PainWeek®

The Future of Spine Surgery: Getting Smaller, Safer, and Better

Ramana Naidu, MD, Steven Falowski, MD, Jason Pope ,MD, Brian Su, MD
Sandy Christiansen, MD, Eric Lee, MD

September 9, 2021

Faculty

Ramana Naidu, MD	*Anesthesiology*
Steven Falowski, MD	*Neurosurgery*
Jason Pope, MD	*Anesthesiology*
Brian Su, MD	*Orthopedic Spine Surgery*
Sandy Christiansen, MD	*Anesthesiology*
Eric Lee, MD	*Physical Medicine & Rehabilitation*

Disclosure

Ramana Naidu, MD

- Speaker Bureau: Avanos, Abbott, Boston Scientific, Nalu, PainTEQ, Relievant, SPR Therapeutics, SonoSite, Vivex
- Scientific Research: Abbott, Vertiflex-Boston Scientific, CereVu, Nalu, Omnia Medical
- Consultant: Abbott, Boston Scientific, Biotronik CereVu, DoctorPlan, ExerAI, KarunaLabs, Medtronic, Nalu, Sonosite, SPR Therapeutics, Spinal Simplicity, Vertos, Vivex
- Stock Options: Bicycle Health, KarunaLabs, CereVu, ExerAI, PainTEQ, Spinal Simplicity
- Stockholder: DoctorPlan

Learning Objectives

- Describe the new procedures that can address low back pain
- Summarize the myriad pain generators of low back pain
- Cite the Level 1 evidence for certain procedures for specific indications
- Compare the risks and benefits of several different interventional pain therapies and surgeries

What's Wrong with Spine Surgery?

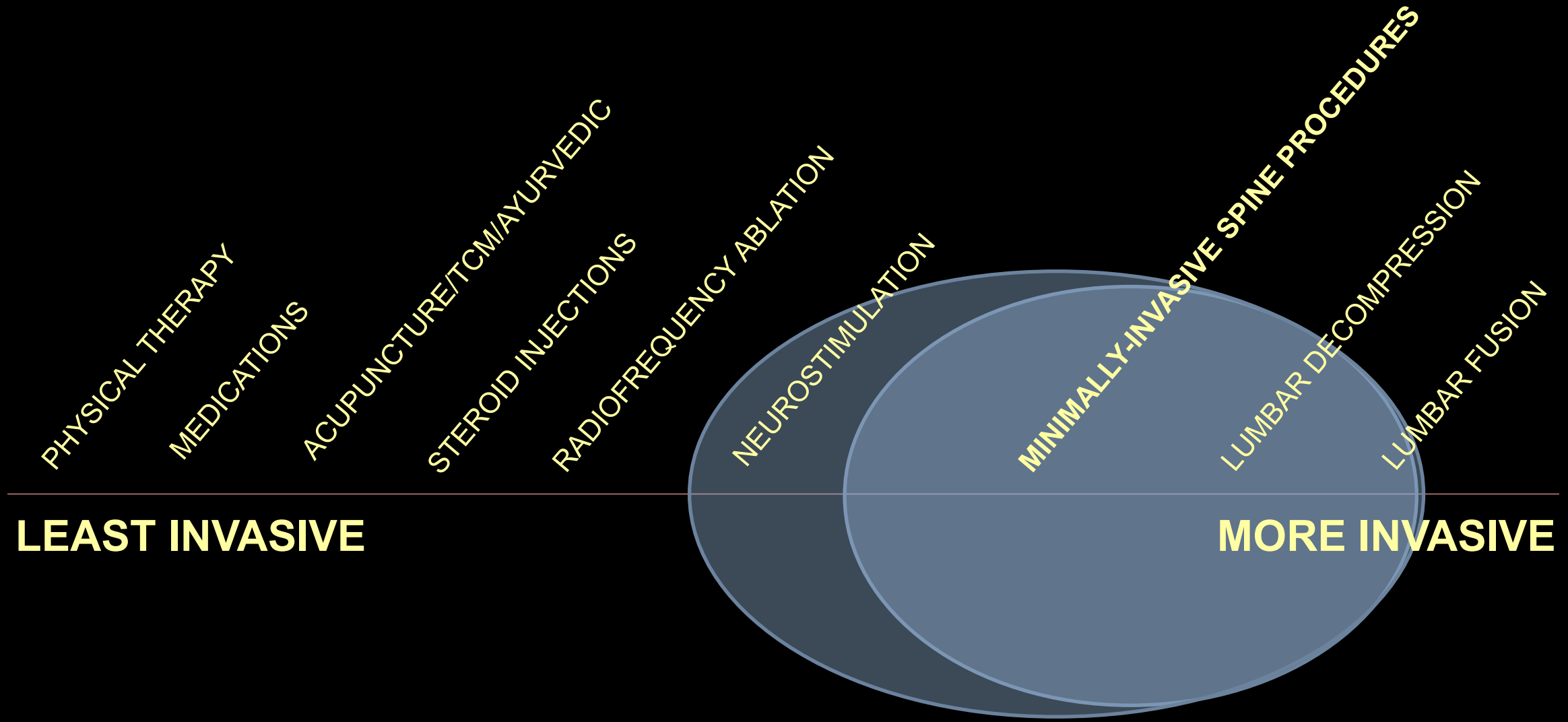
- My patients come back worse than when I sent them
- My patients take a long time to recover, and it's tough

Less invasive
Decreased Length-of-Stay

What's Wrong with Interventional Pain Management?

- My patients aren't getting sustained relief

Shift to non-steroidal
SUSTAINABLE procedures.


PHYSICAL THERAPY
MEDICATIONS
ACUPUNCTURE/TCM/AYURVEDIC
STEROID INJECTIONS
RADIOFREQUENCY ABLATION
NEUROSTIMULATION
MINIMALLY-INVASIVE SPINE PROCEDURES
LUMBAR DECOMPRESSION
LUMBAR FUSION
LEAST INVASIVE
MORE INVASIVE

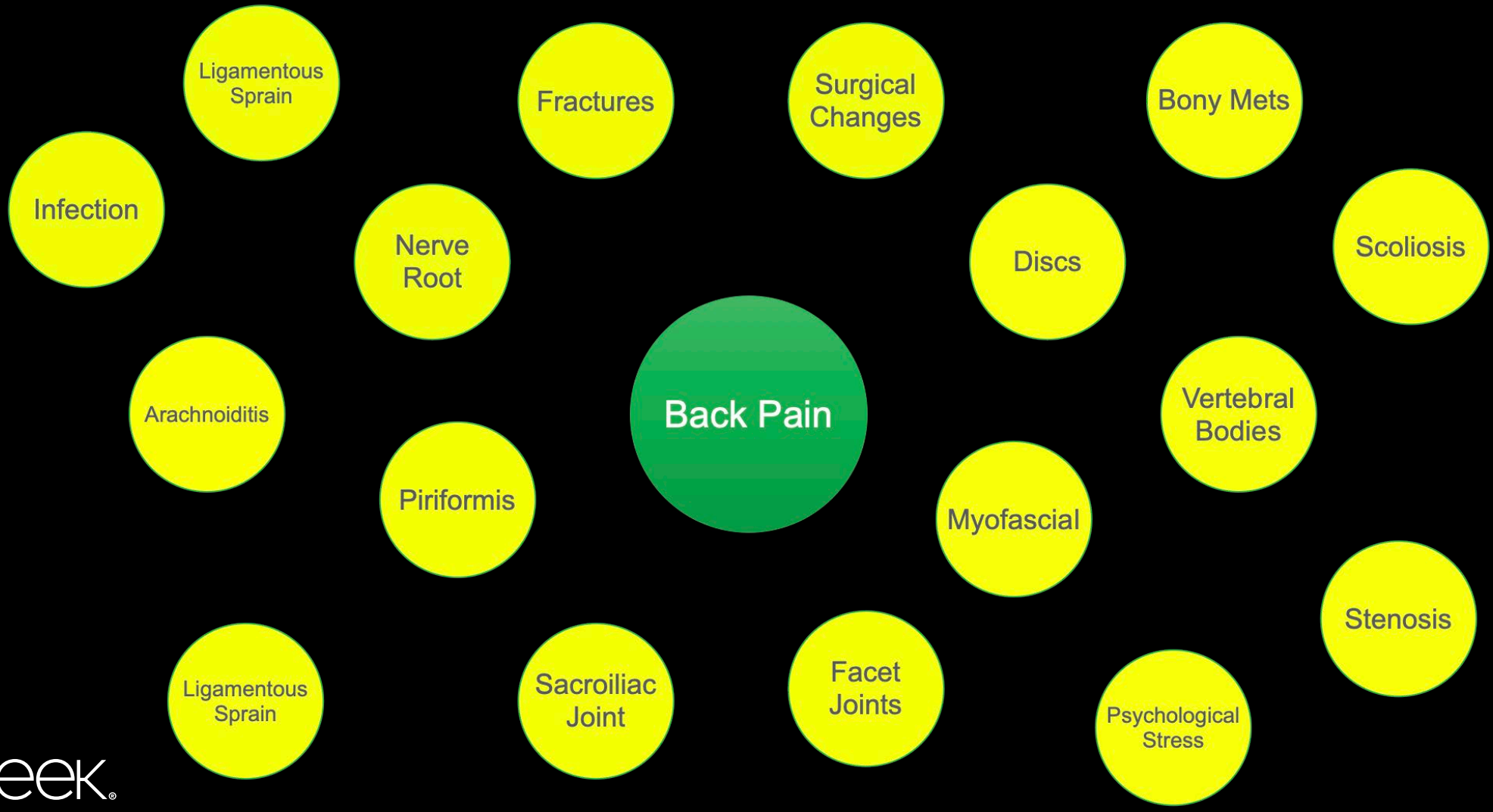
Logic

- Diagnosis
- Diagnosis
- Diagnosis

- 4) Condition-Specific Menu of Options:
  - Risks/Benefits
  - Evidence
  - Invasiveness
  - Duration of Relief
  - Cost
  - Patient Preference

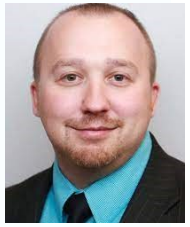
- 5) Measure Outcomes

Condition-Specific Evidence



Spinal Biomechanics

- Discogenic
- Vertebrogenic
- Vertebral Compression Fracture



- Facetogenic Pain (Lumbar Spondylosis without Myelopathy)
- Lumbar Spinal Stenosis (Central and Lateral Recess)
- Sacroiliac Joint Dysfunction

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Thank You

- President of PACIFIC SPINE × PAIN SOCIETY

- President-Elect PACIFIC SPINE × PAIN SOCIETY

PACIFIC SPINE & PAIN SOCIETY

Aria RESORT & CASINO LAS VEGAS

PAINWEEK®

September 10-12, 2021

Steven M. Falowski MD

Vertebrogenic/Discogenic Pain

Disclosure

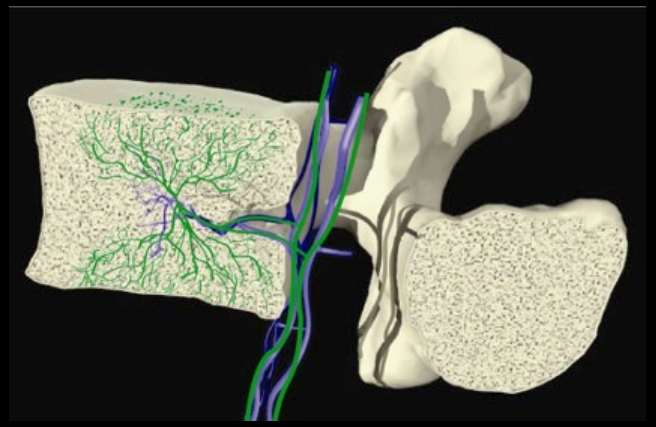
Title & Affiliation

Steven M. Falowski MD
Director Functional Neurosurgery
Neurosurgery Associates of Lancaster
Lancaster, PA

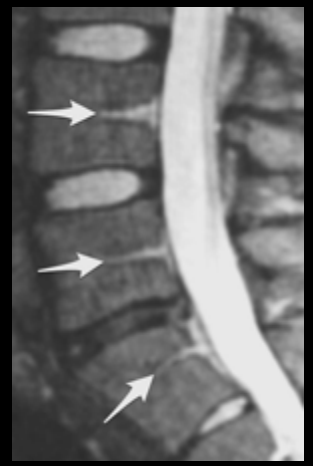
Vertebrogenic Pain is a Paradigm Shift in the Science of CLBP

- For decades, treatments ignored the endplates and focused on the disc
- Vertebral endplates are more innervated than intervertebral discs1
- PGP 9.5 positive nociceptors confirmed at the vertebral endplates
- Basivertebral nerve (BVN) innervates the endplates and transmits pain signals from the vertebral endplates to the CNS [2]

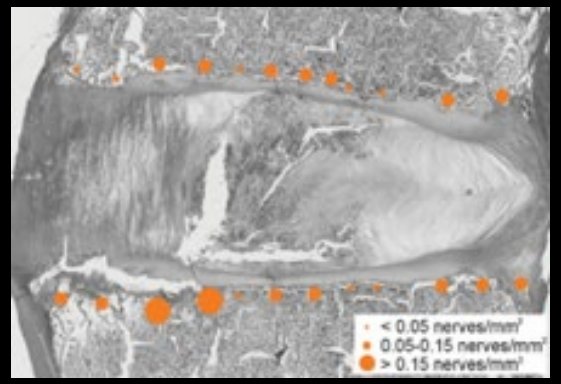
Distribution of the basivertebral nerve



Basivertebral Foramen



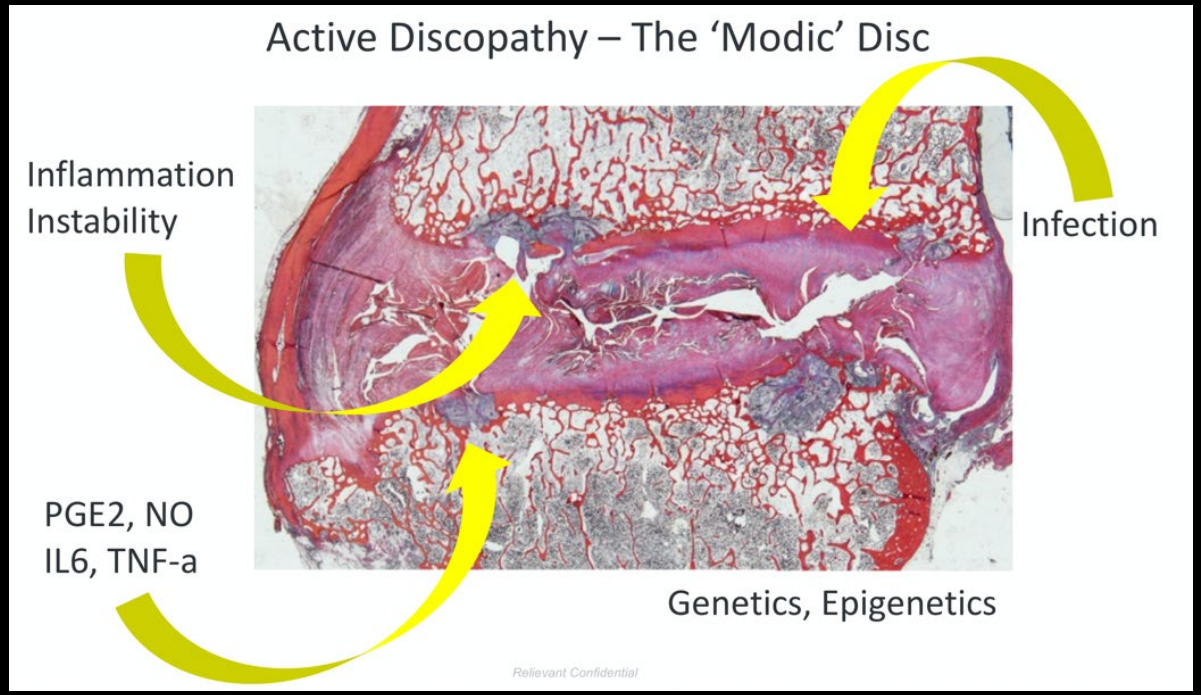
Distribution of PGP+ nerve fibers across endplate



[1]Fields AJ, Liebenberg EC, Lotz JC. The Spine Journal 2014;14(3):513-521.
[2]Bailey JF, Liebenberg E, Degmetich S, Lotz JC. Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra. Journal of Anatomy 2011;218(3):263-70.

Extensive Independent Research Supports Pathobiology of Vertebrogenic Pain

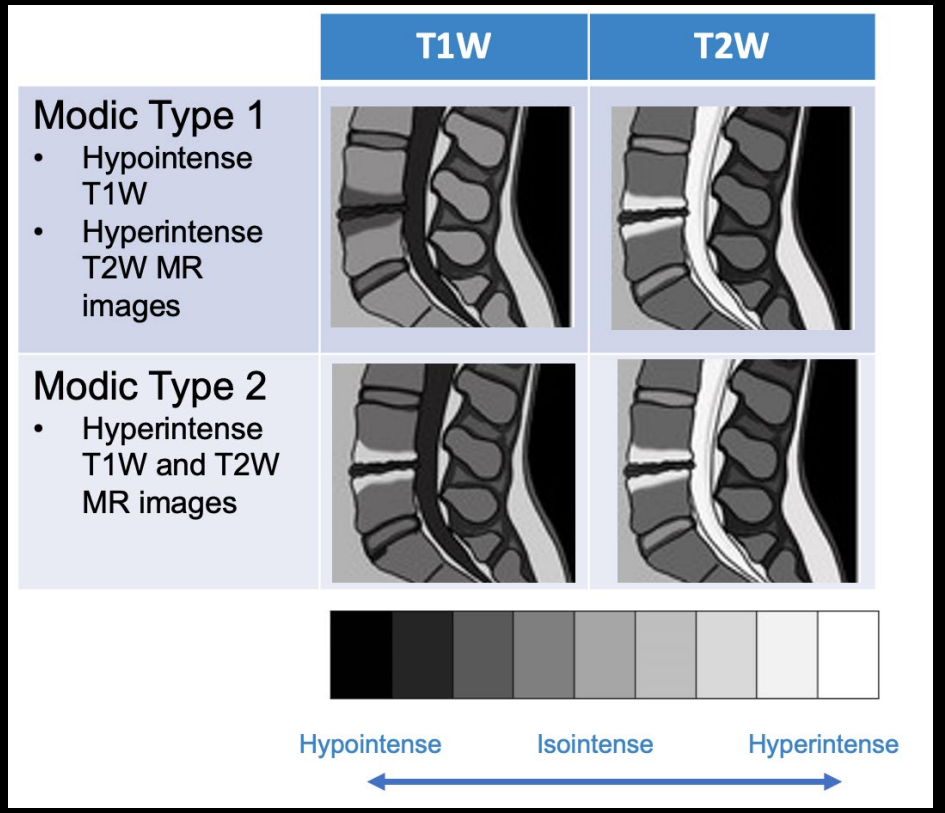
- Endplate defects allow proinflammatory disc tissue to leak into the bone marrow, inciting an inflammatory response
- Chronic endplate inflammation leads to Modic changes (MC) on MRI
- Prevalence and density of endplate nociceptors higher in vertebral bodies with MC[1]



[1] Dudli S et al. ISSLS Prize Winner; 2017

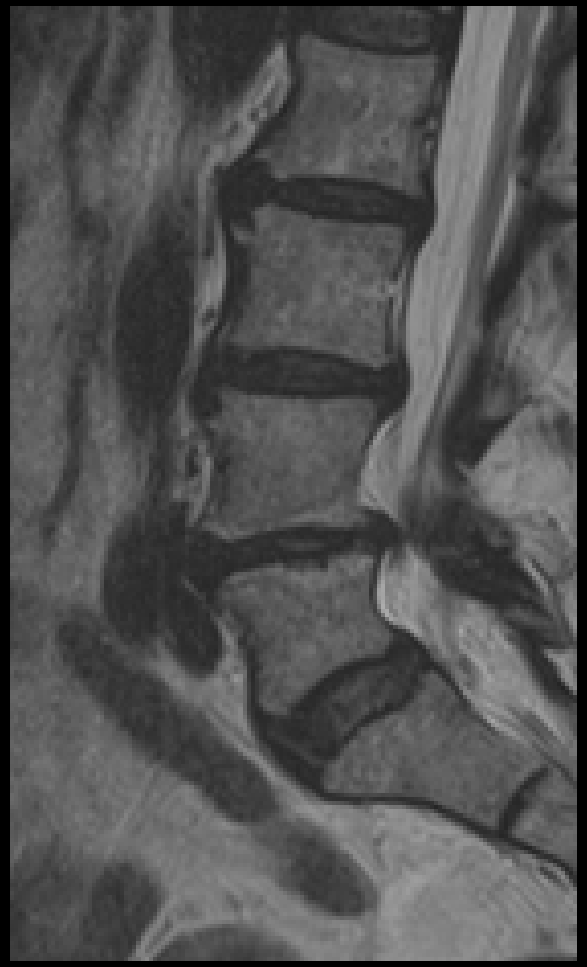
Modic Changes are Correlated with Severe CLBP

