Lumbar Spinal Stenosis: Direct Lumbar Depression Procedure

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Lumbar Spinal Stenosis: Direct Lumbar Decompression

- CONSULTANT: SORRENTO THERAPEUTICS – RESINIFERATOXIN
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- 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.

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

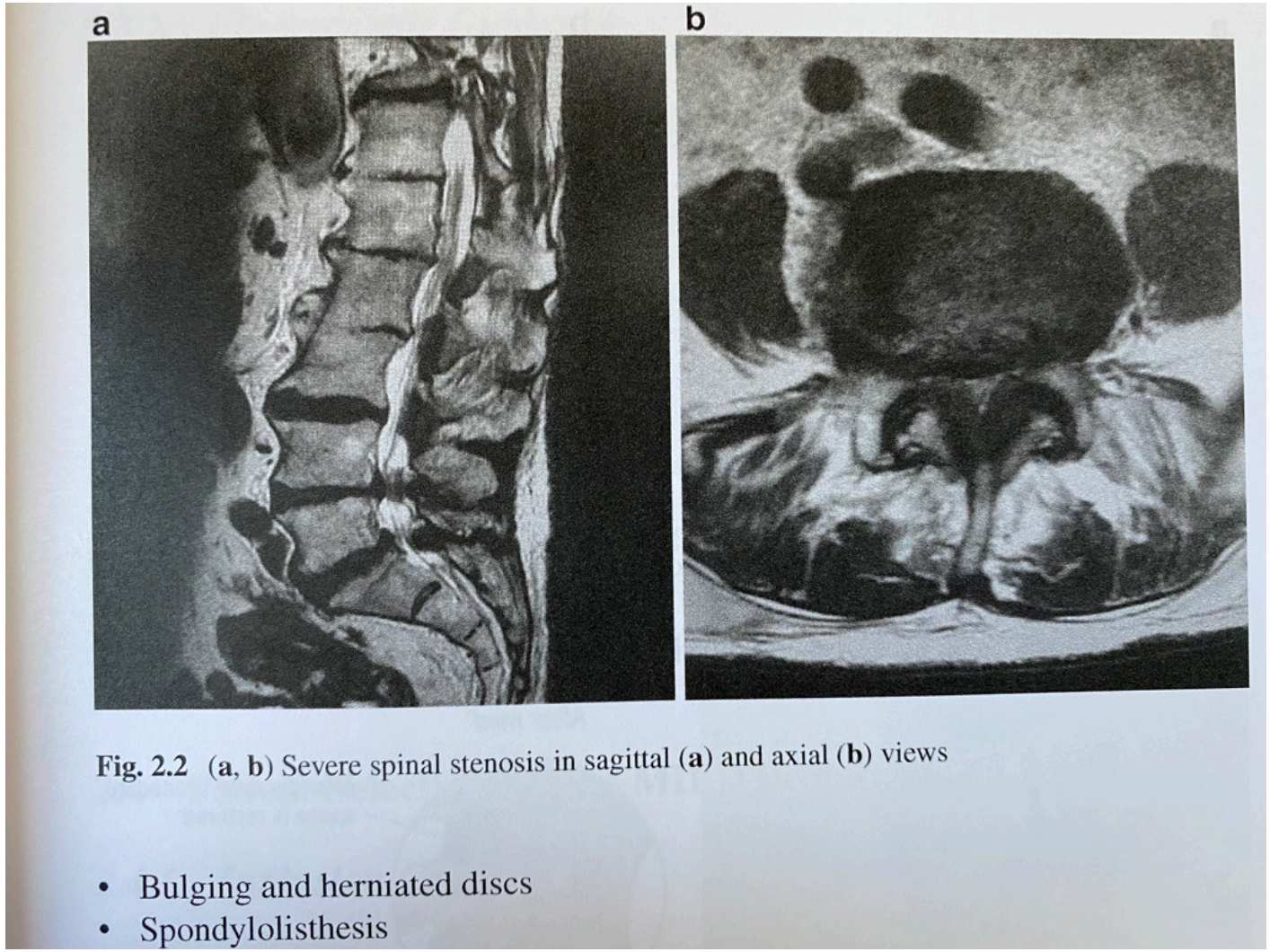


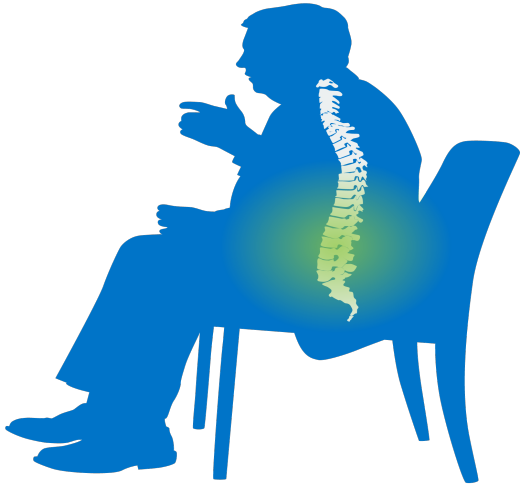
Fig. 2.2 (a, b) Severe spinal stenosis in sagittal (a) and axial (b) views

