Overview of Lumbar Spine Surgery

Kris Radcliff, MD

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PROGRESSIVE
SPINE & ORTHOPAEDICS

Biography

- 45
- School – Harvard Undergrad, Duke Medical, Baylor Residency
- Fellowship Thomas Jefferson (Philadelphia)
- Professor Depts of Orthopedic and Neurological Surgery at TJUH

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Outline

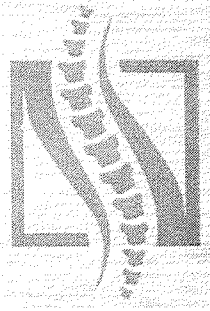
- What is a Spine Surgeon
- Evidence
- Minimally Invasive
- DISC Replacement
- Opioids

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What is a Spine Surgeon

- Unique subspecialty
- Hand surgery (orthopedics or hand)
- Physicians who are trained to diagnose and surgically manipulate the nerves, discs, and special structures of the spine
- Go to spine meetings
- Perform spine surgery
- Perform spine CME
- Malpractice covers spine

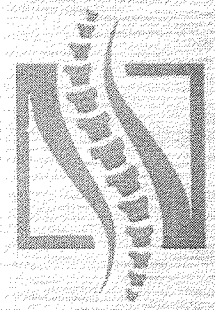


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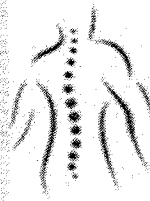
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Spine Surgery

- Specific specialty within medicine
  - Two accepted pathways to perform
  - Most neurological surgeons perform spine/cranial
  - Most orthopedic surgeons do not perform spine surgery
  - Most orthopedic spine surgeons perform only spine surgery
  - Societies and Guidelines are moving in that direction



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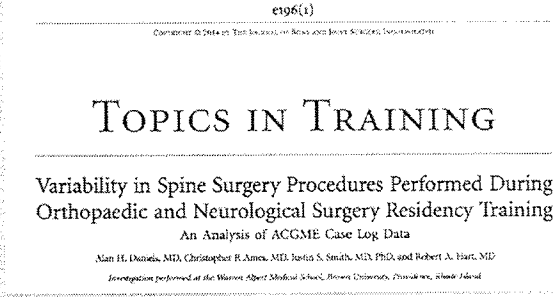


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Orthopedic versus Neurological Surgeons

- Orthopedic surgeons ~ 100 spine cases during residency
- Neurological Surgeons ~550 spine cases during residency
- After fellowship, orthopedic surgeons complete approximately 400 spine surgeries which is equivalent to neurological surgeons during residency

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e196(1)

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TOPICS IN TRAINING

Variability in Spine Surgery Procedures Performed During Orthopaedic and Neurological Surgery Residency Training

An Analysis of ACGME Case Log Data

Matt H. Daniels, MD, Christopher B. Ames, MD, Justin S. Smith, MD, PhD, and Robert A. Hart, MD

Investigation performed at the Warren Alpert Medical School, Brown University, Providence, Rhode Island

Hospital Credentialing Form Example

- Not All Orthopedic Surgeons Can Do Spine Surgery

QUALIFICATIONS FOR ORTHOPEDIC SURGERY OF THE SPINE

To be eligible to apply for core privileges in orthopedic surgery of the spine, the initial applicant must meet the following criteria:

Meet criteria for orthopedic surgery, plus successful completion of an accredited fellowship in orthopedic surgery of the spine.

Required previous experience for Initial Appointment: Applicants for initial appointment must be able to demonstrate performance of surgery of the spine procedures, reflective of the scope of privileges requested, at least 20 times during the last 12 months, or demonstrate successful completion of an ACGME- or AOA-accredited residency, clinical fellowship, or research in a clinical setting within the past 12 months.

Reappointment requirements: To be eligible to renew core privileges in orthopedic surgery of the spine, the applicant must meet the following maintenance of privilege criteria:

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Hospital Credentialing

Granular Level – Specific Procedures

Orthopedic Surgery

~~1. Amputation surgery including immediate prosthetic fitting in the operating room~~
~~2. Arthrocentesis, diagnostic~~
~~3. Arthrodesis, osteotomy and ligament reconstruction of the major peripheral joints, excluding total replacement of joint~~
~~4. Arthrography~~
~~5. Arthroscopic surgery~~
~~6. Biopsy and excision of tumors involving bone and adjacent soft tissues~~
~~7. Bone grafts and allografts~~
~~8. Carpal tunnel decompression including endoscopic~~
~~9. Closed reduction of fractures and dislocations of the skeleton~~
~~10. Debridement of soft tissue~~
~~11. Excision of soft tissue/bony masses~~
~~12. Fasciotomy and fasciectomy~~
~~13. Fracture fixation~~
~~14. Growth disturbances such as injuries involving growth plates with a high percentage of growth arrest, growth inequality, epiphysiodesis, stapling, bone shortening or lengthening procedures~~
~~15. Ligament reconstruction~~
~~16. Major arthroplasty, including total replacement of knee joint, hip joint, shoulder~~
~~17. Management of infectious and inflammations of bones, joints and tendon sheaths~~
~~18. Muscle and tendon repair~~
~~19. Open and closed reduction of fractures~~
~~20. Open reduction and internal/external fixation of fractures and dislocations of the skeleton~~
~~21. Orthotripsy~~
~~22.~~ 1. Perform history and physical exam
~~23. Reconstruction of non-spinal congenital musculoskeletal anomalies~~
~~24. Removal of ganglion (palm or wrist; flexor sheath)~~
~~25. Repair/reconstruct ligament knee~~
~~26. Total joint replacement revision~~
~~27. Total joint surgery~~
~~28. Treatment of extensive trauma, excluding spine~~

Surgery of the Hand (as a subspecialty of Orthopedic Surgery)

~~1. Arthroplasty of large and small joints, wrist or hand, including implants~~
~~2. Arthroscopy of the hand, wrist and small joints~~
~~3. Bone graft pertaining to the hand~~
~~4. Carpal tunnel decompression including endoscopic~~
~~5. Fasciotomy and fasciectomy~~
~~6. Fracture fixation with compression plates or wires~~
~~7. Fusion of joints of the hand and wrist~~
~~8. Microvascular procedures excluding replantation~~
~~9. Neurorrhaphy and related nerve procedures to include, but not limited to, decompression and transfers~~
~~10. Open and closed reductions of fractures of the upper extremity~~
~~11. Perform history and physical exam~~
~~12. Removal of soft tissue mass, ganglion palm or wrist, flexor sheath, etc.~~
~~13. Removals of bone mass or mass of unknown origin~~

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Society Standards

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Standards of Professionalism

Orthopaedic Expert Opinion and Testimony

Adopted April 18, 2005; Amended May 12, 2010 (effective for expert opinions offered on or after May 12, 2010; expert witness opinions rendered prior to May 12, 2010 are governed by the original Standards of Professionalism for Orthopaedic Expert Witness Testimony, adopted April 18, 2005)

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

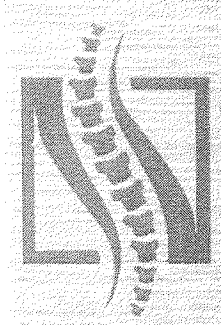
Mandatory Standard:

7. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall provide statements only about subject matters in which he or she has relevant clinical experience and specific orthopaedic knowledge in the areas of medicine that are the subject of the proceeding.

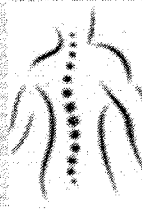
10. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall be engaged in the active practice of orthopaedic surgery or demonstrate enough familiarity with present practices to warrant designation as an expert on the subject matter of the inquiry.

Challenges for Some Experts

- "Relevant Clinical Experience"
- "Enough familiarity with present practices"
  - Minimally Invasive Spine Surgery
  - Disc Replacement
  - Robotics
  - Navigation



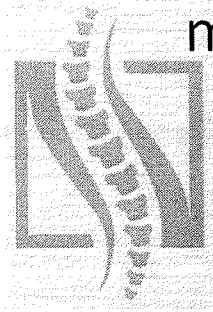
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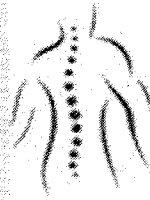
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Societies - Consensus Definitions

- American Society of Spine Radiology (ASSR), American Society of Neuroradiology (ASNR), and North American Spine Society (NASS)
- Literature Search
- Expert Opinion
- "Physicians need standard terms for normal and pathologic conditions of lumbar discs. Terms that can be interpreted accurately, consistently, and with reasonable precision are particularly important for communicating impressions gained from imaging for clinical diagnostic and therapeutic decision-making."

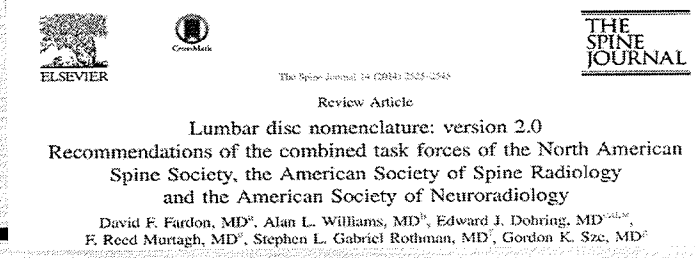


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Society Definitions



- Degeneration may include any or all of the following: desiccation, fibrosis, narrowing of the disc space, diffuse bulging of the annulus beyond the disc space, fissuring (ie, annular fissures), mucinous degeneration of the annulus, intradiscal gas, osteophytes of the vertebral apophyses, defects, inflammatory changes, and sclerosis of the end plates

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Definitions

ELSEVIER

THE SPINE JOURNAL

Review Article

Lumbar disc nomenclature: version 2.0
Recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the American Society of Neuroradiology

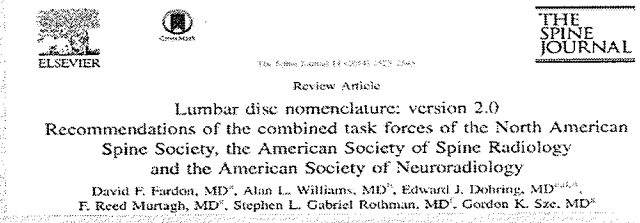
David F. Fardon, MD[a], Alan L. Williams, MD[b], Edward J. Dohring, MD[c,d,e], F. Reed Murtagh, MD[f], Stephen L. Gabriel Rothman, MD[g], Gordon K. Sze, MD[h]

- Because there is a confusion in the differentiation of changes of pathologic degenerative processes in the disc from those of normal aging, the classification "degenerated disc" includes all such changes, thus does not compel the observer to differentiate the pathologic from the normal consequence of aging.

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Society Definitions



- Whether or not a 'less than violent" injury has contributed to or been superimposed on a degenerative change is a clinical judgment that cannot be made based on images alone; therefore, from the standpoint of description of images, such discs, in the absence of significant imaging evidence of associated violent injury, should be classified as degeneration rather than trauma.

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Bulge vs Herniation

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THE SPINE JOURNAL

Review Article

Lumbar disc nomenclature: version 2.0
Recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the American Society of Neuroradiology

David F. Fardon, MD[a], Alan L. Williams, MD[b], Edward J. Dohring, MD[c,d], F. Reed Murtagh, MD[e], Stephen L. Gabriel Rothman, MD[f], Gordon K. Sze, MD[g]

- The terms "bulge" or "bulging" refer to a generalized extension of disc tissue beyond the edges of the apophyses. Such bulging involves greater than 25% of the circumference of the disc and typically extends a relatively short distance, usually less than 3 mm, beyond the edges of the Apophyses.
- Bulging, by definition, is not a herniation. Application of the term "bulging" to a disc does not imply any knowledge of etiology, prognosis, or need for treatment or imply the presence of symptoms.

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Annular tear

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David F. Fardon, MD[a], Alan L. Williams, MD[b], Edward J. Dohring, MD[c,*], F. Reed Murtagh, MD[d], Stephen L. Gabriel Rothman, MD[e], Gordon K. Sze, MD[f]

- The term "fissures" describes the spectrum of these lesions and does not imply that the lesion is a consequence of injury.

- Use of the term "tear" can be misunderstood because the analogy to other tears has a connotation of injury, which is inappropriate in this context. The term "fissure" is the correct term. Use of the term "tear" should be discouraged and, when it appears, should be recognized that it is usually meant to be synonymous with "fissure" and not reflective of the result of injury

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Incidence of Degenerative Changes

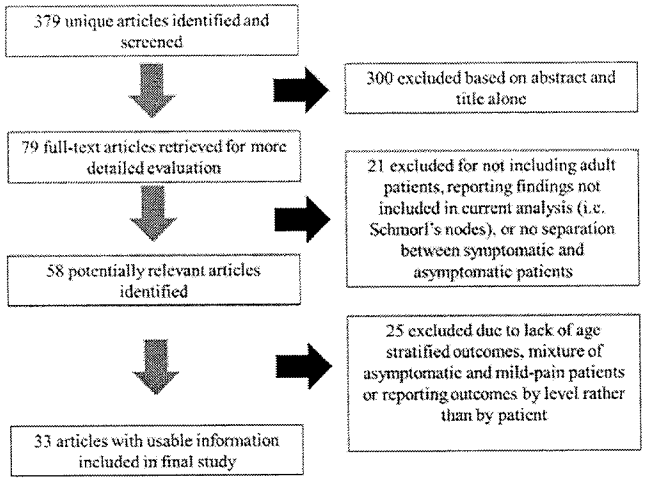


Table 2: Age-specific prevalence estimates of degenerative spine imaging findings in asymptomatic patients[a]

	Age (yr)						
Imaging Finding	20	30	40	50	60	70	80
Disk degeneration	37%	52%	68%	80%	88%	93%	96%
Disk signal loss	17%	33%	54%	73%	86%	94%	97%
Disk height loss	24%	34%	45%	56%	67%	76%	84%
Disk bulge	30%	40%	50%	60%	69%	77%	84%
Disk protrusion	29%	31%	33%	36%	38%	40%	43%
Annular fissure	19%	20%	22%	23%	25%	27%	29%
Facet degeneration	4%	9%	18%	32%	50%	69%	83%
Spondylolisthesis	3%	5%	8%	14%	23%	35%	50%

[a] Prevalence rates estimated with a generalized linear mixed-effects model for the age-specific prevalence estimate (binomial outcome) clustering on study and adjusting for the midpoint of each reported age interval of the study.

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ORIGINAL RESEARCH
SPINE

Systematic Literature Review of Imaging Features of Spinal Degeneration in Asymptomatic Populations

W. Brinjikji, P.H. Luetmer, B. Comstock, B.W. Bresnahan, L.E. Chen, R.A. Deyo, S. Halabi, J.A. Turner, A.L. Avins, K. James, J.T. Wald, D.F. Kallmes, and J.G. Jarvik

Clinical Importance

Table 5

Imaging Findings Likely Clinically Important vs. Likely Clinically Unimportant

Likely Clinically Important	Likely Clinically Unimportant
• Moderate or severe stenosis*	• Annular Fissure
• Disc extrusion	• Disc height loss
• Nerve root displacement or compression	• Mild stenosis (central, lateral recess or foraminal)
• Endplate edema (Type 1 endplate change)	• Nerve root contact without displacement/compression
• Grade 2 or higher listhesis	• Grade 1 listhesis
	• Disc dessication
	• Disc bulge
	• Disc protrusion
	• Facet degeneration (any severity)

* central, lateral recess or foraminal

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HHS Public Access
Author manuscript
Contemp Clin Trials. Author manuscript; available in PMC 2016 November 01.

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Contemp Clin Trials. 2015 November ; 45(0 0): 157–163. doi:10.1016/j.cct.2015.10.003.

Lumbar Imaging with Reporting of Epidemiology (LIRE)- Protocol for a Pragmatic Cluster Randomized Trial

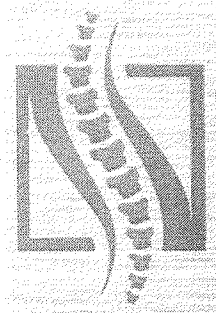
Jeffrey G. Jarvik, MD, MPH, Bryan A. Comstock, MS, Kathryn T. James, PA-C, MPH, Andrew L. Avins, MD, MPH, Brian W. Bresnahan, PhD, Richard A. Deyo, MD, MPH, Patrick H. Lustman, MD, Jenna L. Friedly, MD, Eric N. Meier, MS, Daniel C. Cherkin, PhD, Laura S. Gold, PhD, Sean D. Rundell, DPT, PhD, Safwan S. Halabi, MD, David F. Kallmes, MD, Katherine W. Tan, Judith A. Turner, PhD, Larry G. Kessler, ScD, Danielle C. Lavallee, PhD, Kari A. Stephens, PhD, and Patrick J. Heagerty, PhD

Asymptomatic vs Symptomatic

Outcomes

Outcome	No. of Studies	OR (95% CI)	Prevalence Asymptomatic	Prevalence Symptomatic	*P* Value[a]	I^2 (%)
Annular fissure	6	1.79 (0.97–3.31)	11.3% (9.0%–14.2%)	20.1% (17.7%–22.8%)	.06	59
High-intensity zone	4	2.10 (0.73–6.02)	9.5% (6.7%–13.4%)	10.4% (8.0%–13.4%)	.17	72
Central spinal canal stenosis	2	20.58 (0.05–798.77)	14.0% (10.4%–18.6%)	59.5% (54.9%–63.9%)	.32	94
Disc bulge	3	7.54 (1.28–44.56)	5.9% (3.8%–8.9%)	43.2% (38.2%–48.2%)	.03	90
Disc degeneration	12	2.24 (1.21–4.15)	34.4% (31.5%–37.5%)	57.4% (54.8%–59.8%)	.01	89
Disc extrusion	4	4.38 (1.98–9.68)	1.8% (0.1%–3.7%)	7.1% (5.4%–9.4%)	<.01	0
Disc protrusion	9	2.65 (1.52–4.62)	19.1% (16.5%–22.3%)	42.2% (39.3%–45.1%)	.00	62
Modic changes	5	1.62 (0.48–5.41)	12.1% (9.6%–15.2%)	23.2% (21.7%–27.3%)	.43	65
Modic 1 changes	2	4.01 (1.10–14.55)	3.2% (0.7%–9.4%)	6.7% (4.2%–10.4%)	.04	0
Spondylolisthesis	4	1.59 (0.78–3.24)	3.2% (1.8%–5.8%)	6.2% (4.4%–8.7%)	.20	0
Spondylolysis	2	5.06 (1.65–15.53)	1.8% (0.0%–5.3%)	9.4% (6.6%–12.4%)	<.01	0

[a] *P* values are computed from the meta-analysis of ORs. Prevalence data are provided for reference but are not meant for statistical comparison.



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Brinjikji AJNR 2015



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Future of Radiology…

Computer Interpretation of Radiology Reports (Natural Language Processing)

Computer Interpretation of Images

HHS Public Access
Author manuscript
Acad Radiol. Author manuscript; available in PMC 2023 March 01.

Published in final edited form as:
Acad Radiol. 2022 March ; 29(Suppl 3): S188–S200. doi:10.1016/j.acra.2021.09.005.

