PainWeek

Spinal Stenosis: Current Treatment Options

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Disclosure

- Consultant/Independent Contractor:
  Abbott, Biotronik, Boston Scientific, Nalu, Nevro, Saluda, SI-Bone, Vertos
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- Advisory Board: Biotras
- Stock Shareholder: Nalu

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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 Booysen
- 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 Booysen
- 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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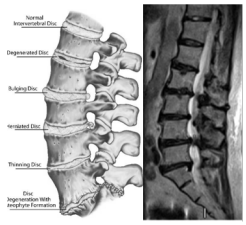
LSS: Natural History

- 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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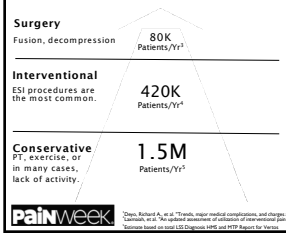
LSS: Existing Treatment Paradigm

Millions of Patients Seek LSS Treatment Annually



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

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[3]Deyo, Richard A., et al. "Trends, major medical complications, and charges associated with surgery for lumber spinal stenosis in older adults." Jama303.13 (2010): 1259-1265 & MTP Report for Versus Medical 2013.
[4]Lasmaki, et al. "An updated assessment of utilization of interventional pain management techniques in the Medicare population: 2005-2013." Pain Physician 18.2 (2015): E111-E127 & MTP Report for Versus Medical 2013.
[5]Estimate based on total LSS Diagnosis HMS and MTP Report for Versus

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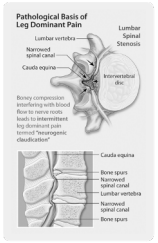
Neurogenic Intermittent Claudication (NIC)

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: 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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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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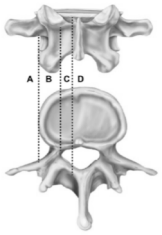
LSS: Anatomic Location of Stenosis



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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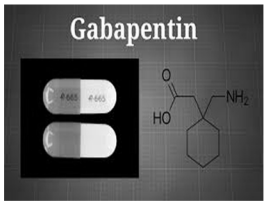
LSS Treatment: Medication Therapy

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



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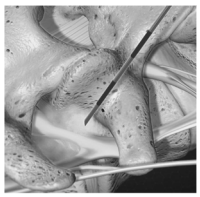
LSS Treatment: Epidural Injection

- 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, pnz160, https://doi.org/10.1093/pm/pnz160
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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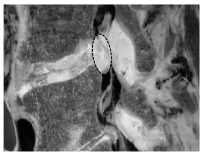
LSS Treatment: Percutaneous Image-Guided Decompression (PILD)

- 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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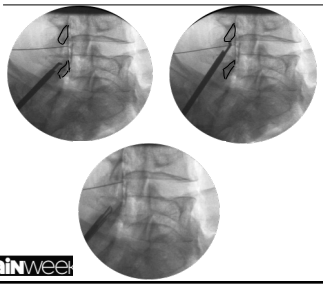
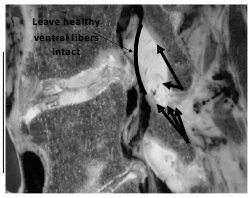
LSS Treatment: PILD Procedure





Decompression of inferior and superior lamina

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ENCORE Study 2-year Outcomes
Confirmed Long-term Safety and Efficacy[3]

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

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Steven PS, Chafin TB, Golovac 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. 2018;43:789–794.

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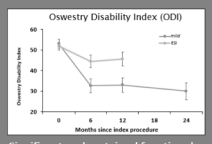
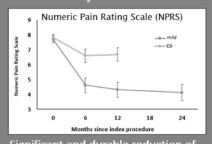
ENCORE Study 2-year Outcomes
Functional and Pain Improvement Compared to ESIs[3]



- 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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[3]Staats PS, Chafin TB, Golovac 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. 2018;43:789-794.

