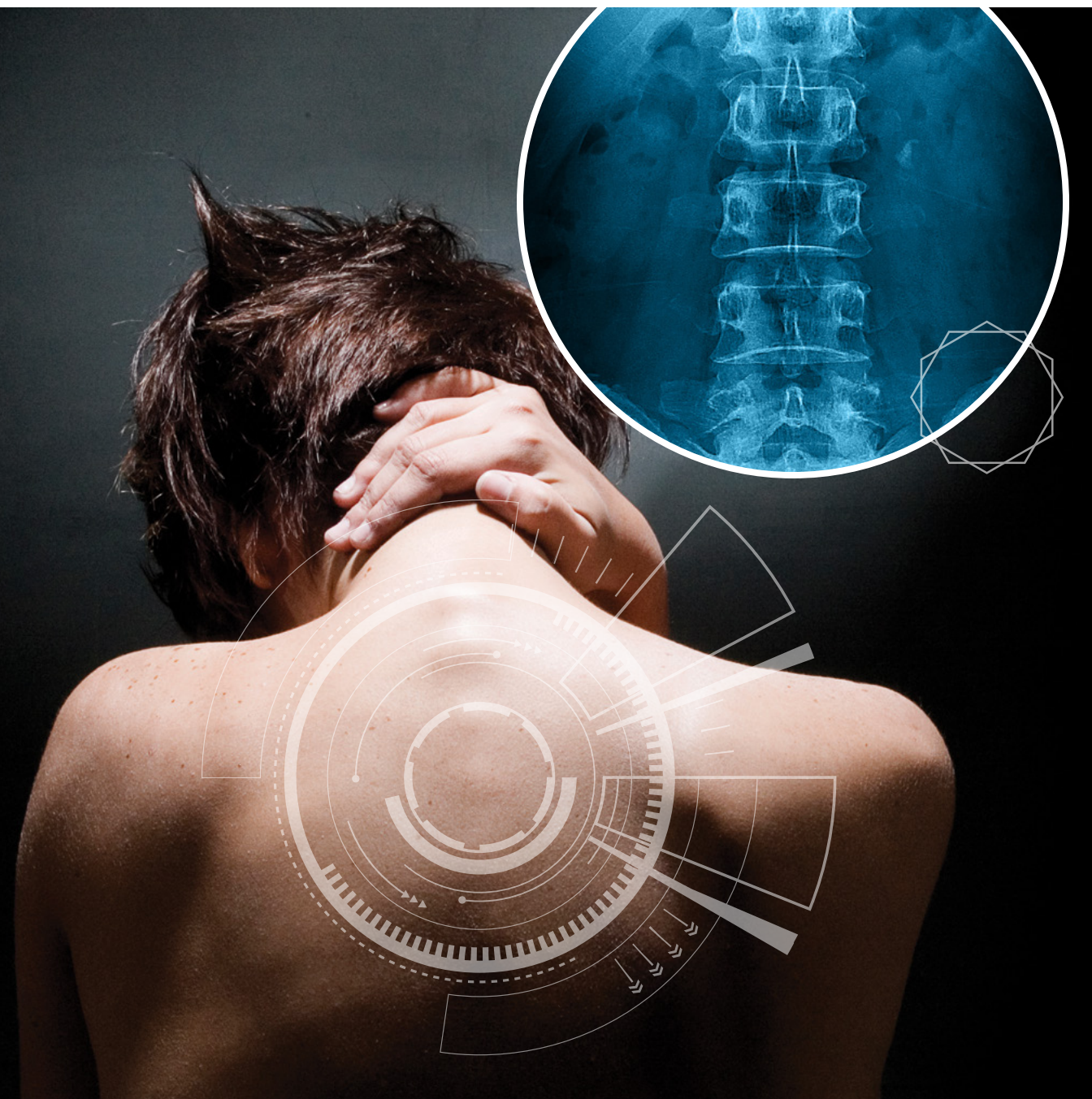


Complex Spine

VOLUME 7



COMPLEX SPINE

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. Each year, more than 3,123 patients have surgery for complex conditions such as spinal cord injuries and spinal tumors, as well as for more common problems such as sciatica, degenerative disc disease, spinal stenosis and cervical and lumbar disc herniation.

