Minimally Invasive Treatment of Lumbar Spinal Stenosis

APRIL 27TH, 2019

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OOA ANNUAL CONVENTION

Learning Objectives

Define lumbar spinal stenosis

Define neurogenic claudication

Identify the prevalence of LSS

Implement basic treatment of LSS

Make appropriate referrals to specialists

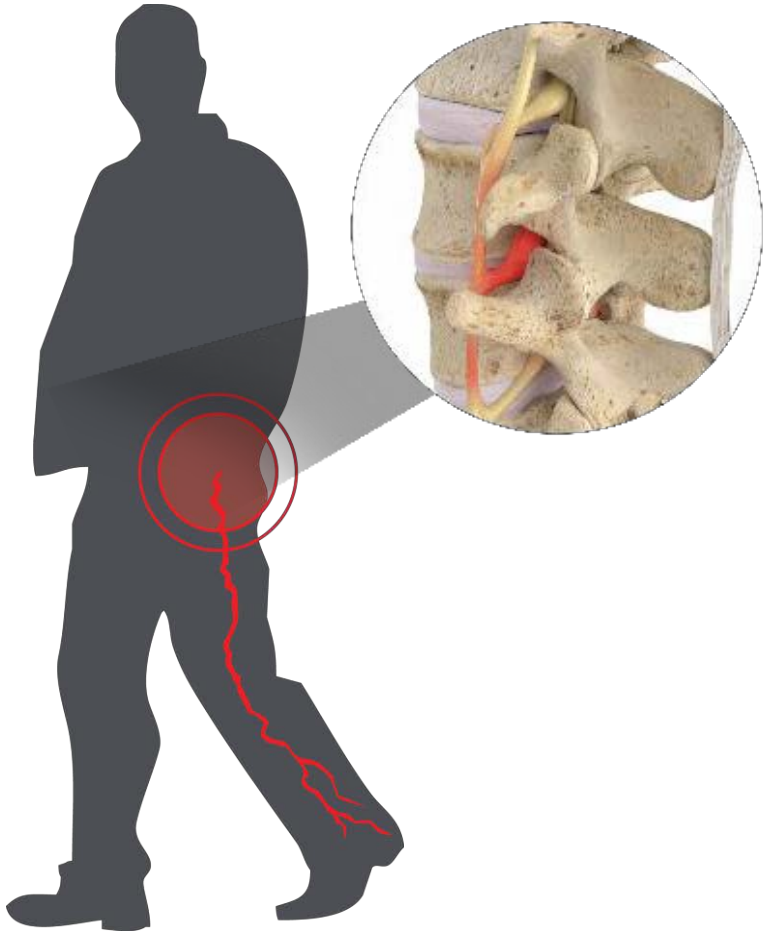
Gain familiarity with advanced treatments

The Problem

Lumbar spinal stenosis patients are suffering…

Narrowing of spinal canal causes pain, weakness, immobility, reduces quality of life

- 1.4M annual US diagnoses[1]
- 1.5M ESIs provide only temporary relief[2]
- >175K decompression surgeries[2]
- #1 reason for spine surgery in elderly[3]
- Fastest growing type of lumbar surgery in US[4]



[1] Qessential Medical Market Research 2015.
[2] American Medical Association's RBRVS Data Manager Program 2013.
[3] Deyo et al. 2010.
[4] Weinstein et al. 2008.

Lumbar Spinal Stenosis

"condition and symptom constellations that arise from decreased canal space with the lumbar spinal column" – North American Spine Society

Canal diameter <10-12mm on MRI/CT

Very common in older patients

Greater than 50% prevalence in patients greater than 60 years old

More common with higher BMI

No difference between males and females

Majority are asymptomatic

Neurogenic claudication

Burning, aching leg pain

Heaviness in back and/or lower extremities

Relieved by sitting, relieved by flexion

Worse with walking

“Shopping cart sign”

Normal reflexes, sensation, motor sitting or lying

Diagnosis is more history than physical exam dependent

Clinical Presentation of Symptoms

When a patient walks, they extend their spine which can induce and exacerbate stenosis related symptoms

