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and Volker Musahl, MD**
Improving Outcomes
for Multiple Ligament
Knee Injuries



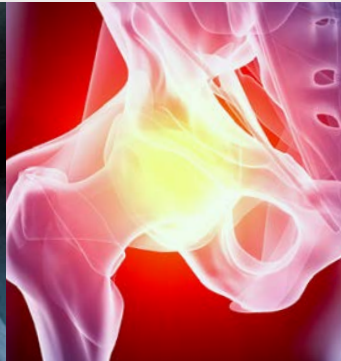
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ABOUT THE **DEPARTMENT OF
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Founded in 1953 as a separate department of the University of Pittsburgh School of Medicine, the Department of Orthopaedic Surgery is committed to delivering the highest quality of diagnostic and therapeutic patient care to both adults and children for a diverse spectrum of orthopaedic disorders. To this aim, the department seeks to meet the needs of 21st century orthopaedic care not only by integrating the latest biological and technological advancements in orthopaedic science, but equally by leading the development of novel treatment modalities through distinguished basic science and clinical research programs. In addition, the Department of Orthopaedic Surgery seeks to be a leader in educating the next generation of orthopaedic surgeons through its residency and fellowship training programs, which include comprehensive, in-depth exposure to all specialties of orthopaedic care and advanced surgical experience.

Freddie H. Fu, MD, DSc (Hon), DPs (Hon)
Chairman



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James J. Irrgang, PhD, PT

Volker Musahl, MD

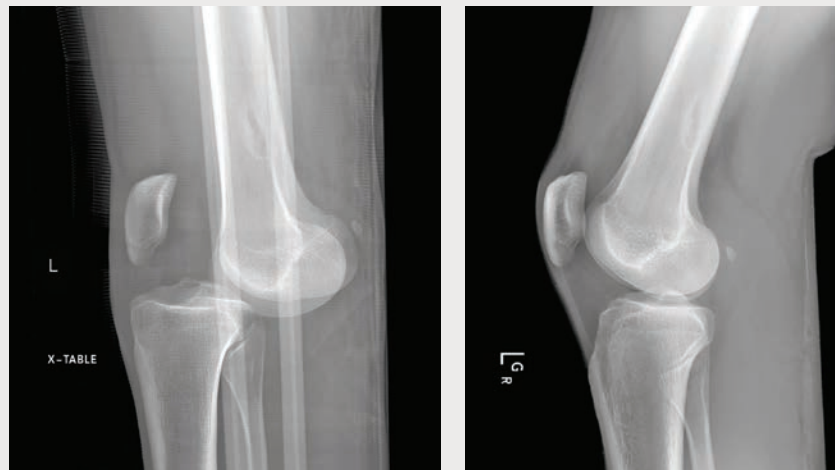


IMPROVING OUTCOMES FOR MULTIPLE LIGAMENT KNEE INJURIES

In 2017, researchers from the Department of Orthopaedic Surgery were awarded a major new grant¹ (Contract Number: W81XWH-17-0073) from the United States Department of Defense (DoD) to study and determine optimal timing for surgery and rehabilitation of multiple ligament knee injuries (MLKIs). Officially titled the *Surgical Timing and Rehabilitation (STaR) for Multiple Ligament Knee Injuries (MLKIs): A Multicenter Integrated Clinical Trial*², the \$4.5 million randomized trial is led by co-principal investigators **James J. Irrgang, PhD, PT**, professor and director of clinical research in the Department of Orthopaedic Surgery and chairman of the Department of Physical Therapy, and **Volker Musahl, MD**, associate professor and chief of sports medicine.

Current high-level evidence is scarce to nonexistent regarding when it is best to perform surgery and rehabilitation for cases of multiple ligament knee injuries to optimize outcomes and return individuals with an MLKI to, or as close as possible to, their preinjury level of activity and physical function. Most of the guiding principles used now are based on ACL reconstruction surgery, where early surgery and early rehabilitation after surgery is the standard of care. However, MLKIs are a much broader-spectrum, heterogeneous injury when considering what and how many different structures of the knee could be affected, and what kind of corrective surgery is required to repair the damaged tissues. These serious, complex, multidimensional injuries, while not exceedingly common in occurrence

(the incidence in the general population is not exactly known but may be approximately 0.072 per 100 patient-years in civilians with orthopaedic injuries³), are quite devastating in their consequences. These injuries are often accompanied by significant nerve and vascular trauma, as well as fractures and injury to surrounding tendons and structures. MLKIs often are the result of high-energy trauma incidents, as well as high-impact sports such as football and other strenuous activities such as military training. MLKIs carry with them a range of potential postsurgical and rehabilitation complications. These include poor wound healing, arthrofibrosis, posttraumatic osteoarthritis, pain, and persistent joint instability, among other challenges.



Pre- and post-reduction multiple ligament knee injury x-rays.