Jefferson Health is considered a leader in orthopedics according to *U.S. News & World Report*, making it a much sought-after referral center. It is also a designated Level 1 Regional Resource Trauma Center in Pennsylvania, with patients arriving in critical condition.

Back and neck pain and other spine-related issues can make even routine activities, like dressing and walking, difficult and painful. The spine team at Jefferson's Health's Department of Orthopaedic Surgery is skilled in using the latest and most minimally invasive procedures so that patients experience shorter hospital stays, quicker recoveries and less time sidelined from work, family and sports. In some cases, surgery is enhanced by the use of Jefferson Health's new state-of-the-art hybrid operating suite, based at Jefferson Methodist Hospital in South Philadelphia, which is equipped with advanced imaging systems and robotic technology.

Spine care at Jefferson Health also stands out because it is continually informed by research. Our spine surgeons are nationally recognized researchers, dedicated to identifying optimal surgical and non-surgical treatments and approaches to preventing spine disorders and injuries. Their research is also focused on enhancing the value of care, providing outstanding results for patients while striving to minimize costs to the healthcare system.

This volume of Jefferson Health's ongoing series of *Outcomes & Research* reports highlights some of the research published by the spine team at the Department of Orthopaedic Surgery.

Sincerely,

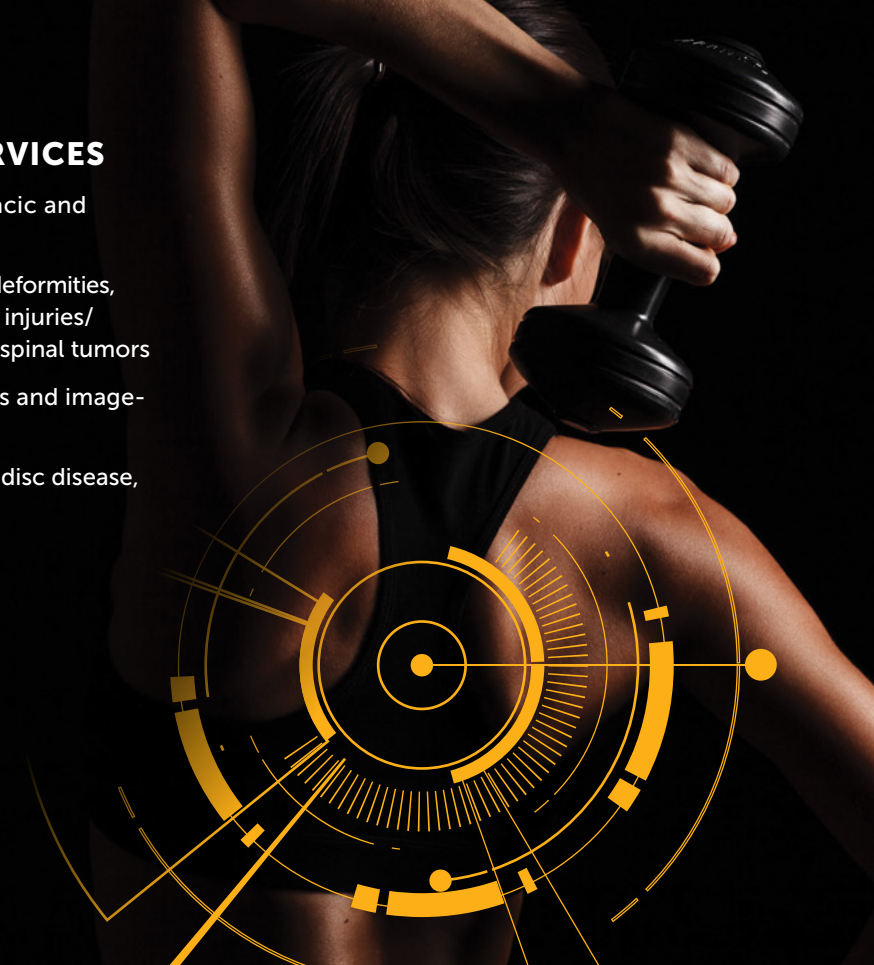
Alexander R. Vaccaro, MD, PhD, MBA

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



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



Orthopaedics Chair Tops in Spine Research

Alexander R. Vaccaro, MD, PhD, MBA, Richard H. Rothman Professor and Chairman of the Department of Orthopaedics and Professor of Neurosurgery at Thomas Jefferson University Hospitals, has been named the top-rated expert in spine research in the world by *Expertscape*, an online platform that ranks persons and institutions according to their demonstrated expertise in specific medical diseases, conditions and treatments.

Dr. Vaccaro was honored for the vast portfolio of research he published from 2012–2022. Two other Jefferson Health spine surgeons also earned top worldwide rankings for their research: Chris Kepler, MD (16th), Greg Schroeder, MD (19th) and Alan Hilibrand (53rd).

Expertscape examines all medical publications that are indexed in the National Library of Medicine's MEDLINE database, scoring each