- ✓ Standing/walking provokes symptoms
- ✓ Pain/weakness in legs

- ✓ Patient leans forward while walking to move around more comfortably: "Shopping Cart Scenario"

- ✓ Sitting (flexion) relieves symptoms

Radiology

LSS not limited to the spinal canal

Can be foraminal or lateral recess stenosis

No clear criteria

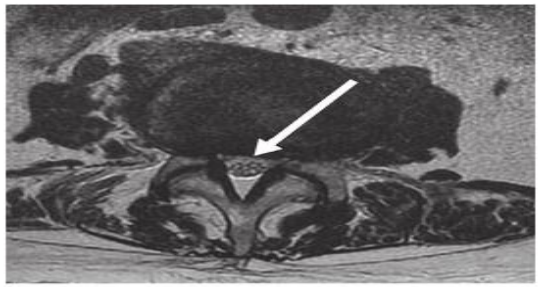
Combination of ligamentum flavum hypertrophy, facetogenic hypertrophy, disc disease

MRI best study

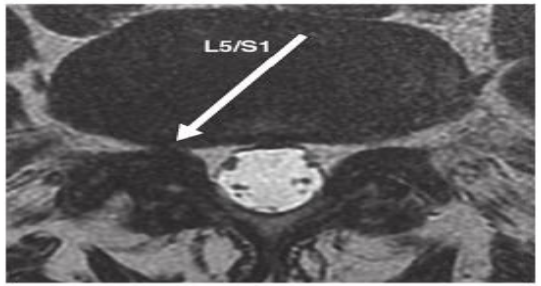
CT Myelogram good alternative

Plain films – not helpful for characterizing the spinal canal but helpful for identifying degenerative spondylisthesis which may be causing LSS

