Advanced Interventions for Spinal Stenosis

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AAPM 2022
38TH ANNUAL MEETING

Learning Objectives

Upon completion of this activity, the participant should be able to:

1. Understand the symptomology of Lumbar Spinal Stenosis (LSS)
2. Evaluate the severity of different types of LSS
3. Select effective and appropriate treatment options for LSS patients

Hagedorn Disclosures

- Abbott – consultant, advisory board member, funded research
- Boston Scientific – consultant, advisory board member
- Medtronic – honoraria, funded research
- Nevro – consultant, advisory board member
- Saluda – consultant, funded research

- This presentation does not contain off-label or investigational use of drugs or products.

Leong Disclosures

- CONSULTANT: SORRENTO THERAPEUTICS – RESINIFERATOXIN
- GRANT/RESEARCH SUPPORT: WEX PHARMACEUTICALS – HALNEURON (TETRODOTOXIN)
- SPEAKER'S BUREAU: NONE
- SHAREHOLDER: NONE
- OTHERS:
  - Co-director of Advocacy and Legislative Fellowship, North American Neuromodulation Society
  - Board of Directors (Secretary), Pacific Spine and Pain Society
  - Board of Directors, American Society of Pain and Neuroscience

This presentation contains no off-label and/or investigational uses of drugs or products.

Understanding LSS- *Symptoms*

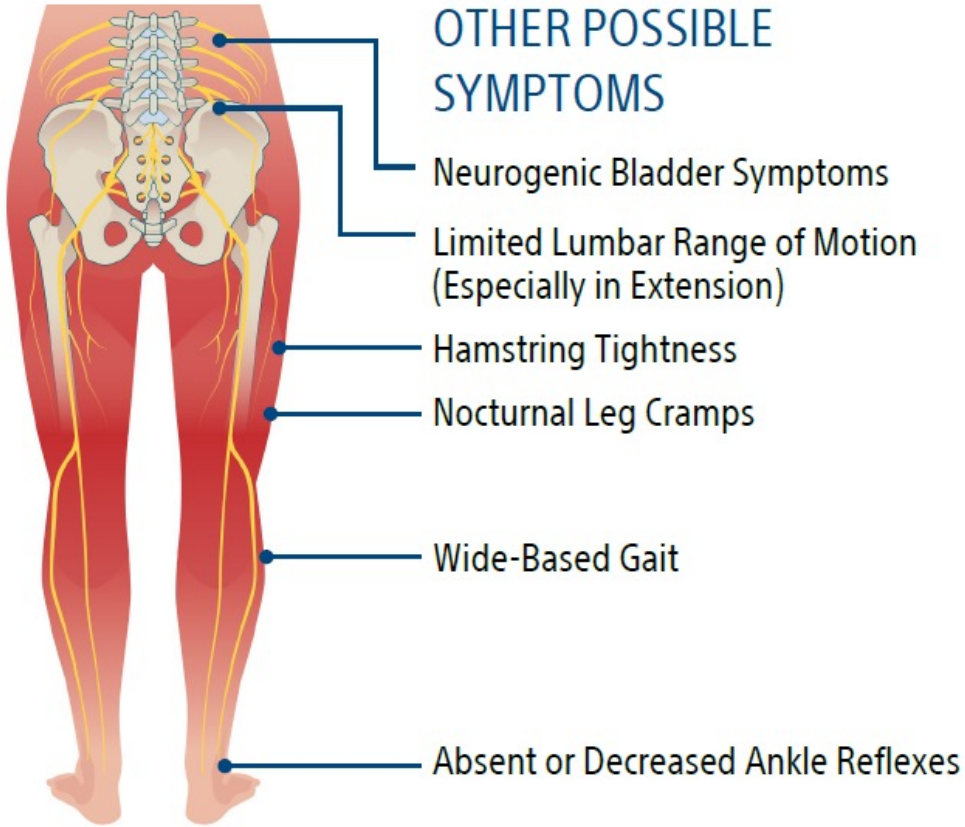
PRIMARY SYMPTOMS

Neurogenic Intermittent Claudication (NIC):

- Pain, numbness, cramping, and/or fatigue in the legs or buttocks with or without back pain.
- More commonly bilateral and associated with central canal stenosis.

Radicular Pain and Radiculopathy:

- Pain, numbness, cramping, and/or fatigue following a specific dermatome(s).
- More commonly unilateral and associated with lateral recess and/or foraminal stenosis.



References:

- Genevay S, Atlas SJ. Lumbar spinal stenosis. Best Pract Res Clin Rheumatol. 2010;24(2):253-265.
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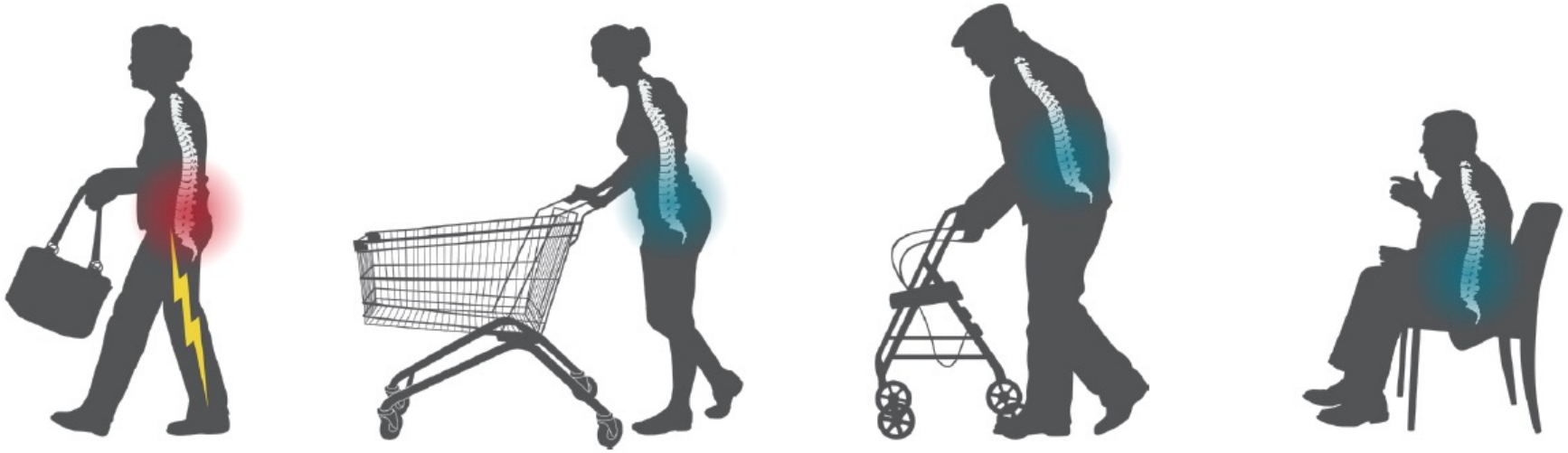
Understanding LSS- *Patient Presentation*

PAIN RELIEF IN FLEXION



EXTENSION

Extension provokes symptoms, pain/weakness in legs

"SHOPPING CART" SIGN

Leaning forward while walking to ambulate more comfortably

FLEXION

Sitting relieves symptoms

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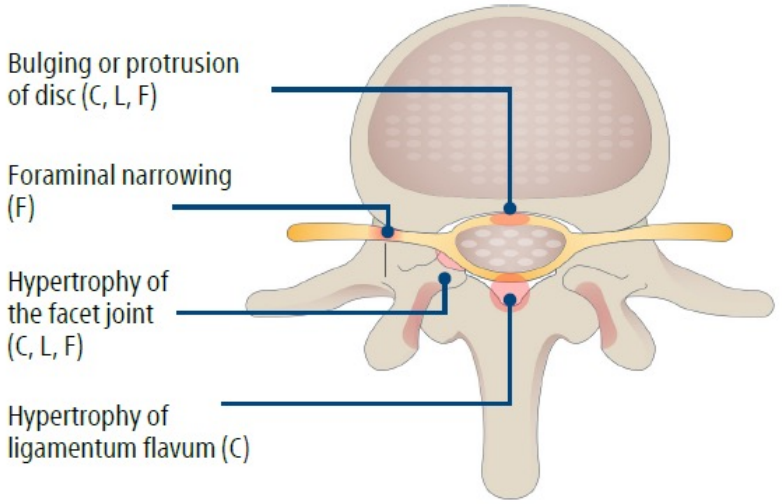
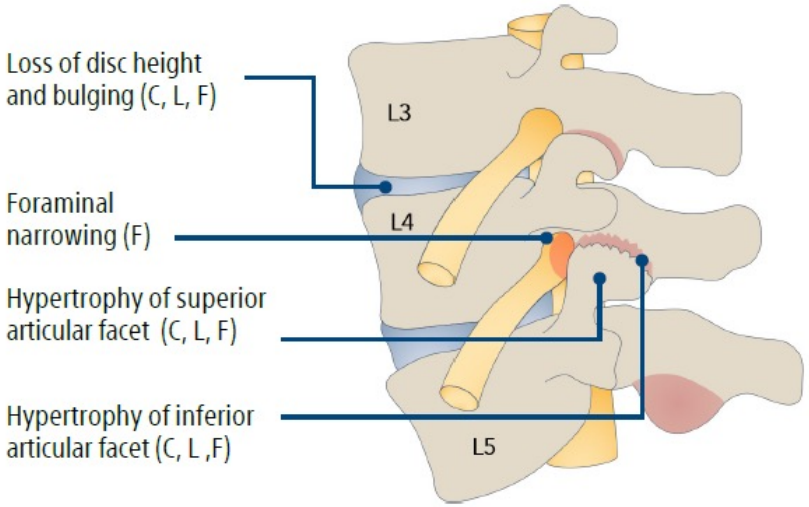
Understanding LSS- *Types & Causes*

TYPES OF LSS

CENTRAL CANAL (C)	LATERAL RECESS (L)	FORAMINAL (F)





References:

- Genevay S, Atlas SJ. Lumbar spinal stenosis. Best Pract Res Clin Rheumatol. 2010;24(2):253-265.