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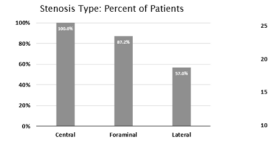
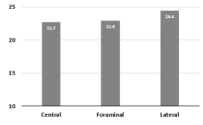
ENCORE Study 2-year Outcomes
Significant Improvement by Stenosis Type[3]





Majority of patients had multiple types of stenosis

Significant functional improvement regardless of stenosis type

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[3]Staats PS, Chafin TB, Golovac 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. 2018;43:789-794.

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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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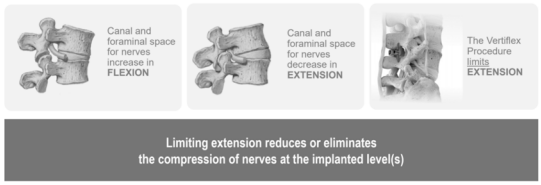
Interspinous Spacer: Extension Blocker

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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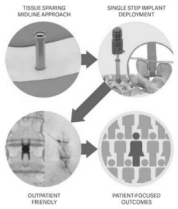
Interspinous Decompression Procedure

- 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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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

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Nunely. PD et al. J Pain Research, 2018

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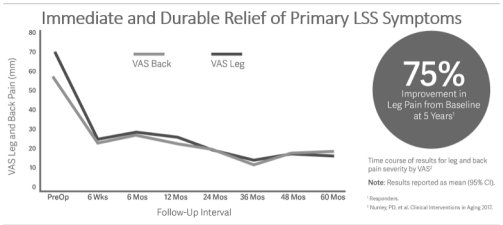
LSS Treatment: IPD 5 Year IDE Study Results



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IDE Study: Primary End Point (ZCQ)

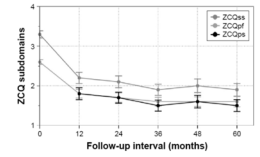

Figure 1 Time course of results for each subdomain of the ZCQ: ss, pf, ps.
Note: Results reported as mean (95% CI).
Abbreviations: pf, physical function; ps, patient satisfaction; ss, symptom severity; ZCQ, Zurich Claudication Questionnaire.

Success Criteria[4*]	Success Rates[4*]
≥ 0.5 point improvement in physical function	75% of Patients ZCQss
≥ 0.5 point improvement in symptom severity	81% of Patients ZCQpf
score of ≤ 2.5 points on patient satisfaction domain	90% of Patients ZCQps
84% of Patients demonstrated success in 2 out of 3 ZCQ domains	

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

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IDE Study: Secondary End Point (VAS)

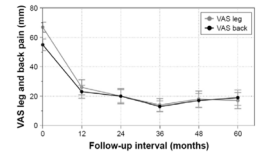

Figure 2 Time course of results for leg and back pain severity by VAS.
Note: Results reported as mean (95% CI).
Abbreviation: VAS, visual analog scale.

Success Criteria[4*]	Success Rates[4*]
≥ 20 mm improvement in pain VAS	80% of Patients VAS leg
≥ 20 mm improvement in pain VAS	65% of Patients VAS back

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

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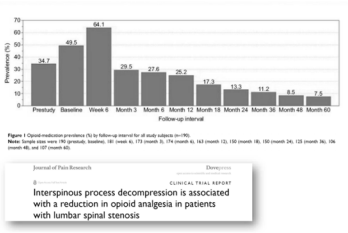
IDE Study: Secondary End Point (Opioid Reduction)



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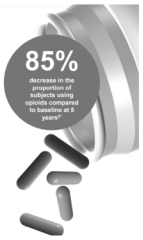
CLINICAL TRIAL REPORT

