

Non-CME Webinar Series
designed with the trainee in mind
first Tuesday of the month

ASRA PAIN MEDICINE
THE ASSOCIATION OF PAIN PROGRAM DIRECTORS

Lumbar Spinal Stenosis: Exam, Diagnosis, and Minimally Invasive Approaches (MILD, Vertiflex, and Endoscopic Decompressions)

Tuesday, May 2, 2023

7-8:30 pm ET

Introduction

- Lumbar spinal stenosis (LSS) is a commonly encountered condition
  - Prevalence of 47% in 60-69 y/o USA population in early 2000s[1]
  - >200,000 adults in USA are affected[6]
- LSS is the most common reason for spine surgery in >65 y/o population
- In 2007, Medicare paid >1.6 billon dollars for hospital costs of decompression or decompression + fusion surgeries in LSS treatment[2]
- Common referral indication to the Pain Clinic and Spine Center practices

Introduction

- As defined by the North American Spine Society[3]:
  - Degenerative LSS is “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.”
- To summarize…
  - LSS is an anatomic observation
  - Neurogenic intermittent claudication is the resultant clinic syndrome[4]

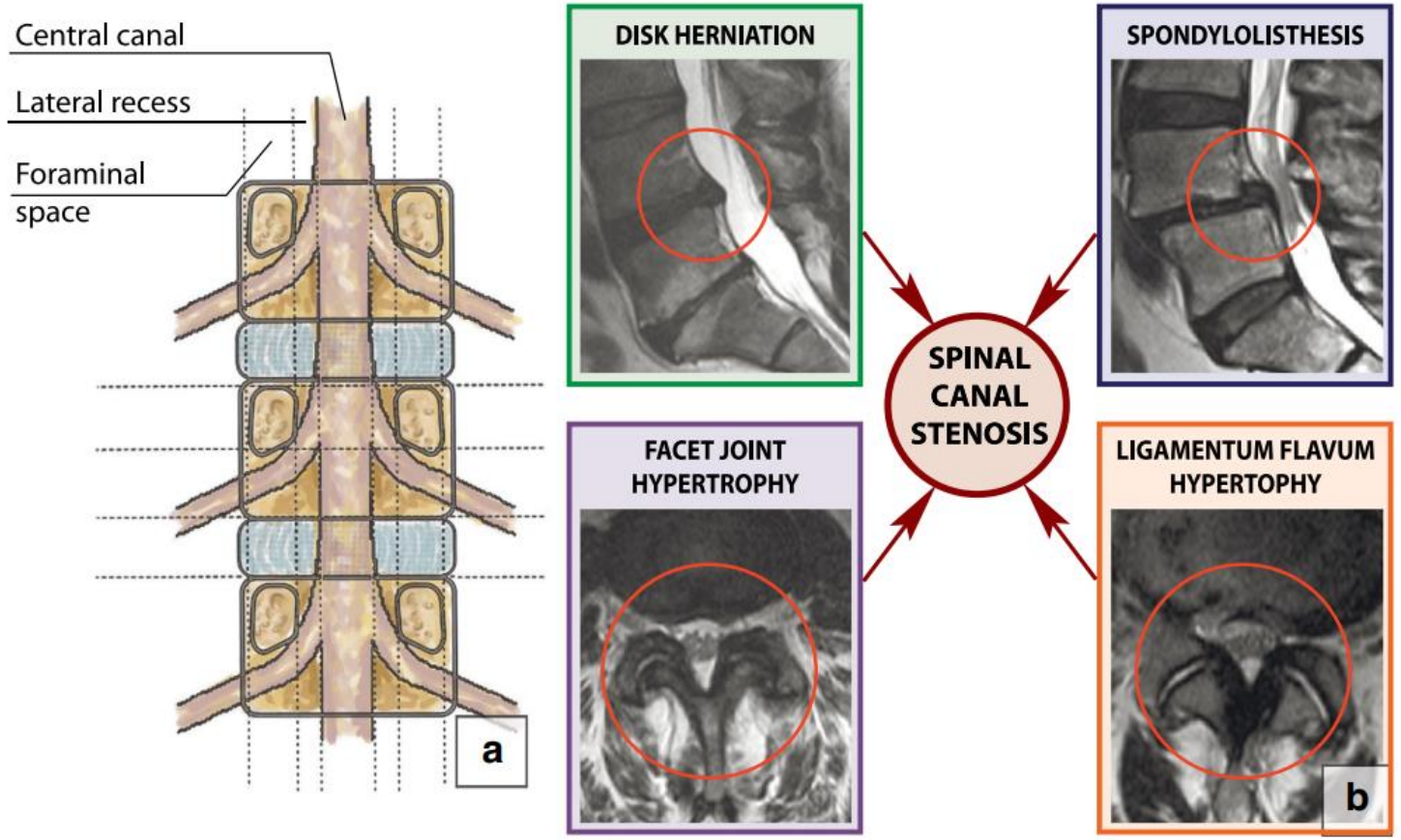
Classification

- Etiologic Classification
  - Congenital/Developmental
    - Accounts for 10-15% of patients presenting with NIC symptoms[4]
    - Generally secondary to short pedicles
    - Causes:
      - Idiopathic or unknown prenatal insult
      - Achondroplasia syndromes
  - Acquired
    - Degenerative/spondylotic changes (disc/ligament/facet/osteophytes/spondylolisthesis)
    - Post-traumatic
    - Iatrogenic (ex. adjacent segment disease after lumbar fusion)
    - Misc. (Paget's, space occupying lesions, etc.)