A Comparison of Natural Language Processing Methods for the Classification of Lumbar Spine Imaging Findings Related to Lower Back Pain

International Journal of Spine Surgery, Vol. 14, Supplement 3, 2020, pp. S86–S97
https://doi.org/10.14444/7133
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Feasibility of Deep Learning Algorithms for Reporting in Routine Spine Magnetic Resonance Imaging

KAI-UWE LEWANDROWSKI, MD,[1] NARENDRAN MURALEEDHARAN, BASME,[2] STEVEN ALLEN EDDY, MD,[3] VIKRAM SOBTI, MD, MBA,[4] BRIAN D. REECE, MD,[5] JORGE FELIPE RAMIREZ LEON, MD,[6] SANDEEP SHAH, MSEE, MBA[7]

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Reliability Analysis of Deep Learning Algorithms for Reporting of Routine Lumbar MRI Scans

KAI-UWE LEWANDROWSKI, MD,[1] NARENDRAN MURALEEDHARAN, BASME,[2] STEVEN ALLEN EDDY, MD,[3] VIKRAM SOBTI, MD, MBA,[4] BRIAN D. REECE, MD,[5] JORGE FELIPE RAMIREZ LEON, MD,[6] SANDEEP SHAH, MSEE, MBA[7]

Radiography 28 (2022) 674–683
Contents lists available at ScienceDirect
Radiography
journal homepage: www.elsevier.com/locate/radi

Development of lumbar spine MRI referrals vetting models using machine learning and deep learning algorithms: Comparison models vs healthcare professionals

A.H. Alanazi [a, b, *], A. Cradock [a], L. Rainford [a]

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Outline

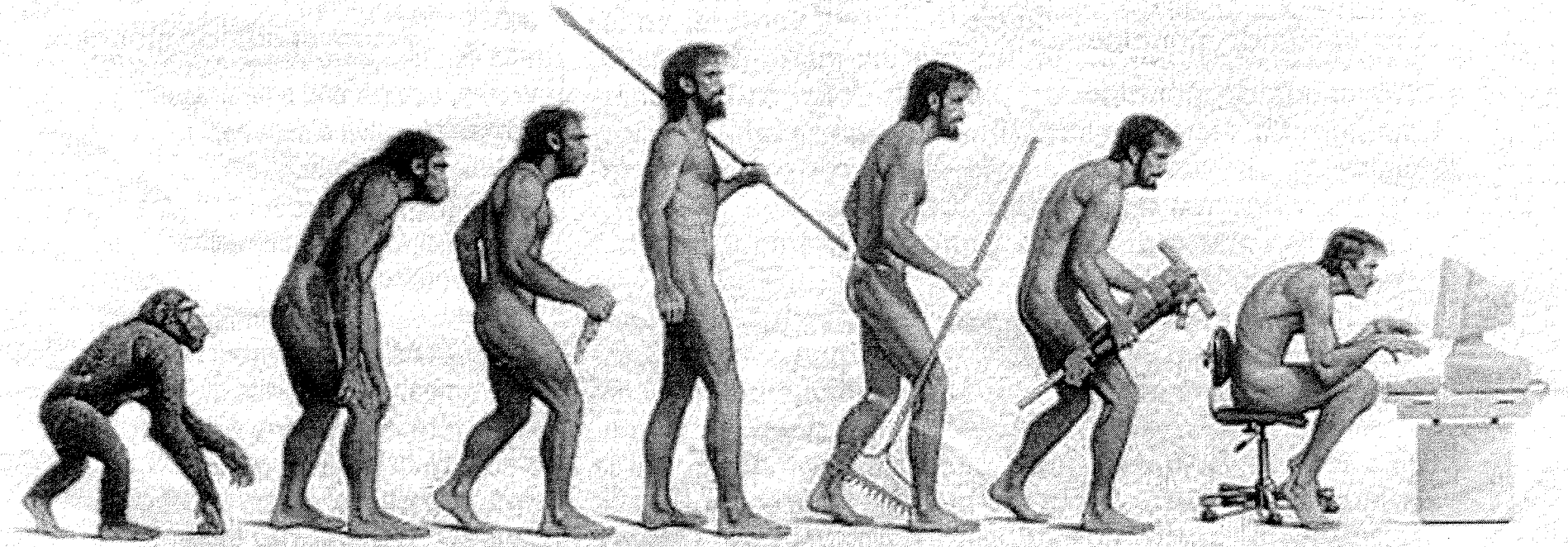
- What is a Spine Surgeon
- Clinical Research/Evidence
- Minimally Invasive
- DISC Replacement

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Why Clinical Research?

- Goal to Predict Outcome



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Research

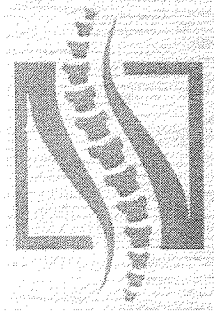
- Study patients with similar conditions to understand outcomes, complications, etc
- Outside of anecdotal experience
- Extrapolation





Challenges with Research

- Follow up
- Inclusion/Exclusion Criteria
- Outcome Measures
- Statistical Analysis
- Numerous Journals
- "Can Find An Article on Anything"



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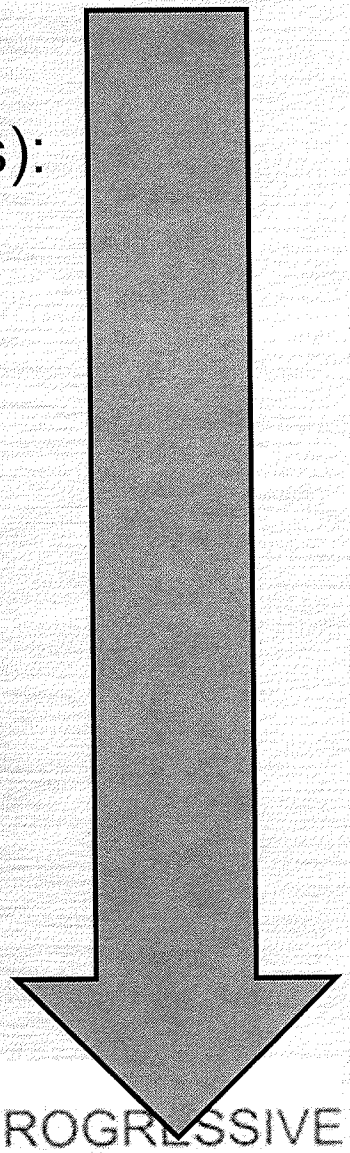


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Types of study design

- Non-Experimental Design (Observational Studies):
  - Case reports
  - Case series
  - Ecologic (Aggregate) Study
  - Cross-Sectional (Prevalence Study) Study
  - Case control studies
  - Cohort (Incidence, Longitudinal Study) Study

- Experimental Design:
  - Non-randomized clinical trials
  - Randomized clinical trials

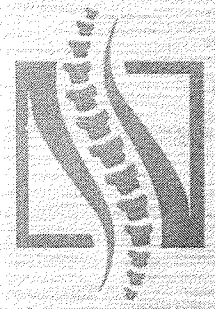


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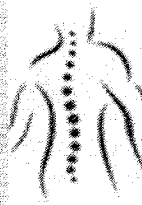
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Example of Clinical Research -SPORT

- How do patients who have persistent radiculopathy following a lumbar disc tolerate surgery or nonsurgical treatment?



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The SPORT Study

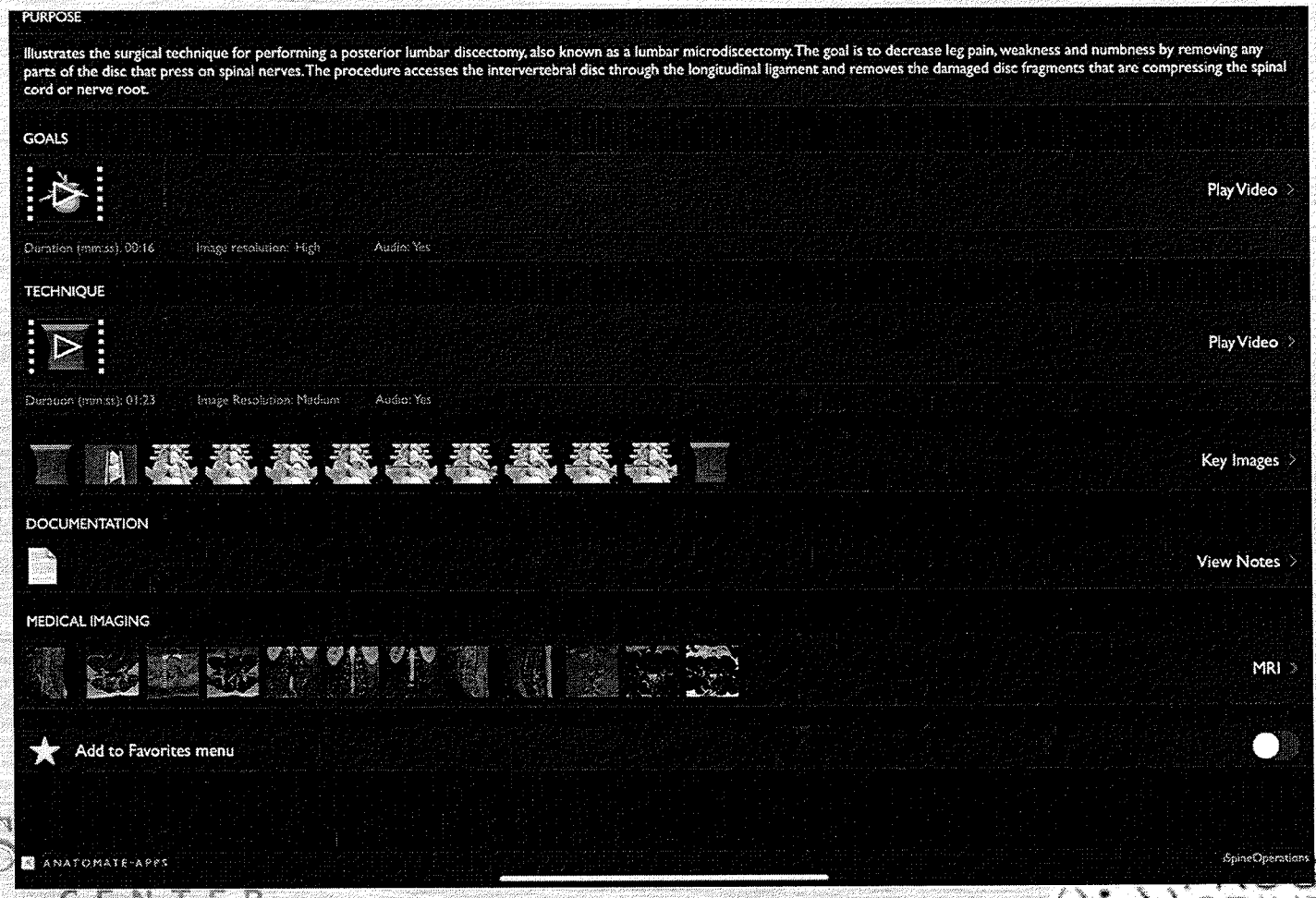
Background Information

- Largest surgical study funded by US gov't
- Over 100 physicians at 13 centers
- Almost 3000 patients enrolled (2000 – 2005)
  - lumbar disc herniation (leg pain)
  - lumbar spinal stenosis (no instability)
  - degenerative spondylolisthesis / stenosis
- Randomized (RCT) and observational (OBS)

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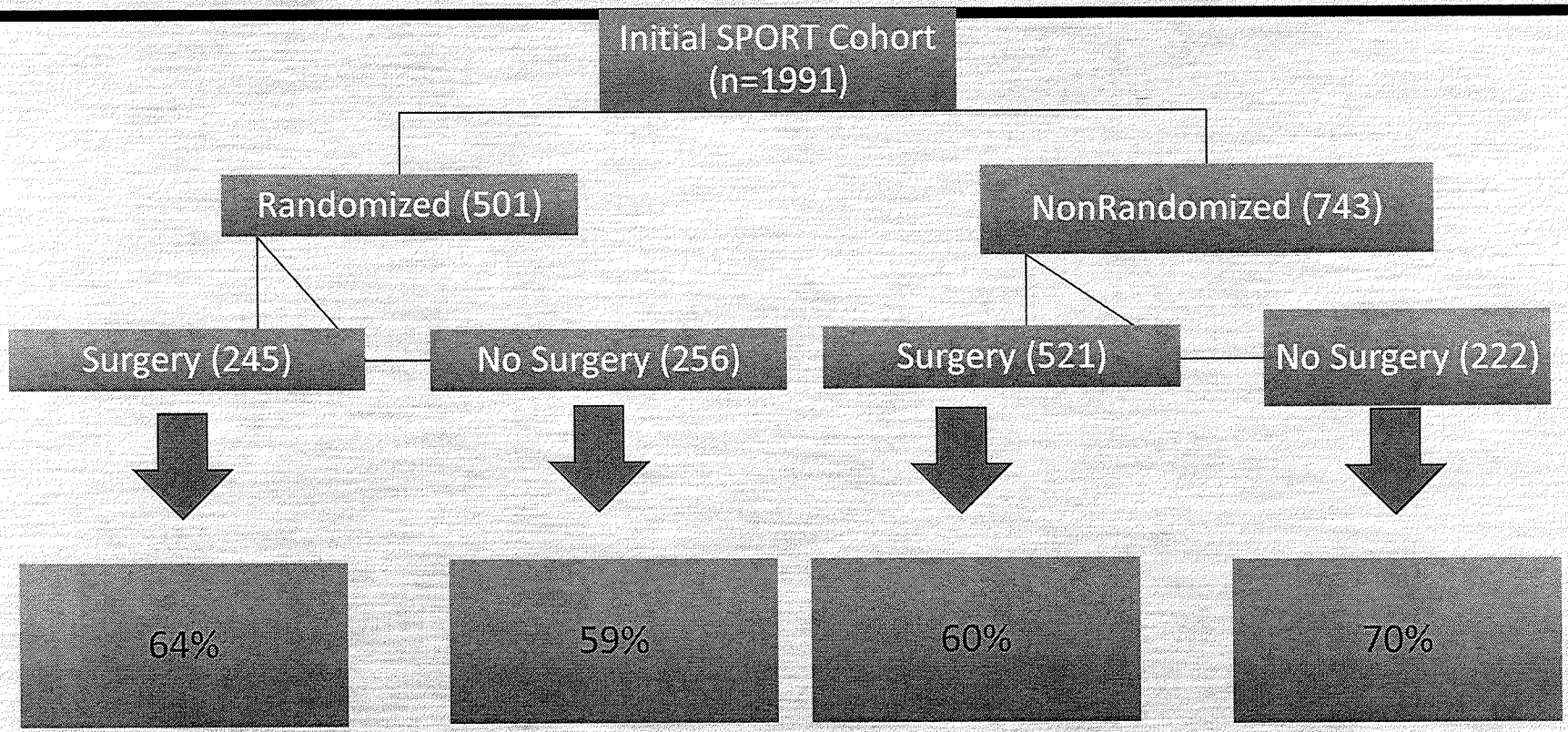
PROGRESSIVE SPINE & ORTHOPAEDICS

Discectomy Animation



CENTER
PROGRESSIVE SPINE & ORTHOPAEDICS

8 Year Follow Up?



Approximately 60%

Lurie Spine 2013

Complications

- No Related Deaths
- No Cauda Equina Syndrome
- No Paralysis
- 3% Dural Tear Rate
- 15% Reop Rate by 8 Years
  - 85% Recurrent HNP at Same Level

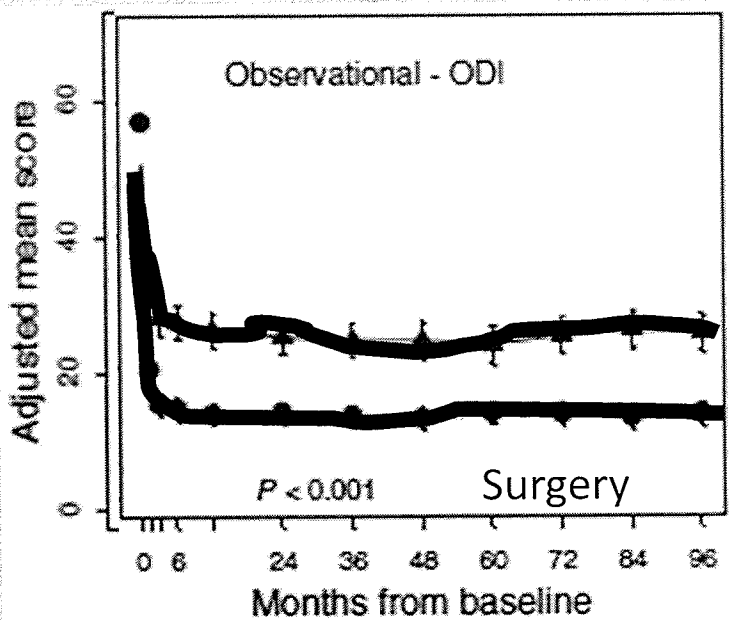
Spinal Disc CENTER

Lurie Spine 2013

PROGRESSIVE SPINE & ORTHOPAEDICS

Treatment Effects

- Relative Improvement in Outcome with Surgery
  - SF36 BP 12.6 (10.4-14.8)
  - SF36 PF 12.8 (10.8-14.9)
  - ODI -12.7 (-14.3 to -11)
  - Sciatica Bothersome -2.2 (-2.7



Spinal Disc
CENTER

Sport Subanalyses

- Other Analyses
  - Less Improvement with Surgery
    - Work Comp, Diabetic Patients
  - More Improvement with Surgery
    - Back Pain, Upper Lumbar Herniations, Married, Worsening Pain
  - No Effect on Outcome
    - ESI, Dural Tear, Specific Centers, Opioids
  - Worse overall outcome (surgery or nonsurgery)
    - Obesity, Duration of Symptoms > 6 Months

Desai Neurosurgery 2012

Desai JNS Spine 2011

Rihn JBJS 2011

Radcliff Spine 2013

Radcliff Spine 2012

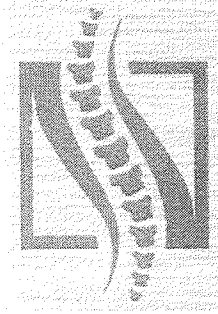
Pearson Spine 2012

Atlas Spine 2010

Freedman Spine 2011

Pearson Spine 2008

Lurie JBJS 2008



Spinal Disc
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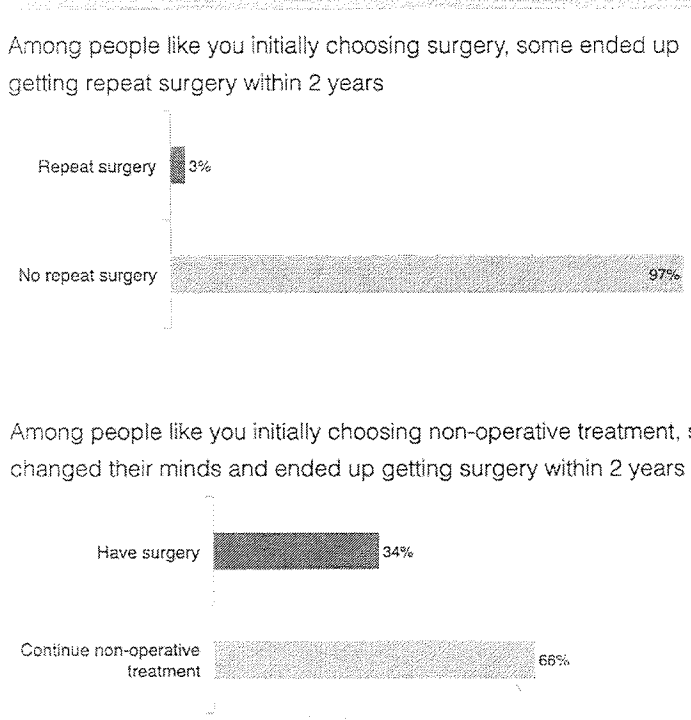


