Jefferson Health®

# ORTHOPAEDIC

## *OUTCOMES & RESEARCH*

HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

## CONTENT



# **A MESSAGE** FROM THE CHAIR

Dear Colleagues,

I am pleased to share Jefferson Health's annual *Orthopaedic Outcomes & Research* report from the Department of Orthopaedic Surgery. The past year has been especially productive for our combined team from Rothman Orthopaedic Institute at Jefferson Health, Philadelphia Hand to Shoulder Center at Jefferson Health, 3B Orthopaedics, the Abington Orthopedic & Spine Institute – Jefferson Health, and the orthopaedic services of Jefferson Health hospitals in New Jersey, as we continued to make significant advances in clinical care and research.

The theme we chose for this year's report is "Return to Your Life," which captures the essence of what motivates us every day, whether in the hospital, the clinic or the laboratory. Every new diagnostic method, surgical technique, clinical trial and scientific discovery contributes to our goal of returning patients to their busy lives, restored in function and relieved of pain.

The healthcare environment is changing rapidly, which requires both an openness to new opportunities and demands, as well as a recommitment to the core values that have always served our patients well.

Our mission is clear: To make a strong and respectful doctor-patient relationship at the center of every encounter; to deliver the highest quality of care measurable by quality metrics; to conduct clinical and basic science research that will enhance the well-being of our community and patients worldwide; and to educate the next generation of orthopaedic specialists.

So much is happening. Technology is allowing us to stay connected with our patients following surgery and generate data that points the way to even better patient outcomes. Laboratory findings are identifying the molecular bases of orthopaedic diseases and revealing pathways to new treatments and prevention therapies.

I invite you to read this report for a glimpse of the wide range of research done at Jefferson Health in every orthopaedic subspecialty, including spine, hand and wrist, shoulder and elbow, hip and knee, foot and ankle, orthopaedic oncology, sports medicine and basic science.

I also invite you to learn more about our research and clinical services by going to our website, **JeffersonHealth.org/Ortho**. To refer a patient please call **215-503-8888** or have your patient call **1-800-JEFF-NOW**.

Thank you for your interest. I wish you a Happy New Year.

Sincerely,

Alexander R. Vaccaro, MD, PhD, MBA

*Richard H. Rothman Professor and Chair*
*Department of Orthopaedic Surgery, Jefferson Health*
*Sidney Kimmel Medical College, Thomas Jefferson University*




## How Orthopaedic Care at Jefferson Health is Transforming Lives

Orthopaedics is about getting people back to their lives—back to their jobs, families, the activities that give them purpose and pleasure.

That goal is central to every aspect of clinical care and research undertaken at Jefferson Health's **Department of Orthopaedic Surgery**, and it is why Jefferson is among the busiest and most well-known orthopaedic programs in the country.

The Department of Orthopaedic Surgery benefits from the combined energy and scientific curiosity of clinicians from Rothman Orthopaedic Institute at Jefferson Health, Philadelphia Hand to Shoulder Center at Jefferson Health, 3B Orthopaedics, the Abington Orthopedic & Spine Institute–Jefferson Health, and the orthopaedic services of Jefferson Health hospitals in New Jersey, with each group committed to translating their research into even better outcomes and satisfaction for patients.

Last year the department performed **37,825** orthopaedic procedures and oversaw the training of **30** residents, **19** clinical fellows and **18** research fellows. Jefferson Health's team of orthopaedic surgeons and scientists also published **267** research articles, presented findings at leading medical conferences and shared knowledge that helped advance the care of patients worldwide.

U.S. News & World Report once again recognized the important work being accomplished at Jefferson Health, naming Rothman Institute at Thomas Jefferson University Hospitals as the **10th** best orthopaedic program in the nation in 2019, and best in our region once again.

Jefferson Health clinicians and scientists are at the forefront of using advances in diagnostic imaging, medical management, surgical techniques, implant materials and rehabilitative therapy to improve patient outcomes. Their research also is helping to tackle critical societal problems, including the ever-rising cost of health care and the devastating opioid epidemic.

**Among the many research findings to emerge from the Department of Orthopaedic Surgery at Jefferson Health:**

**Complex Spine:** Researchers found that patients who put off surgery for cervical radiculopathy have worse clinical outcomes than those who turn to surgical relief sooner for their symptoms.

**Hand and Wrist:** Sleep disturbances improve more quickly following carpal tunnel release when an endoscopic procedure is done rather than an open one.

**Shoulder and Elbow:** Preoperative screening for depression in patients slated for arthroscopic rotator cuff repair can identify those at heightened risk for opioid dependence following surgery.

**Hip and Knee:** The use of aspirin as prophylaxis against venous thromboembolism can lower mortality risk following primary total joint arthroplasty.

**Foot and Ankle:** Porous metal wedges provide an attractive alternative to autograft and allograft in the setting of corrective osteotomies for severe flexible pes planovalgus.

**Orthopaedic Oncology:** There are fewer discrepancies between initial readings of radiographic images and second-opinion readings when images are interpreted at the start by radiologists specially trained in musculoskeletal radiology.

**Sports Medicine:** Time from surgery is only one of several criteria that should be used to determine return to play following surgical stabilization for traumatic anterior shoulder instability.

**Basic Science:** Researchers are developing ways to attach antibiotics and other anti-microbial agents to the surfaces of implant materials to lower the risk of periprosthetic joint infection.

The pages ahead contain more details on research initiatives from Jefferson Health's Department of Orthopaedic Surgery that are helping to return patients to their lives.

## SURGICAL VOLUMES AT JEFFERSON HEALTH

Close to
**10,500**
**JOINT REPLACEMENT** PROCEDURES

More than
**8,590**
**HAND AND WRIST** PROCEDURES

Over
**3,550**
**SHOULDER AND ELBOW** PROCEDURES

Over
**4,300**
**SPORTS MEDICINE** PROCEDURES

Approximately
**5,500**
**SPINE** PROCEDURES

Over
**1,700**
**TRAUMA** PROCEDURES

More than
**2,200**
**FOOT AND ANKLE** PROCEDURES

**950**
**GENERAL ORTHOPAEDIC** PROCEDURES

More than
**400**
**ORTHOPAEDIC ONCOLOGY** PROCEDURES

Surgical volumes include all procedures performed at Jefferson Health hospitals and ambulatory surgery centers.
*Source: Jefferson internal data, Fiscal Year 2019*

**267** research publications

**62** physicians with national or board titles

**80** active funded clinical trials

# COLLABORATIVE **CARE**

The Department of Orthopaedic Surgery is proud to work closely and collaboratively with our colleagues across several other top departments at Jefferson Health.

## Department of Nursing

Our nurses are renowned for the extraordinary care and compassion they provide to every patient who comes through our door for orthopaedic and spine care. Highly regarded for their knowledge and expertise, they are sought after as presenters at national and international conferences, as contributors to nursing journals and as leaders of professional nursing organizations. Seven Jefferson Health hospitals are proud to be MAGNET®-designated, including Thomas Jefferson University Hospital.

## Department of Anesthesiology

Jefferson Health's Department of Anesthesiology is a national leader in acute pain management for patients with conditions of the hand, wrist, arm, elbow and shoulder. The anesthesia team specializes in ultrasound-guided upper extremity regional nerve blocks and performs more than 2,000 surgical and invasive procedures annually. Our anesthesiologists also commonly perform lower extremity nerve blocks to manage acute pain in patients with conditions of the leg, knee, ankle or foot. The Department of Anesthesiology is home to the Anesthesiology Research Laboratory, which conducts timely, state-of-the-art research, often in partnership with the Department of Orthopaedic Surgery, on topics like managing prolonged post-operative pain and the role of opioids.

## Department of Rehabilitation Medicine

Jefferson Health physiatrists and therapists have been leaders in rehabilitation medicine for more than 30 years. Our comprehensive team of occupational therapists, physical therapists, speech language pathologists, rehabilitation nurses, therapeutic recreation specialists, social workers and psychologists support a staff of board-certified physiatrists to treat both non-surgical and post-operative orthopaedic patients. The Department of Rehabilitation Medicine is also home to the Regional Spinal Cord Injury Center of the Delaware Valley. Thomas Jefferson University Hospital – in affiliation with Magee Rehabilitation Hospital, now a part of the Jefferson Health system – is designated as one of the nation's 14 Model Spinal Cord Injury Centers by the National Institute on Disability and Rehabilitation Research.

## Sidney Kimmel Cancer Center–Jefferson Health

A leading center for practice-changing discovery and comprehensive cancer treatment, Jefferson's Sidney Kimmel Cancer Center (SKCC) has been known as a Designated Center by the National Cancer Institute since 1996, and is one of only 71 institutions in the nation to hold this prestigious recognition. Our multi-disciplinary teams at SKCC bring together specialists for treatment planning, resulting in some of the highest survival rates in the nation. The Jefferson Sarcoma and Bone Tumor Center combines the oncology services of SKCC with the expertise of the Department of Orthopaedic Surgery, and is focused on providing the highest quality oncologic resections of extremity bone and soft tissue malignancies while preserving maximal function.

## Department of Radiology

The Musculoskeletal Radiology Division of the Department of Radiology is one of the largest and best-known groups in the country. Our physicians serve as consultants to Philadelphia's four major sports teams and numerous visiting professional athletes. In addition to internationally recognized expertise in musculoskeletal imaging, our clinicians offer a wide variety of minimally invasive procedures, some of which are not offered by anyone else in the region, such as thermal radiofrequency ablation of tumors, including osteoid osteomas. The Division is one of a few centers in the country to provide a full range of diagnostic musculoskeletal ultrasound.

## Vickie & Jack Farber Institute for Neuroscience–Jefferson Health

At the Vickie & Jack Farber Institute for Neuroscience, we bring together the cross-disciplinary expertise of Jefferson Health physicians, clinicians and researchers specializing in spine disorders to collaborate as never before. Faculty are drawn from more than a dozen departments throughout Jefferson. Together, our neurosurgeons and orthopaedic spine surgeons work to research, treat, prevent and find cures for spine disorders. Jefferson Health has the nation's top spine surgeons and researchers—physicians who perform thousands of surgical procedures each year and have pioneered breakthrough procedures that set the clinical standards for surgical techniques nationwide.

## Orthopaedic Trauma Services

Since 1987, Thomas Jefferson University Hospital has been an accredited Level I Regional Resource Trauma Center and a referral center for multiple suburban communities and trauma centers in the region to treat a wide variety of trauma-related conditions. With one of the highest transfer volume rates in Pennsylvania, our Emergency Department provides immediate surgical services and care to critically injured patients. Our orthopaedic experts collaborate with emergency physicians to provide immediate specialized care for limb-threatening or life-altering orthopaedic injuries. Our surgeons are available in house 24/7 to perform immediate surgical procedures to critically injured patients.




# COMPLEX **SPINE**

Jefferson Health spine surgeons are leaders in the clinical and research communities. They are experts in the treatment of both complex spine and common spine conditions, including degenerative disc disease, spinal stenosis, cervical and lumbar disc herniations, spinal fractures, spinal cord injury and spinal tumors. Spinal cord injury patients benefit from the added knowledge and experience that stems from Thomas Jefferson University Hospital's designation as a Level 1 Regional Resource Trauma Center and a federally designated Regional Spinal Cord Injury Center, in affiliation with Magee Rehabilitation Hospital.

The spine team is led by Alan S. Hilibrand, MD, past president of the Cervical Spine Research Society (CSRS) and Alexander Vaccaro, MD, PhD, MBA Chair of Orthopaedic Surgery at Jefferson Health and current President of CSRS.

The spine team's broad research agenda includes evaluations of surgical techniques, laboratory research and cost-effectiveness analyses. They are helping to define best practices in spine surgery amid a healthcare environment that demands both excellence and efficiency.

Here is a look at some of the research published over the past year:

### Longer Preoperative Duration of Symptoms Negatively Affects Health-related Quality of Life After Surgery for Cervical Radiculopathy

Cervical radiculopathy can result in significant pain, disability and reduced quality of life. Fortunately, cervical radiculopathy is generally self-limiting, and a large portion of patients see significant improvement with nonoperative therapies including immobilization, nonsteroidal anti-inflammatory drugs, physical therapy, cervical traction and epidural steroid injections. Surgery is indicated when symptoms are refractory to nonoperative treatment. Although four to eight weeks of conservative treatment is generally suggested, this approach is based on limited data. There is little data in the literature regarding the effects of duration of radicular symptoms on health-related quality of life (HRQOL) outcomes.

## SERVICES

- **Treatment for cervical, thoracic and lumbosacral spine conditions**
- **Treatment for scoliosis, spine deformities, spondylolisthesis, spinal cord injuries/trauma, spinal infections and spinal tumors**
- **Minimally invasive techniques and image-guided technology**
- **Comprehensive treatment of disc disease, including disc replacement**

Jefferson Health spine surgeons led by Gregory Schroeder, MD, conducted a study to examine the issue. They did a retrospective analysis of prospectively collected HRQOL outcomes data for 216 patients who underwent anterior cervical decompression and fusion for radiculopathy.

The mean age of the patients was 51.9 years and they had a mean follow-up of 16 months. For purposes of the analysis, the researchers grouped the patients into three categories: Those who had cervical radiculopathy for less than six months before surgery (86 patients), those with symptoms for six months to two years (61), and those with symptoms more than two years before surgery (69).

The analysis, reported in *Spine*, found that patients benefitted from spine surgery for cervical radiculopathy regardless of how long they had waited to have surgery. The absolute postoperative score for patient-reported outcomes did not vary based on the duration of symptoms.

However, when researchers conducted a regression analysis, they found that worse outcomes were associated with radiculopathy symptoms lasting for more than two years before surgery. Patients in that group tended to have lower scores on the postoperative Short Form-12 Physical Component Score and the Short Form-12 Mental Component Score and higher postoperative Neck Disability Index, neck pain and arm pain compared to patients who had radiculopathy for less than six months before surgery. Using another measure, the analysis found that the recovery ratio was statistically significantly improved in patients who had surgery within six months of symptom onset, with demonstrated improvements in NDI, neck pain and arm pain, compared to patients whose pre-surgical symptoms persisted for six months to two years or more than two years.

The researchers said the key takeaway point from the study was that "delaying surgical treatment for cervical radiculopathy may result in less than optimal outcomes." Surgeons at Jefferson Health generally recommend a trial of non-operative care including physical therapy anti-inflammatory medications and often epidural injections. However, if these are not effective, earlier surgical intervention may lead to improved outcomes.

## Patient Adoption and Utilization of a Web-Based and Mobile-Based Portal for Collecting Outcomes After Elective Orthopaedic Surgery

Healthcare providers increasingly collect patient-reported outcomes (PROs) via web-based platforms. It is thought that the use of such technology can enhance communication between healthcare providers and patients and perhaps reduce healthcare expenditures.

Jefferson Health spine surgeons led by Alexander Vaccaro, MD, PhD, MBA conducted a study to evaluate the use of an online platform available to patients undergoing elective orthopaedic surgery between September 2014 and February 2017 at Jefferson Health. The platform allowed patients to access outcome questionnaires and physical therapy exercise and education videos. It also had a messaging component allowing patients to reach out to the clinic with questions.

Staff briefed patients before they went home on how to access the website and download the mobile app if they chose. Age, sex, log-in frequency, PRO completion rates and number of messages were retrospectively reviewed. The results were reported in *American Journal of Medical Quality.*

The percentage of patients who initially logged into the patient portal was consistent across age groups, ranging from about 80% to nearly 85%. But differences in usage emerged after that.

The research team found message frequency, log-in rates and PRO compliance were highest for patients aged 40 to 51, 51 to 60 and 61 to 70, respectively.

More specifically, patients aged 41 to 50 logged in most frequently, those aged 51 to 60 messaged the clinic most frequently, and those aged 61 to 70 were more compliant with completing the assigned PROs.

Younger patients were more likely to download the mobile app; yet, regardless of age, patients who downloaded the mobile app were more engaged. For the 18 to 30 group, log-in frequency increased 2.5-fold and PRO compliance improved 44% in the mobile app group.

"This study demonstrates that portal interaction varies by age and that data capture is highest in patients who chose the mobile app," the researchers reported.

They noted that their study found that both the youngest and the oldest patients were least likely to use the platform to report outcomes data. Younger patients aged 18 to 30 only logged into the portal four times on average, for instance, compared to 13 times for middle-aged patients.

"The younger patient's engagement with the platform likely reflects their overall low activation in their own health, while the older patient's engagement likely reflects physical barriers and their more limited access to technology," the researchers said.

They said that to get more people to use web-based healthcare platforms, there will have to be strategies targeting different patient populations.

"Electronic PRO capturing systems improve data accuracy and completion, patient compliance and monetary savings when compared to traditional survey methods," the researchers noted. "In an era when physician reimbursement rates, in part, rely on reporting patient outcomes, these online portals for patient engagement will become increasingly key to managing patient care and demonstrating value to payers."

## Utilization of Time-driven Activity-based Costing to Determine the True Cost of a Single or 2-Level Anterior Cervical Discectomy and Fusion

Healthcare payers are shifting from using volume-based reimbursement to value-based reimbursement such as bundling all services from the preoperative visit through 90 days after surgery. As reimbursement practices change, it is imperative to understand the true cost of surgical procedures. A model known as time-driven activity-based costing can determine cost of care by calculating the actual resources used in each step of the care cycle.