article on several factors such as the type of research and the journal where the work was published. Dr. Vaccaro has had more than 1,020 peer-reviewed publications in his career, covering a wide range of topics, including cervical spine trauma, traumatic brain injuries in American football players, and prolonged opioid use after lumbar fusion. He has also edited over 62 textbooks.

Research is key to the long-running record of clinical success achieved by Jefferson Health's spine team. In 2022 alone, the spine team published 92 publications that have advanced the knowledge and treatment of an array of orthopedic diseases and injuries.

"It's an honor to be recognized for our team's commitment to further the world's knowledge of the treatment and conditions of the spine," Dr. Vaccaro said when the *Expertscape* rankings were announced.

Cefazolin Prophylaxis in Spine Surgery: Patients are Frequently Underdosed and at Increased Risk for Infection

Surgical site infection (SSI) is a common complication after spine surgery, with an incidence of approximately 3%. SSI can lead to increased morbidity and mortality, and treatment may require prolonged or repeated admissions, wound debridement, implant removal and prolonged antibiotic therapy. Strategies to prevent SSI include glycemic control, smoking cessation, weight loss, topical vancomycin powder, betadine irrigation and perioperative prophylactic antibiotics.

The use of perioperative prophylactic antibiotics to decrease the risk of perioperative infections is the standard of care in most orthopedic surgeries. Cefazolin is the most commonly administered prophylactic antibiotic because it has a broad spectrum of activity against gram-positive and gram-negative bacteria. While cefazolin dosing is typically based on the patient's weight, it is not clear what the optimal dosing should be to lower the risk of infection following spine surgery.

Jefferson Health spine surgeon Gregory Schroeder, MD, and colleagues conducted a retrospective study of patients who had spine surgery to determine whether inadequate weight-based dosing of cefazolin affects infection rates after spinal fusions and to identify the optimal dosing of the antibiotic.

The single-center analysis included 2,643 patients who underwent posterior cervical or lumbar spinal fusion between January

2000 and October 2020. Patients were grouped based on the institution-determined adequacy dosing standards: 1 g for (less than) 60 kg; 2 g for 60 to 120 kg; and 3 g for (greater than) 120 kg.