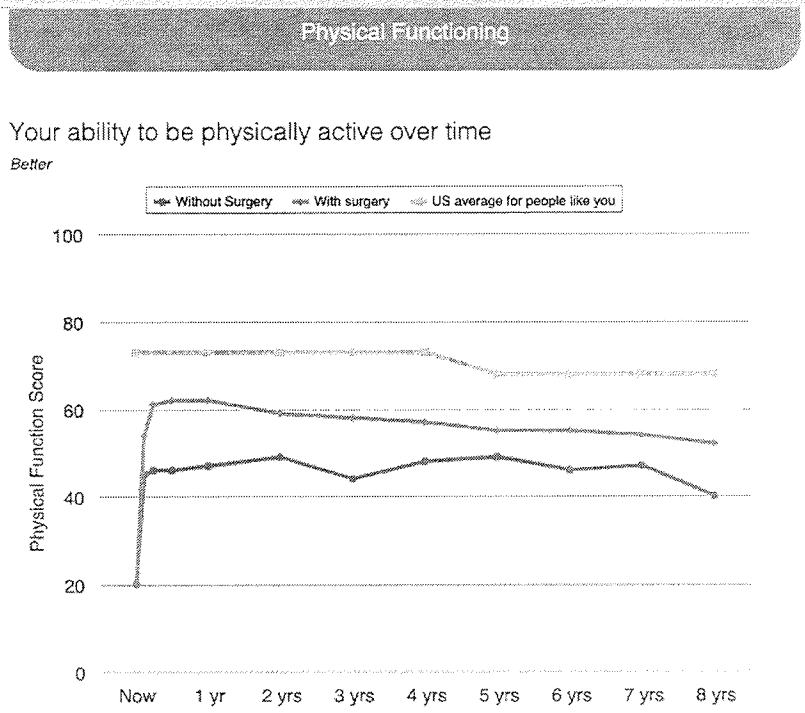
PROGRESSIVE
SPINE & ORTHOPAEDICS

The Future

(http://spinesurgerycalc.dartmouth.edu/calc/introduction.html).

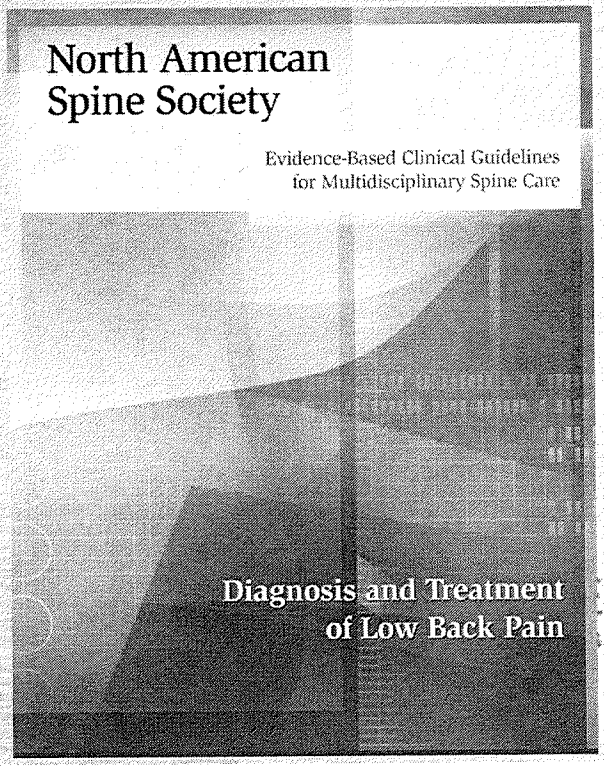
- Outcome calculators
- Predictive Analytics





Contribution of Research - Guidelines

Surgical Treatment	
Surgical Question 1. In patients with low back pain, does surgical treatment vs medical/interventional treatment alone decrease the duration of pain, decrease the intensity of pain, increase the functional outcomes of treatment and improve the return-to-work rate?	A systematic review of the literature yielded no studies to adequately address this question.
Surgical Question 2. In patients with low back pain, are there predictive factors which determine the benefit of initial treatment with surgical intervention versus initial medical/interventional treatment?	A systematic review of the literature yielded no studies to adequately address this question.
Surgical Question 3. In patients undergoing fusion surgery for low back pain, which fusion technique results in the best outcomes for the following: decreased duration of pain, decreased intensity of pain, increased functional outcomes of treatment and improved return-to-work rate? a. Posterolateral fusion without internal fixation vs b. Posterolateral transverse fusion with internal fixation vs c. Stand-alone (anterior) interbody fusion vs d. Transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) vs e. Circumferential fusion (anterior interbody, lateral techniques)	There is insufficient evidence to make a recommendation for or against a particular fusion technique for the treatment of low back pain. **Grade of Recommendation: I**
Surgical Question 4. In patients undergoing fusion surgery for low back pain, are clinical outcomes, including duration of pain, intensity of pain, functional outcomes and return-to-work status, different for multi-level fusions vs single level fusions?	A systematic review of the literature yielded no studies to adequately address this question.
Surgical Question 5. In patients undergoing fusion surgery for low back pain, does radiographic evidence of fusion correlate with decreased duration of pain, decreased intensity of pain, increased functional outcomes of treatment and improved return-to-work rate?	There is insufficient evidence to make a recommendation regarding whether radiographic evidence of fusion correlates with better clinical outcomes in patients with low back pain. **Grade of Recommendation: I**



NASS Coverage Recommendations

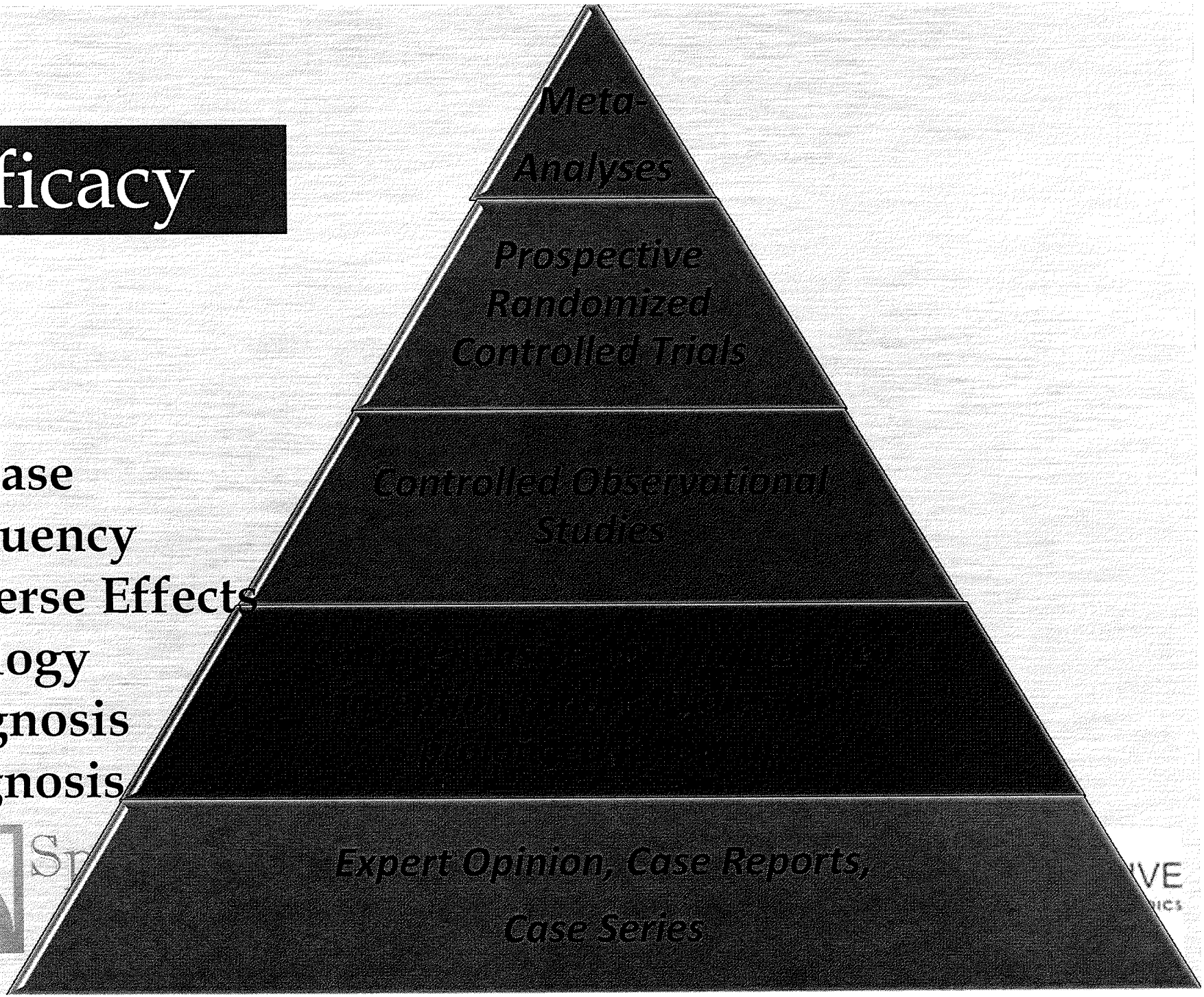
Can be helpful to adjudicate treatment disputes

Scope and Clinical Indications

Lumbar fusion (regardless of the technique, which includes noninstrumented fusion) may be indicated for the following diagnoses with qualifying criteria, when appropriate.

1. **Infection** (including tuberculosis) involving the spine in the form of discitis, osteomyelitis or epidural abscess in EITHER of the following cases:
   a. Instability is present
   b. Debridement and/or decompression is anticipated to result in instability
2. **Tumor** involving the spine or spinal canal in EITHER of the following cases:
   a. Instability is present
   b. Resection and/or decompression is anticipated to result in instability
3. **Traumatic injuries,** including fractures, fracture-dislocations, dislocations, or traumatic ligamentous disruption in EITHER of the following cases:
   a. Instability is present
   b. Decompression of the spinal canal is anticipated to result in instability
   c. Bracing even though an option, not feasible secondary to medical status, additional injuries or comorbidities
4. **Deformity** that includes the lumbar spine (eg, scoliosis that is restricted to the lumbar spine or a thoracolumbar deformity that ends in the lumbar spine) that meets ALL of the following criteria:
   a. Sagittal or coronal imbalance of at least 5 cm is present, as measured on long-plate, standing radiographs of the entire spine OR documented progression of deformity by at least 10° as measured on consecutive radiographs over a one year period OR a fixed curve greater than 30° in the coronal plane OR lateral listhesis of at least 10%[1] OR proximal junctional kyphosis defined as a segmental Cobb angle of at least 10° or 10° of progression from the immediate postoperative images[2]
   b. Substantial functional limitation including severe back pain, difficulty ambulating and decreased ability to perform activities of daily living
   c. Failure of nonoperative treatment
5. **Stenosis** in the lumbar spine (either central or foraminal), as an adjunct to decompression (either direct or indirect, the latter of which can be affected via a lateral interbody fusion or anterior interbody fusion with disc space distraction and realignment), that meet ANY of the following criteria: (note: assumption is that the patient fulfills criteria for stenosis decompression as per *Lumbar Laminectomy Coverage Recommendation*)[3]
   a. Dynamic instability is present, as documented by flexion-extension radiographs or comparison of a supine and upright image, defined as a difference in translational alignment between vertebrae greater than 3 mm between views
   b. Spondylolisthesis (defined as at least 3 mm of anterolisthesis of the upper vertebra in relation to the lower vertebra) is present, either isthmic (ie, secondary to a posterior arch fracture) or degenerative type
   c. Cases in which decompression will likely result in iatrogenic instability, such as foraminal stenosis, during which greater than 50 percent of the facet joint will be removed to adequately decompress the exiting nerve root, or in which disc

Efficacy



Disease
Frequency
Adverse Effects
Etiology
Diagnosis
Prognosis

Journals

Journal (best to worst)	Impact Factors
New England Journal of Medicine	31.736
Nature	30.432
Lancet	15.397
Journal of Neurosurgery	2.626
Spine	2.311
Am. J. of Sports Medicine	2.270
J. Bone Joint Surg (A)	2.046
J. of Trauma	1.617
J. Bone Joint Surg (B)	1.457
CORR	1.208

http://www.genebee.msu.su/journals/if02a.html

Spinal Disc CENTER

PROGRESSIVE SPINE & ORTHOPAEDICS

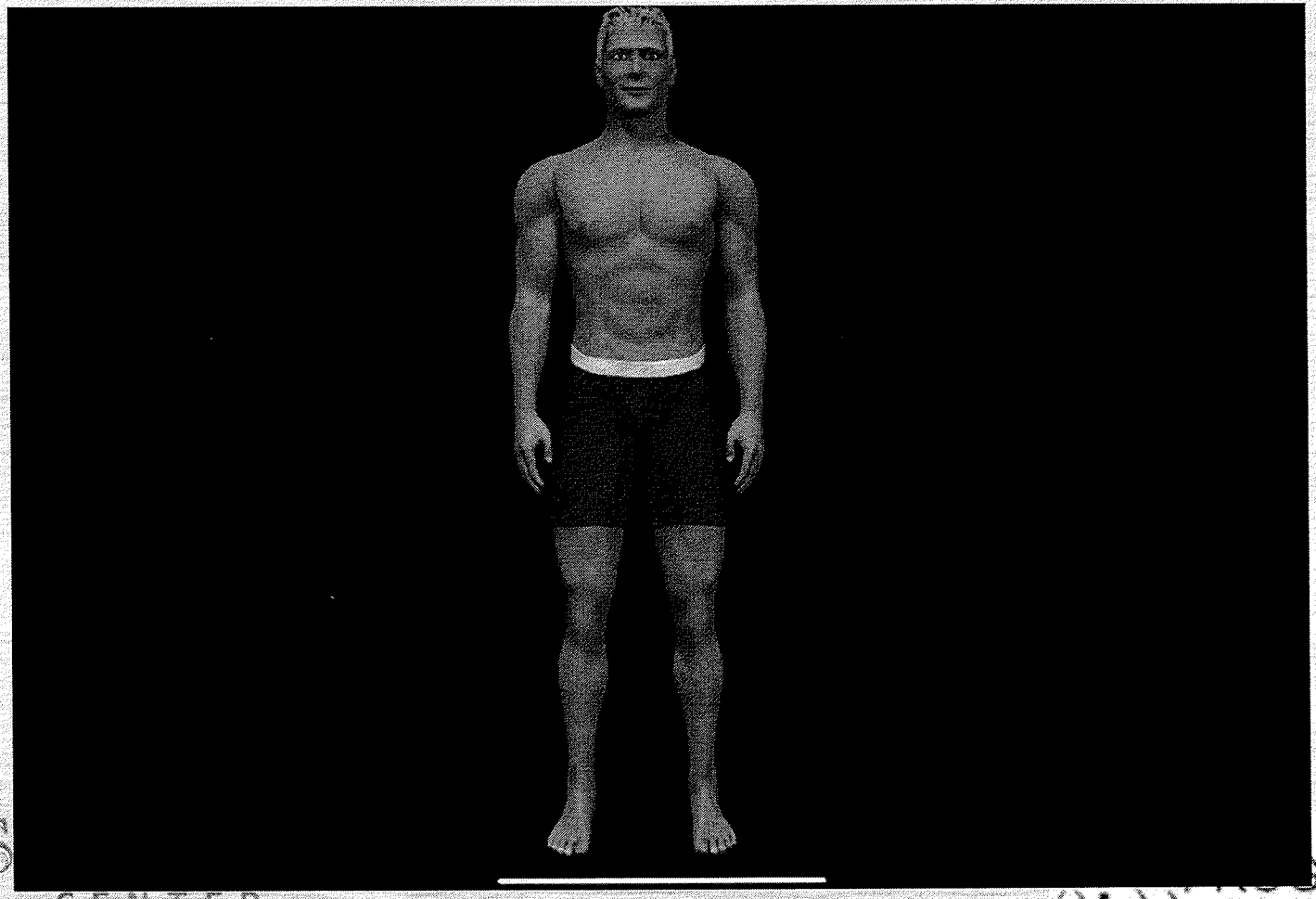
Outline

- Spine Surgeon
- Clinical Evidence
- Minimally Invasive
- Disc Replacement
- Opioids

Spinal Disc CENTER

PROGRESSIVE SPINE & ORTHOPAEDICS

Laminectomy Animation



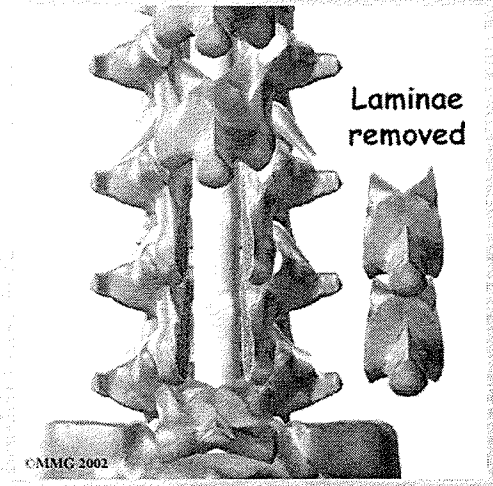
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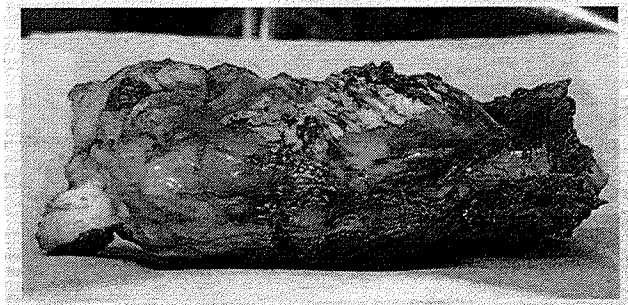
GRESSIVE
SPINE & ORTHOPAEDICS

Lumbar laminectomy

- Oldest, most reliable spine proce
- Bone cutting











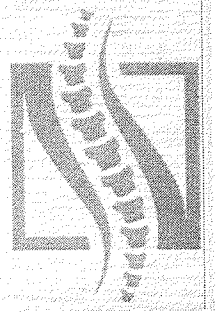
Spinal Disc
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PROGRESSIVE
SPINE & ORTHOPAEDICS