Jefferson Health spine surgeons utilized such a model to determine the true cost of care for 27 patients who underwent a single or 2-level anterior cervical discectomy and fusion (ACDF) by one of three surgeons at the Rothman Orthopaedic Specialty Hospital. To build an accurate process map, a research assistant accompanied each of the patients to every step in the care cycle including the preoperative visit, the preadmission testing, the surgery and the postoperative visits for the first 90 days. All resources utilized and the time spent with every member of the care team were recorded. Results were published in *Clinical Spine Surgery.*

## Leading the Way

In addition to their extensive clinical and research work, Jefferson Health's spine surgeons are leaders in the spine community, making their mark on numerous societies and leadership organizations. Their involvement in 2019 included:

- Alexander R. Vaccaro, MD, PhD, MBA, became President of the Cervical Spine Research Society.
- Alan S. Hilibrand, MD, MBA, was elected Treasurer of the American Academy of Orthopaedic Surgeons.
- D. Greg Anderson, MD, Jeffrey Rihn, MD, and Kris Radcliff, MD, continued to serve on the CSRS Board of Directors.
- Mark Kurd, MD, was the President of the Association for Collaborative Spine Research (ACSR), a Deputy Editor of *Clinical Spine Surgery* and a board member of ISASS.
- Michael Gratch, MD, became a member of the AAOS Board of Councilors and the Advocacy Council of the Pennsylvania Orthopaedic Society.
- Kris Radcliff, MD, became the Chair of the AAOS Spine Instructional Course Committee and Program Chair for the 2020 ISASS Annual Meeting in Puerto Rico.
- Gregory Schroeder, MD, served as the 2019 Program Chair of both the CSRS Annual Meeting and the NASS Summer Spine Meeting.
- Marc Levine, MD, became the President of the New Jersey Medical Society and continues to serve in leadership roles in the New Jersey Orthopaedic Society.

Of the 27 patients prospectively followed, 11 underwent a single-level ACDF and 16 underwent a 2-level fusion. The total average cost for the 1-level ACDF was $27,558. That included costs of $15,309 for hospital disposable resource charges (including everything from pain medication to spinal instrumentation), $4,491 for intraoperative personnel (surgeon, resident/fellow, anesthesia, nursing, surgical technician, neuromonitoring, radiology, technician and orderlies) and $4,705 for specialty hospital overhead, among other costs. The average total cost for the 2-level ACDF was $30,566. None of the patients had complications, which would have increased the costs.

"Reimbursement for the bundle of care surrounding a 1- or 2-level ACDF should be no less than $29,299 to cover the true costs of the care for the entire care cycle," the report said. "However, this cost may not include the true cost of all capital expenditures, and therefore may underestimate the cost."

One limitation of the study was that it was done at a small specialty hospital, so the findings may not apply to community or acute-care hospitals. The total costs also did not include the cost of treating radiculopathy prior to surgery, including preoperative visit, initial workup (including MRI) and nonsurgical treatment.

## Does Riluzole Influence Bone Formation? An in vitro Study of Human Mesenchymal Stromal Cells and Osteoblast

Clinical trials for riluzole for treatment of spinal cord injuries are ongoing, and early results are promising. The drug may benefit SCI patients from a neurologic perspective, but little is known about riluzole's effect on bone formation, fracture healing or osteogenesis.

To explore the issue, Jefferson Health spine researchers led by Gregory Schroeder, MD, Christopher Kepler, MD, and Alexander Vaccaro, MD, PhD, MBA conducted an in vitro study using human mesenchymal stromal cells (hMSCs) and osteoblasts (hOB) that were obtained from healthy donors and cultured in the laboratory.

The cells were treated with riluzole of different concentrations (50, 150, 450 ng/ml) for one, two, three and four weeks. Cytotoxicity was evaluated as was the induction of osteogenic differentiation of hMSCs. Differentiation was evaluated by measuring alkaline phosphatase (ALP) activity and with Alizarin red staining. Osteogenic gene expression of type 1 collagen (Col1), osteocalcin (ocn), Runx2, Sox9, Runx2/Sox9 ratio were measured by qRT-PCR.

According to a report in *Spine*, key findings included:

- Up to seven days of treatment with riluzole did not affect hMSC or hOB cell viability.
- Osteogenic gene expression was not affected by treatment of hMSCs with 50 ng/mL of riluzole.
- High-dose (450 ng/mL) riluzole led to a decrease in osteogenic gene expression including Runx2 and type 1 collagen in hMSCs.
- An upregulation of ALP mRNA expression was noted in hOBs at three weeks after treatment with high-dose riluzole.

"While riluzole may have neuro-protective effect, it has no evident effects on the viability of function of either hMSCs or hOBs," the study concluded. "Additionally, the activity of ALP in both cell types is upregulated by high-dose riluzole, which may indicate that high-dose riluzole can increase osteogenic metabolism and subsequently accelerate bone healing," it noted, adding however, that "at high concentration, riluzole leads to a decrease in osteogenic gene expression."

There now is a large multicenter study looking at riluzole in SCI patients.

## Economic and Outcomes Analysis of Recalcitrant Cervical Radiculopathy: Is Nonsurgical Management or Surgery More Cost Effective?

Cervical radiculopathy is a relatively common condition with an age-adjusted incidence of 83 per 100,000 people. Neck pain and radiculopathy represent the fourth most significant burden of disease in the U.S., but there remains uncertainty about the most effective and efficient approach to managing it. Many patients get nonsurgical resolution with oral steroidal and nonsteroidal anti-inflammatory medication, physical therapy and cervical traction. For patients with persistent radiculopathy, anterior cervical discectomy and fusion (ACDF) is a reliable surgical intervention resulting in durable long-term symptom resolution. It is not clear, however, at what point it makes sense to turn from medical management to surgery.

Jefferson Health spine researchers Jeffrey Rihn, MD, and Alan S. Hilibrand, MD, conducted an analysis to compare the economical and clinical effectiveness of the use of cervical epidural injections and continued physical therapy versus surgical management in cases of cervical radiculopathy that failed six weeks of conservative management.

They created a theoretical cohort of patients and assigned them to treatment with either ACDF or cervical epidural injections and continued physical therapy. They then compared the two treatment approaches using a Marcov chain decision tree model.

The researchers reported in the *Journal of the American Association of Orthopaedic Surgeons* that surgery might be the better option. They found that the average incremental cost-effectiveness ratio associated with ACDF was $6,768 per quality-adjusted life year over the lifetime of the patient. In comparison, the incremental cost-effectiveness ratio associated with cervical injections ranged from $9,033 to $4,044, per quality-adjusted life year based on the success rate. "If a greater than 50% success rate is feasible, then there may be a role for attempts of cervical epidural injections before surgery," they said. "However, if this rate of success cannot be consistently achieved, then ACDF without a presurgical attempt of invasive nonsurgical management would be the most cost-effective course of management of these patients."

They said practitioners should consider their own track record with cervical injections in their patient population to help decide how best to proceed with managing patients' radiculopathy.

In general, most spine surgeons at Jefferson Health offer the patient both an injection or surgery, and let the patient make the decision. Some patients really want to try an injection or two, while others choose surgery.

## Encouraging Signs

The summer of 2019 will go down as one of the most enjoyable in recent memory for Margaret "Margie" Schernecke. No, there were no European vacations, trips to Hawaii or any other extravagances that came her way.

But on the Fourth of July at the Jersey Shore, Margie more than kept pace with her eight-year-old granddaughter, going from the swimming pool to the beach, to chasing each other around the house shooting water pistols.

For Margie, who had suffered for years with debilitating back pain, it was like heaven. "I had to come back home to get some rest because they had me doing so much down there," she says. "I loved it."

A year ago, Margie's back pain made it difficult for her to walk with her husband to the grocery store, carry the laundry upstairs, and stand long enough in the kitchen to prepare a meal.

Her liberation from back pain began, oddly enough, when she fell in the kitchen and broke her leg on New Year's Eve, 2018. She was rushed to Jefferson, where she was treated by Dr. James Krieg, director of Jefferson's Orthopedic Trauma Services. When the issue of her back pain came up, it was suggested that she see Dr. Christopher Kepler, an orthopaedic spine surgeon with the Rothman Orthopaedic Institute at Jefferson Health.

After seeing numerous doctors over the years, each with their own version of "you have to have this done, or you have to have that done," Margie knew she had finally met her guy. "It was fortuitous because he was just wonderful. He gave me so much encouragement, as did his entire team. I had never experienced anything like it from a doctor before."

In October 2018, Dr. Kepler rebuilt her lower back—from the L2 to L5 segments —to relieve pain. She was on her feet the next day, saying she "felt like a million bucks."

Margie follows up with Dr. Kepler a couple of times a year, and visits the Rothman Orthopaedics facility in the Nova Care Complex for physical and aqua therapy. "I have friends down there and when I go visit they all say, 'Wow Margie, you look terrific.' That is so encouraging."

> "He gave me so much encouragement, as did his entire team. I had never experienced anything like it from a doctor before.
>
> ***— MARGARET SCHERNECKE***




# **HAND** AND **WRIST**

The hand is involved in almost every aspect of living. Injuries or disorders involving the hand or wrist can significantly interfere with work and leisure activities and in some cases even be life altering if not properly treated.

Thousands of patients every year seek out the hand and wrist team at Jefferson Health, which draws from the expertise of specialists from Rothman Orthopaedic Institute at Jefferson Health and the Philadelphia Hand to Shoulder Center at Jefferson Health.

The hand and wrist team at Jefferson Health performed more than **8,590** surgeries this year and cares for many other patients whose pain or injury can be resolved using nonsurgical treatment. Whether the case involves a simple fracture suffered in a fall or a complex nerve condition, the goal is the same: To return patients as quickly as possible to a pain-free, active life.

The hand and wrist team is at the forefront of the latest surgical techniques and innovative approaches, and their care is enhanced by the wide range of research they conduct. They are dedicated to reducing complications from surgery and identifying the safest and most effective means for relieving postoperative pain amid societal concerns about opioid abuse.

Here are some of the research issues they recently tackled:

## Preoperative Exposure to Benzodiazepines or Sedative/Hypnotics Increases the Risk of Greater Filled Opioid Prescriptions After Surgery

Rothman Orthopaedic Institute at Jefferson Health

Several studies have found that the use of opioid analgesics in the acute setting increases the likelihood of persistent use. Patients undergoing orthopaedic surgery are thought to be at higher risk of developing opioid dependence in the postoperative period, but the existing research on the use of opioids in the setting of hand surgery, in particular, is limited and mostly derived from large insurance database studies.

## SERVICES

- **Hand and wrist surgery**
- **Microvascular surgery**
- **Joint replacement and reconstruction for hand arthritis**
- **Treatment of carpal and cubital tunnel syndrome**
- **Treatment of Dupuytren's disease**
- **Treatment of/for traumatic injuries**

Jefferson Health researchers led by Bryan Hozack, MD, conducted a study to help pinpoint which hand surgery patients might be most at risk for opioid dependence postoperatively. They focused on three key questions: 1) Is a positive history of the use of benzodiazepines and sedative/hypnotics associated with greater numbers of filled postoperative opioid prescriptions after hand surgery? 2) Is a positive history of use of more than one controlled substance, a mood disorder, or smoking associated with a great number of filled opioid prescriptions? 3) Is preoperative use of opioids associated with a greater number of opioid prescriptions filled after hand surgery?

"Opioid abuse is a public health problem, though other controlled substances such as benzodiazepines and sedatives/hypnotics should not be overlooked and contribute to the problem," the researchers reported in *Clinical Orthopaedics and Related Research*.

The study prospectively enrolled patients who underwent elbow, wrist and hand surgery performed by two hand surgeons at an outpatient surgery center from January 4, 2017 to April 28, 2017. A total of 209 patients 18 and older met the study criteria and were included in the analysis. The researchers obtained patient demographics, including age, gender, diagnosis and type of surgical procedure from the electronic medical record (EMR). The types of procedures were divided into bony and soft tissue.

The EMR was also used to determine patients' social history, such as smoking and history of mood and pain disorders. Information was obtained on type of anesthesia used, opioid use intraoperatively and in the recovery room, and discharge opioid prescriptions in the form of morphine equivalent units (MEUs). The average MEU prescribed by the physicians was 155.6 (the equivalent of 35 pills of Tylenol #3 or 21 pills of oxycodone 5 mg) when a prescription was provided at discharge from the surgical center.

The Pennsylvania Drug Monitoring Program (PDMP) website was used to document all prescriptions of controlled substances filled six months before and after the surgical procedure. The database contains links to similar sites in several other states, which allowed for a broader look.

The results included:

- Patients exposed to benzodiazepines filled a greater number of opioid prescriptions postoperatively than those who were not (2.2 prescriptions versus 1.2) and the same trend held true for people exposed to sedatives/hypnotics (2.3 prescriptions filled versus 1.2).
- Patients with a current or former history of smoking or mood disorders also filled more opioid prescriptions after surgery than patients without those histories. (For smoking, it was 1.9 filled versus 1.2; for mood disorders, 2.0 versus 0.9).
- Patients without prior exposure to opioid medications had very limited use of opioid medication after hand surgery. Patients with a history of opioid use filled 3.3 prescriptions following surgery compared to 0.8 for patients not previously exposed to opioids.
- Of the 290 patients, 222 (76%) filled the first postoperative prescription regardless of their initial opioid use status.

**Numbers of Postoperative Opioid Prescriptions Filled and Associations with Benzodiazepine and Sedative/Hypnotic**

| Medication | Not Exposed | Exposed | Mean Difference (95% CI) | p Value |
|---|---|---|---|---|
| Benzodiazepine | 1.2 ± 1.3 | 2.2 ± 1.5 | 1.1 (0.5, 1.5) | < 0.001 |
| Sedative/hypnotic | 1.2 ± 1.4 | 2.3 ± 2.9 | 1.1 (0.3, 1.9) | 0.006 |
| CI = confidence interval | | | | |

**Source:** Bryan Hozack, MD

"Based on the results of this study, we are now more aware of the potential problems of patients with exposure to controlled substances, and we are more attentive about reviewing their history of substance use in the PDMP website, which is an important resource," the researchers reported. "In addition, we now provide much more detailed preoperative counseling regarding the use and abuse of opioid medication in patients with exposure to benzodiazepines, sedatives, and those with a smoking history and mood disorders."

They said that "further studies evaluating the interaction between these controlled substances and the effect of the degree of opioid exposure in the preoperative period will help to improve the practitioner's understanding of these complex issues." Such studies are ongoing at Jefferson Health.

**ISI Scores Preoperatively, Postoperatively and at 3-Month Intervals**

| Variable | Pre-Op | No. | First POV | No. | 3 mo | No. | *P* |
|---|---|---|---|---|---|---|---|
| All* | 10.63 | 128 | 7.6 | 112 | 4.13 | 78 | <.001 |
| Decompression † | 10.81 | 91 | 7.89 | 80 | 3.98 | 54 | .528 |
| Transposition † | 10.47 | 34 | 7.03 | 31 | 4.46 | 24 | |
| Electromyography | | | | | | | |
| Mild ‡ | 11.71 | 17 | 8.94 | 17 | 3.10 | 10 | .635 |
| Moderate ‡ | 11.51 | 53 | 8.47 | 45 | 5.47 | 30 | |
| Severe ‡ | 8.67 | 42 | 6.03 | 38 | 3.39 | 31 | |
| McGowan | | | | | | | |
| I § | 11.46 | 41 | 7.87 | 39 | 3.76 | 25 | .143 |
| II § | 12.23 | 48 | 10.53 | 38 | 5.44 | 27 | |
| III § | 6.76 | 29 | 2.77 | 26 | 3.20 | 20 | |
| WC ‖ | 13.21 | 19 | 9.61 | 18 | 4.83 | 12 | .168 |
| Non-WC | 10.09 | 86 | 6.89 | 73 | 4.32 | 50 | |

ISI, Insomnia Severity Index; POV, postoperative visit; WC, workers' compensation.

* *P* values are reported for the main effect of time on ISI scores.
† *P* values are reported for the main effect of in situ decompression vs. transposition over time.
‡ *P* values are reported for the main effect of electromyography severity (mild vs. moderate vs. severe) over time.
§ *P* values are reported for the main effect of McGowan grade (I vs. II vs. III) over time.
‖ *P* values are reported for the main effect of insurance type (WC insurance vs. non-WC insurance) over time.

**Source:** Joseph Said, MD

## Prospective Evaluation of Sleep Improvement after Cubital Tunnel Decompression Surgery

### Rothman Orthopaedic Institute at Jefferson Health

Compromised sleep is a common symptom of patients with compressive neuropathies such as carpal tunnel syndrome (CuTS). It is estimated that as many as 78% of CuTS patients have poor sleep, but to what degree sleep patterns change after ulnar nerve decompression is not well understood.

Rothman Orthopaedic Institute at Jefferson Health researchers led by Joseph Said, MD, undertook a study to determine if decompression surgery results in improved sleep. Consecutive patients with electrodiagnostic-proven CuTS indicated for decompression were prospectively enrolled. Demographic data, McGowan grade, electrodiagnostic (electromyography) severity, visual analog scale pain score, the 11-item version of the Disabilities of the Arm, Shoulder and Hand questionnaire, and the Insomnia Severity Index (ISI) scale data were collected prospectively and at two weeks and three months prospectively. The ISI is a validated questionnaire used by researchers to evaluate sleep disturbance. It is scored on a scale of 1 (no symptoms) to 10 (a threshold for insomnia). A decrease of 6 points or more represents a clinically important difference.

There were 145 patients enrolled, with 97% of them available at two weeks and 72% at the final three-month follow-up. The patients (58% women and 42% men) had a mean age of 55. Surgical decompression consisted of 102 in situ releases and 43 transpositions, all performed by fellowship-trained orthopaedic hand surgeons on an outpatient basis.

The average preoperative Insomnia Severity Index score for the entire cohort was 10.7, which is above the threshold for a diagnosis of insomnia. The mean score improved to 7.6 points at two weeks and to 4.1 at three months, which is consistent with the resolution of insomnia.

There was no difference in the extent of sleep improvement between in situ decompression and transposition. Similarly, electromyography and McGowan grade did not appear to significantly affect the extent of sleep improvement.

"Patients undergoing CuTS decompression surgery, irrespective of surgical type and preoperative severity, experienced an improvement in sleep quality from a preoperative characterization of insomnia to normal sleep postoperatively by the three-month postoperative visit," the researchers concluded.