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

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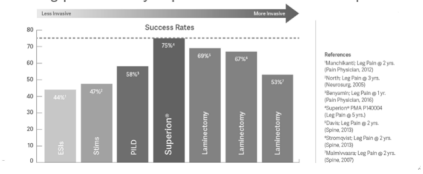
LSS Treatment: IPD 5 Year IDE Study Results

Successful Reduction in Leg Pain Among Treatments

Leg pain severity improvement with LSS Therapies



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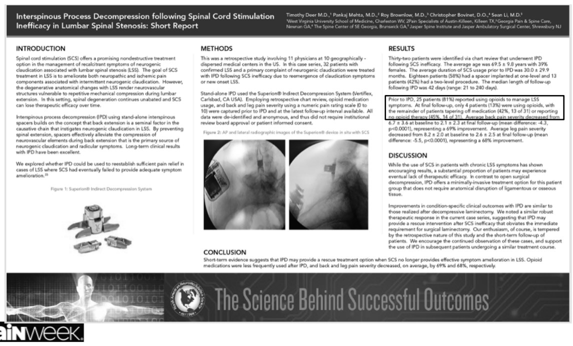

Interspinous Process Decompression following Spinal Cord Stimulation Inefficacy in Lumbar Spinal Stenosis: Short Report

Timothy Deer M.D.,[1] Pankaj Mehta, M.D.,[2] Roy Brownlow, M.D.,[3] Christopher Bovinet, D.O.,[4] Sean Li, M.D.[5]
[1]West Virginia University School of Medicine, Charleston WV, 2Pain Specialists of Austin-Killeen, Killeen TX,[3]Georgia Pain & Spine Care, Newnan GA,[4] The Spine Center of SE Georgia, Brunswick GA,[5] Jasper Spine Institute and Jasper Ambulatory Surgical Center, Shrewsbury NJ

INTRODUCTION

Spinal cord stimulation (SCS) offers a promising nondestructive treatment option in the management of recalcitrant symptoms of neurogenic claudication associated with lumbar spinal stenosis (LSS). The goal of SCS treatment in LSS is to ameliorate both neuropathic and ischemic pain components associated with intermittent neurogenic claudication. However, the degenerative anatomical changes with LSS render neurovascular structures vulnerable to repetitive mechanical compression during lumbar extension. In this setting, spinal degeneration continues unabated and SCS can lose therapeutic efficacy over time.

Interspinous process decompression (IPD) using stand-alone interspinous spacers builds on the concept that back extension is a seminal factor in the causative chain that instigates neurogenic claudication in LSS. By preventing spinal extension, spacers effectively alleviate the compression of neurovascular elements during back extension that is the primary source of neurogenic claudication and radicular symptoms. Long-term clinical results with IPD have been excellent.

We explored whether IPD could be used to reestablish sufficient pain relief in cases of LSS where SCS had eventually failed to provide adequate symptom amelioration.[23]

Figure 1: Superion® Indirect Decompression System

METHODS

This was a retrospective study involving 11 physicians at 10 geographically - dispersed medical centers in the US. In this case series, 32 patients with confirmed LSS and a primary complaint of neurogenic claudication were treated with IPD following SCS inefficacy due to reemergence of claudication symptoms or new onset LSS.

Stand-alone IPD used the Superion® Indirect Decompression System (Vertiflex, Carlsbad, CA USA). Employing retrospective chart review, opioid medication usage, and back and leg pain severity using a numeric pain rating scale (0 to 10) were captured prior to IPD and at the latest follow-up interval available. All data were de-identified and anonymous, and thus did not require institutional review board approval or patient informed consent.

Figure 2: AP and lateral radiographic images of the Superion® device in situ with SCS

RESULTS

Thirty-two patients were identified via chart review that underwent IPD following SCS inefficacy. The average age was 69.5 ± 9.8 years with 39% females. The average duration of SCS usage prior to IPD was 30.0 ± 29.9 months. Eighteen patients (58%) had a spacer implanted at one-level and 13 patients (42%) had a two-level procedure. The median length of follow-up following IPD was 42 days (range: 21 to 240 days).