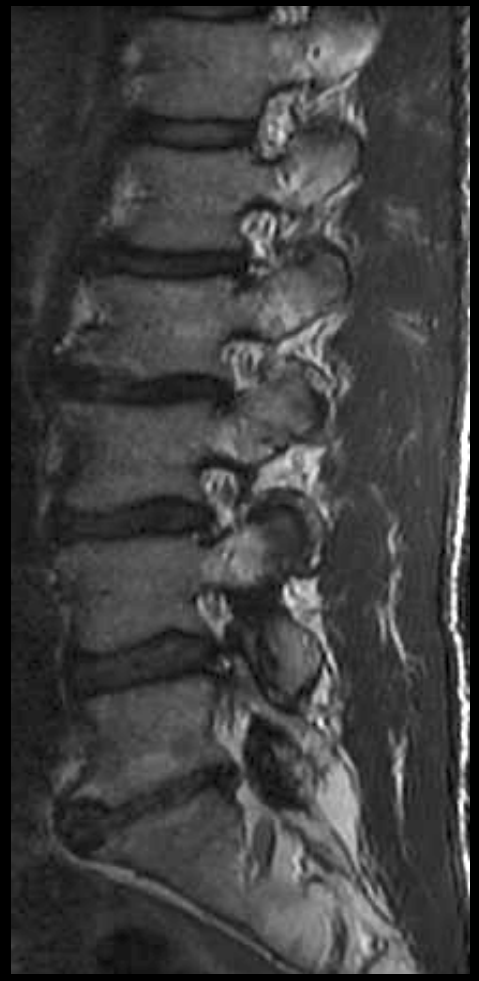
- Research findings:
- Association between discography and moderate to severe Type 1 and Type 2 Modic changes1
- 38% sensitivity
- 88% specificity with moderate Modic 1 and 2
- 100% specificity with severe Modic 1 and 2
- Modic Changes were associated with historical LBP, and with severity and duration of symptoms ($p<.05$)2
- Patients with MC Type 1 seek care more often and have poor outcomes to conservative treatment[3,4]



[1] Weishaupt D et al. Radiology; 2001
[2] Mok F et al. The Spine Journal; 2016
[3] Jensen OK et al. The Spine Journal; 2014
[4] Jensen RK et al. BMC Musculoskelet Disord; 2011

Modic Changes Are Also Binary – Minimal Modic Still Reflects Endplate Damage





Vertebrogenic Pain Characteristics

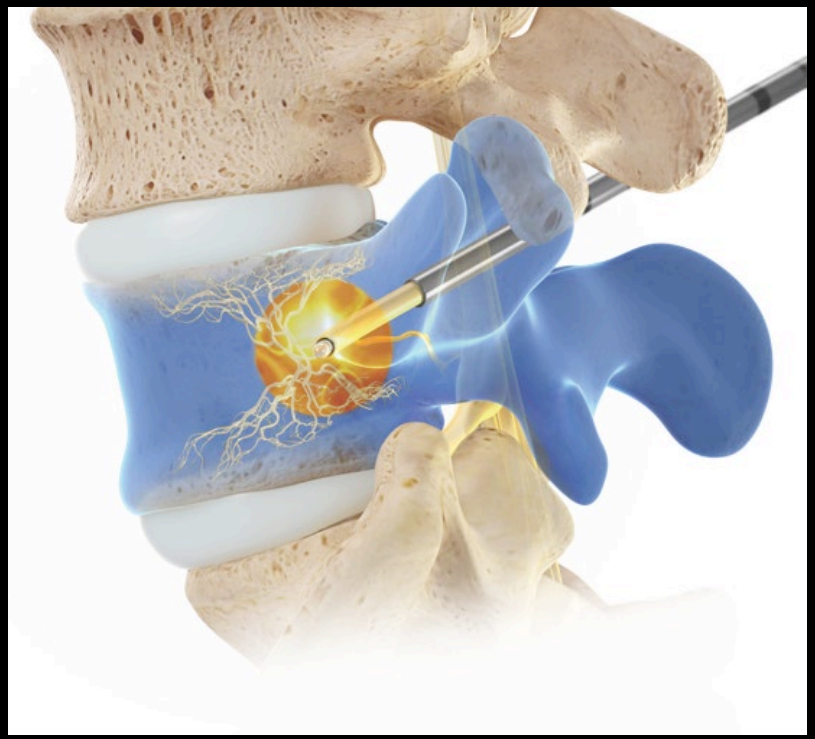
Evaluation of 410 patient-completed pain body diagrams and 296 baseline MRIs from clinical study patients with primary inclusion of vertebrogenic pain and Modic Changes found:

- Low back pain was located midline / paraspinal in >85% of patients
- < 10% had pain below the mid-gluteal line (though radiating pain to the knee was allowed)
- Pain was exacerbated by sitting and flexion
- 45% were Pfirrmann Grade III or below, 27% Grade IV, and 28% Grade V
- Nearly 3/4 of these patients had intensity changes at L5/S1
- Intensity changes were typically <10% of vertebral body height

Historically, there have been few treatment options to offer these patients…this has changed with intraosseous BVN ablation

BVN Ablation Patient Indications

- Chronic Low Back Pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI changes consistent with Modic Type 1 or Type 2 at one or more levels from L3 to S1



Strong Clinical Foundation Supporting BVN Ablation

	Trial	Lead Author	# of Subjects	Publication
SMART	SMART Pivotal RCT vs Sham	Fischgrund	225 (147/78)	European Spine Journal
	SMART 2 Year Outcomes	Fischgrund	106	Int'l Journal of Spine Surgery
	SMART 5 Year Outcomes	Fischgrund	100 (n=US PP)	European Spine Journal
INTRACEPT	INTRACEPT Pivotal RCT vs Conservative Care	Khalil	140 (66/74) *Interim Analysis* 104 (51/53)	The Spine Journal
	INTRACEPT 1 Year Outcomes BVN Arm + 6 Mo Outcomes on crossover Arm	Smuck	127	Regional Anesthesia and Pain Management
Prospective, Single-Arm Study	Prospective, Single-Arm Study 3 mo Clinical Results	Truumees	28	European Spine Journal
	Prospective, Single-Arm Study 12 mo Clinical Results	Macadaeg	47	NASSJ

Jason E. Pope MD, FIPP, DABPM

Review and Recommendations of Surgical Treatments for Lumbar Degenerative Spinal Disease

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Title & Affiliation

Jason E. Pope MD, FIPP, DABPM
Chairman, Pacific Spine and Pain Society
President, American Society of Pain and Neuroscience

Disclosure

- Consulting Fee (e.g., Advisory Board): Ethos, Flowonix, Saluda, Painteq, Aurora Spine, Thermaquil, Abbott, Medtronic, Vertos, SPARK, SPR Therapeutics, WISE, Tersera
- Contracted Research (Principal Investigators must provide information, even if received by the institution): Ethos Labs, Flowonix, Saluda, Painteq, Aurora Spine, Thermaquil, Celeri Health, Abbott, Medtronic, AIS, Boston Scientific, Vertos, Spark
- Stock Shareholder (Individual stocks/Stock options; diversified mutual funds do not need to be disclosed): PainTeq, Aurora Spine, Thermaquil, Celeri Health, SpineThera, AGR, NIS, Vertos, Spark

Learning Objectives

- Describe evidence on surgical treatments for spinal stenosis, including interspinous spacers, percutaneous interspinous spacers, lateral percutaneous interspinous fusion , and surgical decompression with and without fusion
- List Practice recommendations for lateral percutaneous interspinous fusion for the treatment of spinal stenosis

PACC Guidance Development

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PSPS Guidance Development

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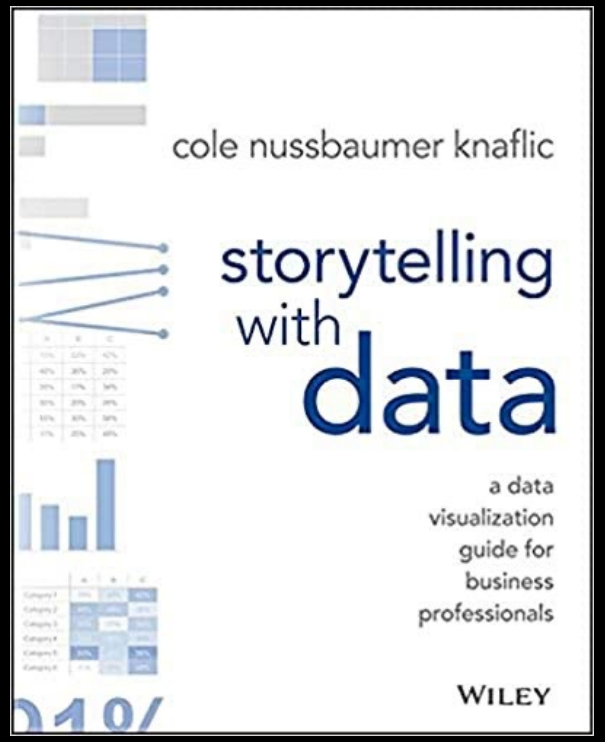


Evidence Synthesis, Grading and Recommendation Grade

Table 1. Level of Relationship Disclosure.

Disclosure Level	Definition
Level 1	include nonfinancial disclosures that would not affect the judgment of a Task Force member. These disclosures do not require any action.
Level 2	include financial disclosures of $1,000 or less and nonfinancial disclosures that are relevant to a topic but not anticipated to affect the judgment of the Task Force member for that topic. These disclosures are announced at the Task Force meeting, but do not limit the Task Force member's participation in the topic process.
Level 3	include financial disclosures of a larger amount and significant nonfinancial disclosures that may affect the Task Force member's view on the topic. Actions for Level 3 disclosures vary according to the nature of the conflict, and may include preventing the member from serving as lead of a topic or on the workgroup of a topic, preventing the member from serving as a primary spokesperson for a topic, or preventing the member from taking part in all topic activities.

The Level of Evidence, based on the current USPSTF criteria and adapted by Machnicanti, is highlighted below.

cludes consistent results from well-designed, well-conducted studies in
ve populations that directly assess effects on health outcomes.
sufficient to determine effects on health outcomes, but the strength of the
limited by the number, quality, or consistency of the individual studies,
ility to routine practice, or indirect nature of the evidence on health

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited
sign or conduct, gaps in the
health outcomes.

Table 2. Quality of Evidence, based on the USPSTF criteria

Evidence Level	Definition
I	At least one controlled and randomized clinical trial with proper design
II-1	Well designed, controlled, nonrandomized clinical trial
II-2	Cohort or case studies add well designed controls, preferably multicenter
II-3	Multiple series compared over time, with or without intervention, and surprising results
III	Experience driven opinions, clinical observations

Evidence Synthesis, Grading and Recommendation Grade

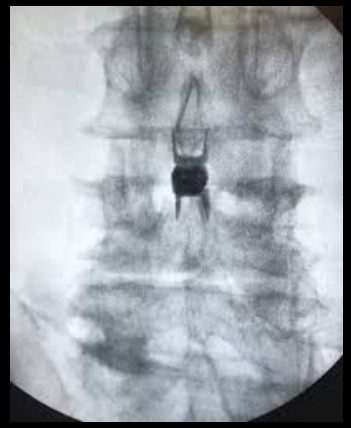
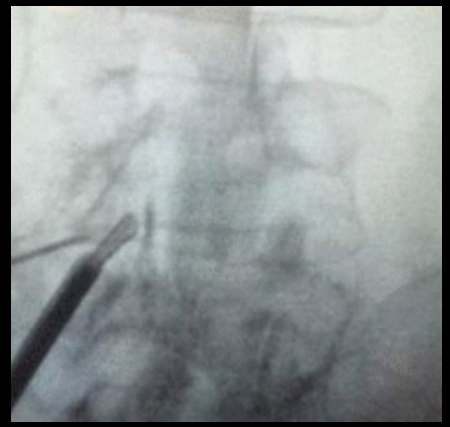
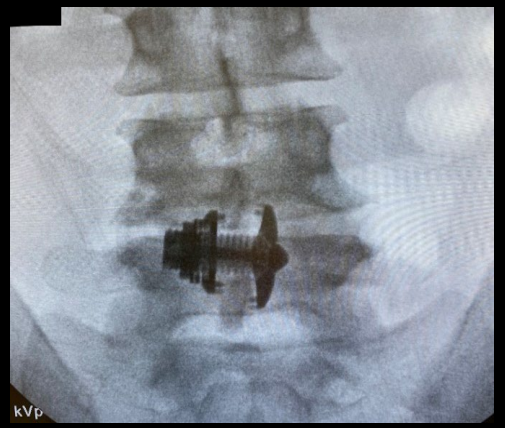
Table 4. Recommendation Grade Level

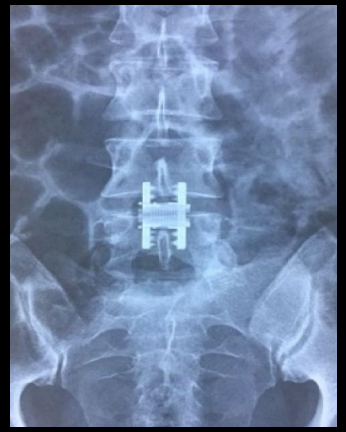
Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

U.S. Preventive Services TASK FORCE

Evidence on Surgical Treatments for Spinal Stenosis

Percutaneously-Implanted Interspinous Spacers
Percutaneous Image-Guided Lumbar Decompression (PILD)
Lateral Percutaneous Interspinous Fusion
Surgical Interspinous Fusion
Laminectomy with and Without Fusion




Evidence on Interspinous Spacers for Spinal Stenosis

Study	Number of subjects selection criteria	Control	Intervention	Outcomes measures	Time of measurement	Results	Conclusions	USPSTF Evidence Ranking
Patel et al (2014) [52]	N= 391 Inclusion criteria: Moderate spinal stenosis Failed 6 months conservative therapy Grade 0 or 1 spondylolisthesis	Decompression with interspinous spacer (X-stop) - 201	Indirect decompression with Superion interspinous spacer. = 190	Primary: Zürich Claudication Questionnaire Composite Secondary: ODI VAS-Leg VAS-Back Patient Satisfaction Radiographic Findings Reoperations Adverse Events	3, 6, 12, 18, 24 months	Primary composite endpoint similar to control. Secondary outcomes (ODI, VAS-L, VAS-B, and satisfaction are statistically similar to control. No radiographic findings of dislodgements with intervention. Reoperation rate by 24 months was 23.2% for intervention and 18.9% for control Adverse events was similar between both groups.	Demonstrated non-inferiority to the control group.	I
Nunley et al (2017) [54]	N = 88 This study followed the intervention group from the Patel et al study to 60 months.	Decompression with interspinous spacer (X-stop). Only until 24 months (reported in Patel et al)	Indirect decompression with Superion interspinous spacer. = 88 Of 121 eligible patients, 88 continued with study until the 60-month mark.	Primary: Zürich Claudication Questionnaire Composite Secondary: ODI VAS-Leg VAS-Back Patient Satisfaction Adverse Events	12, 24, 26, 48, 60 months	Primary composite endpoint success maintained for 5 years. Secondary outcomes (ODI, VAS-L, VAS-B, and satisfaction are maintained for 5 years.	Demonstrated sustained benefit of the intervention to 5 years.	Level II-3

Practice Recommendations on Percutaneous Interspinous Spacers

Practice Statement		Evidence Grade	Recommendation Grade
1.	The use of interspinous spacer via indirect decompression meets its successful endpoint (ZCQ composite) in 70-80% of patients with moderate lumbar spinal stenosis with neurogenic intermittent claudication at 12, 24, 36, 48, and 60 months.	Good	B
1.	Present evidence supports the use of percutaneously-implanted interspinous spacer devices in patients with radiological evidence of mild-to-moderate degenerative LSS and no worse than a grade I spondylolisthesis, with flexion-based relief of neurogenic claudication symptoms	Good	B
1.	Since interspinous spacers and surgery are considered equally cost effective, the less invasive interventions should be strongly considered.	Good	B

Evidence on PILD for the Treatment of Spinal Stenosis

Study	Number of subjects Selection Criteria	Control	Intervention	Outcomes Measures	Time of Measurement	Results	Conclusions	USPTF Evidence Ranking
Brown L. 2012 [64]	38	Lumbar interlaminar steroid injections (LESI)	MILD procedure	VAS, ODI, ZCQ	6 weeks and 12 weeks	Mean baseline VAS for the MILD group was 6.8 and 3.8 at 6 weeks ($p<0.01$) and 3.4 at 12 weeks ($p<0.0.1$). There was no difference in VAS scores in the LESI group from baseline to 6 weeks. The LESI group was allowed to crossover to MILD at 6 weeks. Those who crossed over to MILD also had pain improve from VAS score of 7.4 to 4.5 ($p <0.01$). There was also statistically significant improvement in ODI and ZCQ when compared with the LESI group.	MILD was found to be superior to LESI in terms of VAS, ODI and ZCQ with similar safety outcomes and had no significant complications in each group.	I
Benaymin RM et al. 2016 [65]	302	Lumbar interlaminar steroid Injections (LESI)	MILD procedure	ODI, NPRS, ZCQ	1 year	Improvement in all three outcome measurements. ODI responder rate in the MILD group was 58% and 27.1% in the control group ($p<0.001$). There was also statistically significant improvement in NPRS and ZCQ measures at one year when compared to the active control.	MILD was found to provide durable pain relief at one year and was found to be statistically superior to LESI. There were no differences in safety between LESI and MILD.	I
Pope et al 2021 [66]	147	Lumbar spinal stenosis	MILD performed unilaterally or bilaterally	Safety measures of nerve injury, infection, hematoma, death, or allergy to contrast	90 days	There were no reported complications at the day of service of the procedure, or the immediate post-operative period, as defined within the first 2 weeks, or during the 3-month follow-up (+/- 2 weeks) for either the epidurogram or no-epidurogram treatment groups, as this represents the upper limit of a "global period" for minimally invasive spine procedures.	MILD was sas safe to be performed with or without epiduogram	II-3

Evidence on PILD for the Treatment of Spinal Stenosis (cont'd)

Pope et al 2021 [66]	147	Lumbar spinal stenosis	MILD performed unilaterally or bilaterally	Safety measures of nerve injury, infection, hematoma, death, or allergy to contrast	90 days	There were no reported complications at the day of service of the procedure, or the immediate post-operative period, as defined within the first 2 weeks, or during the 3-month follow-up (+/- 2 weeks) for either the epidurogram or no-epidurogram treatment groups, as this represents the upper limit of a "global period" for minimally invasive spine procedures.	MILD was sas safe to be performed with or without epiduogram	II-3
Deer et al, 2021 [89]	N=155; spinal stenosis with lumbar spinal stenosis with neurogenic claudication; 78 were allocated to CMM-Alone, and 77 to MILD-CMM.	Conservative medical management	MILD	1 vear primary endpoint, randomized prospective trial; The incidence of device or procedure-related adverse events was analyzed. Follow-up	Walking intolerance and includes 6-month, 1-year and 2-year assessments, with 1-year being primary. Patients in the MILD-CMM group are followed at 3, 4, and 5 years. This is a report of interim 6-month outcomes.	Of 155 patients enrolled at 19 US interventional pain management centers, 78 were allocated to CMM-Alone, and 77 to MILD-CMM At 6-months, the validated walking tolerance test demonstrated statistical superiority of MILD-CMM versus CMM-Alone ($p<0.001$). The incidence of patients receiving a subsequent disallowed procedure, and thereby considered treatment failures in their study group, was statistically significantly higher in CMM-Alone versus MILD-CMM ($p<0.001$). There were no device or procedure-related adverse events in either group.	At 6-months, the mild Procedure combined with CMM provided statistically superior objective real-world outcomes versus CMM-Alone. There were no device or procedure-related adverse events reported in either study group.	I

