our model of choice due to their size, joint space volume, hardness to multiple surgeries and musculoskeletal similarities to humans (criterion 1). This rabbit model utilizes a custom-made titanium tibial press-fit implant that allows for immediate weight-bearing after surgery and full use of the limb within seven days of surgery (criterion 2).

This implant has an articular surface that interacts with the periprosthetic joint space and a shaft that interacts with the intramedullary space, similar to implants used in humans. It also uses a clinically relevant bacterial strain, *Staphylococcus aureus*, which accounts for up to 38% of knee and hip PJIs.<sup>3</sup> It is bioluminescently marked for easy tracking and identification (criterion 3).





**Figure 1: Experimental Schematic.** All rabbits are implanted with a titanium press-fit tibial implant. Control and infected rabbits were given an intra-articular injection of saline or *S. aureus*, respectively, prior to capsule closure. Two weeks later, when rabbits have a productive infection with biofilm (denoted with XX), all rabbits will undergo I&D treatment. Rabbits will be sacrificed two weeks post-I&D for postmortem analysis of bacterial biofilm formation and bacterial burden.

We have developed multiple readouts for productive infection and bacterial burden, including scanning electron microscopy of the implant to assess biofilm formation and cultures/bioluminescence to assess bacterial burden. Peripheral white blood cell and C-reactive protein levels are also being assessed using this model and may be further expanded to include synovial fluid sampling for cellular analysis (criterion 4).

We have built on current models and gone beyond the recommendations of Carli et al. by adding an I&D step two weeks after implantation and inoculation, which is clinically relevant and has not been done with any other

PJI animal model to date. This rabbit model of knee PJI enables the testing of novel local treatment modalities that are generated in the microbiology field. ■

*Dr. Visperas is a Research Coordinator, Department of Orthopaedic Surgery; Dr. Piuzzi is Associate Staff, Department of Orthopaedic Surgery; Mrs. Klika is a Research Program Manager, Department of Orthopaedic Surgery; Dr. Samia is Associate Professor, Department of Chemistry, CWRU; Dr. Barsoum is CEO and President, Cleveland Clinic Florida; and Dr. Higuera-Rueda is Chairman, Department of Orthopaedic Surgery, Cleveland Clinic Florida.*

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# HOW PATIENT DATA ARE DRIVING A NEW PARADIGM IN ORTHOPAEDIC CARE

DATA SYSTEM AIMS TO IMPROVE ORTHOPAEDIC CARE AND DRIVE DOWN HEALTHCARE COSTS



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Musculoskeletal disorders pose a significant health and economic burden and account for more than half of all chronic conditions in people age 50 or older in industrialized countries. Studies also show \$874 billion (5.7% of the GDP) is spent annually in the U.S. on healthcare for patients with musculoskeletal diagnoses. In response, some orthopaedic leaders are calling for greater attention to outcomes research to improve the quality of evidence-based patient care.

Kurt Spindler, MD, Vice Chair for Research in Cleveland Clinic's Orthopaedic & Rheumatologic Institute and Director of the Amy and David Krohn Family Orthopaedic Outcomes Center, notes that understanding factors that predict poor outcomes is essential to improve and economize care.

"We need to discern between patients who should undeniably proceed with surgery versus those who should consider deferring it until a modifiable risk factor is corrected," says Dr. Spindler. "Robust outcomes data will fuel evidenced-based research that will inform these decisions going forward."

## What is the Outcomes Management and Evaluation (OME) system?

In 2015, Dr. Spindler piloted what is now the Outcomes Management and Evaluation (OME) system at Cleveland Clinic to collect episode-of-care information and patient-

reported outcomes in sports medicine for anterior cruciate ligament repairs and partial meniscectomies. The program, which demonstrated early success, has rapidly expanded since then. As of August 2019, the system had collected patient demographic data, episode-of-care information and patient-reported outcomes, including postoperative pain, function and satisfaction, for over 45,000 unique cases at 16 different Cleveland Clinic hospitals and ambulatory surgery centers.

