ORTHOPAEDIC OUTCOMES & RESEARCH

2021 REPORT

Jefferson Health®

ORTHOPAEDIC & OUTCOMES RESEARCH

Complex Spine

VOLUME 3

Jefferson Health®

COMPLEX SPINE 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

Dear Colleagues,

I am especially excited to share this yearly Outcomes & Research report from the spine team at The Department of Orthopaedic Surgery at Jefferson Health.

Our spine program just stepped into the future with the opening of a new hybrid operating room at Jefferson Methodist Hospital that was built specifically for spine surgery. Now we can take complex deformity cases and those with infections, tumors and trauma and treat them in a minimally invasive fashion using robotic, augmented reality. This allows us to decrease surgery time and provide more efficient, cost-effective care. The collaboration that happens between orthopedics, neurosurgery, general surgery, vascular surgery, rehab, nursing and medicine has really changed our ability to provide great modern care to our patients.

The hybrid OR has an observation room where we can teach residents, fellows and visiting professors, but most importantly, surgeons in the community who have a complicated case and who want to learn. They can send us their patients, then sit in the observation room and can watch the whole process.

The placement of this state-of-the-art hybrid OR at Jefferson Methodist Hospital, easily accessible on South Broad Street in Philadelphia, was done with great thought. We appreciate that patients want the convenience and personalized service that can come from being at a hospital with a community focus, but they do not want to sacrifice the experience that an academic, research-based surgical team brings to every case.

Our spine surgeons are sought out for their expertise in treating complex and potentially life-altering conditions, including spinal cord injuries, spinal tumors, spinal deformity, and osteomyelitis. They bring the same level of proficiency to treating more common conditions, such as degenerative disc disease, spinal stenosis and cervical and lumbar disc herniation that can dramatically diminish the quality of a patient's life if not properly addressed.

The Regional Spinal Cord Injury Center of the Delaware Valley, in affiliation with Magee Rehabilitation Hospital, is designated as one of the nation's 14 Model Spinal Cord Injury Centers by the National Institute on Disability and Rehabilitation Research (NIDRR) in the U.S. Department of Education's Office of Special Education and Rehabilitative Services (OSERS), and the only one in the Delaware Valley.

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

Does an Uninstrumented Level Increase the Rate of Revision Surgery in a Multilevel Posterior Cervical Decompression and Fusion?

Degenerative compression of the cervical spinal cord that causes spinal cord dysfunction is also known as cervical spondylotic myelopathy (CSM). Patients with CSM often present with nonspecific symptoms of neck and shoulder pain, upper and lower extremity weakness or gait imbalance, loss of fine motor skills and radiculopathy. Compression of the cervical spinal cord is typically multifactorial, due to degeneration of the intervertebral discs, facet and uncovertebral joints, and ligamentous structures.

There are multiple surgical options for the treatment of CSM, including anterior, posterior and combined approaches. There is debate over the preferred approach for multilevel CSM, although multiple studies have demonstrated the safety and efficacy of posterior cervical decompression and fusion (PCDF) surgery.

With advanced pathology, however, it can be difficult to safely obtain posterior cervical screw fixation at every operated level. It is unclear whether skipping a level of fixation during PCDF surgery affects surgical outcomes regarding fusion and revision rates.

To study this issue, a research team from Thomas Jefferson University Hospital and the Rothman Institute, led by Gregory Schroeder, MD, used an institutional database of patients who underwent PCDF surgery. Patients were included in the study if they had screws placed at every level or had a single level without screws bilaterally. Patients were excluded if the surgery was performed for tumor, trauma or infection, if they were younger than 18 years old, or if there was less than a year of follow-up data.

A total of 157 patients met inclusion criteria, with 86 undergoing a PCDF with instrumentation at all levels and 71 with a single uninstrumented level. The mean follow-up of the patients was 46.5 months.

The study, published in *Clinical Spine Surgery*, found near identical revision rates for the two groups—26% for those without a skipped level and 25% for those with a skipped level. Factors that significantly predicted the need for revision were: Proximal fixation level in the upper cervical region, having the fusion end at C7, prior surgery, and myelopathy. Skipping a single level, however, was not predictive of revision.

The researchers noted that "in contrast to other reports, the C2 sagittal vertical axis did not affect reoperation rates."

From the results of this study, it seems that a level of instrumentation can safely be skipped without negatively impacting the outcome of the PCDF surgery.

The researchers cautioned that it would be ideal to have longer-term follow-up of patients to reach firm conclusions regarding the study question.

Factors That Predict the Need for Revision Surgery

Logistic Regression to Determine Predictors of Revision				
	Univariable Regression Analysis		Bivariable Regression Analysis Also Controlling for an Uninstrumented Level	
Predictors	**Odds Ratios (95% CI)**	***P***	**Odds Ratios (95% CI)**	***P***
Age (y)	0.98 (0.95, 1.01)	0.253	0.98 (0.95, 1.02)	0.386
Follow-up	1.00 (0.99, 1.00)	0.167	1.00 (0.99, 1.00)	0.187
Ethnicity				
White	Reference	White-Black: 0.577	Reference	White-Black: 0.247
Black	0.58 (0.16, 1.67)	White-Hispanic: 1.000	0.31 (0.05, 1.16)	White-Hispanic: 1.000
Hispanic	NA	Black-Hispanic: 1.000	NA	Black-Hispanic: 1.000
Total number of levels	1.22 (0.95, 1.56)	0.117	1.26 (0.95, 1.68)	0.108
Start level				
C3-C7	Reference	0.019*	Reference	
C0-C2	2.26 (1.14, 4.44)		2.16 (1.00, 4.64)	0.0478*
End level				
C7	Reference	C7-T1: 0.033*	Reference	C7-T1: 0.039*
T1	0.46 (0.23, 0.93)	C7-T24: 0.761	0.43 (0.19, 0.95)	C7-T24: 0.291
T24	1.15 (0.44, 2.286)	T1-T24: 0.135	1.78 (0.60, 5.23)	T1-T24: 0.068
C7 screw				
(1) Lateral mass	Reference	(1) vs. (2): 0.720	Reference	(1) vs. (2): 0.939
(2) Pedicle	0.78 (0.40, 1.52)	(1) vs. (3): 0.992	1.16 (0.46, 2.91)	(1) vs. (3): 0.937
(3) Skipped level	0.90 (0.12, 4.58)	(2) vs. (3): 0.983	1.39 (0.16, 8.89)	(2) vs. (3): 0.977
Level skipped				
6	Reference		NA	NA
7	2.46 (0.30, 16.41)	0.351		
Prior surgery				
No prior	Reference		Reference	
Prior	21.01 (9.61, 49.01)	<0.001*	25.75 (10.65, 68.35)	<0.001*
Indication				
Radiculopathy	Reference		Reference	
Myelopathy	7.73 91.60, 55.29)	0.017*	17.01 (2.62, 332.14)	0.011*
BMI	0.98 (0.93, 1.03)	0.474	0.95 (0.89, 1.02)	0.154
Preoperative lordosis	0.98 (0.95, 1.00)	0.069	0.98 (0.95, 1.01)	0.131
PreoperativeC2-C7 SVA	1.00 (0.98, 1.03)	0.761	1.01 (0.98, 1.03)	0.497
Skipped	0.99 (0.49, 1.98)	0.972	NA	NA

Multiple univariable regressions were performed, followed by bivariable regression that controls for both if a level was uninstrumented and the variable.

*Demonstrates statistical significance $P < 0.005$.

BMI indicates body mass index; CI, confidence interval; NA, not available; SVA, sagittal vertical axis.

Source: Gregory Schroeder, MD

Non-Mobile Adjacent Level Cervical Spondylolisthesis Does Not Always Require Fusion in Patients Undergoing ACDF

Spondylolisthesis, slippage of one vertebra in relation to another, is commonly seen in the lumbar spine. However, degenerative cervical spondylolisthesis (DCS) is less well studied. Radiographically, these degenerative slips are accompanied by loss of disc height, facet arthrosis and sometimes instability. Clinically, they may be associated with neck pain and myelopathy.

Anterior cervical discectomy and fusion (ACDF) is a safe and reliable procedure to achieve neural decompression. However, spine surgeons are often faced with patients who present with compression of the neural elements at one level and an adjacent level spondylolisthesis without significant neural compression. Routine fusion of a questionably symptomatic adjacent level could lead to increased short and long-term complications associated with fusing multiple levels. However, not fusing a level with radiographic signs of instability and degeneration may lead to poorer clinical outcomes and higher reoperation rates.

Up to now there has been a paucity of data examining long-term outcomes of patients undergoing ACDF with or without a preoperative adjacent-level spondylolisthesis. Jefferson Health spine researchers led by Gregory Schroeder, MD, designed a study to elucidate any differences in healthcare-related quality of life outcomes (HRQoL) between the two groups before and after surgery.

The study, published in *Spine*, involved a retrospective review of consecutive patients who underwent ACDF. Adjacent level spondylolisthesis was defined on radiograph as anterior displacement (>1 mm) of the vertebra in relation to an adjacent "to be fused" level. Patients were categorized as either AS or NAS. Preoperative and one-year postoperative outcomes, including Short Form-12 Physical and Mental Component Scores, Neck Disability Index, Visual Analog Score for arm and neck pain, and rate of revision surgery, were compared between the two groups. Radiographic changes were also analyzed for patients with AS.

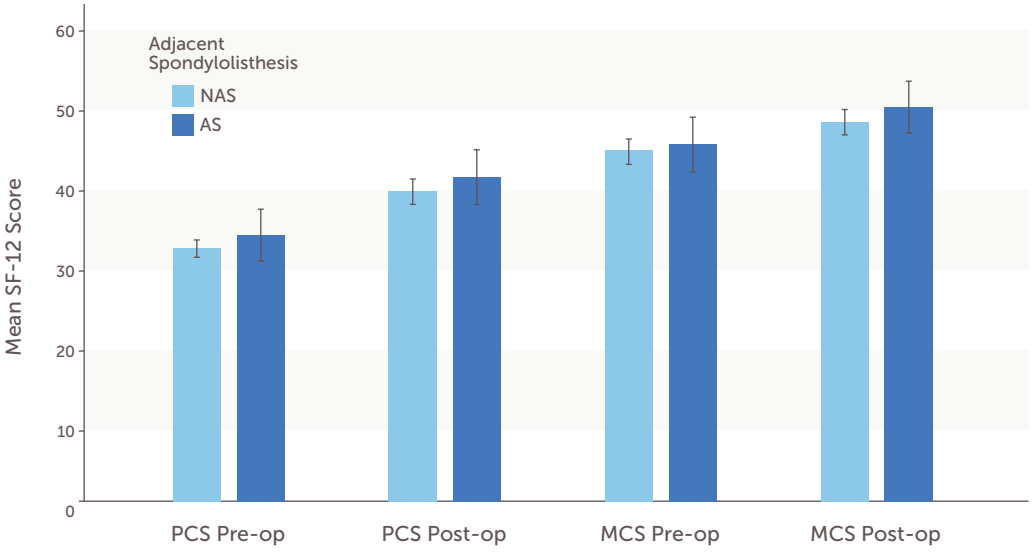
The study included 264 patients, including 53 with an adjacent level spondylolisthesis (AS) and 211 with no adjacent level spondylolisthesis (NAS). The analysis found that both groups improved significantly from baseline as measured by the patient outcomes and there were no significant differences in pain, disability or function between the two groups at an average follow-up of 19.8 months.

After accounting for confounding variables, the presence of an AS was not a predictor of any postoperative outcome, the study found. Also, revision rates did not differ between the two groups.

"The presence of an AS was not a predictor of poorer clinical outcomes," the Jefferson Health researchers reported. "This is the first study to investigate the effect of AS in patients undergoing ACDF and suggests that an adjacent-level spondylolisthesis does not need to be included in a fusion construct if it is not part of the primary symptom generating pathology."