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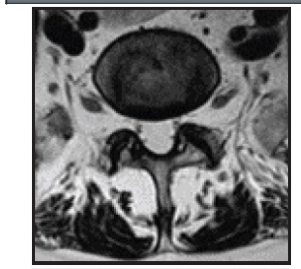
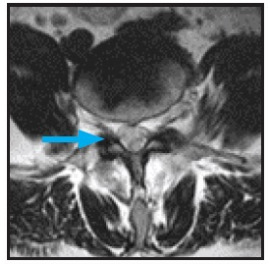
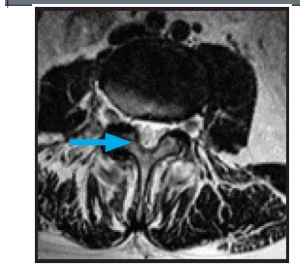
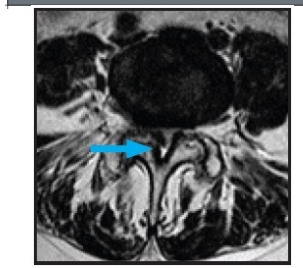
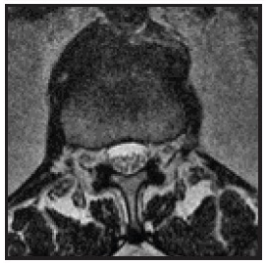
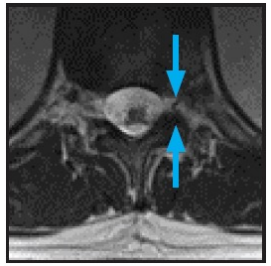
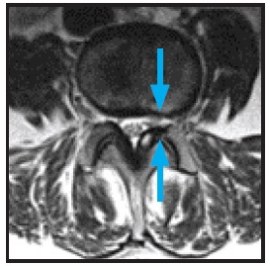
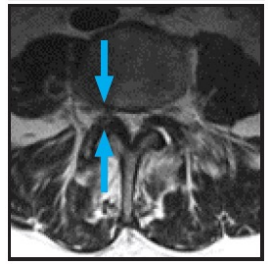
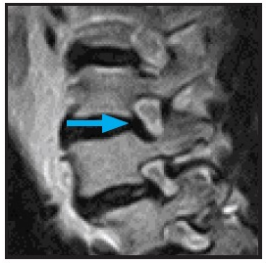
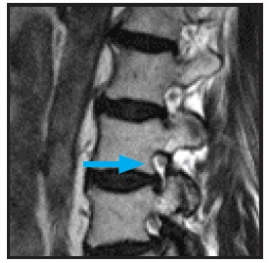
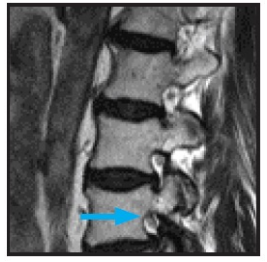
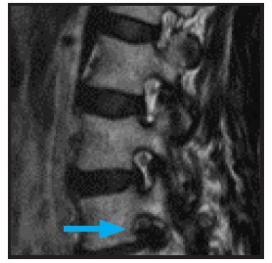
Evaluating LSS- *Severity*

	NORMAL (No reduction in space compared to adjacent levels)[1]	MILD (<25% Reduction in space compared to adjacent levels)[1]	MODERATE (25-50% Reduction in space compared to adjacent levels)[1]	SEVERE (>50% Reduction in space compared to adjacent levels)[1]
CENTRAL LSS (TRANSVERSE T2 MRI)				
LATERAL RECESS LSS (TRANSVERSE T2 MRI)				
FORAMINAL LSS (SAGITTAL T2 MRI)				

References:
- Herkowitz H, Dvorak J, et al. The Lumbar Spine, Third Edition. 2004..

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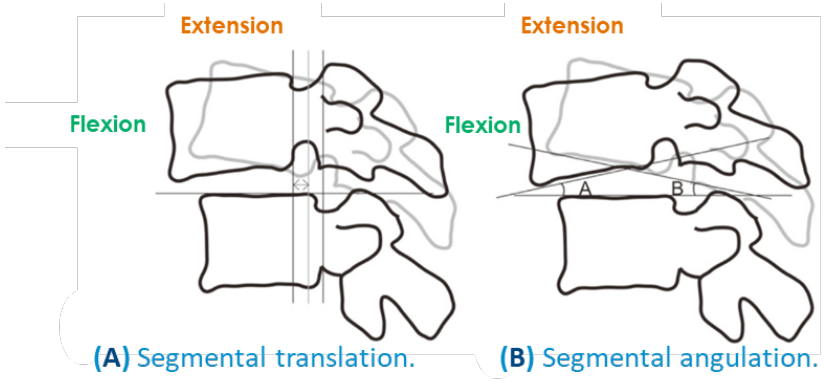
Evaluating LSS- *Stability*

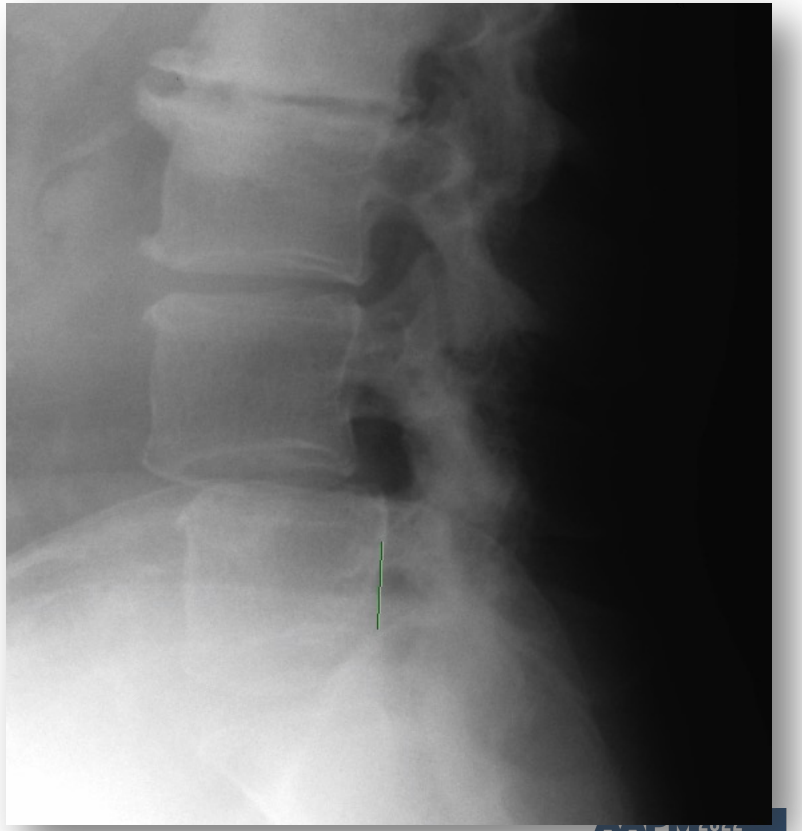
Spondylolisthesis with sagittal translation

- A flexion/extension radiographic study is recommended to evaluate instability
- **>3mm sagittal** translation is considered excessive



Staub and Holman Normal Motion Data

Level	Volunteers	Mean (mm)	SD (mm)
Sagittal Translation of Nondegenerative Motion Segment			
L2-3	135	2.42	0.69
L3-4	139	2.69	0.76
L4-5	143	2.66	0.99
L5-S1	110	0.53	0.87



References:

- Staub BN, Holman PJ, Reitman CA, Hipp J. Sagittal plane lumbar intervertebral motion during seated flexion-extension radiographs of 658 asymptomatic nondegenerated levels. J Neurosurg Spine. 2015;23(6):731-738.
- White AA, Panjabi MM. Clinical Biomechanics of the Spine. 2nd ed. Lippincott; 1990.

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Lumbar Spinal Stenosis: Direct Lumbar Depression Procedure

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Lumbar Spinal Stenosis: Direct Lumbar Depression Procedure

- Learning Objectives
  - General treatment paradigm for Lumbar Spinal Stenosis
  - Brief presentation and pearls for Percutaneous Lumbar Decompression procedure
  - Highlights of MiDAS ENCORE study
- Literature References
  - Deer TR, Grider JS, Pope JE, et al for the Lumbar Stenosis Consensus Group. The MIST guidelines: the Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. *Pain Pract*. 2019;19(3):250-274. doi: 10.1111/papr.12744.
  - Staats PS, Chafin TB, Golovac S, Kim CK, Li S, Richardson WB, Vallejo R, Wahezi SE, Washabaugh EP 3rd, Benyamin RM, for the MiDAS ENCORE Investigators. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43:789-794.

Lumbar Spinal Stenosis

- NASS defines LSS as “a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal.”
- Typically people over 50 years old
- Most common reason for spine surgery in elderly
- 250 to 500k US residents for current estimate
- Traditional treatments:
    - Physical therapy: little evidence of axial bracing
    - Medication management: NSAIDs, neuropathics, opioids
    - Epidural injections
    - Percutaneous adhesiolysis
    - Surgical decompression with or without fusion