- 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

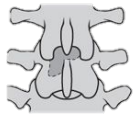
CURRENT LSS TREATMENT OPTIONS

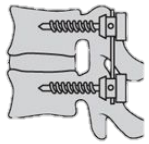
Conservative

PT
Meds

Interventional Options

ESI
Perc Decomp





Surgical Options

Interspinous Process Distraction Devices

Open Laminotomy
Open Laminectomy

Fusion

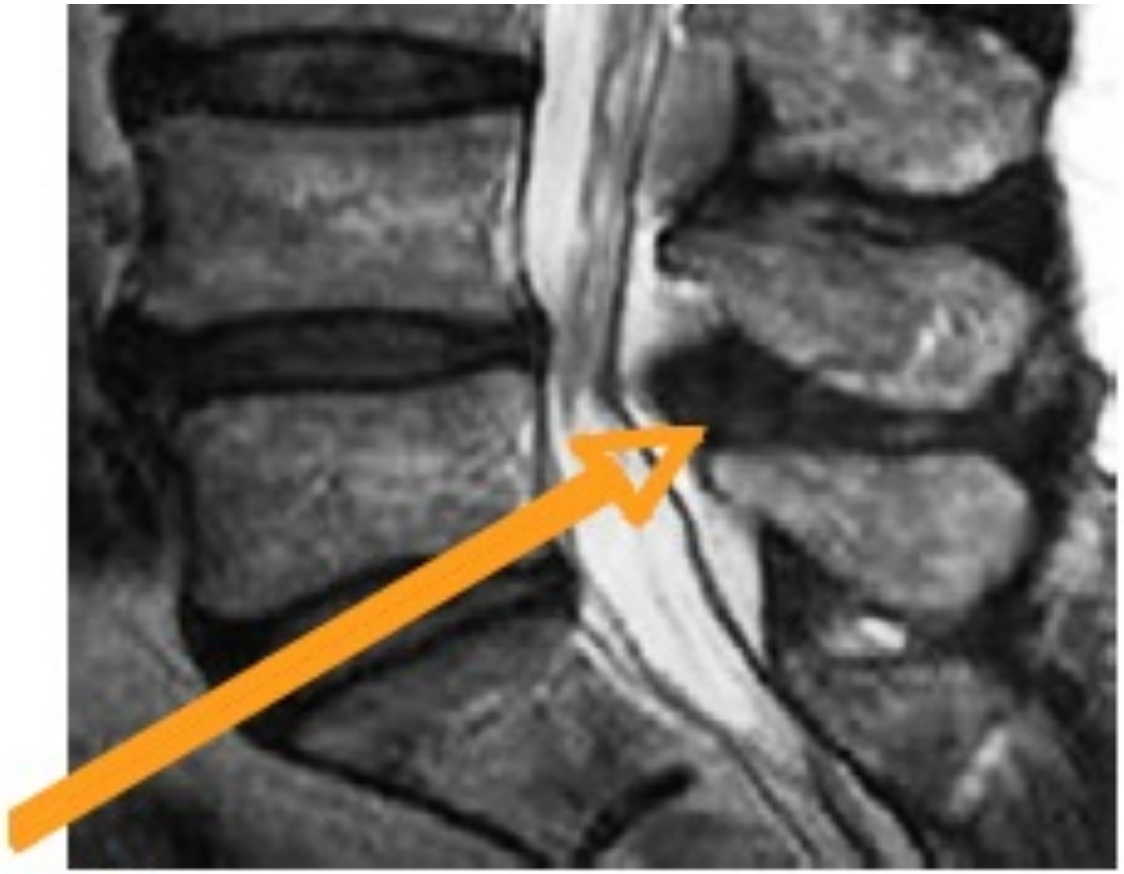
Low risk – Less Invasive

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

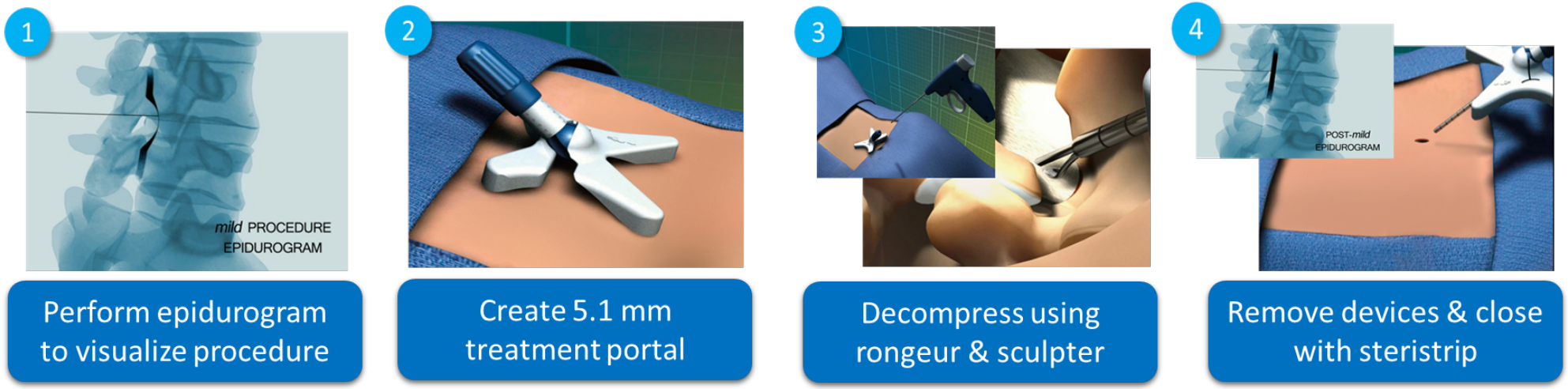
