



Spinal Stenosis: Current Treatment Options

Sean Li, MD
Adjunct Clinical Associate Professor
Rutgers New Jersey Medical School, Newark, NJ
Regional Medical Director
Premier Pain Centers
Affiliate of National Spine and Pain Centers
Shrewsbury, NJ

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Disclosure

- Consulting Fee (eg, Advisory Board):
Abbott, Avanos, Biotronik, Boston Scientific, Grunenthal, Nalu, Nevro, PainTeq, Saluda, SI Bone, SPR Therapeutics, Vertos
- Contracted Research (Principal Investigators must provide information, even if received by the institution):
Avanos, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, SPR Therapeutics
- Stock Shareholder (individual stocks/stock options; diversified mutual funds do not need to be disclosed):
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Learning Objectives

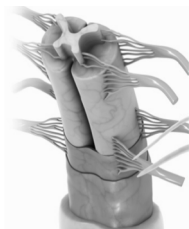
- Discuss the pathophysiology of lumbar spinal stenosis (LSS)
- Review clinical presentation of LSS
- Define neurogenic claudication
- Explore treatment continuum of LSS
- Review body of evidence supporting LSS treatment
- Review MIST consensus guidelines



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Outline

- Lumbar spinal stenosis (LSS)
- Pathophysiology
- Natural history
- Clinical presentation
- Neurogenic intermittent claudication (NIC)
- Diagnosis and evaluation
- Physical exam findings
- Treatment options
 - Conservative
 - Interventional
 - Minimally invasive
 - Surgical
- MIST consensus guidelines for LSS



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Lumbar Spinal Stenosis (LSS)

- Degenerative condition, 50% with lower back pain
- First described by Sachs and Frankel, 1900
- Clinically description by Henk Verbiest, 1954
- US Social Security Act: LSS as disabling condition

"pseudoclaudication, established by acceptable imaging, manifested by chronic nonradicular pain and weakness, and resulting in inability to ambulate"

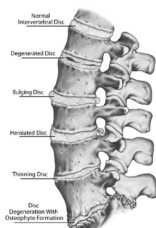
- Over \$100 billion/year due to reduced productivity



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LSS: Natural History

- Progressive condition
- Radiographically persists for decades before symptoms
- Degenerative cascade:
 - Loss of disc height
 - Loss of spinal ROM
 - Change in spinal balance
 - Osteophyte formation
 - Facet degeneration
 - Buckling of ligamentum flavum
 - Impingement of spinal cord and nerves



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LSS: Prevalence

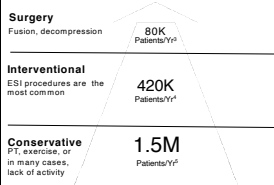
- Common degenerative spine disorder that affect QOL
- 14 million Americans with symptomatic LSS
- 109,000 diagnosed with LSS per year
- 6% prevalence from 850 myelograms, by De Villiers and Booyen
- Framingham Study, for age 60-69, prevalence up to 47.2%
- Often lead to surgical intervention
- 136 per 100,000 Medicare patients underwent surgery 2002-2007



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LSS: Existing Treatment Paradigm

Millions of Patients Seek LSS Treatment Annually



- Many are treated with opioids, physical therapy, serial ESIs, or no treatment
- Minimally invasive procedures have expanded interventional pain treatment options



Chen, Richard A, et al. "Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults." *Spine* 33(13) (2018): 1329-1336 & HTF Report for Verano Medical 2013.
 *Lussier, et al. "The global prevalence of conditions of interventional pain management techniques in the Medicare population 2005-2013." *PLoS One* 10(2) (2015): E115417 & HTF Report for Verano Medical 2013.
 †Source based on revised Opioid Report and HTF Report for Verano.