MRI with causes of spinal stenosis

- Diwan S, Deer T. Advanced Procedures for Pain Management Springer 2018

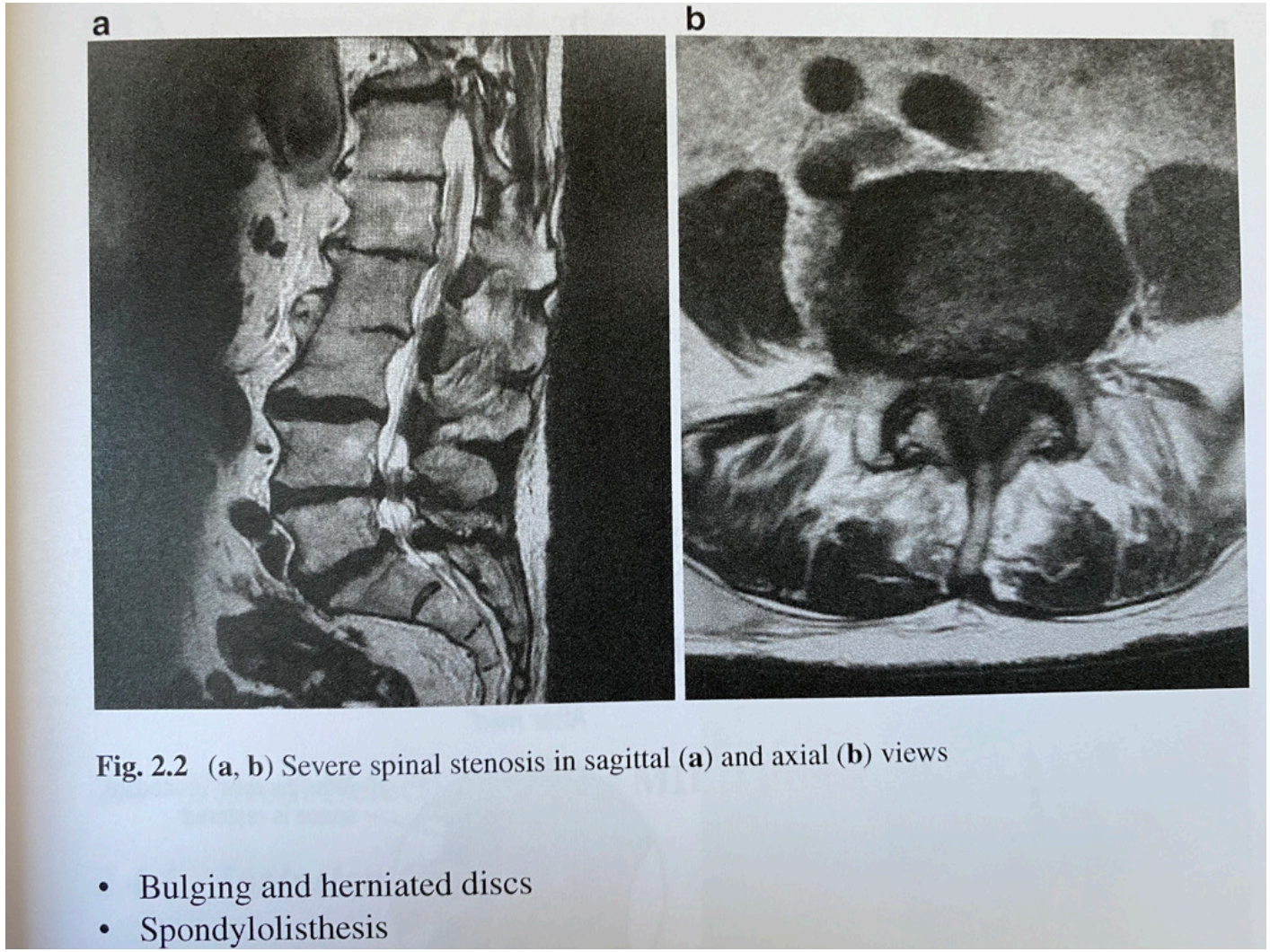


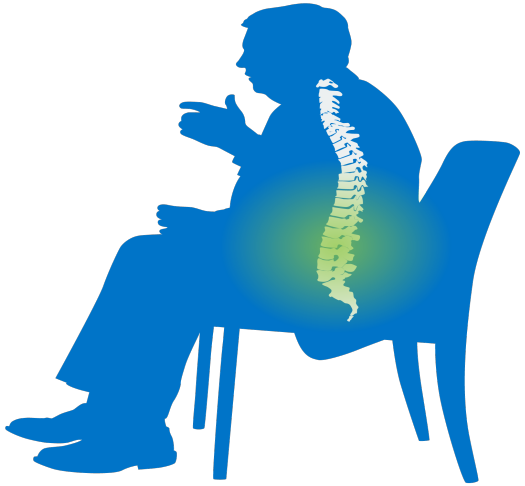
Fig. 2.2 (a, b) Severe spinal stenosis in sagittal (a) and axial (b) views

- Bulging and herniated discs
- Spondylolisthesis

Spinal Stenosis Physical Examination

- May be asymptomatic
- Central canal stenosis > ***neurogenic claudication*** = hallmark
- Foraminal or lateral recess stenosis > radicular pain
- Loss of normal lumbar lordosis
- May sit and walk in a forward-flexed posture (shopping cart sign)
- Straight leg raising test typically absent
- Weakness in L5 (extensor hallucis longus) most common motor finding
- Stoop test: patient is asked to walk with exaggerated lumbar extension until symptoms of neurogenic claudication are noted
- Can be confused in elderly population with vascular claudication

Target Patients : LSS & Neurogenic Claudication



- ✓ Standing/walking provokes symptoms
- ✓ Pain/weakness in legs

- ✓ Patient lean forward while walking to move around more comfortably: “Shopping Cart Sign”

- ✓ Sitting (flexion) relieves symptoms

Image courtesy of Vertos Medical Inc

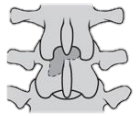
CURRENT LSS TREATMENT OPTIONS

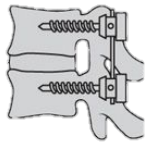
Conservative

PT
Meds

Interventional Options

ESI
Perc Decomp





Surgical Options

Interspinous Process Distraction Devices

Open Laminotomy
Open Laminectomy

Fusion

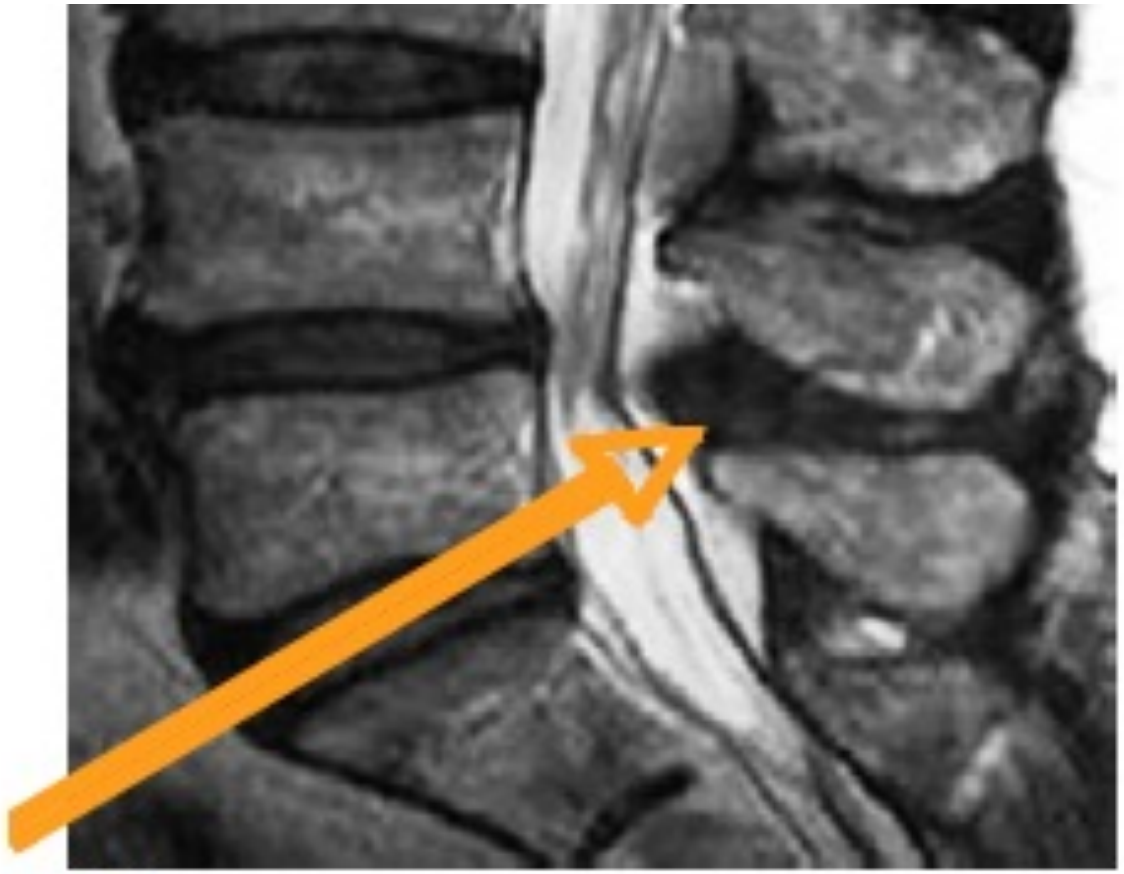
Low risk – Less Invasive

Higher risk – More Invasive

Image courtesy of Vertos Medical, Inc

Minimally Invasive Lumbar Decompression

- Lumbar spinal stenosis: back pain / leg pain
- Neurogenic claudication
- Ligamentum flavum hypertrophy > 2.5 mm



Ligamentum Flavum

Percutaneous Decompressive Laminotomy Kit

- Trocar, Stabilizer, Depth Gauge, Bone and Tissue Sculpter

Image courtesy of Vertos Medical, Inc

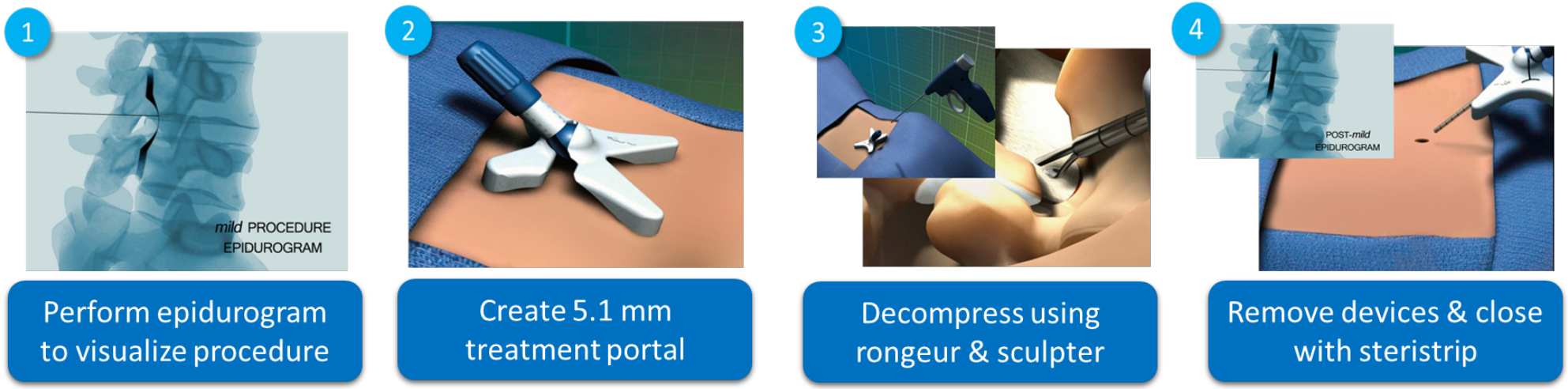
Additional Supplies to the kit

- ✓Touhy needle to access epidural space
- ✓Spinal needle 5 to 6 in in length for local infiltration
- ✓Skin marker
- ✓Scapel for skin incision to accommodate trocar
- ✓Myelographic contrast
- ✓Topical skin adhesive and skin closure strips

How do you perform it?

- Positioning – flatten the lordosis with pillows 2 to 3
- Draw safety tracks: connect spinous processes and bilateral midpedicular lines
- Have to have an epidural at the site of treatment
  - To see how far to advance, confirm completion of treatment
  - When all else, caudal approach with catheter