Classification

- Anatomic Classification
  1. Central canal
  2. Lateral (subarticular) recess[7]
     - Lateral border = pedicle
     - Dorsal border = SAP
     - Ventral border = vertebral body, disc
  3. Neural foramen

- LSS is most common at L4-5 followed by L3-4



Kushchayev SV, Glushko T, Jarraya M, et al. ABCs of the degenerative spine. *Insights Imaging*.):253-274. doi:10.1007/s13244-017-0584-2018;9(2z

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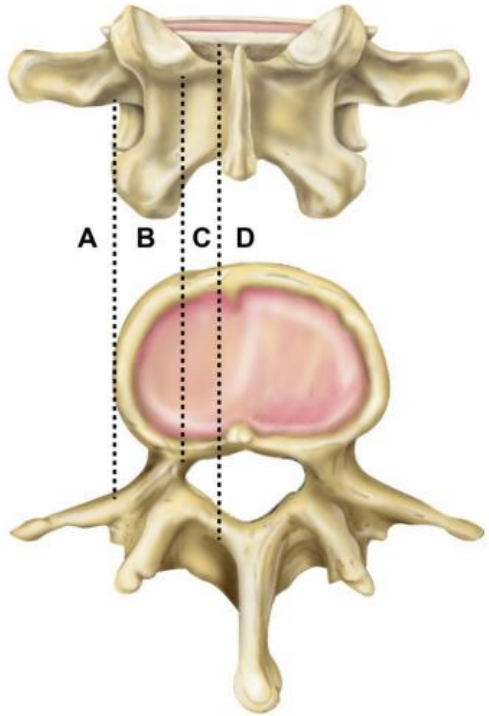
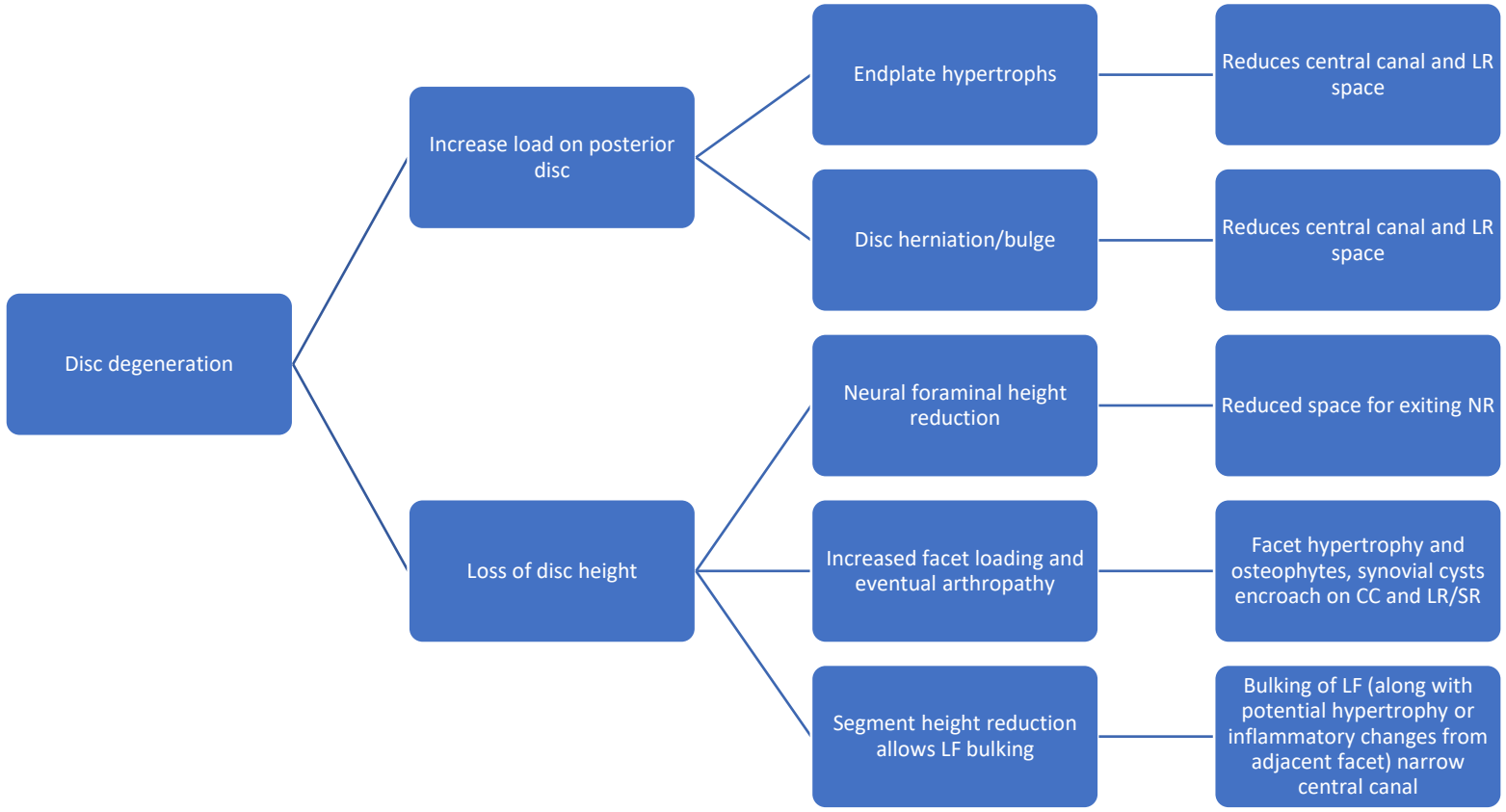