Prior to IPD, 25 patients (81%) reported using opioids to manage LSS symptoms. At final follow-up, only 4 patients (13%) were using opioids, with the remainder of patients tapering off medication (42%, 13 of 31) or reporting no opioid therapy (45%, 14 of 31). Average back pain severity decreased from 6.7 ± 3.6 at baseline to 2.1 ± 2.3 at final follow-up (mean difference: -4.3, p<0.0001), representing a 69% improvement. Average leg pain severity decreased from 8.2 ± 2.0 at baseline to 2.6 ± 2.5 at final follow-up (mean difference: -5.5, p<0.0001), representing a 68% improvement.

DISCUSSION

While the use of SCS in patients with chronic LSS symptoms has shown encouraging results, a substantial proportion of patients may experience eventual lack of therapeutic efficacy. In contrast to open surgical decompression, IPD offers a minimally-invasive treatment option for this patient group that does not require anatomical disruption of ligamentous or osseous tissue.

Improvements in condition-specific clinical outcomes with IPD are similar to those realized after decompressive laminectomy. We noted a similar robust therapeutic response in the current case series, suggesting that IPD may provide a rescue intervention after SCS inefficacy that obviates the immediate requirement for surgical laminectomy. Our enthusiasm, of course, is tempered by the retrospective nature of this study and the short-term follow-up of patients. We encourage the continued observation of these cases, and support the use of IPD in subsequent patients undergoing a similar treatment course.

CONCLUSION

Short-term evidence suggests that IPD may provide a rescue treatment option when SCS no longer provides effective symptom amelioration in LSS. Opioid medications were less frequently used after IPD, and back and leg pain severity decreased, on average, by 69% and 68%, respectively.

The Science Behind Successful Outcomes

PAINWeek.

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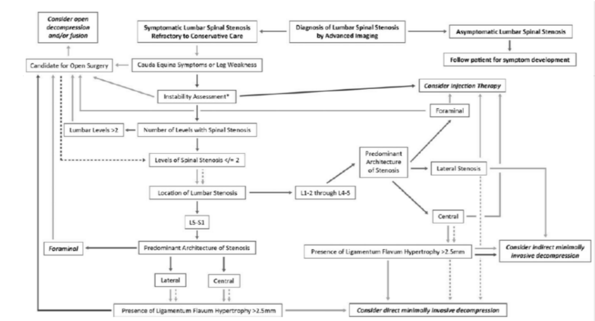

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[c]Deer TR, Grider JS, Pope JE, et al for the Lumbar Stenosis Consensus Group. The MIST guidelines: the Lumbar Spinal Stenosis Consensus Group guidelines for minimally invasive spine treatment. Pain Pract. 2019;19(3):250-274. doi: 10.1111/papr.12744.

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MIST: A Consensus-Driven Sequence of Treatment for LSS

Confirm LSS with NC

1. Physical examination
2. Advanced imaging

Assess Spinal Stability

- Use flexion/extension films to determine score

Evaluate Ligamentum Flavum (LF) Hypertrophy (> 2.5 mm)

- LF present
- Stability ≤ grade 2 spondylolisthesis

→ **PILD Direct Decompression**

- Non-LF multifactorial causes
- Stability = grade 1 spondylolisthesis

→ **ISS Indirect Decompression**

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Abbreviations: PILD, percutaneous image-guided lumbar decompression; ISS, interspinous spacers

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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®[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%; 7.5%; Procedure-related 14.2%; 15.9%		Intraoperative 9.9%; Postoperative 12.3%	23.3%; 18% early – 6% late
Device- and procedure-related serious AEs	**0%**	8.4%	9.5%		
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

PainWeek

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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

PainWeek

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Thank You!

PainWeek

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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)

PainWeek

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Questions

The presence of ligmentum 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)

PainWeek

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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 injectin 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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