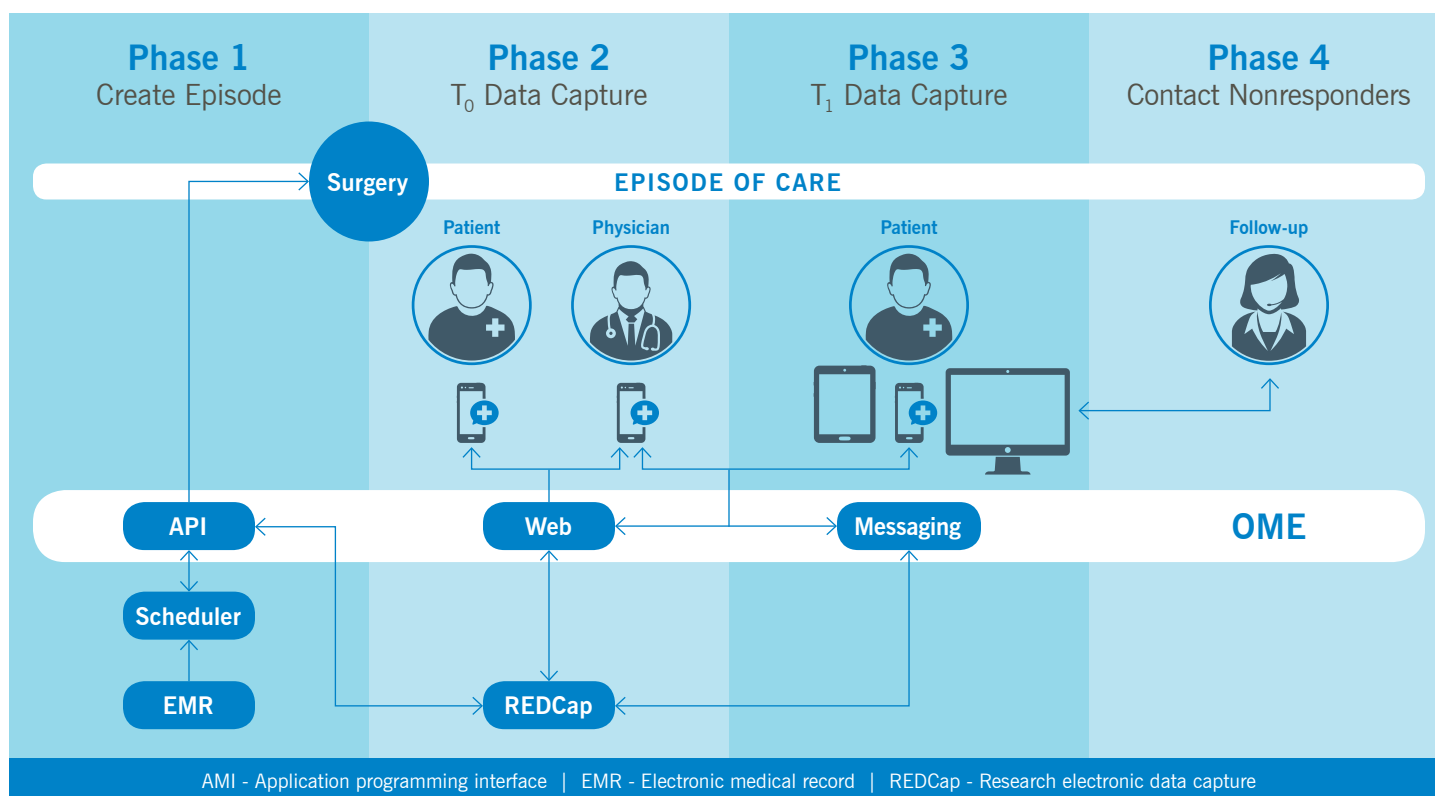
The initiative has already resulted in nearly 20 research publications — and with almost 40 active studies. While the earlier publications aim to validate the utility of the system as a research tool, the next wave of studies will start to ask questions of the data, Dr. Spindler says. "It was critical that we first answer the questions, 'Does it work, and is it efficient?' before we leverage this data to inform point-of-care decisions."

## OME demonstrates favorable outcomes in rotator cuff repair

The utility and value of OME is evidenced in rotator cuff repair. Kathleen Derwin, PhD, biomedical engineer in Cleveland Clinic's Lerner Research Institute and Director of the Musculoskeletal Research Center, recently authored two studies published in the *Journal of Shoulder and Elbow Surgery*, both stemming from OME data on rotator cuff repair.

"WE DETERMINED OME IS A VALID TOOL FOR FURTHER INVESTIGATIONS OF FACTORS IMPACTING QUALITY AND OUTCOMES OF ROTATOR CUFF REPAIR."





The Outcomes Management and Evaluation (OME) system is used across the institution to systematically collect patient-reported outcome measures.

The first study demonstrated the validity and efficiency of OME, compared with electronic medical record data, in rotator cuff repair. “Notably, OME had significantly higher data counts for 25% of variables in our analysis,” she says. “We determined OME is a valid tool for further investigations of factors impacting quality and outcomes of rotator cuff repair.”

Taking this one step further, in the second study, co-authored with Eric Ricchetti, MD, shoulder surgeon in Cleveland Clinic’s Department of Orthopaedic Surgery, the team asked a different question of the OME data: What can we learn about how rotator cuff repair surgery is performed in our health system?

The research team found that tear size, a greater number of torn tendons, double-row repair technique and the surgeon were significantly associated with a greater number of anchors used for rotator cuff repair. “These data tell us there is notable variation in surgical techniques when approaching rotator cuff repair,” remarks Dr. Ricchetti. He notes that surveying surgeons about their particular approach, in addition to analyzing patient-reported outcomes one and two years after the surgery, will add insight to this investigation.

Ultimately, this work will help standardize procedures and develop new understandings — in rotator cuff repair and other elective orthopaedic surgeries — as to why some approaches may be more effective for a particular cohort of patients.

### What’s next?

Dr. Spindler is eager to continue building the program by expanding into new sites and adding new episodes of care across orthopaedic and nonorthopaedic specialties.