## Prospective Evaluation of Early Postoperative Complications after Distal Biceps Tendon Repairs

Rothman Orthopaedic Institute at Jefferson Health

Surgery is considered an acceptable treatment option for improving functional outcome after distal biceps tendon rupture (DBTR). However, there is a risk of operative complications for DBTR due to the proximity of neurovascular structures around the elbow. Possible complications include nerve injury (lateral antebrachial nerve, radial nerve, posterior interosseous nerve), heterotrophic ossification, wound infection and rerupture. The risks of DBTR surgery are dependent on the technique used. Historically, 1-incision techniques have been associated with a high rate of nerve injury (15% to 33%), while 2-incision techniques have resulted in a higher incidence of heterotrophic ossification (15%) and radioulnar synostosis (5%). However, newer techniques using suture anchors, tenodesis screws, and suture buttons have aimed to reduce complications.

To date, the incidence of complications has been largely determined by retrospective studies and a few prospective studies, only one of which offered a comparison between the 1-incision and 2-incision techniques. To better understand the issue, Rothman Orthopaedic Institute at Jefferson Health researchers led by Jonas Matzon, MD, conducted a large prospective study of primary DBTR. A total of 212 repairs performed by 37 orthopaedic surgeons in three different subspecialties were included in the analysis.

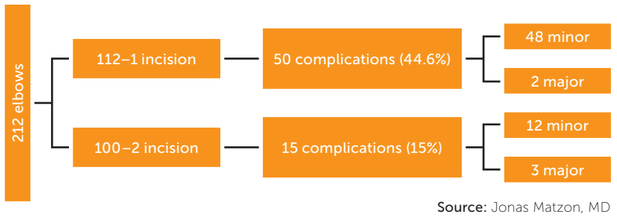
Among the results published in *Journal of Hand Surgery*:

- 65 of 212 patients (30.7%) had complications, including 50 patients (44.6%) in the 1-incision group and 15 patients (15%) in the 2-incision group.
- 60 patients (28.3%) developed a minor complication.
- 57 patients (26.9%) had sensory neurapraxias, including 47 after a 1-incision procedure and 10 after a 2-incision procedure, which was a statistically significant difference.
- Of the patients with neuropraxias, 94.7% of cases were resolved or improving at the time of the last follow-up.
- Five patients of the total cohort (2.4%) developed a major complication, defined as a return to the operating room in the postoperative period due to deep infection or rerupture.

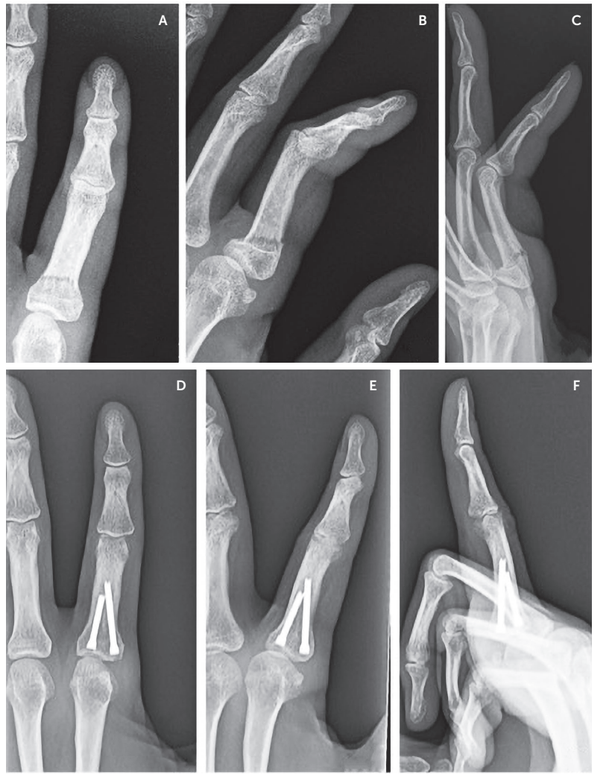
"The complication rate after DBTR appears to be higher than two other retrospective studies and is predominantly in the form of transient neurapraxias," the researchers concluded. "This study confirms that there is a higher complication rate with 1-incision techniques as compared to 2-incision techniques."

That said, "surgeons should feel confident continuing to use the technique with which they are the most comfortable, as the rate of major complications and unresolved neurapraxias appears to be similar between both techniques."

**Flow chart describing complications by procedure type.**




**Source:** Jonas Matzon, MD




Preoperative (A) posteroanterior, (B) oblique, and (C) lateral radiographs demonstrating transverse metaphyseal fracture of the index finger proximal phalanx with dorsal angulation. Postoperative (D) posteroanterior, (E) oblique and (F) lateral radiographs following dual antegrade intramedullary headless screw fixation of the proximal phalanx.

**Source:** Randall Culp, MD

## Dual Antegrade Intramedullary Headless Screw Fixation for Treatment of Unstable Proximal Phalanx Fractures

Philadelphia Hand to Shoulder Center at Jefferson Health

Phalangeal fractures are among the most commonly occurring of all upper extremity fractures, of which the proximal phalanx is most often injured.

Intramedullary headless screw (IMHS) fixation is among the newest options for treatment of unstable proximal phalanx fractures, but a single IMHS may provide inadequate fixation for certain fracture patterns.

A research team led by Randall Culp, MD, conducted a study to evaluate the short-term clinical outcomes in a pilot series of patients with proximal phalanx fractures treated with dual antegrade IMHS fixation. They performed a retrospective chart review of patients with a minimum of one year of follow-up. Postoperative outcome measures included range of motion, grip strength, Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) outcome scores, return to full-duty work interval, and complications.

Ten patients, with a total of 10 fractures, met the study inclusion criteria. The mean age of patients was 39 years and average follow-up was 84 weeks. Final postoperative active motion was 258° (range 245°-270°), mean grip strength was 97% (range 84%-104%) of the uninjured side, and mean QuickDASH score was 3.9 (range 0-13.6). No complications occurred and no patients required additional intervention.

Reporting in the journal *Hand*, the researchers said "duel antegrade IMHS fixation of proximal phalanx fractures resulted in excellent motion, near-normal grip strength, positive self-reported patient outcomes, and no complications with follow-up of at least one year."

They said the method could be useful to "surgeons faced with unstable proximal phalanx fractures in need of stable fixation, who wish to avoid the drawbacks associated with plate fixation."

"Further study in a larger number of patients is warranted to determine if this promising technique is superior to other modes of fixation."

## Tendinosis Develops from Age—and Oxygen Tension-Dependent Modulation of Rac1 Activity

Philadelphia Hand to Shoulder Center at Jefferson Health

Age-related tendon degeneration (tendinosis) is characterized by a phenotypic change in which tenocytes display characteristics of fibrochondrocytes and mineralized fibrochondrocytes.

Since tendon degeneration has been noted in vivo in areas of decreased tendon vascularity, Jefferson Health researchers led by Rowena McBeath MD, PhD, hypothesized that hypoxia is responsible for development of the tendinosis phenotypes, and that these effects are more pronounced in aged tenocytes.

They tested the hypothesis in a series of laboratory experiments and reported the results in *Aging Cell*.

They found that hypoxic (1% $O_2$) culture of aged, tendinotic and young human tenocytes resulted in a mineralized fibrochondrocyte phenotype in aged tenocytes, and a fibrochondrocyte phenotype in young and tendinotic tenocytes.

Investigation of the molecular mechanism responsible for this phenotype change revealed that the fibrochondrocyte phenotype in aged tenocytes occurs with decreased Rac1 activity in response to hypoxia.

In young hypoxic tenocytes, however, the fibrochondrocyte phenotype occurs with concomitant decreased Rac1 activity coupled with increased RhoA activity. Using pharmacologic and adenoviral manipulation, the researchers confirmed that the hypoxic effects on the tenocyte phenotype are directly linked to the activity of RhoA/Rac1 GTPase in in vitro human cell culture and tendon explants.

"These results demonstrate that hypoxia drives tenocyte phenotype changes, and provide a molecular insight into the development of tendinosis that occurs with aging," Dr. McBeath said.

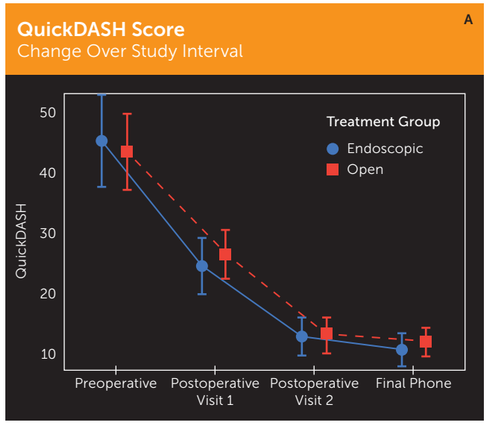
Understanding the biological mechanisms that drive tendon pathology will ultimately result in improved preventive and clinical treatments.

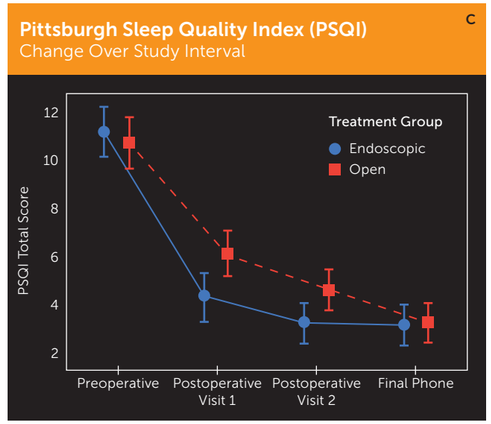
## Sleep Disturbance and Response to Surgical Decompression in Patients with Carpal Tunnel Syndrome: A Prospective Randomized Pilot Comparison of Open versus Endoscopic Release

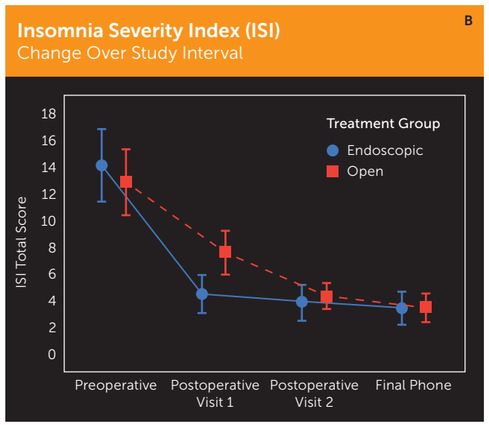
Philadelphia Hand to Shoulder Center at Jefferson Health

Sleep disturbance is a common complaint of patients with carpal tunnel syndrome (CTS). While carpal tunnel release (CTR) surgery has been shown to relieve subjective sleep-related complaints, research is lacking on the global effect on sleep using validated sleep measures. Additionally, it is not known if open CTR or endoscopic CTR produce differing degrees of sleep-symptoms relief.

Jefferson Health researchers led by Patrick Kane, MD, conducted a prospective study in which they randomized 60 patients to either open CTR or endoscopic CTR surgery. Prior to surgery, the patients were administered three baseline self-reported outcome measures: The Pittsburgh Sleep Quality Index (PQSI), the Insomnia Severity Scale (ISI) and the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) survey, which were subsequently administered at three preoperative time points, one to two weeks, four to six weeks, and six to 12 months.




Interval plot of mean values of (A) the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH), (B) Insomnia Severity Scale (ISI), and (C) Pittsburgh Sleep Quality Index (PQSI) outcome measures plotted over the duration of study enrollment. Interval bars represent 95% confidence intervals.

**Source:** Patrick Kane, MD

Results, which were published in *Acta Biomed*, included:

- All 60 patients experienced significant improvements in their three outcome scores by their first postoperative visit compared to preoperatively.
- Endoscopic CTR provided superior improvement to open CTR at the first postoperative visit for ISI and at the second visit for PSQI.
- There were no significant differences between the two groups for the QuickDASH at any time point, or for the ISI/PSQI at the final follow-up.

"Endoscopic and open CTR both improve sleep symptoms postoperatively in the short-term, which is sustained for 6-12 months, although the endoscopic CTR does so more rapidly," the report said.

The researchers said that it might be best for patients who report sleep symptoms to undergo endoscopic CTR because of the quicker sleep symptoms relief. Surgeons may want to screen patients with the PSQI or ISI to identify those patients.

## All the Right People

In the moments following a horrific injury that nearly took his right hand, Bruce Goebel said a prayer to himself. "I just prayed that I had the perfect people in my path that day."

That day was February 21, 2018. Bruce was in the woodworking shop of his family's business when his right hand accidently got caught in a sawing device and was almost completely severed from his arm. After applying his own tourniquet, Bruce was rushed to the nearest trauma center. But something didn't feel right. A deeply spiritual man, Bruce implored his caregivers to "call someone in the city, I'm sure they do this." The call went to Jefferson, where Dr. Rowena McBeath of the Philadelphia Hand to Shoulder Center at Jefferson Health, was waiting.

After 14 hours of surgery, and four days of a medically induced coma, he awoke – right hand intact. That in itself was a blessing, he says, and a product of the right people being there when he needed them most. "I was blessed to have Dr. McBeath waiting for me when I got to Jefferson," Bruce says. "She is one awesome physician and the care I received at Jefferson was unbelievable."

He also credits the ambulance driver for "hanging around" at the first trauma center and being available to transport him to Jefferson. "He was the coolest guy ever," Bruce recalls. "They were talking about taking me in the helicopter and he said, 'I'll have him at Jefferson before you even get clearance to take off.'"

Some would say it was just professionals doing their jobs. Bruce feels it was something more. "It was an answer to a prayer. Like I said, I needed perfect people in my path. I don't know who they're going to be, just put them in my path."

Bruce continues to regain the use of his hand and drives once a week to the Philadelphia Hand to Shoulder Center in Center City for specialized physical therapy. "The nerves are firing; they're just not speaking to the muscles yet," he explains. "I can move my fingers around, but I can't make a fist or pull the trigger on a screw gun."

> "I want to be able to do everything—that's what I said the first day I went to physical therapy. It might take a while, but I'm willing to do the work and I'm willing to put in the time.
>
> — ***BRUCE GOEBEL***

For the time being, Bruce's role at Goebelwood Industries, Inc. – the family owned and operated corporation started by his father and grandfather in 1952 – has shifted to more work in the office than in the shop. But he's determined to regain complete use of his hand and get back on the shop floor. "I want to be able to do everything—that's what I said the first day I went to physical therapy. It might take a while, but I'm willing to do the work and I'm willing to put in the time."

An avid outdoorsman, he's also looking forward to hunting and fishing with his family in the near future. Bruce and his wife have a grown daughter and two grown sons.

His faith is playing a large role in his recovery, allowing him to envision a day when he can squeeze the trigger on a screw gun, or reel in a big one off the coast of the Jersey Shore. "Right now I drive the boat and the kids get to reel in the fish. I'm just happy that I'm doing it with them."




## **SHOULDER** AND **ELBOW**

Shoulder and elbow specialists at Jefferson Health are highly sought after for common problems such as tendonitis and rotator cuff injuries as well as for especially challenging needs such as total elbow arthroplasty and total shoulder arthroplasty.

No matter how straightforward or complex a case may be, the team is committed to putting together a comprehensive plan for every patient that extends from diagnosis to treatment to rehabilitative services if needed.

Because the team also is dedicated to conducting scientific research, patients benefit from the latest understanding of shoulder and elbow disorders and developments in surgical techniques and materials. The team is at the forefront of research on some of the most pressing issues in orthopaedics, including periprosthetic joint infection and opioid use and potential abuse following surgery.

Here is a sampling of some of those important findings:

### Treatment of Periprosthetic Joint Infection of the Elbow: 15-Year Experience at a Single Institution

Rothman Orthopaedic Institute at Jefferson Health

Despite evolution in the use of total elbow arthroplasty (TEA), complication and survival rates have remained inferior to those of total joint arthroplasty in the hip and knee. Periprosthetic joint infection (TJI) following TEA remains the second leading cause of revision surgery.

Jefferson Health researchers led by Surena Namdari, MD, sought to understand more about infection and reoperation after TEA by retrospectively analyzing an institutional database of TEA cases performed from 2001 to 2016. They identified 26 patients who were treated for PJI after TEA who met the study criteria. The researchers then compared 10 patients who underwent irrigation and debridement (I&D) with component retention to 16 patients who had component explantation, antibiotic spacer placement and reimplantation of a revision TEA.

## SERVICES

- **Shoulder and elbow surgery, including replacement, arthroscopy and open**
- **Treatment of rotator cuff injuries**
- **Distal biceps and triceps rupture repair**
- **Tendonitis treatment**
- **Treatment of shoulder and elbow fractures and instability**
- **Brachial plexus repair reconstruction**

The mean age of the 26 patients was 64.3. In the total group, there were three polymicrobial infections, 13 *Staphylococcus aureus* infections, four of which were methicillin-resistant *S. aureus* cases (MRSA), and six patients with negative culture results.

Ten of the 26 patients (38.5%) underwent I&D with component retention. Five of those patients (50%) had recurrent infection at an average of 3.1 years.

Of 16 patients who underwent antibiotic spacer placement, 12 (75%) underwent 2-stage reimplantation of a TEA. Among those with reimplantation, 4 of 12 (33.3%) required reoperation. In 3 of 12 (25%), reoperation was required for infection, while 1 of 12 (8.3%) required surgery for mechanical complication.

"PJI of the elbow continues to present a challenging problem," the researchers reported in *Journal of Shoulder and Elbow Surgery*. "This analysis of a high-volume institution over a long study period highlights the challenges of successful management of elbow PJI."

But despite some discouraging numbers, the study provided useful information to help guide treatment decisions when PJI occurs after TEA.

The researchers concluded "that prosthetic resection with or without delayed reimplantation provides the highest chance of infection eradication." On the other hand, "certain patients (those with poor health or well-fixed components) may be suitable for I&D and component retention, with a demonstrated 50% success rate over three years."

The researchers cautioned that longer-term follow-up may result in higher infection rates in both groups.