The study is significant because it indicates that in select patients, a slightly smaller surgery with less risk complications and an easier recovery can be done without jeopardizing patient outcomes, Dr. Schroeder said.

Outcomes for Patients Undergoing ACDF



Change in HRQoL measures at pre- and post-operative visits. NAS indicates no adjacent spondylolisthesis; AS, adjacent spondylolisthesis; SF-12 physical component summary; MCS, SF-12 mental component summary; HRQoL, healthcare-related quality of life.

Source: Gregory Schroeder, MD

Risk Factors for Prolonged Opioid Use and Effects of Opioid Tolerance on Clinical Outcomes After Anterior Cervical Discectomy and Fusion Surgery

Prescription opioid use and abuse continues to be a compelling public health concern. Among medical subspecialities, orthopedic surgery has one of the highest rates of opioid prescription and chronic opioid use. Some recent reports estimated that 20% to 55% of spine patients undergoing elective spine surgery have used opioids preoperatively. Understanding opioid use and its subsequent effects should be of the utmost concern to orthopedic surgeons.

Jefferson Health spine researchers led by Christopher Kepler, MD, and Gregory Schroeder, MD, conducted a study to determine risk factors for prolonged opioid use and to investigate whether opioid-tolerance preoperatively affects patient-reported outcomes following anterior cervical discectomy and fusion (ACDF) surgery.

The study involved 92 patients who underwent ACDF for degenerative cervical pathologies. They were retrospectively identified and their opioid usage before surgery was investigated using a state-sponsored prescription drug monitoring registry. Opioid-naïve and opioid tolerant groups were defined using criteria most consistent with the Federal Drug Administration (FDA) definition.

Patient-reported outcomes were then collected from the participants, including the Short Form Health Survey (SF-12), Physical Component (PCS-12) and Mental Component (MSC-12), the Neck Disability Index (NDI) and the Visual Analog Scale Arm (VAS Arm) pain scores.

Results were published in *Spine*. The analysis found that opioid tolerance (pre-surgery) was a significant predictor for prolonged opioid use after ACDF. Duration of opioid usage preoperatively was also found to be a significant predictor for continued use after surgery. No other risk factors were found to be significant predictors of prolonged opioid use after surgery, the researchers said.

Both groups overall experienced improvement in patient-reported outcomes after surgery. Opioid-tolerant users demonstrated greater improvement in NDI and PCS-12 scores, when compared to the opioid-naïve group, a finding that was inconsistent with previous research. The Jefferson Health researchers said it was possible that patients with chronic opioid use may have an altered perception of pain, disability and physical health, which could possibly skew their self-reported outcomes toward the positive.

"The results of this study may provide a better understanding of potential risk factors for prolonged opioid use in surgical patients, and assist providers in stratification to set appropriate pain expectations for patients after ACDF," the researchers said, adding that additional studies with larger sample sizes could help further inform the issue.

Predictors of Prolonged Opioid Use After ACDF

Patient-reported Outcomes in Opioid-naive and Opioid-tolerant Users						
	Naive Opioid User (n=54)	*P**	Opioid-tolerant User (n=38)	*P**	*P*†	Multiple Linear Regression (Beta Coeficient [95% CI], *P*‡)
NDI						
Pre	40.2 (34.6, 47.2)	0.005**	42.3 (35.4, 49.1)	<0.001**	0.63	−13.7 (−21.8, −5.6), 0.002**
Post	22.0 (8.00, 46.0)		16.0 (5.0, 36.0)	0.39		
Delta	−13.0 (−18.0)		−19.4 (−26.3, −12.6)		0.12	
RR	0.23 (0.00, 0.68)		0.59 (0.03, 0.76)		0.25	
%MCID	38.8%		60.5%		1.00	
PCS-12						
Pre	33.0 (28.4, 42.0)	0.41	31.8 (25.3, 37.8)	<0.001**	0.12	6.99 (2.59, 11.4), 0.003**
Post	41.7 (28.6, 51.7)		41.9 (32.1, 51.5)		0.78	
Delta	4.94 (2.47, 7.40)		9.00 (5.07, 12.9)		0.08	
RR	0.11 (0.00, 0.26)		0.08 (0.00, 0.21)		0.13	
%MCID	31.5%		47.4%		0.18	
MCS-12						
Pre	42.4 (33.1, 56.3)	0.45	51.9 (43.6, 59.2)	0.53	0.04**	1.47 (−5.65, 8.58), 0.69
Post	49.2 (37.2, 57.4)		54.2 (48.5, 59.7)		0.03**	
Delta	0.70 (−6.09, 10.3)		1.02 (−2.33, 8.12)		0.90	
RR	0.02 (−0.10, 0.19)		0.00 (−0.05, 0.14)		0.96	
%MCID	15.6%		24.6%		0.10	
VAS Neck						
Pre	6.01 (3.00, 7.74)	<0.001**	6.10 (3.02, 8.20)	<0.001**	0.63	−1.08 (−2.65, 0.50), 0.18
Post	2.49 (0.65, 5.02)		3.13 (0.82, 5.33)		0.16	
Delta	−2.25 (−4.67, 0.00)		−2.16 (−4.90, 0.00)		0.67	
RR	0.40 (0.00, 0.81)		0.37 (0.00, 0.75)		0.96	
%MCID	40.7%		34.2%		0.68	
VAS Arm						
Pre	6.19 (4.08, 8.35)	<0.001**	6.00 (4.14, 8.16)	<0.001**	0.62	−0.55 (−2.15, 1.05), 0.50
Post	2.17 (0.00, 5.00)		1.70 (0.00, 4.79)		0.87	
Delta	−3.13 (−4.03, −2.24)		−3.03 (−4.27, 1.79)		0.89	
RR	0.68 (0.30, 1.00)		0.63 (0.00, 0.91)		0.22	
%MCID	50.0%		47.4%		0.97	

* Wilcoxon rank test to compare preoperative to postoperative scores.

† Mann–Whitney U test Pearson χ^2 to compare means or proportions between groups.

‡ Multiple linear regression analysis using opioid-naive groups as baseline for comparison controlling for age, sex, BMI, smoking status (never, current, former) follow-up (months), preoperative diagnosis (radiculopathy, myelopathy, radiculomyelopathy), workers compensation status, and preoperative mental health diagnoses (none, depression, anxiety, or both).

** Indicates statistical significance (P<0.05)

% MCID indicates perentage of patients reaching the minimum clinically important difference; MCS-12, Mental Component Score of the Short Form-12 Health Survey; NDI, Neck Disability index; PCS-12, Physical Component Score of the Short Form-12 Health Survey; RR, Recovery ratios; VAS Arm, Visual Analogue Scale Arm pain; VAS Neck, Visual Analogue Scale Neck pain.

Source: Christopher Kepler, MD and Gregory Schroeder, MD

Trends in Leadership at Spine Surgery Fellowships

Not only do spine fellowship leaders play a critical role in the development of skills in their trainees, but they also help foster an environment that encourages research and the future pursuit of leadership roles.

While there have been studies examining leadership characteristics in various fields of medicine, no study has focused on leadership trends among orthopedic surgery training programs.

Jefferson Health researchers led by Chester J. Donnally, III, MD, decided to examine the demographics and academic training backgrounds of current spine fellowship leaders. They used the 2018 and 2019 North American Spine Surgery Fellowship Directories to identify 103 fellowship leaders, including 67 fellowship directors, 19 co-directors and 16 individuals with a synonymous leadership title.

The analysis found that of the 103 fellowship leaders, 99 were men and just four were women. The average age was 52.9. The leaders tended to have strong research backgrounds, rating high on the Scopus H-Index, which is a measure of the productivity and impact of the published work of a researcher.

The analysis, published in *Spine*, also looked at the specialty training of the spine fellowship leaders: 89 of the 103 were trained in orthopedic surgery, 13 in neurosurgery and one in a combined orthopedic surgery and neurosurgery training.

The residency programs that most often produced future spine fellowship leaders were Case Western Reserve University, University of California, San Diego, Johns Hopkins University and Hospital for Special Surgery, New York. The fellowship programs most likely to produce future fellowship leaders were Case Western Reserve University, Washington University in St. Louis, and Rothman Orthopaedic Institute at Thomas Jefferson University.

The Jefferson researchers said it is not clear why fellowship leaders tend to come from certain residency and fellowship programs, but they said "perhaps these programs are inclined to offer training positions to individuals with a desire to seek academic leadership roles." These programs might also have curriculums that establish skills needed to attain leadership roles and have faculty who mentor their trainees toward academic and educational leadership.

The researchers said the low representation of women in spine fellowship leadership roles, "is likely a result of the fact that historically orthopedic surgery, and particularly spine surgery, has been a male-dominated field." While residency programs are now graduating more women, it may take years for women to be better represented in upper leadership ranks.

The researchers said their analysis of basic demographic and training information for spine fellowship leaders could not quantify more subjective factors that often influence a person's career path – from professional mentors and a desire to teach new surgeons, to personal factors that come into play when making career choices.

More research is needed to better understand what factors influence whether a spine surgeon will ascend to a leadership role.

Characteristics of Spine Surgery Leadership

The Roles, Demographics, and Training of Spine Fellowship Leaders	
Overall Leadership:	**N (%)**
Total fellowship program leaders	103 (100.00%)
Fellowship directors	67 (65..04%)
Co-fellowship directors	19 (18.44%)
Other title*	17 (16.50%)
Demographics and Training:	**N (%)**
Male	99 (96.12%)
Female	4 (3.88%)
Mean age	52.85 years
Mean FL Scopus H-index	23.75
Orthopedic surgery	89 (86.41%)
Neurosurgery	13 (12.62%)
Orthopepedic surgery and Neurosurgery	1 (0.97%)

*Note: "Other titles" included the following: Chief of Spine Service, Director of Spine Institute, Medical Director, Medical Founder.

FL indicates fellowship leader.