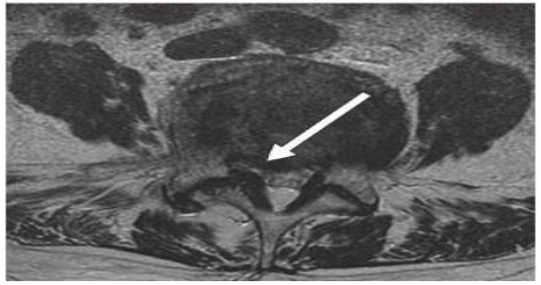
Canal stenosis

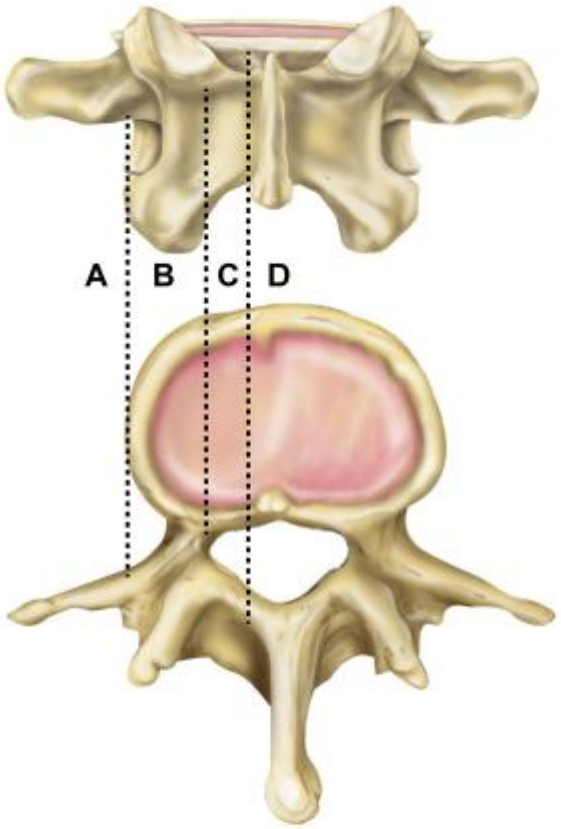


Neuroforaminal stenosis



Lateral recess stenosis

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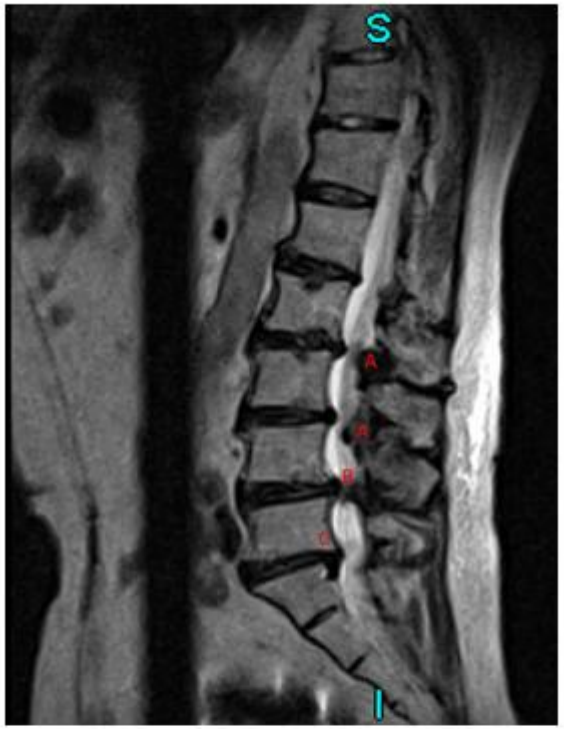
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Proper diagnosis

Severity of stenosis on imaging frequently does not correlate with severity of symptoms