They said the research community "must continue research endeavors to more fully elucidate the factors precluding successful infection treatment. In the meantime, the surgeon must weigh the high recurrence rate associated with component retention against the morbidity of a planned 2-state exchange."

## Comparative Study of Cultures and Next-Generation Sequencing in the Diagnosis of Shoulder Prosthetic Joint Infections

Rothman Orthopaedic Institute at Jefferson Health

Periprosthetic joint infections (PJI) of the shoulder remain a difficult diagnostic challenge. Serum and synovial markers used to diagnose lower extremity PJI have performed poorly for shoulder PJI. As a result, diagnosis commonly relies on the accuracy of positive or negative cultures. Next-generation sequencing (NGS) can sequence an entire bacterial genome from samples of tissue or fluid, but the usefulness of the technique in the diagnosis of PJI in the shoulder is unknown.

Jefferson Health researchers led by Surena Namdari, MD, conducted a study to determine the correlation between NGS and routine cultures in revision shoulder arthroplasty.

All patients undergoing revision shoulder arthroplasty between July 2016 and April 2017 were prospectively enrolled, regardless of clinical suspicion of infection. A total of 44 total revision arthroplasty cases were included in the analysis, including 32 single-stage revisions and 12 antibiotic spacer placements. Tissue samples from each case were collected in the operating room and sent for culture and NGS.

The researchers reported their results in *Journal of Shoulder and Elbow Surgery*. Findings include:

- At least one positive culture specimen was present in 23 patients (52.3%) and 12 (29.5%) of those patients had at least two positive culture specimens with the same organism. There were no polymicrobial culture results.
- NGS identified at least one positive specimen in 17 patients (38.6%) and in 16 (36.4%) of these at least two specimens identified the same organism.
- A mean of six organisms was identified in the cultures that were NSG positive.
- When the researchers looked specifically at cases deemed to be definitely infected and probably infected based on certain criteria, *Cutibacterium acnes* was the most common bacterial species cultured (8 of 13 cases {61.5%} and identified by NGS (12 of 17 cases {70.1%}).

After comparing results from culture and NGS, the researchers said that there was only "fair concordance" between culture and NGS.

"This indicates that most cases in which culture results indicated infection were not the same cases in which NGS indicated infection," the study said.

"Given the poor concordance between culture and NSG data, there remains significant uncertainty about our current methods of diagnosing shoulder PJI," the researchers reported. "Bacteria were commonly identified in cases of revision shoulder arthroplasty by both culture and NSG. Although culture data suggest that bacterial loads in revision arthroplasty are most commonly monomicrobial, NGS data suggest that bacterial loads in revision arthroplasty are most commonly polymicrobial."

Given the limited concordance between culture and NGS shown in this research project, "further study will be necessary to determine the role of NGS in the diagnostic algorithm," they concluded.

"Jefferson Health surgeons are still using cultures to identify infection at the time of revision, but it is not a perfect diagnostic tool," said Matthew Ramsey, MD, one of the study authors.

## The Distress and Risk Assessment Method Predicts Postoperative Narcotic Use in Patients Undergoing Rotator Cuff Repair

Rothman Orthopaedic Institute at Jefferson Health

The Distress and Risk Assessment Method (DRAM), which is a measure of psychological distress, predicts poor outcomes in spine, hip and knee surgery. But research to date has not found DRAM to be a good predictor of post-operative patient-reported outcomes after arthroscopic rotator cuff repair (RCR).

Jefferson Health researchers led by Joseph Abboud, MD, undertook a study to look at the correlation between preoperative DRAM scores, modified Zung scores and postoperative narcotic use in patients who underwent arthroscopic RCR.

The prospective cohort study enrolled adult patients with full-thickness rotator cuff tears at a single institution. Exclusion criteria included patients with prior narcotics use. A total of 150 patients were enrolled from October 2017 to January 2019, with 114 patients completing all preoperative and postoperative questionnaires.

Preoperative DRAM scores were collected from every patient. Patients were classified as "normal" or "at risk" for distress and/or depression based on their DRAM responses, specifically the Modified Zung Depression Index component. Postoperative narcotic use was evaluated via survey, and pills used were converted to total morphine equivalent units (MEUs).

The researchers reported in *Journal of Shoulder and Elbow Surgery* that higher DRAM scores predicted higher opioid use postoperatively.

They also found that modified Zung scores, which were used to classify patients as either "normal" (a score under 17) or "at risk for distress and/or depression" (a score of 17 or higher), were a good predictor of opioid use. Patients classified as "at risk" (which turned out to be 39% of the cohort) tended to use more MEUs after shoulder surgery.

"Baseline psychological distress (DRAM) can predict narcotic requirements after RCR and serve as a powerful tool to identify patients at risk for increased narcotics requirements postoperatively," the researchers said. "In our cohort 39% of patients showed evidence of baseline depression, which highlights a potential role of the modified Zung score to identify patients in need of preoperative psychological counseling."

"The role of mental health disorders on orthopaedic outcomes should not be understated," the researchers said. They suggested that doctors could offer patients who score high on distress/depression assessments "preoperative psychological counseling, use preoperative narcotic consents that allow for close monitoring and individualize multimodal pain regimens to help limit narcotic use and abuse in the future."

In addition, "Further studies should evaluate if DRAM scores show significant improvement after RCR," the researchers said.

Jefferson Health shoulder surgeons now try to identify and offer preoperative counseling to patients deemed at high risk for opioid overuse. They are also moving toward opioid-free rotator cuff surgery, said Matthew Ramsey, MD.

## Interscalene Block with and without Intraoperative Local Infiltration with Liposomal Bupivacaine in Shoulder Arthroplasty

Rothman Orthopaedic Institute at Jefferson Health

Pain management after shoulder arthroplasty is an important variable in the perioperative period that can influence participation in physical therapy, discharge from the hospital or outpatient surgery center and patient satisfaction.

With the growing opioid epidemic, national focus has shifted to the use and misuse of opioids in all areas of medicine. As a result, increased emphasis has been placed on alternative pain management strategies that can reduce narcotic utilization after orthopaedic surgery.

Interscalene brachial plexus blockade (ISBPB) is an effective anesthetic technique for shoulder arthroplasty. However, "rebound pain" can increase the patient's postoperative pain experience and narcotic usage. Exparel (liposomal bupivacaine) injected into the soft tissue at the surgical site has theoretical efficacy for up to 72 hours after administration.

Jefferson Health researchers led by Gerald Williams, MD, conducted a study to evaluate postoperative pain scores and narcotic consumption following shoulder arthroplasty performed with either ISBPB alone or ISBPB plus intraoperative Exparel.

From August 1, 2016 to February 15, 2017, 78 patients undergoing primary shoulder arthroplasty were randomly assigned to revive an ISBPB (39 patients) with Exparel or without (39 patients). The primary outcome variable was morphine equivalent units (MEUs) consumed over the first 24 hours after surgery. Secondary outcomes included intraoperative narcotic administration and visual analog scale (VAS) scores for pain at 0, 8, 16, 24, 48 and 72 hours after surgery.

The findings were reported in *The Journal of Bone and Joint Surgery*. They included:

- Total narcotic consumption over the first 24 hours after surgery was significantly lower in the ISBPB alone group compared to the ISBPB plus Exparel group (an average of 18.9 MEUs versus 35.3 MEUs).
- Intraoperative narcotic consumption averaged 10.6 MEUs for the ISBP group and 12.3 MEUs for the ISBP plus Exparel group.
- The VAS pain scores did not differ significantly between the two groups at any point during the first 72 hours after surgery, and both groups experienced similar levels of rebound pain between 0 and 24 hours after surgery.

"Patients treated with local infiltration of Exparel required significantly more postoperative narcotics and demonstrated no significant reduction in pain scores over the first 72 hours after primary shoulder arthroplasty," the researchers concluded. "Local soft tissue infiltration of Exparel does not appear to have substantial value when added to a pain protocol that includes an ISBPB."

The findings were somewhat unexpected.

"The increased need for narcotics in patients treated with combined ISBPB and local infiltration of Exparel is surprising," the researchers noted. They said it was possible that those patients getting the combined approach ended up with a "double rebound phenomenon," in which patients experienced more pain both after the effect of the ISBPB subsided and after the effect of Exparel subsided. The study did not track narcotic use beyond the first 24 hours, so it is unclear whether the same differences in usage would have persisted as time went on.

## Single Versus Double-bundle Suture Button Reconstruction of the Forearm Interosseous Membrane for the Chronic Essex-Lopresti Lesion

Philadelphia Hand to Shoulder Center at Jefferson Health

Essex-Lopresti injuries are rare yet potentially devastating injuries for which no standard treatment has been determined. It is generally agreed that reconstruction of the ruptured interosseous membrane (IOM) is critical to restore forearm stability for the chronic Essex-Lopresti injury. Positive outcomes have been reported following IOM reconstruction with a single-bundle suture button (Mini TightRope®) construct, although recent work suggests that double-bundle Mini TightRope® IOM reconstruction is biomechanically superior.

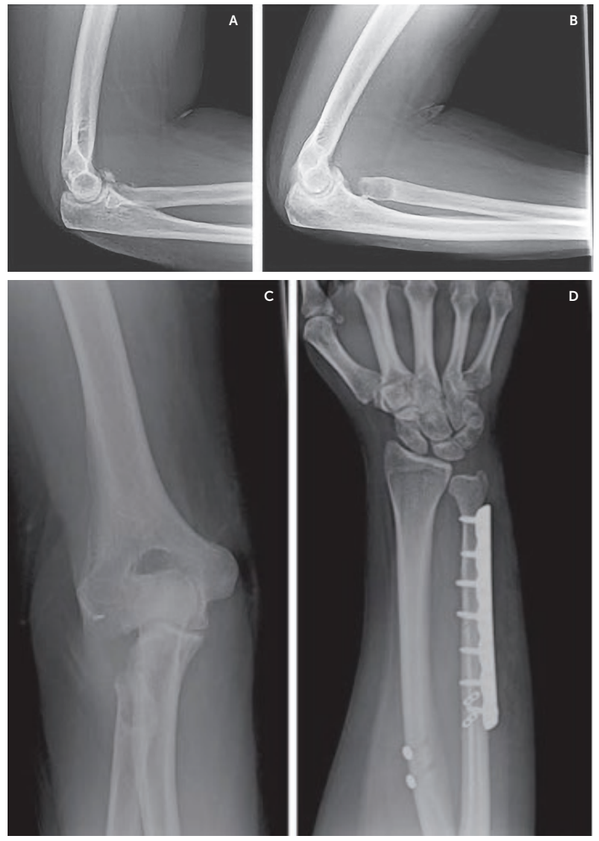
Researchers led by Michael Gaspar, MD, MBA, conducted a study to determine whether double-bundle Mini TightRope® reconstruction of the forearm IOM results in superior clinical outcomes compared to the single-bundle technique.

Five patients with chronic Essex-Lopresti injuries treated with double-bundle Mini TightRope® IOM reconstruction were matched to five patients treated with single-bundle Mini TightRope® reconstruction. Improvement in clinical examination measures and patient-reported outcomes was compared between the groups. The results of the retrospective review were published in *European Journal of Orthopaedic Surgery & Traumatology*.

The researchers reported that results were good to excellent in all 10 patients. At final follow-up, forearm rotation was significantly better in the single-bundle group, while maintenance of ulnar variance was better in the double-bundle group. No significant differences were noted between the two groups for any other numerical outcomes, and no complications occurred.

The researchers said the study had limitations because it was small and retrospective.

"Despite these shortcomings, our study provides clinical evidence that double-bundle Mini TightRope® IOM reconstructions afford greater resistance to forearm instability but at a cost of decreased forearm rotation compared to single-bundle reconstruction. Surgeons may find this information useful when treating patients with Essex-Lopresti lesions and looking to optimize either stability or functional motion," they concluded.




Initial post-injury lateral radiograph of the elbow of a 39-year-old male who sustained a comminuted radial head fracture after a fall from a ladder (A). He was treated at an outside institution with a radial head excision and subsequently developed significant ulnar-sided wrist pain in addition to progressive pain at his elbow (B,C). He was treated definitively with a USO, TFCC repair, and double-bundled IOM reconstruction using the Mini-TightRope® device (D).

**Source:** Michael Gaspar, MD, MBA




## **HIP** AND **KNEE**

Last year Jefferson Health hip and knee specialists performed close to **10,500** primary or revision hip and knee arthroplasties, making the joint replacement program among the busiest in the country.

Demand for primary total hip arthroplasty and total knee arthroplasty will continue to increase as the population ages and more older persons expect to maintain an active, pain-free lifestyle. At the same time, there is a growing need for revision surgery, in part a reflection of an increasing number of younger, active patients undergoing primary total joint replacement (TJA) as well as limitations in implant longevity.

Jefferson Health's hip and knee surgeons are dedicated to the latest surgical methods and materials backed up by research evidence. They and their teams are also highly skilled in diagnostic imaging, pain management, rehabilitation therapies and prevention measures.

They are leaders in the orthopaedic field and widely published in the literature, tackling important questions related to maximizing patient outcomes and controlling unnecessary costs. Their research advances the understanding of ways to prevent periprosthetic joint infections and venous thromboembolism, both troubling complications of TJA that can result in mortality, extended hospital stays, added costs and poor outcomes for patients.

Ongoing research at Jefferson Health is challenging some assumptions about how joint replacement care should be organized before, during and after surgery, including whether outpatient physical therapy is necessary following joint replacement. The beneficiaries of all the research are patients, who want to return to their lives as quickly and safely as possible.

### SERVICES

- **Hip and knee replacement, partial knee replacement**
- **Joint revision surgery**
- **Adult joint reconstruction and preservation procedures**
- **Treatment of hip and knee disorders**
- **Pelvic reconstruction, osteotomy and hip-impingement surgery**
- **Joint infection**

The following summaries are just two of the many research findings published last year:

## Self-Directed Home Exercises Versus Outpatient Physical Therapy After Total Knee Arthroplasty: Value and Outcomes Following a Protocol Change

Until recently, outpatient physical therapy was considered a staple of the total knee arthroplasty (TKA) postoperative care pathway. Proponents of formal outpatient physical therapy argue that it is necessary to preserve range of motion following TKA, noting that failure to preserve motion poses a large health burden on the patient and the healthcare system. But recent studies have suggested that routine postoperative physical therapy (OPPT) is unnecessary for total hip arthroplasty (THA) and some studies have suggested the same may be true to TKA. It has been suggested that similar results may be achieved with self-directed home exercise programs (HEP) in place of formal physical therapy, which can be costly to both patients and the healthcare system.

Jefferson Health researchers led by James Purtill, MD, conducted a study to compare the safety, efficacy and health economics of formal (OPPT) compared to a self-directed HEP.

A single-surgeon retrospective study was conducted of 520 consecutive patients undergoing primary unilateral TKA from 2016 to 2018. All 251 TKAs performed in 2016 were routinely prescribed OPPT, while all 269 TKAs in 2017 completed a self-directed HEP alone for two weeks. At their two-week checkup any patient who had less than 90° range of motion was prescribed outpatient therapy. Any other patient who wanted formal physical therapy was similarly prescribed.

Results of the study were reported in *The Journal of Arthroplasty*. Overall, 65.8% of patients in the home exercise program did not require OPPT. There were no significant differences in the percentage of patients whose range of motion was less than 90° at two weeks (14% of those in physical therapy versus 11.9% of those who exercised at home). The researchers did not identify any risk factors for failing HEP. There were no differences between the OPPT and HEP groups in the percentage of patients who required manipulation under anesthesia.

There were big cost differences, however, between the two groups. On average, Medicare patients who received outpatient physical therapy incurred an increase in average cost of $1,340 and patients with private insurance had $1,893 more in costs compared to those who didn't do physical therapy.

"OPPT requires significant resource utilization and poses substantial costs to both the healthcare system and value-based payment models, for example, bundled payments models," the researchers reported. "It is thus important to understand which costly practices are necessitated."

"Given the cost advantage of HEP and similar clinical outcomes compared to OPPT, it is reasonable that orthopaedic surgeons consider HEP initially after primary unilateral TKA," the study concluded. "Close follow-up is recommended as OPTT can be reserved for patients who are not able to demonstrate satisfactory ROM at their first postoperative visit."

The researchers said the study had limitations, including its relatively small size and the fact that all cases were done by a single surgeon, making it impossible to say whether the results are generalizable.

They said further investigation comparing OPPT and HEP is warranted, particularly with large cohorts that might make it possible to detect small differences in patient outcomes. Additional research is underway at Jefferson Health.

## The Use of Aspirin for Prophylaxis Against Venous Thromboembolism Decreases Mortality Following Primary Total Joint Arthroplasty

Guidelines from the American Academy of Orthopaedic Surgeons and the American College of Chest Physicians allow physicians managing total joint arthroplasty (TJA) patients the freedom to choose from among a number of agents to minimize the risk of venous thromboembolism (VTE). In the United States, aspirin has emerged as the prophylaxis of choice because of its efficacy in preventing clots and benign safety profile. While aspirin is known to have cardioprotective qualities, its potential cardioprotective effects when administered as VTE prophylaxis remain unknown.

A Jefferson Health research team led by Javad Parvizi, MD, investigated the influence of VTE prophylaxis, including aspirin, on mortality following TJA. They used an institutional database to retrospectively review the cases of 31,133 patients who underwent primary TJA from 2000 to 2017. Patients were grouped into one of two cohorts based on VTE prophylaxis administration: aspirin (25.9% of patients) and non-aspirin (74.1%). Mortality was assessed using an institutional mortality database that is updated biannually.

Among the findings reported in *The Journal of Bone and Joint Surgery*:

- The overall mortality rate for all the TJA patients was 0.2% at 30 days and 0.6% at one year.
- Patients in the non-aspirin cohort had three times the risk of death at 30 days (0.3% compared 0.1% for aspirin), and twice the risk of death at one year (0.7% versus 0.3%).
- At one year, the primary cause of death in the non-aspirin group was cardiac-related. In the aspirin group, the rate of cardiac-related death was almost five times lower than in the non-aspirin group.
- Risk factors for mortality at one year were higher age, history of congestive heart failure, cerebrovascular disease, malignancy and history of prior myocardial infarction.