Figure 3. Lumbar vertebrae: illustration of anatomical spaces. A, The extraforaminal space is lateral to the neuroforamen. B, The foramen is created by the roof and floor of the adjacent pedicles. C, The lateral recess begins laterally at the pedicle and covers the area medially to the start of the central canal. D, The central canal encompasses the area between the lateral recess and is bound anteriorly by the vertebral body or disc and posteriorly by the vertebral arch. Courtesy of T. Dolan, Department of Academic Multimedia, University of Kentucky, Lexington, Kentucky, U.S.A.

Deer, et al. (2019), The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. Pain Pract, 19: 250-274.

Pathophysiology



All contribute to reduction in space for neurovascular elements

All 3 areas of potential stenosis (CC, SR/LR, NF) have reduced space during lumbar extension and when upright (axial loading).

Figure summarizes key points from: Maus TP. Imaging of spinal stenosis: neurogenic intermittent claudication and cervical spondylotic myelopathy. Radiol Clin North Am. 2012;50(4):651-679.

Presentation

- Neurogenic intermittent claudication
  - Variety of symptoms including pain or discomfort occurring in the buttocks , thigh or lower leg (+/- back).[3, 5]
    - Exacerbated by upright exercise or positions (lumbar extension)
    - Remitted by lumbar flexion (shopping cart sign), sitting, squatting or laying down
    - Often described as LE cramping, weakness, numbness, fatigue or imbalance
    - Typically, B/L symmetric symptoms
- More specific dermatomal pain/symptoms (potentially unilateral) in pre-dominant lateral recess or foraminal stenosis
- Vast majority of patients with LSS also report concomitant low back pain
  - Literature suggests the low back pain is not a direct result from the spinal stenosis, but more likely a sequalae of the lumbar spondylosis (i.e. facet arthropathy)

Presentation

- Be aware of common LSS mimickers:
  - MSK
    - SIJ pathology, bursitis (trochanteric, ischial), hip osteoarthritis, sacral insufficiency fracture
  - Neuro
    - Lumbosacral plexopathies, thoracic myelopathy, peripheral neuropathy (esp. combined with axial low back pain), mononeuropathies (ex. LFCN)
  - Vascular
    - Peripheral arterial disease

	Symptoms	
Activity	**PAD**	**LSS**
Cycling	Worse	No change
Walking uphill	Worse	Minimal (lumbar flexion)
Climbing stairs	Worse	Minimal (lumbar flexion)
Standing (after brief exertion)	Improve	No change (or worsen)

Physical Exam

- Majority of patients with LSS have a **normal** neuromuscular exam
- Roughly 10% of symptomatic LSS patients will have a +SLR
- Focus of the exam should be "ruling out" LSS/NIC mimickers
  - Evaluate for MSK disorders, vascular disease, neurologic deficits
  - SIJ or facet arthropathy contributing to the pain?
- If diagnosis unclear by standard history taking and exam findings…
  - Stoop test
    - Patient evokes NIC symptoms by walking (especially w/ exaggerated lumbar extension), then they are asked to either "stoop forward" while walking or sit down in a lumbar flexion position.[8]
  - Have the patient stand for a while
  - Walk them around the clinic until symptom onset

Imaging Overview

- NASS guidelines for imaging of patients suspected to have symptomatic LSS:[3]
  - **Lumbar spine MRI** is the recommended imaging modality.
  - CT myelography is preferred if MRI not available, contraindicated or inconclusive
  - CT only for those who have contraindications to MRI or CT myelography
- The correlation between radiographic and clinical severity of spinal stenosis is poor.[8]
- There are numerous radiologic criteria for lumbar spinal stenosis. **Interpretation of the MRI by the treating physician or surgeon is recommended**.[8]

LSS Imaging - Instability

- Evaluating for instability with lumbar spine radiographs with flexion and extension views is important
  - >3mm sagittal translation is a “direct sign” of degenerative instability in the setting of spondylolisthesis.[7]
  - Look for other “indirect signs” of instability