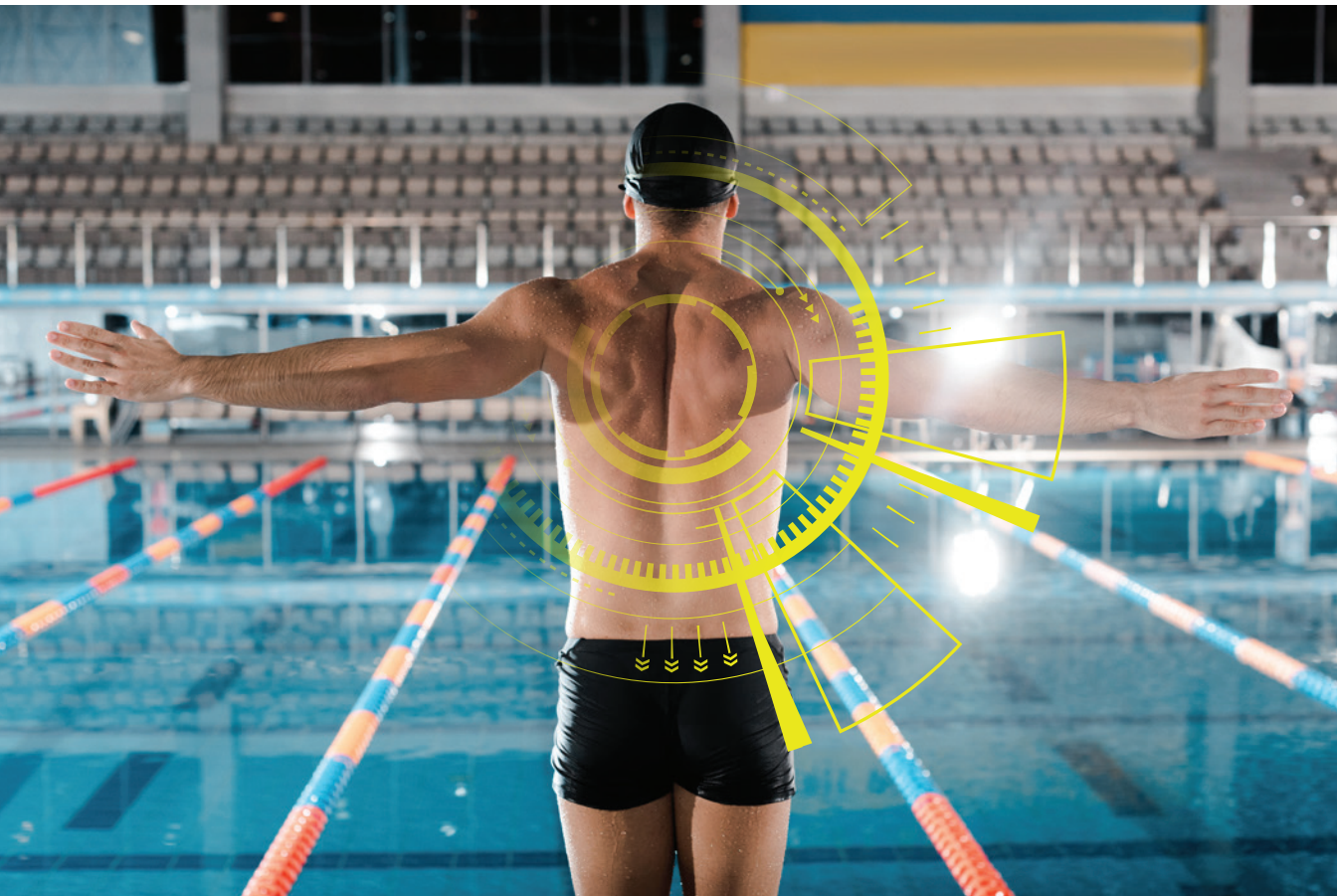
Source: Chester J. Donnally, III, MD

SPINE SURGICAL VOLUME (JEFFERSON HEALTH)
November 2019 to November 2020

Abington Hospital	523
Abington – Lansdale Hospital	94
Jefferson Washington Township Hospital	196
Jefferson Methodist Hospital	145
New Britain Surgical Center	60
Physician Care Surgical Hospital	203
Rothman Orthopaedic Specialty Hospital	496
Thomas Jefferson University Hospital	1,307
GRAND TOTAL	**3,024**

Surgical volumes include all procedures performed at Jefferson Health hospitals and ambulatory surgery centers.

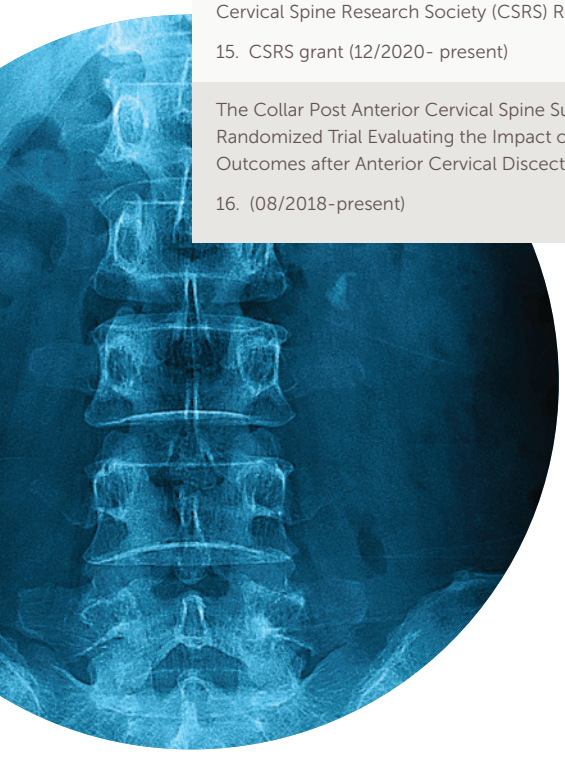
Source: Jefferson internal data



Funded Clinical Trials

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. 1. Bioventus, LLC (01/2016–present)	Barrett Woods, MD; Kristen Radcliff, MD
Thoracolumbar Burst Fractures (AOspine A3, A4) in Neurologically Intact Patients: An Observational Multi-Center Cohort Study Comparing Surgical Versus Non-Surgical Treatment. 2. AO Foundation (10/2016–current)	Gregory Schroeder, MD; 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. 3. Innovative Surgical Designs (08/2017–current)	Mark Kurd, MD
A Multi-Center, Prospective, Comparative Study of Anterior Versus Posterior Surgical Treatment for Lumbar Isthmic Spondylolisthesis. 4. AO Foundation (11/2016–current)	Alexander R. Vaccaro, MD, PhD, MBA; Chris Kepler, MD, MBA; Gregory Schroeder, MD
A Multi-Center, Open-Label, Prospective Study of SpinalStim (MOP-SS) as Adjunctive Care Following Lumbar Fusion Surgery. 5. Orthofix (06/2017–current)	Kristen Radcliff, MD; Barrett Woods, MD
Clinical Study Protocol for the Investigation of the Simplify Cervical Artificial Disc Two Level. 6. Simplify Medical (09/2017–current)	Kris Radcliff, MD; Barrett Woods, MD
Prospective, Non-Interventional, Long-Term Follow-Up Study for Subjects who Received Standard of Care, CLARIX™ 100, or CLARIX™ CORD 1K during Discectomy. 7. TissueTech (07/2018–current).	Greg Anderson, 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. 8. Invibio, LTD (08/2018–current)	Mark Kurd, MD
An Assessment of P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion with Instrumentation. 9. 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. 10. 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). 11. Orthofix (03/2018–current)	Mark Kurd, MD; Barrett Woods, MD; Kris Radcliff, MD
A Post-Market, Prospective, Multi-Center, Nonrandomized Study to Assess Posterolateral Lumbar Fusions Using Fibergraft BG Matrix. 12. Prosidyan, Inc. (07/2019–current).	Gregory Schroeder, MD; Guy Lee, MD; Chris Kepler, MD, MBA
Clinical Evaluation of Fortilink TETRAfuse Interbody Fusion Device in Subjects with Degenerative Disc Disease (FORTE). 13. RTI Surgical, Inc. (06/2019–current).	Chris Kepler, MD, MBA; David Kaye, 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. 14. Camber Spine Technologies (04/2019–current)	David Kaye, MD
Cervical Spine Research Society (CSRS) Registry. 15. CSRS grant (12/2020- present)	Gregory Schroeder, MD
The Collar Post Anterior Cervical Spine Surgery (C-PASS) Study: a Multi-Center Randomized Trial Evaluating the Impact of Post-Operative Bracing on Clinical Outcomes after Anterior Cervical Discectomy and Fusion 16. (08/2018-present)	Alexander Vaccaro, MD, PhD, MBA

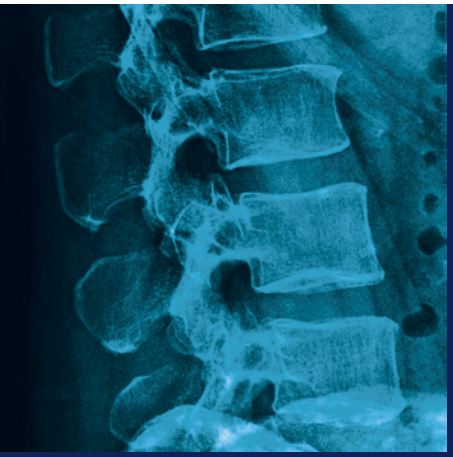


Jefferson Health

Jefferson Health
Department of Orthopaedic Surgery
Philadelphia, PA 19107

Patient Appointments: **1-800-JEFF-NOW**
Patient Transfers: **1-800-JEFF-121**
Physician Referrals: **215-503-8888**

JeffersonHealth.org/Ortho



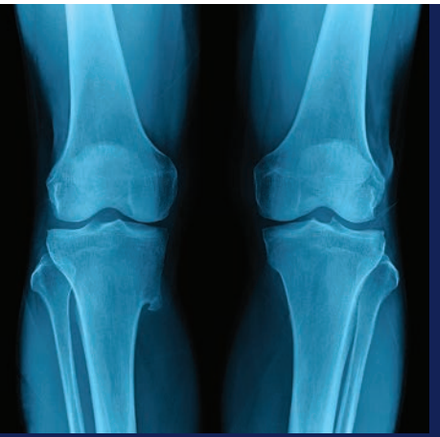
CS 21-0873

Jefferson Health

Jefferson Health
Department of Orthopaedic Surgery
Philadelphia, PA 19107

Patient Appointments: **1-800-JEFF-NOW**
Patient Transfers: **1-800-JEFF-121**
Physician Referrals: **215-503-8888**

JeffersonHealth.org/Ortho



CS 21-0131

ORTHOPAEDIC & OUTCOMES RESEARCH

Hip & Knee

VOLUME 1

Jefferson Health

Furthering the Treatment of Orthopaedic Disease

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 infections

Jefferson Health is a leader in joint replacement, performing 7,979 hip, knee and partial arthroplasties in 2019. *U.S. News & World Report* once again named **Jefferson Health's Department of Orthopaedic Surgery** as the best orthopaedic program in the Philadelphia region.

The program stands out because of its commitment to outstanding patient care and innovative clinical and laboratory research that furthers the understanding and treatment of orthopaedic disease.

Our hip and knee specialists publish about 100 peer-reviewed articles each year. They explore critical topics such as prevention of periprosthetic joint infection and thromboembolism following joint replacement and organization of surgical care – before, during and after surgery – to improve patient outcomes.

Because Jefferson Health's team of hip and knee surgeons performs so many joint arthroplasties each year, our large institutional database provides a wealth of information that can be mined to identify ways to enhance patient care.

Using our institutional database, our research team developed an algorithm that was then turned into a mobile app. The app can be used by doctors preoperatively to help predict a patient's risk of developing periprosthetic joint infection (PJI) postoperatively. By doing that they can place patients on prophylactic antibiotics if deemed necessary. Another app developed at Jefferson Health can help predict whether irrigation and debridement surgery will likely be a success or failure in a patient who has developed PJI. The end goal of the risk prediction tools is to ensure that patients get the optimal care for their individual needs.

The healthcare system is changing rapidly for both patients and providers, but Jefferson Health joint specialists remain steadily focused on delivering research-informed care that is made even better by the added knowledge that flows from our highly experienced surgical team.

What follows is an overview of some of the important joint research published recently by Jefferson Health specialists.

2020 Frank Stinchfield Award: Identifying Who Will Fail Following Irrigation and Debridement for Prosthetic Joint Infection

Prosthetic joint infection (PJI) is one of the most pressing problems in orthopaedic surgery, resulting in additional surgeries, longer and more costly hospital stays and poor outcomes for patients.

Jefferson Health joint surgeons have a robust research agenda that focuses on identifying patients at high risk for PJI and developing best practices for preventing and treating infections.

An award-winning study published earlier this year examined the use of irrigation and debridement (I&D) surgery, which is usually reserved for patients presenting with acute PJI. While the procedure is helpful for some patients, failure rates for the intervention are reported to be between 30% and 80%. Having an objective assessment tool to predict whether a given PJI patient is likely to benefit from I&D would be useful for treatment decision-making.

A team of Jefferson Health researchers led by Javad Parvizi, MD, utilized machine learning methods to develop an algorithm that serves as an easy-to-use tool for predicting I&D success or failure. They explained how they developed the algorithm for the tool in a study published in *The Bone & Joint Journal*.

The study drew on data collected for an international, multicenter retrospective study of 1,174 revision total hip (THA) and total knee (TKA) arthroplasties undergoing I&D for PJI between January 2005 and December 2017. Of that total, 405 patients (34.4%) failed treatment with I&D.