“We’ve already seen a high volume of research activity coming out of the OME,” he says. “We hope to continue engaging more physicians and researchers at different sites to accrue more patient data. We believe this is a real opportunity to personalize orthopaedic care and drive down healthcare costs.” ■

*Dr. Spindler is Vice Chair for Research in Cleveland Clinic’s Orthopaedic & Rheumatologic Institute and Director of the Amy and David Krohn Family Orthopaedic Outcomes Center.*

*Dr. Derwin is Director of the Cleveland Clinic Musculoskeletal Research Center.*

*Dr. Ricchetti is a staff surgeon in the Department of Orthopaedic Surgery.*

### Suggested readings

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BMUS: The Burden of Musculoskeletal Diseases in the United States. BMUS: The Burden of Musculoskeletal Diseases in the United States. <https://www.boneandjoint-burden.org>



# NEW HYBRID REMOTE PATIENT MONITORING SYSTEM FEASIBLE AND MOTIVATING FOLLOWING TOTAL KNEE ARTHROPLASTY

APP, WITH SMART KNEE SLEEVE, STORES AND SHARES KEY DATA POINTS ABOUT A PATIENT'S REHABILITATION



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A feasibility trial conducted at Cleveland Clinic validates a new remote patient monitoring (RPM) system for patients under 80 who were discharged home following total knee arthroplasty (TKA), according to a study published recently in the *Journal of Arthroplasty*.

## New insights into rehabilitation

Approximately 90% of recovery from TKA occurs outside the clinic, when a patient's activity level and exercise regimen play a significant role in the rehabilitation process. The proprietary RPM system from FocusMotion gives patients real-time motion feedback through an avatar, charting progress made each day, and sends users notifications reminding them to exercise or take the weekly self-assessment. This innovation may provide several benefits to patients, providers and payers, including increased patient engagement with rehabilitation, better insight into negative outcomes, and a cost-effective and user-friendly means to collect, store and share the information.

"Traditionally speaking, we receive very little objective data to indicate how our patients are recovering after discharge," states Brendan Patterson, MD, Chair of Cleveland Clinic's Department of Orthopaedic Surgery. "Insights into the patient experience of rehabilitation from TKA might help shape future therapies and interventions, and could give us a better handle on the ultimate value of TKA."

## Combined with the app, smart knee sleeve collects several important data points

In the trial, 25 patients downloaded an RPM application to their personal iOS devices, wore a smart neoprene knee sleeve during unsupervised exercise once daily, and completed a semistructured interview at three months postop. The study, funded by the Orthopaedic Research and Education Foundation, sought to obtain information as to the number of interruptions in data transmission and patient acceptance of the RPM system.

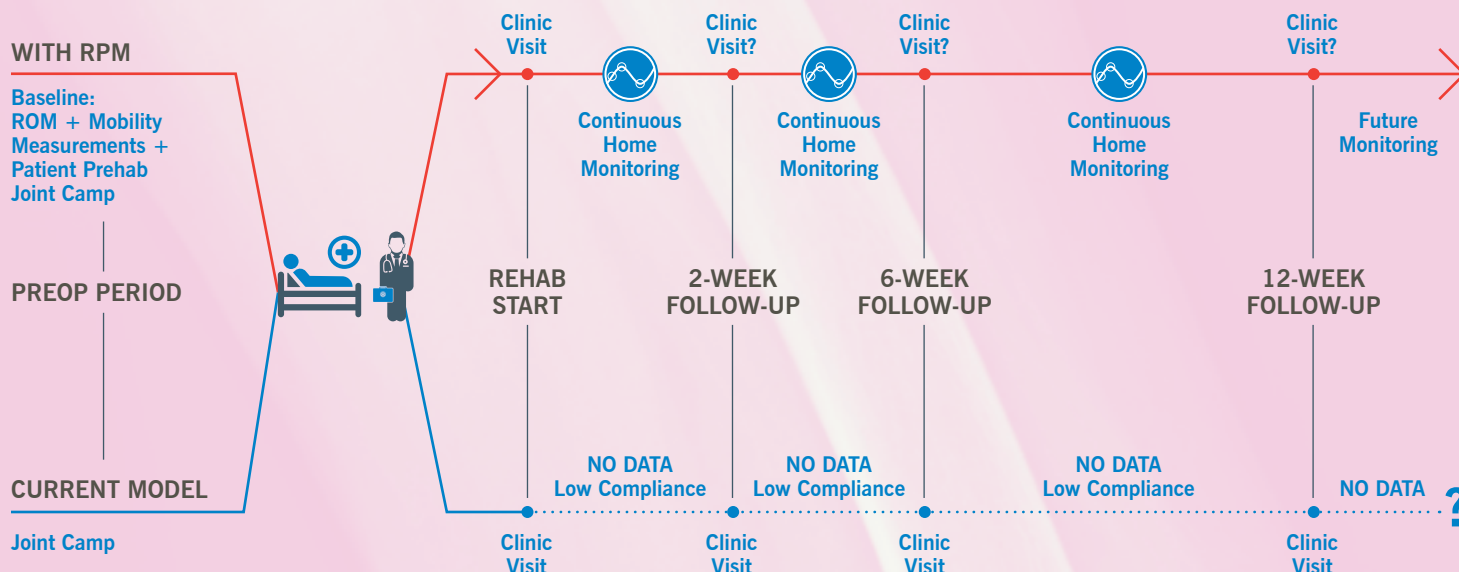
Participants downloaded the app preoperatively, and baseline data were obtained. The knee sleeve was paired with the patient's iOS device postoperatively — before discharge — and participants were instructed to perform daily rehabilitation exercises and to complete a weekly survey. Two sensors on the knee sleeve transmitted spatial orientation changes, reporting daily compliance with a home exercise program and range of motion (i.e., knee flexion). When combined with the app, the RPM system collected the following additional data points: mobility, defined by number of steps; weekly patient-reported outcomes and opioid consumption, defined as the number of pills consumed in the past week. The patient-facing application gave participants full access to their data, as well as an avatar illustrating the patient's range of motion while performing the exercise sets.