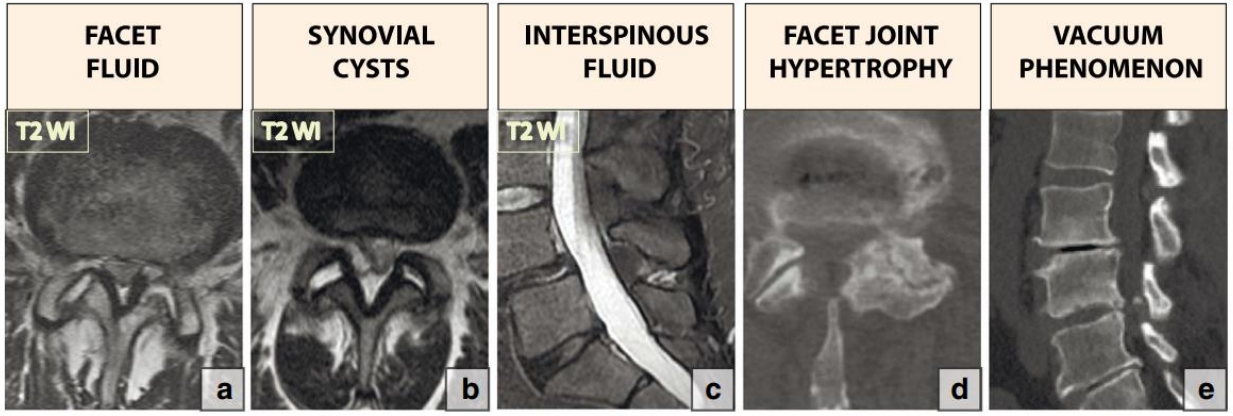
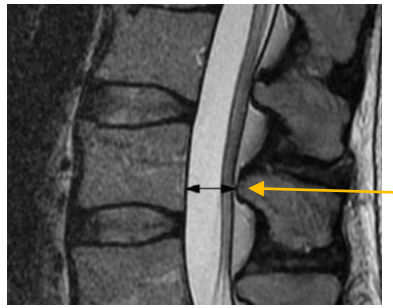


Fig. 20 Features that are suggestive of the presence of instability in spondylolisthesis: (**a**) facet fluid, (**b**) synovial cyst, (**c**) interspinous fluid, (**d**) facet joint hypertrophy and (**e**) the vacuum phenomenon

Kushchayev SV, Glushko T, Jarraya M, et al. ABCs of the degenerative spine. *Insights Imaging*.):253-274.

LSS Imaging - Severity

- The MIST Guidelines (The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment) published in *Pain Practice* recommends the following criteria:



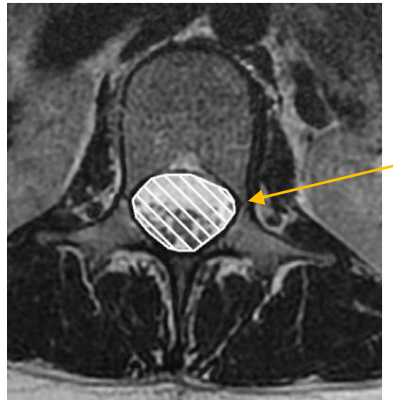


Table 4. Stenosis Classification Criteria: Compression Ratio in Relation to Normal Size[12]

	Central (Spinal Compression)	Lateral (Compression of Lateral Recess)
Mild	<1/3	<1/3
Moderate	1/3 to 2/3	1/3 to 2/3
Severe	>2/3	>2/3

Table 6. Quantitative Radiologic Criteria for Stenosis

Central Stenosis	Lateral Stenosis	Foraminal Stenosis
Anteroposterior diameter of dural/thecal sac (<10 mm)	Lateral recess height (<2 mm)	None found
Thecal sac area compression in % of normal midsagittal diameter	Lateral recess depth (<2 to 3 mm)	
Cross-sectional area of dural tube/sac*		

*The authors suggest that the cross-sectional area of the dural sac should be considered the most important parameter to document.

Table 5. Qualitative Radiologic Criteria for Stenosis

Central Stenosis	Lateral Stenosis	Foraminal Stenosis
Central zone compromise	Lateral recess nerve compression	Foraminal nerve root impingement*
Relationship between fluid around the cauda equina		Foraminal zone compromise

*As there are many descriptions of foraminal nerve root impingement, the grading system by Pfirrmann et al. was recommended.[22]