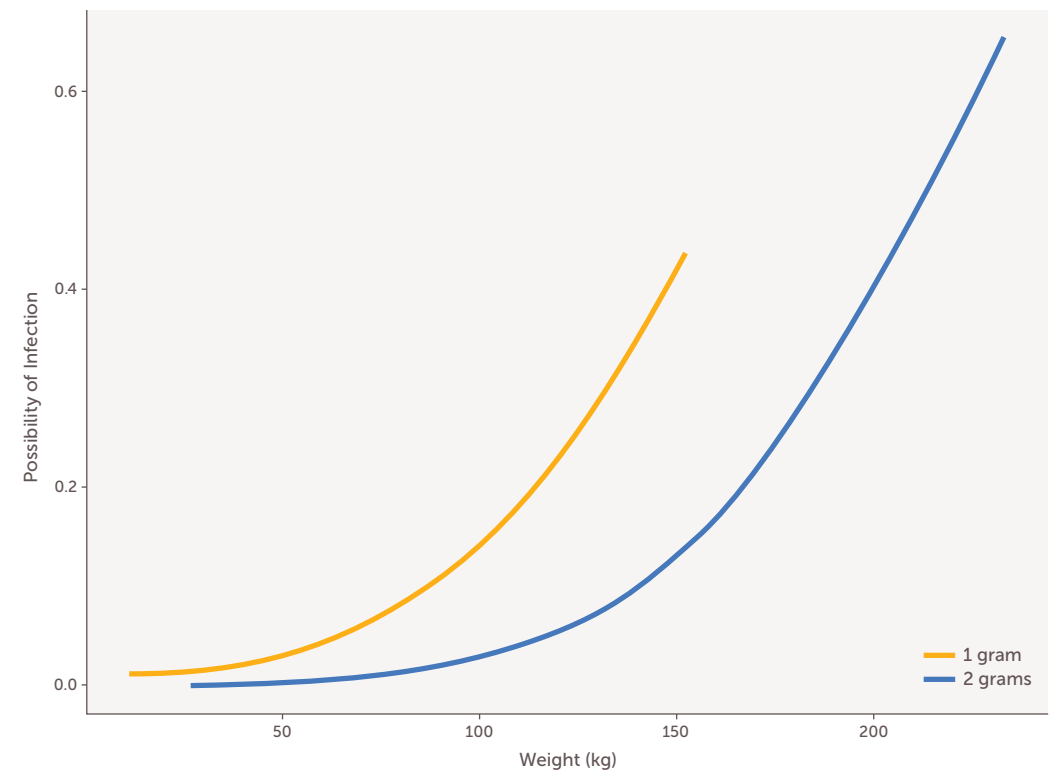
In the total cohort, 95 infections (3.6%) were identified. An analysis by dosing groups found that the infection rate was higher in the inadequately dosed group (5.86%) compared to the adequately dosed group (2.58%). Adequate dosing of cefazolin was a predictor of decreased infections after lumbar fusion, but not posterior cervical fusion.

The researchers then regrouped patients into two groups: those who received 1 g of cefazolin (818 patients) and those who got 2 g (1,806 patients). The infection rate among the 1 g group was 5.01% compared to a rate of 2.77% among those dosed at 2 g.

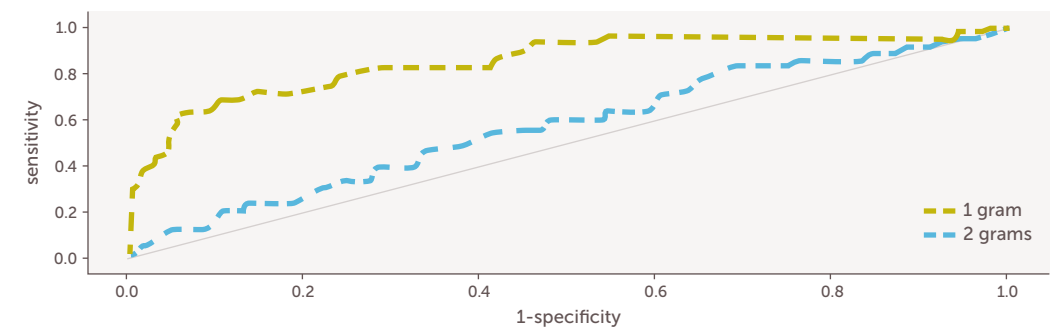
“Appropriate preoperative weight-based cefazolin dosing is imperative in preventing spine infections after spine arthrodesis procedures,” the researchers reported in *The Spine Journal*. “A cefazolin dose of 2 g was superior to that of 1 g, particularly for patients above 80 kg.”