## Patients find the system both easy to use and motivating

Results indicate that the RPM system is a valid way to collect, measure, store and transmit patient-related data, from activity levels to range of motion to opioid use. There were no technical issues that resulted in data disruptions during the entire 14-week trial period.

All patients indicated that the system was engaging, citing the app's ease of use, real-time feedback during exercise and daily notifications as motivating factors. In fact, half of the patients requested additional, incrementally difficult exercises in order to advance their recovery regimens.

In terms of patient-reported outcomes, patient mobility returned to baseline measurements by six weeks postop, and exceeded baseline by 30% at three months postop. Patients generally stopped using opioids by postoperative day 5, according to their responses to the weekly questionnaire. At 62%, daily exercise compliance was more than double the previously reported rate; we suspect that just knowing their exercise performance was being monitored may have contributed to patient



Schematic representing potential paradigm shift in postoperative monitoring of total knee arthroplasty with the remote patient monitoring system. ROM = range of motion; RPM = remote patient monitoring.

compliance, though this was not our intent. There was a mean 39.3-point improvement in patient-reported outcomes at three months. Measured by the knee sleeve, the mean knee flexion of 119 degrees was consistent with measurements taken in the clinic.

“We were surprised by how much the patients engaged with the application and drew motivation to further strengthen their postoperative knee,” notes Prem Ramkumar, MD, MBA, a resident at Cleveland Clinic and the study’s lead author.

Additionally, patients found the RPM system easy to use, rating it 2.6 on a scale of 1 to 10, in order of increasing difficulty. The most commonly reported problem with the RPM system was the need to recharge the knee sleeve every three days.

In one central location on the app, the patient was prompted to do daily exercises; the app then provided real-time range of motion feedback and visually charted each patient’s compliance with home exercises, opioid usage, patient-reported outcome scores and mobility, which both the patient and the surgeon could see. All 22 patients who completed the interview at three months reported that they found the experience to be engaging and motivating as they recovered from their surgeries.

### The new era of remote patient monitoring

Dr. Ramkumar acknowledges that the market for remote monitoring is very new and highly dependent on data

acquisition to draw more nuanced insights and contribute to diagnostics. As this is only a feasibility study with just 22 patients, further investigation is required. The next phase of this research is a prospective randomized control trial to determine whether patients using this RPM system need to be seen as frequently postoperatively as those without the technology.

“The main takeaway from this study is the validation that remote patient monitoring in orthopaedics is here, today,” states Dr. Patterson. “With the increase in virtual visits and the opportunity to offer Cleveland Clinic’s world-class care to more patients, this technology may become essential.”

Dr. Ramkumar has disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect; institutional support; or association with an entity in the biomedical field that may be perceived to have potential conflict of interest with this work. For full disclosure statements, refer to <https://doi.org/10.1016/j.arth.2019.05.021>. ■

*Dr. Patterson is Chair of the Department of Orthopaedic Surgery.*

*Dr. Ramkumar is a resident in the Department of Orthopaedic Surgery.*

**Note:** Images repurposed from *J Arthroplasty*; Ramkumar P, Haeberle H, Ramanathan D, et al.; Remote patient monitoring using mobile health: validation of a wearable and machine learning-based surveillance platform; ©2019, with permission from Elsevier.

“WITH THE INCREASE IN VIRTUAL VISITS AND THE OPPORTUNITY TO OFFER CLEVELAND CLINIC’S WORLD-CLASS CARE TO MORE PATIENTS, THIS TECHNOLOGY MAY BECOME ESSENTIAL.”

# RECONSTRUCTING NONUNIONS OF THE DISTAL TIBIA

## AN INNOVATIVE APPROACH TO SALVAGING THE ANKLE JOINT



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Nonunions of distal tibia fractures represent some of the most complex cases an orthopaedic surgeon can face. Distal tibial nonunions can be associated with open fracture, infection, poor skin quality, broken hardware and osteopenia. These factors, independently or in combination, can make successful reconstruction a challenge. For instance, in addition to the presence of traumatic lacerations, previous surgical incisions may have been placed in a suboptimal location, limiting the potential for alternative approaches. Similarly, broken hardware can interfere with the placement of new hardware needed during the revision procedure. Additionally, patient risk factors such as diabetes, smoking and peripheral vascular disease also contribute significantly to the incidence and complexity of nonunion in distal tibia fractures.