NASS Criteria

Lumbar decompression, including the spectrum of options noted above, may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. **Lumbar spinal stenosis**, primary or recurrent, meeting the following criteria:
    a. Signs and symptoms of neurogenic claudication or radiculopathy correlated with imaging
    b. Six weeks of nonoperative treatment; a longer period of 12 weeks can be considered if patients are still functional without any neurologic deficits
    c. The following can mitigate the need for initial nonoperative trial
        i. Severity of symptoms causes forced bed rest or places one at significant risk for a fall
        ii. Stenosis results in functionally limiting motor weakness or numbness
        iii. Progressive neurologic deficit
        iv. Severity of symptoms preventing work and not responding to initial nonoperative treatment
2. **Synovial facet cyst** associated with either radiculopathy or neurogenic claudication
    a. Signs and symptoms of neurogenic claudication/radiculopathy correlating with imaging
    b. At least 6 weeks of nonoperative treatment
    c. The following can mitigate the need for initial nonoperative trial
        i. Severity of symptoms causes forced bed rest or places one at significant risk for a fall
        ii. Stenosis results in functionally limiting motor weakness
        iii. Progressive neurologic deficit
        iv. Severity of symptoms preventing work and not responding to initial nonoperative treatment
3. **Cauda Equina Syndrome** caused by prominent compression of the thecal sac in the lumbar spine, with resultant saddle (perineal) anesthesia, new onset loss of bowel/bladder function, or new onset of lower extremity neurologic deficits not explained by a more proximal lesion
    a. Once diagnosis of acute cauda equina syndrome is established, urgent surgery is indicated
4. **Tumor:** In order to perform any of the following:
    a. Open biopsy to determine further treatment options
    b. Direct decompression of the spinal canal
    c. Access to the spinal canal/ventral spine for intralesional or en block resection
    d. Laminoplasty can be considered as an alternative method to access the spinal canal
5. **Fracture:** In order to perform any of the following:
    a. Removal of fractured posterior elements causing spinal stenosis
    b. Access the spinal canal to address retropulsion of the vertebral body
    c. To address a traumatic cerebrospinal fluid leak
6. **Epidural/subdural hematoma:** To decompress the spinal canal and evacuate the hematoma
7. **Infection:** In order to perform any of the following:
    a. Decompression of the spinal canal and evacuation of an abscess
    b. To access disc space for biopsy and/or debridement
        i. Clinical progression despite initial antibiotic management
        ii. Need to isolate the organism and failure/inability to do so via less invasive mechanisms (ie, image-guided needle biopsy)
8. **Degenerative/Isthmic Spondylolisthesis**
    a. Signs and symptoms of back pain, radiculopathy and/or neurogenic claudication, correlated with imaging
    b. Six weeks of nonoperative treatment; a longer period of 12 weeks can be considered if patients are still functional without any neurologic deficits
    c. The following can mitigate the need for initial nonoperative trial:
        i. Severity of symptoms causes forced bed rest or places one at significant risk for a fall
        ii. Stenosis results in functionally limiting motor weakness
        iii. Progressive neurologic deficit
        iv. Severity of symptoms preventing work and not responding to initial nonoperative treatment



PROGRESSIVE SPINE & ORTHOPAEDICS

Laminectomy with Disc

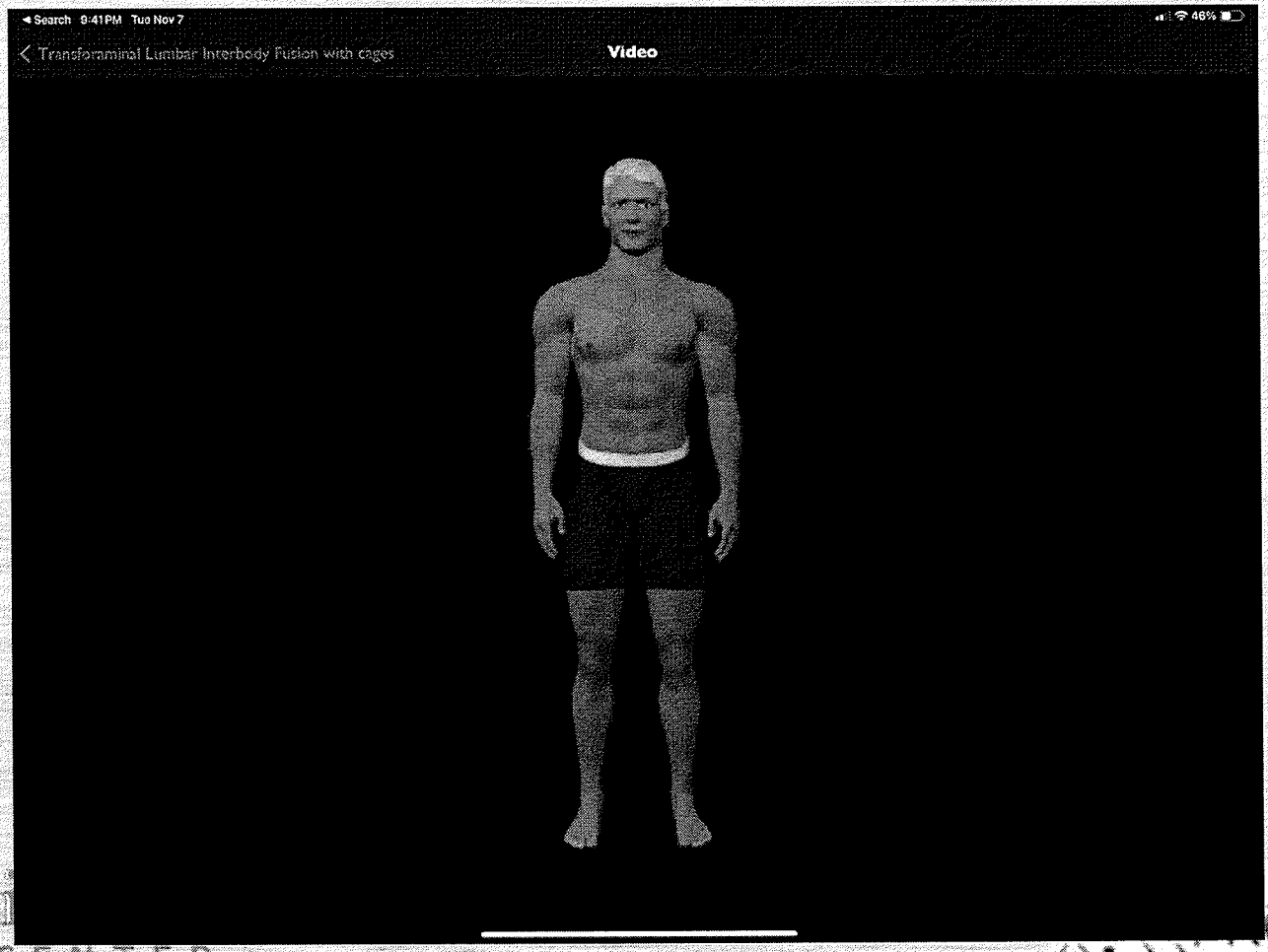


NASS Criteria

Lumbar discectomy (which can be performed using a variety of techniques including but not limited to open discectomy, endoscopic assisted discectomy, microscope assisted discectomy, and less invasive tube assisted discectomy) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Infection involving the disc space in EITHER of the following cases:
    a. In order to perform an open disc biopsy and culture when an organism has not been identified by other less invasive means (e.g. blood cultures, percutaneous needle biopsy)
    b. In order to perform a disc space/spinal canal debridement if ANY of the following is present:
        i. Lack of clinical response to an appropriate course of antibiotics
        ii. Epidural abscess with associated neurological deficits
        iii. Signs of systemic sepsis associated with the disc space infection
2. Cauda equina syndrome associated with a lumbar disc herniation, defined as any combination of saddle (perineal) anesthesia, new onset loss of bowel and/or bladder control (incontinence or retention) or new onset of lower extremity neurological deficits not explained by a more proximal lesion
3. Primary or recurrent lumbar disc herniation with radiculopathy
    a. Indicated when both criteria are met:
        i. Lumbar radiculopathy is present and a correlative lesion is present on advanced imaging
        ii. Presence of symptoms for at least 6 weeks and inability to tolerate or failure to respond to 4 weeks of nonsurgical care, including but not limited to physical therapy, chiropractic treatment, and/or fluoroscopic-guided epidural steroid injections
    b. The following can mitigate the need for initial nonoperative trial and support earlier surgical intervention
        i. Severe pain forcing bed rest or preventing work and unresponsive to initial nonoperative treatment
        ii. Herniation results in functionally limiting motor weakness (eg, foot drop)
        iii. Progressive neurological deficit

Lumbar Fusion Animation



Spi CENTER

OGRESSIVE SPINE & ORTHOPAEDICS

Screws and Rods



CENTER

SPINE & ORTHOPAEDICS

Cage



CENTER

SPINE & ORTHOPAEDICS

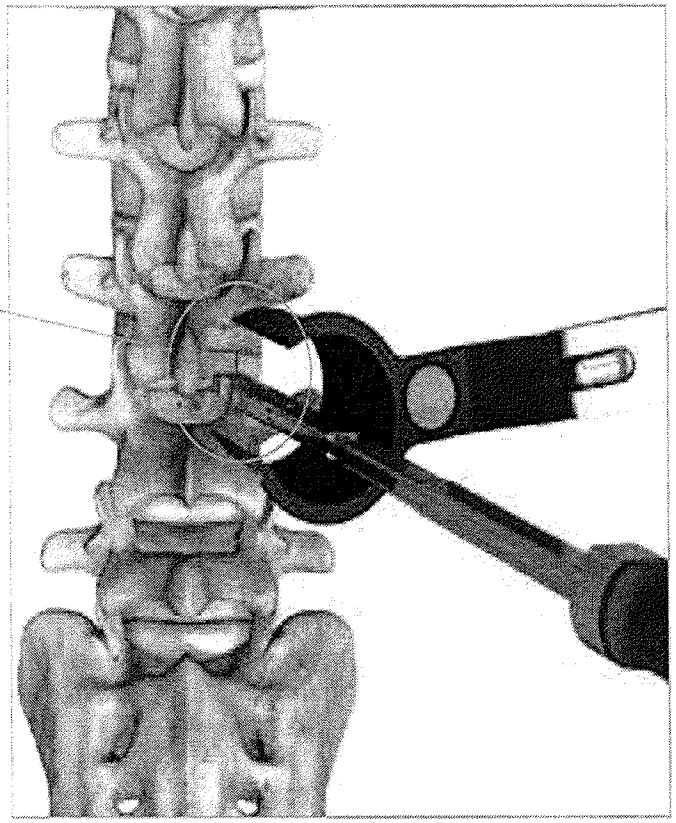
Minimally Invasive Approaches

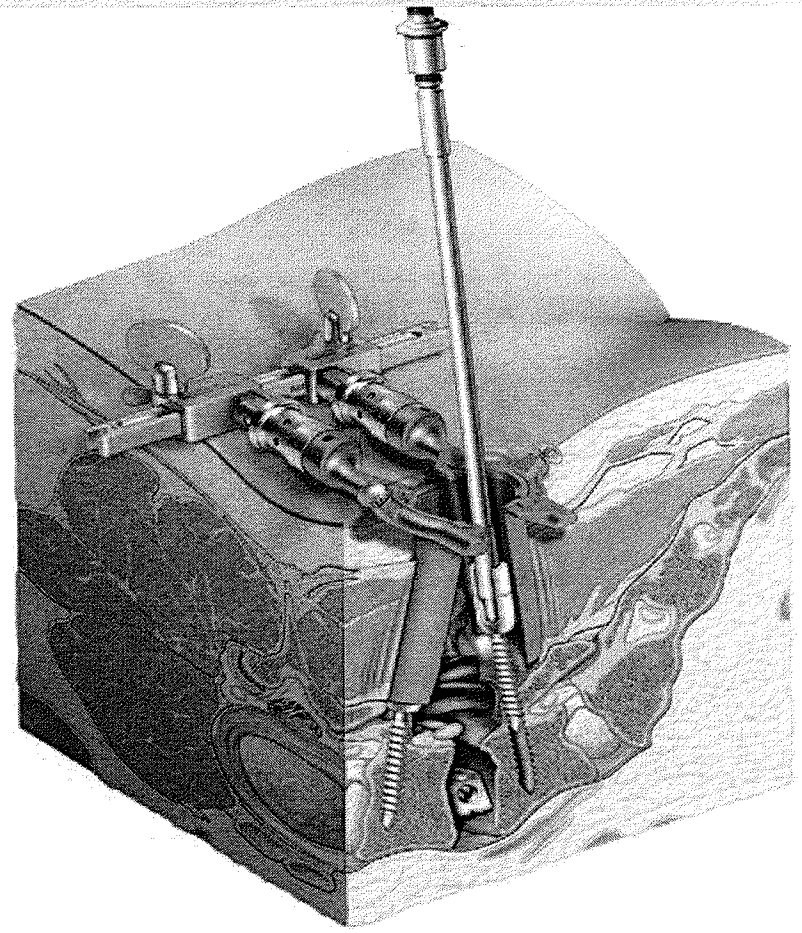




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SPINE & ORTHOPAEDICS

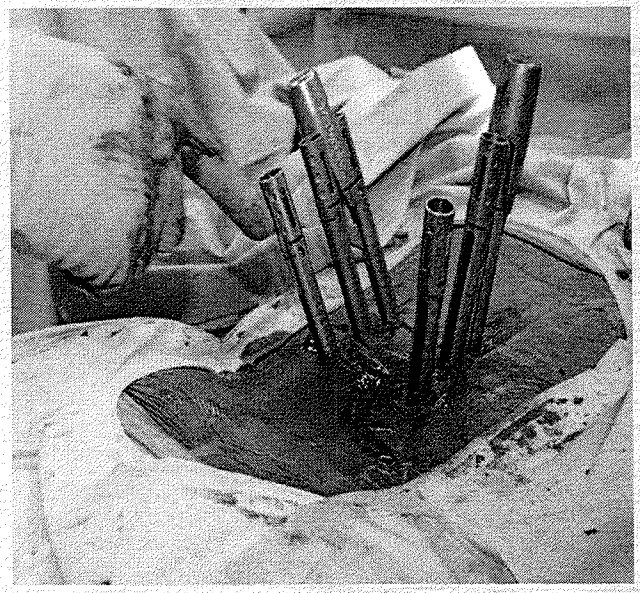


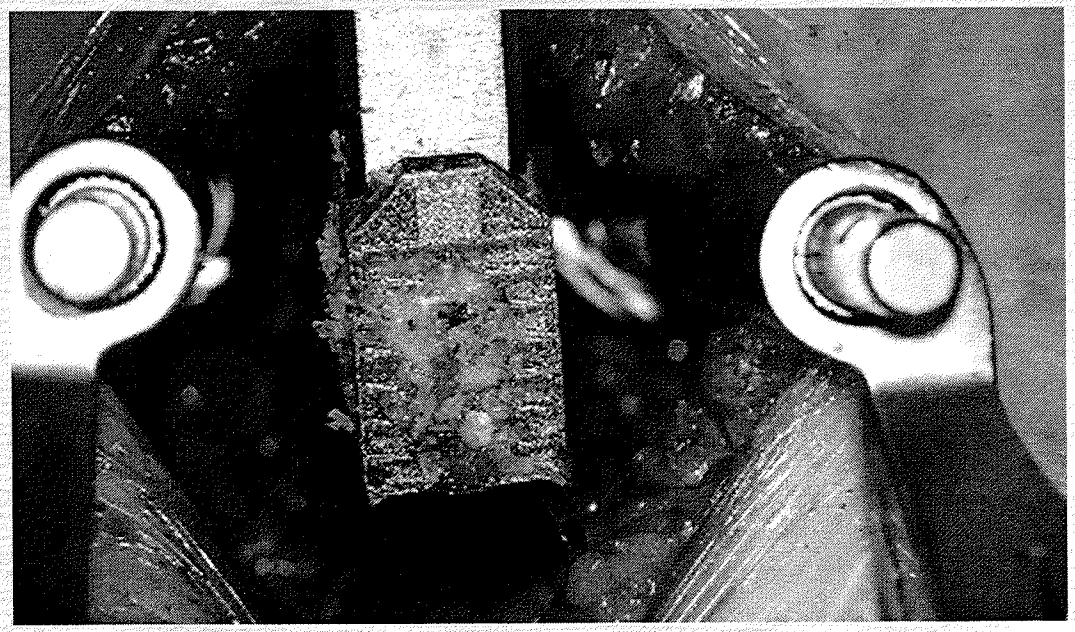


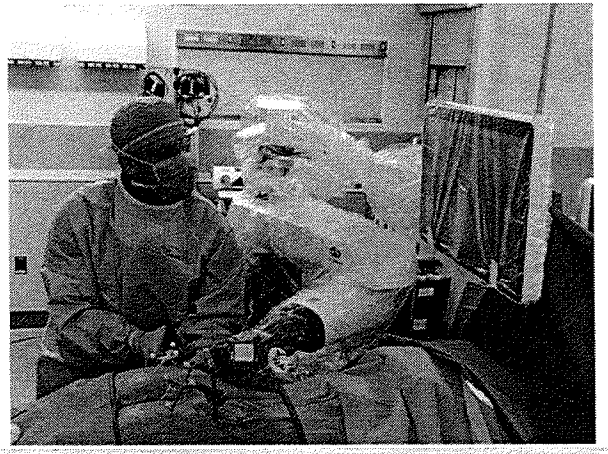
Spinal Disc
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PROGRESSIVE
SPINE & ORTHOPAEDICS