Additional Supplies to the kit

- ✓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

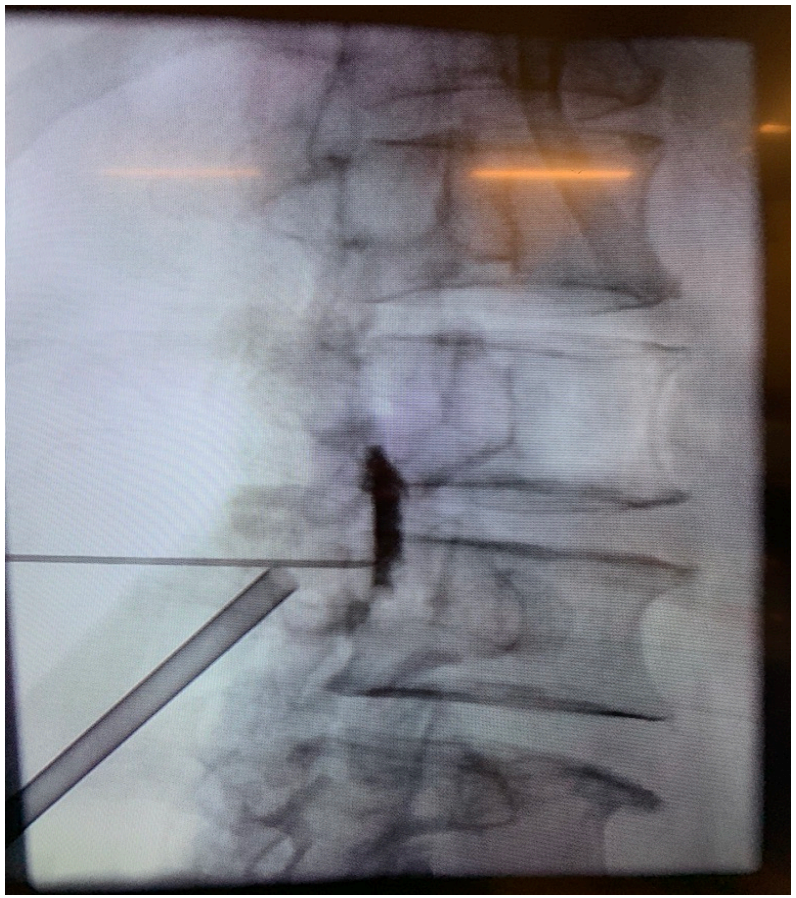


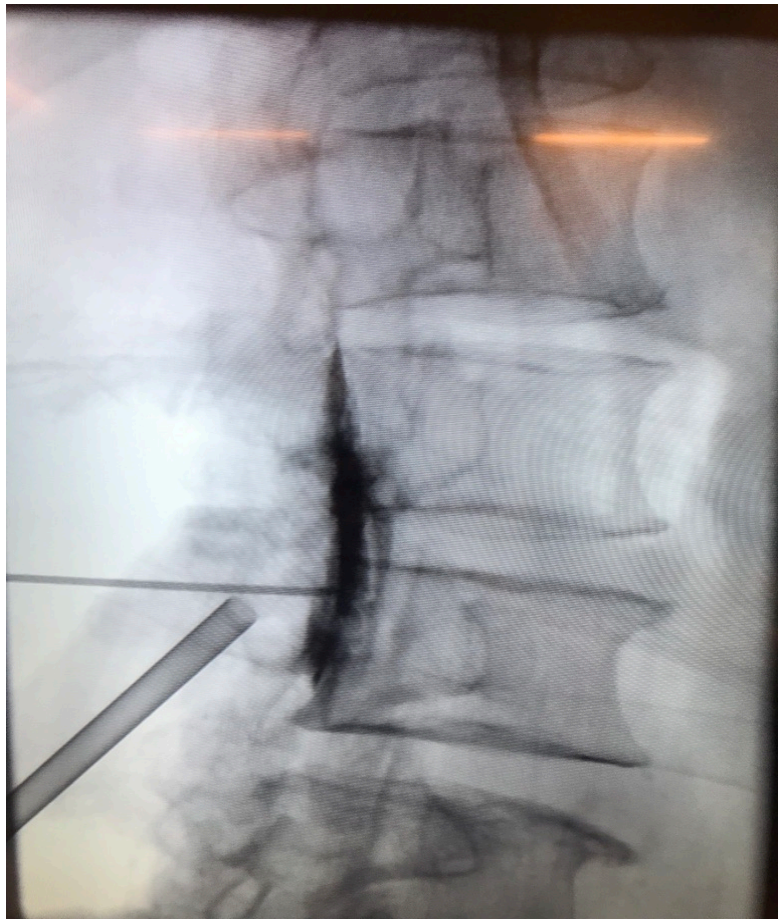
Constant visualization using epidurogram throughout procedure is critical to safety and efficacy.