The analysis identified 52 variables, including demographics, comorbidities and clinical and laboratory findings, that could influence I&D outcomes. The researchers found that 10 of the variables were most associated with I&D failure: In order of importance, the variables were serum CRP levels, positive blood cultures, indication for index arthroplasty other than osteoarthritis, not exchanging the modular components, use of immunosuppressive medication, late acute (haematogenous) infections, methicillin-resistant *Staphylococcus aureus* infection, overlying skin infection, polymicrobial infection and older age.

The resulting algorithm was tested using cross-validation and was found to be an accurate predictor of I&D failure when the prediction was compared to what happened to the patients. For instance, in 63 patients with a 10% probability for failure according to the predictor tool, the actual failure rate was 11.1%; in patients with a failure probability of 10% to 20%, the actual failure rate was 19.4%; and when probability failure was 20% to 30%, the actual failure rate was 25%. Of 55 patients with a failure probability of above 60%, 70.9% failed I&D.

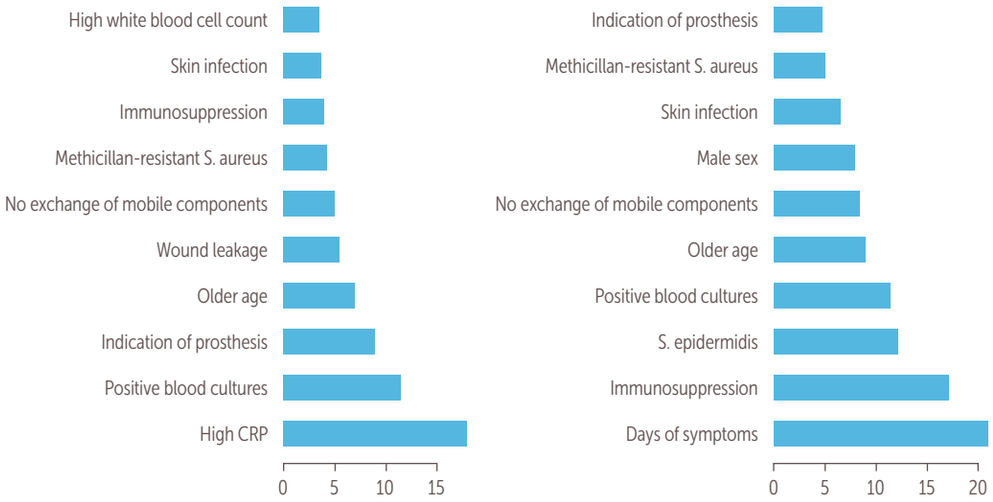
The Jefferson Health research team used the algorithm to develop an easy-to-use app-based tool. The app is currently being incorporated into the ICM (International Consensus Meeting) Philly app and website, that includes several other PJI-related calculators that are being used by physicians at Jefferson and worldwide.

"We believe this tool can be used in clinical practice to improve decision-making and patient counseling," the researchers reported in their paper, though they said the tool "needs to be validated in an external cohort of patients to confirm its accuracy."

The Hip Society annually gives out three scientific awards for papers submitted from training programs. The Frank Stinchfield Award is given to a resident or fellow – in this case Noam Shohat, MD, of Jefferson Health – who submitted an outstanding contribution concerning hip problems.

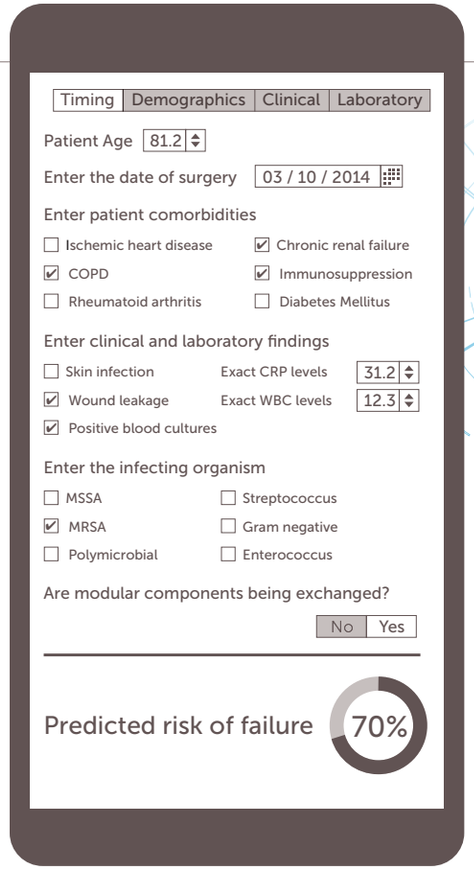
Dr. Shohat said that unsuccessful I&D places a burden on the patient and increases healthcare costs. It has also been suggested that an unsuccessful I&D may compromise the outcome of subsequent 2-stage exchange arthroplasty.

Factors Influencing I&D Outcomes



Random forest analysis stratified based on acute (postoperative; left) and acute haematogenous (right) infections. S. aureus, Staphylococcus aureus; S. epidermidis, Staphylococcus epidermidis .

Source: Javad Parvizi, MD



Source: Javad Parvizi, MD

Risk Factors for Unplanned Admission to the Intensive Care Unit After Elective Total Joint Arthroplasty

Despite improved surgical and anesthesia technology, as well as advances in perioperative protocols, a large number of patients undergoing total joint arthroplasty (TJA) are at risk of serious medical complications that require intensive care unit (ICU) admission. With the recent move toward performing TJA in ambulatory surgical centers and on an outpatient basis, it is important to recognize patients that may require intensive care in the postoperative period.

Jefferson Health researchers led by Javad Parvizi, MD, conducted a study to identify risk factors for ICU admission following elective total hip (THA) and total knee (TKA) arthroplasty.

The study utilized Jefferson's institutional electronic database to identify THA and TKA procedures done between 2005 and 2017. There were 12,342 THA patients, with 132 of them having an unplanned ICU admission. There were 10,976 TKA patients, with 114 needing ICU.

Demographic, preoperative and surgical variables were collected and compared between the two groups.

The findings, published in *The Journal of Arthroplasty,* included:

- For THA, older age, bilateral procedure, revision surgery, increased Charlson comorbidity index, general anesthesia, increased estimated blood loss, decreased preoperative hemoglobin, and increased preoperative glucose level were independently associated factors for increased risk of ICU admission.
- For TKA, increased age, increased body mass index, bilateral procedure, revision surgery, increased Charlson comorbidity index, increased estimated blood loss, general anesthesia and increased preoperative glucose were independently associated with ICU admission.

The researchers noted that all the procedures included in the analysis were done at a high-volume center with surgeons specializing in joint reconstruction. They cautioned that the findings may not be generalizable to all facilities and practices.

"Identifying risk factors for admission to the ICU following elective TJA may help surgeons risk stratify patients and allow for higher risk arthroplasty surgeries to be performed in the appropriate setting," where an ICU is available, the researchers said.

Unplanned ICU Admission: Logistic Regression Analysis for Total Hip Arthroplasty

Coefficients	Estimate	*P* Value	Odds Ratio	95% CI[a]
Age	0.06	<.001	1.06	1.04, 1.08
BMI	-0.01	.491	0.99	0.95, 1.02
Gender	-0.03	.876	0.97	0.63, 1.47
Type of index surgery				
Primary	Ref.			
Revision	0.69	.006	1.99	1.21, 3.25
Simultaneous joint surgery				
Unilateral	Ref.			
Bilateral	2.58	<.001	13.16	4.87, 31.42
CCI	0.58	<.001	1.79	1.64, 1.96
Anesthesia type				
General	Ref.			
Spinal	0.48	.040	0.62	0.39, 0.98
Preop hemoglobin	0.10	.003	0.90	0.84, 0.97
Preop glucose	0.01	<.001	1.0057	1.0025, 1.0088
EBL	0.001	<.001	1.0014	1.0011, 1.0018
Surgery duration	0.002	.217	1.002	0.9988, 1.0053

CI, confidence interval; BMI, body mass index; CCI, Charlson comorbidity index; EBL, estimated blood loss; preop, preoperative; Ref., reference.

[a] 95% CI values are given as the lower and upper bound.

Source: Javad Parvizi, MD

Unplanned ICU Admission: Logistic Regression Analysis for Total Knee Arthroplasty

Coefficients	Estimate	*P* Value	Odds Ratio	95% CI[a]
Age	0.06	<.001	1.06	1.04, 1.09
BMI	0.05	.001	1.06	1.02, 1.09
Gender	0.21	.364	1.23	0.78, 1.92
Type of index surgery				
Primary	Ref.			
Revision	0.70	.012	2.02	1.16, 3.48
Simultaneous joint surgery				
Unilateral	Ref.			
Bilateral	2.38	<.001	10.82	5.78, 19.88
CCI	0.68	<.001	1.97	1.78, 2.18
Anesthesia type				
General	Ref.			
Spinal	-0.86	.001	0.42	0.26, 0.69
Preop hemoglobin	-0.01	.819	0.99	0.90, 1.11
Preop glucose	0.01	<.001	1.01	1.008, 1.014
EBL	0.002	<.001	1.00216	1.00129, 1.003
Surgery duration	-0.005	.065	0.99	0.9886, 1.0002

CI, confidence interval; BMI, body mass index; CCI, Charlson comorbidity index; EBL, estimated blood loss; preop, preoperative; Ref., reference.

[a] 95% CI values are given as the lower and upper bound.

Source: Javad Parvizi, MD

Overlapping Surgery Increases Operating Room Efficiency Without Adversely Affecting Outcomes in Total Hip and Knee Arthroplasty

Although the practice of overlapping surgery has been commonplace for many years, recent scrutiny has led to investigations into its safety and utility. Several recent studies have demonstrated that overlapping surgeries in total hip (THA) and knee (TKA) arthroplasty do not increase the rates of complications, but whether this practice is cost-effective has not been addressed in the literature.

Jefferson Health researchers led by P. Maxwell Courtney, MD, conducted a study to determine the effect of overlapping surgery on procedural costs and surgical productivity during THA and TKA.

The researchers identified all patients undergoing primary THA or TKA from 2015 to 2018 by 18 surgeons at two orthopaedic specialty hospitals affiliated with Jefferson Health. Procedural and personnel costs were calculated for each case using a time-driven activity-based costing algorithm.

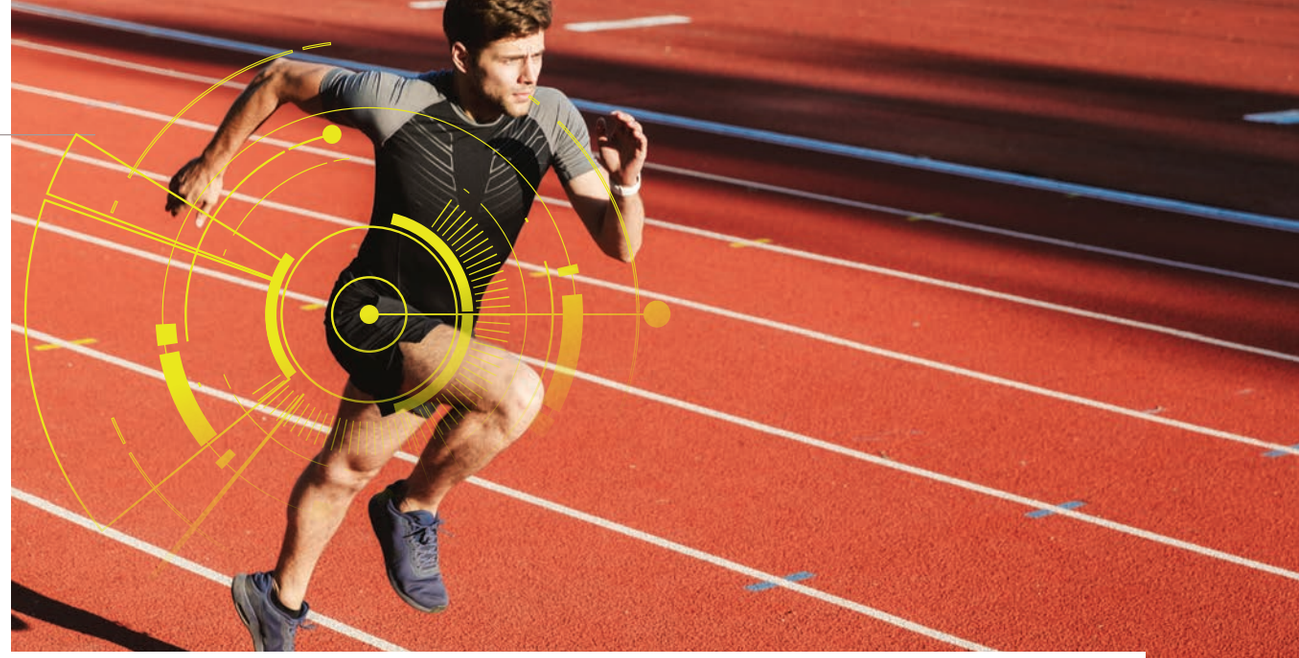
Overlap of surgical time by at least 30 minutes was used to define an overlapping procedure. The researchers compared costs and outcomes between overlapping and non-overlapping procedures, standardizing all costs to eight-hour time blocks.