Evidence on PILD for the Treatment of Spinal Stenosis (cont'd)

Meknail N et al 2021 [90]	N = 75; symptomatic lumbar spinal stenosis	none	MILD procedure	Retrospective analysis through 5 vear follow-up	Primary outcome was incidene of open lumbar decompressive surgery adt the same index leel as the MILD; secondary outcome measures were NRS change and opioid medications from baseline to 3,6,12 months. Post procedure complications	9/75 patients underwent a open decompressive surgery during the 5 vear follow-up, subjects experienced statistically significant reductions in pain (6.6 to 3.7) and opioid medications from baseline.	The MILD procedure is durable and effective at 5 years	II-3

Practice Recommendations on PILD

Practice Statement	Evidence Grade	Recommendation Grade
The PILD procedure has demonstrated superiority to lumbar epidural steroid injection in the treatment of lumbar spinal stenosis secondary to hypertrophied ligamentum flavum.	Good	A

Evidence on Lateral Percutaneous Interspinous Fusion for the treatment of Spinal Stenosis

Study	Number of subjects Selection Criteria	Control	Intervention	Outcomes Measures	Time of Measurement	Results	Conclusions	USPTF Evidence Ranking

Practice Recommendations for Lateral Percutaneous Interspinous Fusion for the treatment of Spinal Stenosis

Practice Statement	Evidence Grade	Recommendation Grade
Presently there are no direct studies on the use percutaneous interspinous fusion devices for the treatment of LSS. While there are biomechanical studies to support its use in LSS, in the presence of both central canal and neural foramen narrowing, the efficacy in treating neurogenic claudication symptoms themselves has yet to be proven. The authors agree while there is promise to the use of interspinous fusion systems for treatment of LSS with and without instability, further studies on stand-alone interspinous fusion for the treatment of LSS is warranted.	Poor	I

Evidence on Interspinous Fusion for the treatment of Spinal Stenosis

Study	Number of subjects Control selection criteria	Intervention	Outcomes measures	Time of measurement	Results	Conclusions	USPTF Evidence Ranking
Scalfani et al 2020 (68)	N =53; spinal stenosis none	Polyaxial interspinous fusion system	A retrospective, non-randomized, single-center chart review; preoperative and perioperative data. A postoperative numerical pain rating scale and modified MacNab classification score were obtained from each patient in the cohort via phone survey	1 year	Median hospital stay was 2 days (range 1-7 days). There were no reported perioperative blood transfusions or cases of radiographic fracture/migration of the device at the 6 week post-operative time point. MacNab result was obtained in 48% of all patients. Patients with preoperative pain scores greater than 8/10 reported more pain improvement than patients with preoperative pain scores less than 5 (0 points, $p = 0.96$, $n = 8$). Patients with a BMI less than 30 had significantly better MacNab outcome classifications than patients with a BMI greater than 30.	The polyaxial interspinous fusion system produces significant clinical improvement when employed to treat patients with stenosis, herniated disc, or low grade spondylolisthesis. This device can be implanted with a low complication rate and short postoperative hospital admission time. Patients with high pre-operative pain score and BMI under 30 can be predictors of better clinical outcome and should be considered prior to implantation	II-3

Evidence on Interspinous Fusion for the treatment of Spinal Stenosis (cont'd)

Kim et al 2012 (69)	N = 40; lumbar spinal stenosis, degenerative spondylolisthesis, disc herniation	Spinal fusion with pedicle screw fixation	Interspinous fusion device, posterior interbody fusion	Dynamic lateral radiographs, visual analogue scale (VAS), and Korean version of the Oswestry disability index (K-ODI) scores were evaluated in both groups.	12 to 22 months	The lumbar spine diseases in the IFD group were as followings; spinal stenosis in 26, degenerative spondylolisthesis in 12, and intervertebral disc herniation in 2. The mean follow up period was 14.24 months (range; 12 to 22 months) in the IFD group and 18.3 months (range; 12 to 28 months) in pedicle screw group. The mean VAS scores was preoperatively 7.16±2.1 and 8.03±2.3 in the IFD and pedicle screw groups, respectively, and improved postoperatively to 1.3±2.9 and 1.2±3.2 in 1-year follow ups ($p<0.05$). The K-ODI was decreased significantly in an equal amount in both groups one year postoperatively ($p<0.05$). The statistics revealed a higher incidence of ASD in pedicle screw group than the IFD group ($p=0.029$)	Posterior IFD has several advantages over the pedicle screw fixation in terms of skin incision, muscle dissection and short operative time and less intraoperative estimated blood loss. The IFD with PLIF may be a favorable technique to replace the pedicle screw fixation in selective case.	II-2

Evidence on Interspinous Fusion for the treatment of Spinal Stenosis (cont'd)

Schmidt et al. (2018) [70]	N=225 Decompression alone=110 Decompression with interspinous spacer=115 Inclusion criteria: Moderate spinal stenosis Failed 3 months conservative therapy VAS>50 No dynamic instability	Open Decompression alone	Open surgical decompression versus open surgical decompression with placement of interspinous spacer	Primary end point included Oswestry Disability Index (ODI) scores, the presence of secondary surgery or lumbar injections, neurological status, and the presence of device- or procedure-related severe adverse events Secondary end points included visual analog scale (VAS) scores, Zürich Claudication Questionnaire (ZCQ) scores, narcotic usage, walking tolerance, and radiographs.	2 years	Composite endpoint superior for decompression with spacer, as well as having less secondary interventions Decompression alone had higher rate of narcotic use Walking Distance Test results > 2 times the improvement with use of spacer Patient reported outcomes (ODI, ZCQ, VAS) were the same between groups	Demonstrated no significant difference in the individual patient-reported outcomes (e.g., ODI, VAS, ZCQ) between the treatments when viewed in isolation. The CCS (survivorship, ODI success, absence of neurological deterioration or device- or procedure-related severe adverse events) is statistically superior for use of the spacer. It increases walking distance, decreases compensatory pain management, and maintains radiographic foraminal height, extending the durability and sustainability of a decompression procedure.	I

Evidence on Interspinous Fusion for the Treatment of Spinal Stenosis (cont'd)

Musacchio et al. (2016) [71]	N=225 Decompression with Coflex=110 Decompression with pedicle screw fixation=115 Inclusion criteria: Moderate to Severe spinal stenosis 1-2 lumbar levels Minimum ODI score of at least 40%; and VAS back pain score of at least 50	Decompression with pedicle screw fixation	Decompression with Coflex versus Decompression with pedicle screw fixation	Success criteria required that a patient meet 4 criteria: 1) >15 point improvement in Oswestry Disability Index (ODI) score; 2) no reoperation, revision, removal, or supplemental fixation; 3) no major device-related complication; and 4) no epidural steroid injection after surgery.	5 years	50.3% of Coflex vs. 44% of Pedicle screw fixation met the composite success criteria. Reoperation/revision rates were similar in the two groups Both groups had statistically significant improvement through 60 months in ODI scores VAS, SF-12, and ZCQ significant improvement On the SF-12 and ZCQ, Coflex group scores were statistically significantly better during early follow-up	Both treatment groups achieved and maintained statistically significant improvements on multiple outcome assessments throughout 5-year follow-up. On some clinical measures, there were statistically significant differences during early follow-up favoring Coflex. At no point were there significant differences favoring pedicle screw fixation. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with coflex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels.	I

Evidence on Interspinous Fusion for the treatment of Spinal Stenosis (cont'd)

Falowski et al 2021 [72]	N = 32; spinal stenosis and lumbar degenerative disc disease	None, retrospective	Interspinous fusion device	Serious adverse events, specifically nerve injury, hematoma, infection, and death, were analyzed quantitatively for reported complications within 90 days from the procedure. In addition, VAS was analyzed for patient reported outcomes.	90 days	Adverse event rate was 0% with no incidences of reoperation, or device removal. Estimated blood loss was recorded as less than 50 cc for all patients. The preoperative pain assessment demonstrated an average pain score of 8.1 and a postoperative pain score of 2.65 equating to a percentage pain reduction of 67%.	Demonstrates the success and safety of ISF being performed by interventional pain physicians in an outpatient setting. It is a valuable tool in the treatment of moderate to severe lumbar spinal stenosis and degenerative disc disease that has decreased morbidity and significant efficacy.	II-3

Practice Recommendations for Interspinous Fusion for the Treatment of Spinal Stenosis

Practice Statement		Evidence Grade	Recommendation Grade
1.	Decompression and interlaminar stabilization with coflex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels.	Good	B
2.	Surgical interspinous fixation alone for the treatment of degenerative disc disease in the clinical context of spinal stenosis and neurogenic claudication is a viable treatment option	Fair	C

Evidence on Surgical Decompression with and without Fusion for the treatment of Spinal Stenosis

Study	Number of subjects Selection Criteria	Control	Intervention	Outcomes Measures	Time of Measurement	Results	Conclusions	USPSTF
Malimivarra et al [81]	94 patients,	Non-surgical treatment	Surgical treatment	Oswestry Disability Index, data on the intensity of leg and back pain (scales, 0-10), as well as self-reported and measured walking ability	6, 12, 24 months	Both treatment groups showed improvement during follow-up. At 1 year, the mean difference in favor of surgery was 11.3 in disability (95% confidence interval [CI], 4.3-18.4), 1.7 in leg pain (95% CI, 0.4-3.0), and 2.3(95% CI, 1.1-3.6) in back pain. At the 2-year follow-up, the mean differences were slightly less: 7.8 in disability (95% CI, 0.8-14.9) 1.5 in leg pain (95% CI, 0.3-2.8), and 2.1 in back pain (95% CI, 1.0-3.3). Walking ability, either reported or measured, did not differ between the two treatment groups.	Although patients improved over the 2-year follow-up regardless of initial treatment, those undergoing decompressive surgery reported greater improvement regarding leg pain, back pain, and overall disability.	I

Evidence on Surgical Decompression with and without Fusion for the treatment of Spinal Stenosis (cont'd)

Atlas SJ et al [82]	148 eligible consenting patients initially enrolled, 105 were alive after 10 years (67.7% survival rate). Long-term follow-up between 8 and 10 years was available for 97 of 123 (79%) patients	Non-surgical treatment	Surgical treatment	Patient-reported symptoms of leg and back pain, functional status, and satisfaction	8- to 10-year follow-up	Outcomes at 1 and 4 years favored initial surgical treatment. After 8 to 10 years, a similar percentage of surgical and nonsurgical patients reported that their low back pain was improved (53% vs. 50%, P = 0.8), their predominant symptom (either back or leg pain) was improved (54% vs. 42%, P = 0.3), and they were satisfied with their current status (55% vs. 49%, P = 0.5). Patients initially treated surgically reported less severe leg pain symptoms and greater improvement in back-specific functional status after 8 to 10 years than nonsurgically treated patients.	Among patients with lumbar spinal stenosis completing 8- to 10-year follow-up, low back pain relief, predominant symptom improvement, and satisfaction with the current state were similar in patients initially treated surgically or nonsurgically. However, leg pain relief and greater back-related functional status continued to favor those initially receiving surgical treatment.	II-3
Weinstein JN et al [83]	289 patients enrolled in the randomized cohort and 365 patients enrolled in the observational cohort, with 12 weeks of symptoms and confirmatory imaging	Non-operative care	Decompressive laminectomy	SF-36, physical functional scales, modified ODI	6 weeks, 3 months, 6 months, and yearly up to 4 years	The clinically significant advantages for surgery previously reported were maintained through 4 years, with treatment effects for bodily pain 12.6 (95% confidence interval [CI], 8.5-16.7); physical function 8.6 (95% CI, 4.6-12.6); and Oswestry Disability index -9.4 (95% CI, -12.6 to -6.2).	Patients with symptomatic spinal stenosis treated surgically compared to those treated nonoperatively maintain substantially greater improvement in pain and function through 4 years.	II-1
Försth et al [84]	247 patients, 50-80 yrs with lumbar spinal stenosis at one or two adjacent vertebral levels	Decompression surgery alone	Decompression surgery plus fusion surgery	ODI, 6 minutes walk test	2 and 5 years	There was no significant difference between the groups in the mean score on the ODI at 2 years (27 in the fusion group and 24 in the decompression-alone group, P=0.24) or in the results of the 6-minute walk test. Among the patients who had 5 years of follow-up, there were no significant differences between the groups in clinical outcomes	Among patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, decompression surgery plus fusion surgery did not result in better clinical outcomes at 2 years and 5 years than decompression surgery alone.	II-1

Evidence on Surgical Decompression with and without Fusion for the treatment of Spinal Stenosis (cont'd)

Ghogawala Z et al [85]	66 patients, stable degenerative grade 1-2 spondylolisthesis and symptomatic lumbar spinal stenosis	Decompressive laminectomy alone	Laminectomy with posterolateral instrumented fusion	SF-36, ODI	2 and 4 years	The fusion group had a greater increase in SF-36 physical-component summary scores at 2 years after surgery than did the decompression-alone group (15.2 vs. 9.5, for a difference of 5.7; 95% confidence interval, 0.1 to 11.3; P=0.046). The increases in the SF-36 physical-component summary scores in the fusion group remained greater than those in the decompression-alone group at 3 years and at 4 years (P=0.02 for both years). With respect to reductions in disability related to back pain, the changes in the Oswestry Disability Index scores at 2 years after surgery did not differ significantly between the study groups (-17.9 in the decompression-alone group and -26.3 in the fusion group, P=0.06).	Among patients with degenerative grade I spondylolisthesis, the addition of lumbar spinal fusion to laminectomy was associated with slightly greater but clinically meaningful improvement in overall physical health-related quality of life than laminectomy alone.	II-1

Practice Recommendations on Surgical Decompression with and without Fusion for the treatment of Spinal Stenosis

Practice Statement	Evidence Grade	Recommendation Grade
Current literature demonstrates that the addition of fusion in the management of LSS alone yielded no clinical improvements over decompression.	Good	A

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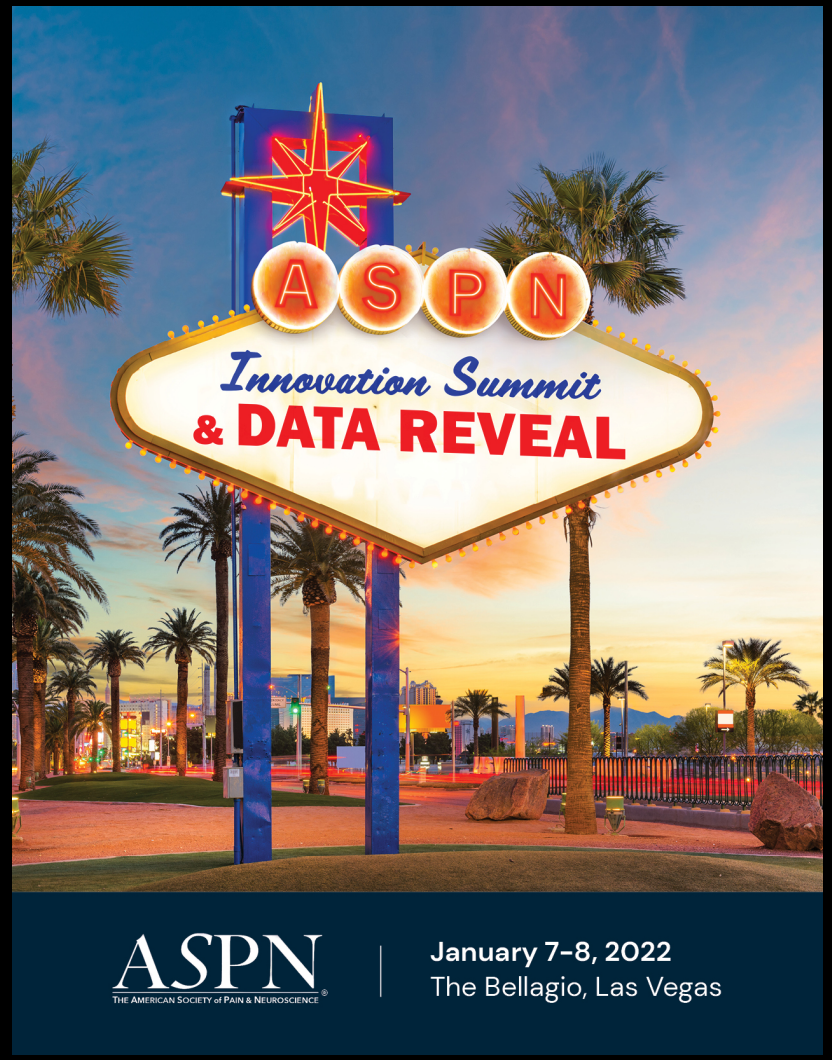
PACIFIC SPINE × PAIN SOCIETY



PAINWEEK®

Brian W. Su, MD

Minimally Invasive Advances in Lumbar Spine Surgery

PAINWEEK®

Title & Affiliation

Spine Surgeon
Co-Surgeon in Chief
Chief Development and Strategy Officer
California Orthopedics and Spine

Medical Director of Spine Surgery | Marin General Hospital
Director | Marin Healthcare District Board
Chairman | Marin Specialty Surgery Center

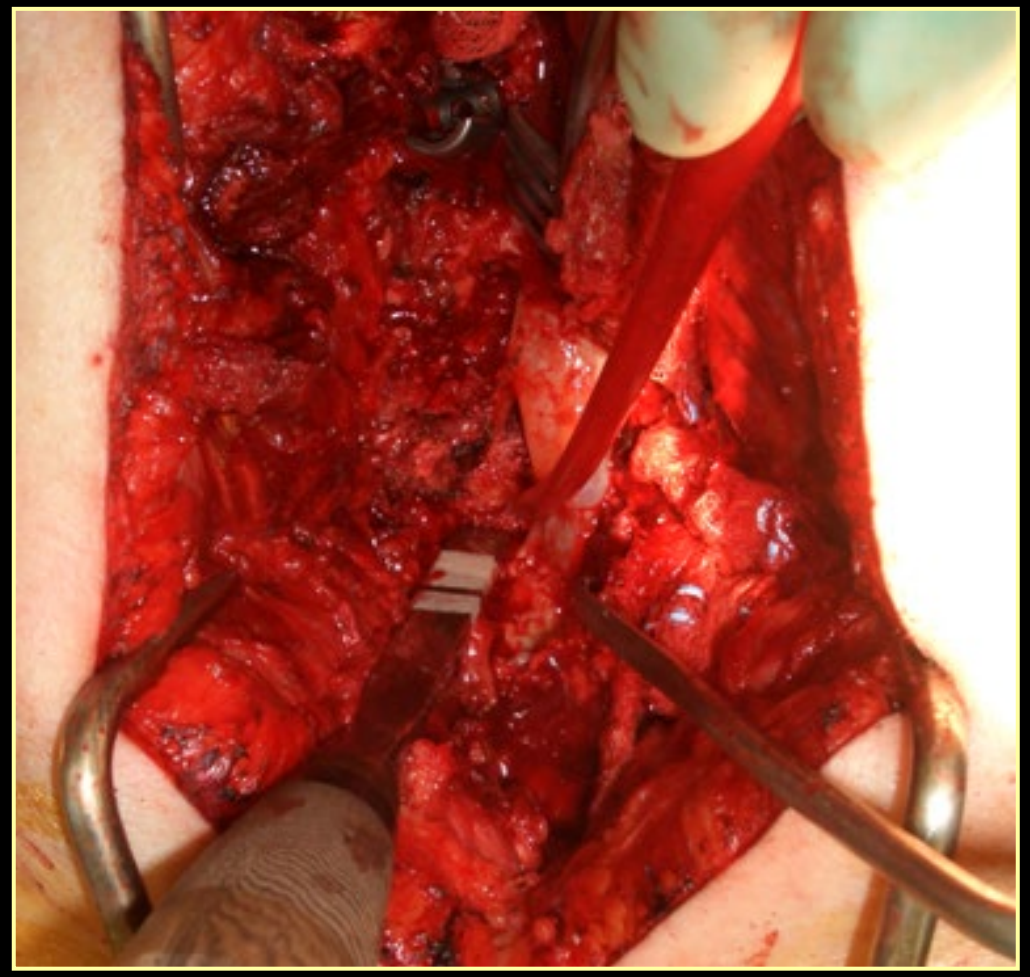
Disclosure

Nothing to disclose

Learning Objectives

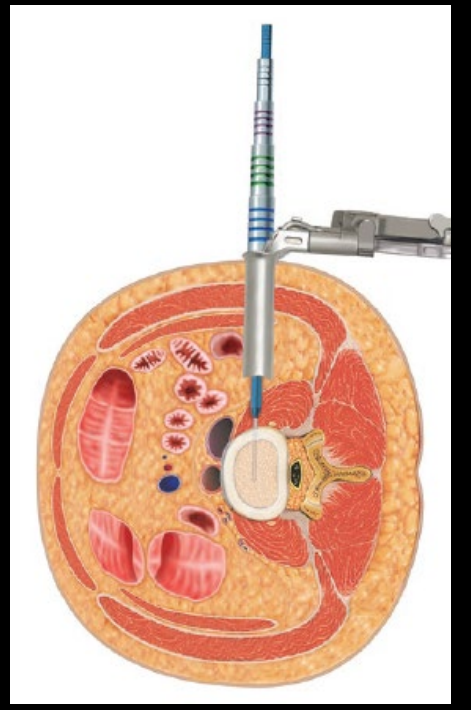
- Differentiate open lumbar surgery from minimally invasive lumbar surgery
- Describe examples of minimally invasive lumbar surgery such as anterior lumbar interbody fusion (ALIF), isthmic spondylolisthesis, transforaminal lumbar interbody fusion (TLIF), lateral lumbar interbody fusion (LLIF), and unilateral laminotomy bilateral decompression