Same Instrumentation

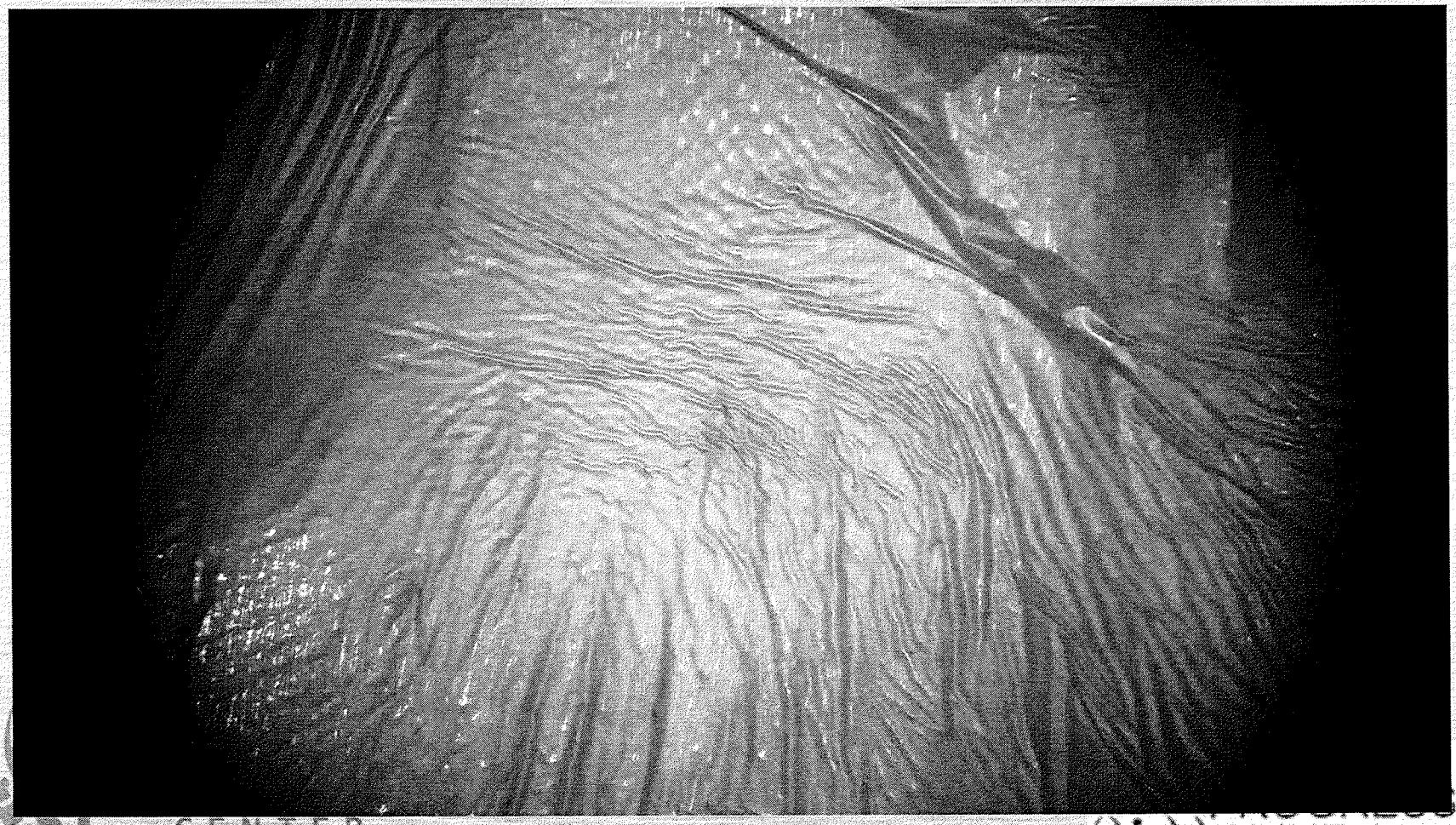






PROGRESSIVE SPINE & ORTHOPAEDICS

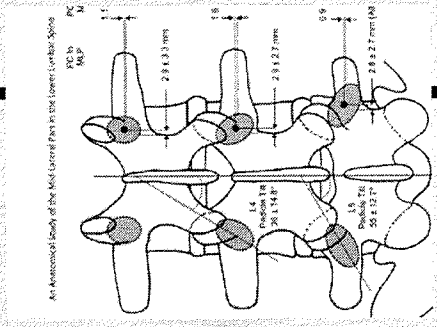
Minimally Invasive



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SPINE & ORTHOPAEDICS

Screws



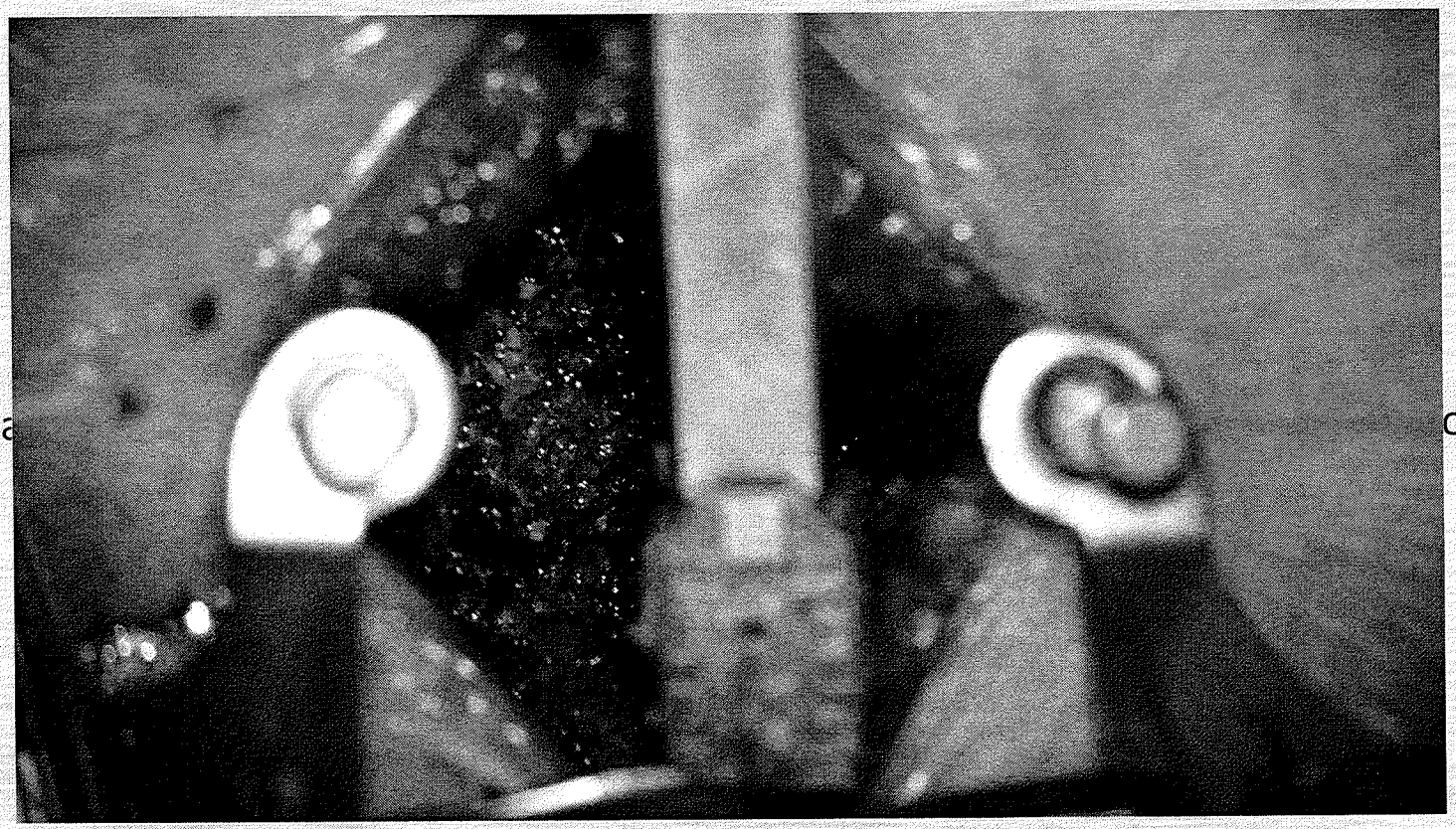
Lateral



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PROGRESSIVE SPINE & ORTHOPAEDICS

Cage



Hea ot

Medial

Spinal Disc CENTER

PROGRESSIVE SPINE & ORTHOPAEDICS

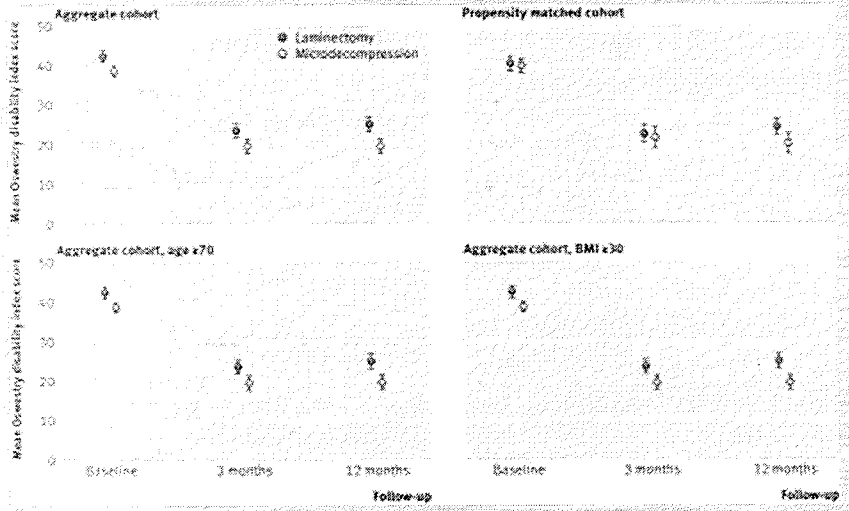
Minimally Invasive Surgery

- Same outcome (driven by the underlying diagnosis)
- Fewer short term complications (infections, hematomas, etc)
- Best for one to two level surgery

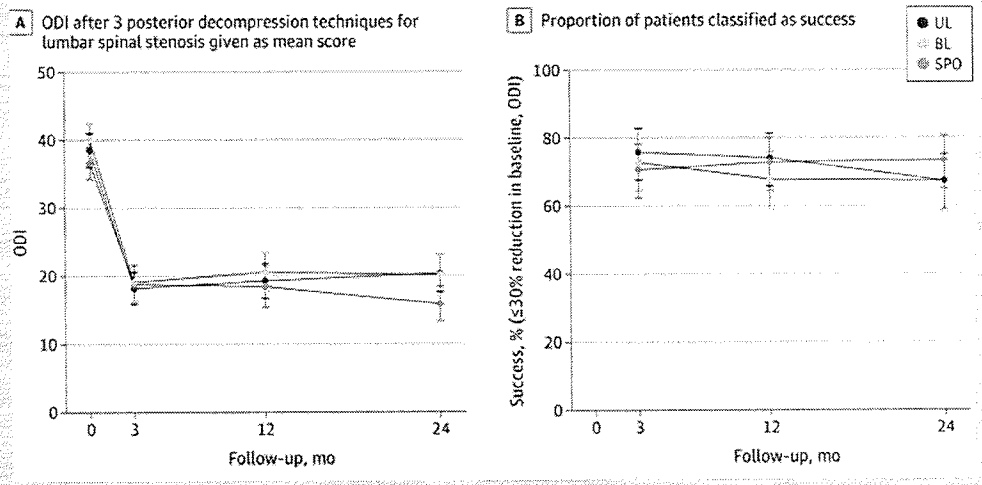
Spinal Disc CENTER

PROGRESSIVE SPINE & ORTHOPAEDICS

Minimally Invasive Spine



Nerland BMJ. 2015; 350: h1603.



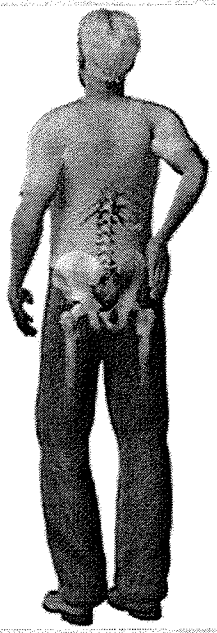
Hermansen JAMA Netw Open. 2022 Mar; 5(3): e224291.

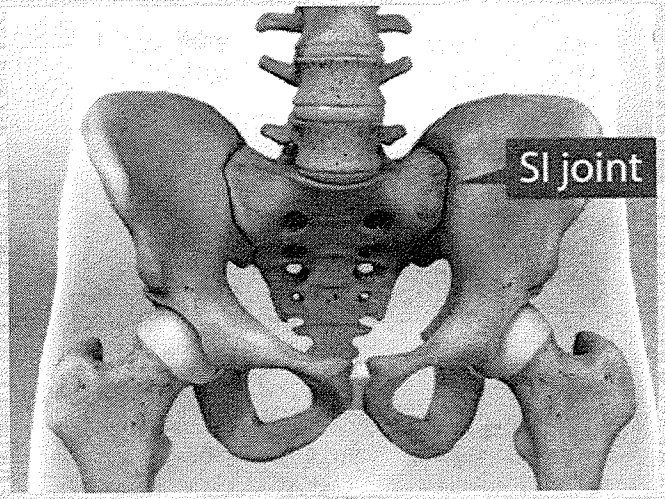
Spinal Disc CENTER

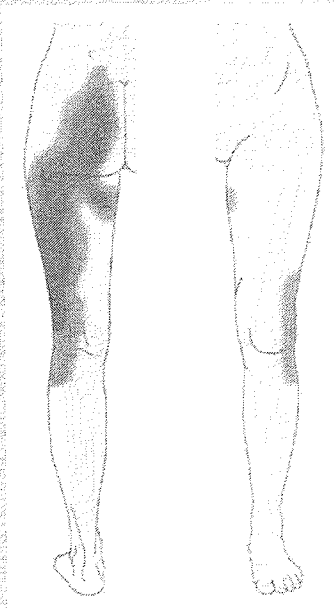
PROGRESSIVE SPINE & ORTHOPAEDICS

SI Joint Pain

Sacroiliac Joint Dysfunction



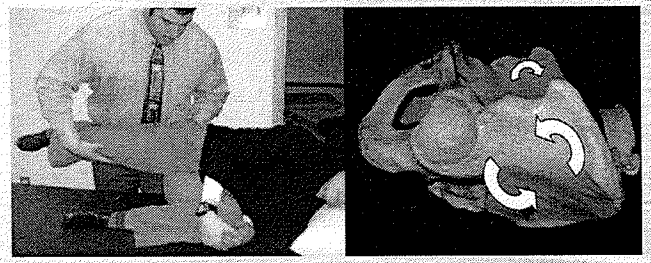


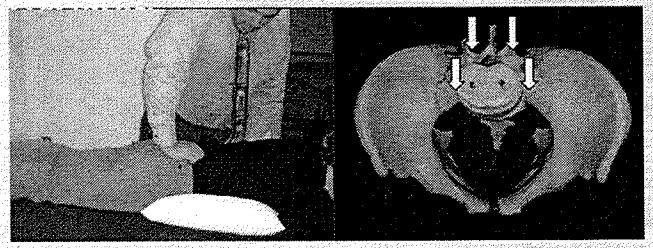


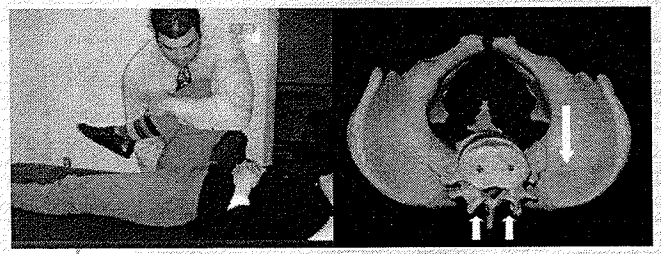
Spinal Disc CENTER

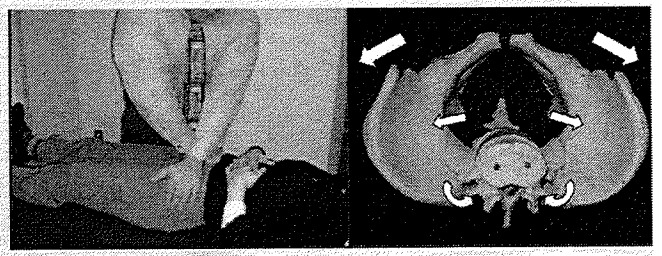
PROGRESSIVE SPINE & ORTHOPAEDICS

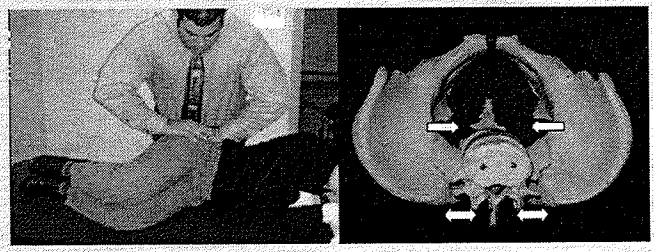
SI Joint Exam

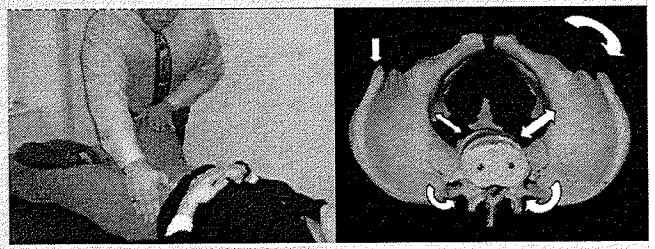












Spinal Disc
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PROGRESSIVE
SPINE & ORTHOPAEDICS

SI Workup

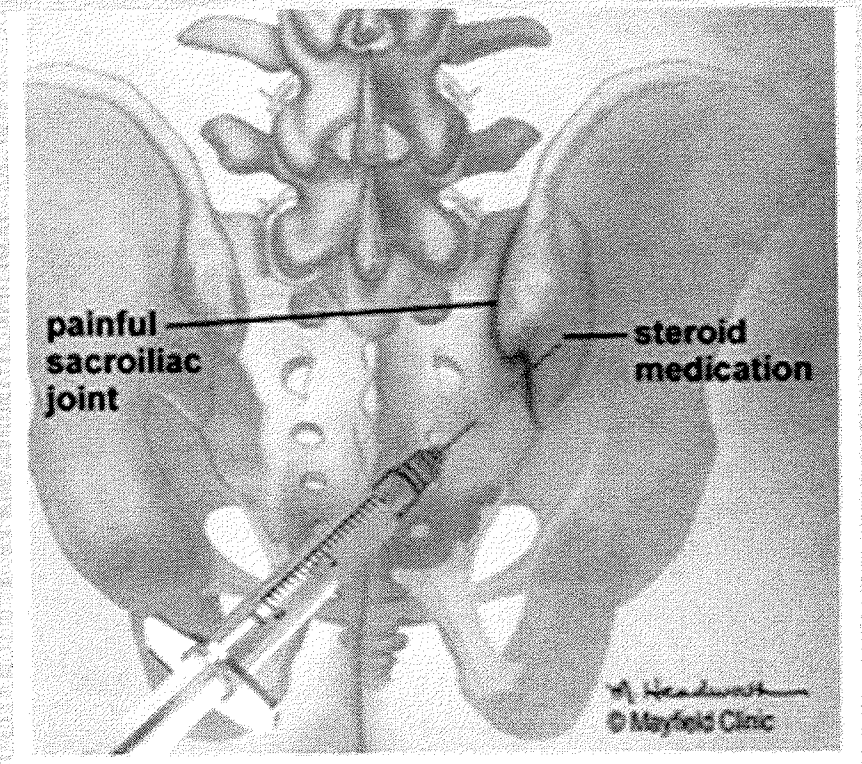
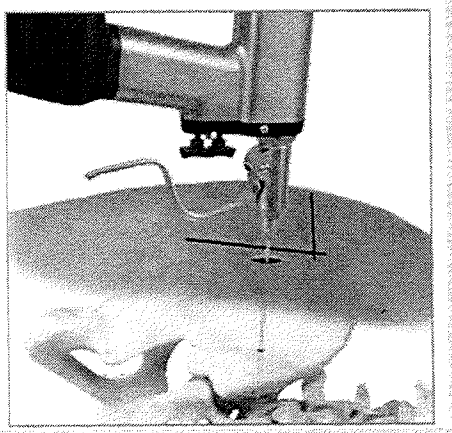


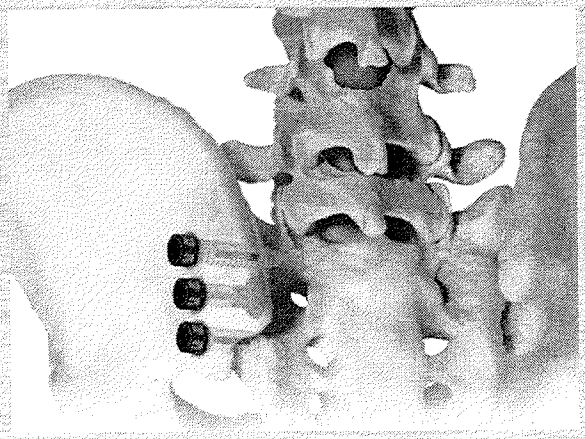
Figure 2. A needle is gently guided into the sacroiliac joint using x-ray fluoroscopy. An anesthetic and corticosteroid mixture (green) is injected into the inflamed joint.