Assess other confounders – facetogenic/SI joints/myofascial

History is key

Physical exam observation focused

Rule out vascular causes

Spondylisthesis

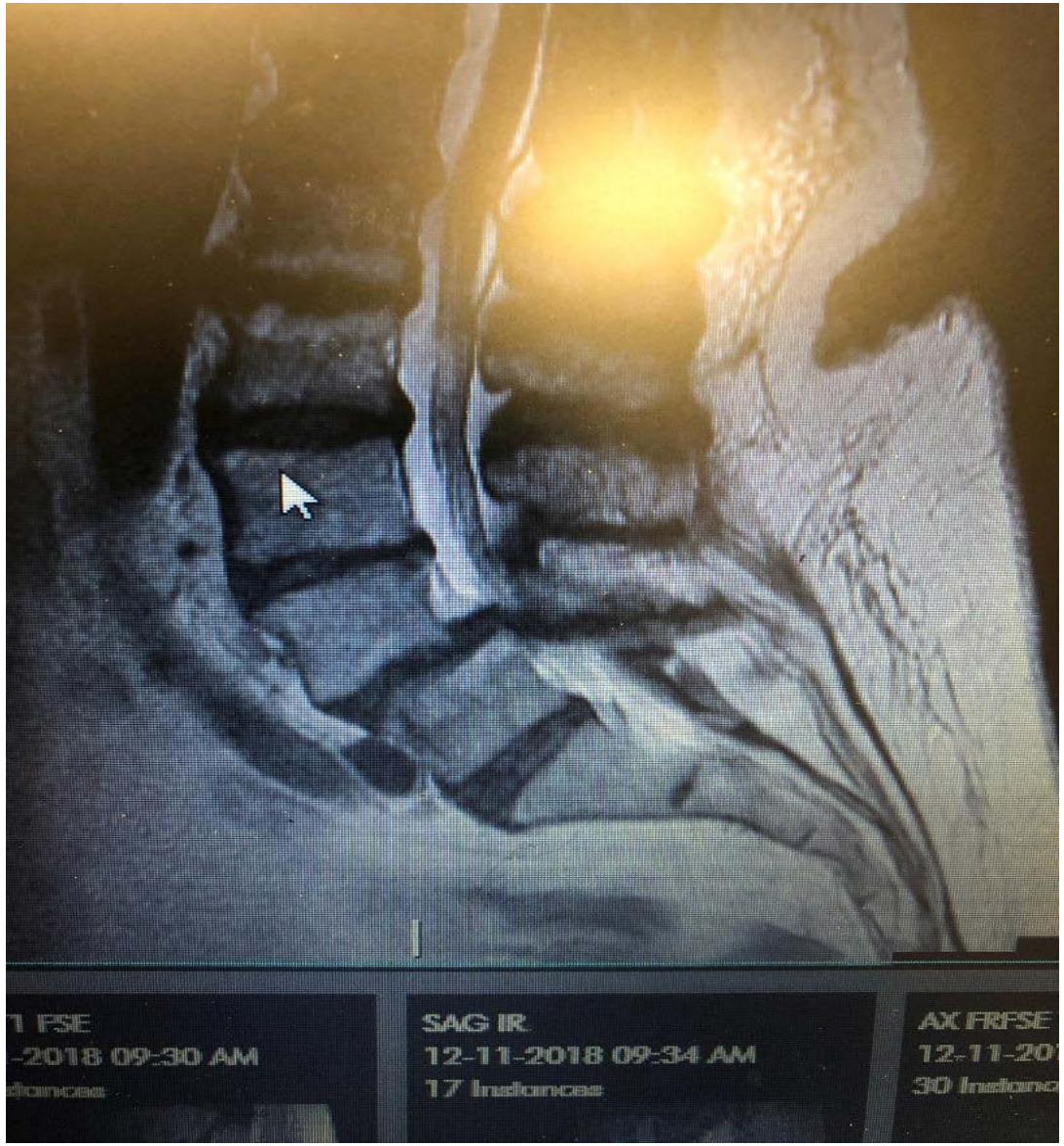
Very frequently a cause of LSS

May need surgical correction

Flexion/extension films: check for instability

Grade 1 frequently stable, Grade 2 surgical indication, may beautofused if old and stable

Fluid in facet joints marker of instability on MRI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17 Instances

Medications

NSAIDs – limited efficacy, cardiac, renal, GI risk

Gabapentin, pregabalin – limited efficacy, neurocognitive side-effects

Traditional opioids – same as placebo in studies, anecdotal evidence more favorable

TCAs/SNRIs – limited efficacy

Tramadol, levorphanol, tapentadol, methadone

Non pharmacologic conservative treatments