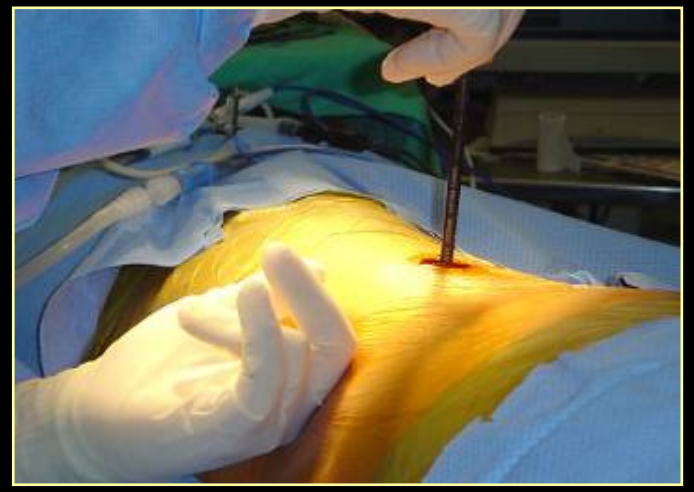
Open Lumbar Surgery



Minimally Invasive Surgery

- Goals are the same as open
  - Decompress, Realign, and Stabilize
- “Smaller incisions”
- Less collateral damage to achieve the same goals
  - Retraction of soft tissue
- Shorter LOS, less pain, lower rates of infection



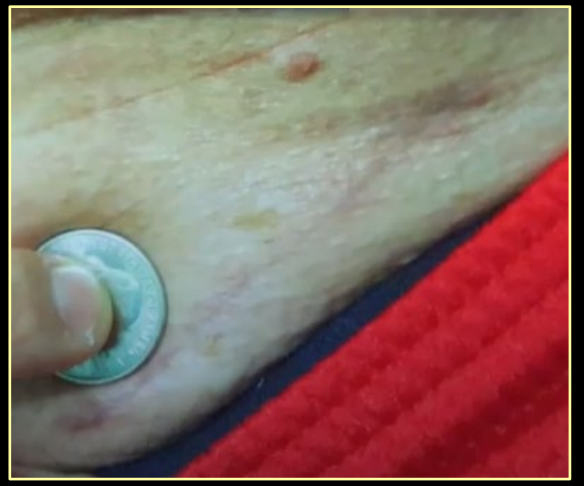


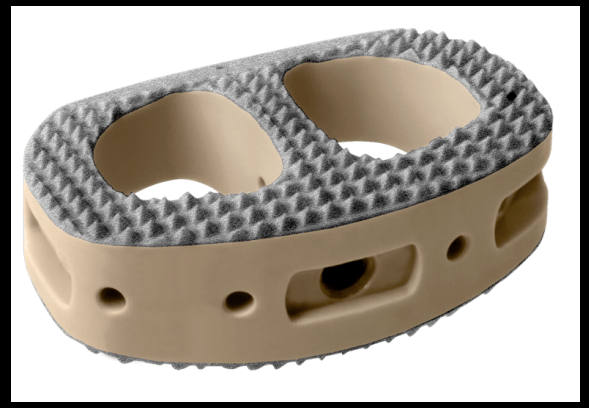
Minimally Invasive Surgery

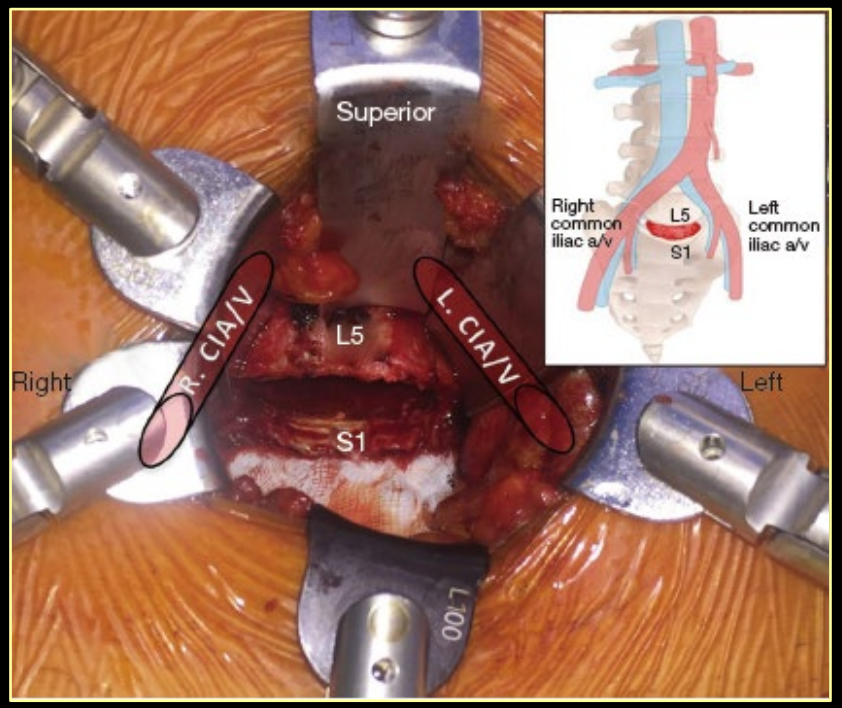
- Anterior Lumbar Interbody Fusion (ALIF) + Minimally invasive posterior Screw fixation
- Transforaminal Lumbar Interbody fusion (TLIF)
- Lateral Interbody Fusion (LIF)
- Unilateral laminotomy bilateral decompression (ULBD)

ALIF

- Anterior Lumbar Interbody Fusion
- Small incision over lower abdomen
- Remove entire disc
- Reconstruct height with cage



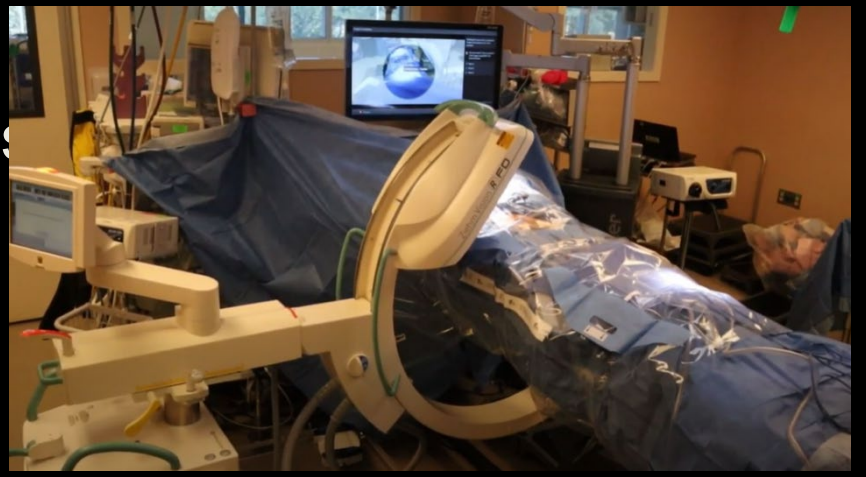


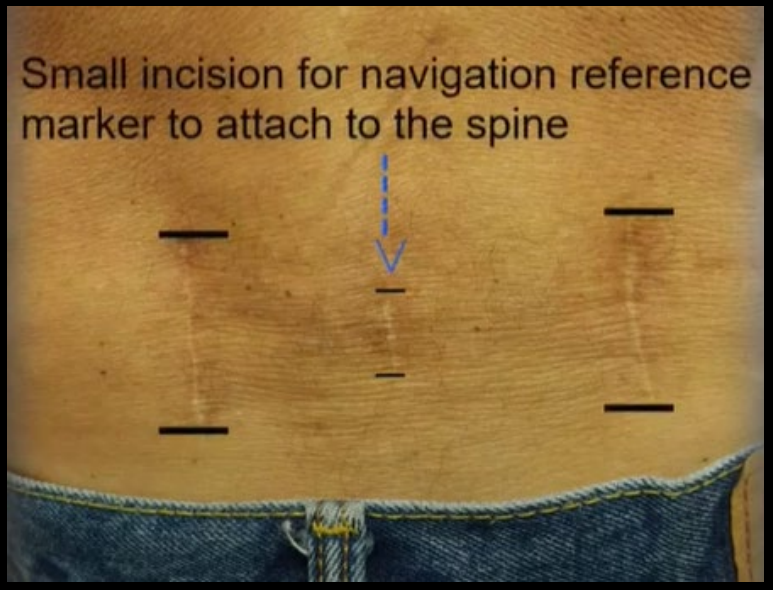


PainWeek

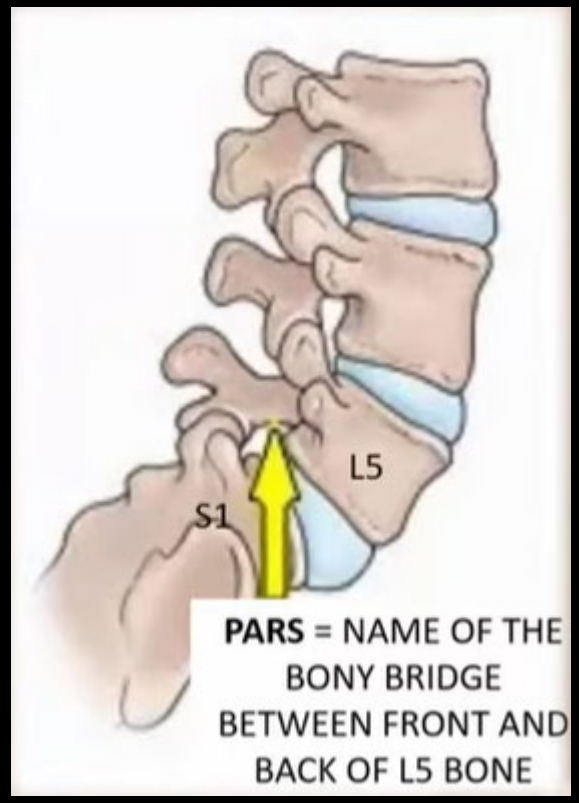
MIS Screw Placement

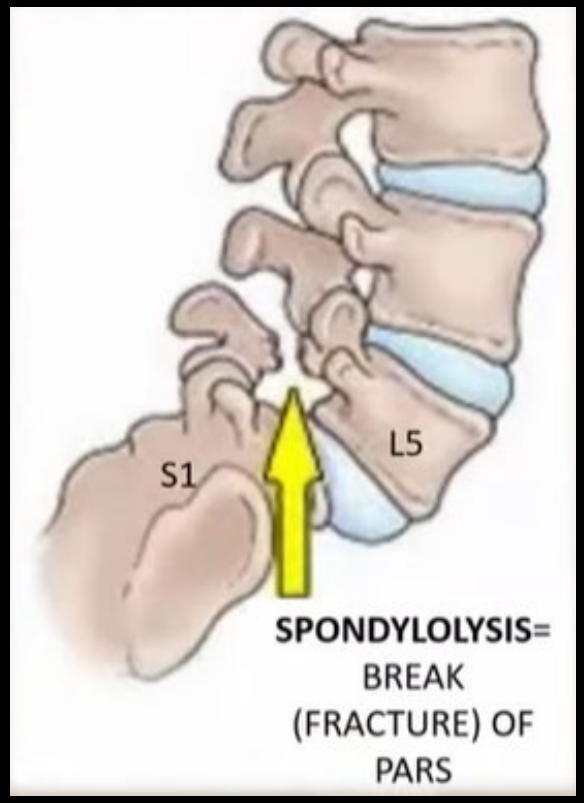
- Xray or Navigation
- Placement of pedicle screws through small incis