They suggested that “surgeons should have a conversation with the anesthesia provider during the surgical timeout to ensure adequate preoperative cefazolin dosing.”

To address this, Jefferson surgeons are ensuring that all patients receive an optimal antibiotic dose prior to the start of every case.



Predicted infection risk based on weight and cefazolin dosage from a logistic regression model.



Receiver operating characteristic curve for infection using 1 g and 2 g cefazolin doses. A dose of 1 g cefazolin generated an optimal cutoff value of 80.74 kg with a corresponding area under the curve of 0.850 with 95% confidence intervals of 0.777–0.924. A prophylactic dose of 2 g generated a cutoff value of 83.91 kg with a corresponding area under the curve of 0.575 and 95% confidence intervals of 0.493–0.657.

Source: Gregory Schroeder, MD



What Is the Role of Dynamic Cervical Spine Radiographs in Predicting Pseudarthrosis Revision Following Anterior Cervical Discectomy and Fusion?

Since its inception in the 1950s, anterior cervical discectomy and fusion (ACDF) has become the most commonly performed cervical spine procedure. It has both a low complication profile and long-term efficacy.

Although relatively uncommon, symptomatic pseudarthrosis, which exhibits as axial neck pain, often with recurrent radiculopathy, can be a cause for revision surgery.

Surgical exploration of the fusion mass has been considered the gold standard for confirming arthrodesis, though dynamic radiographs are an effective surrogate. Historically, the criteria for determining arthrodesis have been ≤ 2 mm of interspinous motion across each instrumental level and radiographic demonstration of bridging trabecular bone between adjacent vertebrae. Those radiographic parameters were subsequently replaced by computed tomography (CT) scans, which better correlate with fusion rates based on intraoperative findings. Recently, dynamic radiographs displaying < 1 mm of interspinous motion across each construct level combined with ≥ 4 mm of supra-adjacent interspinous motion proved comparable to CT imaging.

The majority of patients undergoing ACDF report improvements in patient-reported outcomes one-year postoperatively. However, those who develop symptomatic pseudarthrosis tend to report less improvement. Given the increased healthcare expenditures for patients who undergo revision, there is a need to better understand the radiographic factors that may predict

whether revision surgery is needed and what the outcomes may be for patients with either symptomatic or asymptomatic pseudarthrosis.

A team of Jefferson Health spine researchers, led by Christopher Kepler, MD, conducted a study to explore three points: if dynamic radiographs accurately predict pseudarthrosis revision in a cohort of asymptomatic patients who underwent ACDF; how adjacent segment motion is affected by the fusion status; and how clinical outcomes differ between patients with symptomatic and asymptomatic pseudarthrosis.

The retrospective cohort study, published in *The Spine Journal*, included 597 adult patients with preoperative and postoperative cervical spine flexion-extension radiographs who underwent primary one- to four-level ACDF by a Jefferson Health surgeon over a 10-year period. The cases amounted to 1,203 ACDF levels, with most patients undergoing a multi-level procedure. The overall pseudarthrosis rate in the study cohort was 36%, with significant differences in rates depending on the number of levels done – 22.2% for one level, 34.8% for two, 49.7% for three, and 75% for four-level ACDF. The overall rate for revision due to pseudarthrosis was 4.9% (29 patients) with no significant differences in revision rates among the different ACDF levels.