Bracing (LSO) provides support and modest pain relief

Helps with completion of PT

Improved walking distance and pain score with LSO

Flexion based PT helpful for some

Injections

Caudal injections helpful

Allows more anterior spread of injectate vs traditional approaches

Steroid may not be necessary

Interlaminar vs bilateral TFESI

Facet procedures

Racz Lysis of Adhesions

Series of injections not indicated

Anticoagulants/antiplatelets

Never hold for facet procedures

Hold for interlaminar injections

Expert opinion is changing for TFESI and caudal injections

Remember these are elective procedures, communicate with PCP/cardiology

Percutaneous Image-Guided Lumbar Decompression (PILD)

Vertos mild only product available

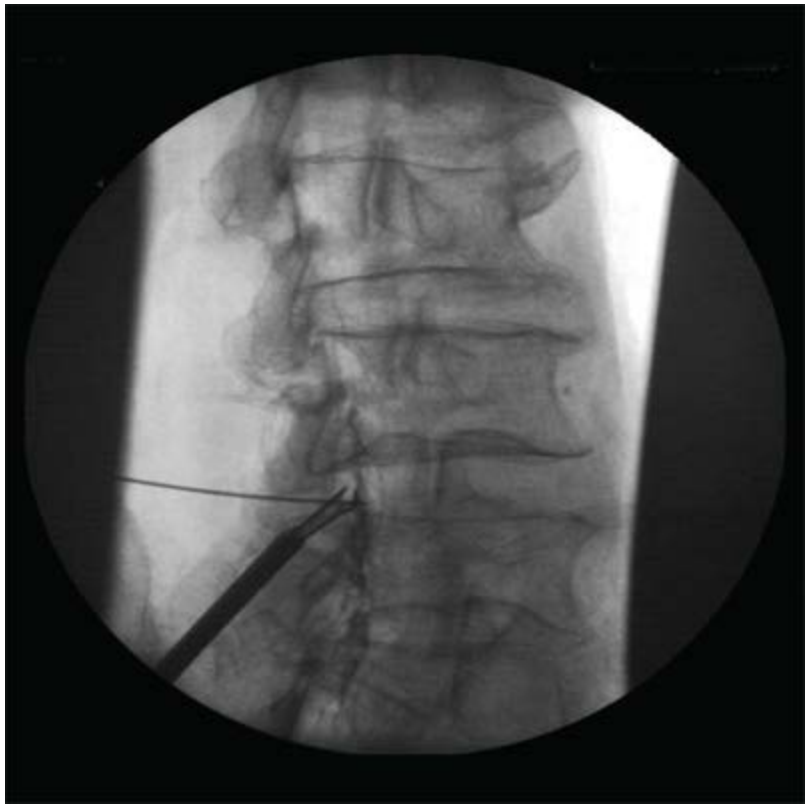
Epidurogram then use stabilizer and lateral /contralateral fluoroscopy to remove bits of lamina and ligamentum flavum