Of the 4,786 consecutive procedures, 968 (20.2%) overlapped by at least 30 minutes. Although overlapping rooms increased mean operating time by 8.3 minutes and operating room personnel costs by $80 per case, overlapping surgeons could perform significantly more procedures per eight hours (7.6 versus 6.4), increasing the total eight-hour profit margin by $1,215 per procedure. There was no difference in 90-day readmission rate, length of stay, or rate of discharge home between the two groups.

"Overlapping noncritical portions of procedures in primary THA and TKA appear to be both a safe practice and an effective strategy," the researchers said in a report in *The Journal of Arthroplasty*. They noted, however, "we believe it is paramount to remain transparent about this practice with patients." They said many institutions now include information on the possibility of overlapping surgeries and working with residents and fellows on patient consent forms.

"We believe the results of this study can aid surgeons in delivering appropriate informed consent about the utility of overlapping surgery, while providing administrators and hospital staff with the information to promote overlapping surgery for its economic benefits," the researchers said. They noted that further study is needed to determine the applicability of the findings to all hospital systems.

As a teaching institution, Jefferson has always had a responsibility to train the next generation of surgeons. "Overlapping minor portions of a case with residents and fellows under the direct supervision of the attending has been shown in this and other studies to be both safe for patients and cost-effective for institutions to provide care for more patients," Dr. Courtney said.



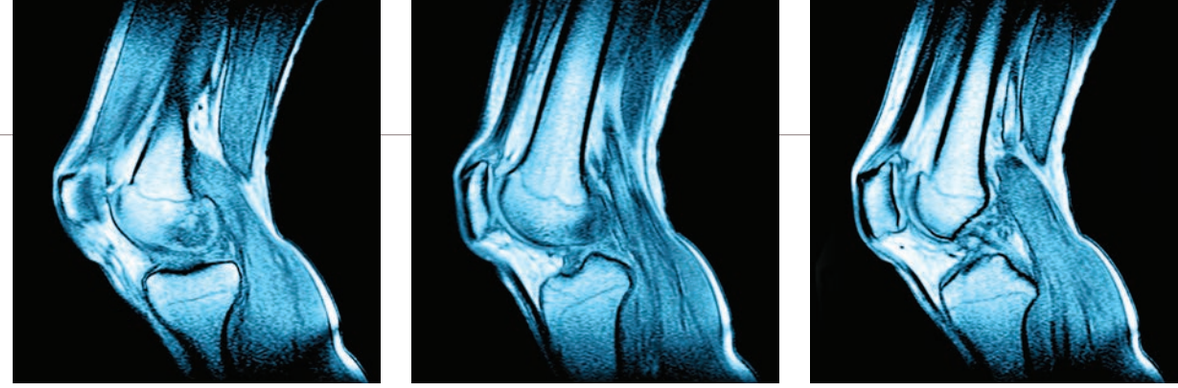
Comparison of Patient Characteristics.

Variable	Non-overlapping Case (N = 3818)		Overlapping Case (N = 968)		*P* Value
Patient age	63.10	9.91	61.49	9.96	.2791
BMI	29.96	5.06	30.02	5.01	.2886
CCI	0.30	0.61	0.28	0.61	.2652
Gender					.0739
Male	1700	44.5	462	47.7	
Female	2118	55.5	506	52.3	
Joint					<.0001
TKA	1691	44.3	331	34.2	
THA	2127	55.7	637	65.8	
Congestive heart failure	16	0.4	2	0.2	.3112
Chronic pulmonary disease	329	9.2	93	9.9	.5025
Cerebrovascular disease	29	0.8	4	0.4	.2833
Dementia	10	1.3	2	0.2	1.0000
Diabetes mellitus	279	7.8	55	5.9	.0437
Cancer	60	1.7	13	1.4	.5285
Myocardial infarction	42	1.2	13	1.4	.5990
Chronic liver disease	76	2.1	16	1.7	.4187
Peripheral vascular disease	33	0.9	8	0.9	.8411
Chronic kidney disease	38	1.1	6	0.6	.2408
Connective tissue disease	121	3.4	33	3.5	.8393

BMI, body mass index; CCI, Charlson comorbidity index; TKA, total knee arthroplasty; THA, total hip arthroplasty.

Bold indicates P < .05.

Source: Matthew Austin, MD and P. Max Courtney, MD



General Assembly, Prevention, Operating Room – Surgical Technique: Proceedings of International Consensus on Orthopedic Infections

Jefferson Health's Robert E. Booth, Jr., MD, was part of a team of invited delegates who examined current research papers on preventing knee infections at the International Consensus Meeting (ICM) on Musculoskeletal Infection held in Philadelphia. Based on the research, delegates presented questions on topics of interest in the cause and treatment of knee infections. Delegates voted in favor of (or against) the findings of the research that best answered these questions. The consensus answers to the questions were submitted to various medical journals for publication as well as for publication in a consolidated book form. Here are their recommendations, published in The Journal of Arthroplasty:

Q. Should the knife blade be changed after skin incision for deep dissection?

A. Yes. There are studies demonstrating that bacteria from the superficial planes of the skin can contaminate the scalpel and potentially transfer this into deeper tissue.

Q. Does operative time affect the risks of surgical site infections/periprosthetic joint infections (SSI/PJIs)?

A. Yes. Prolonged operative time may be a result of a considerable and inescapable level of complexity of the surgery. Coordinated efforts to reduce the operative times without technically compromising the procedure can provide additional benefits for infection prevention.

Q. Do antibiotic coatings on implants reduce the rates of SSI/PJIs?

A. The use of antibacterial coatings on implants has been shown to reduce SSI and/or PJIs based on in vitro and preclinical animal model studies. The use of antibiotic-coated implants in a small series of patients appears to be encouraging. Larger-scale studies to prove the value of these technologies are needed.

Q. Does the size of an implant (volume) used during orthopaedic procedures influence the incidence of subsequent SSI/PJIs?

A. While a smaller implant may theoretically represent a smaller substrate for colonizing bacteria, there have been no conclusive studies linking implant size and the incidence of subsequent PJIs.

Q. Does the use of C-arm intraoperatively increase the risk of subsequent SSI/PJI in patients undergoing orthopaedic procedures?

A. There are no studies that establish a link. However, based on available studies, it appears that the "sterile" cover of C-arm is often contaminated during the surgery. All efforts should be made to prevent the cover or any other part of the C-arm from coming into contact with the surgical field.

Q. Does the use of computer navigation, patient-specific instrumentation, and robot-assisted surgery influence the incidence of SSI/PJI after orthopaedic procedures?

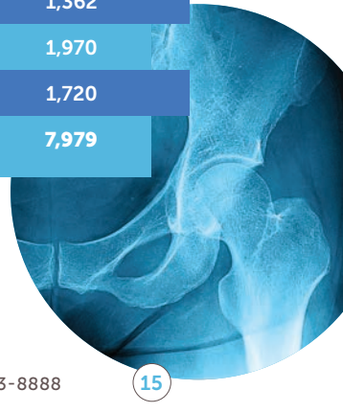
A. The use of these technologies has not been shown to reduce the risk of SSI/PJI. However, an increase in operative time that may occur because of using the technologies may increase SSI/PJI risk.

JOINT REPLACEMENT SURGICAL VOLUME (JEFFERSON HEALTH)
June 2019 to July 2020

Abington Hospital	865
Abington – Lansdale Hospital	482
Jefferson Bucks Hospital	443
Jefferson Torresdale Hospital	173
Jefferson Cherry Hill Hospital	629
Jefferson Washington Township Hospital	287
Jefferson Health Navy Yard	36
New Britain Surgical Center	12
Physician Care Surgical Hospital	1,362
Rothman Orthopaedic Specialty Hospital	1,970
Thomas Jefferson University Hospital	1,720
TOTAL	**7,979**

Surgical volumes include all procedures performed at Jefferson Health hospitals and ambulatory surgery centers.

Source: Jefferson internal data



Funded Clinical Trials

1. 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)
2. Trabecular Metal Femoral Hip Stem Used within the Zimmer Biomet Hip Registry. Zimmer Biomet (02/09/2012–ongoing) (Carl Deirmengian, MD)
3. Post-Market Study of the Stryker Orthopaedics Triathlon TS Total Knee System. Stryker (04/01/2012—ongoing) (Alvin C. Ong, MD)
4. Persona Outcomes Knee Study (POLAR). Zimmer Biomet (03/01/2013–ongoing) (Matthew S. Austin, MD)
5. Retrieval of Discarded Surgical Tissue. National Disease Registry Institute (01/12/2004–ongoing) (James J. Purtill, MD; William J. Hozack, MD;)
6. Triathlon Tritanium Knee Outcomes Study. Stryker (04/2014–present) (Alvin Ong, MD; Zachary Post, MD)
7. Post Market Study of the Stryker Orthopaedics Triathlon PKR Knee System. Stryker (11/2013–present) (Alvin Ong, MD, Zachary Post, MD)
8. 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)
9. Clinical Outcomes Reporting Study. Stryker Orthopaedics (10/2013–current) (Javad Parvizi, MD; William Hozack, MD; Matthew Austin, MD; Gregory Diermengian, MD; James J. Purtill, MD; Alvin C. Ong, MD, MD; Zachary Post, MD; Eric Smith, MD; Robert Good, MD; Eric Levicoff, MD; Peter Sharkey, MD)
10. 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; Gregory Diermengian, MD; James J. Purtill, MD; William J. Hozack, MD)
11. Post-Market Study of Robotic-Arm Assisted Total Knee Arthroplasty. Stryker, Corp. (07/2016–current) (William J. Hozack, MD)
12. A Retrospective Study of the Navio Robotic-Assisted Surgical System. Smith and Nephew (07/2017–current) (Jess Lonner, MD)
13. Intermediate Clinical and Radiographic Outcomes of Isolated Patellofemoral Arthroplasty and Modular Bicompartmental Knee Arthroplasty. Zimmer Biomet (09/2017–current) (Jess Lonner, MD)
14. 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)
15. A Prospective, Post-Market, Multi-Center Evaluation of the Clinical Outcomes of the Trident II Acetabular Shell. Stryker (09/2017–current) (Alvin C. Ong, MD)
16. Prospective Post-Approval Clinical Follow-Up Study of the Commercially Available U2 Knee System. United Orthopedic Corporation (7/2018–current). (Arjun Saxena, MD)
17. 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)
18. 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)
19. Multi-Center Clinical Evaluation of the ATTUNE Cementless Rotating Platform Total Knee Arthroplasty. DePuy Synthes (07/2019–current). (Zachary Post, MD)
20. Multi-Center Clinical Evaluation of the ATTUNE Revision System in Revision Total Knee Arthroplasty. DePuy Synthes (05/2019–current). (Zachary Post, MD)
21. Multi-Center Clinical Evaluation of the ATTUNE Revision System in Complex Primary Total Knee Arthroplasty. DePuy Synthes (05/2019–current). (Zachary Post, MD)
22. Post-Market Study of Robotic-Assisted Total Knee Arthroplasty Utilizing the Navio Surgical System. Smith and Nephew, Inc. (03/2019–current). (Alvin Ong, MD)