The researchers reported that, to their knowledge, the study was the first of its kind. They said the study had limitations, however, including the fact that it was retrospective and not a randomized clinical trial. There could have been some selection bias in which patients were given aspirin and which were not.

"Given the wide variety of options for prophylaxis against VTE, the safety and efficacy of these agents must be considered," the researchers concluded. "The present study demonstrates an association between the use of aspirin as prophylaxis against VTE and a reduced risk of mortality following primary TJA. Orthopaedic surgeons should be aware of this added benefit of aspirin when selecting prophylaxis."

Dr. Parvizi said additional studies on aspirin are ongoing at Jefferson Health, including evaluations of 90-day admission and wound complications in patients receiving aspirin versus those given other anticoagulation agents.

## New Hip Gets Mike Back on Track

As president and CEO of the Dover International Speedway, Mike Tatoian is always on the move, making sure everything and everyone is in place to give fans an engine-revving experience. So when his right hip began troubling him—and started slowing him down—he pulled into the pit stop and sought help.

Mike found it in Gregory K. Deirmengian, MD, an orthopaedic surgeon with Rothman Orthopaedic Institute at Jefferson Health. Dr. Deirmengian diagnosed him with developmental dysplasia of the hip (DDH). In DDH, the ball of the thighbone doesn't fit into its socket in the pelvis, so it can become dislocated easily, resulting in pain and osteoarthritis, which progressively worsen. Dr. Deirmengian told Mike he would need a hip replacement before 60.

Mike could have gotten the surgery at any time, but he was in no hurry. Fit, active, and still in his early 50s, he thought he was too young for hip surgery. He was also concerned about rehab and missed work: "There's never a good time to get a flat tire." As the arthritis became more painful over the next few years, Mike began limiting his activities—no more golf, gardening or long walks with his wife, Tammy. To prepare for a trip to Europe in April 2016, he stuffed his suitcase with an assortment of ointments, straps, wraps and medicines.

"Those are the kinds of things you start thinking about more: how am I going to get through it, as opposed to wanting to just enjoy it," Mike says.

When Tammy reminded him of all the activities he had given up, including those they used to do together, he realized his hip was affecting her as much as him. He was finally ready for surgery.

Dr. Deirmengian and his team replaced Mike's right hip on January 13, 2017. It was a Friday, Mike recalls, but he wasn't worried about bad luck. Jefferson Health's Joint Replacement Program is one of the most prestigious in the nation, performing close to **10,500** surgeries a year. "Obviously, whoever's doing this," gesturing to his hip, "has to know what they're doing. I never doubted this would go well."

What did surprise Mike, though, was how smooth his hospital stay was. Since he's in the "people event business," he notices all the individuals who contribute to good outcomes. At Thomas Jefferson University Hospital, everyone—from the valet and receptionist to the maintenance staff—got top marks from Mike. "My wife and I both had a great experience," he says.

> "Forty-five days after my surgery, I completely forgot I've got this implant, right? That, to me, is success."
>
> ***— MIKE TATOIAN***

About six weeks after the surgery, while traveling for work, Mike set off the metal detector at the airport. He made sure his pockets were empty, but he set it off again—and then a third time. He was stumped until the security agent asked about hip surgery. "Forty-five days after my surgery, I completely forgot I've got this implant, right?" Mike says, "That, to me, is success."


# **FOOT** AND **ANKLE**

Anyone who walks around wearing a pedometer knows how much work the foot and ankle do. Reaching the desired daily 10,000 steps is hard enough, but it is estimated that a person walks 100,000 miles during a lifetime.

With each step, the 28 bones and more than 100 ligaments and tendons that make up the foot and ankle are called on to be flexible, strong and able to handle quick turns and changes in surface. They must absorb a lot of pressure.

It's little wonder then, that foot and ankle problems occur so often, whether a persistently sore toe that makes it impossible to wear "real" shoes or an acute injury suffered in a fall or athletic event. As the saying goes, if your feet hurt everything hurts.

Jefferson Health's foot and ankle specialists are experts at both common and complex foot and ankle problems. They offer a range of operative and nonoperative care and are often sought out by patients who were unable to find a satisfactory solution elsewhere. They are leaders in total replacement of the ankle, deformity corrections, flat foot reconstruction, surgical correction of ankle and foot arthritis and tendon problems, as well as bunionectomy and hammertoe corrections.

What makes Jefferson Health's foot and ankle surgeons stand out even more is their commitment to research, which helps optimize the care of patients and gets them back to living. They investigate new surgical approaches and materials and how to most effectively and safely manage pain. Their research on opioid prescribing following foot and ankle surgery raises important questions about what role the doctor has in balancing a patient's need for pain relief versus minimizing the possibility that unused opioid pills will end up being abused by the patient or someone else.

## SERVICES

- **Total ankle replacement surgery**
- **Complex deformity reconstruction**
- **Achilles tendon rupture and tendonitis treatment**
- **Treatment of ankle sprains and fractures**
- **Treatment of foot and ankle arthritis**
- **Talus and lisfranc fracture/ dislocation repair**
- **Posterial tibial tendonitis treatment**
- **Treatment of tarsal tunnel syndrome**
- **Hallux valgus surgery**
- **Hallux ridigus surgery**
- **Flat foot reconstruction**
- **Treatment of various foot conditions**

Here is a look at some of their recently published research:

## Determination of Minimum Clinically Important Difference (MCID) in Visual Analog Scale (VAS) Pain and Foot and Ankle Ability Measure (FAAM) Scores After Hallux Valgus Surgery

Visual analog scale (VAS) and Foot and Ankle Ability Measure activities of daily living (FAAM-ADL) are commonly used for measuring patient-reported outcomes in hallux valgus correction. Another measure, minimum clinically important difference (MCID), quantifiably defines a threshold for determining whether a treatment leads to clinically significant improvement and refers to the smallest change in an outcome measure that is important from the patient's perspective of being happy with the outcome of their surgery. In the context of VAS, MCID refers to a clinically significant change in pain score. In the context of FAAM-ADL, MCID refers to a clinically significant change in function.

Jefferson Health researchers led by division chief Steven Raikin, MD, conducted a study to determine MCID in VAS pain and FAAM-ADL scores for hallux valgus corrections and additionally to identify variables influencing achievement of the VAS pain MCID.

**Calculated MCID Values for Each MCID Method**

| MCID Method | VAS Pain | FAAM-ADL |
|---|---|---|
| Standard deviation (SD) approach | 1.8 pts | 11.1 pts |
| Average change approach | 5.2 pts | 12.9 pts |
| Change difference approach | 4.3 pts | 22.7 pts |

**Percentage of Patients Who Obtained a Change Greater Than or Equal to Each MCID Method for VAS Pain and FAAM-ADL**

| MCID Method | VAS Pain | FAAM-ADL |
|---|---|---|
| Standard deviation (SD) approach | 125/170 (73.5%) | 59/153 (38.6%) |
| Average change approach | 69/170 (40.6%) | 54/153 (35.3%) |
| Change difference approach | 83/170 (48.8%) | 32/153 (20.9%) |

**Abbreviations:** MCID (Minimum Clinically Importance Difference); VAS (Visual Analog Scale); FAAM-ADL (Foot and Ankle Ability Measure Activities of Daily Living).
**Source:** Steven Raikin, MD

Patients undergoing hallux valgus surgery were retrospectively included in the study. VAS pain (on a scale of 0, no pain, to 10, maximal pain), FAAM-ADL (on a scale of 0, no function, to 100, maximum functional ability) and six-point Likert pain satisfaction surveys were collected preoperatively and at a minimum of one-year postoperatively.

Patients reporting low postoperative satisfaction scores 1 through 3 were categorized as "dissatisfied" and those with high satisfied scores of 4 through 6 were classified as "satisfied." Three methodologies, one known as a distribution-based method and two characterized as anchor-based methods, were used to calculate MCID. A logistic regression was also calculated to determine if one group (defined by sex, pain satisfaction, preoperative VAS pain, concomitant lesser toe correction, and specific hallux valgus correction procedure) had a greater likelihood of achieving the VAS pain MCID threshold. A total of 170 patients with an average of 23.6 months of postoperative follow-up were included in the analysis, which was reported in *Foot & Ankle International*.

The mean preoperative VAS pain score was 6.59 points, and the mean postoperative VAS pain score was 2.6 points. The average improvement after surgery was 3.98 points. The average improvement in FAAM-ADL score was only 7.4 points, which is consistent with the fact that hallux valgus affects the patient more from a pain perspective than functionally.

When outcomes were considered through the lens of the MCID models, a VAS pain improvement of 1.8 to 5.2 points indicated a clinically significant improvement in pain after hallux valgus surgery that was not due to a measurement error. At the same time, a FAAM-ADL improvement of 11.1 to 22.7 points indicated a clinically significant improvement in patients function after surgery.

By those measures, a higher percentage of patients (73.5%) in the study achieved clinically significant improvement from a pain perspective after hallux valgus correction, while a smaller percentage (38.6%) achieved a clinically significant improvement from a functional standpoint. Having a preoperative pain score of greater than 5 was associated with a significantly higher degree of satisfaction with the surgical outcome of a bunionectomy.

Patients who had moderate deformity correction with proximal first metatarsal osteotomy or severe deformity correction with first tarsometatarsal arthrodesis and higher preoperative pain scores had significantly higher odds of meeting VAS pain MCID.

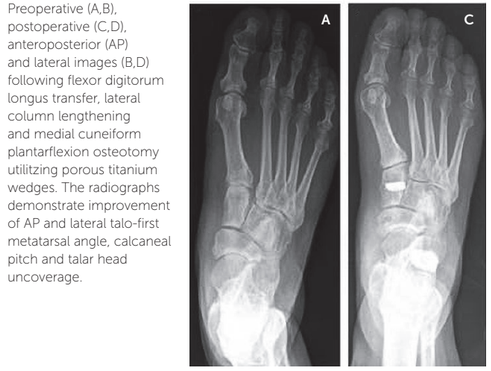
"With the increasing prevalence of patient-reported outcomes as a metric of operative success it is important to quantify these outcomes in a clinically significant fashion," the researchers reported. "This study established a baseline for the use of MCID in the evaluation of hallux valgus operative efficacy."

Dr. Raikin said discussions based on the MCID concept are already taking place at Jefferson Health to help guide patient expectations before surgery.

## Severe Flexible Pes Planovalgus Deformity Correction Using Trabecular Metallic Wedges

Lateral column lengthening and plantarflexion dorsal opening wedge osteotomy of the medial cuneiform are two commonly used procedures to address the deformity seen in severe flexible pes planovalgus deformity. Traditionally, iliac crest autograft or allograft has been used to fill the osteotomy sites. Porous metallic wedges can be used as an alternative to avoid the concerns of collapse and nonunions associated with both autograft and allograft.

Jefferson Health researchers led by Steven Raikin, MD, conducted a retrospective review of patients who had corrective osteotomies utilizing metallic wedges to address flexible pes planovalgus and at least two years of follow-up. Preoperative radiographic measurements (anteroposterior [AP], and talo-first metatarsal angle,




Preoperative (A,B), postoperative (C,D), anteroposterior (AP) and lateral images (B,D) following flexor digitorum longus transfer, lateral column lengthening and medial cuneiform plantarflexion osteotomy utilitzing porous titanium wedges. The radiographs demonstrate improvement of AP and lateral talo-first metatarsal angle, calcaneal pitch and talar head uncoverage.

**Source:** Steven Raiken, MD

**Preoperative and Postoperative Median Radiographic Measurements**

| | Preoperative Measurment | Postoperative Measurement | *P* Value [a] |
|---|---|---|---|
| AP talo-first metatarsal angle | 17.6 | 5.1 | <.001 |
| Calcaneal pitch angle | 13.1 | 18.2 | <.001 |
| Lateral talo-first metatarsal angle | -19.8 | -3.9 | <.001 |
| Lateral talocalcaneal angle | 49.6 | 45.2 | <.001 |
| Talonavicular uncoverage angle | 31.6 | 12.5 | <.001 |

**Abbreviations:** AP (Anteroposterior)
[a] There was a significant improvement in all radiographic parameters associated with a pes planovalgus.
**Source:** Steven Raiken, MD

calcaneal pitch, talocalcaneal angle, and talonavicular uncoverage angle) and functional scores (visual analog scale [VAS] pain, Foot and Ankle Ability Measure [FAAM], Activities of Daily Living [ADL] and FAAM sports) were compared to postoperative radiographic measurements and functional scores.

Forty-eight feet in 45 patients with at least two years of follow-up were identified in the Jefferson database. They had an average time from surgery to last follow-up of 35.5 months. There were 27 females and 21 males, with an average age of 48.4. All surgeries were performed by the senior author of the study using commercially available porous metallic wedges from a single company.

The study, reported in *Foot & Ankle International*, found statistically significant improvement in all radiographic and functional scores. For instance, there was a reduction in patients' pain from an average of 5.9 to 3.06 (out of 10), and improvement in FAAM-ADL functional score from 56 to 80/100. Two nonunions were seen, one of which healed with revision surgery while the other was asymptomatic. At the time of last radiologic follow-up, there were no recurrences of deformity or collapse associated with the implants.

"Porous wedges offer an attractive alternative to autograft and/or allograft in the setting of corrective osteotomies for severe flexible pes planovalgus," the researchers reported. "Patients who underwent corrected osteotomies using these wedges demonstrated reliable, effective and stable radiographic correction as well as significant improvement in function and pain."

The approach is now standard at Jefferson Health, Dr. Raikin said.

## Prospective Evaluation of Utilization Patterns and Prescribing Guidelines of Opioid Consumption Following Orthopaedic Foot and Ankle Surgery

Overprescribing of narcotic pain medication is a major culprit in the opioid epidemic plaguing the United States. Orthopaedic surgeons are the third highest opioid prescribers among physicians, accounting for 7.7% of all narcotic prescriptions.

There is limited research in the literature, however, on utilization rates for opioids after lower extremity procedures. Jefferson Health researchers led by Joseph Daniel, DO, conducted a prospective study to examine the issue.

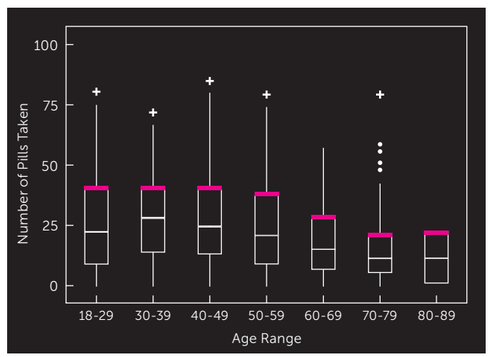
All patients 18 or older who underwent outpatient orthopaedic procedures from September 2016 to September 2017 were prospectively enrolled. Information was collected on patient demographics, preoperative health history, patient-reported outcomes, anesthesia, procedure type, opioid prescription and consumption details.

For the health history, patients were asked to rate their worst pain from 0 to 10 using a visual analog scale (VAS), complete short Form-12 (SF-12) and Foot and Ankle Ability Measure (FAAM) questionnaires, and report any history of depression, anxiety, recreational drug use or tobacco. The morphine equivalent dose was calculated for each opioid prescription and then converted to a 5 mg. oxycodone "pill."

A full set of data was available of 1,009 of 1,027 eligible foot and ankle patients, and 988 were included in the final analysis. Results were published in F*oot & Ankle International*.

Overall, patients consumed a median of 20 pills, whereas the median number of pills prescribed was 40. This resulted in a utilization rate of 50%, with 20,631 pills left unused by patients.

Independent risk factors associated with more opioid consumption were anesthesia type (regional anesthesia and continuous-infusion catheter), age (under 60 years old), preoperative visual analog scale pain report of greater than 6, and bony procedures, but those factors did not completely account for the variance of opioid consumption observed in the patient population, the researchers reported. There was not a statistically significant association between narcotic use and self-reported anxiety or depression.




Boxplots summarizing number of pills consumed as a function of patients' age at time of surgery. Patients 18-59 years old consumed significantly more opioids than 60-79 year-olds († *P*<.02).

**Source:** Joseph Daniel, DO

**Abbreviations:** IQR (Interquarile range); MED (Morphine Equivalent Dose). IQR[a] is the range from the first quartile to the third quartile below which is opioid consumption for the lowest 25% and above which is opioid consumption for the highest 25%.
***** Significant *P* value defined as *P* < .05.