DECOMPRESSION PROCEDURE OVERVIEW

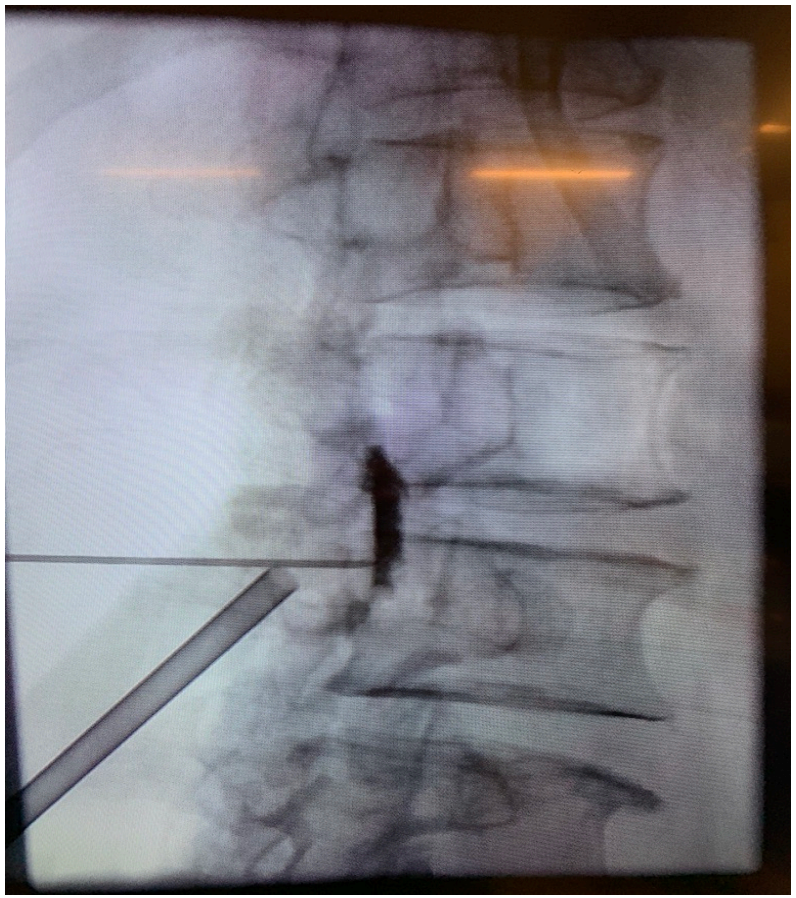


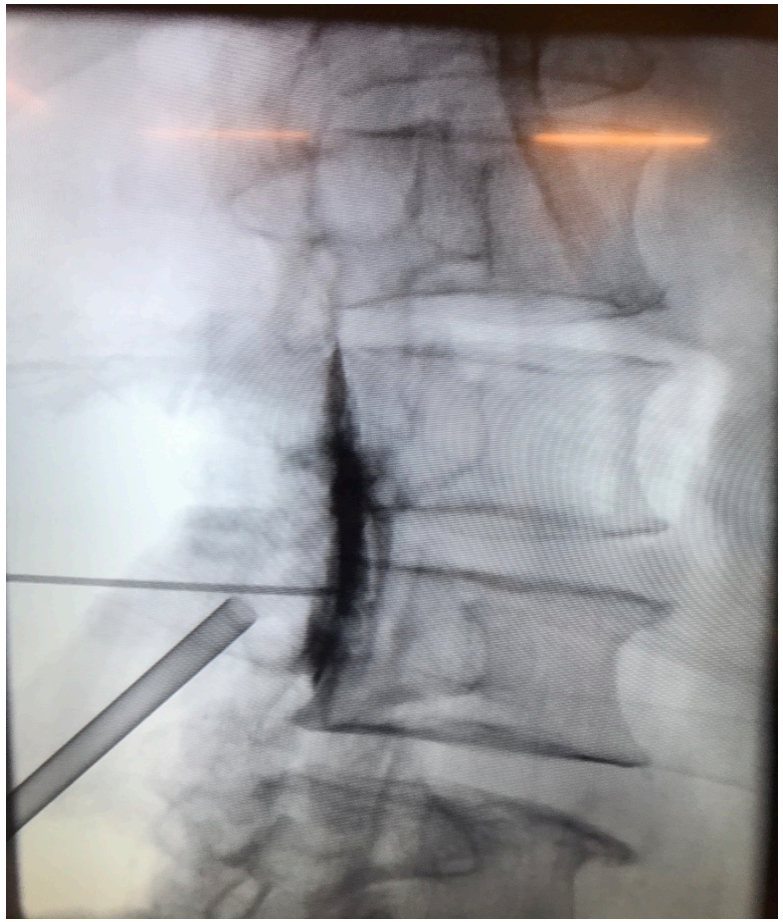
Constant visualization using epidurogram throughout procedure is critical to safety and efficacy.

- Helps ensure instrument use is posterior to dura at all times.
- Contrast changes signal that decompression has been achieved.

Image courtesy of Vertos Medical, Inc

Patient in their 80s





MiDAS Encore Study Protocol

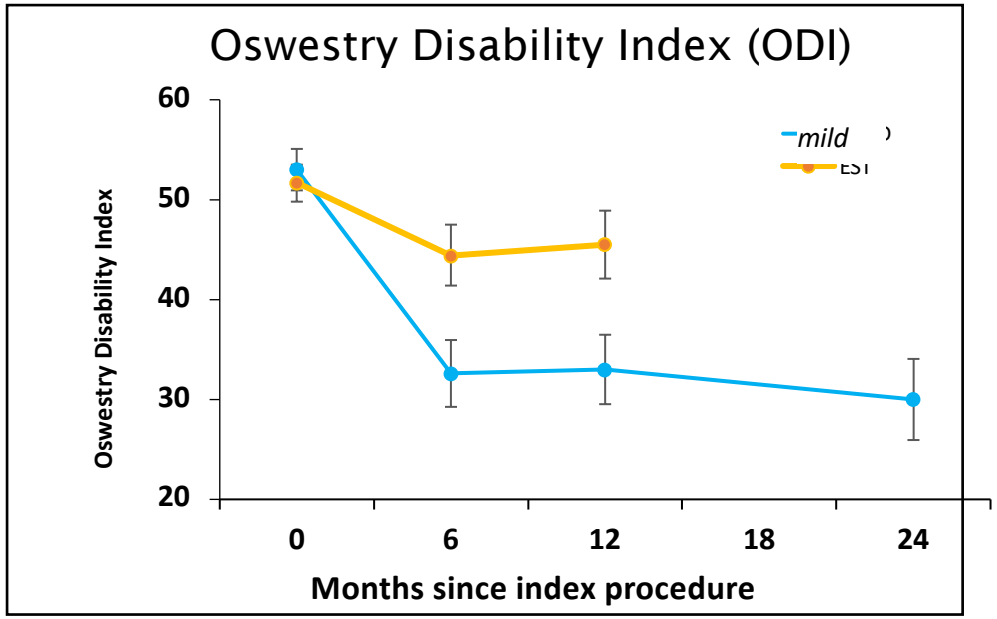
- Coverage with evidence development (CED)
- Prospective, multicenter, randomized controlled
- Randomization:
  - *Percutaneous decompressive laminotomy* versus ESI
- Study visits:
  - Baseline, 6 month, 1 year, 2 years
- Comparative data through 1 year
  - *Percutaneous decompression* -only at 2 years
- Outcome measures: Numeric Pain Rating Scale and ODI

Encore Study Population

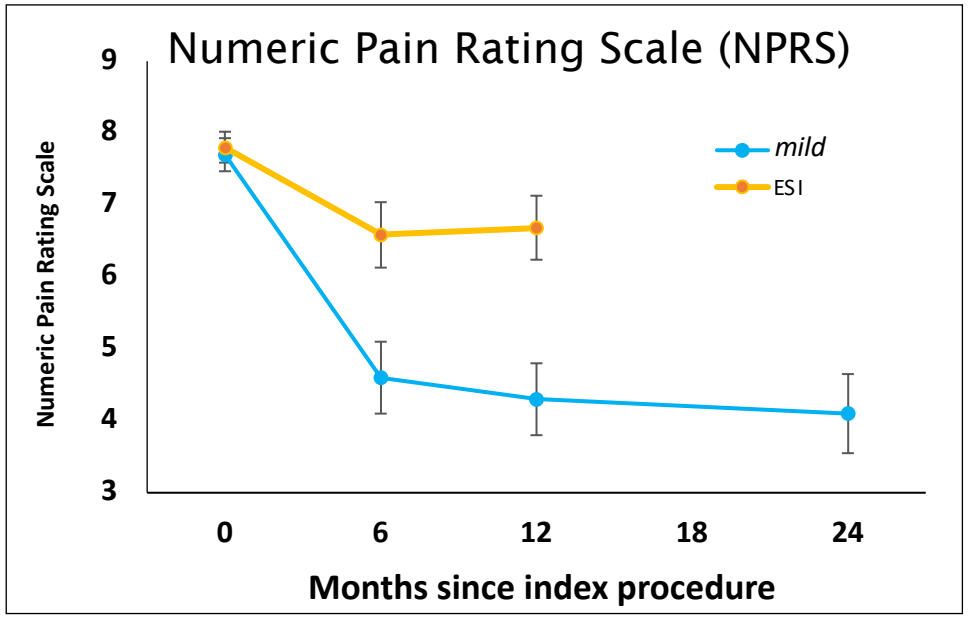
- Patients experiencing neurogenic claudication symptoms
- Hypertrophic ligamentum flavum
  - > 2.5 mm
- 65 years or older
- ODI > 31
- NPRS > 5
- No surgery at any treatment level
- Spondylolisthesis
  - < Grade III

ENCORE Study 2-year Outcomes

Functional and Pain Improvement Compared to ESIs



- Significant and sustained functional improvement through 2-year follow-up
- Mean ODI improvement of 22.7 points at 2 years
  (10-point improvement is clinically significant.)



- Significant and durable reduction of pain through 2-year follow-up
- Mean NPRS improvement of 3.6 points at 2 years
  (2-point improvement is clinically significant.)

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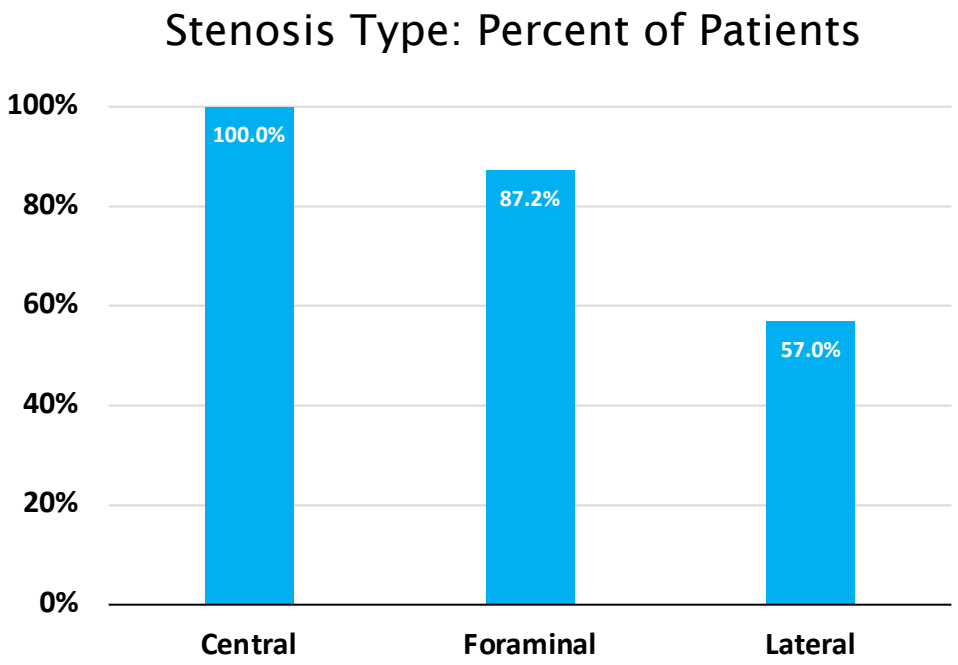
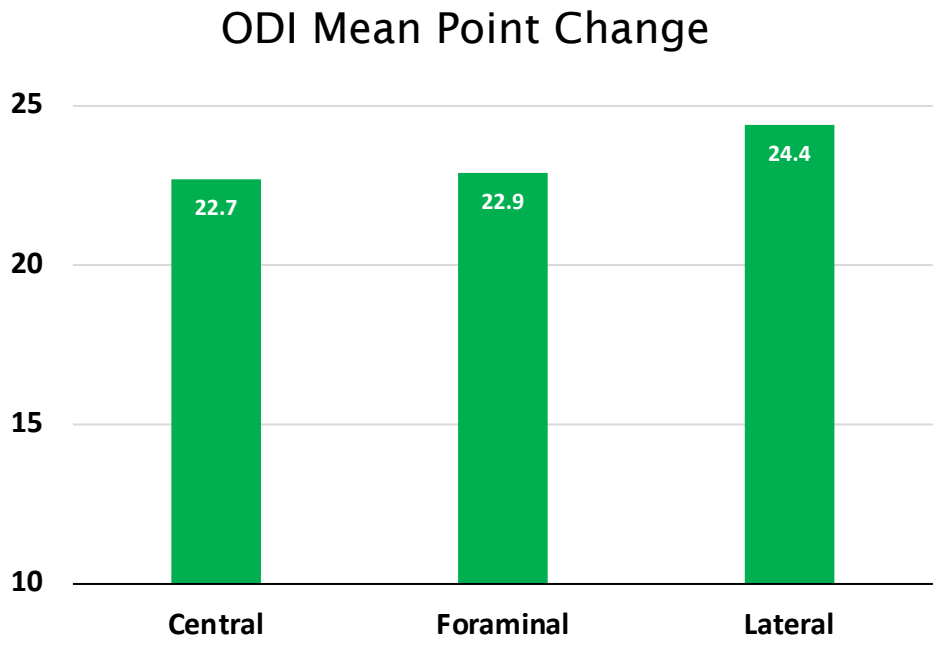
ENCORE Study 2-year Outcomes