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LSS: Clinical Presentation

- Neurogenic intermittent claudication (NIC)
 - Pseudoclaudication
 - Back, leg pain
 - Weakness or cramping
 - Without vascular involvement
- Worsen with walking and standing
- Improve with sitting or forward flexion
- "Shopping cart sign"



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Neurogenic Intermittent Claudication (NIC)

1 The symptoms and location of NIC are:

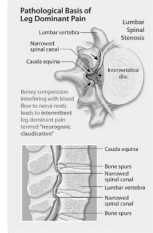
Pain	Cramping	Weakness	Tingling
Legs	Back	Buttocks	

2 Worsened when walking or standing

3 Unilateral or bilateral

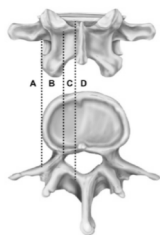
4 Spinal flexion naturally widens the spinal canal and foramen, relieving symptoms

5 NIC symptoms are secondary to LSS



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LSS: Anatomic Location of Stenosis



Type of stenosis

- Central
- Lateral recess
- Foraminal

Cause of stenosis

- Ligamentum hypertrophy
- Disc herniation
- Listhesis of spine

Co-exists with

- DDD
- Facet arthropathy
- Modic changes



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LSS: Diagnosis and Evaluation

- No widely accepted "gold standard" diagnosis criteria
- Imaging → narrowing of spinal canal or foramen
- History and physical exam, presence of NIC
- Key factors in the work-up:
 - Distinction between radiculopathy and NIC
 - Classification of spondylolisthesis when present
 - Rule out instability
- MRI preferred
- With flexion/extension plain films



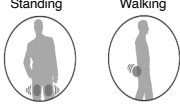
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LSS: Physical Exam Findings

- Kyphotic posture
- Detailed history (NIC characteristics)
- Rule out peripheral vascular involvement
- Difficulties with balance (Modified Romberg Test)
- Zurich Claudication Questionnaire (ZCQ)
- Oswestry Disability Index (ODI)


Pain/Numbness


Standing Walking



RELIEVED when

Bending Sitting






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Stenosis Questionnaire



- Do you have pain or weakness in your legs and/or back when standing and walking?
 - Legs
 - Back
 - Both
- Does the pain or weakness in your legs get worse the longer you stand or walk?
 - Yes
 - No
 - I do not have pain or weakness in my legs
- How would you describe the pain or weakness in your legs (check all that apply)
 - Numbness
 - Aching
 - Cramping
 - Shooting
 - Fatigue / Weakness
 - I do not have pain or weakness in my legs
- Is the pain or weakness in your legs while walking relieved when you lean over objects such as a walker or shopping cart?
 - Yes
 - No
 - I do not have pain or weakness in my legs
- Does the pain or weakness in your back get worse the longer you stand or walk?
 - Yes
 - No
 - I do not have pain or weakness in my back
- How would you describe the pain or weakness in your back (check all that apply)
 - Numbness
 - Aching
 - Cramping
 - Shooting
 - Fatigue / Weakness
 - I do not have pain or weakness in my back
- Is the pain or weakness in your back while walking relieved when you lean over objects such as a walker or shopping cart?
 - Yes
 - No
 - I do not have pain or weakness in my back
- Is the pain or weakness in your legs relieved when you sit down?
 - Yes
 - No
 - I do not have pain or weakness in my legs
- Is the pain or weakness in your back relieved when you sit down?
 - Yes
 - No
 - I do not have pain or weakness in my back



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LSS Treatment: Lifestyle Modification

- Exercise
- Maintain ideal body weight
- Core strengthening
- Often too late once LSS become symptomatic

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LSS Treatment: Physiotherapy and Rehabilitation

- Multidisciplinary rehabilitation can be effective for mild LSS
- Results vary due to inconsistent patient participation
- Patient tend to seek more interventional options
- NASS, insufficient evidence supporting PT for LSS



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LSS Treatment: Medication Therapy

- Same guidelines as chronic low back pain
- NSAID
- Anticonvulsants
- Corticosteroids
- Muscle relaxers
- Antidepressants
- Opioids

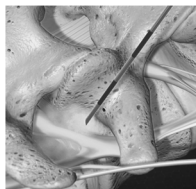


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LSS Treatment: Epidural Injection