- 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

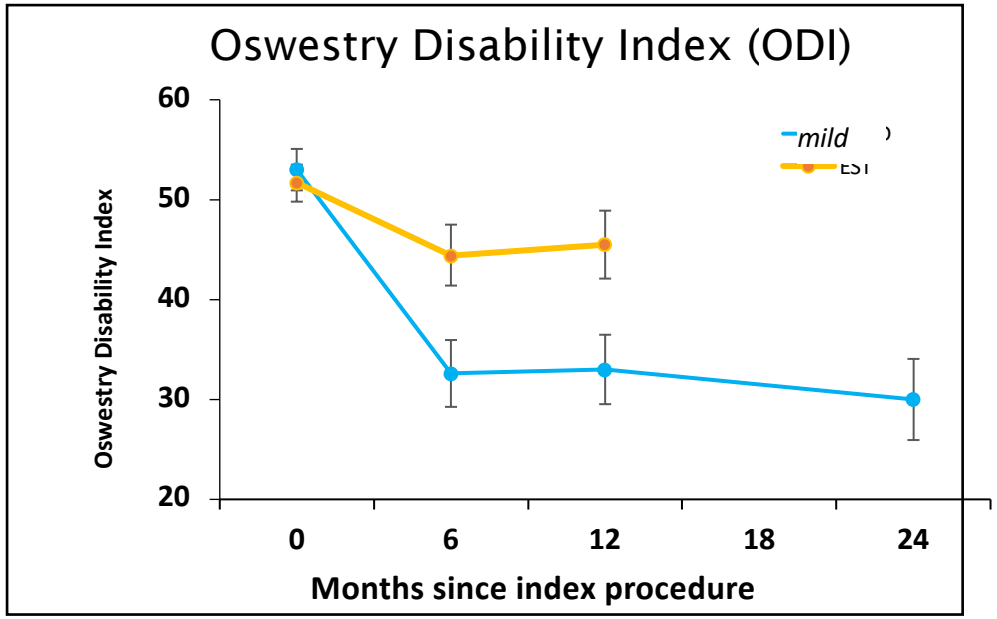
- Coverage with evidence development (CED)
- Prospective, multicenter, randomized controlled
- Randomization:
  - *Percutaneous decompressive laminotomy* versus ESI
- Study visits:
  - Baseline, 6 month, 1 year, 2 years
- Comparative data through 1 year
  - *Percutaneous decompression* -only at 2 years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

Encore Study Population

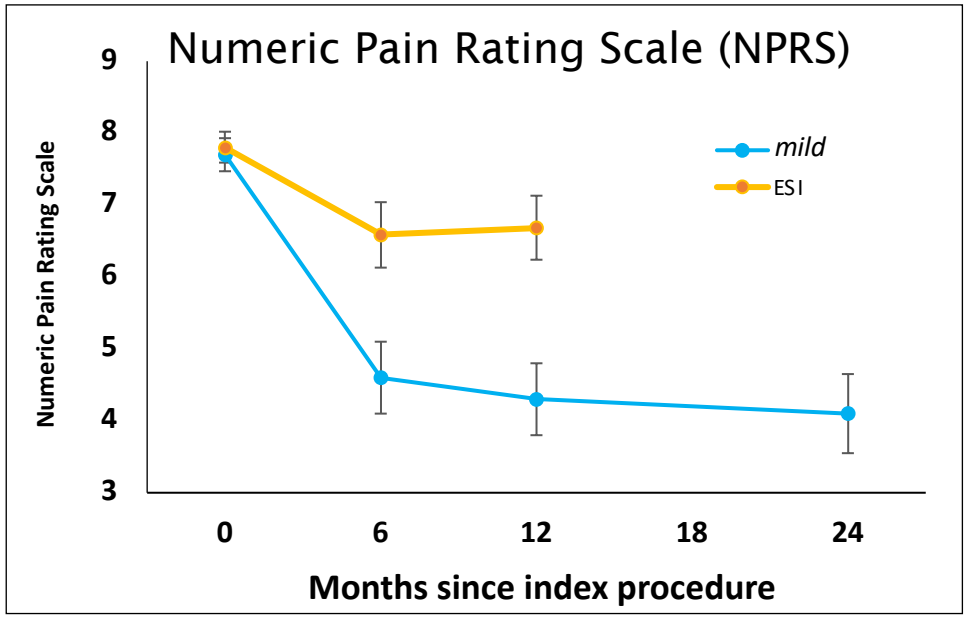
- Patients experiencing neurogenic claudication symptoms
- Hypertrophic ligamentum flavum
  - > 2.5 mm
- 65 years or older
- ODI > 31
- NPRS > 5
- No surgery at any treatment level
- Spondylolisthesis
  - < Grade III