Given the significant resources in time and costs of training and maintaining their active duty members, achieving better outcomes for individuals who suffer this type of injury is of significant concern for the DoD. For military personnel, return to duty at previous levels after sustaining an MLKI may be as low as 40 percent. In the civilian population, return to work at preinjury levels is on the order of 80 percent, however, this is dependent on the type of work the individual does. Furthermore, the time to return to preinjury activity level has not been studied.

This Study Will Address a Gap in the Literature

Why isn't there currently a good body of evidence to support the optimal timing of surgery and rehabilitation for these injuries? Dr. Musahl explains that it comes down to two main factors with these particular injuries. "If you examine the literature, it is very difficult to find studies that are prospective because of the severity of this injury and concomitant factors such as vascular and nerve injuries, open fractures, and head and poly-trauma. This makes it difficult to randomize patients in a study. This is why most of the studies done to date have been small in cohort size, and universally retrospective in nature."

This alludes to the second reason for a lack of clear-cut evidence for timing of treatment — the relative rarity of these injuries. "The only way that you can have a powerful enough study of this injury, because of the relatively low incidence coupled with the fact that we will necessarily exclude many patients from the trial because of concomitant injuries, is to design a multi-center trial," says Dr. Irrgang.

STaR Trial Participating Sites	Site PI
University of Pittsburgh (Lead Site)	James Irrgang, PhD
University of Pittsburgh - DCC	Charity Moore Patterson, PhD
Brown University	Brett Owens, MD
Health Partners Institute for Education and Research (Minneapolis, Minnesota)	Jonathan Cooper, DO
Hospital for Special Surgery (New York)	Anil Ranawat, MD
Keller Community Army Hospital (West Point, New York)	Matthew Posner, MD
Mayo Clinic (Rochester, Minnesota)	Bruce Levy, MD
Nova Scotia Health Authority – Queen Elizabeth Health Sciences Center	Cathy Coady, MD
San Antonio Military Medical Center	Travis Burns, MD
St. Michael's Hospital (Toronto)	Daniel Whelan, MD
TRIA Orthopaedic Center (Bloomington, Minnesota)	Bradley Nelson, MD
Tripler Army Medical Center (Honolulu, Hawaii)	Craig Bottoni, MD
University of Cincinnati	Brian Grawe, MD
University of Connecticut	Robert Arciero, MD
University of Kentucky Research Foundation	Darren Johnson, MD
University of Michigan	John Grant, MD
University of Minnesota	Jeff Macalena, MD
University of New Mexico Health Sciences Center	Robert Schenck Jr., MD
University of Texas Health Sciences Center at Houston	Christopher Harner, MD
University of Virginia	Mark Miller, MD
University of Washington (Seattle)	Albert Gee, MD
University of Western Ontario (London, Ontario)	Alan Getgood, MD
Walter Reed National Military Medical Center (Bethesda, Maryland)	Jeffrey Giuliani, MD
Washington University (St. Louis)	Matthew Matava, MD
William Beaumont Army Medical Center (El Paso, Texas)	Mark Pallis, MD

With a pilot grant from the DoD in 2015, that's exactly what Drs. Irrgang and Musahl accomplished: developing the protocols, assembling the sites and necessary analytical resources including an onsite data center and statistician, and eventually building a trial framework that the DoD has now funded in full to attempt to shed the necessary light on how best to treat these injuries.

Drs. Irrgang and Musahl have assembled a cohort of 24 United States Armed Forces entities and academic medical centers across the United States and Canada that will be participating in the trial and enrolling patients. **Andrew Lynch, PhD, PT**, assistant professor in the Department of Physical Therapy at the University of Pittsburgh, is serving as the qualified clinical investigator for rehabilitation in the study. Dr. Musahl is serving in that role from a surgical perspective. **Charity Moore Patterson, PhD**, professor in the Department of Physical Therapy, will serve as co-investigator and lead biostatistician for the study.

Study Aims and Details

The STaR Trial is comprised of two separate studies examining subpopulations of individuals with an MLKI and randomizing them into appropriate arms of the study based on injury criteria, timing of presentation, and concomitant injuries that would require or preclude early surgical treatment.



Photo depicting a current rehabilitation patient with a previously dislocated knee and multiple ligament injury.

The first aim of the study is to determine the combined effects related to the timing of surgery and rehabilitation on the amount of time it takes for enrolled patients to return to their preinjury status and activity. Individuals presenting for treatment within six weeks of surgery who are between the ages of 14 and 65 will be eligible for the study and will include both military personnel and civilians who have a multiple ligament knee injury. Individuals with a past history of knee reconstruction, or those who have associated vascular injury, polytrauma, or traumatic brain injury, will be excluded from participation.