- Injection of local anesthetic with or without corticosteroid
- North American Spine Society (NASS), Grade B: for short term relief of NIC
- Manchikanti et al. 2014, showed significant relief of LSS pain interlaminar and caudal ESI
- NEJM, 2014 showed conflicting data




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Medicine Pain Medicine, pnc1160, <https://doi.org/10.1093/pm/pnc1160>
Published: 25 July 2019

The Effectiveness of Lumbar Transforaminal Injection of Steroid for the Treatment of Radicular Pain: A Comprehensive Review of the Published Data

Clark C Smith, MD, MPH , Zachary L McCormick, MD, Ryan Mattie, MD, John MacVicar, MBChB, MPainMed, Belinda Duszynski, BS, Milan P Stojanovic, MD

- Systematic review of the literature
- 49% at 1 month, 48% at 3 months, 43% at 6 months, 59% at 1 year
- Lack of controlled studies
- Lack of high-quality evidence demonstrating effectiveness for the treatment of radicular pain due to spinal stenosis

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LSS Treatment: Surgical Treatment

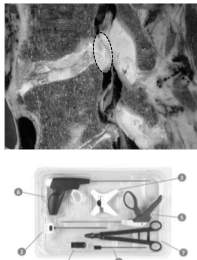
- Most common reason for spinal surgery among patients >65 years
- Goal is to increase the cross-sectional area of the affect spinal canal
- Decompressive laminectomy without fusion "gold standard"
 - SPORT trial, at 4 years diminishing benefits compared to conservative care
 - Single level procedure resulted in better outcomes and less complications
- Decompressive laminectomy with fusion
 - For patients with spondylolisthesis
 - SLIP trial, 14% rate of reoperation due to adjacent level disease
- Medicare 2000-2007, fusion rate increased 15-fold, as well as complications, cost
 - Required reoperation within 2 years
 - FBSS 25%, at 2 years

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LSS Treatment: Percutaneous Image-Guided Decompression (PILD)

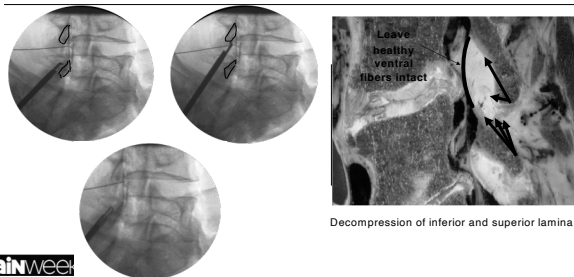
- Debulk the hypertrophied dorsal ligamentum flavum
- Image-guided percutaneous approach
- Key safety factor is the epidurogram
- Ligament greater than 2.5mm
- Outpatient procedure
- Under mild sedation
- 24 month data, MiDAS ENCORE trial
- Approved by Medicare



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LSS Treatment: PILD Procedure



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ENCORE Study 2-year Outcomes Confirmed Long-term Safety and Efficacy³

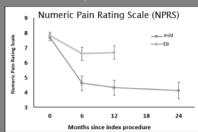
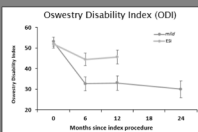
- | Study Protocol | Study Population |
|--|--|
| <ul style="list-style-type: none"> Coverage with evidence development (CED) Prospective, multicenter, randomized controlled Randomization: <ul style="list-style-type: none"> mild versus ESI Study visits: <ul style="list-style-type: none"> Baseline, 6 month, 1 year, 2 years Comparative data through 1 year <ul style="list-style-type: none"> mild-only at 2 years Outcome measures: <ul style="list-style-type: none"> Oswestry Disability Index (ODI) Numeric Pain Rating Scale (NPRS) | <ul style="list-style-type: none"> Patients experiencing neurogenic claudication symptoms Hypertrophic ligamentum flavum <ul style="list-style-type: none"> > 2.5 mm 65 years or older ODI > 31 NPRS > 5 No surgery at any treatment level Spondylolisthesis <ul style="list-style-type: none"> < Grade III |



Travers PL, Chaffin TB, Gilman S, et al. 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. 2016;41:781-794.