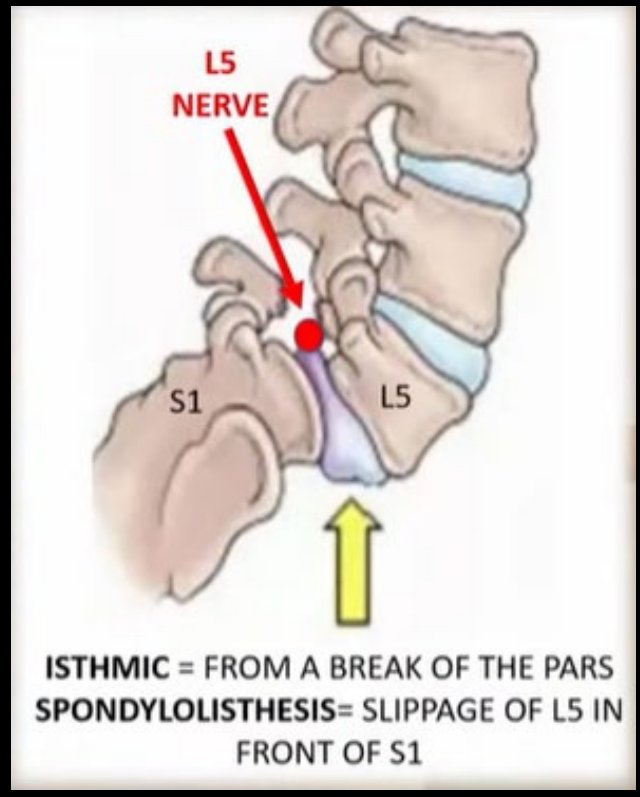




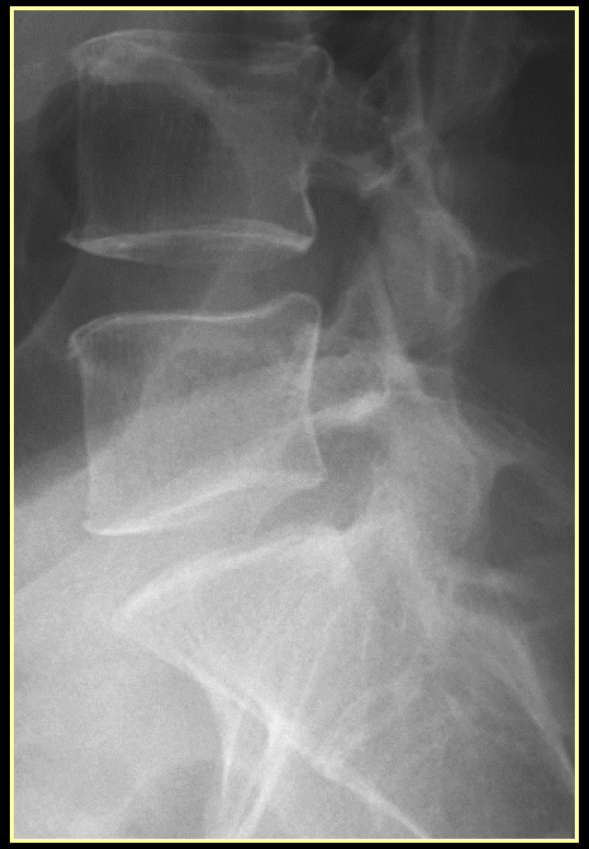
L5/S1 Isthmic Spondylolisthesis

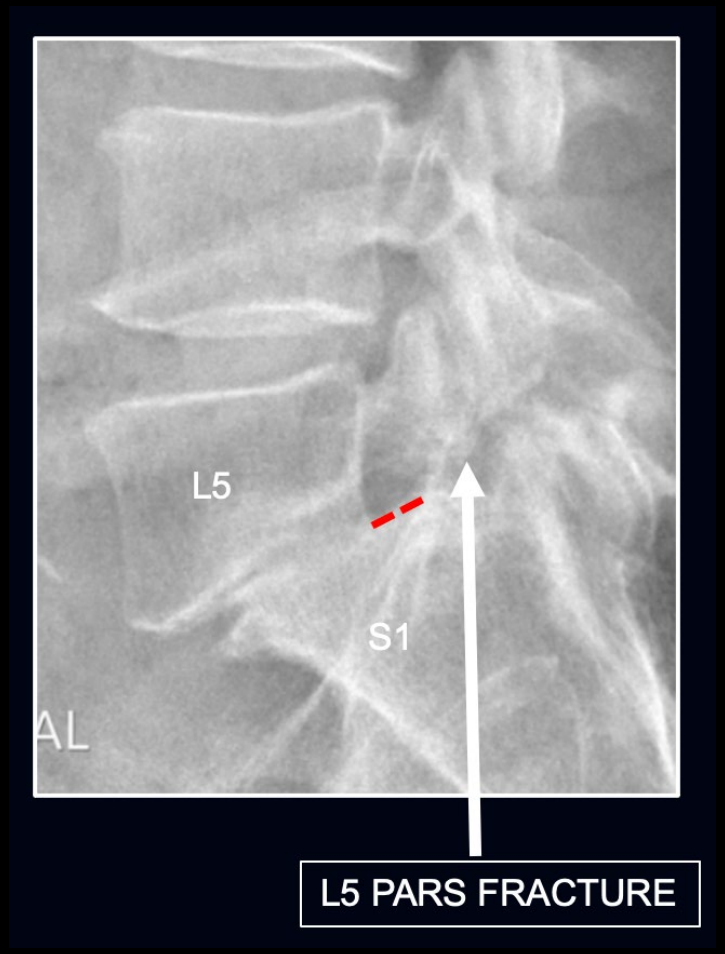


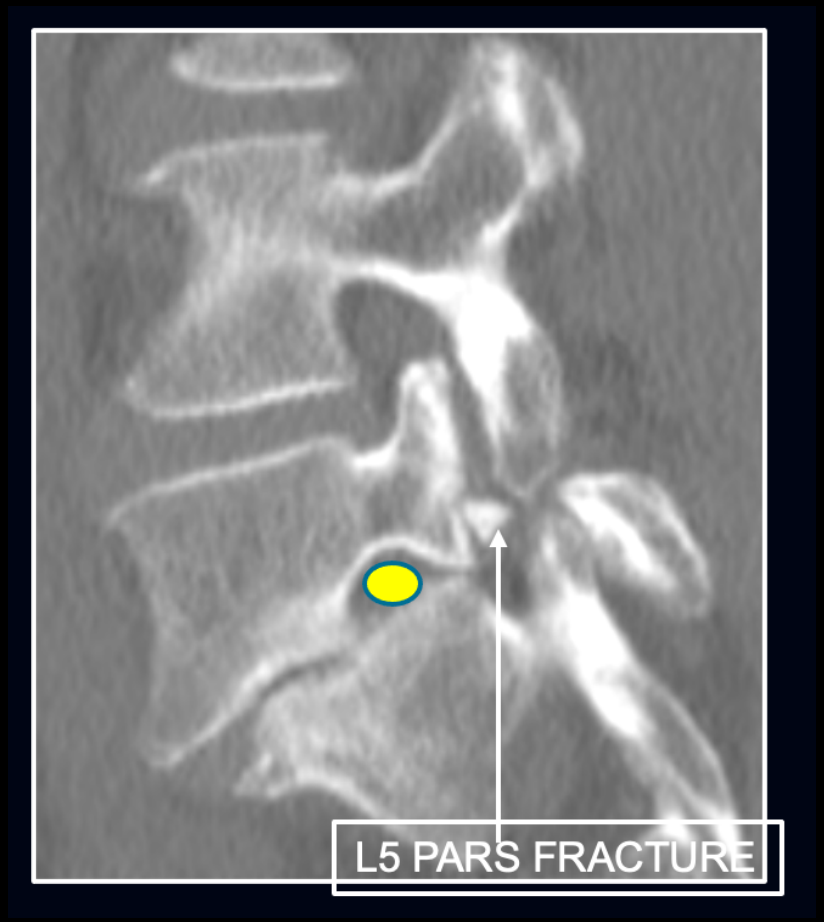




L5/S1 Isthmic Spondylolisthesis







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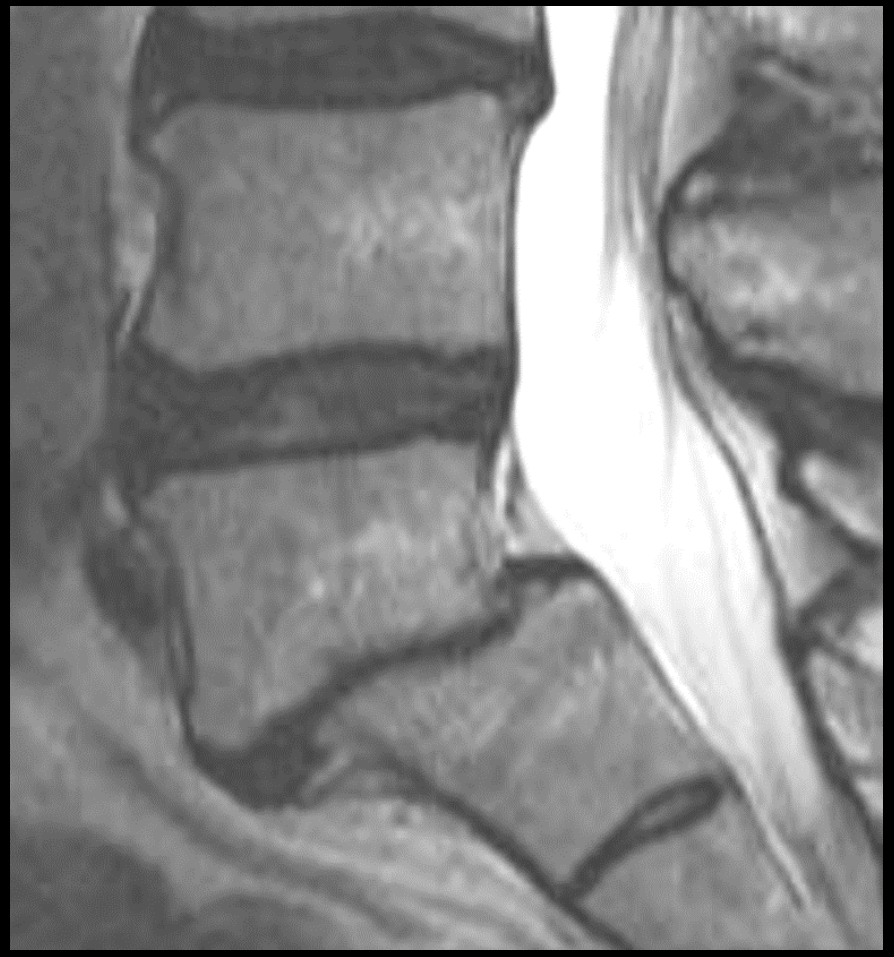
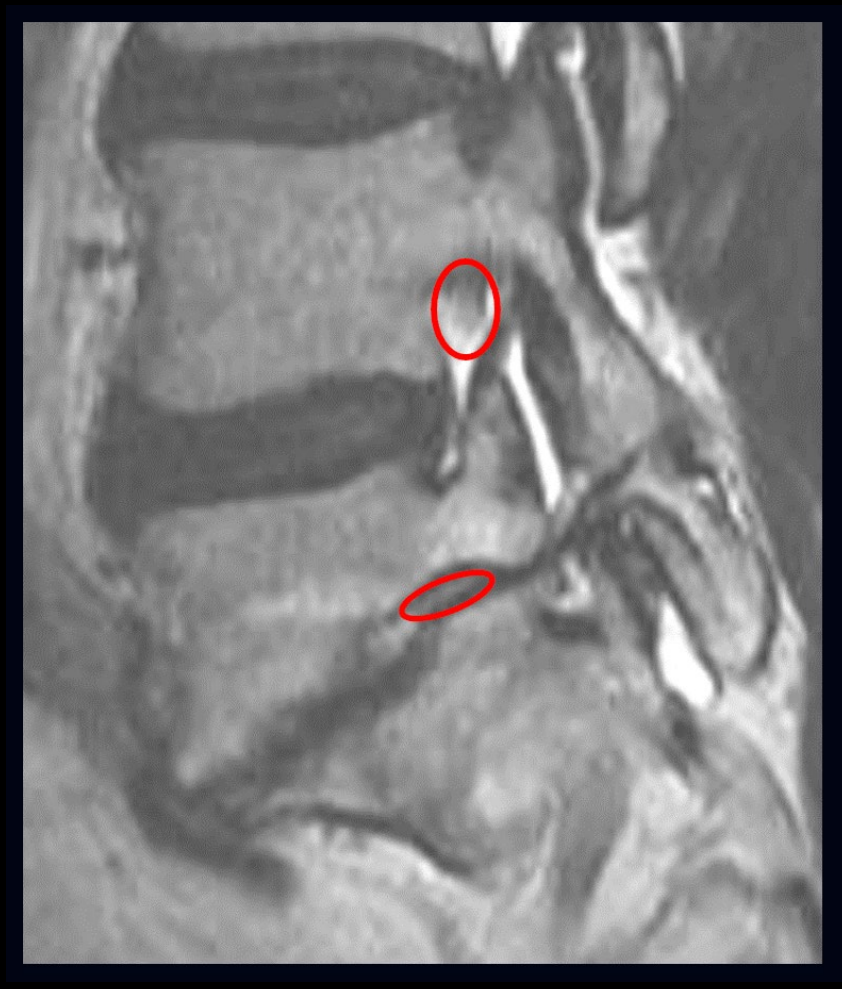
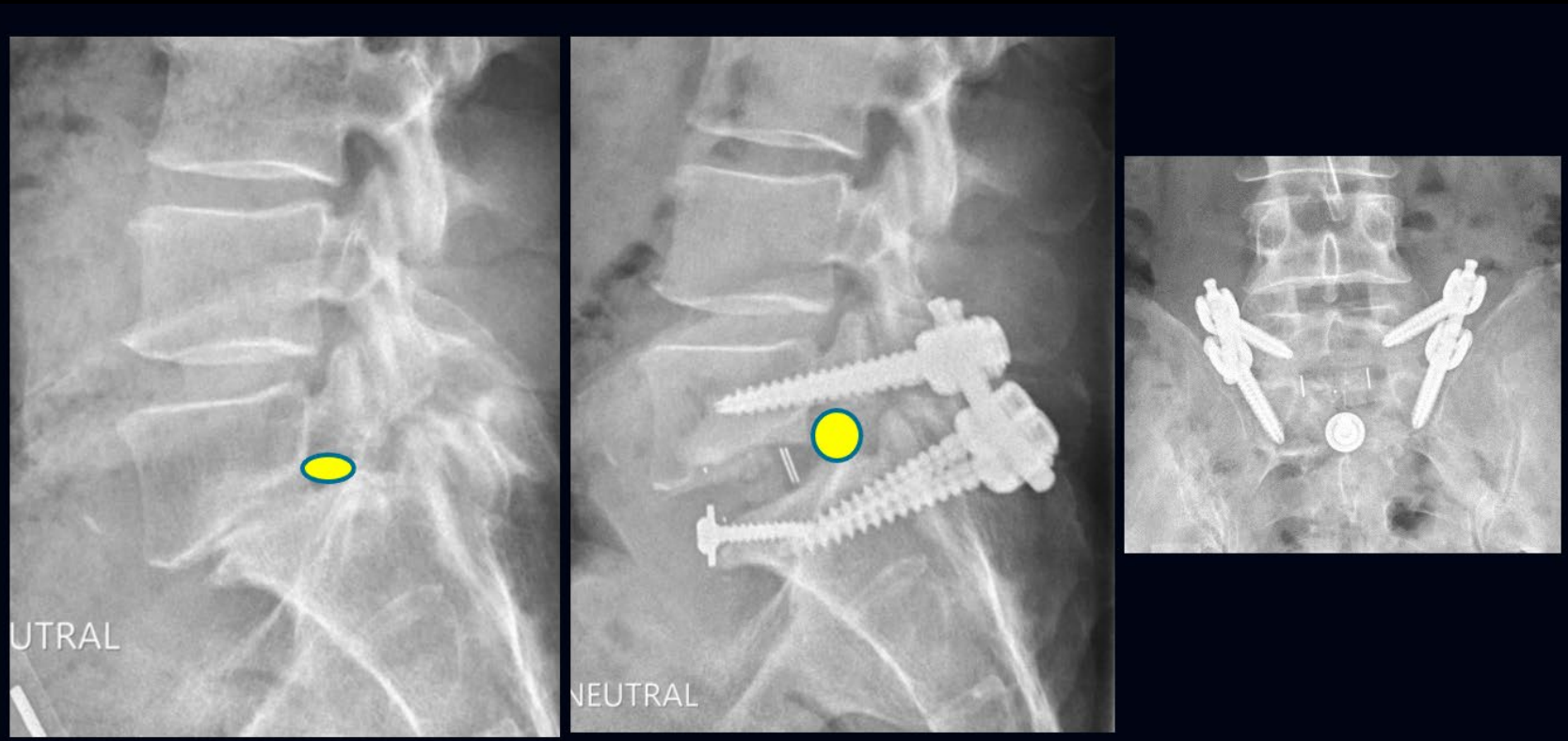




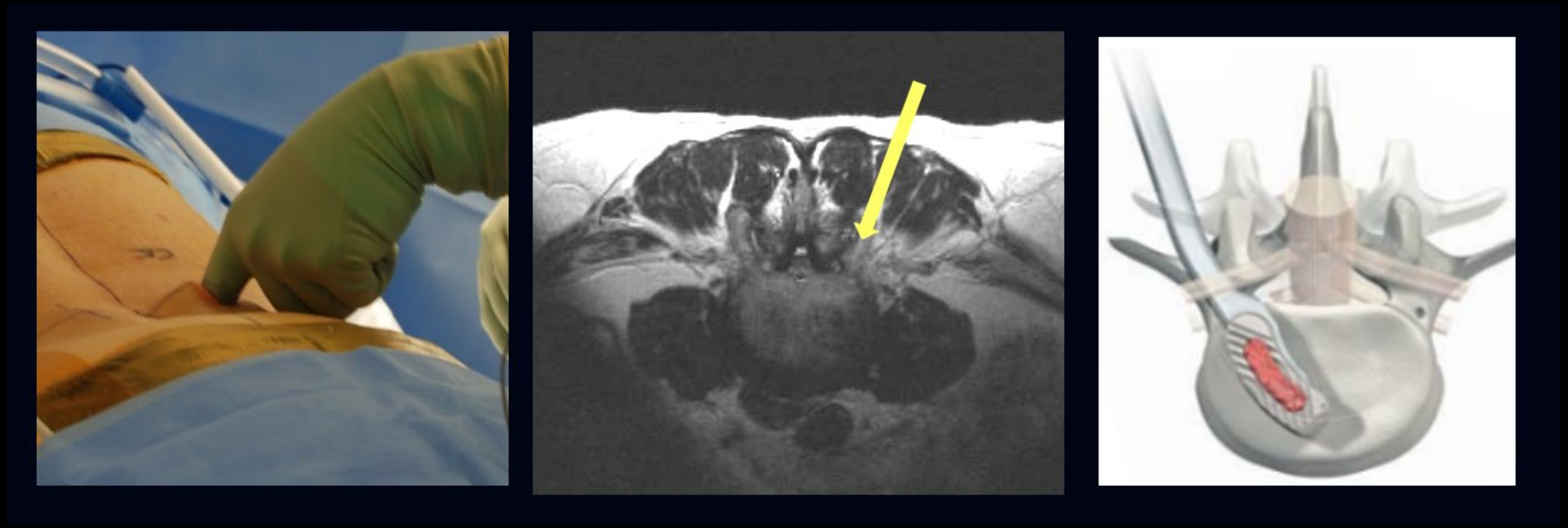
L5/S1 Isthmic Spondylolisthesis



- 1 hour ALIF + 1 hour MIS L5 & S1 Screws
- One day hospital stay

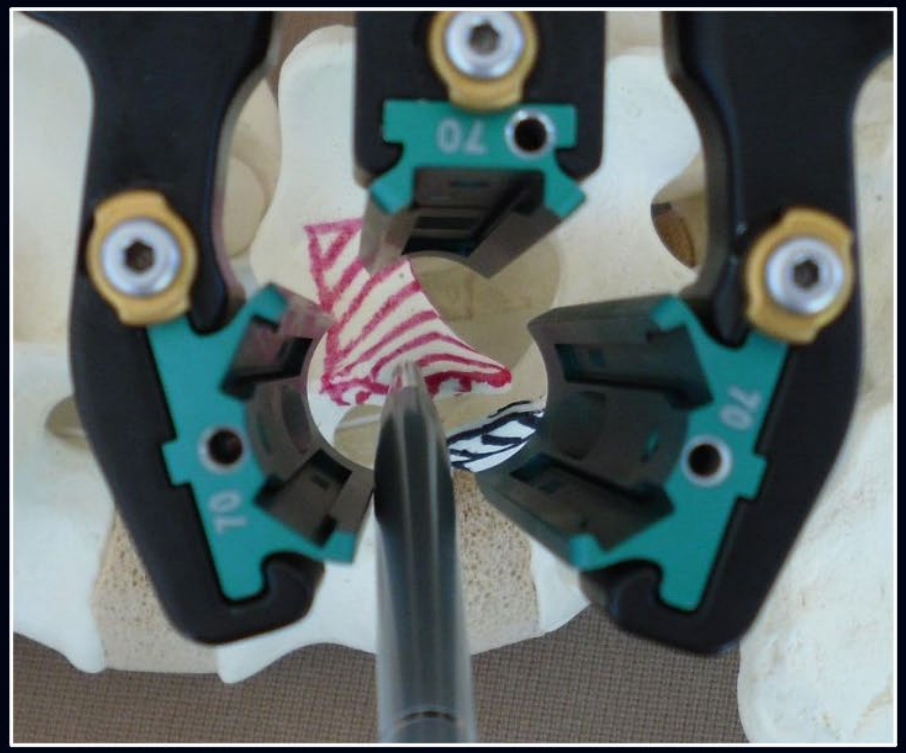
TLIF

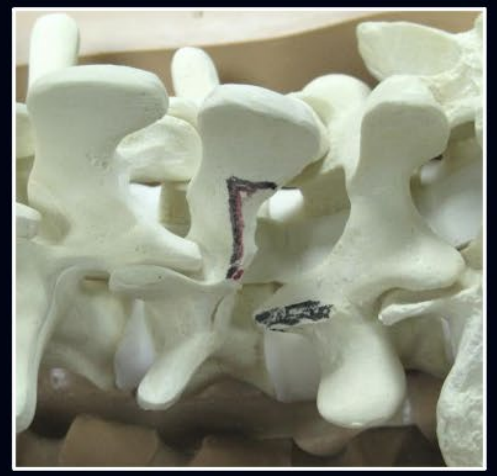
- Transforaminal Lumbar Interbody Fusion
- 2 small lateral incisions
- Removal of disc and insertion of cage
- Supported by MIS Pedicle Screws