The difference in interspinous process motion between flexion and extension radiographs postoperatively was used to determine motion at each level of the ACDF construct. Pseudarthrosis was defined

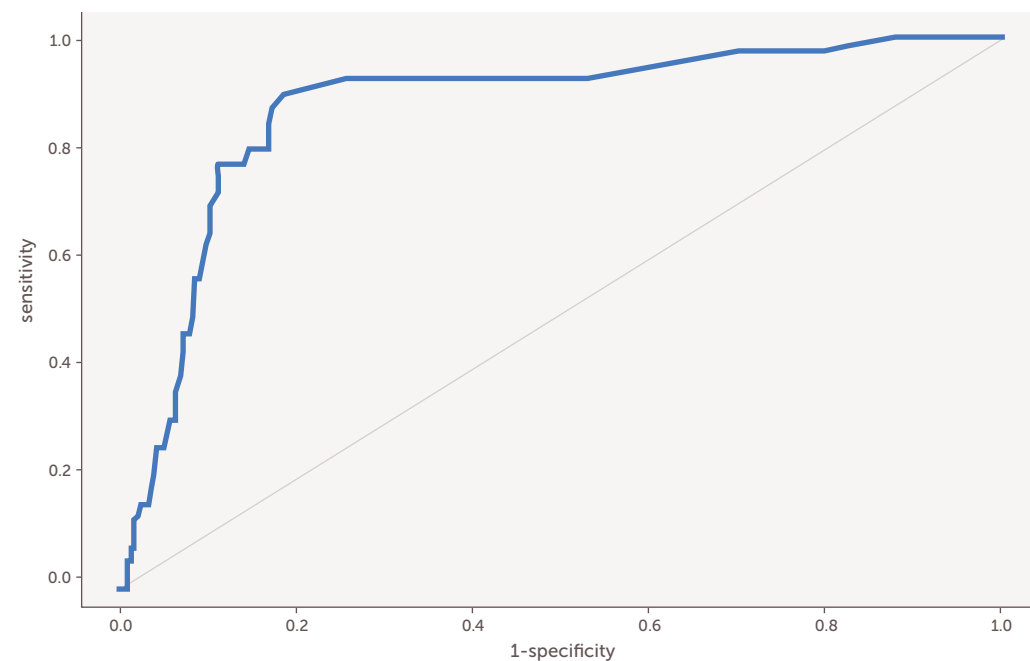
COMPLEX SPINE

as ≥ 1 mm interspinous process motion on dynamic radiographs. A receiver operating characteristic (ROC) curve was generated to predict the probability of surgical revision for pseudarthrosis based on millimeters of interspinous motion at each instrumented level. In addition, patient-reported outcome measures on several standardized scales were reviewed to assess the effect of pseudarthrosis on clinical outcomes.

The ROC analysis identified a "cutoff" value of 1 mm of interspinous process motion for generating an optimal area under the curve (AUC). The negative predictive value of one-year postoperative dynamic radiographs was

99.6%, whereas the positive predictive value was 13.7%, the analysis found. In addition, the researchers found that not only does the presence of a pseudarthrosis matter, but also the location of it. Patients who had a pseudarthrosis at the highest level were more likely to need revision surgery than if the pseudarthrosis was at the lower level. Interestingly, overall at one year there was not a difference in patient outcomes in patients with or without a pseudarthrosis.

Because of these findings, patients at Jefferson with a pseudarthrosis are being monitored closely, but are only taken back to the OR if they are symptomatic.



Receiver operating characteristic analysis for predicting pseudarthrosis revision based on millimeters of interspinous motion at each level of the ACDF Construct. AUC = 0.868. ACDF, anterior cervical discectomy and fusion.

Source: Christopher Kepler, MD



Clinical Outcomes at One-year Follow-Up for Patients with Surgical Site Infections After Spinal Fusion

Elective lumbar spine surgery is often performed for the management of pain and functional disability due to spinal stenosis, spondylolisthesis or disc herniations. The procedure has increased in popularity over the past decades.

Surgical site infections (SSIs) are among the most common complications, with the prevalence of SSI after spine surgery ranging from 0.5% to 18%, according to various published reports. Despite persistent focus on infection and prevention measures including screening protocols, rates of spinal SSI have not improved.

As healthcare systems in the U.S. and elsewhere increasingly emphasize the value of delivered care, there is a need to understand the clinical impact of SSIs.