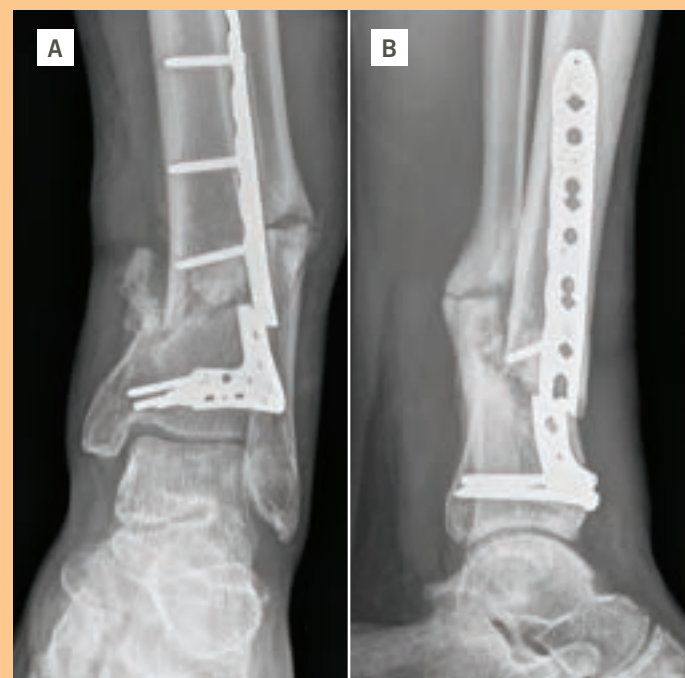
The status of the ankle joint itself can also further complicate reconstructive options. If the articular anatomy of the tibial plafond is in reasonable condition, then the focus of the reconstruction can be on addressing only the metaphyseal nonunion. However, if the damage to the plafond is severe enough that it is not deemed amenable to reconstruction, then a reconstructive procedure that combines ankle fusion with concomitant repair of the nonunion may need to be considered.

This article describes our preferred approach for addressing distal tibial nonunions, both when the ankle joint is spared as well as when the ankle cannot be salvaged and concomitant fusion is required.

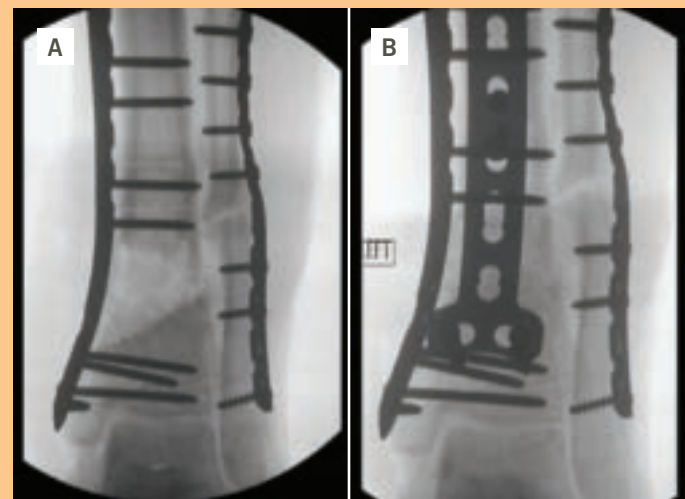
### Two are better than one

Open distal tibia fractures with a medial laceration are often treated with an anterolateral plate to avoid placing hardware through the open wound. This construct may not be adequate to resist the significant bending and torsional forces in the distal leg, resulting in nonunion and breakage of the plate (Figure 1A, 1B). To address this complication, we have utilized a dual-plating technique along with aggressive cancellous bone graft that has been successful in achieving union of distal tibial metaphyseal nonunions.

With this technique, careful attention must be paid to the handling of the skin and the placement of the surgical incisions. The previously placed anterolateral incision must be reopened to remove the broken hardware.



**Figure 1A, 1B:** Anteroposterior (A) and lateral (B) radiographs demonstrate a distal tibial nonunion after medial open fracture initially treated with anterolateral plating. Note the fracture of the plate adjacent to the nonunion.



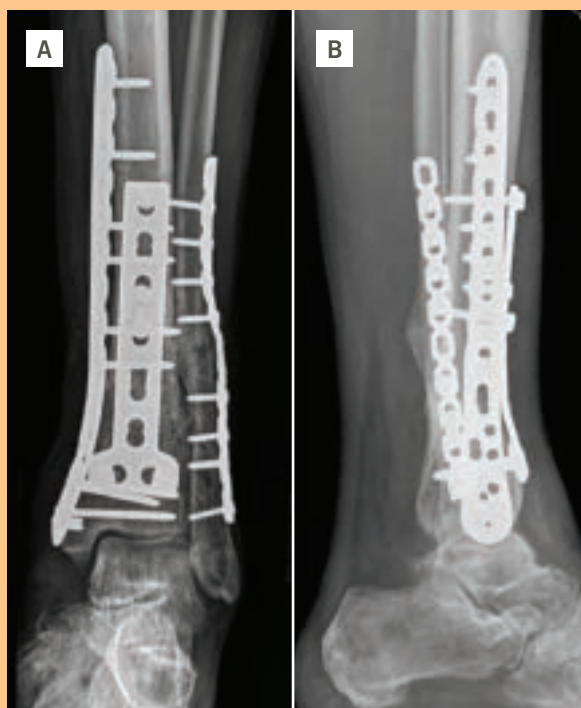
**Figure 2A:** Fluoroscopic anteroposterior (AP) image demonstrates the large metaphyseal bone defect present after debridement of the nonunion.

**Figure 2B:** Fluoroscopic AP image demonstrates appearance after aggressive cancellous bone grafting using femoral intramedullary autograft. Note second anterior T-plate has been placed over the bone graft.



A separate medial incision is required to fully expose the nonunion and to allow for biplanar plate fixation. The skin bridge between these two incisions must be maximized while minimizing undermining of the skin flaps to avoid marginal necrosis. A third posterolateral incision may be needed if the fibula also needs to be addressed.