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ENCORE Study 2-year Outcomes Functional and Pain Improvement Compared to ESIs³

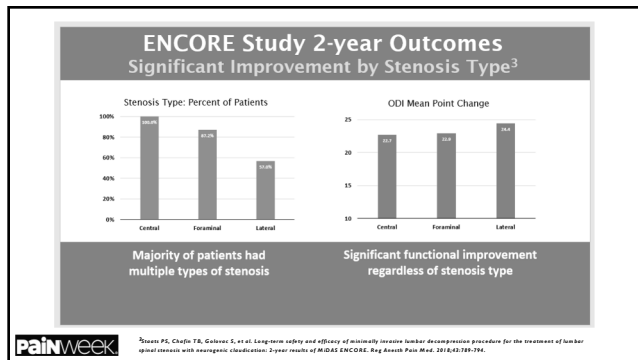


- Significant and sustained functional improvement through 2-year follow-up
- Mean ODI improvement of 22.7 points at 2 years (10-point improvement is clinically significant.)
- Significant and durable reduction of pain through 2-year follow-up
- Mean NPRS improvement of 3.6 points at 2 years (2-point improvement is clinically significant.)



Travers PL, Chaffin TB, Gilman S, et al. 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. 2016;41:781-794.

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Percutaneous Image-Guided Decompression (PILD) 5-year Durability Data

- 2010-2015, retrospective review at Cleveland Clinic
- 75 patient with LSS underwent PILD procedure
- No severe complications
- 9 patients required surgical decompression
- Statistically significant pain reduction, and functional improvement
- Statistically significant reduction in daily MME at 3, 6, 12 months

PainWeek McKhail, N. et al. Pain Practice, 2021

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LSS Treatment: Interspinous Process Decompression (IPD)

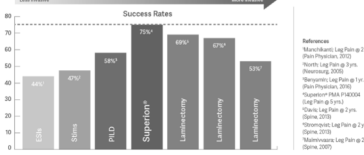
- Various spacers have been introduced
- Currently the Superior device is only one on the market that is placed percutaneously
- Serves as a back stop preventing compression of the spinal canal and lateral recess during extension

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LSS Treatment: IPD 5 Year IDE Study Results

Successful Reduction in Leg Pain Among Treatments
 Leg pain severity improvement with LSS Therapies



References:
 • Minimally Invasive Leg Pain at 2 Yrs (Pain Physician 2012)
 • Spine Leg Pain at 2 Yrs (Neurosurg Focus 2012)
 • Reoperations Leg Pain at 1 Yr (Pain Physician 2012)
 • Spine Leg Pain at 2 Yrs (Spine 2012)
 • Spine Leg Pain at 2 Yrs (Spine 2012)
 • Minimally Invasive Leg Pain at 2 Yrs (Spine 2012)



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LSS Treatment: IPD PRESS Registry

Success greater than or equal to IDE Data
 ~4,000 Patients Tracked in 2 Registries

	1 Year IDE	1 Year Registries ¹	2 Year IDE
WAS - Back Pain	63%	67%	67%
WAS - Leg Pain	71%	74%	76%
Reoperations/Revisions	13%	4%	20%
Spinous Process Fractures	16%	1%	16%
Functional Objective	N/A	76%	N/A
Patient Satisfaction	81%	82%	84%

¹ One Year Registry data compiled from PRESS, Direct Patient Consent Registry, and Complaint Reporting System through Feb 2019



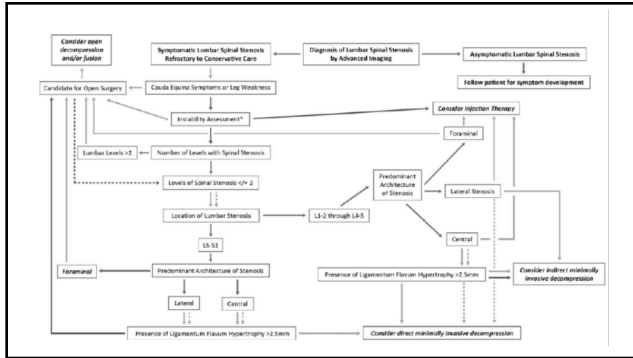
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LSS Treatment: Procedure Related Risk