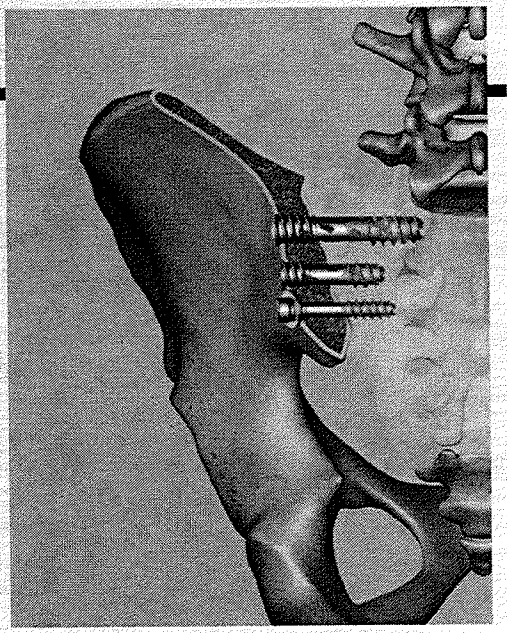
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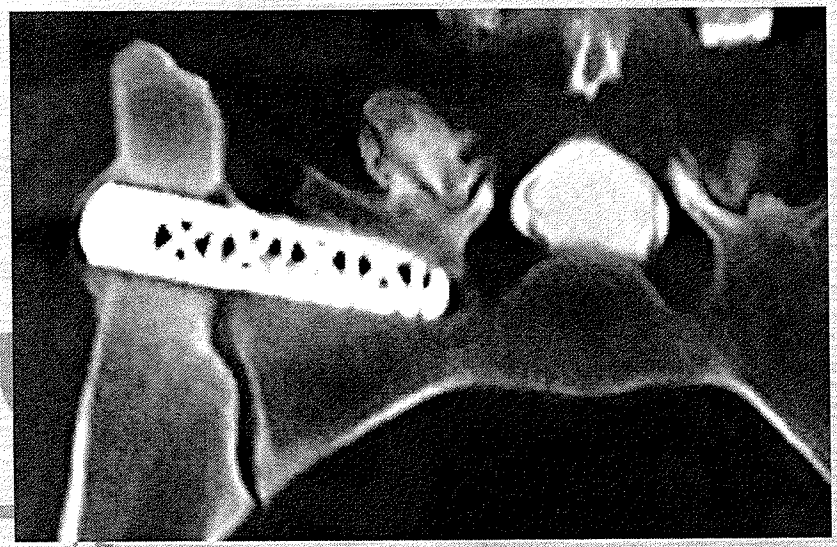
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SI Fusion







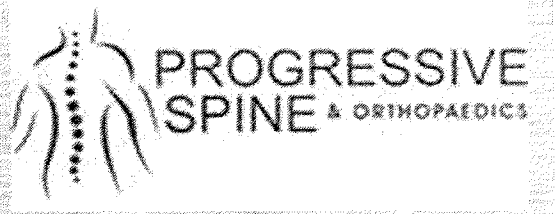




Spine Surgery

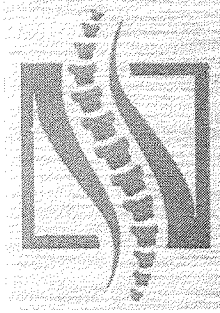
- Exposure Related Morbidity
- "Why does this patient still hurt? Everything healed."
- Nerve root retraction
- "Why cant they go back to work?"





Outline

- Spine Surgeon
- Evidence
- Minimally Invasive
- DISC Replacement
- Opioids



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Device Studies – Mobi C

Five-year Results of Cervical Total Disc Replacement Compared with Anterior Discectomy and Fusion for Treatment of 2-level Symptomatic Degenerative Disc Disease: A Prospective, Randomized, Controlled, Multicenter FDA IDE Clinical Trial

Kris Radcliff, MD[1]; Domagoj Coric, MD[2]; Todd Albert, MD[3]

[1]Rothman Institute, Thomas Jefferson University, Egg Harbor, NJ; [2]Carolina Neurosurgery and Spine Associates, Charlotte, NC; [3]Hospital for Special Surgery, New York, NY

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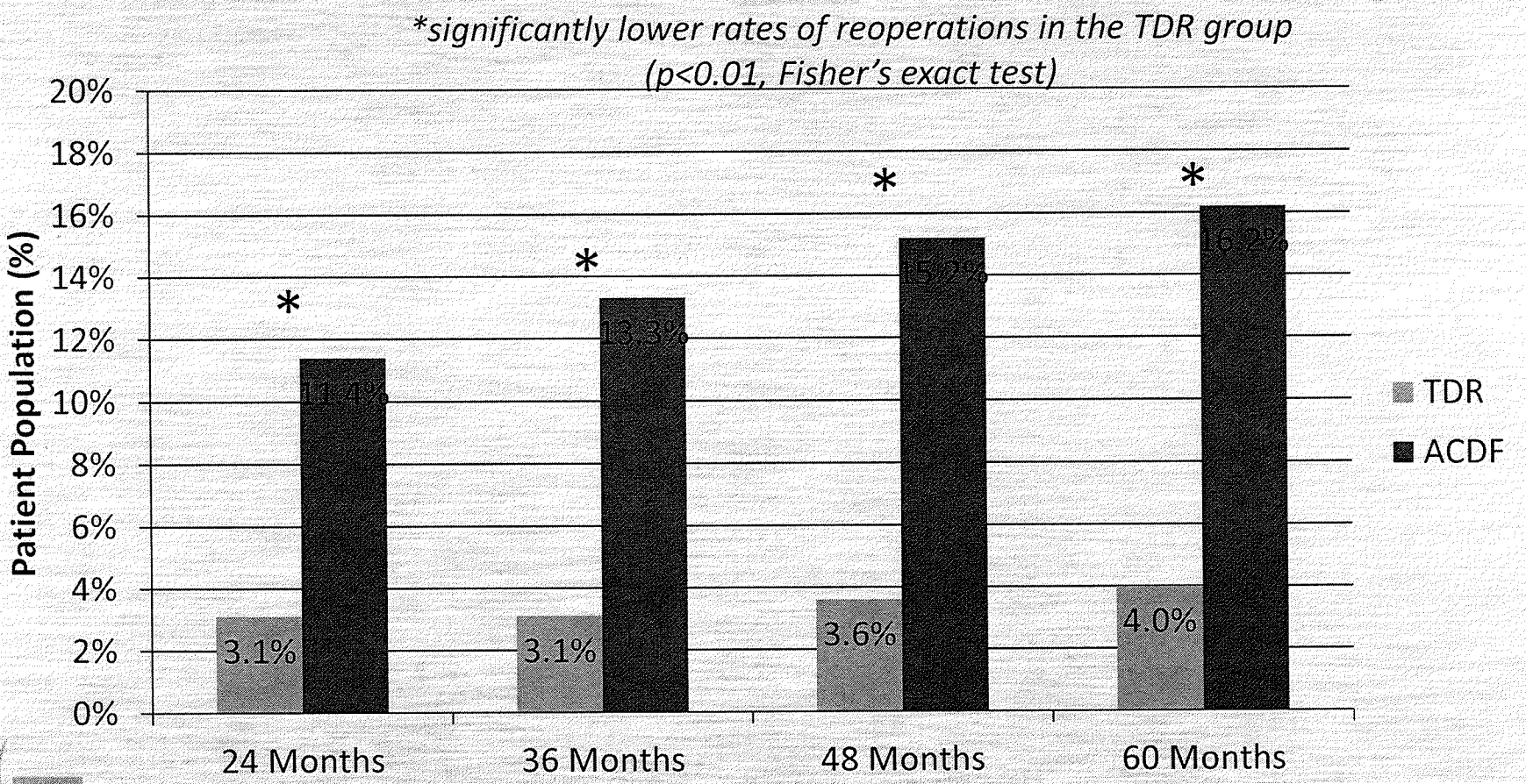
Overall Better/Worse

	2-Level		
VAS Neck Pain*	Mobi-C	ACDF	P value
Improved	86.0%	77.7%	0.15
Not improved	9.0%	15.5%	
Worse	5.0%	6.8%	

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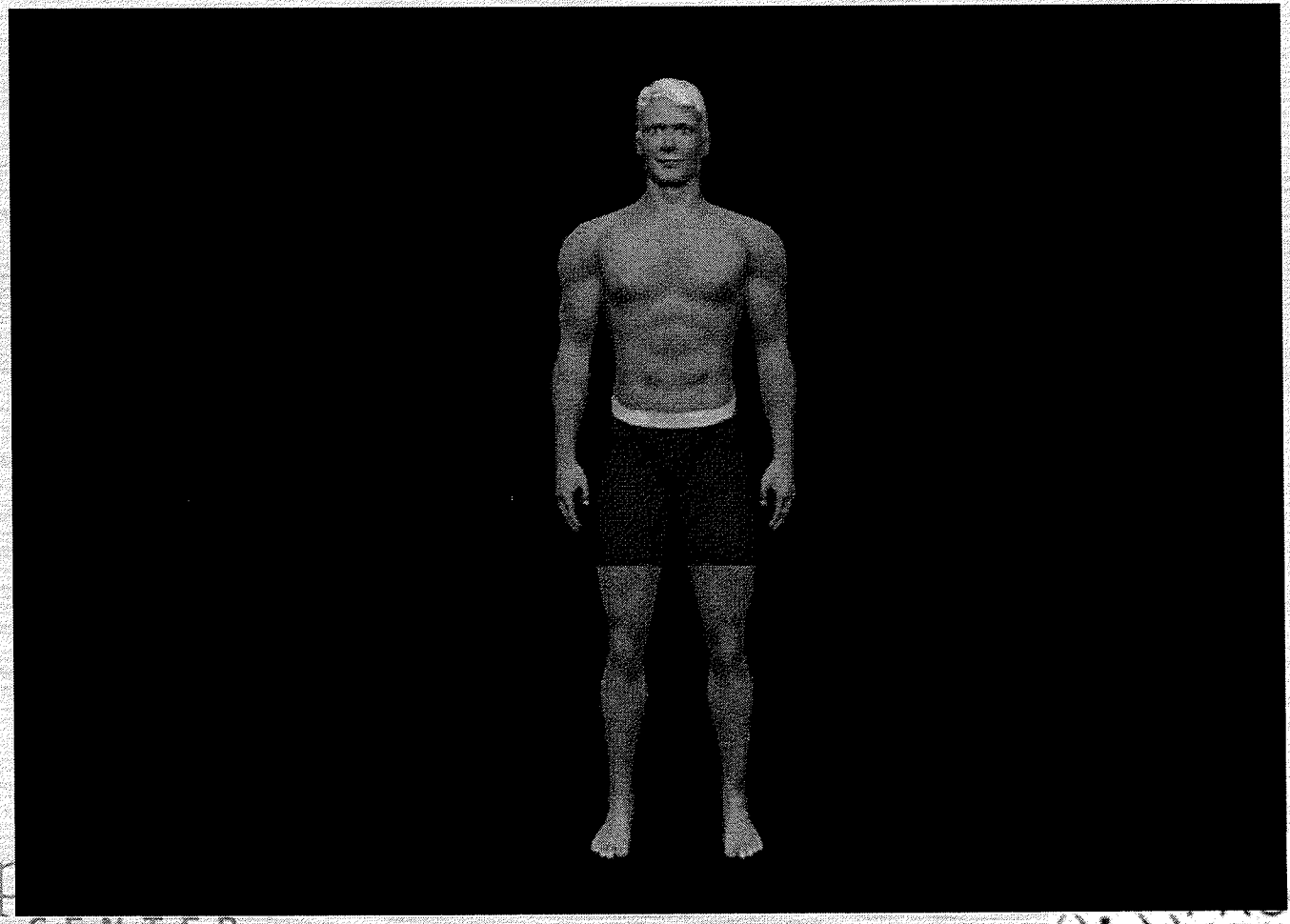
Subsequent Surgeries (Index Levels)



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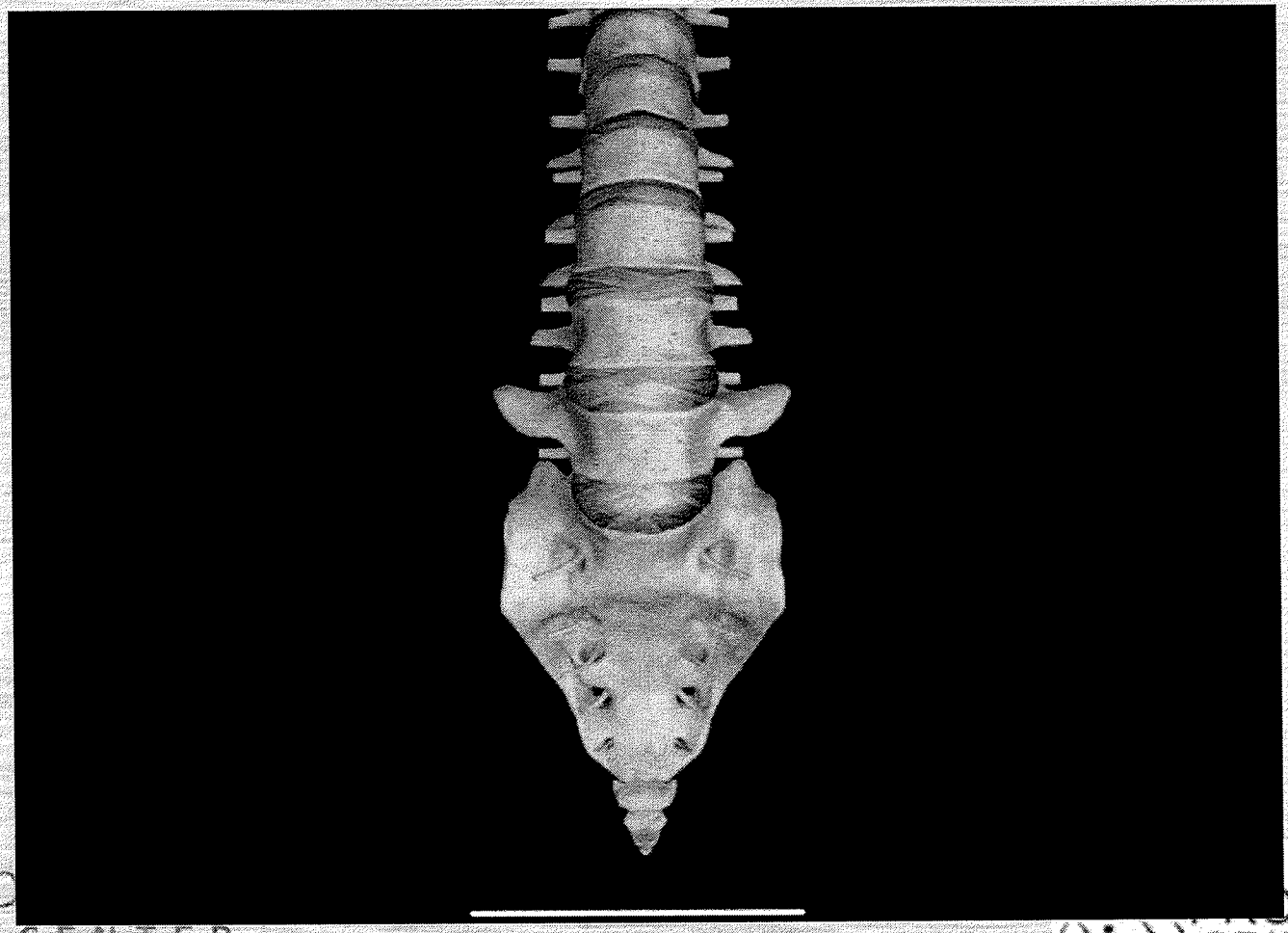
Lumbar Disc Replacement



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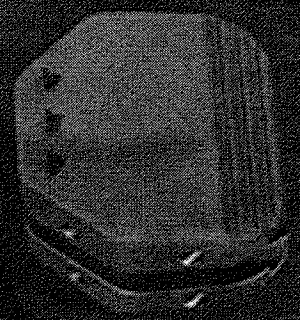
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Disc Replacement Animation



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activL® Artificial Disc



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CONFIDENTIAL

Final Long-Term Reporting from a Randomized Controlled IDE Trial for Lumbar Artificial Discs in Single-Level Degenerative Disc Disease: 7-Year Results

Kris Radcliff, MD,[1] Jack Zigler, MD,[2] Ernest Braxton, MD,[3] Glen Buttermann, MD,[4] Dom Coric, MD,[5] Peter Derman, MD, MBA,[2] Rolando Garcia, MD, MPH,[6] Anton Jorgensen, MD,[7] Nicole C. Ferko, MSC,[8] Aaron Situ, MSC, MQF,[8] James Yue, MD[9]

[1]Rothman Orthopedic Institute, Philadelphia, Pennsylvania, [2]Texas Back Institute, Plano, Texas, [3]Vail Health Vail Summit Orthopaedics and Neurosurgery, Vail, Colorado, [4]Midwest Spine & Brain Institute, Stillwater, Minnesota, [5]Carolina Neurosurgery and Spine Associates, Charlotte, North Carolina, [6]Orthopedic Care Center, Aventura, Florida, [7]Ortho San Antonio, San Antonio, Texas, [8]CRG-EVERSANA Canada, Inc, Burlington, Ontario, Canada, [9]Frank H. Netter School of Medicine, Quinnipiac University, Hamden, Connecticut

Presented by Kris Radcliff, MD[1]

This study was funded by Aesculap Implant Systems, LLC.

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Methods

Study Design: prospective, multicenter, randomized, controlled investigational device exemption study.

Patients: single-level, lumbar DDD who had failed >6 months non-operative care who were followed to 7 years.

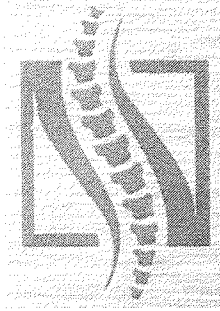
Interventions: randomized to receive activL (n=218) or ProDisc-L (n=65). Charité was not included in the 7-year analysis as it is not commercially available.