23. 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)

24. Perioperative Antibiotic prophylaxis in Patients Undergoing Elective Total Knee Arthroplasty: A prospective, randomized, open-label, controlled multi-center trial (Javad Parvizi, MD; Scott Brown, MD; David Nazarian, MD)

25. The Effect of Oral Nutrition Optimization on Complications following Total Joint Arthroplasty (Javad Parvizi, MD; Matthew Austin, MD)

26. A study investigating the normal microbiome of the knee and hip. (8/2020-current) (Javad Parvizi, MD)

27. ROSA Total Knee Post Market Study. ZimmerBiomet (09/2020-current) (Ari Seidenstein, MD; Harlane Levine, MD)

28. Dual Mobility vs Single-bearing Components in THA at High Risk for Prosthetic Dislocation. (4/2019-current) (Paul Maxwell Courtney, MD; Chad Krueger, MD)

29. Dual Mobility vs Single bearing components in revision THA. (9/2018-current) (Paul Maxwell Courtney, MD; Chad Krueger, MD)

30. A Prospective Multicenter Longitudinal Cohort Study of the MyMobility Platform. ZimmerBiomet (7/2019-current) (Gregg Klein, MD; Jess Lonner, MD)

31. An Open-Label Study to Evaluate Tissue Distribution, Plasma Pharmacokinetics, Safety and Tolerability after a Single Intravenous Dose of TNP-2092 in Adult Participants Undergoing Primary Total Hip or Knee Arthroplasty. TenNor Therapeutics, Ltd. (7/2020-current) (Javad Parvizi, MD)

Jefferson Health

Jefferson Health
Department of Orthopaedic Surgery
Philadelphia, PA 19107

Patient Appointments: **1-800-JEFF-NOW**
Patient Transfers: **1-800-JEFF-121**
Physician Referrals: **215-503-8888**

JeffersonHealth.org/Ortho

CS 21-0555

ORTHOPAEDIC & OUTCOMES RESEARCH

Hand & Wrist

VOLUME 2

Jefferson Health

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 traumatic injuries

Dear Colleagues,

I am happy to share this Jefferson Health update on some exciting clinical care and research developments in the area of hand and wrist care.

The past year has been challenging for all of us. But we remain committed to advancing research that helps improve patient outcomes and contributes to a better understanding of a long list of hand and wrist conditions that can be debilitating and even life altering if not properly treated.

Our Department of Orthopaedic Surgery is fortunate to have the combined expertise of hand and wrist specialists from the Rothman Orthopaedic Institute at Jefferson Health and the Philadelphia Hand to Shoulder Center at Jefferson Health.

As a major referral center, Jefferson Health treats patients with the most complex injuries and disorders of the hand and wrist, as well as patients with more common conditions who benefit from a highly experienced care team. Considering that the hand and wrist are involved in nearly every task of daily living, even a small amount of dysfunction can diminish people's ability to work, exercise, play sports and take care of themselves and their families.

Our clinical care is strengthened by findings from our research agenda. This past year the hand and wrist team at Jefferson Health published studies on a variety of topics ranging from the risk of infection in trigger release surgery when the procedure is done soon after a corticosteroid injection, to a case report on a ground-breaking heterotopic thumb-to-thumb replantation following a mangled hand injury.

Hand and wrist care is continually being refined as Jefferson Health researchers identify optimal non-operative and operative techniques and embrace promising new technologies such as 3-D printing. On most days it seems as though the future of orthopaedic care is already here.

Take a look at some of the key research by Jefferson Health's hand and wrist team. 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 all the best in 2021.

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

Rothman Orthopaedic Institute Studies

Splinting after Distal Radius Fracture Fixation: A Prospective Cohort Analysis of Postoperative Plaster Splint versus Soft Dressing

Distal radius fractures (DRFs) are among the most common fractures. Incidence is increasing across all age groups worldwide for the past several years, with DRFs being increasingly treated through open reduction internal fixation (ORIF) with locking volar plates.

The effect of postoperative dressing and splinting after DRF ORIF is not well understood.

Jefferson Health researchers led by Spencer Poiset, MD, conducted a prospective cohort analysis to assess differences in functional and radiographic outcomes with the use of plaster splinting or soft dressing following DRF ORIF.

All patients undergoing DRF ORIF with locking volar plates were consecutively enrolled. Preoperative demographic and postoperative radiographic and function outcome data were collected at two weeks and three months postoperatively. Functional data included range of motion (ROM), pain on visual analog scale (VAS), Patient-Rated Wrist Evaluation (PRWE), and quick Disabilities of the Arm, Shoulder and Hand (DASH) scores. Radiographic data included loss of fracture reduction.

A total of 139 patients (79 who had plaster splinting and 60 who had soft dressing) were included in the analysis, which was published in the *Journal of Wrist Surgery.*

The study found that by the first postoperative visit, there was one case of loss of reduction with plaster splinting and one case with soft dressing. Neither group had hardware failure or revision

An example of a postoperative distal radius fracture repair immobilized with a (A) plaster splint and (B) soft dressing.
Source: Jack Abboudi, MD

surgery. There were also no differences in DASH, PRWE or VAS pain scores.

By the final postoperative visit, however, some differences emerged between the two groups. The soft dressing group showed greater ROM in extension by 9.6°, flexion by 10.9° and supination by 4.8° over plaster splinting. The soft dressing group also demonstrated statistically significant improvement in PRWE and DASH scores as well as VAS pain scores as compared with plaster splinting.

"This study finds no benefit in applying a plaster splint over a soft dressing following DRF ORIF with volar locking plate," the researchers concluded. "The less restrictive soft dressing may also grant modest increases in the range of motion at 3 months postoperatively, with no relative increased risk of loss of reduction, increased pain or compromised function."

The researchers said they hoped the findings will help guide postoperative care in the future.

Intramedullary Headless Screw Fixation of Metacarpal Fractures: A Radiographic Analysis for Optimal Screw Choice

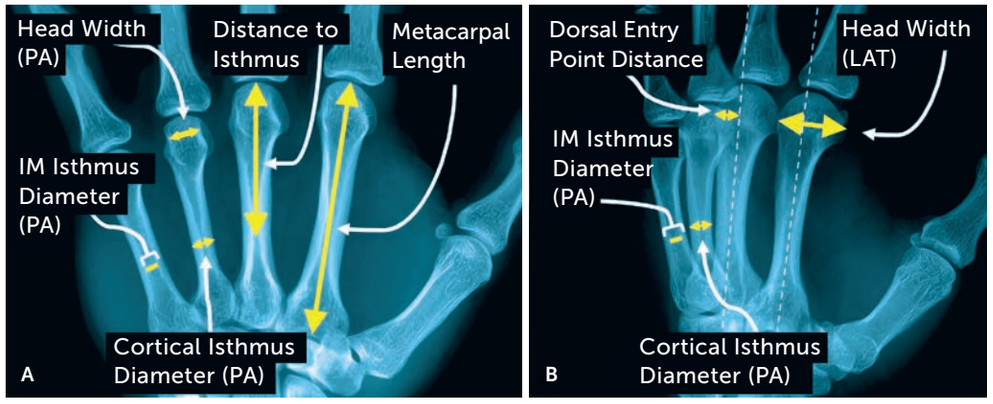
Metacarpal fractures are responsible for 10% of all fractures and account for 18% to 41% of hand injuries presenting to the emergency department or urgent care. Most hand fractures result from a fall, crush injury or direct impact with the hand and can occur in the base, shaft, head or neck. Due to variation in fracture type and pattern, different treatment options should be tailored for each injury presentation. Options for fixation of metacarpal neck and shaft fractures include lag screws, plate fixation, K-wire pinning and intramedullary headless cannulated screw fixation.

Jefferson Health researchers led by Michael Okoli, MD, conducted a study to investigate variations in radiographic anatomy as it relates to intramedullary (IM) fixation of metacarpal fractures and to compare this anatomy with available headless screw dimensions.

Researchers radiographically analyzed posteroanterior and lateral (LAT) radiographs of 120 metacarpals across 30 patients with structural abnormalities. Primary outcomes included IM isthmus diameter, isthmus location, metacarpal cascade, and head entry point collinear with the IM canal. Measurements were compared with a list of commercially available headless screws used for IM fixation.

Findings, published in *Hand*, included:

- The average largest isthmus diameter was in the small metacarpal (3.4 mm), followed by the index (2.8 mm), long (2.7 mm), and ring (2.7 mm) metacarpals.
- The average cascade angle between long and index, long and ring, and long and small was 0°, 24°, and 27°, respectively.
- The appropriate head entry point ranged between 25% and 35% from the dorsal surface of the metacarpal head on a LAT view.
- The retrograde isthmus location of the index and long finger was 39.2 mm and 38.1 mm, respectively.
- Twenty-five screws from seven manufacturers were analyzed, with sizes ranging from 1.7 mm to 4.5 mm.



Depiction of radiographic measurements. *Source: Asif Ilyas, MD*

Only eight of 17 screws between 2.3 mm and 3.5 mm in diameter had a length range above 35 mm.

The researchers noted that while the study found differences between men and women and between metacarpals within the same individual, there are several radiographic landmarks that are relatively consistent, such as distal entry point and cascade angle, which can be used to approximate screw placement and fracture reduction.

"Metacarpal head entry point and cascade angle can help identify the appropriate reduction with the guide pin starting point in the dorsal 25% to 35% of the metacarpal head," the researchers noted. "Surgeons should be mindful to choose the appropriate fixation system in light of the variations between metacarpal isthmus size, isthmus location and available screw lengths."

Risk of Infection in Trigger Finger Release Surgery Following Corticosteroid Injection

Trigger finger or stenosing flexor tenosynovitis of the A1 pulley is a fairly common condition in adults, with an estimated lifetime prevalence of 2%. Corticosteroid injections are the mainstay of nonsurgical treatment and have a reported success rate between 40% and 90%.

Theoretical risks of injection include flare reaction, tendon rupture, local infection, blood glucose elevation and fat atrophy, but limited data exist on these complications.

Jefferson Health researchers led by Jonas Matzon, MD, set out to quantify the risk for infection in trigger finger release surgery after preoperative corticosteroid injection. They retrospectively evaluated all patients undergoing the procedure by 16 surgeons over a two-year period.

The data collected included demographic information, medical comorbidities, trigger finger(s) operated on, presence of a prior corticosteroid injection, date of most recent injection, postoperative signs of infection, and need for surgery due to deep infection. Superficial infection was defined according to Centers for Disease Control and Prevention (CDC) criteria. Deep infection was defined as the need for surgery because of a surgical site infection.

Deep Infections per Injection Interval

Injection Interval, d	Total	DI	% DI	% DI/3 mo
0–30	69	0	0.0	
31–60	190	5	2.6	2.0
61–90	136	3	2.2	
91–120	100	1	1.0	
121–150	98	1	1.0	1.1
151–180	76	1	1.3	
181–210	87	0	0.0	
211–240	95	0	0.0	0.0
241–270	74	0	0.0	
271–300	79	0	0.0	
301–330	79	0	0.0	0.0
331–360	66	0	0.0	
>360	216	0	0.8	
Total	1,342	11	0.8	

Source: Asif Ilyas, MD

A total of 2,480 fingers in 1,857 patients undergoing trigger release surgery were included in the analysis, which was published in *Journal of Hand Surgery*.