Jefferson Health researchers led by Alexander Vaccaro, MD, PhD, conducted a retrospective 3:1 (control: SSI) propensity-matched case-control study of adult patients who underwent thoracolumbar fusion from March 2014 to January 2020 by a Jefferson surgeon. Analyses were done to compare surgical outcomes and patient-reported outcomes between the controls and the SSI group.

A total of 140 patients (105 controls, 35 SSI) were included in the final analysis. The SSI cohort had a significantly greater proportion of patients who underwent readmission (100% versus 0.95%) and revision surgery (28.6% versus 12.4%) when compared to controls.

Spinal fusion significantly improved patient-reported outcomes in both the SSI group and the controls, according to findings published in *Spine*. At the one-year mark following surgery, both groups improved significantly by measure of the Physical Component Score, the Oswestry Disability Index, the Visual Analog Scale (VAS) Back and the VAS Leg, though the control group had significantly better outcomes on the leg scale.

“Development of SSI after thoracolumbar fusion resulted in increased revision rates but did not influence patient improvement in one-year pain, functional ability, or physical and mental health status,” the study concluded.

The researchers said the findings may prove useful for surgeons when counseling patients who develop spinal SSI after thoracolumbar fusion. Jefferson surgeons are making sure these findings inform their discussions with patients.

Table 1 – Patient Demographics

	Control (N=105)	Infection (N=35)	P
Age (mean±SD)(yr)	64.9±8.16	64.3±9.95	0.847
Sex			0.329
Female	51 (48.6)	21 (60.0)	
Male	54 (51.4)	14 (40.0)	
BMI (mean±SD)(kg/m ²)	33.8±6.14	34.6±6.92	0.566
Follow-up (mean±SD)(y)	2.60±1.64	2.69±1.56	0.695
Diabetes	35 (33.3)	12 (34.3)	1.000
Smoking			0.410
Former	41 (39.0)	13 (37.1)	
Nonsmoker	53 (50.5)	21 (60.0)	
Smoker	11 (10.5)	1 (2.86)	
Race			0.210
Black/African American	6 (5.71)	2 (5.71)	
Other	2 (1.90)	3 (8.57)	
White	97 (92.4)	30 (85.7)	
CCI (mean±SD)	0.83±1.11	0.67±0.78	0.873
ASA (mean±SD)	2.71±0.45	2.74±0.56	0.077
Preoperative Diagnosis			
Stenosis	94 (89.5)	26 (74.3)	0.051
Spondylolisthesis	64 (61.0)	26 (74.3)	0.222
Deformity	16 (15.2)	3 (8.75)	0.403
Radiculopathy	8 (7.62)	1 (2.86)	0.450
Disk herniation	7 (6.67)	0 (0.00)	0.203
Neurogenic claudication	6 (5.71)	0 (0.00%)	0.337

ASA indicates American Society of Anesthesiologists Physical Status Classification System, BMI, body mass index, CCI, Charlson Comorbidity Index.

Table 2 – Surgical Data and Outcomes

	Control (N=105)	Infection (N=35)	P
Levels fused	1.74±1.29	2.40±2.10	0.133
Procedure			0.375
Anterior	14 (13.3)	7 (20.0)	
Circumferential	5 (4.76)	0 (0.00)	
Posterior	86 (81.9)	28 (80.0)	
EBL (mean±SD)(mL)	433±509	203±326	0.207
Length of stay (mean±SD)(d)	3.63±1.98	4.80±5.52	0.552
Readmission [n (%)]	1 (0.95)	35 (100)	<0.001*
≤30 d	1 (100)	27 (77.1)	
31–90 d	0 (0.00)	8 (22.9)	
Revision rate [n (%)]	13 (12.4)	10 (28.6)	0.048*

EBL indicates estimated blood loss.
*Statistical significance (P<0.05).