Significant Improvement by Stenosis Type





Majority of patients had multiple types of stenosis

Significant functional improvement regardless of stenosis type

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ENCORE Study Outcomes

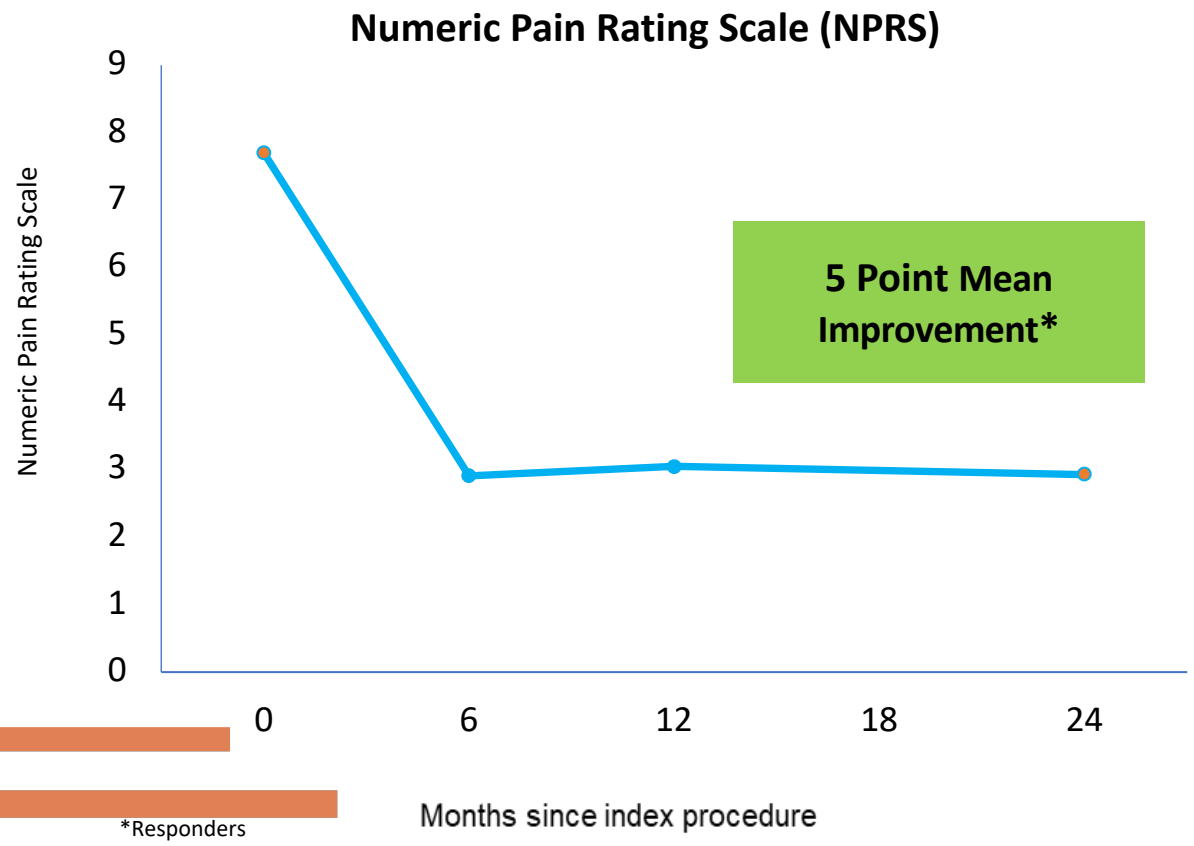
95% of Patients Had Multiple Back Conditions

Other Back Conditions Should Not Be Used as an Exclusion

Characteristic	Presenting Spinal Comorbidities % (n)	ODI Response Rate* at 2Y
Ligamentum flavum hypertrophy	100.0% (149)	72.4%
Bulging disc	89.9% (134)	77.3 %
Foraminal narrowing	87.2% (130)	73.8 %
Facet hypertrophy	86.6% (129)	76.8 %
Facet arthropathy	76.5% (114)	72.7 %
Degenerative disc disease	67.8% (101)	74.3 %
Disk space/height loss	59.1% (88)	79.3 %
Lateral recess narrowing	57.0% (85)	76.3 %
*Percent of patients achieving ODI improvement of ≥10 points.		

Pain Improvement & Patients Resume Daily Activities

LEVEL 1, 2-YEAR MiDAS ENCORE



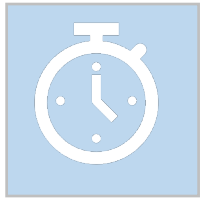
*Responders

PATIENTS TYPICALLY RESUME DAILY ACTIVITIES WITHIN 24 HOURS

WITH NO RESTRICTIONS

Image courtesy of Vertos Medical, Inc

Post-COVID, *percutaneous decompression* Safe, Low-Risk, and Effective Option



Efficient, Safe Procedure:

- Minimally Invasive & quick (Streamlined Technique)
- Steroid-free = no immune suppression
- No general anesthesia, no opioids, no implants

Minimizes Disease Transmission:

- Procedure is not rep-dependent
- Can be done in ASC or hospital outpatient procedure suite
- No in-person PT or follow-up required

Easy to ID & Manage Patients Via Telehealth:

- ID symptoms & review imaging, patient consults
- No ongoing in-office patient mgmt. or PT required

High Per Patient Revenue Generator:

- Higher reimbursed procedure (vs. ESI)

Percutaneous Lumbar Decompressive Laminotomy

MILD vs Superion Literature Review

- MILD since 2010 has 8 studies; 2 RCT's, 3 observational prospective, 3 observational retrospective
    - Modest evidence MiDAS ENCORE trial with 2 year follow up
    - No blinding
    - One procedure hematoma treated with Gel Foam
- Superion since 2010 has 5 studies with the IDE trial = only RCT, 4 observational
    - 5 year improvement 84% of patients (ZCQ, VAS, ODI)
- Minimally invasive spine treatment (MIST) consensus guidelines 2018
    - MILD and Superion have level 1 evidence
    - Based on a single randomized trial for both devices

Summary and Conclusions

- Back pain has a high frequency in adults
- Lumbar spinal stenosis is a common reason for surgery in elderly
- Epidural Steroids
    - Mild to low quality evidence for Back Pain with Radiation to Legs
    - Steroid accumulation over the patient's lifetime
- Percutaneous Decompressive Laminotomy
    - Reapproval from FDA for treatment of Lumbar Spinal Stenosis
    - Bridge between epidural injections and implants or surgery
- Interspinous Spacers
    - Prevents mechanical causes for stenosis and claudication
- MILD is simple, quick, works at L5 / S1 and should be considered earlier

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Lumbar Spinal Stenosis: Superion and SCS Procedures

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Superion

Indications

- 25-50% reduction in central canal and/or neuroforamen
  - Thecal sac or cauda equina compression
  - Nerve root impingement (osseous or non-osseous)
  - *Hypertrophic facets with canal encroachment*
- Associated with the following clinical signs:
  - Moderate impairment (≥2.0 on ZCQ)
  - Able to sit for 50 minutes without pain and walk 50 feet or more

Contraindications

- An allergy to titanium or titanium alloy
- Lumbar spondylolisthesis greater than Grade 1
- Ankylosis
- Fracture of posterior elements
- Scoliosis
- Cauda equina syndrome
- Severe osteoporosis (>2.5 SD below mean on DEXA scan)
- Systemic infection or infection at site of implant
- Prior surgery at area of stenosis
- Morbid obesity (BMI > 40)