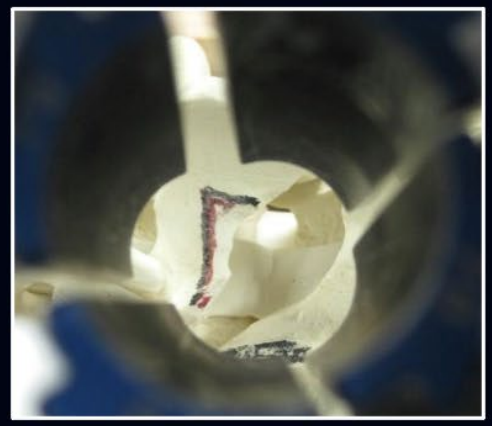


TLIF

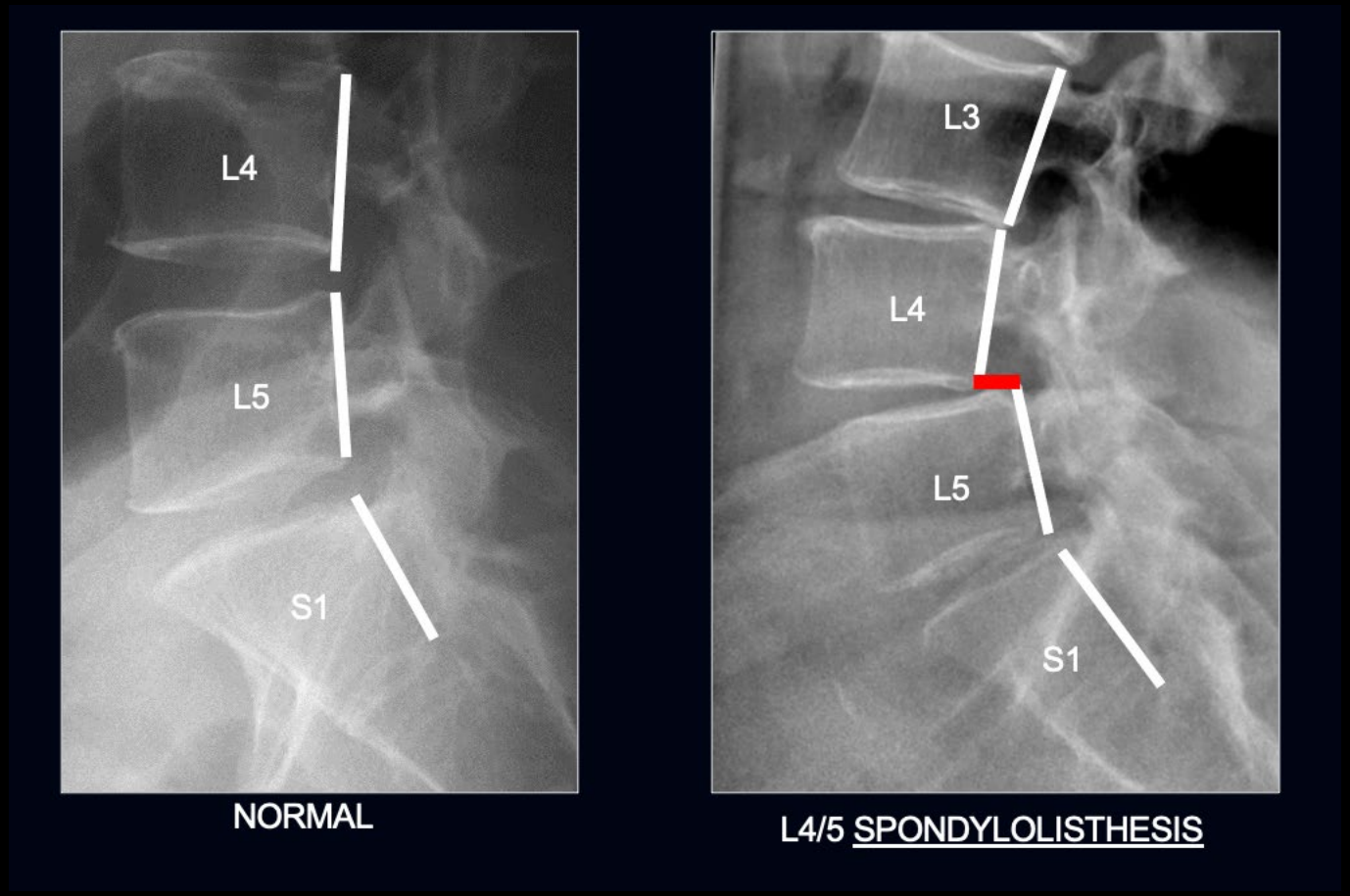
- Visualization through tubes





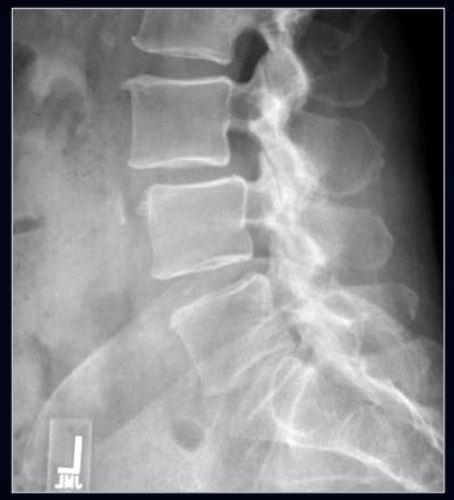


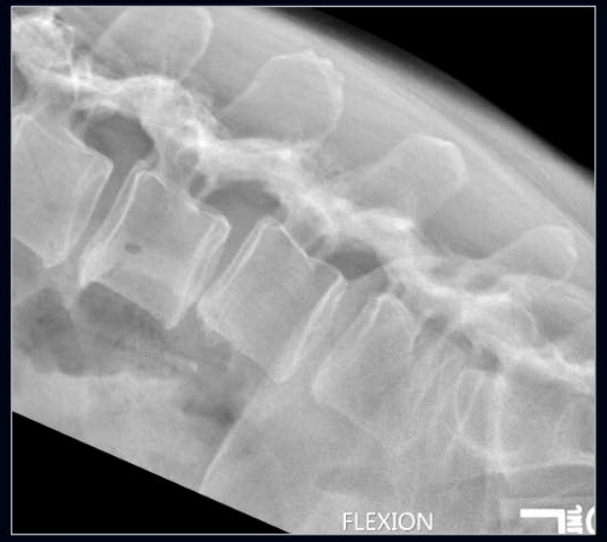
Degenerative Spondylolisthesis

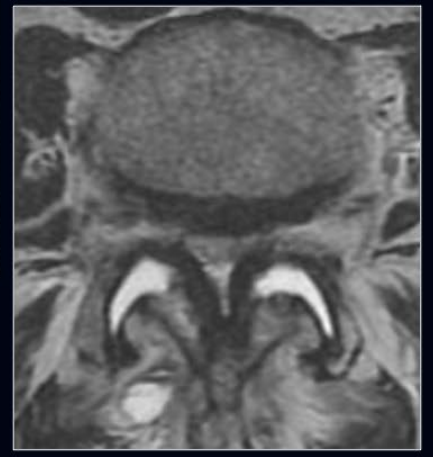


Degenerative Spondylolisthesis

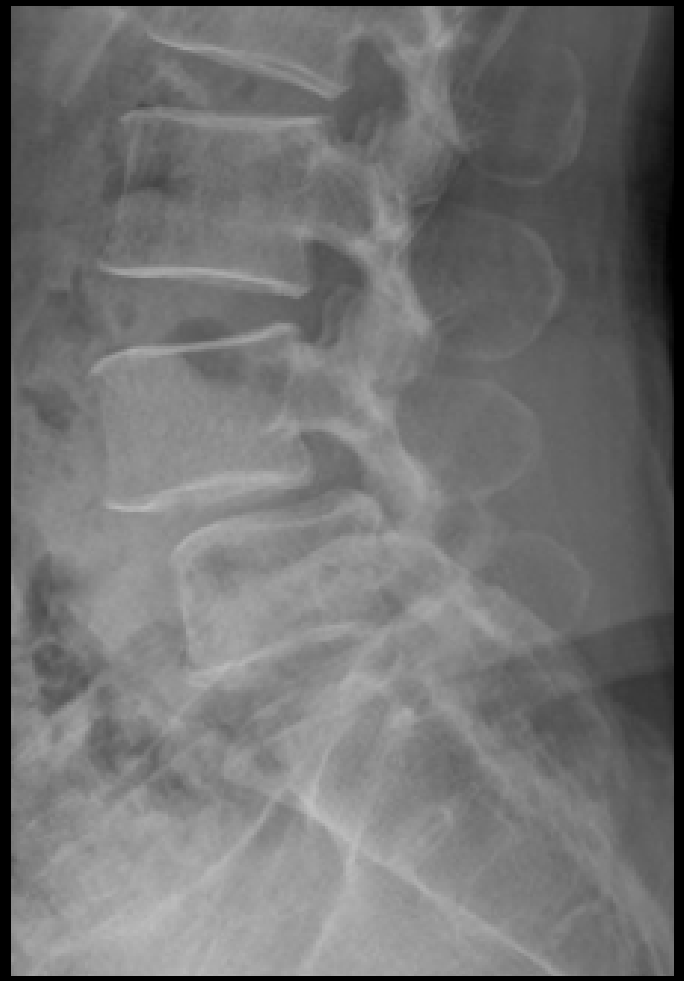
- Instability, Stenosis, Neurogenic Claudication

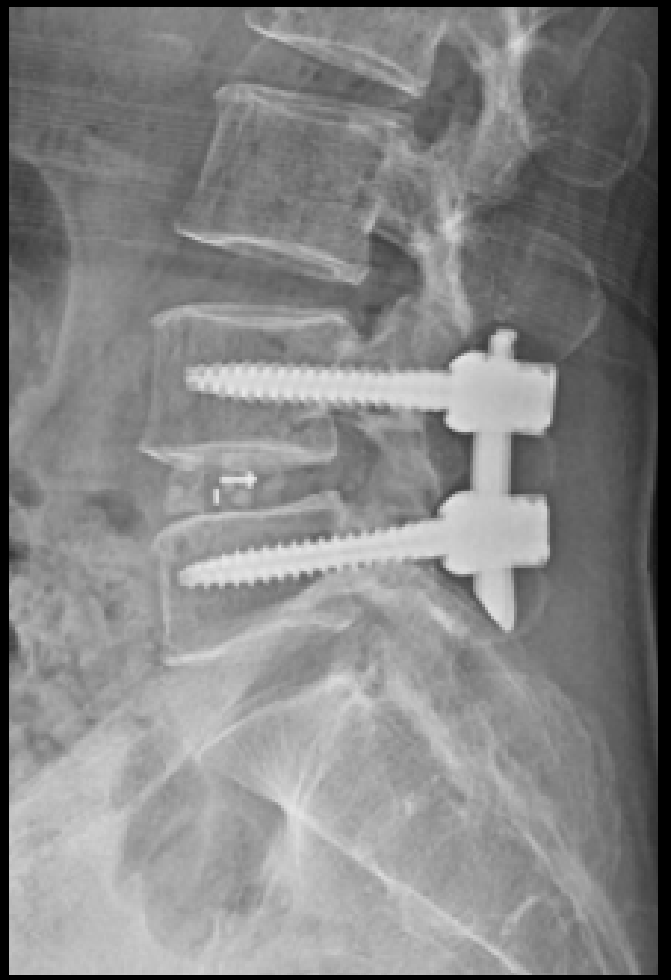


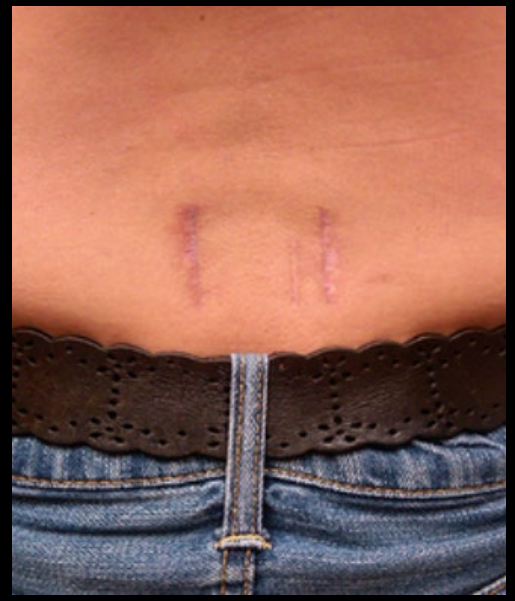




Degenerative Spondylolisthesis

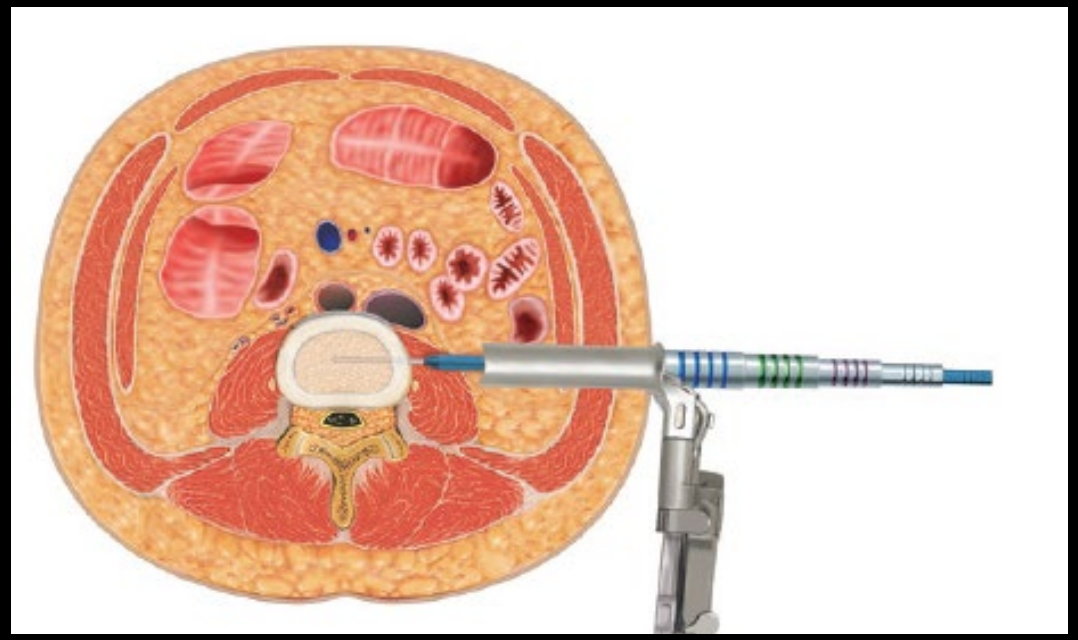


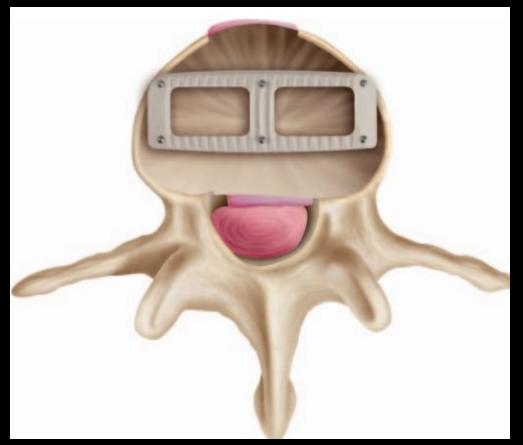




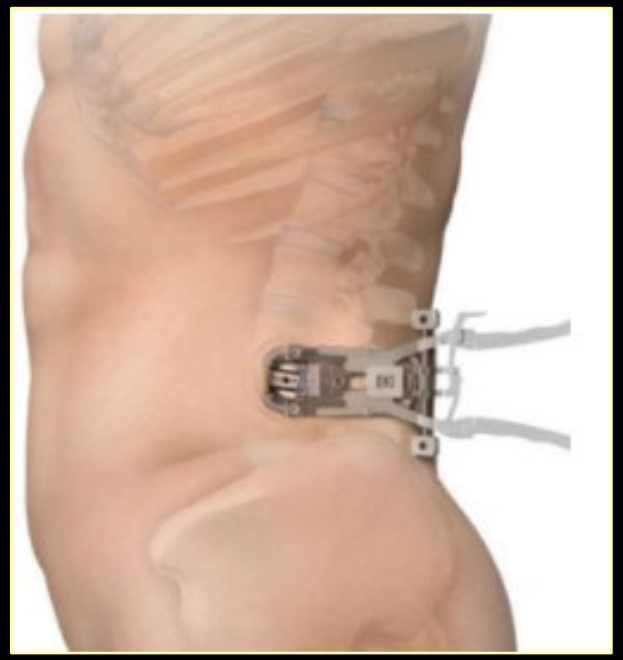
LLIF

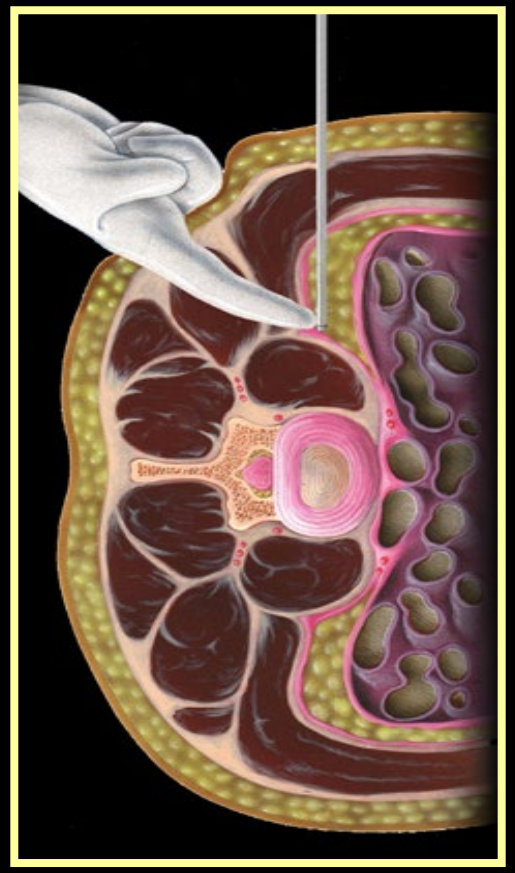
- Lateral Lumbar Interbody Fusion
- Less invasive retroperitoneal approach
- Lateral disc removal and cage placement

