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Spinal Stenosis: Current Treatment Options

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Disclosure

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Learning Objectives

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



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Outline

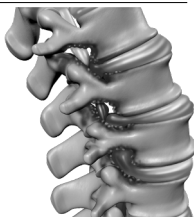
- Lumbar spinal stenosis (LSS)
- Natural history and pathophysiology
- Clinical presentation
- Neurogenic intermittent claudication (NIC)
- Diagnosis and evaluation
- Physical exam findings
- Treatment options
 - Conservative
 - Interventional
 - Minimally invasive
 - Surgical
- MIST consensus guidelines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



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Lumbar Spinal Stenosis (LSS)

- Degenerative condition, 50% with lower back pain
- First described by Sachs and Frankel, 1900
- U.S. Social Security Act: LSS as disabling condition
- 14 million Americans with symptomatic LSS
- 6% prevalence from 850 myelograms, by De Villiers and Booyesen
- 136 per 100,000 Medicare patients underwent surgery 2002-2007
- Over \$100 billion/year due to reduced productivity



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



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LSS: Prevalence

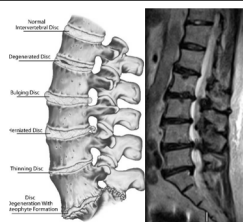
- Common degenerative spine disorder that affect QOL
- 14 million Americans with symptomatic LSS
- 109,000 diagnosed with LSS per year
- 6% prevalence from 850 myelograms, by De Villiers and Booyesen
- Framingham Study, for age 60-69, prevalence up to 47.2%
- Often lead to surgical intervention
- 136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



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LSS: Natural History

- Progressive condition
- Radiographic evidence precedes 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: Existing Treatment Paradigm

Millions of Patients Seek LSS Treatment Annually

Surgery Fusion, decompression	80K Patients/Yr ¹
Interventional ESI procedures are the most common.	420K Patients/Yr ²
Conservative PT, exercise, or in many cases, lack of activity.	1.5M Patients/Yr ³

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

PainWeek ©2015 Richard A. et al. "Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults." Spine 2015; 40(22):1-11 (2015). 120-124 & HTF Report for Versum Medical 2015. Copyright 2015. The medical management of patients of low back pain management techniques in the Medicare population: 2000-2011. The Physician 183 (2015) 611-617 & HTF Report for Versum Medical 2015. Information based on spinalEUS Database HTF and HTF Report for Versum.

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Neurogenic Intermittent Claudication (NIC)

- The symptoms and location of NIC are:**

Pain	Cramping	Weakness	Tingling
Legs	Back	Buttocks	
- Worsened when walking or standing**
- Unilateral or Bilateral**
- Spinal flexion naturally widens the spinal canal and foramen, relieving symptoms**
- NIC symptoms are secondary to LSS**

Pathological Basis of Leg Dominant Pain:

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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"

Shopping Cart Sign
Do you have Lumbar Spinal Stenosis?

Do you experience pain, numbness, and muscle weakness in the lower back and sometimes leg? Do these symptoms get worse when standing straight?

Are symptoms relieved by leaning forward on a shopping cart?

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LSS: Diagnosis and Evaluation

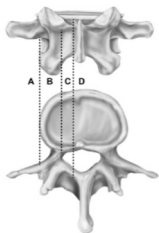
- No widely accepted "gold standard" diagnosis criteria
- Imaging → narrowing of spinal canal or foramen
- History and physical exam, presence of NIC
- Key factors in the work-up:
 - Distinction between radiculopathy and NIC
 - Classification of spondylolisthesis when present
 - Rule out instability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



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LSS: 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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Stenosis Questionnaire

1. Do you have pain or weakness in your legs and/ or back when standing and walking?
 - Legs
 - Back
 - Both
2. 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
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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: 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)



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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

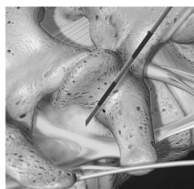
- Same guidelines as chronic low back pain
- NSAID
- Anti-convulsants
- Corticosteroids
- Muscle relaxers
- Anti-depressants
- Opioids



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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
- ENJM, 2014 showed conflicting data



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Medicine

Pain Medicine, pnc160, <https://doi.org/10.1093/pm/pnc160>
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

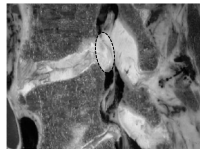
- Most common reason for spinal surgery among patients >65 years
- Goal is to increase the cross-sectional area of the affect spinal canal
- Decompressive laminectomy without fusion "gold standard"
 - SPORT trial, at 4 years diminishing benefits compared to conservative care
 - Single level procedure 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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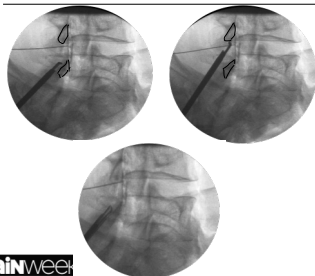
LSS Treatment: Percutaneous Image-Guided Decompression (PILD)

- 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



Decompression of inferior and superior lamina



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

Study Protocol

- Coverage with evidence development (CED)
- Prospective, multicenter, randomized controlled
- Randomization:
 - mild versus ESI
- Study visits:
 - Baseline, 6 month, 1 year, 2 years
- Comparative data through 1 year
- mild-only at 2 years
- Outcome measures:
 - Oswestry Disability Index (ODI)
 - Numeric Pain Rating Scale (NPRS)

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

PainWeek 3. Szabo PL, Chafin TB, Galvani 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;37:791-794.

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

Oswestry Disability Index (ODI)

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.)

Numeric Pain Rating Scale (NPRS)

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.)