LSS Imaging - Severity

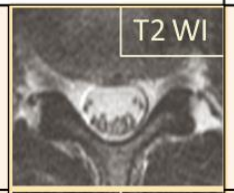
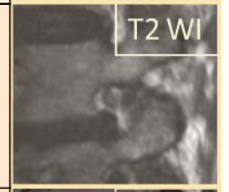
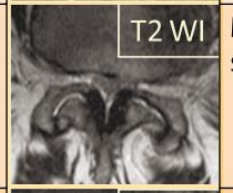
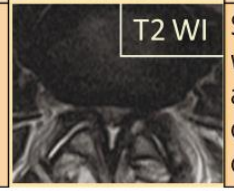
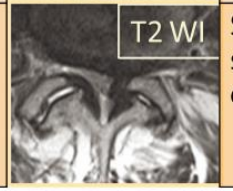
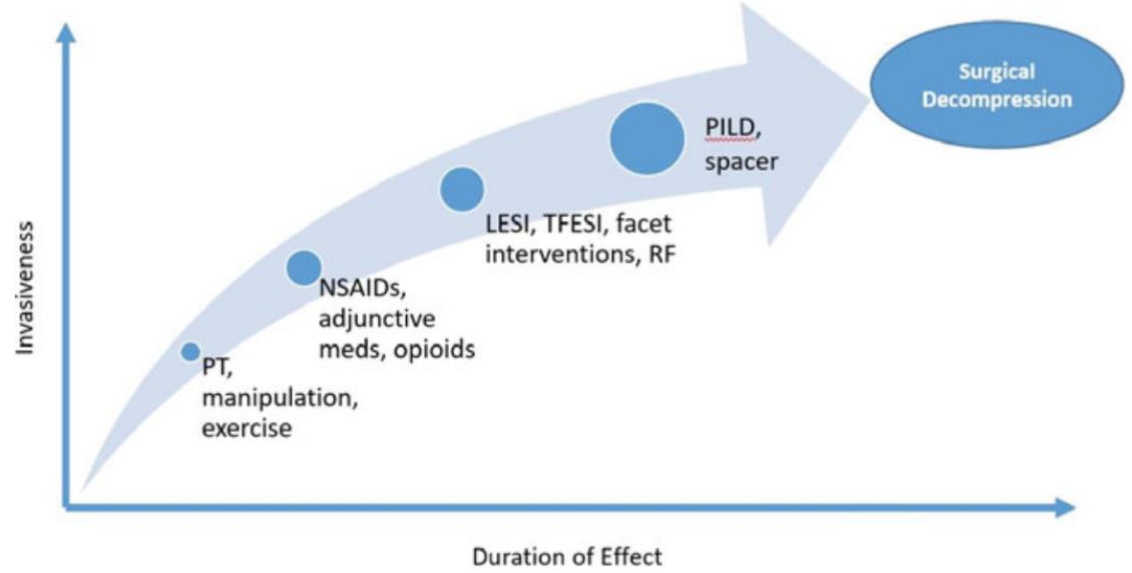
Grade	Central canal		Lateral recess		Foraminal	
Grade 0 Normal						
Grade 1 Mild	Anterior CSF space is mildly obliterated, nerves in cauda equina can be clearly separated from each other.		Narrowing of the lateral recess without root flattening or compression.		Mild foraminal stenosis (<50%).	
Grade 2 Moderate	Cauda equina aggregation.		Narrowing of the lateral recess with root flattening and some preservation of the space lateral to the root in the lateral recess.		Moderate foraminal stenosis (>50%).	
Grade 3 Severe	Entire cauda equina as a bundle.		Severe root compression with severe narrowing and complete obliteration of CSF space surrounding or lateral to the nerve root.		Severe foraminal stenosis (nerve root collapse).	

Fig. 29 A grading of severity of central, lateral and foraminal stenosis on the lumbar spine

Kushchayev SV, Glushko T, Jarraya M, et al. ABCs of the degenerative spine. *Insights Imaging*.):253-274.

Overview of LSS Management

- Conservative care
  - Bracing
  - PT
  - Exercise
  - Gait aids
- Medications
- Epidural steroid injections
- Minimally invasive lumbar decompression
- Interspinous spacers
- Neuromodulation
- Surgical decompression



Deer, T.R., et al. The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. Pain Pract, 19: 250-274.

(Superion™ Indirect Decompression System)

Vertiflex

- One of multiple interspinous spacers devices on the market
  - Targeting 1-2 adjacent levels from **L1-5** (not feasible at L5-S1)
- Provide mechanical block to lumbar extension at the targeted level while ”indirectly” decompressing neurovascular structures
- Interspinous spaces entered US market in 2005
- ISS have been shown to have reduced complication rate compared to decompressive laminectomy, although a higher rate of re-operation.[10]

https://www.bostonscientific.com/en-US/products/indirect-decompression-system/superion-indirect-decompression-system/instructions-for-use.html

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Vertiflex

- Indications
  - Leg/buttock/groin +/- LB symptoms w/ relief in flexion position (despite 6 mo CMM)
  - **Moderate** Degenerative Lumbar Spinal Stenosis
    - 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
      - Evidence of thecal sac and/or cauda equina compression
      - Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements
      - Evidence of hypertrophic facets with canal encroachment
  - **AND** associated with the following clinical signs:
    - Presents with moderately impaired Physical Function (PF) defined as a score of ≥ 2.0 of the Zurich Claudication Questionnaire (ZCQ)
    - Ability to sit for 50 minutes without pain and to walk 50 feet or more.

https://www.bostonscientific.com/en-US/products/indirect-decompression-system/superion-indirect-decompression-system/instructions-for-use.html

(Superion™ Indirect Decompression System)

Vertiflex

- Contraindications
  - An allergy to titanium or titanium alloy
  - Lumbar **spondylolisthesis** greater than Grade 1
  - Ankylosis
  - Fracture of posterior elements
  - **Scoliosis** (Cobb angle >10 degrees)
  - 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)

https://www.bostonscientific.com/en-US/products/indirect-decompression-system/superion-indirect-decompression-system/instructions-for-use.html