Participants in the first study will be randomized into one of four groups:

- Early Surgery and Early Rehabilitation
- Early Surgery and Delayed Rehabilitation
- Delayed Surgery and Early Rehabilitation
- Delayed Surgery and Delayed Rehabilitation

“Our hypothesis at the start is that early surgery and early rehabilitation, and the combination thereof, will lead to better outcomes,” says Dr. Musahl. “Early surgery sometimes enables us to repair structures that may not be possible to repair if there is a delay, because of early degeneration or retraction from connecting tissues. Using tissue grafts and anatomical reconstruction may also afford benefits in this regard. But we may find, too, that in some cases or variations of the injury, patients may benefit from a course of rehabilitation first — the concept of pre-rehab — in essence priming the musculoskeletal system for what is to come after surgery and during the postoperative rehabilitation phase, which for these injuries can be a year or more in duration.”

“The only way you can have a powerful enough study of this injury is to design a multicenter trials.”

James J. Irrgang, PhD, PT

The second aim of the study will seek to determine the effects of the timing of rehabilitation on the time to return to activity. Participants in this aspect of the study will have had an MLKI for which the timing of surgery cannot be randomized. These patients will be randomized into either early or delayed rehabilitation. Participants in this cohort also will have had an injury that precludes their randomization into surgery, or who for one reason or another have refused or declined randomization to surgery.

On the rehabilitation side, there exists little to no evidence at all about how best to rehabilitate these injuries after surgery. “They are just extensive injuries requiring detailed surgery. Typically, surgeons are concerned about progressing an individual too quickly lest they disrupt a repair or graft. This is why I think most individuals with MLKI do very little weight bearing and limited motion for the first four weeks postoperatively. However, when you review the evidence for ACL reconstruction, it overwhelmingly shows better outcomes with early weight bearing, strengthening, and range of motion exercises. The question then becomes: Can you apply those same principles to these more significant injuries and associated surgeries? The concern is that if we are too aggressive early on with rehabilitation, it could disrupt what was repaired, resulting in a knee that is too loose and unstable.

On the other hand, if we delay rehabilitation, particularly combined with early surgery, stiffness and a lack of range of motion may result. This is what we are trying to answer with the early versus delayed rehabilitation question,” says Dr. Irrgang.

Approximate Return to Duty/Work at previous levels after sustaining an MLKI

Military Personnel	40%
Civilian Populations	80%

A unique aspect of this study is the end outcome measure being evaluated. “We are really focused on the time to return to a preinjury level of activity. This will include, for example, participation in military activities, sports activities, and work. This has never really been looked at with knee injuries, even with ACL reconstruction. We don’t have any solid evidence to answer this question of timing, so we are very excited to try and quantify this aspect in our study,” says Dr. Musahl.

Randomization Stratification

Multiple ligament knee injuries present on a spectrum. They can present anywhere from a complete tear or rupture of two ligaments, the ACL and MCL for example, to a complete dislocation that results in tears of all four of the main ligaments with accompanying damage to cartilage, meniscus, and the like. “We think there is a big difference between tearing one cruciate ligament and some other ligament, or tearing both cruciate ligaments with or without additional damage,” says Dr. Irrgang. To account for this spectrum in the study, randomization of participants will be stratified to help control the variability seen in these injuries. “Statistical analysis also will enter into the model of the injury classification to help adjust for these variances.”

Laying the Groundwork for Future Research

While this new trial is just beginning, with patient recruitment set to start in the coming months, Dr. Musahl sees much potential for tangential, even department-wide, and new, related avenues of investigation in the future, such as how biologic applications or interventions may play a role and modulate responses to surgery and rehabilitation in cases of MLKI.

¹ The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-14 is the awarding and administering acquisition office.

² This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Peer Reviewed Orthopaedic Research Program, under Award No. W81XWH-17-2-0073. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.



“Our hypothesis is that early surgery and early rehabilitation, and the combination thereof, will lead to better outcomes.”

Volker Musahl, MD



DIAGNOSING CARPAL TUNNEL SYNDROME WITH ULTRASOUND: BETTER, FASTER, AND COST-EFFECTIVE

Hand and upper extremity surgeon **John R. Fowler Jr., MD**, is not one prone to inflammatory remarks for their own sake; however, his advocacy for the use of ultrasound (US) is vocal and passionate, specifically when discussing the diagnosis of carpal tunnel syndrome (CTS) with US versus what has been used almost exclusively in the past — nerve conduction studies (NCS). “Nerve conduction studies definitely have their place, but the more research I conduct, the more I’m convinced it is not, except in limited circumstances, the most appropriate first line diagnostic for CTS,” says Dr. Fowler.

Dr. Fowler’s work over the last 10 years using, studying, teaching, and advocating for the use of ultrasound imaging to diagnose carpal tunnel syndrome is based in the evidence as much as it is in his unwavering and vocal passion to help patients by offering them a less invasive approach to diagnose their condition. “Less invasive is always good for any kind of test as far as patients are concerned, but the tests have to be reliable, predictable, repeatable, and accurate,” says Dr. Fowler. Much of Dr. Fowler’s work over the last decade and a half has been to prove the case for wider adoption of ultrasound as a first-line test for carpal tunnel syndrome through rigorous study and training.