PainWeek 3. Szabo PL, Chafin TB, Galvani 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;37:791-794.

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ENCORE Study 2-year Outcomes Significant Improvement by Stenosis Type³

Stenosis Type: Percent of Patients

Majority of patients had multiple types of stenosis

ODI Mean Point Change

Significant functional improvement regardless of stenosis type

PainWeek 3. Szabo PL, Chafin TB, Galvani 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;37:791-794.

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LSS Treatment: Interspinous Process Decompression (IPD)

- Various spacers have been introduced
- FDA approved for spinal stenosis with NIC
- Approved by Medicare
- Back stop preventing compression of the spinal canal
- Level one, 5-year evidence
- Minimally invasive alternative to open surgery
- Reduces opioid intake



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Interspinous Spacer: Extension Blocker

For Patients with Neurogenic Intermittent Claudication Secondary to LSS



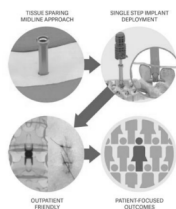
Limiting extension reduces or eliminates the compression of nerves at the implanted level(s)



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Interspinous Decompression Procedure

- Requires no resection of anatomical structures
- Delivered through a small cannula and deployed in a single step
- Completed in an outpatient setting under local or monitored anesthesia care (MAC)
- Near immediate recovery time
- Durable clinical benefit through 5 years
- Completely reversible



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Journal of Pain Research Dovepress
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CLINICAL TRIAL REPORT

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

- **85% reduction** in the proportion of subjects using opioids at 5 years
- Interspinous process decompression is associated with decrease in the need for opioid medications

PainWeek Nandy, PD et al. J Pain Research, 2018

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LSS Treatment: IPD 5 Year IDE Study Results

Immediate and Durable Relief of Primary LSS Symptoms

75% Improvement in Leg Pain from Baseline at 5 Years

Time course of results for leg and back pain severity by VAS[†]
Note: Results reported as mean (95% CI).
[†]Harvey PD, et al. Clinical Interventions in Aging 2017.

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IDE Study: Primary End Point (ZCQ)

Success Criteria**

- ≥ 0.5 point improvement in physical function
- ≥ 0.5 point improvement in symptom severity
- score of ≤ 2.5 points on patient satisfaction domain

Success Rates**

- 75% of Patients ZCQsf
- 81% of Patients ZCQps
- 90% of Patients ZCQss
- 84% of Patients demonstrated success in 2 out of 3 ZCQ domains

Figure 1 Time course of results for each subdomain of the ZCQ. vs. p, ps.
Note: Results reported as mean (95% CI).
 Abbreviations: pf, physical function; ps, patient satisfaction; ss, symptom severity; ZCQ, Zurich Claudication Questionnaire.

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IDE Study: Secondary End Point (VAS)

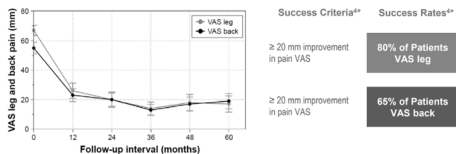


Figure 2 Time course of results for leg and back pain severity by VAS. Note: Results reported as mean (95% CI). Abbreviation: VAS, visual analog scale.

** 60 months and from the population that completed the follow-up



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IDE Study: Secondary End Point (Opioid Reduction)

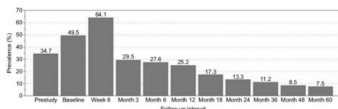
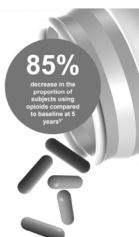


Figure 1 Opioid reduction percentage (%) by follow-up interval for all study subjects (n=76). Note: Sample size varies (92 patients, baseline; 87 cases at 173 months 3, 174 months 6, 143 months 12, 150 months 18, 160 months 24, 128 months 30, 94 months 48, and 85 months 60).

Journal of Pain Research
 Discussion
 CLINICAL TRIAL REPORT
 Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis



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LSS Treatment: IPD PRESS Registry

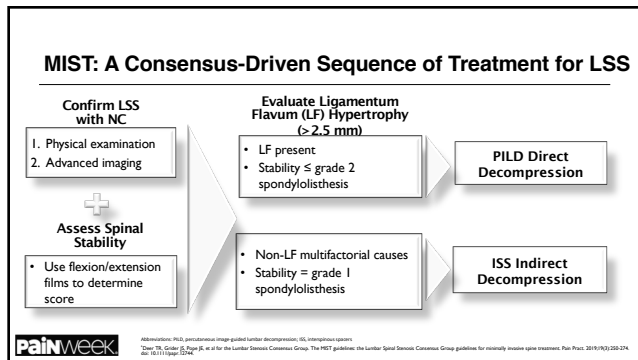
Success greater than or equal to IDE Data
 ~4,000 Patients Tracked in 2 Registries

	1 Year IDE	1 Year Registries*	2 Year IDE
VAS - Back Pain	63%	67%	67%
VAS - 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 Year Year Registry data compiled from PRESS, Direct Patient Consent Registry, and Completed Reporting System through Feb 2019



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LSS Treatment: Procedure Related Risk

2-year Outcomes	mild ¹	Interspinous Process Distraction		Surgical Decompression ^{3,4}	Fusion ^{5,9}
		Superion ^{6,2}	X-STOP ^{6,2,4}		
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 (prior to COVID-19)
- Aging population
- 14 million symptomatic LSS patients
- As many as 94% experience neurogenic claudication
- Conservative therapy and medication management ineffective
- Elderly, medically challenging population
- Minimally invasive options are now available, supported by Level I evidence
- MIST guidelines

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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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Thank You!



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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 (correct answer)



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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 (correct answer)



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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 (correct answer)



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