Procedural Steps

DILATOR ASSEMBLY

CANNULA ASSEMBLY

REAMER

INTERSPINOUS GAUGE

INSERTER

DRIVER

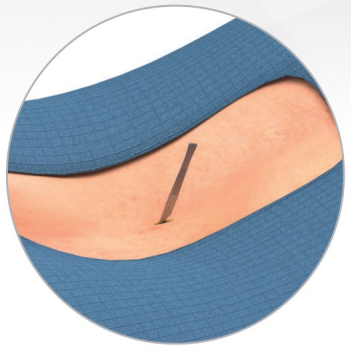


FIG. 3. SKIN INCISION

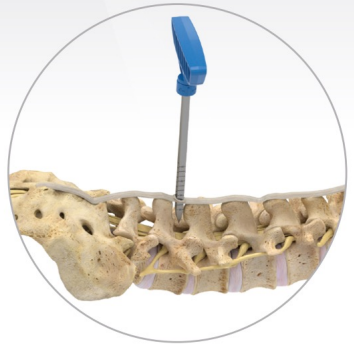


FIG. 4. DILATOR ASSEMBLY

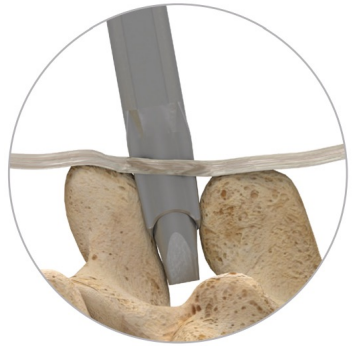


FIG. 4E. CANNULA

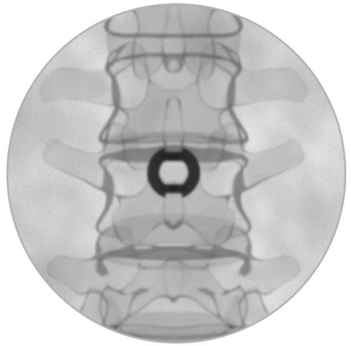


FIG. 4H. A/P CONFIRMATION OF

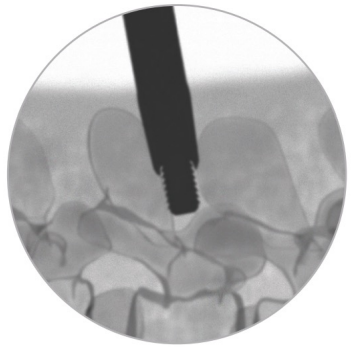


FIG. 5A. CLOSELY MONITOR

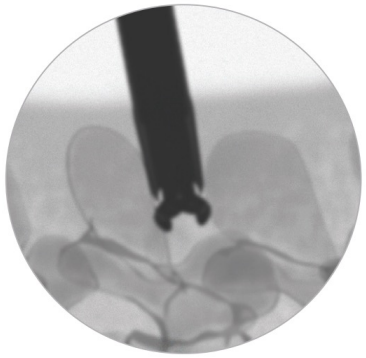


FIG. 6A. CONFIRM DEPTH UNDER

Procedural Steps

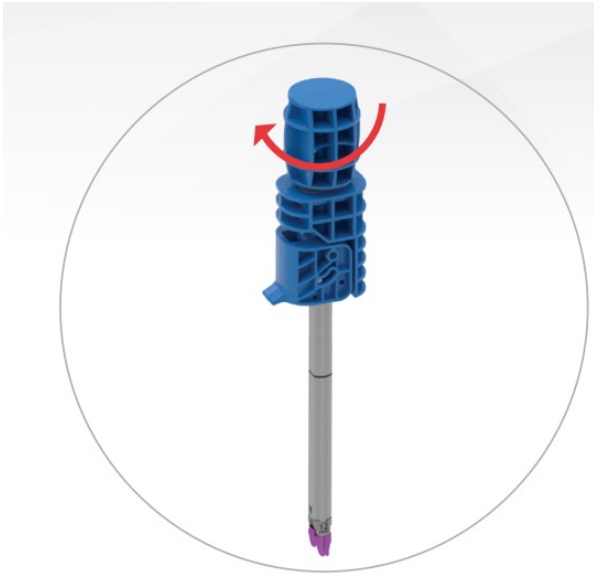


FIG. 8. DRIVER

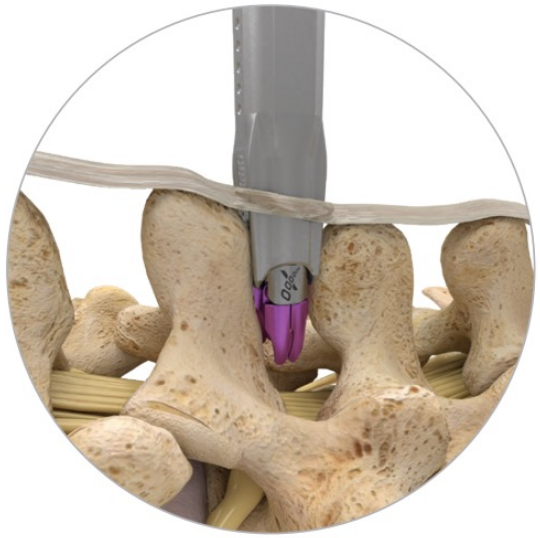


FIG. 8A. MINIMUM INSERTION DEPTH

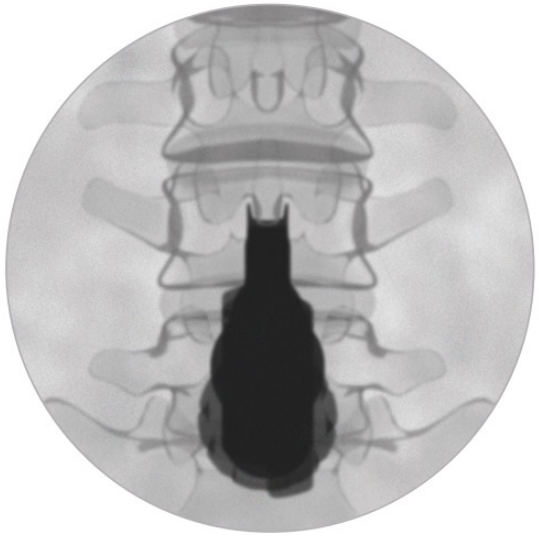


FIG. 8C. VERIFY CONTAINMENT OF SPINOUS PROCESSES

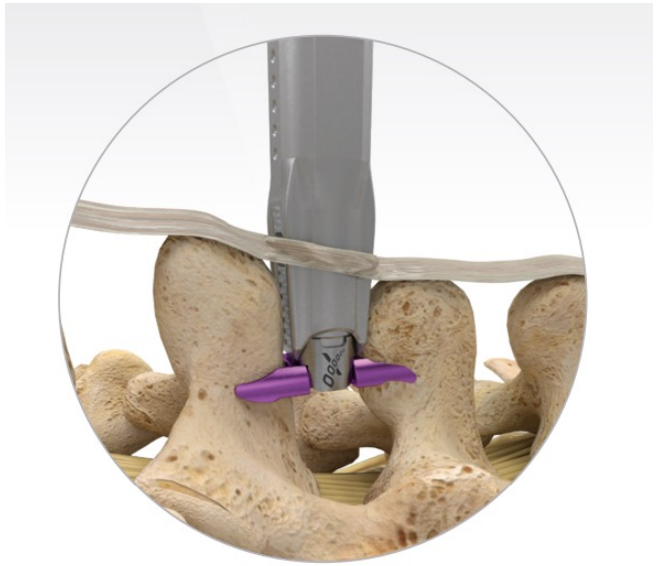
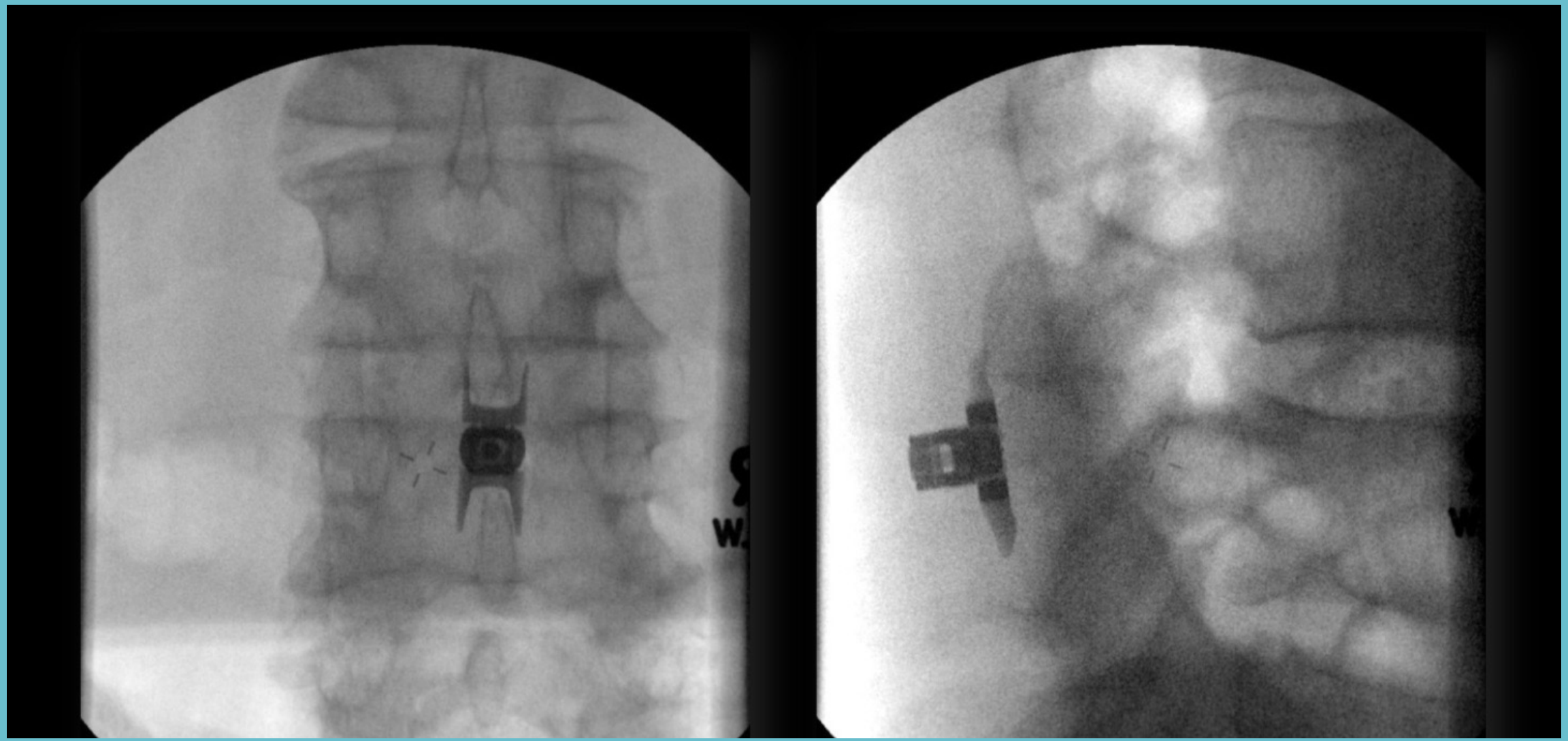
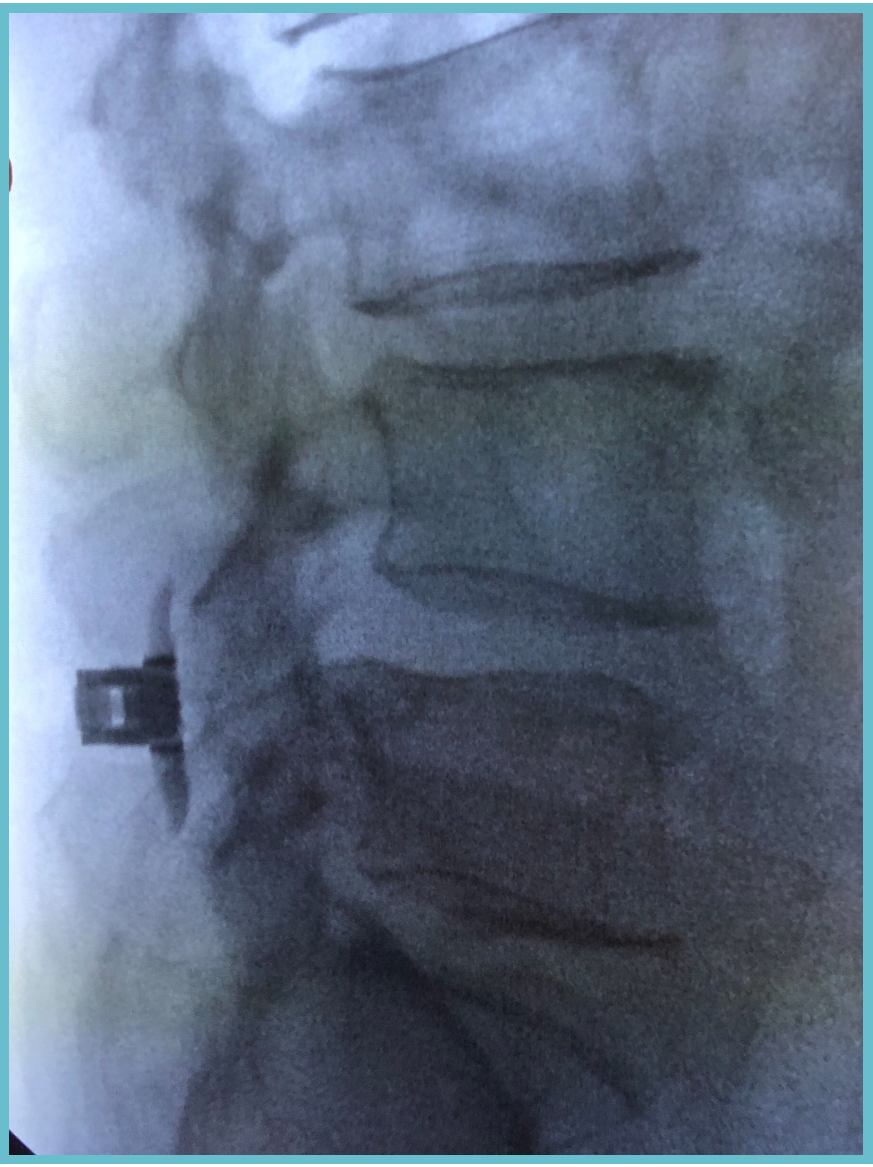
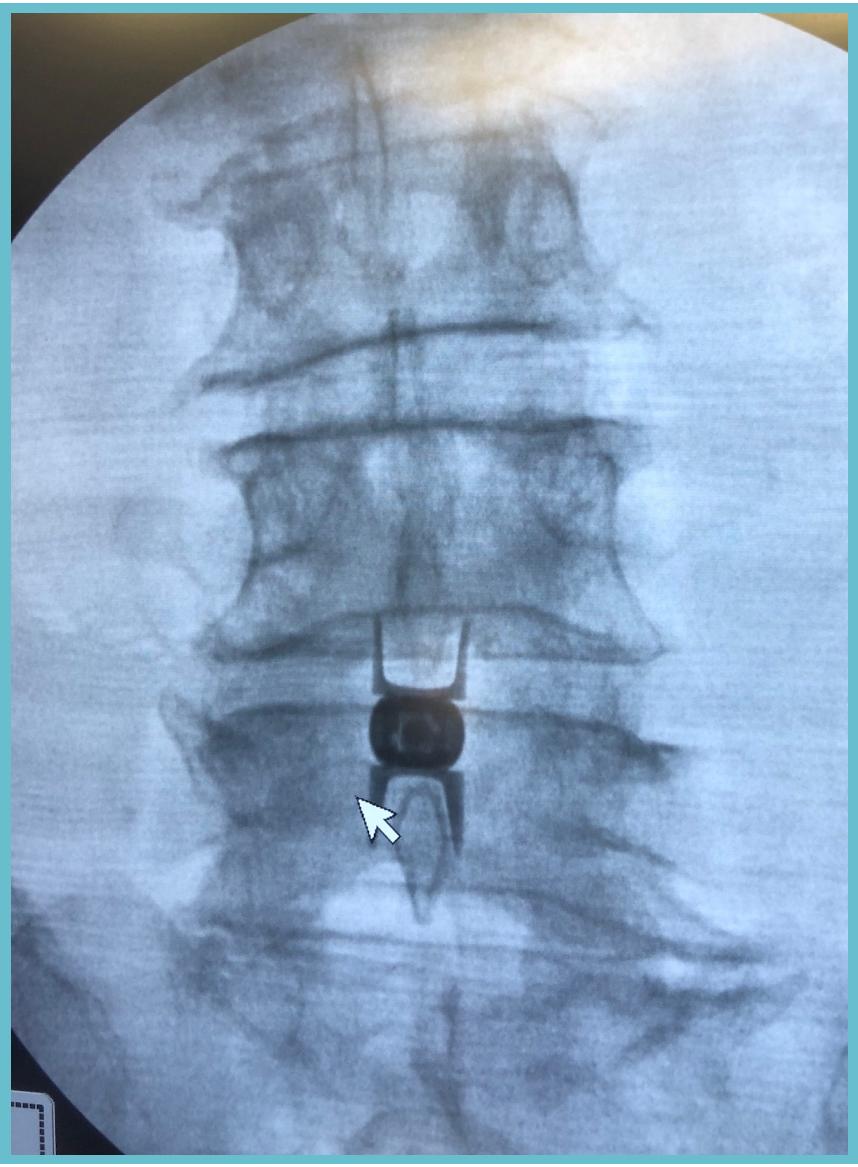