Dr. Fowler first became interested in the use of ultrasound while in residency at Temple University. “We would see patients in clinic, refer them for nerve conduction testing, and half or more of these individuals would return without having gotten the test, due to a lack of appointment

options and associated costs. The discomfort of the test itself likely also played a role in many of these cases. This got me thinking about what alternatives and options might be out there to diagnose these patients,” says Dr. Fowler.

Further work as a surgical fellow at the University of Pittsburgh afforded Dr. Fowler the ability to use ultrasound for all manner of cases, allowing him to greatly increase his knowledge, skill, and accuracy with the technique by conducting nearly 1,000 ultrasound imaging procedures during his training. “This clinical work using a portable US machine at the Hand and Upper Extremity Center really became the impetus and basis for much of my early research.”

Most of Dr. Fowler’s research to date has worked to confirm and expand on past work by others that ultrasound is a very accurate test for carpal tunnel syndrome. In the right scenario, ultrasound has a similar — if not higher — sensitivity and specificity compared to nerve conduction studies. “A focus of my research now is to find ways to minimize the rate of false negatives and false positives,” says Dr. Fowler. Part of Dr. Fowler’s ongoing studies involves understanding whether or not the height, weight, and BMI of individuals matter in terms of their nerve size. “You would think that this would play a role, however, what we are finding is that the size of the individual has very little influence on their median nerve size, perhaps a millimeter or less in most cases.”



Recent Research: Comparing US and NCS in Carpal Tunnel Syndrome

In 2016, Dr. Fowler and colleagues published findings of a study¹ designed to assess the correlation, if any, between cross-sectional area measurements of the median nerve via ultrasound imaging with the motor/sensory latencies of the nerve measured with NCS in patients with suspected carpal tunnel syndrome. This blinded, prospective study examined 87 suspected cases of CTS. Dr. Fowler's study showed a positive correlation between NCS and US (91 percent) in study participants, as well as similar levels of sensitivity and specificity between each testing modality (83 percent and 94 percent, respectively).

Other work by Dr. Fowler involves pre- and postsurgical correlations between findings in diagnostic tests. "If you look at the literature for NCS, you will find that even after the surgery, follow-up testing does not quite show a return to normal, despite the patient feeling 100 percent better and being pain free. We're not sure why that is, but perhaps we can correlate those findings on ultrasound of the median nerve," says Dr. Fowler. At present, Dr. Fowler has assembled a database of more than 500 patients who have had preoperative ultrasound, with 150 of those individuals having had a postoperative, follow-up ultrasound. Analysis is underway between these two patient cohorts to see if the improvements in a patient's nerve cross-sectional areas correspond with their symptoms, or lack thereof.

Another study in progress is examining if there is a way, using ultrasound, to predict how long it will take patients to recover depending on the severity of their carpal tunnel syndrome.

Training a New Generation of Ultrasound Users

Dr. Fowler is actively involved with education, specifically related to the use of ultrasound in orthopaedic surgery, but more generally as well with medical students. As assistant dean for medical student research, Dr. Fowler was instrumental in creating a new musculoskeletal educational program for second year medical students at the University of Pittsburgh in collaboration with **MaCalus V. Hogan, MD**.

Additionally, for the last several years, Dr. Fowler and colleague **Tom Hughes, MD**, have conducted an ultrasound pre-course at the annual meeting of the American Association for Hand Surgery. The six-hour course provides education and training on ultrasound for orthopaedic surgeons, and is offered as a separate registration course.

Some of Dr. Fowler's education with ultrasound imaging has fed recent research projects. Published in 2017, Dr. Fowler's paper² in the journal *Hand*, along with coauthors **Jared Crasto, MD**, and **Michael Scott, MD**, sought to quantify to what degree and within what timeframe an individual could be successfully trained to use ultrasound to detect the signs of carpal tunnel syndrome using ultrasound and nerve cross-sectional area measurements. "Surprisingly, this study showed, in a small cohort, that individuals are able to learn the technique and measure the correct structure — with relatively high degrees of success and accuracy compared to their baseline measurements prior to instruction and against the study controls — in a short period of time."



*Dr. Fowler discusses research findings with orthopaedic surgery resident **Chinedu Nwasike, MD**.*





“Nerve conduction studies definitely have their place, but the more research I conduct, the more I’m convinced it is not, except in limited circumstances, the most appropriate first line diagnostic for CTS.”