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- Notable warnings and anatomic considerations
  - Risk of spinous process fracture
    - 12.1% of patients in one trial.[14]
    - Reduced fracture risk w/ :
      - Device placement at spinolaminar junction
      - Correct device sizing (i.e. don't oversize!)
    - Increased fracture risk w/:
      - More dorsal/shallow placement
      - "Kissing" spinous processes
      - Thin/gracile spinous processes (<20 mm tall)
      - Osteoporosis

https://www.bostonscientific.com/en-US/products/indirect-decompression-system/superion-indirect-decompression-system/instructions-for-use.html

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Medical Devices: Evidence and Research — Dovepress

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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Kevin D Cairns[3]
Louis J Raso[4]
Christopher Kim[5]
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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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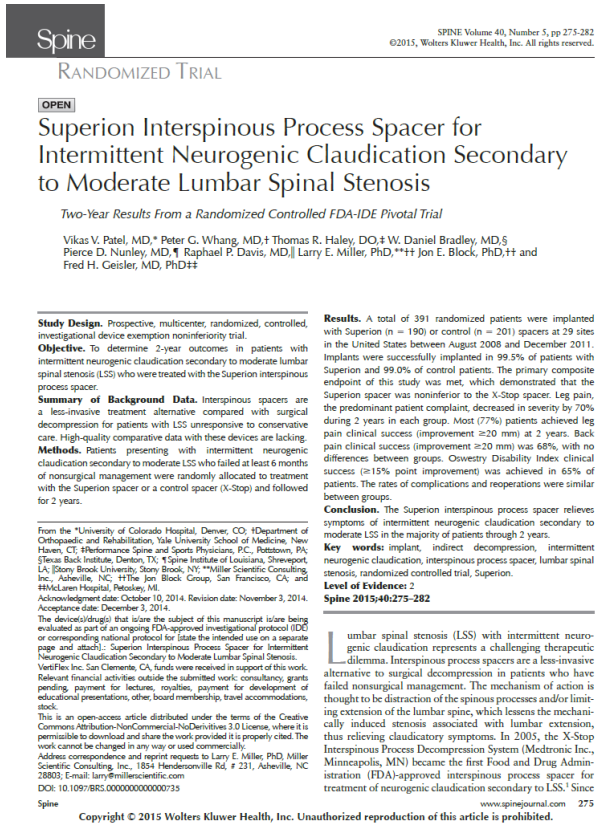
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- N = 316, at 12 months
- Leg pain = 60% improvement
- Back pain = 50% improvement
- 75% leg responder rate and 67% back responder rate
- 80% satisfied, 75% would undergo again

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.

(Superion™ Indirect Decompression System)

Vertiflex



Spine

SPINE Volume 40, Number 5, pp 275-282
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RANDOMIZED TRIAL

OPEN

Superion Interspinous Process Spacer for Intermittent Neurogenic Claudication Secondary to Moderate Lumbar Spinal Stenosis

Two-Year Results From a Randomized Controlled FDA-IDE Pivotal Trial

Vikas V. Patel, MD,* Peter G. Whang, MD,† Thomas R. Haley, DO,‡ W. Daniel Bradley, MD,§ Pierce D. Nunley, MD,¶ Raphael P. Davis, MD,‖ Larry E. Miller, PhD,**†† Jon E. Block, PhD,†† and Fred H. Geisler, MD, PhD‡‡

Study Design. Prospective, multicenter, randomized, controlled, investigational device exemption noninferiority trial.

Objective. To determine 2-year outcomes in patients with intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis (LSS) who were treated with the Superion interspinous process spacer.

Summary of Background Data. Interspinous spacers are a less-invasive treatment alternative compared with surgical decompression for patients with LSS unresponsive to conservative care. High-quality comparative data with these devices are lacking.

Methods. Patients presenting with intermittent neurogenic claudication secondary to moderate LSS who failed at least 6 months of nonsurgical management were randomly allocated to treatment with the Superion spacer or a control spacer (X-Stop) and followed for 2 years.

Results. A total of 391 randomized patients were implanted with Superion (n = 190) or control (n = 201) spacers at 29 sites in the United States between August 2008 and December 2011. Implants were successfully implanted in 99.5% of patients with Superion and 99.0% of control patients. The primary composite endpoint of this study was met, which demonstrated that the Superion spacer was noninferior to the X-Stop spacer. Leg pain, the predominant patient complaint, decreased in severity by 70% during 2 years in each group. Most (77%) patients achieved leg pain clinical success (improvement ≥20 mm) at 2 years. Back pain clinical success (improvement ≥20 mm) was 68%, with no differences between groups. Oswestry Disability Index clinical success (≥15% point improvement) was achieved in 65% of patients. The rates of complications and reoperations were similar between groups.

Conclusion. The Superion interspinous process spacer relieves symptoms of intermittent neurogenic claudication secondary to moderate LSS in the majority of patients through 2 years.

Key words: implant, indirect decompression, intermittent neurogenic claudication, interspinous process spacer, lumbar spinal stenosis, randomized controlled trial, Superion.