FIG. 8D. IMPLANT EXPANDED







Superion vs. X-STOP

- 24 month data, 190 Superion and 201 X-STOP
- Spinous Process Fractures
  - Superion: 11.6%
  - X-STOP: 6.5%
- Device Migration/Dislodgement
  - Superion: 1%
  - X-STOP: 4.5%
- Blood Loss
  - Superion: average 13.5 cc
  - X-STOP: average 38.7 cc

Superion Interspinous Spacer: Instructions for Use. Vertiflex, Inc. San Clemente, CA: 2015.

Nunley, 2017

Clinical Interventions in Aging

Dovepress

ORIGINAL RESEARCH

Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis

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Douglas G Orndorff[3]
William F Lavelle[4]
Jon E Block[5]
Fred H Geisler[6]

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Background: Lumbar spinal stenosis is the most common indication for spine surgery in older adults. Interspinous process decompression (IPD) using a standalone spacer that functions as an extension blocker offers a minimally invasive treatment option for intermittent neurogenic claudication associated with spinal stenosis.

Methods: This study evaluated the 5-year clinical outcomes for IPD (Superion®) from a non-dominal controlled US Food and Drug Administration (FDA) noninferiority trial. Outcomes included Zurich Claudication Questionnaire (ZCQ) symptom severity (sx), physical function (pf), and patient satisfaction (ps) subdomains, leg and back pain visual analog scale (VAS), and Oswestry Disability Index (ODI).

Results: At 5 years, 84% of patients (74 of 88) demonstrated clinical success on at least two of three ZCQ domains. Individual ZCQ domain success rates were 75% (66 of 88), 81% (71 of 88), and 90% (79 of 88) for ZCQsx, ZCQpf, and ZCQps, respectively. Leg and back pain success rates were 80% (68 of 85) and 65% (55 of 85), respectively, and the success rate for ODI was 65% (57 of 88). Percentage improvements over baseline were 42%, 39%, 75%, 66%, and 58% for ZCQsx, ZCQpf, leg and back pain VAS, and ODI, respectively (all $P<0.001$). Within-group effect sizes were classified as very large for four of five clinical outcomes (ie, >1.0; all $P<0.0001$). Seventy-five percent of IPD patients were free from reoperation, revision, or supplemental fixation at their index level at 5 years.

Conclusion: After 5 years of follow-up, IPD with a stand-alone spacer provides sustained clinical benefit.

Keywords: interspinous spacer, lumbar spinal stenosis, Superion, neurogenic claudication, decompression

Introduction

Within 10 years, it is estimated that 64 million older adults will be afflicted with lumbar spinal stenosis, making it the most common indication for spine surgery in individuals older than 65 years.[1,2] This expanding population of patients requires a greater range of treatment options throughout the continuum of care, particularly in the elderly who may not be appropriate candidates for open surgical procedures with the associated risks of general anesthesia.[3] Interspinous process decompression (IPD) is a minimally invasive procedure that can be performed under monitored anesthesia care in an ambulatory surgery center and has been shown to provide comparable clinical performance to decompressive laminectomy for management of symptoms of spinal stenosis.[4]

Neurogenic claudication is the cardinal clinical feature of lumbar spinal stenosis, and limits patients' walking ability and causes a major impact on their quality of life.[5] Intermittent neurogenic claudication is defined as unilateral or bilateral radicular pain

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- N = 88
- "At five years, 84% of patients demonstrated clinical success on at least two of three ZCQ domains. Leg pain success rate was 80% and back pain success rate was 65%. ODI success rate was 65%."

Nunley PD, Patel VV, Orndorff DG, et al. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. Clin Interv Aging. 2017;12:1409-1417.

Nunley, 2018

Journal of Pain Research

Dovepress

CLINICAL TRIAL REPORT

Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis

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Background: Lumbar spinal stenosis (LSS) causes significant pain and functional impairment, and medical management has increasingly included the prescription of opioid-based analgesics. Interspinous process decompression (IPD) provides a minimally-invasive treatment option for LSS.
Methods: This study estimated the type, dosage, and duration of opioid medications through 5 years of follow-up after IPD with the Superion Indirect Decompression System (Vertiflex Inc., Carlsbad, CA USA). Data were obtained from the Superion-treatment arm of a randomized controlled noninferiority trial. The prevalence of subjects using opiates was determined at baseline through 60 months. Primary analysis included all 190 patients randomized to receive the Superion device. In a subgroup of 98 subjects, we determined opioid-medication prevalence among subjects with a history of opioid use.
Results: At baseline, almost 80% (94 of 190) of subjects were using opioid medication. Thereafter, there was a sharp decrease in opioid-medication prevalence from 25.2% (41 of 163) at 12 months to 13.3% (20 of 150) at 24 months to 7.5% (8 of 107) at 60 months. Between baseline and 5 years, there was an 85% decrease in the proportion of subjects using opioids. A similar pattern was also observed among subjects with a history of opiates prior to entering the trial.
Conclusion: Stand-alone IPD is associated with a marked decrease in the need for opioid medications to manage symptoms related to LSS. In light of the current opiate epidemic, such alternatives as IPD may provide effective pain relief in patients with LSS without the need for opioid therapy.