Once hardware has been removed and the dual approach is exposed, the nonunion must be debrided to bleeding healthy bone. The resultant bone defect can be substantial and is filled with cancellous bone graft (Figure 2A, 2B). Both crushed allogenic bone mixed with bone marrow aspirate and retrograde femoral intramedullary cancellous autograft can be successful. Once the defect is densely packed, dual plate fixation is implanted consisting of a medial distal tibial locking plate and anterior T-plate. The medial plate allows for long-segment neutralization of varus/valgus forces while the anterior plate achieves fixation closer to the fracture site and in the plane of motion. This rigid biplanar construct has proven reproducible and effective in salvaging distal tibial nonunions when the ankle joint can be spared (Figure 3A, 3B).



**Figure 3A, 3B:** AP (A) and lateral (B) images demonstrate successful healing at six months of the distal tibia fracture nonunion in Figure 1 treated with double plating.



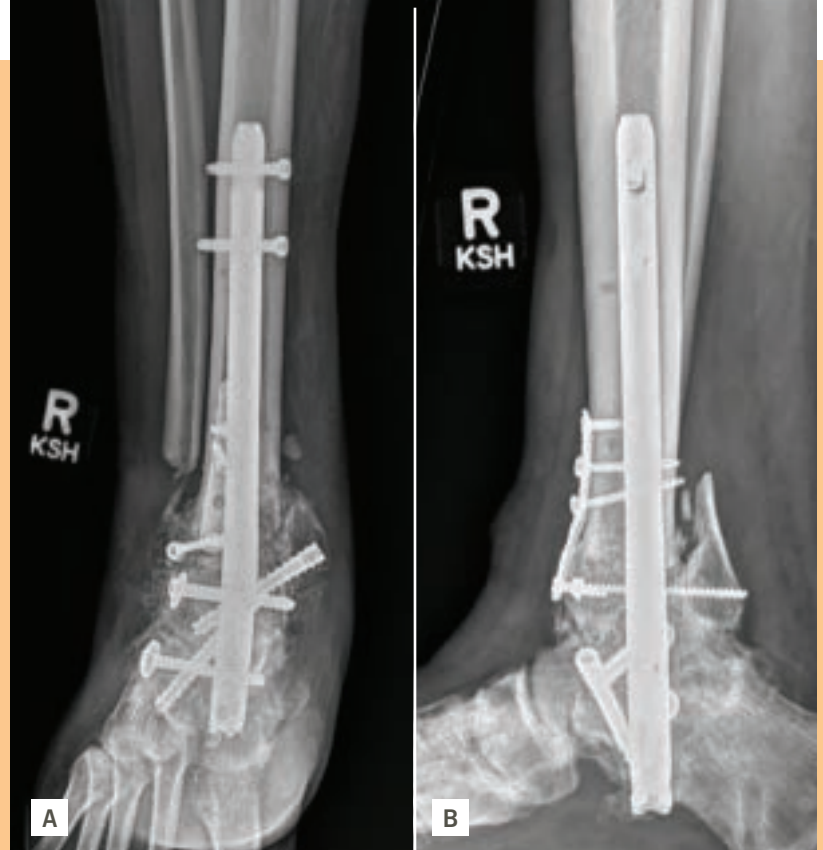
**Figure 4A, 4B:** AP (A) and lateral (B) radiographs demonstrate distal tibia nonunion with severe disruption of the plafond joint surface.

#### Nonunion + damaged joint = difficult fusion

Unfortunately, intra-articular distal tibia fractures can, at times, damage the ankle joint surface so severely as to preclude reconstruction. In this instance, if nonunion develops, it may be necessary to consider fusion of the damaged ankle at the same time as reconstruction of the nonunion (Figure 4A, 4B). At Cleveland Clinic, we have found hindfoot nailing with limited plate and screw fixation of the nonunion to be an effective, albeit imperfect, approach to this problem. Although a hindfoot intra-medullary nail provides rigid, low-profile, long-segment fixation of both the ankle fusion and the nonunion, it necessitates fusion of the subtalar joint as well with resultant hindfoot stiffness. This loss of hindfoot motion must be critically weighed against the putative benefits of this approach on a case-by-case basis to determine whether this approach is appropriate for a given patient.

*continued next page* ➤

**Figure 5A, 5B:** AP (A) and lateral (B) radiographs reveal successful reconstruction of the distal tibial nonunion and fusion of the ankle joint seven months after surgery. Note the one-third tubular plate and screws used to stabilize the major metaphyseal fracture fragments.



With this technique, a transfibular approach is generally required for exposure of both the ankle and subtalar joints. An anteromedial incision is also usually needed to complete the ankle preparation and to fully expose and prepare the metaphyseal nonunion. Just as described previously, the nonunion must be aggressively debrided and packed with cancellous bone graft. Each of the major fracture fragments as well as the ankle joint itself are then pinned in appropriate align-