Level of Evidence: 2

Spine 2015;40:275-282

From the *University of Colorado Hospital, Denver, CO; †Department of Orthopaedic and Rehabilitation, Yale University School of Medicine, New Haven, CT; ‡Performance Spine and Sports Physicians, P.C., Pottstown, PA; §Texas Back Institute, Denton, TX; ¶Spine Institute of Louisiana, Shreveport, LA; ‖Stony Brook University, Stony Brook, NY; **Miller Scientific Consulting, Inc., Asheville, NC; ††The Jon Block Group, San Francisco, CA; and ‡‡McLaren Hospital, Petoskey, MI.

Acknowledgment date: October 10, 2014. Revision date: November 3, 2014. Acceptance date: December 3, 2014.

The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol for [state the intended use on a separate page and attach].: Superion Interspinous Process Spacer for Intermittent Neurogenic Claudication Secondary to Moderate Lumbar Spinal Stenosis.

VertiFlex Inc. San Clemente, CA, funds were received in support of this work. Relevant financial activities outside the submitted work: consultancy, grants pending, payment for lectures, royalties, payment for development of educational presentations, other, board membership, travel accommodations, stock.

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DOI: 10.1097/BRS.0000000000000735

Lumbar spinal stenosis (LSS) with intermittent neurogenic claudication represents a challenging therapeutic dilemma. Interspinous process spacers are a less-invasive alternative to surgical decompression in patients who have failed nonsurgical management. The mechanism of action is thought to be distraction of the spinous processes and/or limiting extension of the lumbar spine, which lessens the mechanically induced stenosis associated with lumbar extension, thus relieving claudicatory symptoms. In 2005, the X-Stop Interspinous Process Decompression System (Medtronic Inc., Minneapolis, MN) became the first Food and Drug Administration (FDA)-approved interspinous process spacer for treatment of neurogenic claudication secondary to LSS.[1] Since

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- Non-inferiority trial, X-stop vs Superion (Vertiflex)
- Total N = 391
  - Superion = 190
  - Control (X-stop) = 201
- Patient outcomes similar b/w the two devices
- Superion group (24 months):
  - Leg pain = 70% improvement
  - Back pain = 65% improvement
  - % of pts who met clinical success criteria
    - Leg pain - 76%
    - Back pain - 67%
    - ODI - 63%

Patel VV, Whang PG, Haley TR, et al. Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. Spine (Phila Pa 1976). 2015;40(5):275-282

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Clinical Interventions in Aging
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ORIGINAL RESEARCH

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

This article was published in the following Dove Press journal:
Clinical Interventions in Aging
6 September 2017
Number of times this article has been viewed

Pierce D Nunley[1]
Vikas V Patel[2]
Douglas G Orndorff[3]
William F Lavelle[4]
Jon E Block[5]
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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 stand-alone 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 randomized controlled US Food and Drug Administration (FDA) noninferiority trial. Outcomes included Zurich Claudication Questionnaire (ZCQ) symptom severity (ss), 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 ZCQss, 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 ZCQss, 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.[4,5]

Neurogenic claudication is the cardinal clinical feature of lumbar spinal stenosis, as it limits patients' walking ability and causes a major impact on their quality of life.[6] Intermittent neurogenic claudication is defined as unilateral or bilateral radicular pain

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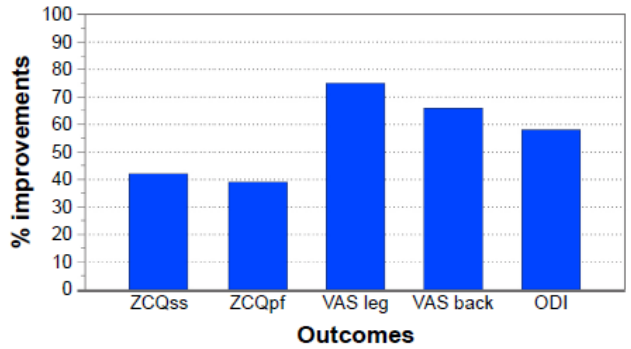


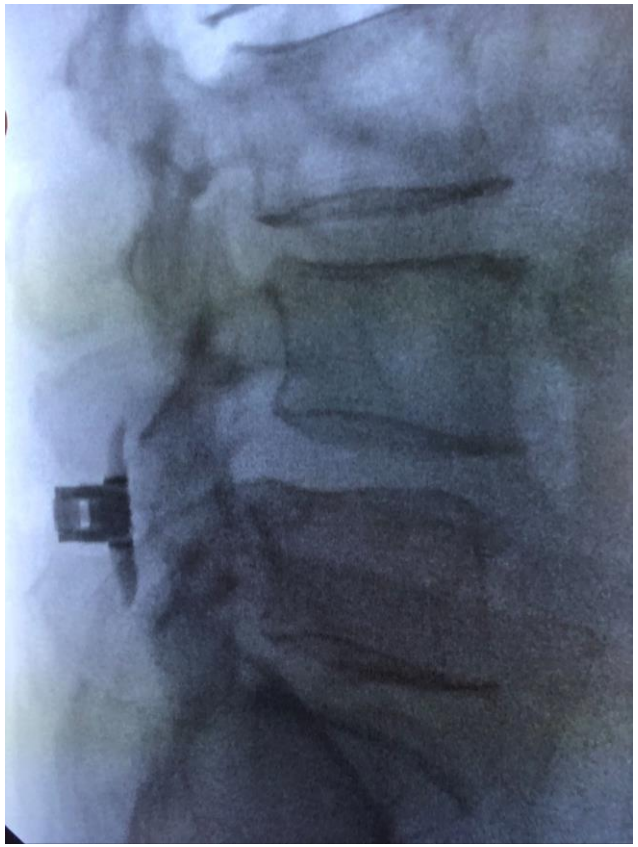
Figure 4 Percentage improvement for each outcome at 5 years compared to preoperative levels.
Note: All changes were statistically significant ($P<0.001$).
Abbreviations: ODI, Oswestry Disability Index; pf, physical function; ss, symptom severity; VAS, visual analog scale; ZCQ, Zurich Claudication Questionnaire.