Among the findings:

- Of the total number of fingers, 53 (2.1%) developed an infection. There were 41 superficial infections (1.7%) and 12 deep infections (0.5%).
- Before surgery, 1,137 fingers had no corticosteroid injection. Of those, one finger (0.1%) developed a deep infection and 17 (1.5%) developed a superficial infection.
- In comparison, 1,343 fingers had a corticosteroid injection before surgery. Of those, 11 (0.8%) developed deep infection and 24 had superficial infection (1.8%).
- Median time from corticosteroid injection to trigger release surgery was shorter for fingers that developed a deep infection (63 days) compared with those that developed no infection (183 days).
- The risk for developing a deep infection in patients who were operated on within 90 days of an injection (8 infections in 395 fingers) was higher compared with patients who were operated on greater than 90 days after an injection (3 infections in 948 fingers).

"Preoperative corticosteroid injections are associated with a small but statistically significant increased rate of deep infections after trigger release surgery," the researchers concluded, noting that the risk seems greater when the injection is given within 90 days of surgery and especially within 31 to 90 days.

"We counsel patients that risk for infection decreases the longer the time from the injection. This may be a consideration in particular when discussing surgery with patients who had a short duration of success with previous corticosteroid injection," the researchers said.

Three-Dimensional Printing in Orthopaedic Surgery

Three-dimension (3D) printing is being incorporated into all kinds of industries and businesses, including health care. While 3D printing was first developed in the 1980s, the technique has more recently been adopted for medical applications.

In an article in *Journal of Bone Joint Surgery*, Jefferson Health researchers led by Kevin Lutsky, MD, explored the history and growing potential of 3D printing in orthopaedic surgery.

"The ability to precisely engineer, complex 3D structures allows for improved preoperative planning for difficult orthopaedic reconstruction cases, such as joint revision surgery and reconstruction in patients with massive bone loss secondary to trauma or malignancy," the article said. Also, "the advent of 3D printing has ushered in the era of 'patient-specific orthopaedics,' with custom-designed, patient-specific implants, instrumentation, models, and bioscaffolds for tissue-engineering applications."

The article outlined various ways of creating files that can be modeled and printed, including computer-assisted design software, a 3D scanner, Digital Imaging and Communications in Medicine files, and online libraries. It also detailed the types of printers used for 3D medical applications, including fused deposition modeling, stereolithography, selective laser sintering and bioprinters.

The article said that orthopaedic applications of 3D printing include the generation of prosthetics and orthotics, intraoperative guides, patient-specific implants and anatomic models for preoperative planning and education.

"The availability of 3D-printed anatomic models may enhance surgeons' preoperative planning and improve orthopaedic education with the generation of anatomic models," the article said.

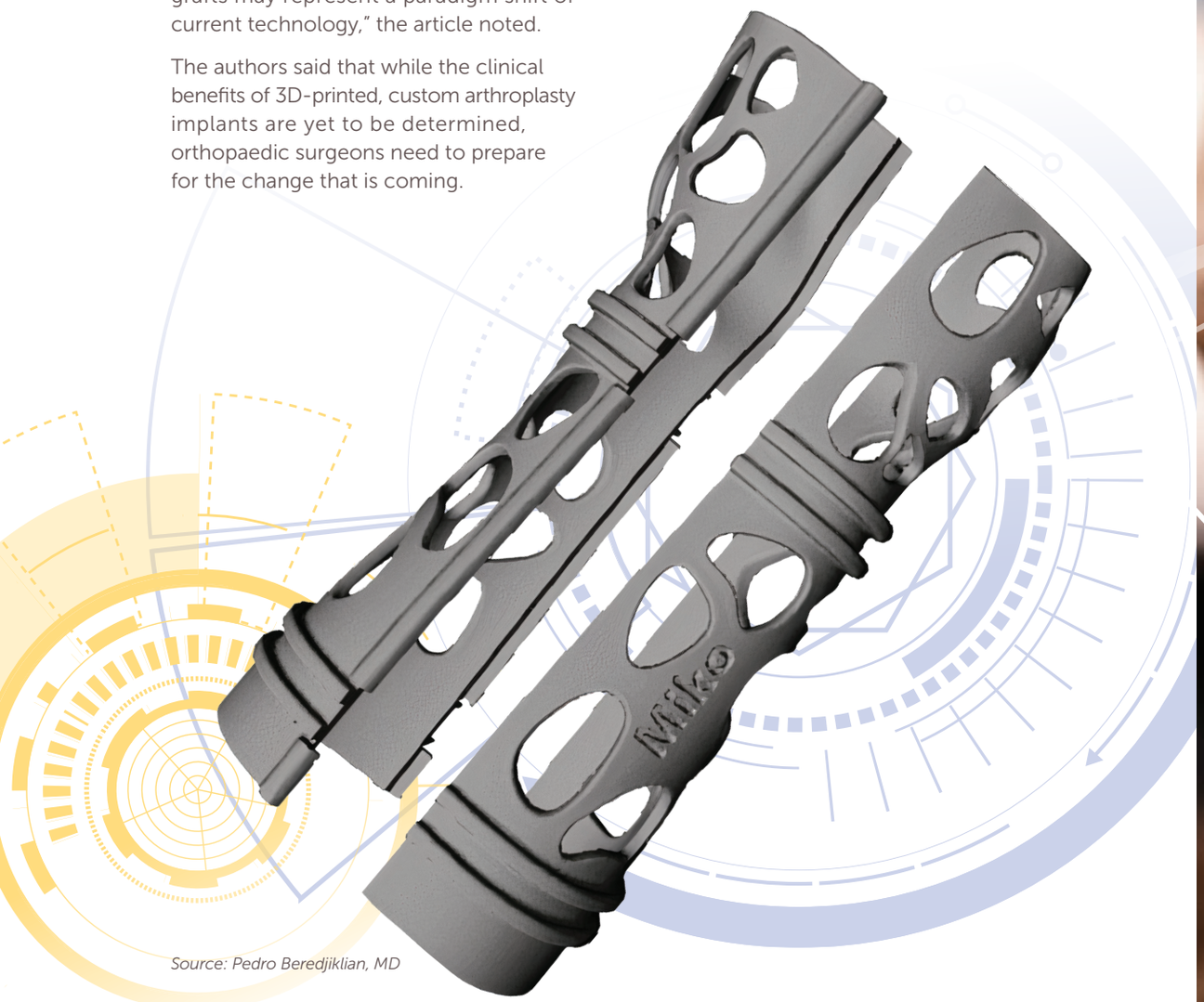
A printed clamshell cast made using a plastic polymer on a desktop fused deposition modeling 3D printer. *Source: Pedro Beredjiklian, MD*

Another potential is that children with an amputation or congenital limb difference can benefit from increased access and diminished cost of 3D-printed prostheses, especially if they live in communities with limited resources.

"Similarly, the biologic augmentation of bone and soft-tissue healing processed with bioactive, tissue size and shape-specific grafts may represent a paradigm shift of current technology," the article noted.

The authors said that while the clinical benefits of 3D-printed, custom arthroplasty implants are yet to be determined, orthopaedic surgeons need to prepare for the change that is coming.

"Orthopaedic surgeons will greatly benefit from familiarizing themselves with the potential of this technology and evaluating the efficacy of currently available technology and devising future applications in clinical practice," the authors recommended. An ongoing research project at Jefferson involves studying outcomes of treatment of upper extremity fractures using 3D-printed orthoses.



Source: Pedro Beredjiklian, MD

Philadelphia Hand to Shoulder Center Studies

Osteochondral Autograft Transplantation for Hand and Wrist Articular Problems

Management of hand and wrist avascular necrosis (AVN) with osteochondral fragmentation (OCF) or focal arthritis can be a challenging problem. A variety of procedures have been described for its treatment.

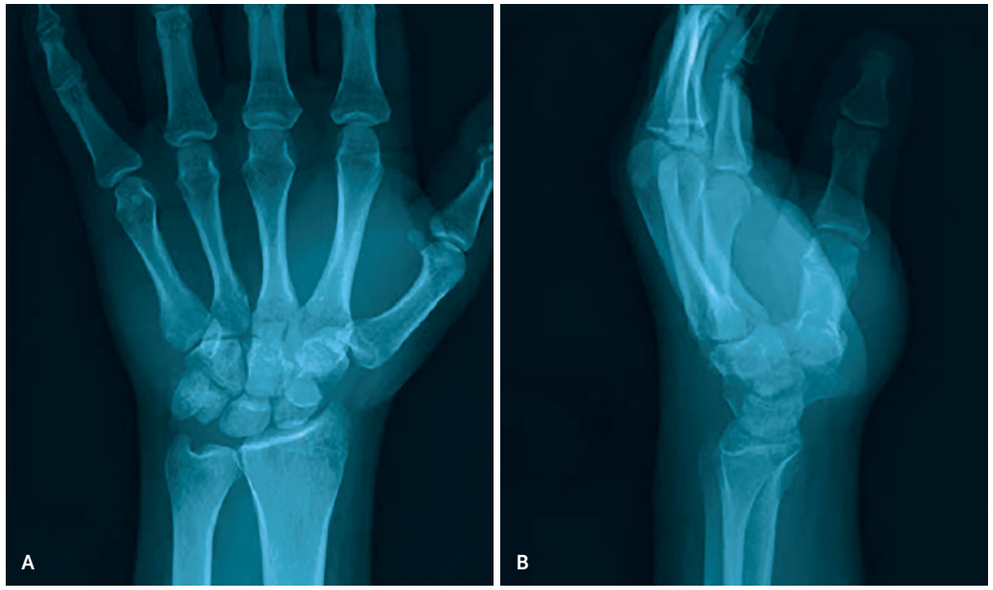
One treatment possibility is osteochondral autograft transplantation systems (OATS), which have been utilized on various focal defects of the knee, ankle, elbow and wrist. In an article in *Techniques in Hand & Wrist Upper Extremity Surgery*, Jefferson Health hand surgeons led by Andrew J. Miller, MD, describe the potential benefits in using the approach in hand and wrist cases, particularly in the treatment of small joint AVN or nonunion OCF of the hand and wrist.

"The application of OATS for problems of the hand and wrist presents a unique opportunity to restore focally damaged cartilage," Dr. Miller said.

The article focused on two case studies in which the authors detailed their use of OATS. The first involved a 13-year-old female who was active in gymnastics and softball for several years. She had an insidious onset of dorsal central right wrist pain that resulted in casting and modification of her activities. Subsequently, CT and MRI scans showed proximal fragmentation and fracture of the capitate consistent with AVN.

The other case involved a 14-year-old male, with a history of Ehlers-Danlos syndrome, who was injured with a direct blow to the right hand. Following initial casting for a diagnosis of a third metacarpal fracture, he developed pain in an adjacent joint. He was subsequently diagnosed with fourth metacarpal AVN.

Both patients underwent an OATS procedure and had favorable results, the researchers reported.



AP and lateral x-rays of a left wrist demonstrating squaring of the proximal capitate. *Source: Andrew Miller, MD*

Contralateral Heterotopic Thumb-to-Thumb Replantation With Free Ulnar Forearm Fasciocutaneous Flap and Targeted Muscle Reinnervation

A mangled hand often presents a difficult clinical scenario for the upper-extremity surgeon, especially when limb salvage may not be possible and amputation results. Few mangled extremity injuries are identical and the literature offers little guidance for managing devastating bilateral injuries.

An awareness of the array of microsurgical reconstructive options may enable the hand surgeon to restore some function even in the direst of circumstances.