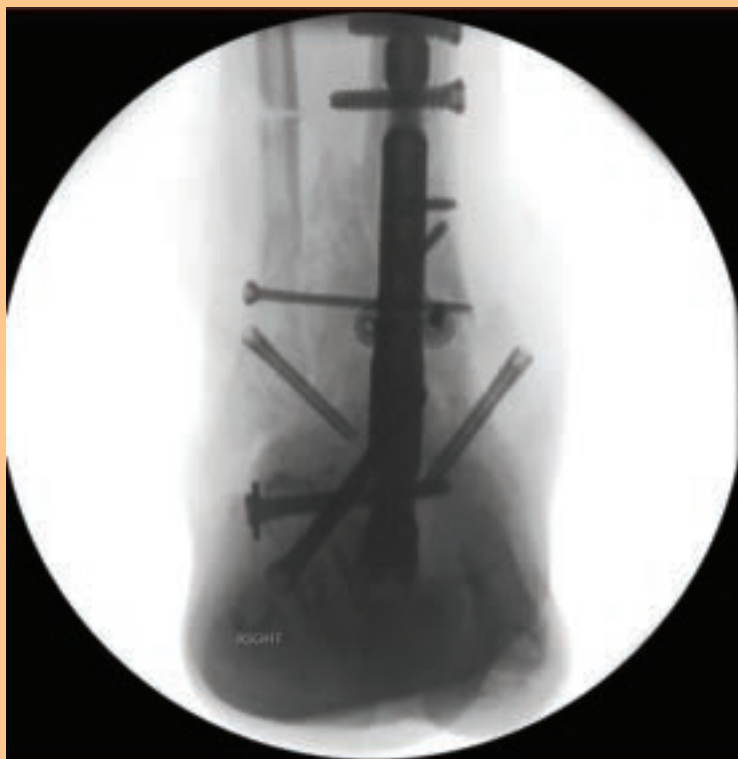
ment. Hindfoot nailing is then performed in standard fashion. Often compression is not needed or desirable due to the concomitant metaphyseal nonunion. However, one-third tubular plates and individual lag screws can be used to buttress and stabilize the major metaphyseal fragments, allowing for modest compression through the nail (Figure 5). Augmentation with bone morphogenetic protein is often indicated. The fibula can either be excised or preserved and stabilized with fixation screws (Figure 6).

#### Key takeaways

Nonunion of a distal tibia fracture represents a severe and complex complication. Double plating with aggressive cancellous bone grafting is a viable technique for salvaging distal tibia metaphyseal nonunions. If the ankle joint is irreparably damaged as well, limited plating along with hindfoot nailing is a useful surgical option. ■

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**Figure 6:** AP fluoroscopic image from a different patient reveals preservation of the distal fibula after osteotomy using screws for fixation.

# ORTHOPAEDIC INFORMATICS PLAYS KEY ROLE IN A NEW ERA OF PATIENT EXPERIENCE

In this new era of focusing on patient experience, it is essential that clinicians use communication technologies to provide digital touch points for our patients. Additionally, the migration from the paper medical record to the digital record has provided significant benefits in patient care.

However, for optimization of the care process, the specific daily workflows of each of the musculoskeletal care subspecialties need to be observed, incorporated and further refined to increase the benefits for both patients and care providers. Managing the challenges of the electronic health record while leveraging existing technologies is imperative so that stakeholders are provided innovative ways to enhance access to and the safety, quality, effectiveness, efficiency and reproducibility of our evidence-based orthopaedic care at Cleveland Clinic.

## What is MATTER?

Addressing this issue in the Department of Orthopaedic Surgery has led to the establishment of a working group consisting of musculoskeletal care providers from within the different subspecialty areas. The first of the working group's projects is the MATTER Program — an acronym standing for Musculoskeletal Access, Triage, Treatment, Education and Retention. MATTER was established to develop technologies and workflows to enhance and optimize patient access and care across the musculoskeletal continuum.

The goal of the MATTER team is to improve every aspect of the clinical experience, from episode-of-care facilitation, patient education and appointment scheduling to assisting the patient to a full recovery. Using what are commonly referred to as medical informatics methodologies and technologies, the MATTER team was created to manage these developments within specific clinical care challenges. Focusing specifically on orthopaedics and musculoskeletal care, the application of informatics provides the bridge between health information technologies and orthopaedic patient care. Orthopaedic informatics involves providing a rational basis to answer the following questions:

1. How can we assemble a dynamic structure to outline the way clinical evidence is pooled, communicated and applied to orthopaedic care?

2. How can we develop organizational processes and structures that minimize the resources we use and maximize the benefits we deliver?

3. What tools and methods need to be developed to help achieve these aims in a manner that is practicable, testable and in keeping with the fundamental goal of providing world-class care to our orthopaedic patients?

## Optimizing technology to improve care

As an example of our current technology developments, our group understands that there are certain situations that require more emergent triage, scheduling and management. A pediatric patient with a fracture is one such example. To address this need, the MATTER team has collaborated with members of the Center for Pediatric and Adolescent Orthopaedic Surgery to pilot a web-based Scheduling Triage and Access Tool (WebSTAT) that enhances the accuracy, appropriateness and efficiency of scheduling a pediatric patient with a fracture. Often, getting that initial appointment is unnecessarily anxiety provoking. This web-based solution provides efficient, immediate and appropriate scheduling with a pediatric orthopaedic specialist, coupled with patient education materials.

As the pilot program is completed and the tool is validated, the MATTER team will expand the solution across the other centers and sections in orthopaedics. MATTER represents a critical first step in continuing the transformation of the clinical experience for orthopaedic patients. ■

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# BONE-PRESERVING SHOULDER SURGERY SHOWS PROMISING OUTCOMES

## NEW STUDY CLINICALLY VALIDATES THE PARADIGM-SHIFTING TECHNIQUE



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A recent proof-of-concept study published in *JSES Open Access* demonstrated the clinical utility of a surgical technique for patients undergoing a total shoulder arthroplasty (TSA). The study validated a technique that has seen greater demand in recent years — first from professional weightlifters and serious athletes and now from a more general patient population in need of a shoulder replacement.