Primary Outcome: composite treatment success, which required patients to meet several criteria involving ODI, neurological status, ROM, freedom from post-operative surgery, and serious device-related adverse events.

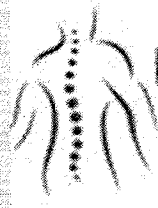
Secondary Outcomes: VAS back and leg pain severity, ODI, QoL via SF-36, patient satisfaction, return to work, opioid usage, ROM, radiographic evaluations of device status, AEs, and reoperations.

Follow-up: Patients returned for follow-up visits at 6 weeks, 3 months, 6 months, and annually thereafter for 7 years. A physical examination, neurological assessment, and 6-view x-rays were performed at follow-up visits.

AE, adverse events; DDD, degenerative disc disease; ODI, Oswestry Disability, Index; QoL, quality of life; ROM, range of motion; SAE, serious adverse events; SF-36, 36-item Short Form Survey.



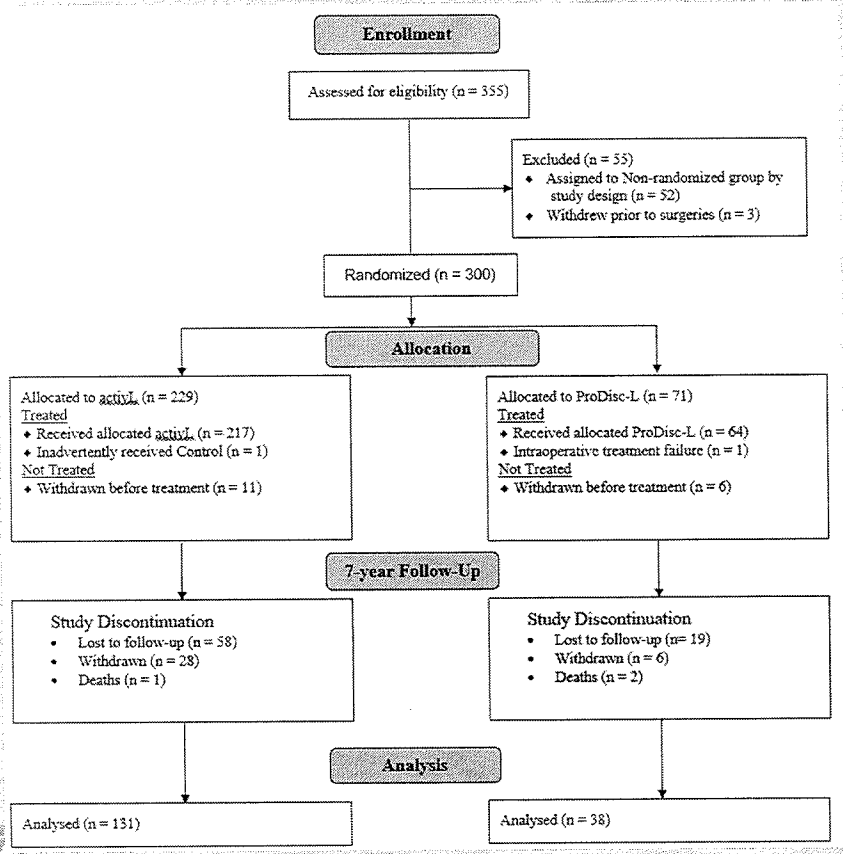
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CONSORT Flow Diagram

Figure 1: CONSORT Flow Diagram – activL vs. Prodisc-L



- In total, 131 patients in the activL arm and 38 in the ProDisc-L arm were included in the analysis at 7-year follow-up
- Through 7 years, the proportion of lost to follow-up was 39.9% in the activL arm and 40.6% in the ProDisc-L arm.
- Patient characteristics between the activL and ProDisc-L arm were balanced among patients at randomization and among patients remaining at 7 years
  - The only exception was the hepatic/biliary status for patients remaining at 7-years ($p < 0.05$)

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ODI and VAS Back & Leg Pain through 7 Years

Figure 2: ODI through 7 years post-treatment for activL vs. ProDisc-L.

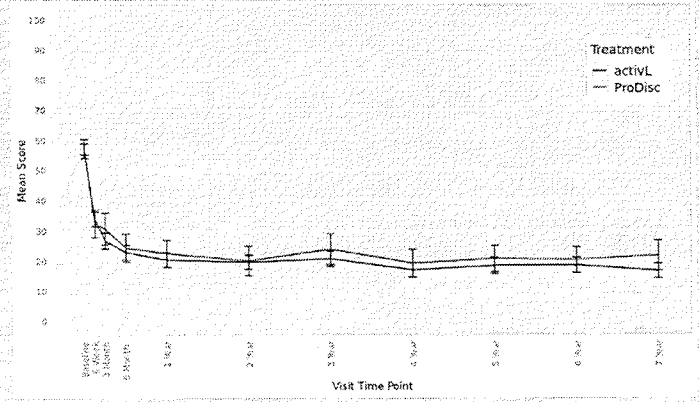
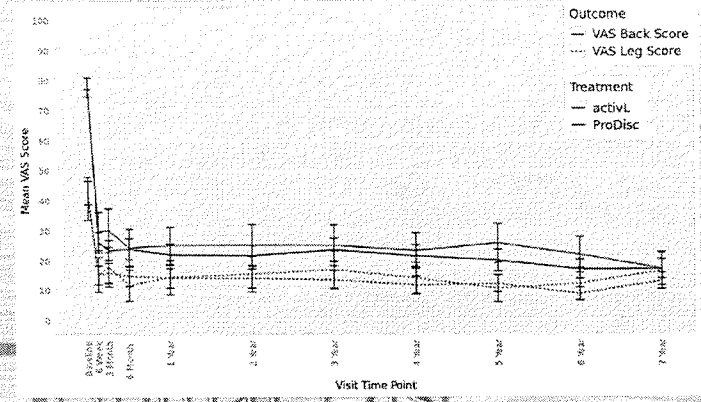


Figure 3: VAS back & leg score through 7 years post-treatment for activL vs. ProDisc-L.



- activL patients experienced **significant improvements** from baseline in ODI and VAS back and leg pain that were **maintained through to 7 years**.
- There were no statistically significant differences between activL and ProDisc-L for these outcomes.

MCS, mental component summary; ODI, Oswestry Disability Index; PCS, physical component summary; SF-36, 36-item Short Form Survey; VAS, visual analog scale.

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QoL and Time to Return to Work through 7 Years

Figure 4: SF-36 MCS and PCS through 7 years post-treatment for activL vs. ProDisc-L.

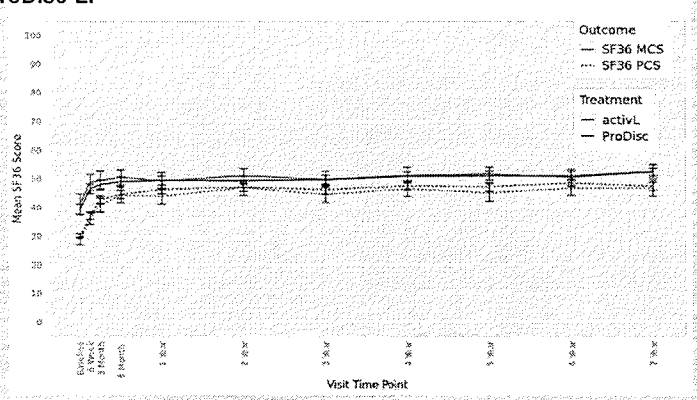
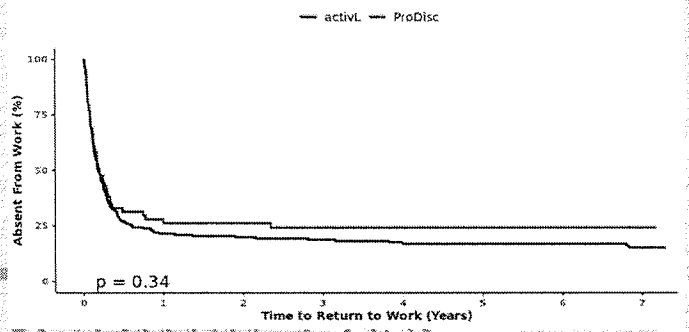


Figure 5: Time to return to work through 7 years for activL vs. ProDisc-L. Kaplan-Meier estimate is 82% with activL and 74% with ProDisc-L.



- activL patients experienced **significant improvements** from baseline in SF-36 PCS and MCS that were **maintained through to 7 years**.
- There were no statistically significant differences between activL and ProDisc-L for these outcomes.

MCS, mental component summary; ODI, Oswestry Disability Index; PCS, physical component summary; SF-36, 36-item Short Form Survey; VAS, visual analog scale.

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Return to Work, SAEs, & Opioid Usage through 7 Years

Figure 6: Freedom from SAEs through 7 years for activL vs. ProDisc-L. Kaplan-Meier estimate is 61.5% with activL and 43.1% with ProDisc-L.

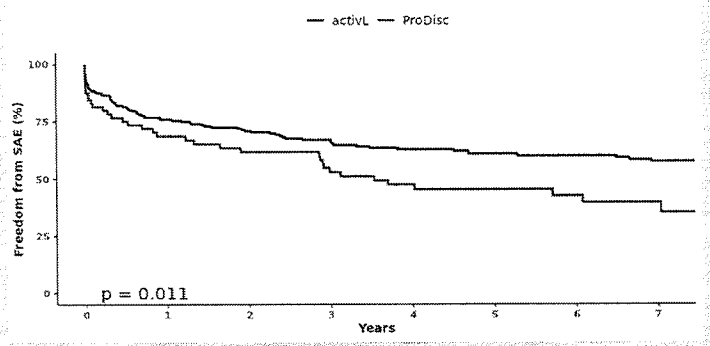
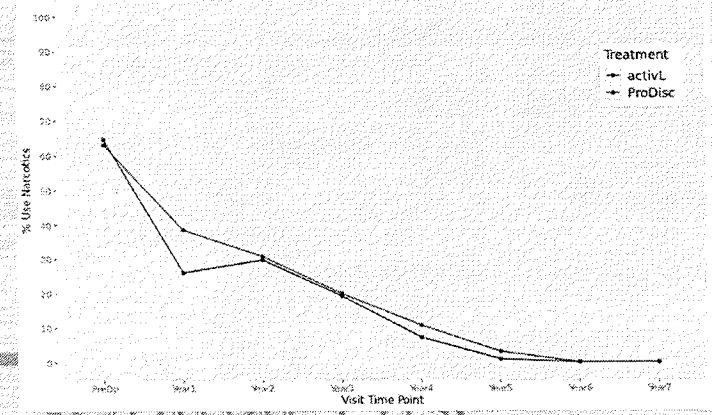


Figure 7: Opioid usage through 7 years post-treatment for activL vs. ProDisc-L.



- activL patients had **significantly greater freedom from SAEs** than ProDisc-L patients through 7 years (p=0.011). No increase in SAEs was observed between years 5 and 7, and the majority of SAEs experienced **were not device related**.
- At each follow-up time point post-op, a **significantly lower proportion of activL and ProDisc-L patients used opioids** compared with baseline (p<0.01 at each time point).
  - **Opioid use was 0% at 7 years.**

SAE, serious adverse events.

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Radiographic Outcomes through 7 Years

Table 2. Radiographic findings at 7 years for activL vs. ProDisc-L artificial discs.*

Radiographic Measure	activL	P value**
FE Rotation (degrees)	5.3 (SD=4.5)	0.0334
FE Translation (mm)	0.7 (SD=0.8)	0.6259
Heterotopic Ossification (% of Class IV)	0% (0/218)	0.0521
Heterotopic Ossification (% of Class III or IV)	3.2% (7/218)	0.7011

*Multiple imputation was used for missing patient data.
**The Fisher exact test for categorical measures and two-sample t test for continuous measures
FE, flexion extension; SD, standard deviation.

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Discussion and Conclusions

High follow-up rate of 73% after 7 years

Long-term, final follow-up results of the activL IDE trial showed:

- Statistically significant improvements observed shortly after surgical intervention are maintained through 7-year follow-up (ODI, VAS)
- activL was more effective at preserving motion and had a more favorable safety profile than ProDisc-L
- Opioid use reduced to 0% after 7 years

These findings support TDR as a safe and effective treatment over the long-term for single-level lumbar DDD in patients who have failed to improve with nonoperative care.

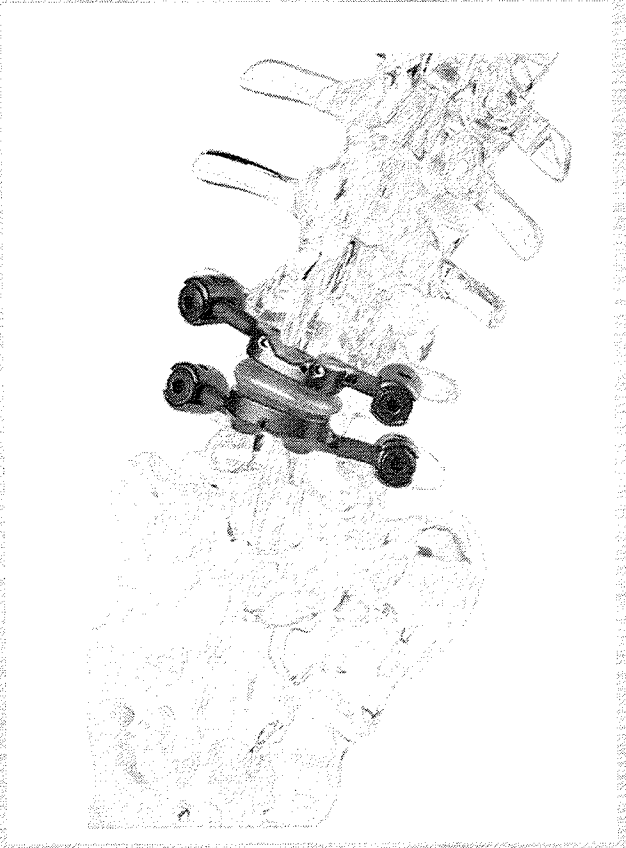
A key limitation of this study is the use of an IDE population with strict inclusion criteria. As inclusion criteria may broaden in clinical practice, some outcome measures may not maintain consistency in level of improvements.

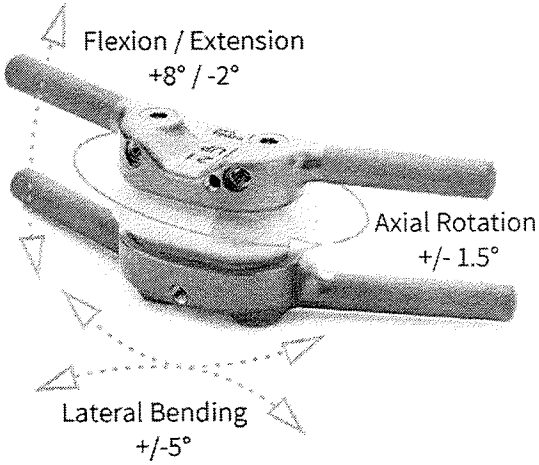
DDD, degenerative disc disease; ODI, Oswestry Disability Index; TDR, total disc replacement; VAS, visual analog scale.

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TOPS





Titanium Endplates with Polycarbonate Urethane (PcU) Center

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TOPS animation (with subtitles) demonstrating the lumbar motion alt...

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Premia Spine



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TOPS™ US IDE Study

Trial Overview

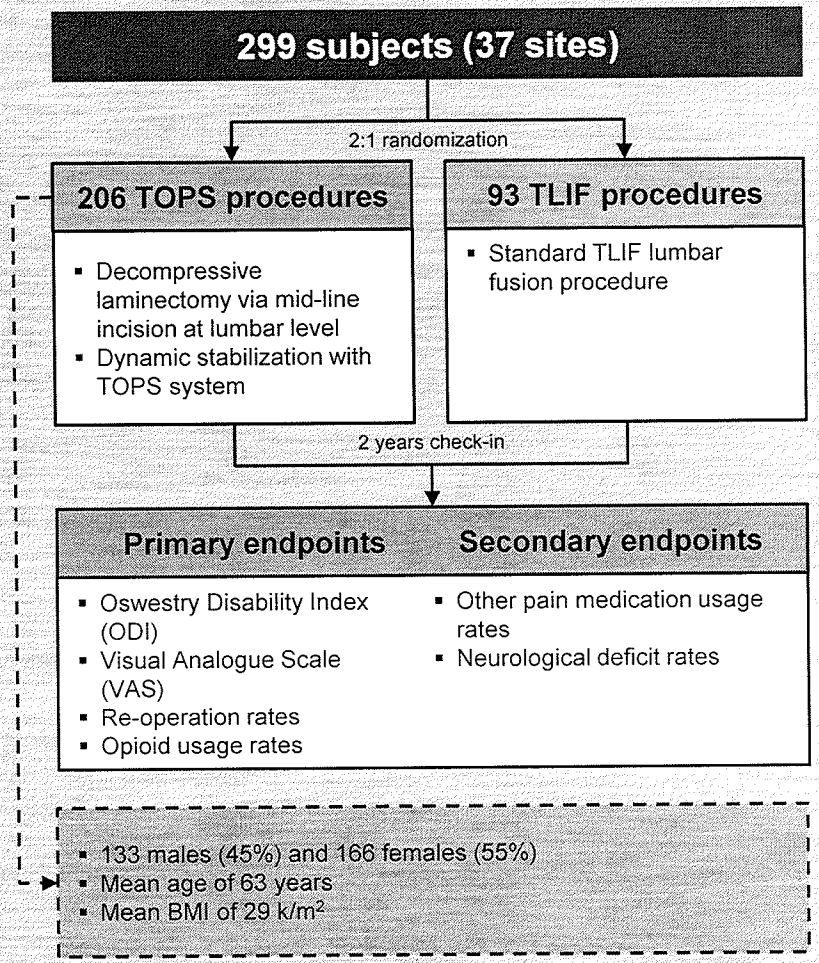
Prospective, multi-center randomized study of TOPS system versus TLIF of 300 patients (1rst look at 299 patients)

Key inclusion criteria:

- Single level pathology – between L2 – L5
- Moderate spinal stenosis, degenerative spondylolisthesis
- At least 40/100 baseline ODI
- 35-80 years old
- Predominant leg (vs. back) symptoms

Key exclusion criteria:

- BMI > 40
- More than 1 level involved or <4mm disc height at index level
- Spondylolisthesis > Grade 1 or lytic spondylolisthesis
- Prior surgery at any lumbar level with instrumentation or at adjacent levels without instrumentation



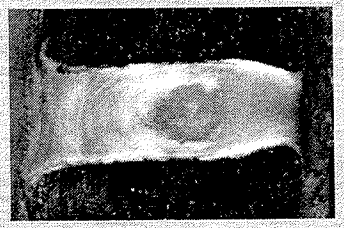
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Where does TOPS fit on the Degenerative Cascade of Pathology?