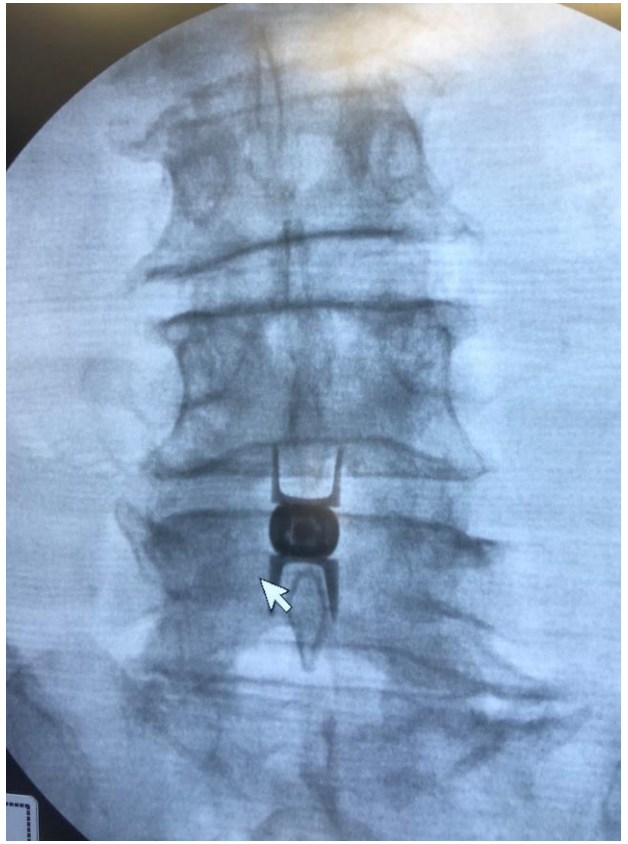
- Same cohort (N=190) of patients in the Patel et al non-inferiority trial
- N = 88 who completed 5y outcome assessment
  - % of pts who met clinical success criteria:
    - Back pain – 65%
    - Leg pain – 80%
    - ZCQss – 75%
    - ZCQpf – 81%
    - ZCQps – 90%
- 142/190 (75%) did not undergo additional surgery at treated level

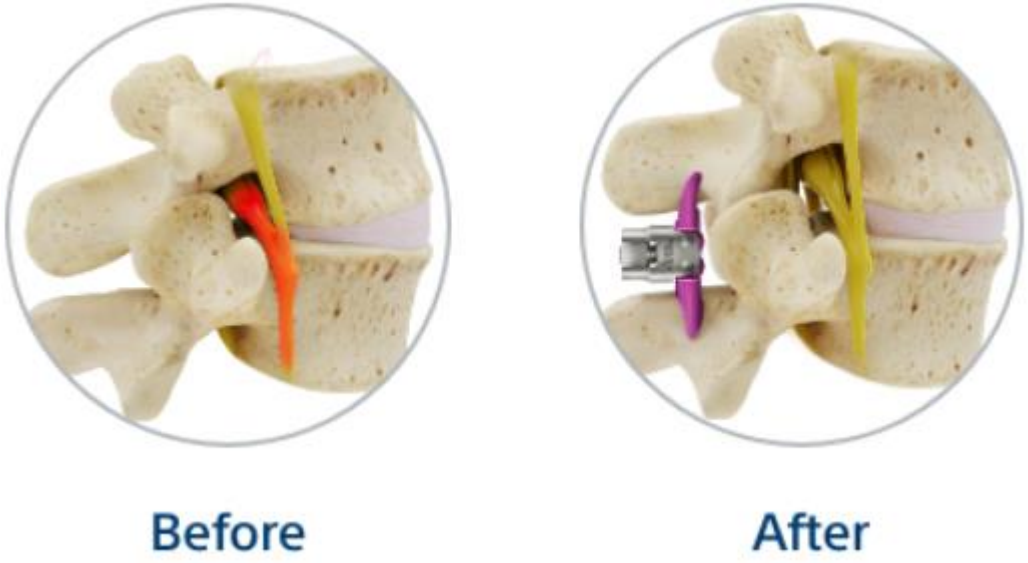
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