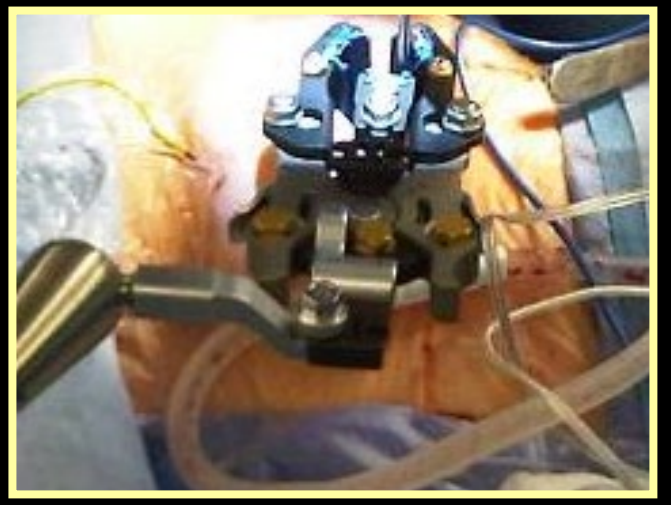




LLIF

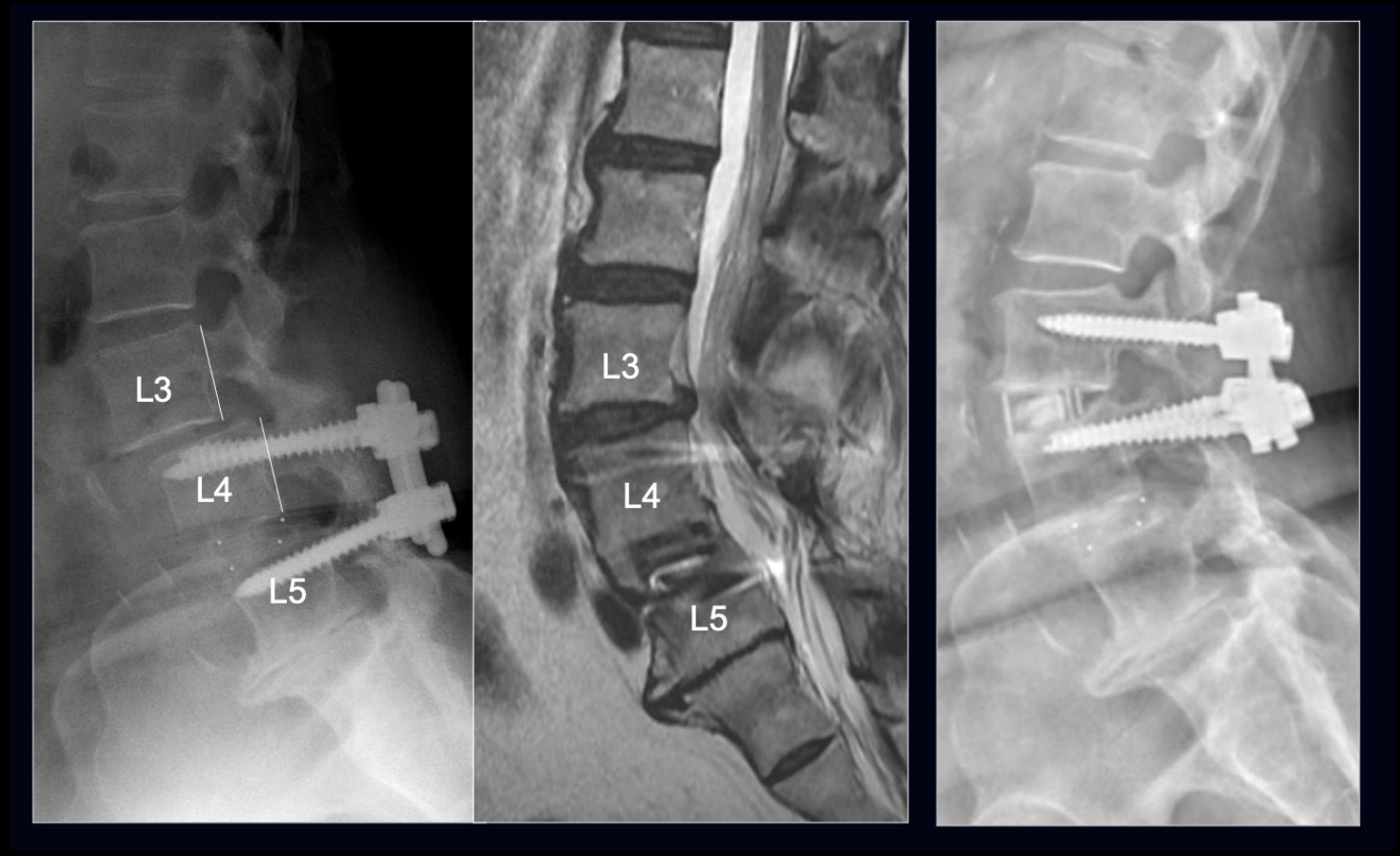






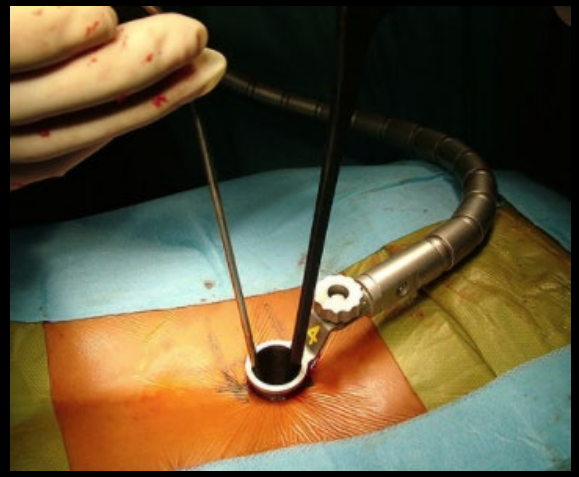
LLIF

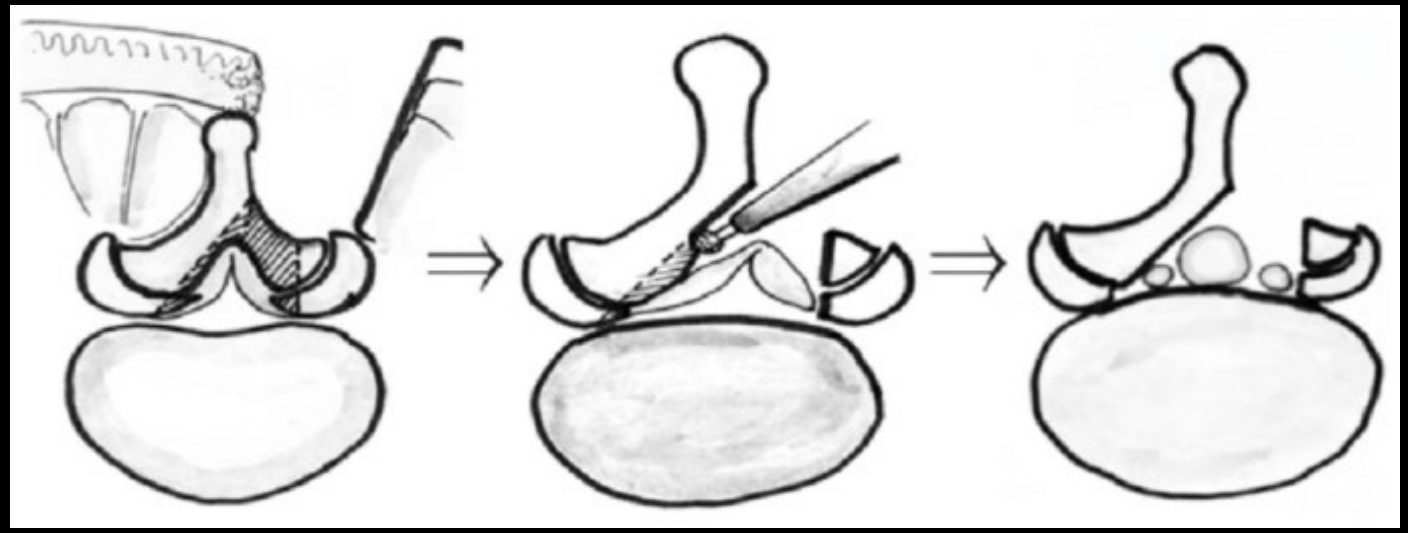
- Ideal for adjacent level disease



ULBD

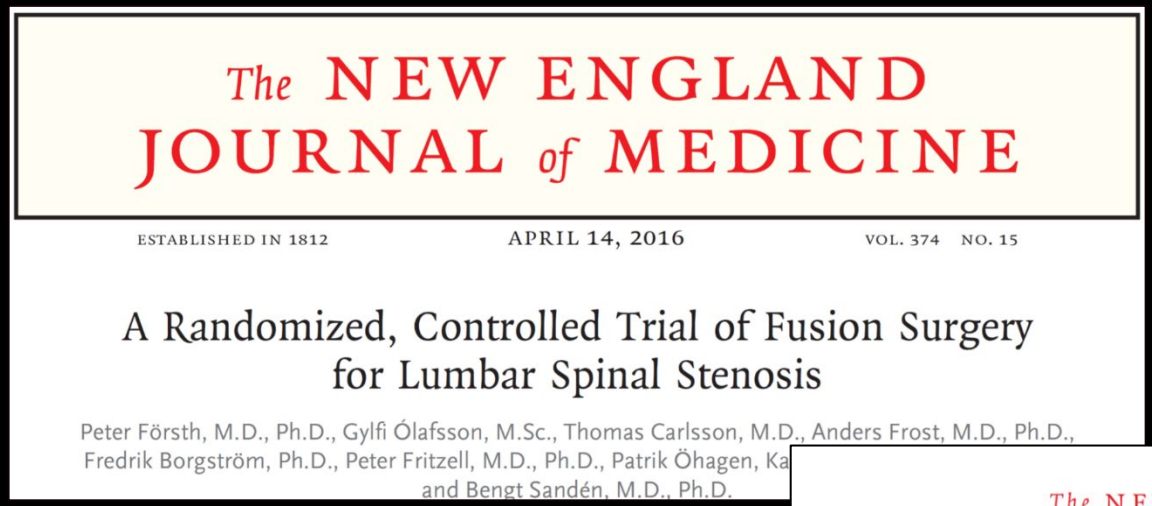
- Unilateral Laminotomy Bilateral Decompression
- Small midline incision
- Preservation of midline stabilizing structures





ULBD

- Need for fusion vs decompression alone with spondylolisthesis increasingly scrutinized

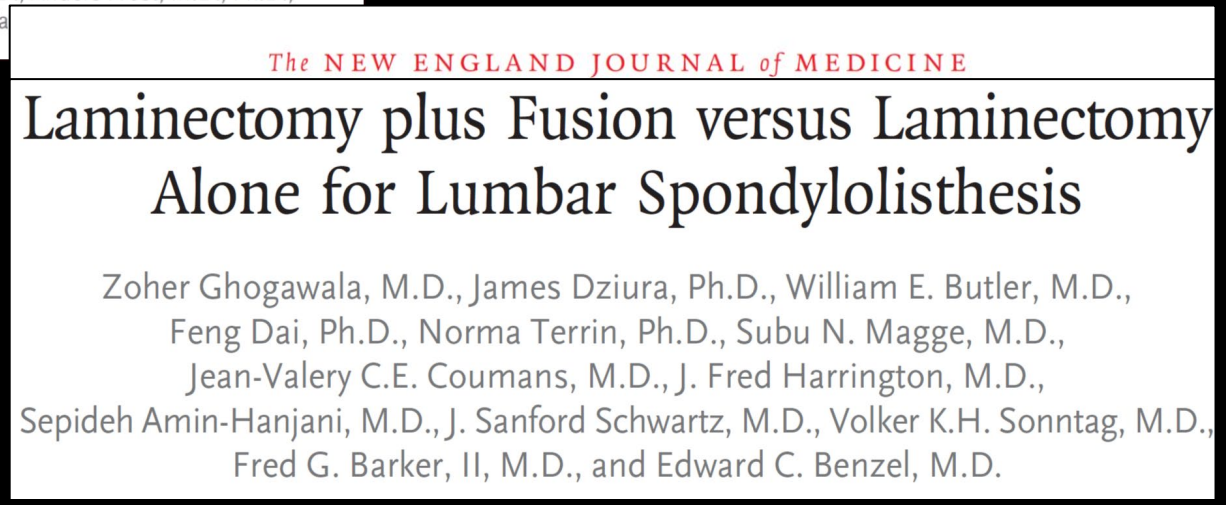


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2016 VOL. 374 NO. 15

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Ka and Bengt Sandén, M.D., Ph.D.



The NEW ENGLAND JOURNAL of MEDICINE

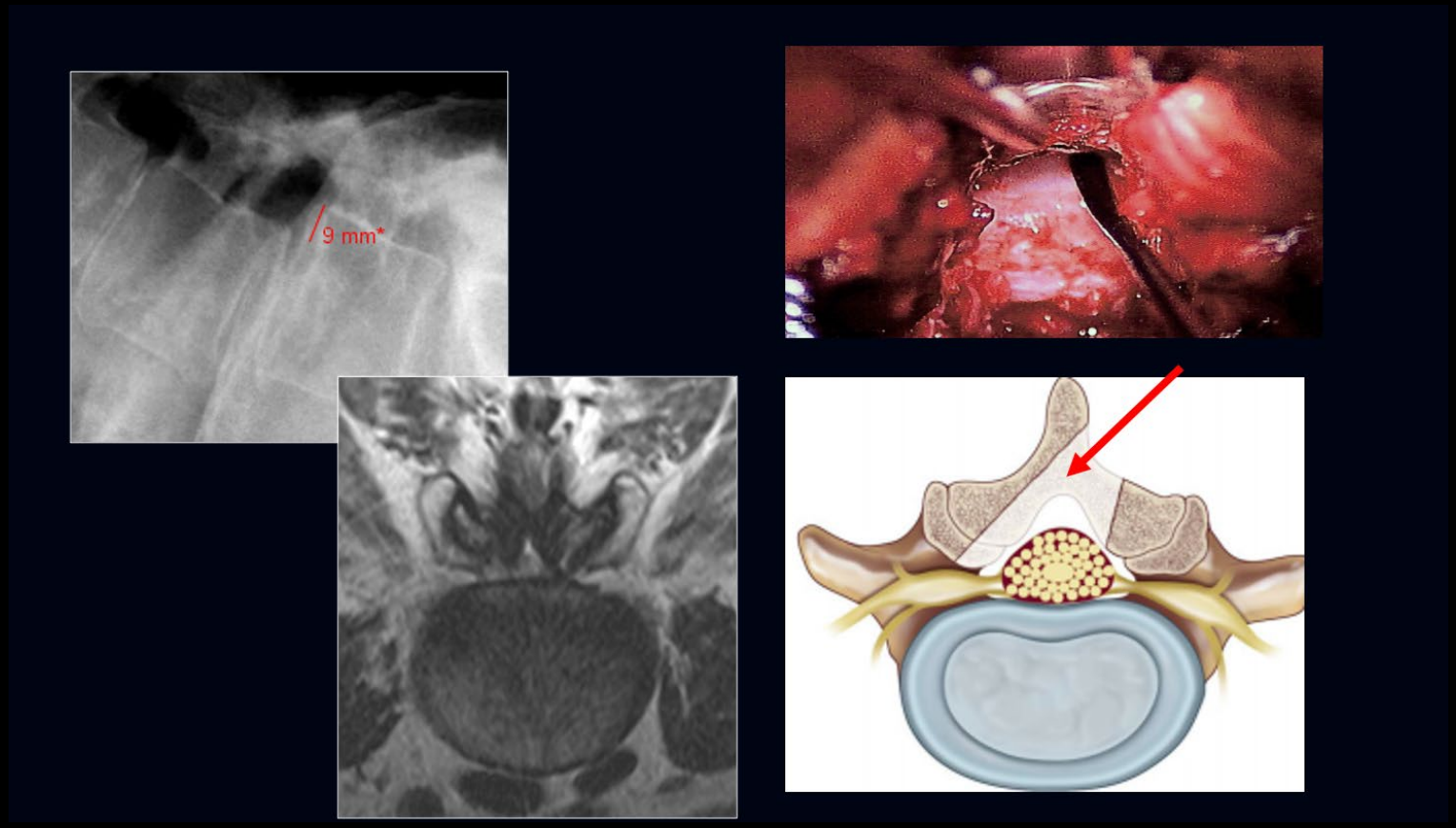
Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis

Zoher Ghogawala, M.D., James Dziura, Ph.D., William E. Butler, M.D., Feng Dai, Ph.D., Norma Terrin, Ph.D., Subu N. Magge, M.D., Jean-Valery C.E. Coumans, M.D., J. Fred Harrington, M.D., Sepideh Amin-Hanjani, M.D., J. Sanford Schwartz, M.D., Volker K.H. Sonntag, M.D., Fred G. Barker, II, M.D., and Edward C. Benzel, M.D.

N Engl J Med 2016;374:1413-23.

ULBD

- Avoids fusion for some patients with spondylolisthesis



ULBD

In Degenerative Spondylolisthesis, Unilateral Laminotomy for Bilateral Decompression Leads to Less Reoperations at 5 Years When Compared to Posterior Decompression With Instrumented Fusion

A Propensity-matched Retrospective Analysis

Calvin C. Kuo, MD,* Maqdooda Merchant, MSc, MA,† Mayur P. Kardile, MD,* Alem Yacob, MD,* Kamran Majid, MD,* and Ravinder S. Bains, MD*

- 164 ULBD vs 437 matched fusion controls
- 5 year follow up
  - Reoperation rate 10% ULBD vs. 17% Fusion
  - Decreased LOS and blood loss with ULBD

SPINE Volume 44, Number 21, pp 1530–1537

Sandy Christiansen, MD

Sacroiliac Joint Dysfunction
Lateral Branch Radiofrequency Ablation and Joint Arthrodesis

Title & Affiliation

Sandy Christiansen, MD
Assistant Professor
Oregon Health & Science University
Comprehensive Pain Center

Disclosure

- Consultant/Independent Contractor: None
- Grant/Research Support: NIH, AVANOS

Learning Objectives

- Explain sacroiliac joint provocative maneuvers to diagnose dysfunction of the joint
- Summarize appropriate timing of referring to a specialist
- Compare studies examining benefit of lateral branch radiofrequency ablation versus sacroiliac joint arthrodesis
- List possible complications of each procedure

Diagnosing Sacroiliac Joint Dysfunction

History

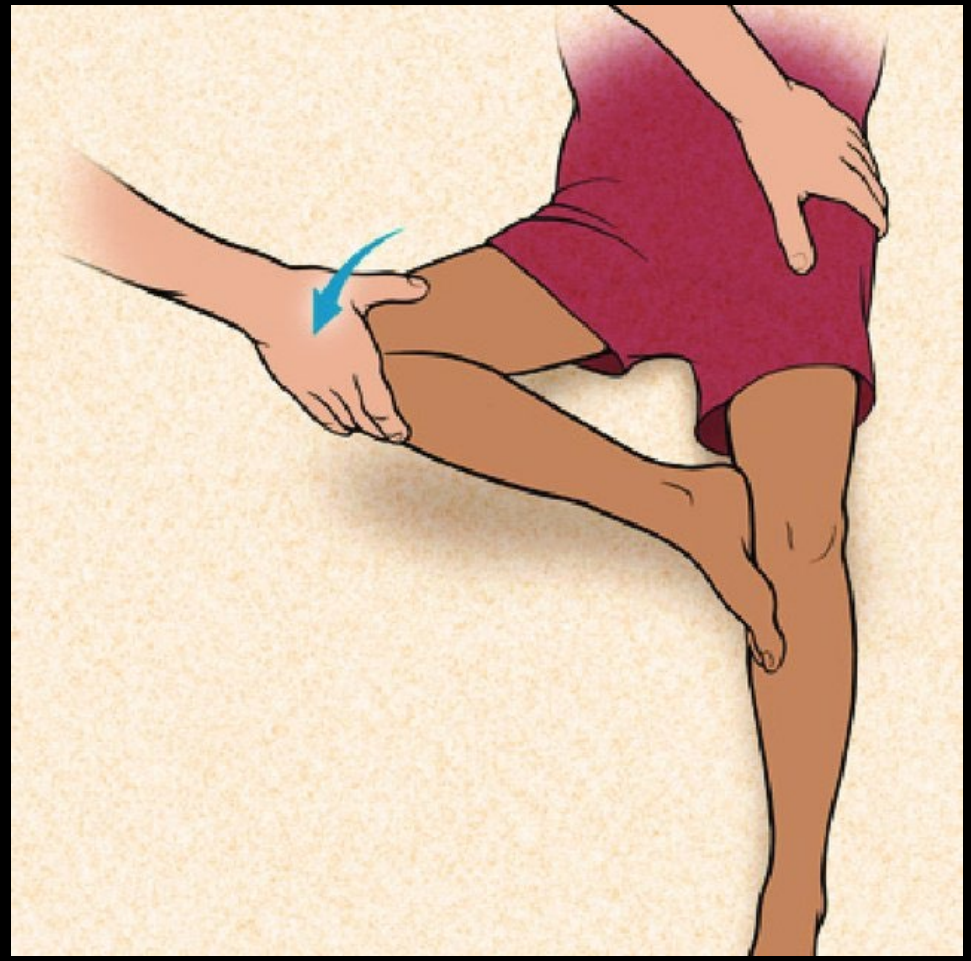
- Sacroiliac joint is primary pain generator in 15-30% of patients with axial low back pain below L5
- More common in women and elderly

Axial Loading	Mobility 	Axial Imbalance
Repetitive low-impact activities (i.e. jogging)	Adjacent segment disease following spine fusion (especially including the sacrum)	Scoliosis
Obesity	Motor vehicle accident or trauma	Leg length discrepancy
Pregnancy	Pregnancy	Gait abnormalities
Falls	Connective Tissue Syndromes (?)	

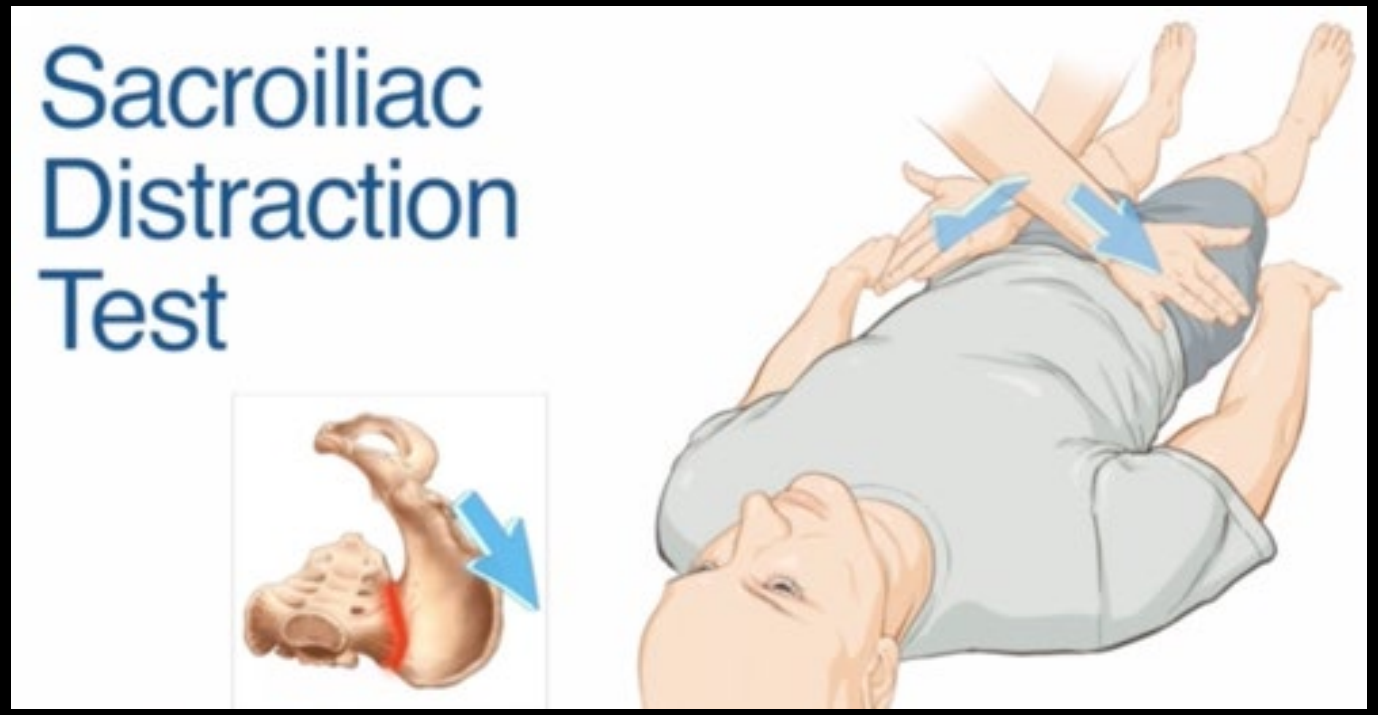
Physical Exam

- No single sign on physical exam can diagnose sacroiliac joint dysfunction
- Gait analysis (if abnormal consider leg length discrepancy)
- Pain on palpation of sacral sulcus
- Always examine the joint above and below (facet joints and hip)
- Lower extremity neurological exam (motor, sensory, reflexes, straight leg raise)
- Three or more positive ***provocative tests*** are 92-94% sensitive