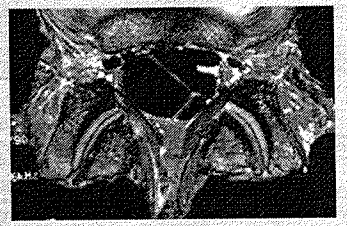
Disc Degeneration

Facet Degeneration



Early Stage

Conservative Tx or Decompression



TOPS "Sweet Spot" for Effectiveness

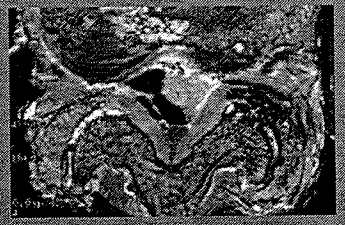
Mild

Severe



Late Stage

Zero motion to preserv
does not "create" m



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Surgery Details

- EBL 205ml
- Surgery 3 Hours 8 Minutes
- LOS 3 Days

Coric D, Nassr A, Kim PK, et al. Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. Journal of neurosurgery Spine. 2023;38(1):115-125. doi:10.3171/2022.7.SPINE22536

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IDE Clinical Trial Results

Non Inferior and Superior to TLIF

Parameter	TOPS	TLIF
Overall study success at 2 years after surgery	**76%** achieved all primary endpoints	**26%** achieved all primary endpoints
No re-operation nor lumbar injection during 2 years	**92%** of TOPS patients	**88%** of fusion patients
Significant ODI Improvement when comparing pre-op to 2-year status (patient-completed questionnaire concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel)	**94%** of TOPS patients	**77%** of fusion patients
No new or worsening neurological deficit during 2 years	**97%** of TOPS patients	**89%** of fusion patients
No Device Major Adverse Event during 2 years	**93%** of TOPS patients	**95%** of fusion patients
Maintenance of motion (TOPS) or achievement of fusion through 2 years	**99%** of TOPS patients	**56%** of fusion patients
Secondary endpoints		
Patients not using any type of pain medication at 2 years	**46%** of TOPS patients	**31%** of fusion patients
Patients stopped using opioid medication during 2 years	**54%** of TOPS patients	**33%** of fusion patients

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Surgical Re-Interventions Summary

	Tops (N=206)				Fusion (N=93)			
	Re-Ops	Subjs	%	Avg Days	Re-Ops	Subjs	%	Avg Days
Durotomy*	4	2	0.96 %	23	1	1	1.04 %	11
Adjacent Segment Disease	0	0	0.0%	0	3	3	3.13 %	380
Pseudoarthosis	0	0	0.0%	0	1	1	1.04 %	771
Screw Misplacement**	1	1	0.48 %	5	0	0	0.0%	0
Screw Loosening / Migration	2	2	0.96 %	517	1	1	1.04 %	32
Unresolved Pain	3	3	1.44 %	483	4	3	3.13 %	323
All ***	10	8	5.3 %	180	10	9	8.3 %	261

* A Tops subject underwent 2 reinterventions for durotomy the second involving conversion to fusion

** Pedical screw misplacement corrected 5 days after TOPS implant. TOPS implant remained in place

*** Same fusion subject underwent a reintervention for both pseudoarthrosis and unresolved pain

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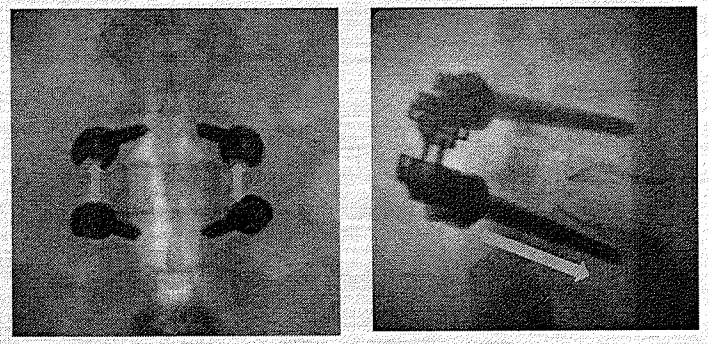
Radiographic Analysis

– Determined by Independent Radiograph Experts

- Spondylolisthesis (mm) at Index Level
  - -4.7 Pre-Op v -3.1 Post-Op
  - 1.6mm difference **is** statistically significant

- **ALL** Dynamic Motion Parameters (Flex/Ext Views) were maintained at 1 year

- **ALL** segments remained mobile at 1 year



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3 Spine/Balanced Back

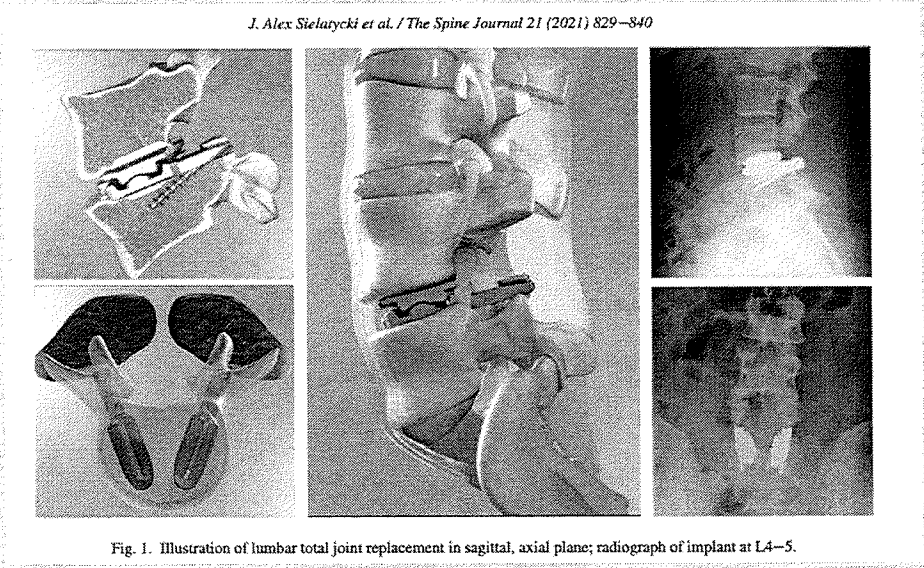


Fig. 1. Illustration of lumbar total joint replacement in sagittal, axial plane; radiograph of implant at L4–5.

The intended indications for this implant include: grade 1 spondylolisthesis, recurrent disc herniation with severe disc degeneration, severe foraminal stenosis requiring facet removal, severe central and recess stenosis requiring removal of >50% of the pars, degenerative disc disease with concurrent facet arthrosis, or any degenerative lumbar condition requiring extensive decompression and discectomy. The LTJR is not intended to treat trauma, tumor, infection, or severe deformity.

Alex Sielatycki J, Devin CJ, Pennings J, Koscielski M, Metcalf T, Archer KR, Dunn R, Craig Humphreys S, Hodges S. A novel lumbar total joint replacement may be an improvement over fusion for degenerative lumbar conditions: a comparative analysis of patient-reported outcomes at one year. Spine J. 2021 May;21(5):829-840. doi: 10.1016/j.spinee.2020.12.001. Epub 2020 Dec 17. PMID: 33346156.

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Retrospective

- N=52 vs 156 TLIF

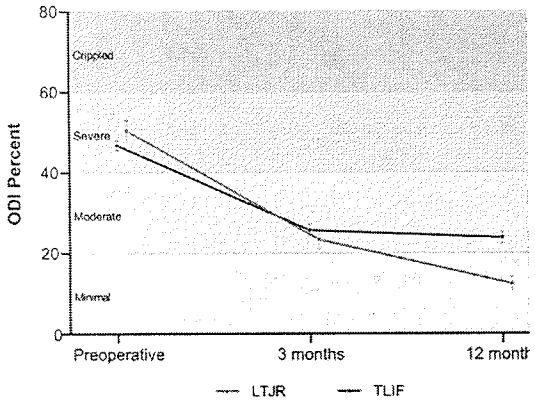
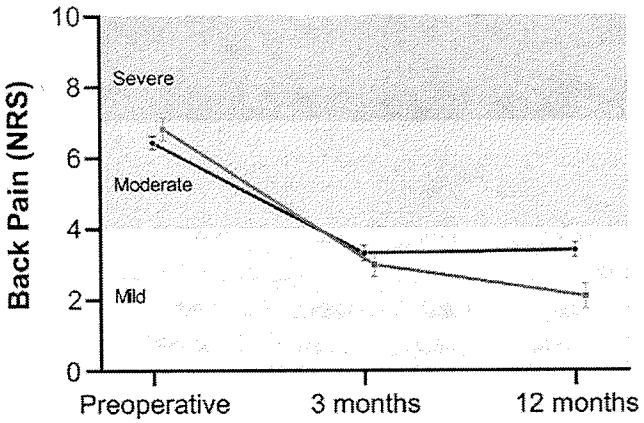
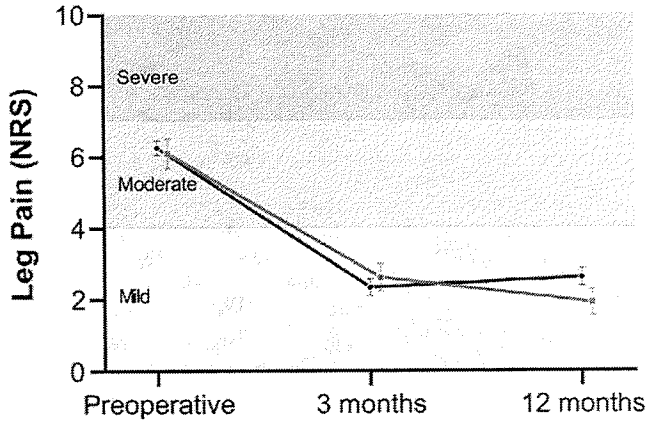


Fig. 2. ODI scores over time by procedure.





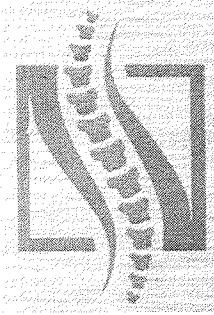
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Reoperations

- Balanced Back
  - There were 15 (18%) surgical adverse events in the first 84 patients undergoing LTJR—8 (9.5%) minor and 7 (8.3%) requiring operative intervention.
    - 3 subsidence events

- TLIF
  - There were 28 (7.8%) surgical adverse events reported within 90 days including: hematoma (3), persistent CSF leak (2), postoperative radiculopathy (5), implant malposition (2), surgical site infection (4), and medical complications (12).



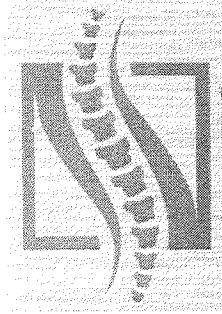
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PROGRESSIVE
SPINE & ORTHOPAEDICS

Conclusion

- Ongoing, Robust Research in Lumbar Motion Preservation
- Extended Indications to Pathologies Outside of Traditional DDD
- Additional Research Pending
- Coding Challenges/Coverage Challenges



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PROGRESSIVE
SPINE & ORTHOPAEDICS

Outline

- Spine Surgeon
- Clinical Evidence
- Minimally Invasive
- Disc Replacement
- Opioids





NJBME Opioids

g) A practitioner shall not issue an initial prescription for an opioid drug for treatment of acute pain in a quantity exceeding a five-day supply as determined by the directed dosage and frequency of dosage. The initial prescription shall be for the lowest effective dose of an immediate-release opioid drug. A practitioner shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid. No less than four days after issuing the initial prescription, upon request of the patient, a practitioner may issue a subsequent prescription for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription provided the following conditions are met:

3) Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L. 2015, c. 74 (N.J.S.A. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;



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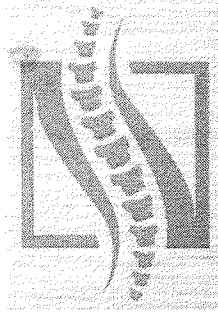
PROGRESSIVE ORTHOPAEDICS

6) Conduct random urine screens at least once every 12 months;

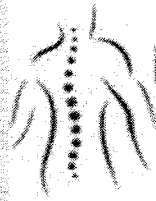
Rule N.J.A.C. 13:35-7.6

Orthopedic Surgeons

- 2.5% of US Physicians
- 8% Opioid Analgesics
- Previous dogma that NSAIDs impair fracture healing
  - Two clinical studies rise above the rest for raising alarm over the use of NSAIDs in fracture-healing. Giannoudis et al. used a retrospective case control model to examine nonunion in nailed femoral shaft fractures. The rather shocking odds ratio for nonunion with the use of NSAIDs was reported as 10.7, but the sample was underpowered, and NSAID use was severely underrepresented in the control group.
  - Sagi et al. showed a high rate of nonunion of the acetabular posterior wall in the group of patients with the longest duration of in- domethacin use in their randomized trial of heterotopic ossification prophylaxis; however, there were only 13 patients in this group61.



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PROGRESSIVE
SPINE & ORTHOPAEDICS

Opioid Variability by Region

Table 1. Initial OME Filled by Procedure and Geographic Region

Procedure	N	Nationwide	Northeast	Midwest	South	West	*P* Value
ACDF (single-level)	3,182	450 (300-675)	450 (300-675)	450 (300-675)	450 (300-675)	450 (375-675)	0.0221
ACL reconstruction	7,577	400 (300-540)	375 (300-450)	375 (300-525)	450 (300-600)	450 (300-600)	<0.0001
Arthroscopic meniscectomy	51,244	300 (200-450)	225 (150-340)	300 (200-400)	300 (205-450)	300 (200-450)	<0.0001
Ankle fracture ORIF	1,172	450 (300-605)	300 (225-450)	375 (285-600)	450 (300-600)	450 (300-720)	<0.0001
Carpal tunnel release	17,363	200 (150-300)	150 (100-225)	150 (135-250)	200 (150-300)	200 (135-300)	<0.0001
Distal radius ORIF	3,903	300 (225-450)	300 (225-375)	300 (225-450)	315 (225-450)	315 (225-450)	<0.0001
Rotator cuff repair	15,292	450 (300-600)	375 (300-450)	450 (300-600)	450 (300-600)	450 (300-600)	<0.0001
Total hip arthroplasty	967	450 (300-600)	450 (300-675)	450 (300-600)	450 (300-600)	450 (300-600)	0.9728
Total knee arthroplasty	1,278	495 (320-750)	480 (375-675)	450 (375-750)	500 (300-800)	525 (300-750)	0.9250
Total shoulder arthroplasty	213	480 (340-720)	400 (260-750)	450 (230-600)	500 (450-750)	560 (450-750)	0.1120

ACDF = anterior cervical discectomy and fusion, ACL = anterior cruciate ligament, OME = oral morphine equivalent, ORIF = open reduction and internal fixation
Median (Q1 to Q3).

Table 2. 90-day Total OME Filled by Procedure and Geographic Region

Procedure	Nationwide	Northeast	Midwest	South	West	*P*-Value
ACDF (single-level)	600 (375-900)	600 (375-900)	600 (340-900)	600 (375-900)	675 (450-1,125)	0.007
ACL reconstruction	510 (375-810)	450 (300-600)	525 (375-800)	570 (375-900)	560 (375-900)	<0.001
Arthroscopic meniscectomy	300 (200-450)	250 (175-375)	300 (200-450)	300 (225-500)	300 (200-600)	<0.001
Ankle fracture ORIF	600 (375-1,000)	450 (300-680)	600 (375-900)	640 (450-1,050)	620 (450-1,300)	<0.001
Carpal tunnel release	200 (150-300)	150 (100-225)	200 (150-300)	225 (150-350)	200 (150-385)	<0.001
Distal radius ORIF	380 (280-600)	300 (225-490)	375 (250-625)	450 (300-640)	425 (300-750)	<0.001
Rotator cuff repair	600 (400-1,000)	450 (320-775)	600 (450-1,000)	650 (450-1,050)	625 (425-1,200)	<0.001
Total hip arthroplasty	675 (450-1,050)	675 (450-1,050)	770 (505-955)	600 (400-1,050)	675 (450-1,050)	0.305
Total knee arthroplasty	1,200 (750-2,000)	1,150 (750-1,875)	1,245 (875-2,100)	1,160 (675-1,800)	1,335 (700-2,350)	0.253
Total shoulder arthroplasty	750 (450-1,125)	600 (410-900)	675 (410-1,000)	840 (480-1,350)	710 (500-940)	0.162

ACDF = anterior cervical discectomy and fusion, ACL = anterior cruciate ligament, OME = oral morphine equivalent, ORIF = open reduction and internal fixation
Median (Q1 to Q3).

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Notable Variability in Opioid-prescribing Practices After Common Orthopaedic Procedures

Sophia A. Traven, MD
Daniel L. Brinton, PhD
Shane K. Woolf, MD
Lee R. Leddy, MD
Michael B. Gottschalk, MD
Harris S. Slone, MD

ABSTRACT

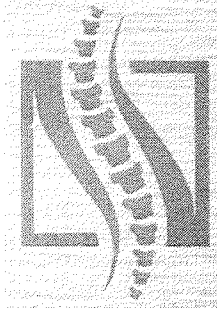
Introduction: The purpose of this study was to evaluate nationwide trends and regional variability in opioid prescriptions after common orthopaedic procedures.

Methods: A retrospective analysis of privately insured subjects from the

Opioids After a Fracture

- Thirty American and 30 Dutch patients were enrolled in a prospective comparative study prior to operative treatment of ankle fractures.
- Patients rated pain and satisfaction with pain relief on postoperative day 1 (POD1) and at time of suture removal (SR). Pain and satisfaction scores were compared and multivariable analysis identified their predictors.

Helmerhorst GT, Lindenhovius AL, Vrahas M, Ring D, Kloen P.
Injury. 2012 Nov;43(11):1958-61.



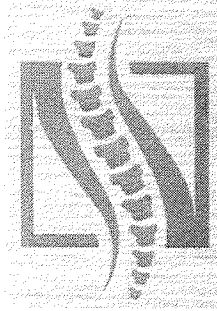
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SPINE & ORTHOPAEDICS

Opioids after a Fracture

- At POD1, a third of Dutch patients used no opioids and a sixth took strong opioids.
- At SR, only 4 of 30 (13%) were taking tramadol and half were taking no medication.
- All of the American patients used strong opioid pain medication on POD1 and 19 of 30 (63%) were still taking strong opioids at SR.
- Patients that did not use opioids and Dutch patients had less pain and equivalent satisfaction with pain relief compared to patients that used opioids and American patients respectively.
- Nationality was the best predictor of pain intensity at POD1.
- Opioid medication was the best predictor of pain at SR and decreased satisfaction with pain management.

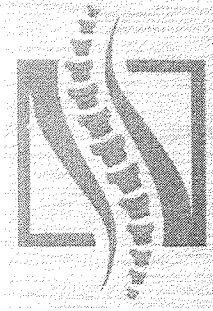


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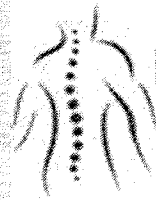


Conclusion

- Ongoing, Robust Research in Spine Surgery Outcomes and Quality
- Minimally Invasive Spine Surgery Does Not Change the Indications for Surgery.
- Motion Preservation Solutions Are An Emerging Alternative to Fusions
- We Have to Change Attitudes About Opioids



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PROGRESSIVE
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Thank you!