John R. Fowler Jr, MD



A CONTINUING LEGACY OF PIONEERING SPORTS MEDICINE AND ACL RESEARCH

Carola F. van Eck, MD, PhD, is one of the newest faculty members to have joined the department in the second half of 2017. A sports medicine specialist, Dr. van Eck's training in orthopaedic surgery included a post-doctoral research fellowship in the department under the mentorship of Freddie H. Fu, MD, followed by her orthopaedic residency training at the University of Pittsburgh from 2011 to 2016. After completing an orthopaedic surgery fellowship at the Cedars-Sinai Kerlan-Jobe Institute in Los Angeles, California, Dr. van Eck returned to Pittsburgh to join the department's impressive roster of faculty members who continue to shape and guide the field of orthopaedic surgery nationally and internationally.

Beyond her research interests, which are numerous and include an emphasis on anterior cruciate ligament (ACL) reconstruction techniques and repair (her PhD thesis examined the changing anatomic ACL reconstruction paradigm), and a busy practice of treating sports medicine patients at the UPMC Rooney Sports Complex, Dr. van Eck also serves as the team physician for Robert Morris University (RMU) in Pittsburgh, as well as being a team physician for the Pittsburgh Passion women's football team. Dr. van Eck also played professional women's football herself from 2008 to 2011 while working as a post-doctoral research fellow in Pittsburgh. With RMU, Dr. van Eck is most involved with football, and men's and women's ice hockey, lacrosse, and basketball, although she treats and covers athletes across all of RMU's 16 Division I NCAA sports programs.

Research Projects in the Pipeline

Dr. van Eck has an extensive research portfolio, co-authoring 69 peer-reviewed publications to date and another 68 abstracts. She is currently engaged in several new projects in collaboration with the department's Orthopaedic Engineering and Sports Medicine Laboratory, which is co-directed by Department Chairman **Freddie H. Fu, MD**, and **Patrick Smolinski, PhD**, from the University of Pittsburgh Department of Mechanical Engineering and Materials Science.



Monica A. Linde-Rosen, MSIE, RN, is the technical manager of the lab, and contributes to and supervises all of its activities and investigations. This lab has, and continues to be, a hotbed for research into ACL reconstruction and surgical techniques, and related biomechanical properties and tissue behavior of the ligament itself. Each year a rotating assortment of international fellows comes to work at the lab and contribute to its ongoing research projects.

Notchplasty and Knee Biomechanics

Dr. van Eck and collaborators in the lab have several new projects in the pipeline and in progress that are focused on aspects of the ACL and reconstruction and repair techniques.

“We are currently working on a grant application to examine the effect notchplasty has on knee biomechanics when performed in the setting of an ACL reconstruction.”

Notchplasty is used routinely in the setting of ACL reconstruction to aid in visualization of the femoral ACL footprint to accomplish anatomic graft placement, as well as to avoid impingement in the intercondylar notch as the graft heals postoperatively. The technique removes a small portion of bone from the lateral femoral condyle. “We think the issue is that the technique leaves the patient with an altered anatomy. The technique is non-anatomic by definition, and we are interested in how this could potentially change a person’s biomechanics,” says Dr. van Eck. The new study in humans would be based on an animal model version¹ previously published by Dr. Fu and colleagues in 2012. The new study would assess changes in knee biomechanics based on the size of the notchplasty performed. Dr. van Eck and colleagues plan to evaluate two different sizes and amounts of bone removal to assess how this change in anatomy would affect the repair and any post-surgical complications.



Radiological study of porcine knee used in notchplasty study.

Repair Versus Reconstruction

Dr. van Eck and the Orthopaedic Engineering and Sports Medicine Laboratory also are engaged in another study related to the ACL regarding the use of internal bracing of surgically repaired ACLs. “There’s been somewhat of a resurgence of late in research into repair of a ruptured ACL versus reconstruction with a graft. This approach, repairing the native ligament, requires the use of some type of internal bracing via a scaffold or other type of rigid suture material while the ACL heals,” says Dr. van Eck. Although the technique is in clinical practice in some settings, Dr. van Eck explains that there is really a lack of quality evidence from a biomechanical and clinical perspective to support whether or not this type of procedure ought to be routinely used, or perhaps confined within a narrow set of clinical indicators. “There are a few case reports and small retrospective examinations of the technique, but nothing concrete exists as to the efficacy and possible complications of this type of repair, and what methodology or type of bracing may be best,” says Dr. van Eck.

This study, in the development phases, will evaluate the biomechanical properties of an internal bracing construct in the setting of ACL and MCL repair or reconstruction to determine whether and to what degree the construct aids in stabilizing the knee after the ligament repair is performed.

“One of my concerns about this approach is if you’re putting something into the knee joint that is more rigid than the native ACL to temporarily stabilize it, this may lead to overconstraining the ligament, thereby putting abnormal forces on the knee joint. We know from other studies that if you overconstrain the knee, it can lead to abnormal wear and osteoarthritis,” says Dr. van Eck. The procedure may also radically change or increase the load to failure point on the ligament by significant degrees, the consequences of which are completely unknown at this point.