Source Alexander R. Vaccaro, MD, PHD

COMPLEX SPINE

SPINE SURGICAL VOLUME (JEFFERSON HEALTH) December 2021 to November 2022	
Thomas Jefferson University Hospital	1,144
Jefferson Abington Hospital	566
Jefferson Bucks Hospital	95
Jefferson Lansdale Hospital	116
Jefferson Methodist Hospital	247
Jefferson Washington Township Hospital	230
Physicians Care Surgical Hospital	293
Rothman Orthopaedic Specialty Hospital	432
GRAND TOTAL	3,123

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. Thoracolumbar Burst Fractures (AOspine A3, A4) in Neurologically Intact Patients: An Observational Multi-Center Cohort Study Comparing Surgical Versus Non-Surgical Treatment.	Barrett Woods, MD;
Bioventus, LLC (01/2016–present)	
Thoracolumbar Burst Fractures (AOspine A3, A4) in Neurologically Intact Patients: An Observational Multi-Center Cohort Study Comparing Surgical Versus Non-Surgical Treatment.	Gregory Schroeder, MD; Alexander R. Vaccaro, MD, PhD, MBA; Chris Kepler, MD, MBA
AO Foundation (10/2016–current)	
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.	Mark Kurd, MD
Innovative Surgical Designs (08/2017–current)	
A Multi-Center, Prospective, Comparative Study of Anterior Versus Posterior Surgical Treatment for Lumbar Isthmic Spondylolisthesis.	Alexander R. Vaccaro, MD, PhD, MBA; Chris Kepler, MD, MBA; Gregory Schroeder, MD
Clinical Study Protocol for the Investigation of the Simplify Cervical Artificial Disc Two Level.	Barrett Woods, MD
Simplify Medical (09/2017–current)	
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.	Mark Kurd, MD
Invibio, LTD (08/2018–current)	
An Assessment of P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion with Instrumentation.	Alexander R. Vaccaro, MD, PhD, MBA; Gregory Schroeder, MD
Cerapedics (06/2018–current)	
Randomized, Controlled Trial of Posterior C1–2 Fusion Versus Bracing Alone for Treatment of Type II Odontoid Process Fractures in the Elderly.	Chris Kepler, MD, MBA; Alexander R. Vaccaro, MD, PhD, MBA; Alan Hilibrand, MD, MBA; D. Greg Anderson, MD; Mark Kurd, MD; Gregory Schroeder, MD
CSRS grant (03/2018–current)	



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<p>A Post-Market, Prospective, Multi-Center, Nonrandomized Study to Assess Posterolateral Lumbar Fusions Using Fibergraft BG Matrix.</p> <p>Prosidyen, Inc. (07/2019–current)</p>	<p>Gregory Schroeder, MD; Guy Lee, MD; Chris Kepler, MD, MBA</p>
<p>Clinical Evaluation of Fortilink TETRAfuse Interbody Fusion Device in Subjects with Degenerative Disc Disease (FORTE).</p> <p>RTI Surgical, Inc. (06/2019–current)</p>	<p>Chris Kepler, MD, MBA; David Kaye, MD</p>
<p>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 Morphogenetic Protein-2.</p> <p>Camber Spine Technologies (04/2019–current)</p>	<p>David Kaye, MD</p>
<p>Cervical Spine Research Society (CSRS) Registry.</p> <p>CSRS grant (12/2020–present)</p>	<p>Gregory Schroeder, MD</p>
<p>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.</p> <p>(08/2018–present)</p>	<p>Alexander Vaccaro, MD, PhD, MBA</p>
<p>Infuse™ Bone Graft (Infuse™) (Recombinant human bone morphogenetic protein-2 (rhBMP-2)/absorbable collagen morphogenetic protein-2 (rhBMP-2)/absorbable collagen sponge (ACS).</p> <p>Medtronic (08/2020–Present)</p>	<p>Gregory Schroeder, MD; Victor Hsu, MD</p>
<p>A Clinical Registry of the ProTi 360°™ Interbody Fusion Devices for the Treatment of Cervical and Lumbar Degenerative Disc Disease.</p> <p>Tyber Medical (02/2021–present)</p>	<p>Joseph Lee, MD; Jose Canseco, MD</p>





Jefferson Health
Department of Orthopaedic Surgery
Philadelphia, PA 19107

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