Anthony Miniaci, MD, a shoulder and sports medicine surgeon in Cleveland Clinic's Department of Orthopaedic Surgery and senior author of the study, notes that this technique is a paradigm shift for shoulder surgery.

"It's less invasive because it's bone preserving," he says. "Most patients who receive this surgery tend to recover very quickly. Depending on the circumstances, they may be discharged the same day or next day."

Preoperative anteroposterior view



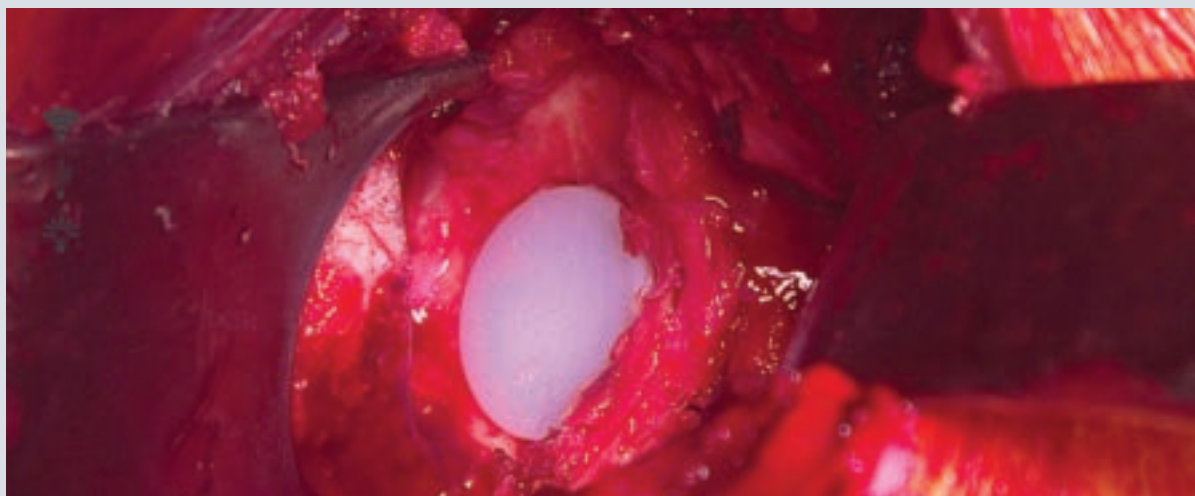
### The technique: a two-part concept

The technique is based on a two-part concept designed to more accurately mimic the anatomy of a patient's humeral head and also use inlay technology that is less invasive and salvages more of the patient's bone.

The humeral component of the replacement is traditionally shaped like a sphere even though anatomically the humeral head is more of an ovoid shape. While using an ovoid-shaped replacement has shown promising results in laboratory studies, this study validates these findings in a clinical setting.

On the glenoid side, where onlay replacement is traditionally used, Dr. Miniaci and his team combined the humeral head replacement with an inlay implant. Instead of gluing the plastic on top of the bone, the surgeons make a little slot for it in the bone, so that it takes some stress off the plastic.

Dr. Miniaci first conceptualized this technique after observing an unmet need in the patient population he was treating, many of them athletes. He was so pleased with the outcomes that he began to use this approach for every shoulder replacement.



The inlay implant is slotted into the bone so that it shares stress with the patient's own glenoid.



Series of intraoperative photos showing humeral head replacement with a bone-preserving oval implant that more closely replicates the patient's anatomy.

### Study results

This retrospective study examined 31 shoulders in 29 patients (25 males, 86.2%; 4 females, 13.8%) with an average age of 58.5 years and mean follow-up of 42.6 months. All patients received a preoperative diagnosis of osteoarthritis and were treated with a combination approach of nonspherical humeral head and inlay glenoid replacement by a single surgeon from 2011 to 2016.

In the two groups, one with preoperative concentric glenoids ( $N = 7$ ) and one with nonconcentric glenoids ( $N = 24$ ), there were no significant differences in patient-reported outcomes including pain relief, function and satisfaction. The technique showed positive outcomes despite differences in glenoid morphology.



Postoperative anteroposterior view

"This is important because while TSA has proved an effective therapeutic approach to treating pain and improving function, there are relatively little data to compare outcomes for concentric and eccentric glenoids," remarks Dr. Miniaci. "This study helps confirm that we can sensibly use this approach for patients with concentric or eccentric glenoids."

The comparison of preoperative with postoperative range of motion also showed a significant improvement in forward flexion. All patients with baseline Penn scores surpassed the 30% clinically important difference threshold on their maximal possible improvement, and 94% met or exceeded the substantial clinical benefit mark.

### What's next?

This proof-of-concept study is a first step in validating the procedure's clinical success. Dr. Miniaci hopes it soon becomes a standard operation for all patients in need of TSA.

"This technique has the potential to alter the standard of care for treating TSA. I am eager to continue exploring this approach and even less-invasive options to treat future patients," he says. ■

***Dr. Miniaci is a shoulder and sports medicine surgeon in the Department of Orthopaedic Surgery.***

Dr. Miniaci reports that he receives financial support (consultant fees, speaker fees, honoraria, royalties, stock options) from Arthrosurface Inc. and Trice Medical, Inc.



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