Keywords: interspinous spacer, Superion, lumbar spinal stenosis, opioids, neurogenic claudication, indirect decompression

Introduction

Lumbar spinal stenosis (LSS) is a common degenerative condition that causes significant pain, disability, functional impairment, and diminished quality of life.[1,2] The clinical feature most commonly attributed to LSS is neurogenic claudication that involves leg symptoms encompassing the buttocks, groin, and anterior thigh, as well as radiating pain down the posterior aspect of the leg to the feet.[3,4] The discomfort associated with LSS is often described as a cramping or burning feeling. Symptoms of neurogenic claudication can be distributed unilaterally or bilaterally, and the patient may suffer concomitant back pain, although leg pain and discomfort are usually more bothersome.[5]

A distinguishing clinical attribute of neurogenic claudication is its relationship to the patient's posture, where lumbar extension increases and flexion decreases pain onset and severity. Symptoms progressively worsen when standing or walking, and are relieved

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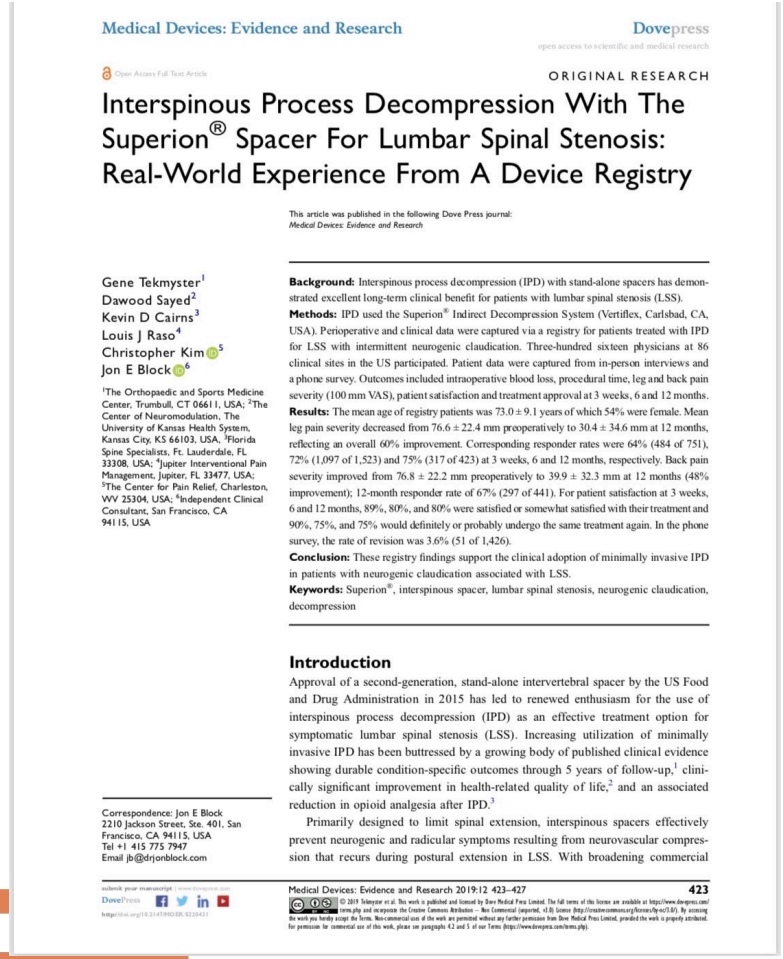
- N = 107
- "Between baseline and five years, there was an 85% decrease in the proportion of subjects using opioids."

Nunley PD, Deer TR, Benyamin RM, et al. Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis. J Pain Res. 2018;11:2943-2948.

AAPM2022 38TH ANNUAL MEETING

Tekmyster, 2019



Medical Devices: Evidence and Research

Dovepress

open access to scientific and medical research

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ORIGINAL RESEARCH

Interspinous Process Decompression With The Superion® Spacer For Lumbar Spinal Stenosis: Real-World Experience From A Device Registry

This article was published in the following Dove Press journal:
Medical Devices: Evidence and Research

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Dawood Sayed[2]
Kevin D Cairns[3]
Louis J Raso[4]
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Background: Interspinous process decompression (IPD) with stand-alone spacers has demonstrated excellent long-term clinical benefit for patients with lumbar spinal stenosis (LSS).

Methods: IPD used the Superion® Indirect Decompression System (Vertiflex, Carlsbad, CA, USA). Perioperative and clinical data were captured via a registry for patients treated with IPD for LSS with intermittent neurogenic claudication. Three-hundred sixteen physicians at 86 clinical sites in the US participated. Patient data were captured from in-person interviews and a phone survey. Outcomes included intraoperative blood loss, procedural time, leg and back pain severity (100 mm VAS), patient satisfaction and treatment approval at 3 weeks, 6 and 12 months.

Results: The mean age of registry patients was 73.0 ± 9.1 years of which 54% were female. Mean leg pain severity decreased from 76.6 ± 22.4 mm preoperatively to 30.4 ± 34.6 mm at 12 months, reflecting an overall 60% improvement. Corresponding responder rates were 64% (484 of 751), 72% (1,097 of 1,523) and 75% (317 of 423) at 3 weeks, 6 and 12 months, respectively. Back pain severity improved from 76.8 ± 22.2 mm preoperatively to 39.9 ± 32.3 mm at 12 months (48% improvement); 12-month responder rate of 67% (297 of 441). For patient satisfaction at 3 weeks, 6 and 12 months, 89%, 80%, and 80% were satisfied or somewhat satisfied with their treatment and 90%, 75%, and 75% would definitely or probably undergo the same treatment again. In the phone survey, the rate of revision was 3.6% (51 of 1,426).

Conclusion: These registry findings support the clinical adoption of minimally invasive IPD in patients with neurogenic claudication associated with LSS.

Keywords: Superion®, interspinous spacer, lumbar spinal stenosis, neurogenic claudication, decompression

Introduction

Approval of a second-generation, stand-alone intervertebral spacer by the US Food and Drug Administration in 2015 has led to renewed enthusiasm for the use of interspinous process decompression (IPD) as an effective treatment option for symptomatic lumbar spinal stenosis (LSS). Increasing utilization of minimally invasive IPD has been buttressed by a growing body of published clinical evidence showing durable condition-specific outcomes through 5 years of follow-up,[1] clinically significant improvement in health-related quality of life,[2] and an associated reduction in opioid analgesia after IPD.[3]

Primarily designed to limit spinal extension, interspinous spacers effectively prevent neurogenic and radicular symptoms resulting from neurovascular compression that recurs during postural extension in LSS. With broadening commercial

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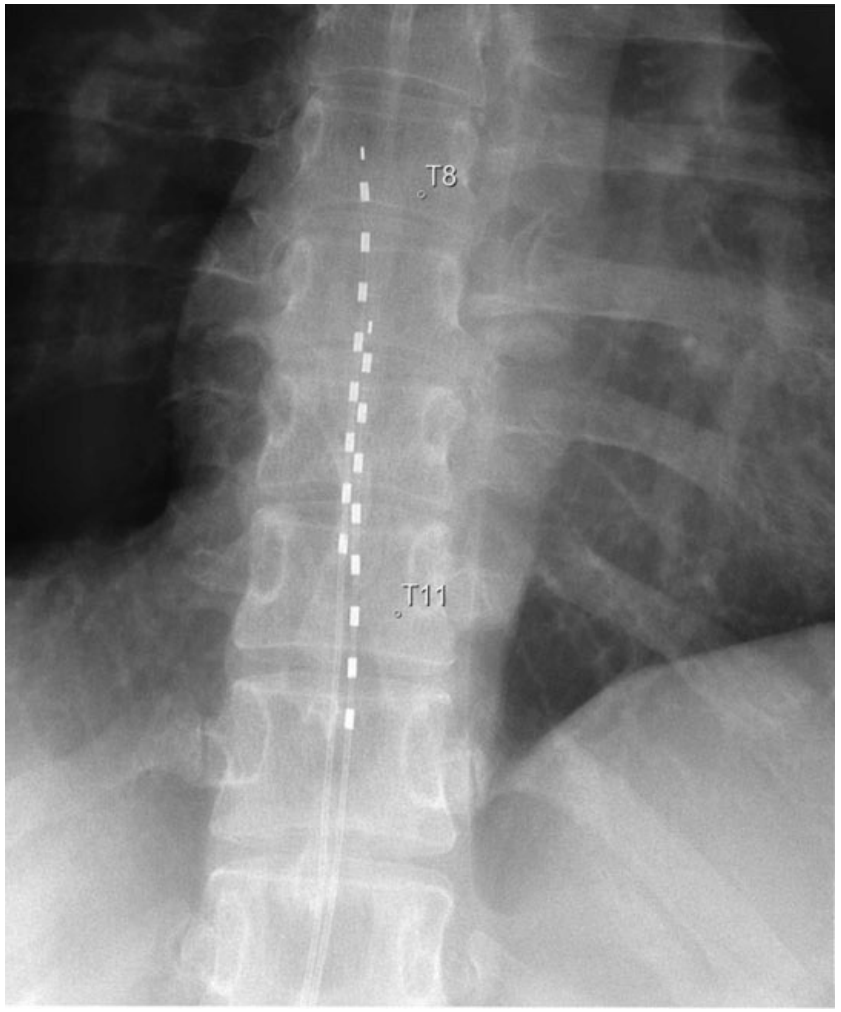
- N = 316, at 12 months
- Leg pain = 60% improvement
- Back pain = 50% improvement
- 75% leg responder rate and 67% back responder rate
- 80% satisfied, 75% would undergo again

Tekmyster G, Sayed D, Cairns KD, et al. Interspinous Process Decompression With The Superion Spacer for Lumbar Spinal Stenosis: Real-World Experience From A Device Registry. *Medical Device Evidence and Research*. 2019.

Spinal Cord Stimulation



Spinal Cord Stimulation

- Two step process.
  1. Trial
     - Temporary stimulation leads are placed percutaneously into the epidural space and secured to the skin for 3-10 days.
  2. Implant
     - If the trial is successful and the patient desires implantation, the leads and implantable pulse generator (IPG) are implanted under the skin in a separate open surgical procedure.

SCS Literature

- Chandler et al.
  - Retrospective, 55 patients, paresthesia-based SCS trial for LSS and associated leg pain.
  - Twenty-one patients underwent permanent implantation with paddle lead
  - 67% reported continued analgesia (greater than 50% subjective relief and/or decrease in medication or improvement in function) at 1.5 years. Twelve patients had a successful trial but choose not to proceed with permanent implant.

Chandler GS, 3rd, Nixon B, Stewart LT, Love J. Dorsal column stimulation for lumbar spinal stenosis. *Pain Physician* 2003;6(1):113-118.

SCS Literature

- Costantini et al.
  - Retrospective, 69 patients with symptomatic back and leg pains attributed to LSS, all treated with paresthesia-based SCS. All patients had failed conservative management.
  - Data were collected with a median follow-up of 2 years (mean 27 months).
  - Results:
    - VAS improved from baseline 7.4±2.3 to 2.8±2.4 ($P<0.05$).
    - Opioid use from 29% to 13%, NSAIDS from 75% to 49%, antidepressants from 33% to 20%, and antiepileptics from 32% to 9% ($P<0.05$).
    - ODI decreased from 34.3±7.6 to 15.7±13.1 at follow-up in this smaller cohort ($P<0.05$).

Costantini A, Buchser E, Van Buyten JP. Spinal cord stimulation for the treatment of chronic pain in patients with lumbar spinal stenosis. *Neuromodulation* 2010;13:275-280.

SCS Literature

- Kamihara et al.
  - Retrospective, 91 patients, paresthesia-based SCS trial for LSS-associated leg pain. A total of 59 patients reported at least 50% pain relief during the trial (64.8%), and 41 patients desired permanent placement and were implanted (45.1%).
  - The mean follow-up was 34.5±22.5 months.
  - The authors defined success as a “good response group” defined as “SCS continued for 1 year or more after implantation” and this result was reported in 39 of 41 patients (95.1%).
  - The significant limitation of this study is the lack of valid pain and/or functional outcome measures, which makes it difficult to assess whether the 95.1% success rate is valid.

Kamihara M, Nakano S, Fukunaga T, et al. Spinal cord stimulation for treatment of leg pain associated with lumbar spinal stenosis. *Neuromodulation* 2014;17:340-345

Conclusions

- Patients who suffer from LSS experience pain that is relieved in flexion

- Multiple treatments options exist for LSS patients. i.e., conservative care, ESI, MILD, ISS, SCS, and more invasive options.
- Key considerations for treatment selection:
  - Severity of LSS
  - Stability of the Index Level
  - Strength of Clinical Evidence


Q.
A.