**Source:** Joseph Daniel, DO

**Opioid Consumption and Prescription Patterns Based on Age, Gender, and Procedural Categorizations**

| | No. of Patients (%) | Median Pills Taken (IQR [a]) | Range of Pills Taken | MED Taken | *P* Value | % Taken (IQR [a]) |
|---|---|---|---|---|---|---|
| Total | 988 | 20 (7, 36) | 0, 101 | 112.4 (39.3, 202.3) | | 50 (20, 84) |
| Sex | | | | | | |
| Female | 612 (62%) | 18 (8, 34) | 0, 80 | 101.2 (45.0, 191.1) | .487 | 48 (20, 80) |
| Male | 376 (38%) | 20 (7, 37) | 0, 101 | 112.4 (39.3, 207.9) | | 50 (20, 90) |
| Procedure Indication | | | | | | |
| Elective | 675 (68%) | 18 (7, 33) | 0, 80 | 101.2 (39.3, 185.5) | .033* | 48 (20, 85) |
| Trauma | 313 (32%) | 22 (8, 39) | 0, 101 | 123.6 (45.0, 219.2) | | 50 (23, 84) |
| Procedure Type | | | | | | |
| Bony | 754 (76%) | 20 (8, 37) | 0, 101 | 112.4 (45.0, 207.9) | .069 | 50 (24, 87) |
| Soft | 234 (24%) | 16 (6, 32) | 0, 60 | 89.9 (33.7, 179.8) | | 40 (15, 78) |
| Procedure Location | | | | | | |
| Forefoot | 408 (41%) | 16 (6, 30) | 0, 101 | 89.9 (33.7, 168.6) | <.001* | 44 (20, 80) |
| Hindfoot | 505 (51%) | 22 (9, 40) | 0, 80 | 123.6 (50.6, 224.8) | | 54 (24, 90) |
| Midfoot | 75 (8%) | 18 (6, 39) | 0, 76 | 101.2 (33.7, 219.2) | | 45 (20, 79) |
| Anesthesia Type | | | | | | |
| Local | 30 (3%) | 7 (3, 12) | 0, 40 | 39.3 (16.9, 67.4) | <.001* | 59 (33, 100) |
| General | 225 (23%) | 14 (4, 27) | 0, 57 | 78.7 (22.5, 151.7) | | 40 (15, 80) |
| Popliteal Block | 517 (52%) | 20 (8, 37) | 0, 101 | 112.4 (45.0, 207.9) | | 50 (20, 80) |
| Popliteal and Saphenous Block | 39 (4%) | 29 (12, 40) | 0, 76 | 163.0 (67.4, 224.8) | | 44 (25, 90) |
| Ropivacaine Catheter | 177 (18% | 27 (13, 41) | 0, 66 | 151.7 (73.1, 230.4) | | 54 (28, 88) |

"Our study found that patients who underwent orthopaedic foot and ankle procedures were overprescribed narcotic medications by nearly twice the amount that was actually consumed," the researchers reported. "Physicians face a challenging task of setting appropriate protocols when balancing pain relief and generalizable guidelines."

They noted that in the cohort they studied, there were just as many patients who took seven or fewer pills as were patients who consumed 35 pills or more.

"Demonstrated by the very wide range of pills taken, it is difficult to predict how many narcotics any individual patient will require after their procedure, and to what degree they will tolerate pain following their surgery," the researchers said.

They noted some patients have the perception that "no amount of pain is acceptable." At the same time, inadequate pain management is one of the most common complaints listed in online patient rating systems, which could lead doctors to "overprescribe" to protect their reputations.

The researchers said further study is warranted "to better define factors that can predict opioid requirement after orthopaedic foot and ankle surgery." They said future studies should also examine the effect of nonsteroidal anti-inflammatory drugs (NSAIDS) use on overall opioid consumption following orthopaedic foot and ankle procedures.

This study has led to a major change in narcotic prescriptions given to patients following foot and ankle surgery throughout the Jefferson Health enterprise. With significantly fewer but appropriate narcotics being prescribed, pain is being optimally managed following surgery, but with many fewer unused pills left over after treatment.


# ORTHOPAEDIC **ONCOLOGY**

Specialists in musculoskeletal oncology handle some of the most complex orthopaedic cases. At Jefferson Health, patients with primary or metastatic tumors of the bone or soft tissue benefit from the combined expertise of surgeons from the Rothman Orthopaedic Institute at Jefferson Health and cancer specialists from the Sidney Kimmel Cancer Center – Jefferson Health. The aim is to ensure that a patient's surgical needs align with overall cancer treatment goals.

Among the cancers regularly treated at Jefferson Health are soft tissue sarcomas, primary bone cancer, including osteosarcoma, Ewing sarcoma and chondrosarcoma, as well as metastatic disease that has spread to the bones.

Many patients are referred to Jefferson Health by outside providers with less experience in dealing with complex musculoskeletal oncology cases. Patients are evaluated by a multidisciplinary team that includes specialists in orthopaedic oncology, musculoskeletal radiologists, medical oncologists and pathologists, all with particular expertise in cancers of the bone and soft tissue.

The musculoskeletal oncology team is also focused on research that will enhance the care of patients, whether by developing new surgical techniques or improving on systematic approaches to delivering patient care.

What follows is a sampling of some of that research:

### Risk Adjustment is Necessary in Value-Based Payment Models for Arthroplasty for Oncology Patients

Total hip arthroplasty (THA) is one of the most successful procedures for improving function and reducing pain. The number of THAs performed annually in the U.S. has reached 1 million, and the procedure accounts for more Medicare expense than any other inpatient procedure. To control healthcare costs, alternative payment models such as bundled payments have been introduced. Instead of traditional fee-for service reimbursement, there is a single contracted price for all services within a given time period.

## SERVICES

- Limb salvage surgery and complete reconstruction
- Osteosarcoma treatment
- Soft tissue sarcoma treatment
- Myeloma treatment
- Evaluation and treatment of spinal tumors
- Treatment of metastatic disease
- Prophylactic fixation
- Imaging and interventional services
- Bone and soft tissue resection
- Radiation and chemotherapy treatment

A concern about bundled payment models is that patients who require more resources or are at higher risk of readmission, complications or reoperations may have reduced access to care because providers may be hesitant to treat complex, high-utilization patients. One such group of patients might be those undergoing THA for malignancy.

Jefferson researchers conducted a study to compare resource utilization and outcomes for patients undergoing THA for malignancy with those undergoing THA for fracture or osteoarthritis.

They used the American College of Surgeons National Quality Improvement database to identify all hip arthroplasties performed from 2013 to 2016 for a primary diagnosis of malignancy (296 patients), osteoarthritis (96,480) and fracture (13,406). The rates of readmissions, reoperation, comorbidities, mortality and surgical characteristics for the three cohorts were compared.

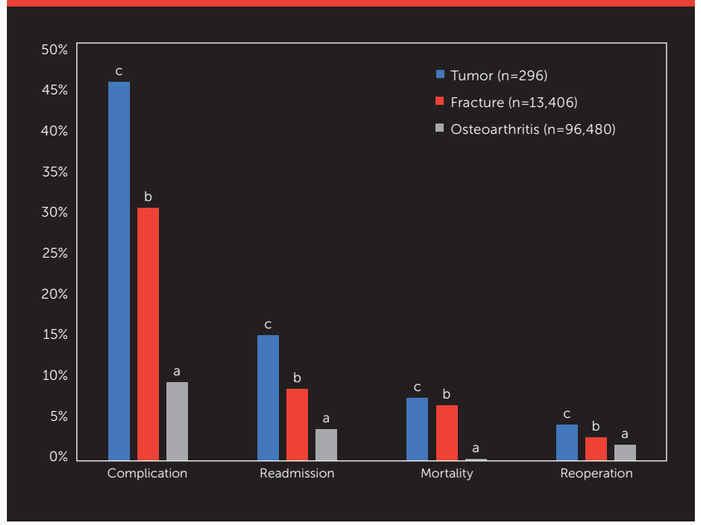
The Jefferson researchers reported their results in *The Journal of Arthroplasty.* Compared to patients undergoing THA for fracture or osteoarthritis, patients getting THA for malignancy had:

- A longer mean operative time (155.7 minutes versus 82.9 minutes versus 91 minutes).
- A longer length of stay (9 days versus 7.2 days versus 2.6 days).
- Less chance of being discharged to home (57.9% of patients went directly home versus 79.8% for osteoarthritis).

When the researchers statistically controlled for demographics and comorbidities, they found that patients undergoing THA for malignancy had more than three times the risk of readmission and reoperation than those who had the hip surgery for fracture or osteoarthritis.

"Patients undergoing THA for malignancy utilize more resources in an episode-of-care and have worse outcomes," the researchers concluded. "Given the clear discrepancies in resource utilization, it is important for reimbursement to account for these discrepancies in order to prevent access to care problems for these high-risk patients."

**Differences in 30-Day Complications, Readmissions, Mortality and Reoperations Stratified Based on Indication for Surgery**




**Source:** Scot A. Brown, MD

**Characteristics of the Patient Population Stratified Based on Indication for Surgery**

| Variable | Osteoarthritis (n= 96,480) | Fracture (n=13,406) | Tumor (n=296) | *P* Value |
|---|---|---|---|---|
| Demographics and Habits | | | | |
| Male Gender | 53,027 (55.0)[a] | 9200 (10.8)[b] | 174 (58.5)[a] | <.001 |
| Mean Age (y) | 65.2 (10.8)[a] | 76.5 (10.0)[b] | 62.1 (13.5)[c] | <.001 |
| Ethnicity (white) | 74,232 (89.3)[a] | 9469 (90.4)[b] | 207 (84.8)[a] | <.001 |
| Smoking History | 11,841 (12.3) | 1645 (12.3) | 38 (12.8) | .958 |
| Mean Body Mass Index (kg/m$^2$) | 30.4 (6.3)[a] | 24.8 (5.5)[b] | 27.6 (6.2)[c] | <.001 |
| Specific Comorbidities | | | | |
| Diabetes | 11,447 (11.9)[a] | 2260 (16.9)[b] | 51 (17.2)[b] | <.001 |
| Obesity (≥30 kg/m$^2$) | 45,569 (47.2)[a] | 1642 (12.2)[b] | 89 (30.1)[a] | <.001 |
| Dyspnea | 4178 (4.3)[a] | 865 (6.5)[b] | 23 (7.8)[b] | <.001 |
| Chronic Obstructive Pulmonary Disease | 3592 (3.7)[a] | 1380 (10.3)[b] | 9 (3.0)[a] | <.001 |
| Congestive Heart Failure | 245 (0.3)[a] | 544 (4.1)[b] | 2 (0.7)[a] | <.001 |
| Chronic Kidney Injury | 25 (0.0)[a] | 95 (0.7)[b] | 0 (0.0) | <.001 |
| Dialysis | 178 (0.2)[a] | 267 (2.0)[b] | 3 (1.0)[b] | <.001 |
| Steroid Use | 3100 (3.2)[a] | 731 (5.5)[b] | 38 (12.8)[c] | <.001 |
| Weight Loss | 162 (0.2)[a] | 129 (1.0)[b] | 21 (7.1)[c] | <.001 |
| Operative and Admission | | | | |
| General Anesthesia | 48,129 (49.9)[a] | 9579 (71.5)[b] | 248 (83.8)[c] | <.001 |
| Mean Operative Time (min) | 91.0 (38.6)[a] | 82.9 (43.6)[b] | 155.7 (98.1)[c] | <.001 |
| ASA Classification | | | | |
| I | 4016 (4.2)[a] | 116 (0.9)[b] | 1 (0.3)[b] | <.001 |
| II | 52,467 (54.4)[a] | 2681 (2681)[b] | 55 (18.8)[b] | |
| III | 38,240 (39.7)[a] | 8123 (60.8)[b] | 191 (65.2)[b] | |
| IV | 16,464 (1.7)[a] | 2422 (18.1)[b] | 46 (15.7)[b] | |
| V | 3 (0.0)[a] | 27 (0.2)[b] | 0 (0.0) | |
| Length of Stay | 2.6 (2.4)[a] | 7.2 (7.2)[b] | 9.0 (10.3)[c] | <.001 |
| Discharge Destination (home) | 76,904 (79.8)[a] | 3680 (28.2)[b] | 165 (57.9)[c] | <.001 |

Continuous variables are presented as mean values (standard deviation) and categorical variables are presented as number of patients (%).
**a,b,c** Significant differences for comparisons of more than 2 variables.

**Source:** American Society of Anesthesiologists (ASA)




# SPORTS **MEDICINE**

Jefferson Health's sports medicine program is one of the largest in the country, caring for athletes of all ages and experience, from youth and high-school players to professional athletes to people who simply like playing sports and staying active. The center is dedicated to both the non-surgical and surgical management of a wide range of sports-related injuries, including common sprains and stress fractures and more complex injuries resulting from competitive sports. While some injuries are due to a specific traumatic event, others are repetitive motion and overuse injuries. Timely diagnosis and appropriate treatment of injury can help prevent long-term repercussions such as osteoarthritis.

The Sports Medicine specialists serve as team physicians for many of Philadelphia's professional and collegiate athletic teams, though they bring the same expertise and dedication to all patients. The overriding goal is to return patients pain-free and confident to their pre-injury level of activity.

Clinicians in the Sports Medicine program are also authors of widely published research. Their research program is one of the largest and most thorough sports research programs in the country. They carry out studies evaluating the diagnosis, nonoperative and operative treatments and preventative measures for the full spectrum of sports injuries. They strive to have the evidence to back up what treatments they provide their patients. Among the topics explored recently are return to play following shoulder stabilization surgery; the evidence behind widely promoted biologic therapies such as stem cell injections; and outcomes for surgical treatments for anterior tibial stress fractures.

Here are a few of those findings:

## Return to Play Criteria Following Surgical Stabilization for Traumatic Anterior Shoulder Instability: A Systematic Review

Instability of the glenohumeral joint is common among young athletes and the problem can be persistent. With nonoperative management, approximately 95% of patients younger than 20 years old have been shown to suffer from recurrent instability events. As a result, many surgeons advocate for surgical stabilization to reduce recurrence and allow the greatest opportunity to return to play.

## SERVICES

- **Arthroscopy of the hip, knee and shoulder**
- **Cartilage restoration procedures: microfracture, osteochondral allograft transplantation and autologous chondryte implantation**
- **Knee ligament reconstruction—ACL surgery**
- **Meniscal transplantation**
- **Patellofemoral joint instability**
- **PCL injury**
- **Rotator cuff repair**
- **Repair and reconstruction of the knee, shoulder and elbow**

Shoulder stabilization surgery requires a period of postoperative rehabilitation for biologic healing to occur, typically followed by conditioning to restore range of motion, strength and coordination prior to safe return to play. It is unclear, however, at what point patients are safe to return to play without restrictions.

A Jefferson Health research team led by Michael Ciccotti, MD, conducted a systematic review of the literature using PubMED and EMBASE to identify and describe criteria used for return to play following surgical stabilization for traumatic, anterior shoulder instability. A literature search from January 1994 to January 2017 yielded 58 Level I to IV studies with at least one stated criterion for return to play.

Seven different categories of return to play criteria were identified, with the most common being time from surgery (89.6% of studies), strength (18.9%) and range of motion (13.8%). Pain, stability, proprioception and postoperative radiographic evaluation were also used. In three-quarters of the studies, time was the sole explicitly stated criteria, with six months post-surgery the most common time point.

"Despite being the most commonly used criterion, and often the only criterion, time from surgery alone is likely necessary but insufficient to ensure safe return to play," the researchers reported in *The Journal of Arthroscopic and Related Surgery*.

They said that it would be useful to use the various criteria cited in the literature to develop a comprehensive checklist of functional criteria that doctors could utilize to help decide when a patient is safe to return to play. Not relying on time alone as a determinant could help reduce the risk of recurrent injury. The checklist of functionally based criteria would reflect what has been proposed for return to play following anterior cruciate ligament reconstruction. Sports researchers at the Rothman Orthopaedic Institute at Jefferson Health are currently developing a comprehensive checklist for athletes with this type of injury.

## The Clinical Evidence Behind Biologic Therapies Promoted at Annual Orthopaedic Meetings: A Systematic Review

Biologic therapies may very well be the future of sports medicine as basic science studies are discovering new signaling pathways and cell lineages that could result in tissue repair and preservation. It has been suggested, for instance, that mesenchymal stem cell therapy could have the potential to modify and perhaps even inhibit the progression of osteoarthritis.

In recent years, biologic therapies (also known as biologics) have increasingly garnered media attention, in turn resulting in many patients asking their physicians for stem cell or other biologic treatments. Such products have been promoted by doctors at leading orthopaedic and sports medicine meetings. It is essential for doctors to keep up with the latest clinical findings on biologic therapies so that they can best advise patients.

Jefferson Health researchers led by Kevin Freedman, MD, and Fotios Tjoumarkaris, MD, conducted a systematic evaluation of the available clinical data for biologic therapies promoted for articular cartilage defects and osteoarthritis of the knee at the 2016 American Orthopaedic Society for Sports Medicine (AOSSM) and the 2017 Arthroscopy Association of North America (AANA) meetings. Biologic products marketed at each conference were identified by reviewing exhibition booths and company websites. A systematic review of the clinical data for each product was then completed using PubMED, EMBASE and company websites. All clinical peer-reviewed studies with Level I-IV evidence were included in the study. Basic science or preclinical studies were excluded.

There were 16 products promoted for biologic therapy for articular cartilage defects or osteoarthritis of the knee at the AOSSM meeting and 11 products promoted at the AANA meeting. A total of 280 articles detailed clinical findings for the products.

Among the findings:

- Of the 280 studies related to the biologics, 36 were Level I evidence, 37 were Level II, 18 were Level III and 189 were Level IV.
- Of the 280 articles, 91% were for four products.
- Of all the biologic products promoted at the two meetings, 65% did not have any peer-reviewed clinical data supporting their use.

"Overall, many biologic therapies promoted at leading arthroscopy and sports medicine conferences did not have clinical evidence evaluating their use in the peer-reviewed literature," the researchers reported in *The Journal of Arthroscopic and Related Surgery*. "Although scientific advancement requires new technology, orthopaedic surgeons should be cautious about using biologic therapies in their practice with no proven efficacy."

The study has a time lag, and the researchers noted that some biologic products may have some supporting clinical data by now. The researchers took care not to negate the potential of biologics in orthopaedic care, noting that "we are currently entering a 'new age' of biologics," but said proof of a product's effectiveness must precede widespread clinical adoption.

"There are likely promising new interventions that, with additional scientific research, will be proven efficacious for our patients," they added. Sports medicine researchers at Jefferson Health are further evaluating the clinical benefits of many of these proposed biologic treatments.

## Outcomes of Surgical Treatment for Anterior Tibial Stress Fractures in Athletes: A Systematic Review

Tibial stress fractures, which are caused by repetitive microtrauma, happen often in athletes. However, stress fractures of the mid-anterior tibia are a relatively uncommon injury among athletes and comprise only 5% to 15% of all tibial stress fractures.

Although most anterior tibial stress fractures heal with nonoperative treatment—usually three to six months of managing the injury—some fractures may require surgical management. Surgical treatment options include intramedullary nailing, tension band or compression plating, and drilling with debridement and bone grafting, each with varying reports of outcomes. The literature, however, lacks a comprehensive review of the different surgical treatment strategies for the management of chronic anterior stress fractures from which general conclusions can be drawn regarding the optimal treatment for elite or high-performing athletes.