There is also the question in ACL repair or reconstruction as to the degree of knee flexion angle the surgeon should tension the device. Most surgeons doing repairs such as these at present are using the same flexion angle as would be done in an anatomic reconstruction. “But that’s purely anecdotal. We do not have good evidence to support that right now. These are the questions we hope to answer with this study,” says Dr. van Eck.

One of Dr. van Eck’s collaborators on this study, Monica Linde-Rosen, suggests that after this initial study concludes, the team ought to conduct an investigation in a living animal model that looks at how the suture or bracing material within the knee joint changes over time. Does it have any wear particles, or resorb into the body, and does it cause an inflammatory response within the knee? These are all secondary aspects of the procedure for which there is no evidence or understanding of the potential long-term consequences.

DR. VAN ECK SERVES AS TEAM PHYSICIAN FOR THE PITTSBURGH PASSION WOMEN'S PROFESSIONAL FOOTBALL TEAM, AND ALSO SERVES AS A TEAM PHYSICIAN FOR ROBERT MORRIS UNIVERSITY. DR. VAN ECK HERSELF PLAYED PROFESSIONAL WOMEN'S FOOTBALL FROM 2008 TO 2011 WHILE WORKING AS A POST-DOCTORAL RESEARCH FELLOW IN PITTSBURGH.





NEW FRONTIERS IN HIP AND KNEE ARTHROPLASTY

Michael J. O'Malley, MD, assistant professor of orthopaedic surgery, is a hip and knee replacement surgery specialist who joined the Department of Orthopaedic Surgery in September 2016. Dr. O'Malley completed his fellowship training at the Rothman Institute of Thomas Jefferson University, preceded by residency training at the University of Pittsburgh and medical school at Temple University. Dr. O'Malley trained under some of the most respected and talented orthopaedic surgeons in the field while at the University of Pittsburgh. He credits Drs. Larry S. Crossett, Brian A. Klatt, and Freddie H. Fu for their mentorship and guidance, shaping the direction of his clinical practice and research, and ultimately being responsible for his return to the department as a faculty member. "Drs. Crossett and Klatt instilled in me their passion and philosophy toward joint replacement and research, how people's lives can be changed with this surgery, and I have carried that forward in my approach and focus as a surgeon and researcher," says Dr. O'Malley.

Hip Arthroplasty—The Direct Anterior Approach

Dr. O'Malley is a proponent and active user of the direct anterior approach to total hip arthroplasty, having trained extensively in the procedure during his fellowship at the Rothman Institute where he gained a proficiency in the technique that has carried forward to his surgical practice in Pittsburgh. "There are pros and cons to this approach, much as there are with any type of surgical procedure. With the direct anterior approach, there is less disruption to muscle attachments, specifically the hip abductors. Some of the literature also suggests faster recovery, less pain, and a quicker discontinuation of the use of walking aids," says Dr. O'Malley. Hip precautions are something not typically needed with the direct anterior approach. With other approaches, there are potential downsides such as increased instability and the need to violate the abductors.

Dr. O'Malley trained on the direct anterior approach at the Rothman Institute in a carefully controlled and rigorous manner. "If you look at the research, there is a learning curve with the direct anterior approach of 50 to 100 cases to achieve proficiency. My focus from the start has been on using this technique and thoroughly understanding how to best conduct the procedure. The training I did as a fellow allowed me to be proficient in the technique immediately during my practice at UPMC, and I believe this has been to the benefit of my patients," says Dr. O'Malley.



Because of Dr. O'Malley's training and proficiency with the direct anterior approach, more than 95 percent of his cases of total hip arthroplasty (more than 200 cases since joining the department) are done in this manner. Only when certain anatomical anomalies exist in a patient will Dr. O'Malley employ an alternate technique.

Another aspect of Dr. O'Malley's direct anterior approach to hip arthroplasty is manifesting in work to develop a clinical pathway of same-day discharge for appropriate hip arthroplasty patients. This pathway is in the early stages of development and may be of great benefit to those patients who are appropriate candidates, as well as the the entire UPMC system.

“Several randomized studies by other groups have shown safety and efficacy of same-day discharge in hip arthroplasty. We are now currently evaluating this approach for our patients to determine if it is viable, safe, and effective.”



Periprosthetic Joint Infections and the Use of Sonication in Clearance and Culture

Periprosthetic joint infections continue to be a leading cause of failure and revision surgeries in hip and knee arthroplasty. Bacteria and organisms that invade a joint and device are known to form a biofilm that is resistant to treatment, and clearing the infection while the device is still in the patient is generally not a viable option.

The use of sonication, an ultrasound-based technique for clearing a device of infectious agents and subsequent gathering of materials for culturing, is relatively new in the field of orthopaedic surgery. Dr. O'Malley and the department were early adopters of the technique from both a clinical use and research standpoint, and they continue these efforts in recently published¹ and ongoing studies.