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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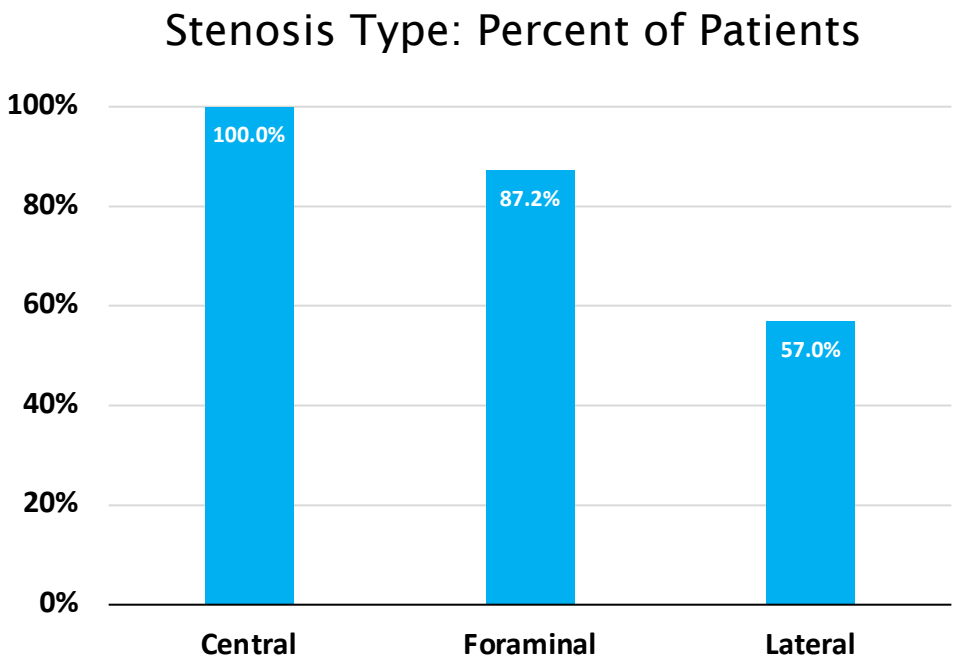
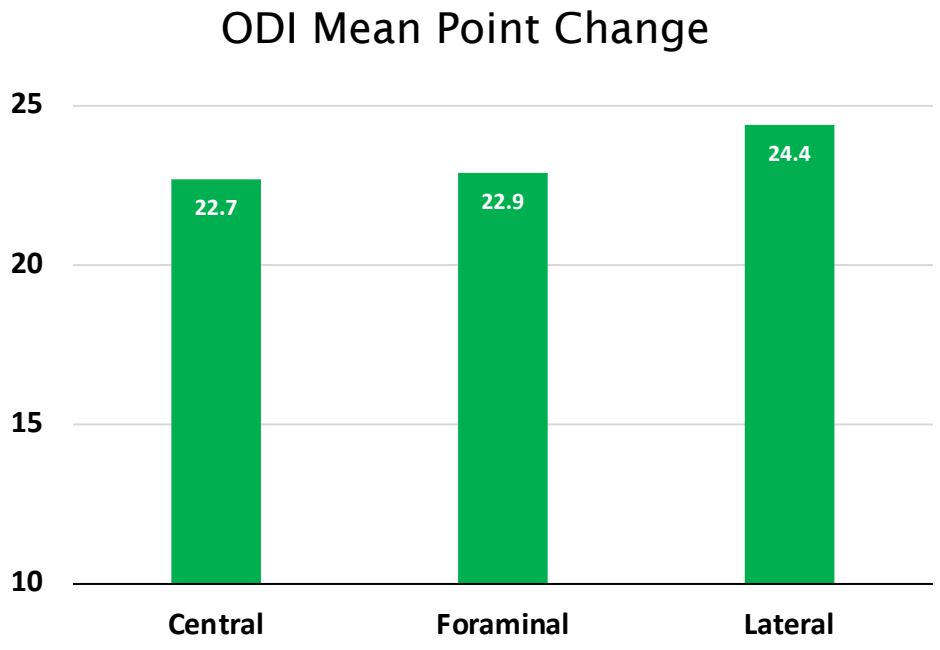
ENCORE Study 2-year Outcomes