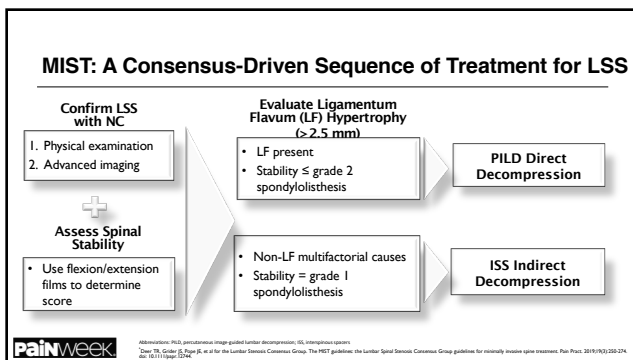
2-year Outcomes	mild†	Interspinous Process Distraction		Surgical Decompression ^{1,4}	Fusion ^{5,9}
		Superion ^{®2}	X-STOP ^{®2,4}		
Reoperation	5.6%	20.0%	14.4-26.0%	6-7.8%	12.5-16.9%
Device- and procedure-related AEs	1.3%	Device-related 11.6%		Intraoperative 9.9%	23.3%
		Procedure-related 14.2%			
Device- and procedure-related serious AEs	0%	8.4%	9.5%		18% early – 6% late
Lumbar spine fractures	0%	16.3%	8.5%	—	4.2%
Removal of hardware	No implants	16.3%	12.4%	No implants	4.3%



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Summary

- Major health issue: 1 in 10 Americans suffer from chronic pain
- Opioid epidemic: #1 health crisis in America
- Aging population
- 14 million symptomatic LSS patients
- 2 million are in treatment, 94% experience neurogenic claudication
- Conservative therapy and medication management ineffective
- Elderly, medically challenging population
- Minimally invasive options are now available for LSS, supported by Level I evidence
- MIST guidelines

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Thank You!



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Questions

Currently there are minimally invasive treatment options for symptomatic lumbar spinal stenosis, percutaneous image-guided lumbar decompression (PILD), and interspinous process decompression (IPD). Both are FDA approved and reimbursed by Medicare. When choosing which procedure, one can refer what set of guidelines?

- a. Zurich Claudication Questionnaire (ZCQ)
- b. North American Spine Society (NASS) guidelines
- c. Minimally Invasive Spine Treatment (MIST) guidelines
- d. American Association of Interventional Pain Physicians (ASIPP) guidelines
- e. North American Neuromodulation Society (NANS) guidelines



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Questions

During the diagnostic work up of symptomatic lumbar stenosis, clinical finding(s) that strongly correlates with neurogenic intermittent claudication is

- a. Pain or discomfort in the legs with walking and standing
- b. Alleviation of symptoms when leaning on a shopping cart
- c. Increased pain or discomfort with extension of lumbar spine
- d. Improved symptoms with sitting or forward flexion
- e. All of the above



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Questions

The presence of ligamentum flavum hypertrophy seen in symptomatic lumbar spinal stenosis may often be associated with additional spinal pathology including.

- a. Degenerative disc disease
- b. Spondylolisthesis
- c. Osteophyte formation
- d. Facet arthropathy
- e. All of the above



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Questions

A 76 year old female presenting with refractory pain and cramping sensation in the lower extremities. Pain seems worse when walking and alleviated with sitting or leaning forwards on a shopping cart. Patient reports once having benefited from lumbar epidural steroid injection in the past. Most recent injection was not helpful. Select the appropriate next diagnostic or treatment options.

- 1. Consider surgical consultation for lumbar decompression surgery
- 2. Obtain updated MRI or CT of the lumbar spine
- 3. Consider minimally invasive lumbar decompression
- 4. Consider indirect interspinous spacer placement
- 5. All of the above



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