The process of sonication quite literally shakes the microbial agents off the device in the lab. For patients deemed to have a chronic infection with a duration of more than three weeks, the standard of treatment entails removal of the implant, followed by the placement of a type of antibiotic-laden spacer, after which the patient is closed and the implant is sent to the lab for sonication and culturing. Bacterial-laden fluids from the sonication process are aliquoted, centrifuged into pellets, and then resuspended and cultured. Patients typically are started on intravenous antibiotics for a defined period and then retested using multiple means. Patients successfully cleared of infection are typically reimplanted about three months after the initial removal procedure.



DR. O'MALLEY IS A PROPONENT AND ACTIVE USER OF THE DIRECT ANTERIOR APPROACH TO TOTAL HIP ARTHROPLASTY. HE TRAINED EXTENSIVELY IN THE PROCEDURE DURING HIS FELLOWSHIP, AND GAINED A PROFICIENCY IN THE TECHNIQUE THAT CARRIED FORWARD IMMEDIATELY TO HIS SURGICAL PRACTICE AT UPMC.

The technique of sonication has been shown in research by Dr. O'Malley and colleagues to produce positive cultures at a much higher rate than the traditional means of using needle aspiration of fluid from the joint. **"With current methods, the success of cultures is approximately 67 percent. Our recent studies with sonication have yielded a positive culture rate of 95 percent in patients with active infections.** The technique is proving to have high sensitivity and specificity. Knowing the bacteria responsible for the infection is crucially important for treatment and results in a much more effective and long-term eradication. This has important consequences for the field," says Dr. O'Malley.

“THE USE OF ROBOTIC PARTIAL KNEE ARTHROPLASTY
AFFORDS A SMALLER INCISION AND VIRTUALLY NO
INCIDENCE OF MALALIGNMENT.”



Dr. O'Malley is also involved in several other periprosthetic joint infection-related studies, primarily with **Brian A. Klatt, MD**, assistant professor of orthopaedic surgery. One study, a multicenter investigation attempting to use next generation PCR sequencing to identify the bacteria in a periprosthetic joint infection, would eliminate the need for culturing. A second study that Dr. O'Malley and colleagues are currently in the midst of researching is an evaluation of a diagnostic test from CD Diagnostics called Synovasure®. "Essentially, what this testing does is look for a molecular marker called alpha defensin as an indicator of infection in the evaluation of synovial fluid. There is a lot of excitement about this test because it has been shown to be both sensitive and specific, and we can obtain results prior to surgery. Our study will compare this test and the use of sonication to see how well the two correlate. This is such interesting and meaningful work, because while the rates of periprosthetic joint infection are low, when they do happen, the consequences are severe," says Dr. O'Malley.

Sleep Quality After Total Joint Arthroplasty

Dr. O'Malley received a grant in 2017 from The Pittsburgh Foundation to study sleep quality and disruption patterns in patients undergoing total joint arthroplasty. The study will monitor patient sleep cycles using Fitbit® devices and questionnaires to determine whether patient sleep is disturbed. The intervention in the study will be a placebo-controlled trial using the nerve medication gabapentin, which is an atypical pain medication with some sedating side effects. Patients enrolled in the study will receive either a dose of 300 mg of gabapentin or placebo, at night before bed, to see if their sleep improves. "We know sleep can be disrupted in the post-surgical period, and it is one of the biggest complaints of patients. They feel great during the day, but their leg hurts at night and their sleep is disrupted. Gabapentin

has been used empirically, but there is no real evidence to support its use as a therapeutic agent. Using the Fitbit® device will really help us to quantify and qualify the sleep disturbances that occur in these individuals, and with the devices we can also track and analyze their activity levels," says Dr. O'Malley.

Partial Robotic-Assisted Knee Arthroplasty

Dr. O'Malley is currently using a robotic-assisted platform for his partial knee replacement surgeries. The robotic system uses computer-controlled navigation to control the burr, removing bone from the joint. "Not all patients are candidates for this approach, but those that are may be afforded a faster recovery period and more normal postoperative feeling in the knee," says Dr. O'Malley.

Another benefit of the robotic approach is that it allows for a more accurate placement of the implant with repeatable results. "By using the robotic approach," says Dr. O'Malley, "you end up with a smaller incision and virtually no incidence of malalignment."



The robotic system uses computer-controlled navigation to control the burr, removing bone from the joint in a precise manner.