Jefferson Health researchers led by Sommer Hammoud, MD, conducted such a review.

They identified 12 studies published between 1984 and 2015, all retrospective case series (Level 4 evidence). Collectively, surgical outcomes for 115 patients (74 males and 41 females) with 123 fractures were included in the review. The overall mean follow-up was 23.3 months.

The most common surgical treatment method was compression plating (52 fractures), followed by drilling (33) and intramedullary nailing (24). Symptom resolution was achieved in 87.8% of fractures (108 of 123). There were 32 reports of complications, resulting in an overall complication rate of 27.8%. Subsequent tibial fractures were reported in eight patients (7%). A total of 17 patients (14.8%) underwent a subsequent procedure after their initial surgery. Following surgical treatment for anterior tibial stress fracture, 94.7% of patients were able to return to sports.

"Our findings indicate that rates of symptom resolution and return to sports are high across all treatment modalities," with the exception of patients who underwent drilling in one case series included in the review, the researchers reported in *The American Journal of Sports Medicine*.

The authors noted that the highest rate of symptomatic hardware was seen in patients treated with intramedullary nailing, with the screws—not the nail itself—appearing to cause symptoms. But unlike when intramedullary nailing is used for traumatic stress fractures, the technique does not commonly result in postoperative anterior knee pain when done for anterior tibial stress fractures. The authors also noted that evidence indicates that drilling may be associated with inferior clinical outcomes compared with compression plating, though the plating is associated with high rates of symptomatic hardware and subsequent plate removal.

Because only Level 4 evidence is available, the Jefferson Health researchers were unable to draw any overall conclusion as to which surgical treatment is best for high-performing athletes.

"Higher level evidence is required to make specific recommendations regarding the optimal treatment modality for high-performance athletes presenting with anterior tibial stress fractures that are refractory to nonoperative management," the researchers reported. They said that while surgical treatment of anterior tibial stress fractures is associated with a high rate of symptom resolution and return to play, "the high complication rate and potential need for subsequent procedures are important considerations for surgeons and patients."




## BASIC **SCIENCE**

### From the Laboratory of Ryan Tomlinson, PhD, Assistant Professor of Orthopaedic Surgery

Bone is continually sensing and converting mechanical cues into biochemical signals, which subsequently direct and mediate both anabolic and catabolic processes in the skeleton. As a result, new bone is formed at sites of high strain and removed in areas of low strain. This process, referred to as strain adaptive bone remodeling, enables bone to efficiently adapt to functional demands by generating bone where it is needed and eliminating bone that is underutilized – a process that has been shown to greatly increase the fatigue strength of bone.

Dr. Tomlinson's research focuses on characterizing the inflammatory signals generated immediately after skeletal loading that direct and organize the subsequent osteogenic processes. In one project, the lab is investigating the role of NGF-TrkA signaling in sensory nerves. Nearly all the nerves in bone express TrkA, the high-affinity receptor for nerve growth factor (NGF). Furthermore, sensory nerves blanket the surfaces of bone in a mesh-like network, a privileged location for the acquisition of mechanical signals.

Using both in vivo and in vitro methods, the lab has demonstrated that NGF is robustly expressed by mature osteoblasts in response to non-damaging mechanical loads. Inhibition of NGF-TrkA signaling impairs load-induced bone formation whereas administration of exogenous NGF increases relative bone formation rates. These effects appear to be facilitated through altered Wnt/β-Catenin signaling, which the lab is investigating by using mice that lack NGF in the osteoblast lineage. The lab also has identified a compound that may provide long-term activation of TrkA to increase load-induced bone formation without the painful side effects of NGF.

In related work, the lab is investigating the role of non-steroidal anti-inflammatory drugs (NSAIDs) on stress fracture risk and repair. In both clinical and preclinical investigation, the lab has clarified a link between overall NSAID usage and stress fracture risk. Research in mice showed that NSAIDs may increase stress fracture risk through two independent mechanisms – diminished load-induced bone formation and decreased bone toughness. The lab also identified NSAIDs that can provide analgesia without affecting stress fracture risk or repair. Upcoming work will involve using unbiased transcriptomics and proteomics to identify potential pharmaceutical targets for the next generation of musculoskeletal pain medication.

In total, the lab's research suggests that modulation of inflammatory signaling may be an attractive target for improving skeletal response to loading and reducing overall fracture risk.

## From the Laboratory of Andrzej Fertala, PhD, Professor of Orthopaedic Surgery

Increased tendon pain and tendon damage is a clinically significant potential complication related to hyperlipidemia. Unlike the well-established pathogenesis associated with increased serum concentrations of total cholesterol (TC), triglycerides (TG), and low-density lipoprotein (LDL) in atherosclerotic cardiovascular disease, the role of hyperlipidemia in promoting tendon damage remains controversial and requires mechanistic clarity.

Various studies in humans indicate a possible association between hyperlipidemia and increased risk for tendon damage. Also, studies in various animal models have demonstrated a link between hyperlipidemia and significant alterations of the mechanical properties of tendons.

A study by Dr. Fertala and colleagues aimed to define the pathomechanisms of tendon damage by analyzing the consequences of excess cholesterol on the integrity of the fibrillar architecture of the tendon in an Achilles tendon rabbit-based model of hypercholesterolemia. The Achilles tendons from rabbits fed with normal-cholesterol (nCH) and high-cholesterol (hCH) diets were harvested and analyzed using histological, spectroscopic, biochemical, and biomechanical assays.

Histologically, hCH tendons and tenosynovium demonstrated hypercellular areas with increased numbers of macrophages infiltrating the tendon structure as compared to nCH tendons. While Oil red staining revealed lipid-rich deposits in hCH tendons, hybridization of tendon tissue with collagen-hybridizing-peptides demonstrated damage to the collagen fibers.

Fourier-transform infrared spectroscopy analyses of the tendons showed the presence of distinct peaks consistent with the presence of cholesterol ester. The hCH tendons displayed regions of poor collagen content that overlapped with lipid-rich regions. The hCH tendons had a significant 4-fold increase in the collagen III to collagen I ratio as compared to nCH tendons. Tendons from the hCH rabbits showed poor biomechanical characteristics in comparison to control. The biomechanical changes were evident at the macro and the nano-level of tendon structure.

The study results support the hypothesis that high-cholesterol diets lead to a weakening of tendons via a mechanism that involves damage to the collagen fibrils. The finding opens a possibility for targeting lipid-binding sites on collagen molecules as a treatment strategy to avoid the harmful consequences hyperlipidemia may have on tendon structure, function and healing.

## From the Laboratory of Noreen Hickok, PhD, Associate Professor of Orthopaedic Surgery

Periprosthetic joint infection (PJI) is one of the most feared and challenging complications that can occur after placement of therapeutic implants, resulting in debilitating pain, decreased mobility and the need for aggressive antibiotic intervention. PJIs can be so serious that total failure of the implant occurs and can account for 25% of failed total knee replacements and 15% of failed total hip replacements. In the worst cases, these infections can be fatal.

Joint infections tend to be particularly virulent and resistant to treatment because of the way that they colonize the surgical site. Bacteria adhere to the metallic surfaces and secrete a biofilm that limits accessibility by antibiotics and attacks by the immune system.

Research led by Dr. Hickok has shown that when implant surfaces are covered with antibiotics and other anti-microbial agents, they are much less susceptible to colonization by bacteria. Research has also shown that much higher doses of antibiotics can be used if they are delivered to the infection sites with more precision.

The goal of Dr. Hickok's research is to tailor interactions between pathogens and bone tissues and implant surfaces in order to allow eradication of bacteria. These studies span fields related to bioengineering, tissue engineering, biochemistry and biology to produce new translational products that can improve the outcome of implantations.

The lab's projects include:

- **Permanently attaching antibiotics to implant surfaces**. The lab has begun testing these implants in pre-clinical models, and further developing them for cancer patients who are more prone to infection due to chemotherapy.
- **Photo-activated compounds that can be used to replace or augment antibiotics**, especially in light-accessible sites, such as gingival tissues in dental implantations. Early results have shown that these compounds may continue to be effective even in the dark, opening the door to a multitude of potential uses.
- **Prophylactic treatment of the spinal sheath that surrounds the spinal stabilization rod**. Infections occur in as many as one in 20 elective spinal surgeries and one in 10 spinal surgeries resulting from traumatic injury. When activated by an ultrasound, the spinal sheath would release high concentrations of combinations of antibiotics directly to the infection site.
- **Biofilms within the joint fluid to combat septic arthrosis**. Infections of this kind are extremely dangerous and can travel through the bloodstream, infecting other sites in the body. Removing the large fibrous bacteria-filled clots is often not enough to prevent septic arthrosis from recurring, so Dr. Hickok's team is investigating the use of ultrasound-activated microbubbles of antibiotics to eliminate infections within the joint fluid.
- **Research to learn how compromised oral health influences other degenerative conditions**. Based on the lab's findings that dental and oral bacteria are present in osteoarthritis and degenerative disc disease samples, the team is now exploring, through inflammatory reactions, the progression of osteoarthritis and DDD.

## From the Laboratory of Christopher Kepler, MD, MBA, Associate Professor, Orthopaedic Surgery; Dessislava Z. Markova, PhD, Research Assistant Professor, Orthopaedic Surgery and David G. Anderson, MD, Professor, Orthopaedic Surgery

Circulating serum microRNAs (miRNAs) have recently become established as promising biomarkers of various disease states such as cancer and cardiovascular disease. However, there has been relatively little research in musculoskeletal disease and no research in spine disease.

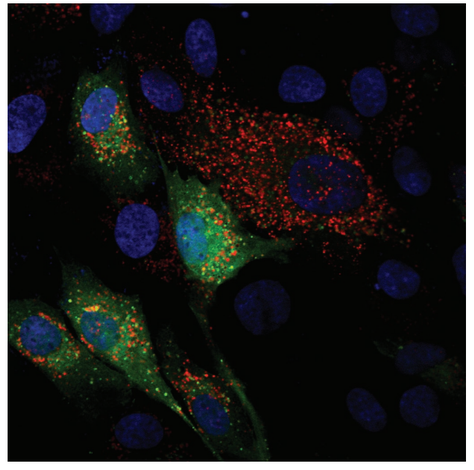
The lab's research interest is to identify a unique serum miRNA profile as a biomarker of degenerative disc disease (DDD) in patients with low back pain compared to healthy controls.

The results from the initial screening assay indicated that 2 miRNAs in DDD patients were substantially higher expressed than those in control subjects, and 11 miRNAs were lower expressed, respectively. There was a significant downregulation in miR-155-5p expression in patients and a trend toward downregulation in miR-146a-5p expression.

A second focus of the lab is to use a rat Intradiscal TNF-α injection injury model to induce intervertebral disc (IVD) degeneration with subsequent measurement of miRNA dysregulation at consecutive timepoints.

## From the Laboratory of Makarand V. Risbud, PhD, Professor of Orthopaedic Surgery and Irving M. Shapiro, PhD, Professor of Orthopaedic Surgery

The intervertebral disc is a complex structure that separates opposing vertebrae and permits a range of motions allowing accommodation of high biomechanical forces on the spine. Drs. Risbud and Shapiro study specific conditions that enhance disc cell survival as well as elucidating factors that dysregulate the local microenvironment and promote degenerative disc disease. Intervertebral disc degeneration and associated low back and neck pain is a ubiquitous health condition that affects millions of people worldwide, and causes high incidence of disability and opioid addiction and results in enormous medical and societal costs.



**Nucleus Pulposus** - Cells within the intervertebral disc.
Source: Makarand V. Risbud, PhD

One ongoing project is the characterization of a mouse model of spontaneous, early-onset disc degeneration. The lack of appropriate small animal models with spontaneous disease onset has impeded the ability to understand the pathogenetic mechanisms that characterize and drive the degenerative process. The lab's work clearly demonstrates that the SM/J mouse strain recapitulates many salient features of human disc degeneration, such as compromised cell survival, loss of cell phenotype, hypertrophic differentiation of nucleus pulposus (NP) cells and extracellular matrix changes that lead to compromised biomechanical function. These mice represent a novel small animal model to understand pathogenesis of disc degeneration.

The lab is also focused on understanding the role of different molecules involved in homeostasis of intervertebral disc cells. The lab recently demonstrated for the first time that carbonic anhydrases are key contributors in regulating NP cell function and pH homeostasis. It was observed that the expression of both CA9 and 12 was dependent on HIF-1 activity in vitro and in vivo. Both these enzymes played a critical role in generation of bicarbonate that maintains intracellular pH. Likewise, lab research has seen that an RNA binding protein, HuR, controls CA12 expression in NP cells in an HIF-1 independent manner and contributes to pH homeostasis. HuR was also seen to control expression of several matrix molecules, making it an important regulator of the NP niche. In contrast to CA9 and 12, hypoxia sensitive CA3 does not participate in pH homeostasis but rather plays a role in antioxidant defense of cells and maintains their survival.

Another major focus of the laboratory has been to understand contribution of osmo-sensing protein tonicity-responsive enhancer-binding protein (TonEBP) in NP function.

Recent studies have shown that the activation of TonEBP occurs by non-osmotic stimuli, including proinflammatory molecules, in cells involved in immune response. However, whether inflammatory stimuli activate TonEBP in NP cells and whether TonEBP controls inflammation during disc degeneration is unknown.

The lab showed for the first time that some of the TNF response in NP cells was TonEBP dependent, implying the possibility of a novel drug target. However, therapeutic strategies targeting this transcription factor for treatment of disc disease must spare osmoprotective, prosurvival, and matrix homeostatic activities.

The lab has also shown that COX-2, a molecule traditionally thought to be only pro-inflammatory, is a TonEBP target and plays a cytoprotective and homeostatic role in NP cells for their adaptation to dynamically loaded hyperosmotic niches. These studies once again highlight the unique niche of the intervertebral disc and underscores the importance of basic research to further the understanding of this tissue.

## From the Laboratory of George Feldman, DMD, PhD, Research Assistant Professor of Orthopaedic Surgery

Developmental Dysplasia of the Hip (DDH), a debilitating condition characterized by incomplete formation of the bones of the hip joint, can lead to dislocation of the femur and crippling arthritis.

Dr. Feldman's research is aimed at identifying the genetic mutation(s) and developing a diagnostic DNA test to identify individuals at risk for this disorder. His studies of the DNA of a four-generation family have found a potentially harmful mutation in the gene encoding an important cell receptor, CX3CR1. In another family, a second potentially harmful mutation was found in the teneurin3 gene.

Both of these DNA changes are thought to delay the maturation of stem cells in forming the cartilage of the hip bone. Identification of these mutations may lay the foundation for an accurate diagnostic test in newborns, while treatment of DDH would prevent hip dysplasia from developing into osteoarthritis.

A second focus of the lab is to find a cause-based treatment to remedy the morbid side effects of nitrogen containing bisphosphonates (NBPs), which are used to prevent osteoporosis and to stop the spread of metastatic cancer to bone. NBPs in high doses cause fracture of the femur and osteonecrosis of the jaw bone. The lab is developing a cause-based drug and local delivery system to prevent these side effects while allowing bisphosphonates to continue their systemic bone-sparing actions.

## From the Laboratory of Theresa Freeman, MS, PhD, Associate Professor of Orthopaedic Surgery

Dr. Freeman has been working in the field of Plasma Medicine to develop therapeutic applications using Cold (non-thermal) Atmospheric Plasmas (CAP) and cold plasma activated liquids (PAL). The generation of both ionized species and electric fields by CAP induces the generation of intracellular reactive oxygen and nitrogen species, which initiate signaling cascades that can stimulate multiple bioelectrochemical effects in tissues.

Using CAP treatment, the Freeman Lab has induced enhanced differentiation of mesenchymal cells, mouse limb growth and extracellular matrix calcification. Together these techniques could be used to promote regeneration of cartilaginous tissues and increase bone formation. Additionally, she is exploring how CAP treatment can be used to destroy biofilms on the surface of titanium implants and together with PAL be used to treat orthopaedic infections clinically.

Importantly, CAP treatment may not only destroy the biofilm and kill the bacteria but modify the bacterial debris and make it more immunogenic to stimulate an immune response. The CAP treatment can be tuned to be used for both killing at high powers and stimulation of regeneration at lower power. Through these studies a better understanding of plasma/cell and tissue interactions can be discovered to increase the potential medical applications this technology can address, especially as viable clinical solutions to a wide range of orthopaedic applications.

Repair and regeneration of tissues after injury or wounding is an important area of study that impacts multiple diseases. In addition to plasma activation of these processes, Dr. Freeman is also studying how inhibition of a protein called Apoptosis signal regulated kinase (ASK1) can reduce tissue damage by decreasing cell death and pro-inflammatory cytokine production. This will not only limit cartilage degeneration by reducing tissue destruction, but could also stimulate endogenous cells to activate repair cascades to generate a more robust healing/regenerative response.