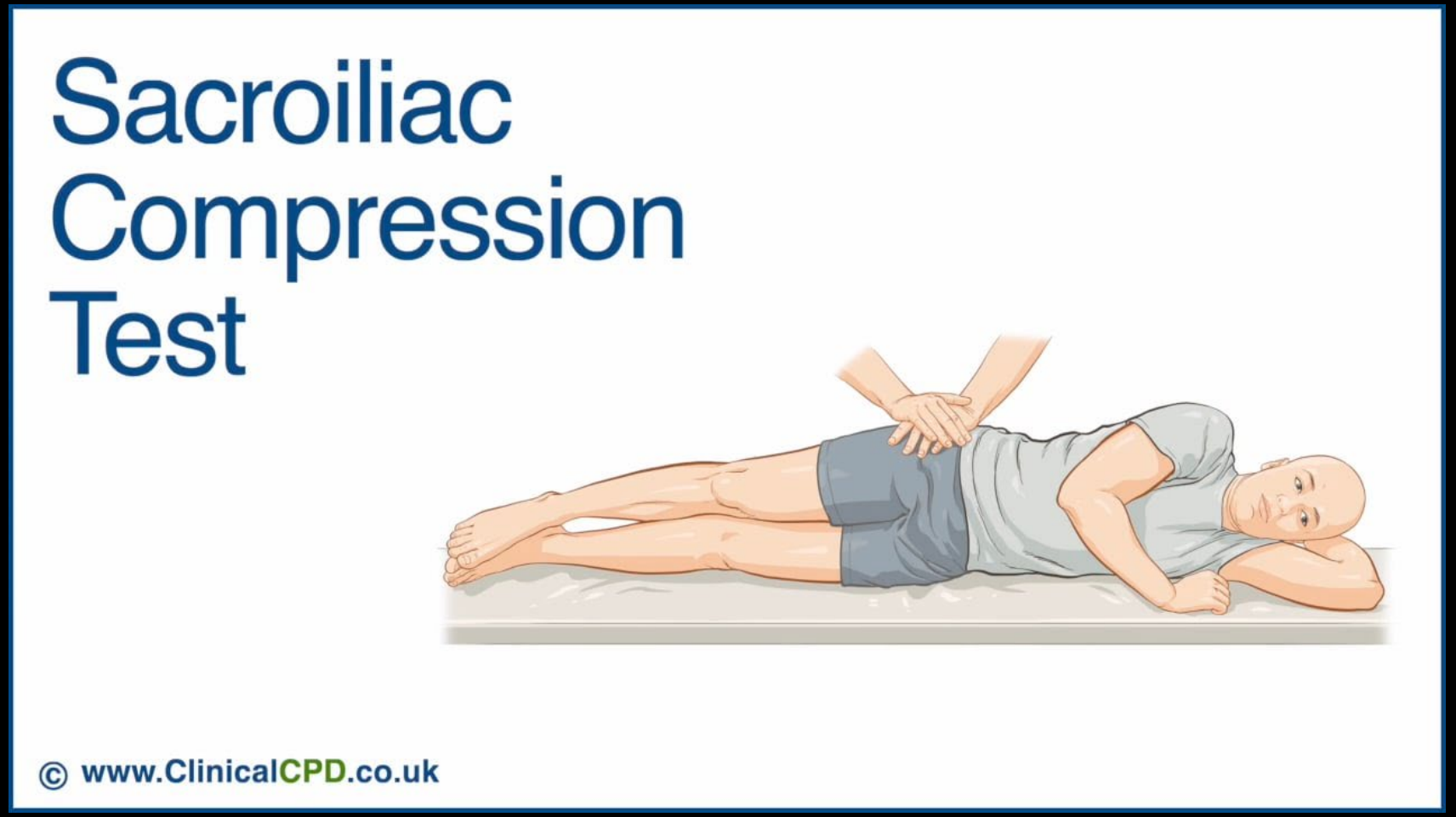
FABER (flexion abduction external rotation) or Patrick's



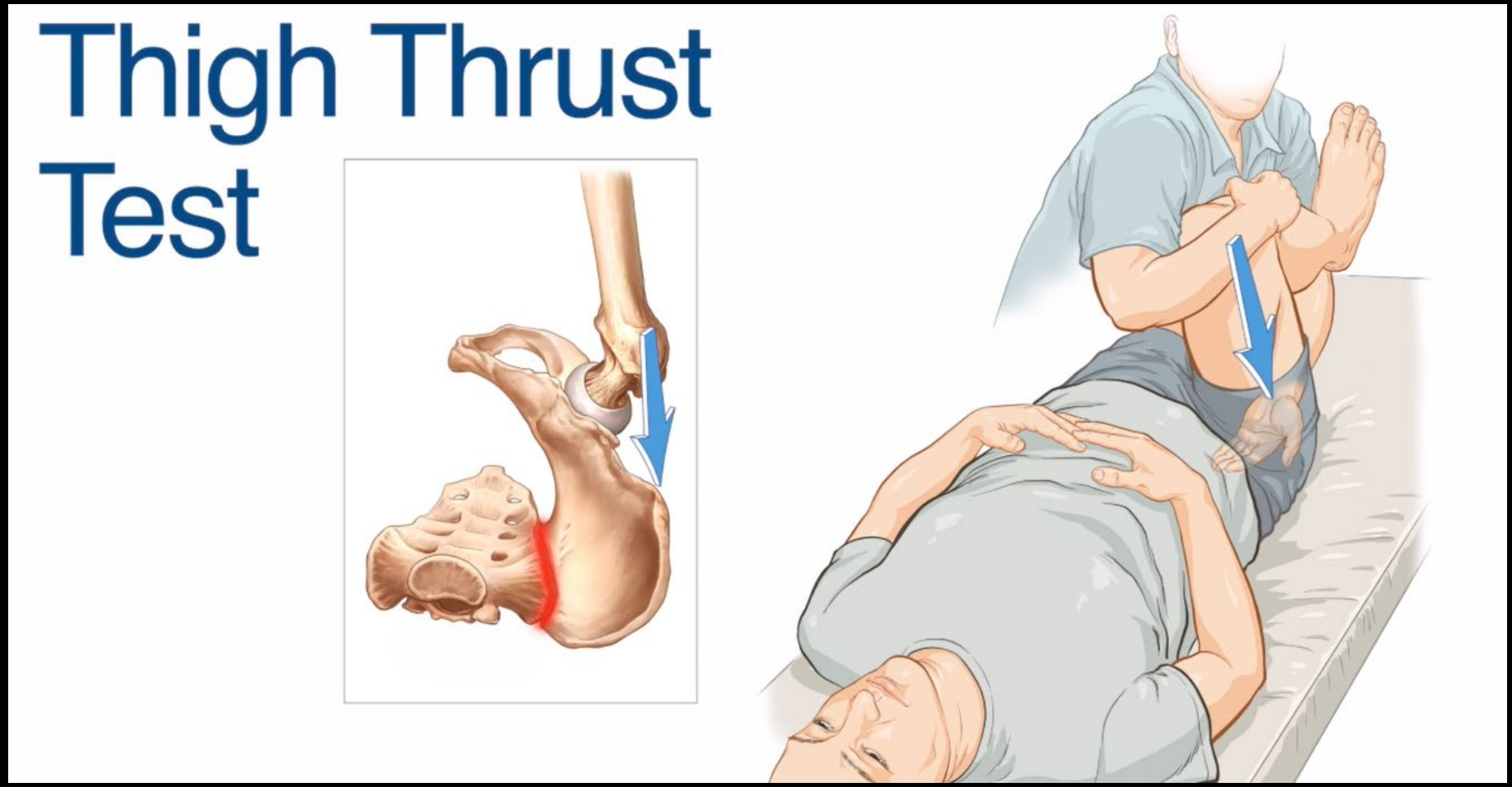
Distraction



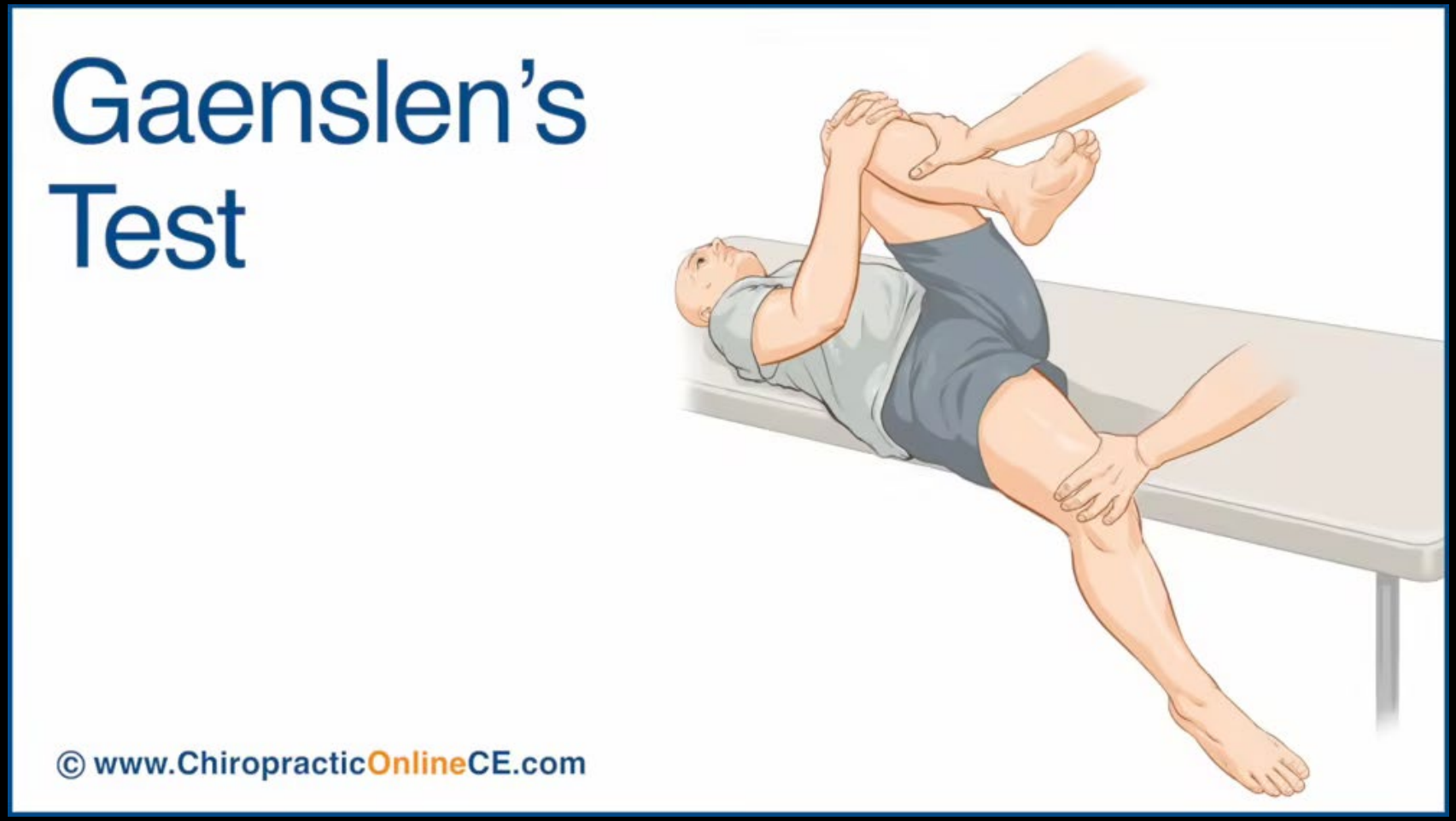
Compression



Thigh Thrust



Gaenslen's



Sacral Thrust

Imaging

- X-ray of the pelvis (AP and oblique) +/- Leg Length
- Unexpected findings: fracture, tumor, infection, spondyloarthropathy, transitional anatomy (Bertolotti's syndrome)
- May consider advanced imaging
  - MRI for tumor, infection, spondyloarthropathies
  - CT is standard for bone destruction or ossification

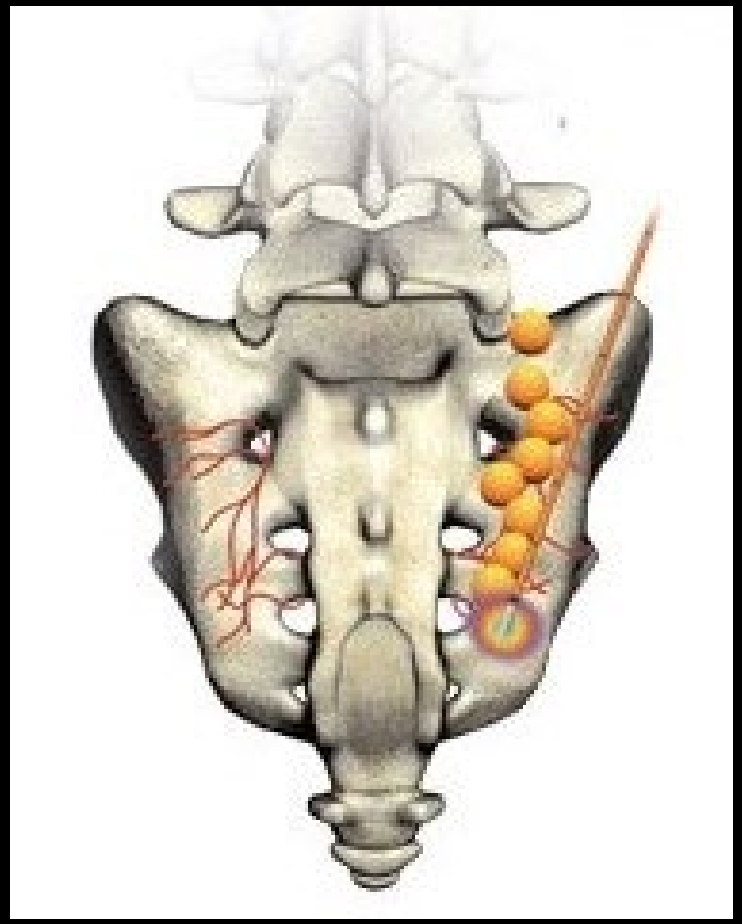
Next Steps

- If X-ray with leg length discrepancy, consider referral for ***custom shoe orthotics***
- After orthotic, referral to ***physical therapy*** *+/- gait analysis with postural dynamic retraining*
- ***Short course of NSAIDS***, if able to tolerate and not contraindicated
- Limited use of sacroiliac joint belt, particularly in pregnant patients
- ***If no benefit after 6-8 weeks, referral to Pain Management or Spine Surgery***

Lateral Branch Radiofrequency Ablation

Anatomy

- Lateral branches of ***S1*** and ***S2*** dorsal rami innervate the posterior joint
- In most individuals, the lateral branches of ***S3*** also contribute
- In some individuals, the dorsal ramus of ***L5*** and ***superior gluteal nerve***
- ***Anatomical variation from person to person as to innervation and location of nerves***



Radiofrequency Ablation – Literature Summary

- Two positive and one negative randomized controlled trial
  - Cohen et al. randomized, placebo controlled study in 28 patients, 57% patients had more than 50% relief at 6 months with cooled radiofrequency
  - Patel et al. randomized, placebo controlled trial with cooled radiofrequency compared to sham in 51 patients, 47% patients had relief
  - Van Tilberg et al. randomized, sham-controlled, double-blind multicenter clinical trial comparing radiofrequency of the sacroiliac joint with a multi-electrode probe to sham procedure and found no statistically significant difference

- Cohen et al. studied clinical factors affecting outcomes in 77 patients and found age > 65, high pre-procedure pain scores, opioid usage, pain extending below the knee were associated with treatment failure

Sacroiliac Joint Radiofrequency Ablation Studies

Table 3. Author and the study type.

Author	Study Type Conducted
Buijs et al (11)	Prospective observational study
Burnham and Yasui (15)	Prospective observational study
Cohen and Abdi (13)	Retrospective study
Cohen et al (32)	Randomized placebo-controlled trial study
Cohen et al, June 2009 (34)	Retrospective study
Ferrante et al (1)	Retrospective study
Gevargez et al (21)	Prospective observational study
Vallejo et al (4)	Prospective observational study*
Kapural et al (33)	Retrospective study
Yin et al (26)	Retrospective study

*Study was excluded due to use of pulsed radiofrequency ablation.

Pain Relief at 3 months

Table 7. Proportion of patients with positive results 3 months after RFA

Author	Total Number of Patients	Patients at 3 Months' Follow-up with ≥50% Relief	Calculated Proportion
Buijs et al (11)	38	24	0.6316
Yin et al (26)	14	9	0.6429
Gevargez et al (21)	38	25	0.6579
Cohen et al (32)	14	9	0.6429
Cohen et al, crossover group (32)	11	6	0.5454
Ferrante et al (1)	33	No data available	N/A
Kapural et al (33)	26	13	0.5000
Cohen and Abdi (13)	9	No data available	N/A
Burnham and Yasui (15)	9	6	0.6667
Cohen et al, June 2009 (34)	77	No data available	N/A

The calculated proportion is also indicated.

Pain Relief at 6 months

Table 8. Proportion of patients with positive results 6 months after RFA

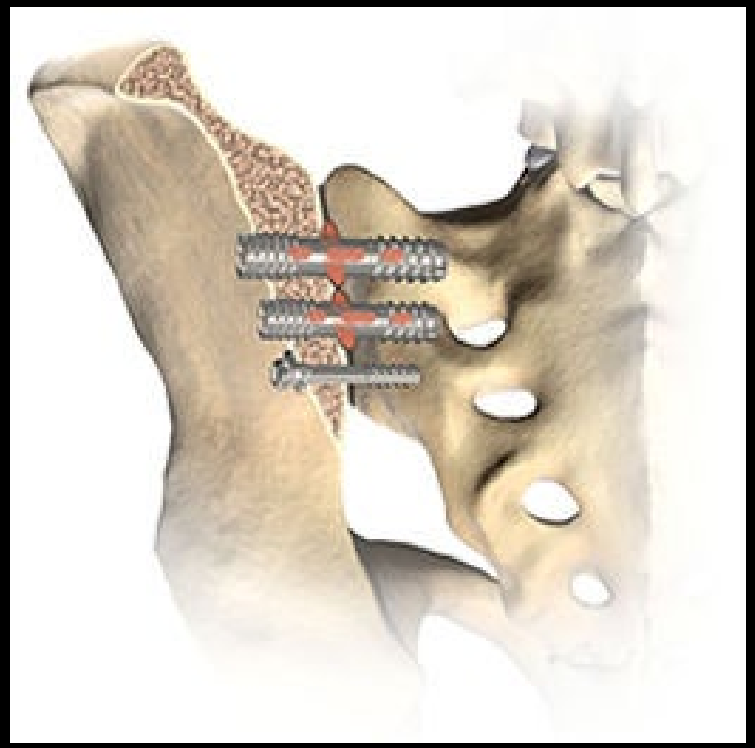
Author	Total Number of Patients	Patients at 6 Months Follow-up with ≥50% Relief	Calculated Proportion
Buijs et al (11)	38	No data available	N/A
Yin et al (26)	14	9	0.6429
Gevargez et al (21)	38	No data available	N/A
Cohen et al (32)	14	8	0.5714
Cohen et al, crossover group (32)	11	4	0.3636
Ferrante et al (1)	33	12	0.3636
Kapural et al (33)	26	No data available	N/A
Cohen and Abdi (13)	9	No data available	N/A
Burnham and Yasui (15)	9	6	0.6667
Cohen et al, June 2009 (34)	77	40	0.5195

Complications

- Post-procedure neuritis – studies range from 0.7% to 10% incidence
- Bleeding
- Infection
- Nerve damage

Sacroiliac Joint Arthrodesis

Surgical Procedure



- Used to treat fractures, instability and pain related to degenerative changes
- Previously was performed open (anterior or posterior approach) but now can be done by a minimally invasive percutaneous technique
- Benefits of percutaneous technique include:
  1) Shorter hospital stay
  2) Decreased duration of limitations on postoperative weight bearing
  3) Decreased blood loss
  4) Smaller incision

Review of Literature

- McGuire el al studied 38 joints with minimally invasive technique, VAS score improvement and fusion rate of 89.5% were noted
- Smith et al – multicenter, industry sponsored, retrospective comparative cohort study in 263 patients comparing open versus percutaneous arthrodesis showed decreased blood loss, surgical time and length of hospitalization in percutaneous group
- INSITE Trial - Level 1 industry sponsored study by Polly et al. studied percutaneous fusion versus nonsurgical management with 24 month follow-up
  - Function (ODI) improvement of >15 points of surgical group (72.5% versus 13%, $p<0.001$)

Complications

- Failure to fuse
- Ongoing pain
- Adjacent segment disease
- Bleeding
- Infection
- Nerve damage, including bowel or bladder dysfunction

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