GERIATRIC FRACTURES: CAUSES, COMPLICATIONS, AND CONTRIBUTING FACTORS

Orthopaedic trauma surgeon **Gele B. Moloney, MD**, joined the Department of Orthopaedic Surgery in September 2016 and currently practices at UPMC Mercy. Dr. Moloney's training included the clinical scientist research track residency at UPMC from 2009 to 2014, followed by an orthopaedic surgery trauma fellowship at the Hospital for Special Surgery in New York City. Dr. Moloney is currently an assistant professor of orthopaedic surgery and is the site principal investigator for the Major Extremity Trauma Research Consortium (METRC), a large, multicenter group conducting a wide range of prospective studies in orthopaedic trauma. As an orthopaedic trauma surgeon, Dr. Moloney sees all manner and type of primary trauma cases and post-traumatic reconstructive procedures. "As an orthopaedic trauma surgeon, every case is different and requires us to try to very quickly understand patient goals and then optimize and individualize their care, often without having the luxury of knowing them prior to the day of their injury. It's a constant challenge, and one of the things that drew me into this area of orthopaedic care," says Dr. Moloney.

Geriatric Fracture Care and Management

Dr. Moloney and **Ivan S. Tarkin, MD**, chief of the Division of Orthopaedic Traumatology, have previously studied and written on the rates and complications associated with geriatric distal femur fractures. Their findings highlight some of the challenges in caring for these individuals. A retrospective cohort study examined local and systemic complications in a cohort of 176 cases of low-energy distal femur fracture in elderly patients. At one-year post-surgical fixation, 25 percent of the patients were deceased. Of the remaining individuals, 24 percent developed a nonunion and went on to require further surgery. More than 80 percent of patients were discharged to a skilled nursing and rehabilitation facility, and 38 percent of individuals had at least one postoperative complication.

Hip fractures in geriatric patients have garnered a lot of attention in the literature and in the general population, and rightly so. However, as Dr. Moloney explains, they are not the only type of fracture that portends patient health declines and bad outcomes. "We started to look at patients with distal femur fractures and found that, while there are similarities to hip fractures in terms of mortality, distal femur fracture patients are much more likely to require secondary surgeries, increasing the burden on both the patient and the health care system trying to manage these challenging cases," says Dr. Moloney.



*Pre- and Postoperative
Distal Femur Nonunion X-rays.*

Preoperative image (left) shows incomplete healing of the fracture. Postoperative image (right) is following secondary reconstruction with supplemental plating and the addition of a bone graft resulting in fracture union.



New Research: Geriatric Distal Femur Fracture and Malnutrition

A new pathway of research that Dr. Moloney and her research colleagues in the trauma division are investigating is to what extent, and to what degree, patient nutrition and malnutrition play in improving outcomes of geriatric patients that suffer a distal femur fracture. Her team began to look at serum markers of nutrition in these patients, primarily albumin levels, and were surprised

to find alarmingly high rates of deficiency, pointing to significant rates of malnutrition in patients 65 and older with low-energy ground level falls and femur fractures. Right away, the associations were clear that independent of other factors, malnutrition was turning out to be a likely good predictor of mortality, nonunion, and postoperative infections. Dr. Moloney and colleagues have much more in the way of findings with this patient cohort and submitted a manuscript for publication that they hope to have published in 2018.

“This line of investigation really coincides with a much bigger trend at UPMC related to the concept of prehabilitation and pre-surgical care, and how these concepts and associated interventions can help to optimize care of these patients. This kind of research and evolving approach to patient care can help us understand and modify care patterns and practice to achieve better outcomes.”

Designing an Intervention Protocol

Coming out of their research into malnutrition and distal femur fracture is the natural question: What can be done from an intervention standpoint to modify patient risk? Dr. Moloney indicates that from a corollary standpoint, they looked at younger patients with high-energy trauma and fractures to their ankle. “Tibial pilon fractures are notoriously bad injuries. However, in patients with this injury who were receiving nutritional supplementation in the hospital, specifically amino acid, vitamin, and protein supplementation, we were seeing lower complication rates and lower reoperation rates. The hypothesis is that perhaps we can extrapolate those results and findings to this geriatric population of distal femur fractures and see if it can improve outcomes,” says Dr. Moloney. Dr. Moloney and colleagues are working on an intervention that would start nutritional supplementation on the same day as the injury and prospectively study patient outcomes.

New Research: Tibial Pilon Fracture Surgery and Nutritional Prehabilitation

As mentioned previously, tibial pilon fractures as the result of high-energy traumatic events are exceptionally difficult injuries to repair surgically and achieve long-term successful outcomes. New research by Dr. Moloney and collaborators **Ivan S. Tarkin, MD**, and **Nicholas J. Greco, MD**, is investigating the role and ability of nutritional prehabilitation to stave off post-surgical complications and suboptimal outcomes in patients with this injury.

Dr. Moloney and colleagues have submitted for publication their findings from a recent two-year study that tracked patient outcomes and complications following tibial pilon fracture in a cohort of 90 patients. Their study looked at infection rates, and rates of nonunion to see if nutritional supplementation was able to show a positive effect on long-term outcomes. Preliminary findings are promising, and more research will need to be conducted, but this could point toward and supply tangential evidence for using nutritional supplementation in geriatric distal femur fractures in order to minimize complications.



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