Additionally, she has several collaborations investigating other aspects of tissue repair. In collaboration with Millicent O. Sullivan, PhD, from the University of Delaware, she studies non-viral gene delivery to promote fracture healing, and with My Mahoney, PhD, from Jefferson's Department of Dermatology and Cutaneous Biology, she explores the role of the epithelium in regeneration and wound healing.

| FUNDED CLINICAL TRIAL | INVESTIGATOR(S) |
|---|---|
| Post Market Clinical Follow-Up Study of the Titan Reverse Shoulder System Used in Primary or Revision Total Shoulder Arthroplasty. *Integra* (06/2014–ongoing) | Surena Namdari, MD; Matthew L. Ramsey, MD |
| A Retrospective and Prospective Data Collection Study of the TITAN Modular Total Shoulder System. *Integra* (03/2015–ongoing) | Surena Namdari, MD; Matthew L. Ramsey, MD |
| Retrospective and Prospective Clinical Outcomes of the Zimmer Nexel Total Elbow. *Zimmer Biomet* (06/2015–ongoing) | Surena Namdari, MD; Matthew L. Ramsey, MD |
| Prospective Post Market Clinical Follow-Up Study of the Zimmer Trabecular Metal Humeral Stem. *Zimmer Biomet* (04/05/2012–ongoing) | Joseph A. Abboud, MD; Surena Namdari, MD |
| Post-Market Clinical Follow-Up Study of the Zimmer Vivacit-E Highly Crosslinked Polyethylene Liner Used with the Continuum Acetabular Shell. *Zimmer Biomet* (10/1/2013–ongoing) | Javad Parvizi, MD; William V. Arnold, MD, PhD |
| Prospective Post-Market Clinical Follow-Up of the Zimmer Biomet Trabecular Metal Reverse; Shoulder System. *Zimmer Biomet* (08/2011–ongoing) | Bradford S. Tucker, MD; Luke S. Austin, MD; Matthew D. Pepe, MD |
| Prospective Clinical Evaluation Treating Subchondral Bone Marrow Lesions with Subchondroplasty for Pain Relief. *Knee Creations LLC* (03/15/2012–ongoing) | Steven Cohen, MD |
| Trabecular Metal Femoral Hip Stem Used within the Zimmer Biomet Hip Registry. *Zimmer Biomet* (02/09/2012–ongoing) | Carl Deirmengian, MD |
| Prospective Post-Market Clinical Follow-up of the Zimmer Biomet Trabecular Metal™ Reverse Shoulder System. *Zimmer Biomet* (08/23/2011–ongoing) | Matthew L. Ramsey, MD; Charles L. Getz, MD |
| Post-Market Study of the Stryker Orthopaedics Triathlon TS Total Knee System. *Stryker* (04/01/2012—ongoing) | Fabio R. Orozco, MD; Alvin C. Ong, MD |
| Persona Outcomes Knee Study (POLAR). *Zimmer Biomet* (03/01/2013–ongoing) | Matthew S. Austin, MD |
| Retrieval of Discarded Surgical Tissue. *National Disease Registry Institute* (01/12/2004–ongoing) | James J. Purtill, MD; William J. Hozack, MD; Richard H. Rothman, MD, PhD |
| Retrospective and Prospective Data Collection Study of the TITAN Modular Total Shoulder System (TSS). *Integra* (08/2014–present) | Surena Namdari, MD; Matthew Ramsey, MD; Joseph Abboud, MD; Mark Lazarus, MD; Gerald Williams, MD; Charles Getz, MD |
| Prospective Post Market Clinical Follow-Up Study of the Zimmer Trabecular Metal™ Total Ankle System. *Zimmer Biomet* (08/2014–present) | Steven Raikin, MD; David Pedowitz, MD |
| Triathlon Tritanium Knee Outcomes Study. *Stryker* (04/2014–present) | Fabio Orozco, MD; Alvin Ong, MD; Zachary Post, MD |
| Post Market Study of the Stryker Orthopaedics Triathlon PKR Knee System. *Stryker* (11/2013–present) | Fabio Orozco, MD; Alvin Ong, MD, Zachary Post, MD |
| Clinical Study Protocol for the Investigation of the Simplify Cervical Artificial Disc. *Simplify Medical* (04/2016–present) | Kristen Radcliff, MD; Barrett Woods, MD |
| A Prospective, Multi-Center Study of Instrumented Posterolateral Lumbar Fusion (PLF) with OsteoAMP® to Evaluate Long-Term Safety and Efficacy in Patients Requiring 1-2 Level Instrumented PLF. *Bioventus, LLC* (01/2016–present) | Barrett Woods, MD; Kristen Radcliff, MD |
| Use of Autologous Adipose-Derived Stromal Vascular Fraction to Treat Osteoarthritis of the Knee; A Controlled, Randomized, Double Blinded Trial. *GID Group* (04/2016–present) | Bradford Tucker, MD |

| FUNDED CLINICAL TRIAL | INVESTIGATOR(S) |
|---|---|
| One Stage Versus Two Stage for Periprosthetic Hip and Knee Infection. *Orthopaedic Research and Education Foundation* (05/2016–present) | Javad Parvizi, MD; Matthew Austin, MD; Greg Diermengian, MD |
| Clinical Outcomes Reporting Study. *Stryker Orthopaedics* (10/2013–current) | Javad Parvizi, MD; William Hozack, MD; Richard H. Rothman, MD, PhD; Matthew Austin, MD; Gregory Diermengian, MD; James J. Purtill, MD; Alvin C. Ong, MD; Fabio R. Orozco, MD; Zachary Post, MD; Eric Smith, MD; Robert Good, MD; Eric Levicoff, MD; Peter Sharkey, MD |
| Manipulation Under Anesthesia (MUA) to Treat Postoperative Stiffness after Total Knee Arthroplasty: A Multi-Center Randomized Clinical Trial. *The Knee Society* (09/2016–current) | Matthew Austin, MD; Javad Parvizi, MD; Antonia Chen, MD; Gregory Diermengian, MD; James J. Purtill, MD; William J. Hozack, MD; Richard H. Rothman, MD, PhD |
| MIS-ReFRESH – Multi-Center, Partially Randonmized, Controlled Trila of MIS Robotic Versus Freehand in Short Adult Degenerative Spinal Fusion Surgeries. *Mazor Robotics, Ltd.* (09/2016–current) | Victor Hsu, MD |
| A Prospective, Single Blinded, Multi-Center, Randomized, Controlled, Pivotal Study to Assess the Safety and Effectiveness of the Inspace Device for Treatment of Full Thickness Massive Rotator Cuff Tears. *Orthospace, Ltd.* (01/2016–current) | Joseph Abboud, MD |
| Influence of Lateralization on Outcomes After Reverse Arthroplasty? A Randomized Controlled Trial. *DJO Surgical* (10/2016–current) | Joseph Abboud, MD; Surena Namdari, MD; Gerald Williams, MD |
| Tornier Shoulder Outcomes Study. *Tornier, Inc.* (10/2014–current) | Joseph Abboud, MD; Mark Lazarus, MD; Gerald Williams, MD; Surena Namdari, MD |
| Pyrocarbon IDE study. *Tornier, Inc.* (03/2016–current) | Joseph Abboud, MD; Surena Namdari, MD; Charles Getz, MD; Mark Lazarus, MD |
| Post-Market Study of Robotic-Arm Assisted Total Knee Arthroplasty. *Stryker, Corp.* (07/2016–current) | William J. Hozack, MD; Fabio R. Orozco, MD |
| A Post-Market, Prospective, Multi-Center, Open-Label, Single Arm Clinical Evaluation of Integra Cadence Total Ankle System in Primary Ankle Joint Replacement. *Integra* (10/2016–present) | David Pedowitz, MD |
| Thoracolumbar Burst Fractures (AOspine A3, A4) in Neurologically Intact Patients: An Observational Multi-Center Cohort Study Comparing Surgical Versus Non-Surgical Treatment. *AO Foundation* (10/2016–current) | Alexander R. Vaccaro, MD, PhD, MBA; Chris Kepler, MD, MBA |
| Prospective, Multi-Center, Randomized Concurrently Controlled Trial to Evaluate the Safety and Effectiveness of the Altum Pedicle Osteotomy System for Use in Lumbar Spinal Stenosis. *Innovative Surgical Designs* (08/2017–current) | Mark Kurd, MD |
| Longitudinal Outcomes Study of the Subchondroplasty Procedure in the Foot/Ankle. *Zimmer Biomet* (09/2017–current) | David Pedowitz, MD |
| Efficacy of Amniotic Tissue (CLARIX™100 & CLARIX™ CORD 1K) in Pain Reduction and Improvement of Function in the Low Back & Leg Pain in Discectomy Patients. *TissueTech* (07/2015–current) | D. Greg Anderson, MD |
| A Post-Market, Prospective, Non-Randomized, Multi-Center, Open-Label Clinical Evaluation of the Integra Titan Modular Shoulder System 2.5 for Primary Shoulder Joint Replacement. *Integra* (03/2017–current) | Matthew L. Ramsey, MD; Surena Namdari, MD |
| A Multi-Center, Prospective, Comparative Study of Anterior Versus Posterior Surgical Treatment for Lumbar Isthmic Spondylolisthesis. *AO Foundation* (11/2016–current) | Alexander R. Vaccaro, MD, PhD, MBA; Chris Kepler, MD; Gregory Schroeder, MD |
| A Retrospective Study of the Navio Robotic-Assisted Surgical System. *Smith and Nephew* (07/2017–current) | Jess Lonner, MD |
| Intermediate Clinical and Radiographic Outcomes of Isolated Patellofemoral Arthroplasty and Modular Bicompartmental Knee Arthroplasty. *Zimmer Biomet* (09/2017–current) | Jess Lonner, MD |

| FUNDED CLINICAL TRIAL | INVESTIGATOR(S) |
|---|---|
| A Multi-Center, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities (RECON). *Axogen* (05/2017–current) | Asif Ilyas, MD; Chris Jones, MD; Fred Liss, MD; Michael Rivlin, MD; Jonas Matzon, MD; Charles Leinberry, MD; Mark Wang, MD |
| The Use of Barbed Sutures in Total Hip Arthroplasty: A Prospective, Randomized, and Controlled Clinical Trial. *Johnson and Johnson* (12/2015–current) | Javad Parvizi, MD |
| Lateral Ankle Ligament Reconstruction with Internalbrace Augmentation: A Prospective Randomized Study. *Arthrex, Inc.* (09/2017–current) | Steven Raikin, MD; David Pedowitz, MD |
| A Prospective, Controlled, Multi-Center, Post-Approval Trial to Evaluate the Long-term Safety and Effectiveness of AUGMENT Bone Graft Compared to Autologous Bone Graft as a Bone Regeneration Device in Foot and Ankle Fusions. *Wright* (07/2017–current) | Steven Raikin, MD |
| Use of Cooled Radiofrequency for the Treatment of Hip Pain Associated with OA of the Hip Compared to Intra-Articular Steroid Injections. *Halyard Health* (05/2017–current) | David Stolzenberg, DO; Joshua Armstrong, DO; Arjun Saxena, MD; Ryan Pfiefer, DO |
| A Multi-Center, Open-Label, Prospective Study of SpinalStim (MOP-SS) as Adjunctive Care Following Lumbar Fusion Surgery. *Orthofix* (06/2017–current) | Kris Radcliff, MD; Barrett Woods, MD |
| Clinical Study Protocol for the Investigation of the Simplify Cervical Artificial Disc Two Level. *Simplify Medical* (09/2017–current) | Kris Radcliff, MD; Barrett Woods, MD |
| A Prospective, Post-Market, Multi-Center Evaluation of the Clinical Outcomes of the Trident II Acetabular Shell. *Stryker* (09/2017–current) | Fabio R. Orozco, MD |
| Prospective Post-Approval Clinical Follow-Up Study of the Commercially Available U2 Knee System. *United Orthopedic Corporation* (7/2018–current). | Arjun Saxena, MD |
| Post-Market, Randomized, Open-Label, Multicenter, Study to Evaluate the Effectiveness of Closed Incision Negative Pressure Therapy Versus Standard of Care Dressings in Reducing Surgical Site Complications in Subjects with Revision of a Failed Total Knee Arthroplasty (PROMISES). *Acelity* (8/2018–current). | Paul Courtney, MD; Arjun Saxena, MD; Javad Parvizi, MD |
| Prospective, Non-Interventional, Long-Term Follow-Up Study for Subjects who Received Standard of Care, CLARIX™ 100, or CLARIX™ CORD 1K during Discectomy. *TissueTech* (07/2018–current). | Greg Anderson, MD |
| A Prospective, Multi-Center, Randomized Concurrently Controlled Trial to Evaluate the Safety and Effectiveness of the Altum® Pedicle Osteotomy System for use in Lumbar Spinal Stenosis. *Innovative Surgical Designs* (03/2018–current). | Mark Kurd, MD |
| A Prospective, Non-Comparative, Multi-Center, Post-Market Clinical Study to Evaluate the Safety and Performance of PEEK-OPTIMA™ HA Enhanced Interbody Cages for the Treatment of Degenerative Disc Disease and Spondylolisthesis in the Lumbar Spine. *Invibio, LTD* (08/2018–current) | Mark Kurd, MD |
| An Assessment of P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion with Instrumentation. *Cerapedics* (06/2018–current). | Alexander R. Vaccaro, MD, PhD, MBA; Gregory Schroeder, MD |
| Randomized, Controlled Trial of Posterior C1-2 Fusion Versus Bracing Alone for Treatment of Type II Odontoid Process Fractures in the Elderly. *CSRS grant* (03/2018–current). | Chris Kepler, MD, MBA; Alexander R. Vaccaro, MD, PhD, MBA; Alan Hilibrand, MD, MBA; D. Greg Anderson, MD; Mark Kurd, MD; Gregory Schroeder, MD |
| A Multi-Center, Open-Label, Prospective Study of CervicalStim Device™ as Adjunctive Care Following Cervical Fusion in Subjects with Degenerative Disc Disease (DDD). *Orthofix* (03/2018–current) | Mark Kurd, MD; Barrett Woods, MD |
| A Randomized Controlled Trial Comparing Intraoperative Surgeon-Performed and Anesthesiologist-Performed Adductor Canal Blockade after Primary Total Knee Arthroplasty. *Sharpe-Stumia Research Foundation* (05/2018–current). | Jess Lonner, MD; Eric Levicoff, MD; Robert Good, MD |
| Prospective Randomized Controlled Double-Blinded Trial Comparing Oxycodone, Ibuprofen and Acetaminophen after Wide Awake Hand Surgery. *American Foundation for Surgery of the Hand Clinical Grant* (08/2017–current). | Asif Ilyas, MD |

| FUNDED CLINICAL TRIAL | INVESTIGATOR(S) |
|---|---|
| Multi-Center Clinical Evaluation of the ATTUNE Cementless Rotating Platform Total Knee Arthroplasty. *DePuy Synthes* (07/2019–current). | Zachary Post, MD |
| Multi-Center Clinical Evaluation of the ATTUNE Revision System in Revision Total Knee Arthroplasty. *DePuy Synthes* (05/2019–current). | Zachary Post, MD |
| Multi-Center Clinical Evaluation of the ATTUNE Revision System in Complex Primary Total Knee Arthroplasty. *DePuy Synthes* (05/2019–current). | Zachary Post, MD |
| A Prospective, Randomized, Double Blind Investigation of Amnios RT for the Treatment of Plantar Fasciitis. *Globus Medical, Inc.* (05/2019–current) | Paul Sullivan, DPM |
| A Post-Market, Prospective, Multi-Center, Nonrandomized Study to Assess Posterolateral Lumbar Fusions Using Fibergraft BG Matrix. *Prosidyan, Inc.* (07/2019–current). | Gregory Schroeder, MD; Guy Lee, MD |
| Clinical Evaluation of Fortilink TETRAfuse Interbody Fusion Device in Subjects with Degenerative Disc Disease (FORTE). *RTI Surgical, Inc.* (06/2019–current). | Chris Kepler, MD; David Kaye, MD |
| Both Bone Forearm Fracture Plating, Pre-contoured Radius Plate Fix. *Acumed, LLC* (04/2019–current). | Chris Jones, MD; Asif Ilyas, MD |
| Cyanoacrylate perioperatively may reduce bacterial colonization of surgical sites in hip and knee surgery: a prospective, randomized trial. *Osteoremedies* (10/2018–current). | Javad Parvizi, MD |
| Photodynamic therapy for Cutibacterium acnes (C. acnes) decolonization of the shoulder dermis. *Orthopaedic Research and Education Foundation* (OREF) (02/2019–current). | Gabe Horneff, MD |
| Post-Market Study of Robotic-Assisted Total Knee Arthroplasty Utilizing the Navio Surgical System. *Smith and Nephew, Inc.* (03/2019–current). | Alvin Ong, MD |
| The use of Liposomal Bupivacaine Interscalene Brachial Plexus Block for Rotator Cuff Surgery: A randomized, double blind, clinical trial. *Pacira* (04/2019–current). | Bradfort Tucker, MD; Fotios Tjoumakaris, MD |
| Plasma, joint fluid and arthroscopy fluid HIV and HCV viral load in shoulder arthroscopy. *Roche Diagnostics Corporation* (02/2019–current). | Surena Namdari, MD; Joseph Abboud, MD; Mark Lazarus, MD; Gabe Horneff, MD; Matthew L. Ramsey, MD |
| Prospective, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Safety and Efficacy of Pulsed Electromagnetic Field (PEMF) Therapy as an Adjunctive Treatment to Surgical Repair of Full Thickness Rotator Cuff Tears. *Orthofix* (06/2019–current) | Anthony Romeo, MD |
| Prospective, Multi-Center, Randomized Clinical Study of Total Shoulder Arthroplasty Comparing Exactech Guided Personalized Surgery (GPS) vs. Conventional Instrumentation. *Exactech* (05/2019–current) | Joseph Abboud, MD; Surena Namdari, MD; Gabe Horneff, MD |
| Operative versus Non-operative Treatment for Atraumatic Rotator Cuff Tears: A Multicenter Randomized Controlled Pragmatic Trial. *Patient-Centered Outcomes Research Institute (PCORI)* (07/2019–current). | Joseph Abboud, MD |
| SPIRA-A 3D Printed Titanium Anterior Lumbar Interbody Fusion Device and Demineralized Bone Matrix Versus a PEEK Anterior Lumbar Interbody Fusion Device and Recombinant Bone Morphogenic Protein-2. *Camber Spine Technologies* (04/2019–current). | David Kaye, MD |
| Glucose Management of Hospitalized Patients Directed by DexCom G6 Continuous Glucose Monitor with Alarms. *Dexcom* (07/2019–current). | Javad Parvizi, MD; Michele Kavin, PA-C |
| In Vivo Model of Human Enthesis Regeneration. *National Institute on Aging* (09/2019–current). | Rowena McBeath, MD, PhD |

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