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

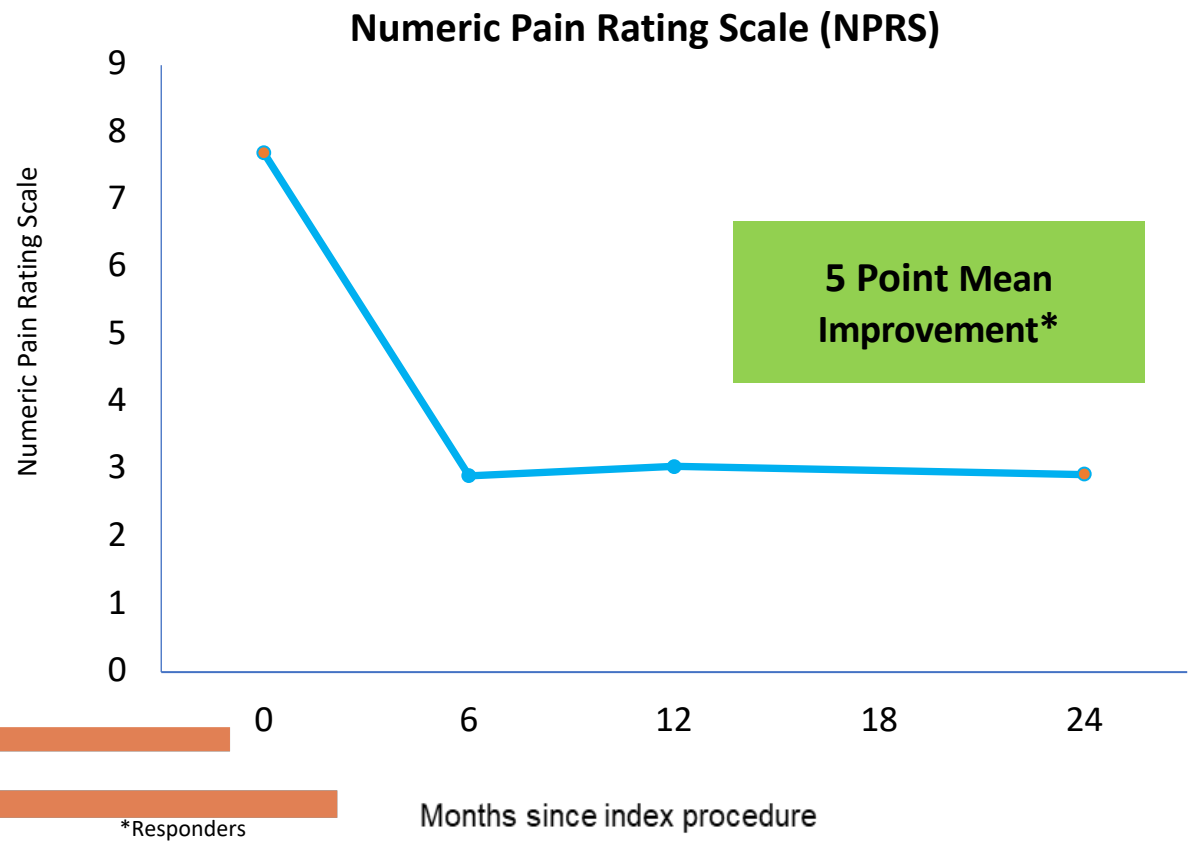
95% of Patients Had Multiple Back Conditions

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



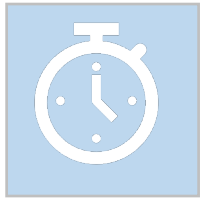
*Responders

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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