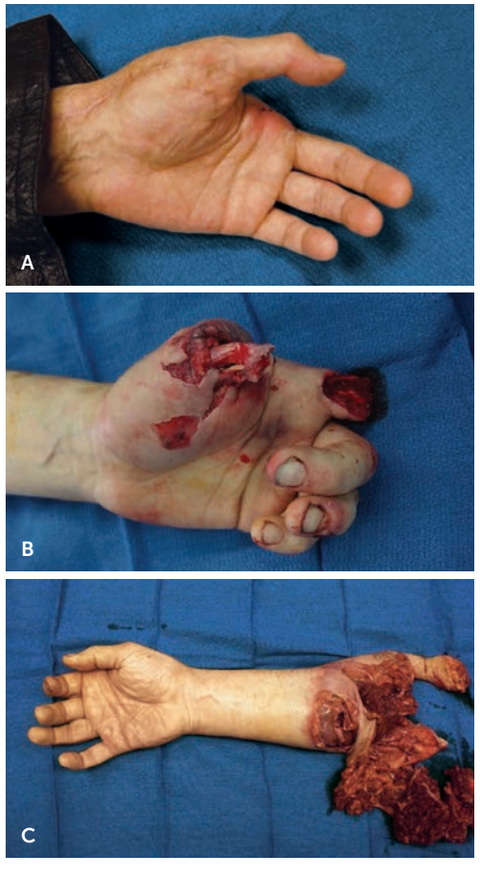
Jefferson Health surgeon Rick Tosti, MD, published a case report of an unusual "spare parts reconstruction" of a bilateral upper-extremity mangling injury treated with a heterotopic thumb-to-thumb replantation, an acute forearm fasciocutaneous free flap, and targeted muscle reinnervation. According to Dr. Tosti, an acute thumb-to-thumb transfer has never been previously reported.

The spare parts surgery involved a 55-year-old man who had been struck by a train. At presentation to the hospital, his right upper extremity was amputated at the distal humerus with degloving of skin to the axilla. The amputated extremity distal to the elbow was in good condition. The man's left upper extremity had an amputated thumb and amputated index finger with exposed bone. The amputated digits were not available to the surgeons.

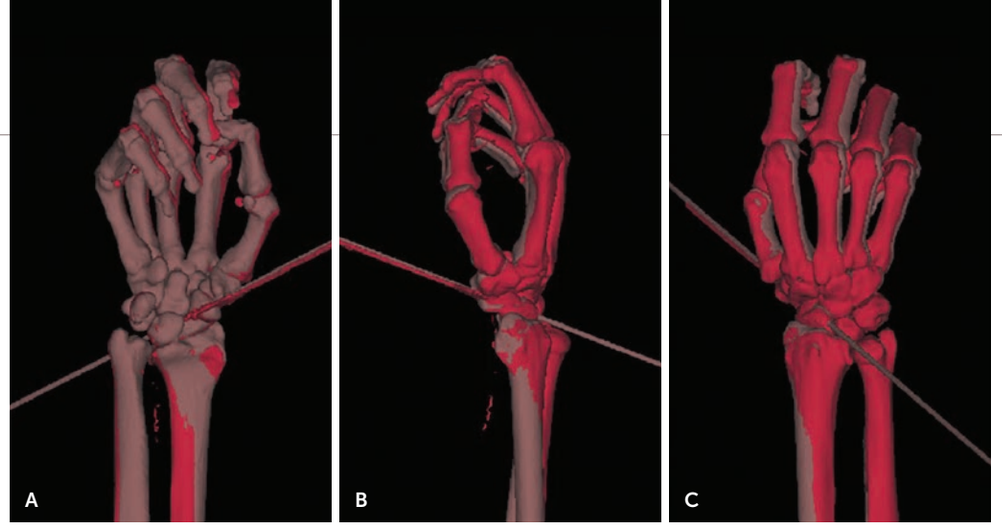
The surgeons describe in detail their technical approach to the complex case in an article in *Journal of Hand Surgery*. They said their overall goal in the multi-step process, including the thumb-to-thumb replantation, was to improve the patient's ability to carry out basic personal needs such as eating, hygiene and toileting. In the absence of the right arm and left thumb, he would have to depend on others.

The surgeons reported that at one year, the patient remained independent and was using his left hand for daily household and self-care activities.

The targeted muscle reinnervation was performed to the stump of the right arm. By transferring nerves to specific regions of the pectoralis muscles, the surgeons said that the risk of pain from a neuroma is reduced and the chance of functioning with an intuitive myoelectric prosthetic is optimized for the future.



Source: Rick Tosti, MD



Preprocedure scaphoid with simulated guidewire surface model and postprocedure scaphoid surface model were overlapped in different views to evaluate the accuracy of the guidewire placement. (A) Palmar view. (B) Lateral view. (C) Dorsal view. *Source: Rick Tosti, MD*

A Cadaveric Study on the Accuracy of an Individualized Guiding Template to Assist Scaphoid Fixation Using Computed Tomography and 3-Dimensional Printing

Screw fixation of an acute scaphoid fracture has become a popular technique due to its well-known mechanical advantages. It has been shown in biomechanical and clinical studies that the central placement of a scaphoid screw improves the healing rate and reduces the immobilization period of a scaphoid fracture. However, precise central placement of the screw in the scaphoid remains a challenging task for surgeons.

Jefferson Health researcher Dan Zlotolow, MD, in collaboration with a group from Beijing, China designed a study using cadaver wrists to evaluate the feasibility and accuracy of scaphoid screw guidewire placement using a computer-assisted-designed 3-dimension-printed surgical guiding template.

Computed tomography (CT) scans of 12 fresh-frozen cadaver wrists were performed and the data were imported into a surgical planning system. A 3D skin surface template block with a guiding hole was generated from the CT data to allow a screw guidewire to be placed in the central third of the scaphoid. The 3D model was printed and then put back into the wrist.

A screw guidewire was inserted through the palmar guide hole into the intact scaphoid and then a post-procedural CT scan was done. The post-procedure data were introduced into the surgical planning system. Angular and linear deviation between the preprocedural simulation and the image of the guidewire was measured in the system to assess accuracy.

The results of using the innovative technique were favorable. The mean angular deviation was 3.85° $\pm$ 1.32° and linear deviations of the 12 specimens were less than 1.1 mm. In addition, no specimen required a repeat drilling to the scaphoid. All of the screw guidewires were considered to be centrally placed in the scaphoid based on study criteria of central placement of the scaphoid screw.

"The use of a computer-assisted 3-dimensional-printed surgical guide template to assist screw guidewire placement into an intact scaphoid, mimicking a nondisplaced scaphoid fracture, showed acceptable accuracy in cadaver wrists," the researchers reported in *Journal of Hand Surgery*.

While the study was conducted using cadaver wrists, the technique shows clinical promise. The researchers noted that "our technique may provide a simple and effective method for the guidance of screw guidance insertion in a nondisplaced scaphoid fracture surgery."

Early Results of Nerve Transfers for Restoring Function in Severe Cases of Acute Flaccid Myelitis

The Centers for Disease Control and Prevention (CDC) confirmed 558 cases of acute flaccid myelitis (AFM) in the U.S. from December 2012 to March 2019. This rare polio-like disease has been recognized in a number of states, with cases peaking in incidence every two years and most cases involving children younger than 15. Cases of AFM have also been confirmed in other countries.

AFM has been defined as an acute onset of flaccid limb weakness affecting one or more limbs. Paralysis occurs five to seven days after initial influenza-like symptoms and may progress quickly in the next 48 to 72 hours to affect the neck, trunk muscles, and cranial nerves. Many patients also have respiratory dysfunction.

More than 75% of AFM patients have incomplete recovery with persistent motor deficits. Studies report recovery plateauing during the first six to nine months, with proximal muscles less likely to recover. For now, the treatment for AFM is mainly supportive because immunomodulating agents have failed to alter its course.

For AFM patients with motor deficits persisting beyond six to nine months, nerve transfer surgery is sometimes performed. The benefits of the surgery, however, have not been clearly established in the medical literature.

Jefferson Health researcher Dan Zlotolow, MD, led a team at Shriners Hospital for Children in conducting a retrospective case analysis of patients with AFM at their center who underwent nerve transfer surgery by a study author between 2007 and 2018. Surgical criteria were persistent motor deficits after six months from onset and available donor nerves.

Thirty-two patients with AFM were evaluated, of whom 16 underwent nerve transfer surgery. Motor function was evaluated by a licensed occupational therapist using the Active Movement Scale preoperatively and during follow-up examinations. Patients with six months or more of follow-up were included in the analysis. Patients who had procedures other than nerve transfers were excluded.

Of the 16 patients who had nerve transfers, 75% were males and the median age was 2.5 years (with ages ranging from four months to 12 years). Forty-five nerve transfers were performed in the 16 patients. Thirteen patients had nerve transfers for shoulder reanimation, eight for elbow flexion and six for elbow extension. One patient had a nerve transfer for finger and thumb extension.

Of the 16 patients, 11 had six months of follow-up and were included in the final analysis, which was published in *Annals of Neurology*. Results included:

- Of nerve transfers done to restore elbow function, 87% of patients had an excellent recovery for elbow flexion.

(A–B) Preoperative examination. (A) Maximum elbow flexion, through Steindler effect. Shoulder pseudosubluxation is evident. (B) Maximum shoulder abduction. (C) Intraoperative picture of shoulder nerve transfer for shoulder external rotation. (D–F) Twelve-month follow-up showing shoulder. (D) Elbow flexion, (E) External rotation, (F) Abduction. *Source: Dan Zlotolow, MD*

- Of nerve transfers to restore elbow extension, 67% of patients had recovery of 50% or more of motion against gravity.
- Of the cases of nerve transfer done for shoulder reanimation, 50% of patients achieved excellent shoulder external rotation, while 20% achieved excellent shoulder abduction.
- Nine of 10 patients (90%) had resolution of shoulder pseudosubluxation following nerve transfer to the suprascapular nerve.

"Restoration of elbow function was more reliable than restoration of shoulder function," the study reported, though it was not clear why that was the case.

Overall, "Patients with AFM with persistent motor deficits 6 to 9 months after onset benefit from nerve transfer surgery," the study concluded.

The researchers added a caveat – that previous research has demonstrated that delayed assessment and intervention in children with nerve injuries can lead to worse outcomes after nerve transfers.

"We recommend early referral of (AFM) patients with incomplete recovery to a center experienced in nerve transfers for timely evaluation and treatment," they said.

Funded Clinical Trials

A Multicenter, 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, Inc: 2017–Current; (Asif Ilyas, MD)

Prospective, Non-Randomized, Multi-Center Clinical Evaluation of Metacarpal Neck Fracture Outcomes Study (aka, MetaNeck Study); Exsomed: 2019–Current; (Asif Ilyas, MD)

The Effects of Surgical Timing on Infection and Union in Open Distal Radius Fractures; 2018–Current (Rick Tosti, MD and Andrew Baron, MD)

Long Thoracic Nerve Transfers for Children with Brachial Plexus Injuries; 2019–Current (Dan Zlotolow, MD and Chase Kluemper, MD)

Restoration of Elbow Flexion in Acute Flaccid Myelitis; 2019–Current (Dan Zlotolow, MD; Scott Kozin, MD; Remy Rabinovich, MD)

Complications of Proximal Phalanx Fractures Treated with Intramedually Screws; 2018–Current (Rick Tosti, MD and Ryan Tarr, MD)

Grants

Prospective Randomized Controlled Double-Blinded Trial Comparing Oxycodone, Ibuprofen and Acetaminophen after Wide Awake Hand Surgery; American Foundation for Surgery of the Hand Clinical: 2017–Current; (Asif Ilyas, MD)

ASSH: 2015–Current; (Michael Rivlin, MD); 2019–Current; (Asif Ilyas, MD)

Sharpe Strumia: 2017–Current (Jack Abboudi, MD); 2017–Current (Christopher Jones, MD)