No defined end point

Is covered by Medicare but as part of a study

Risk of dural tear

Minimal to no current availability



Vertiflex Superion

Interspinous spacer

Some similarities to Medtronic X Stop (not available)

Not a fusion product (Aurora ZIP, PainTeq Axle), no bone graft

Intended to use induced flexion to create an indirect compression

Minimally invasive

Being used by multiple physicians in Oklahoma

Wide use in Europe before US commercialization

Titanium (MRI compatible)

Moderate stenosis, not greater than 2 adjacent segments (L1-L5)

Superion US IDE Clinical Trial

Largest & Most Extensive Stenosis Device IDE Trial

Randomized, Prospective, Controlled, Multi-center

Moderate Lumbar Stenosis

29 US Sites

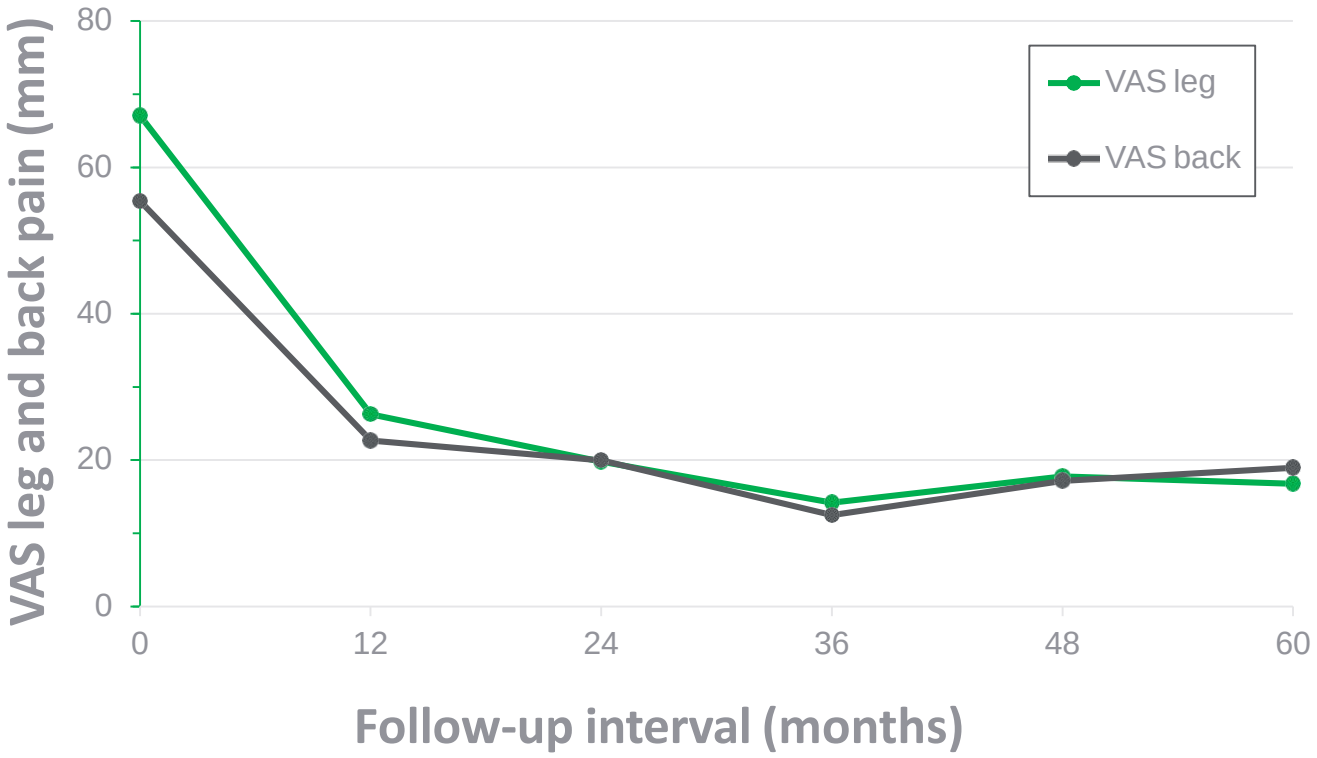
470 Subjects

24 Month Follow-Up through 60 months

>94% Retention

PMA APPROVED

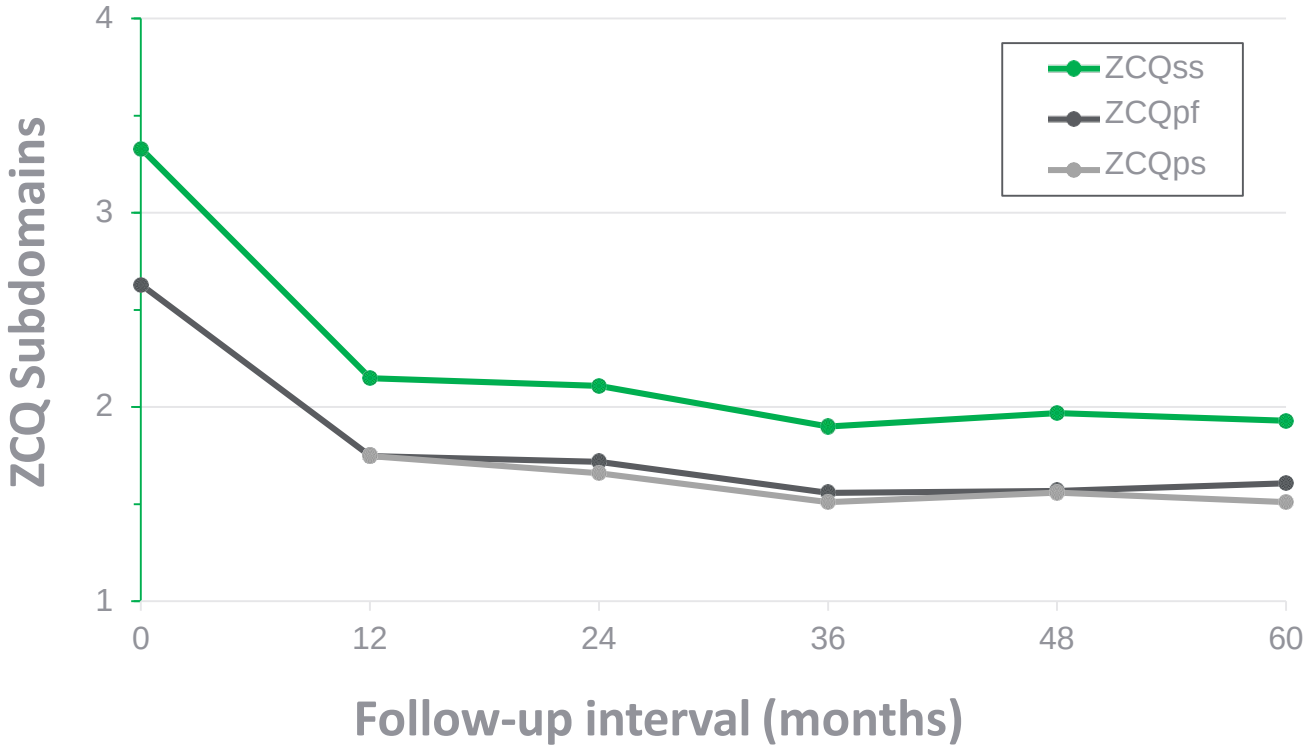
VAS Leg & Back Pain



75%
improvement in leg pain scores from baseline at 5 years

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

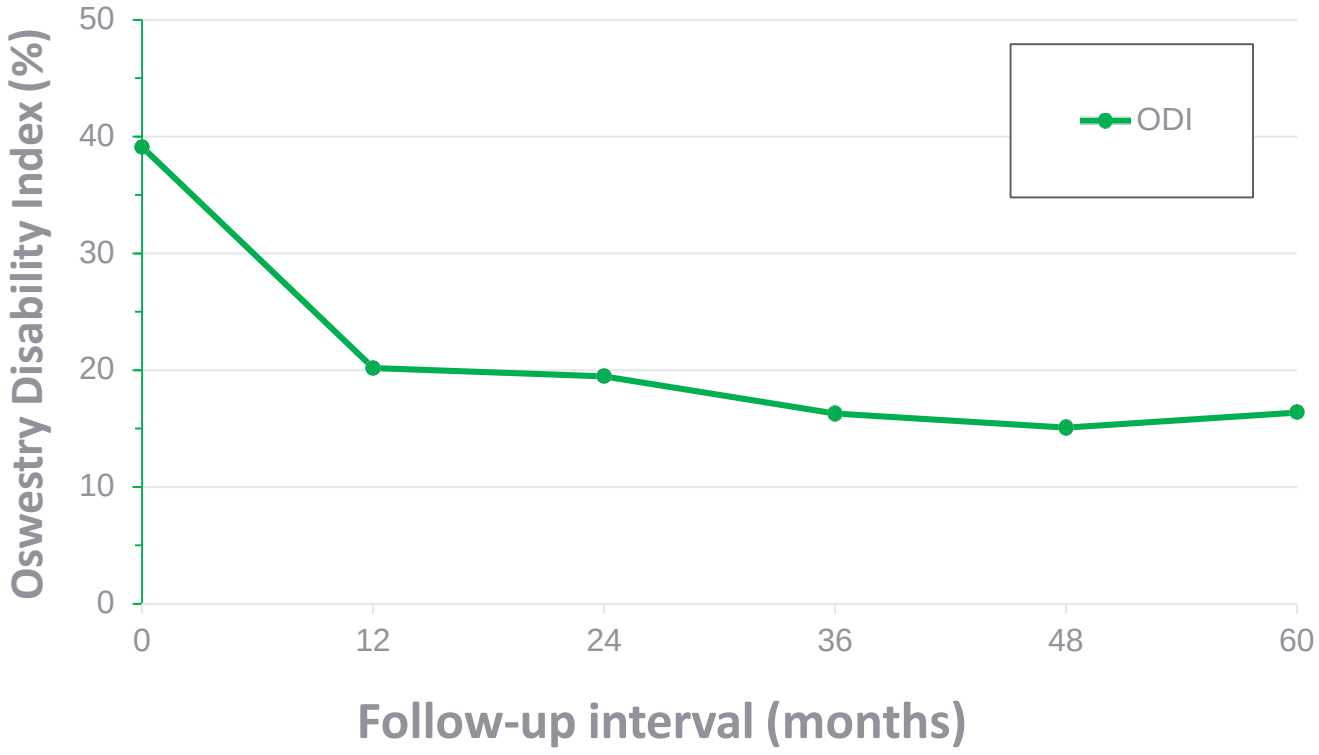
ZCQ Subdomains



90%
Patient Satisfaction at 5 years

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

Oswestry Disability Index



>50%
improvement
in scores
from baseline
at 5 years


Clinical Interventions in Aging

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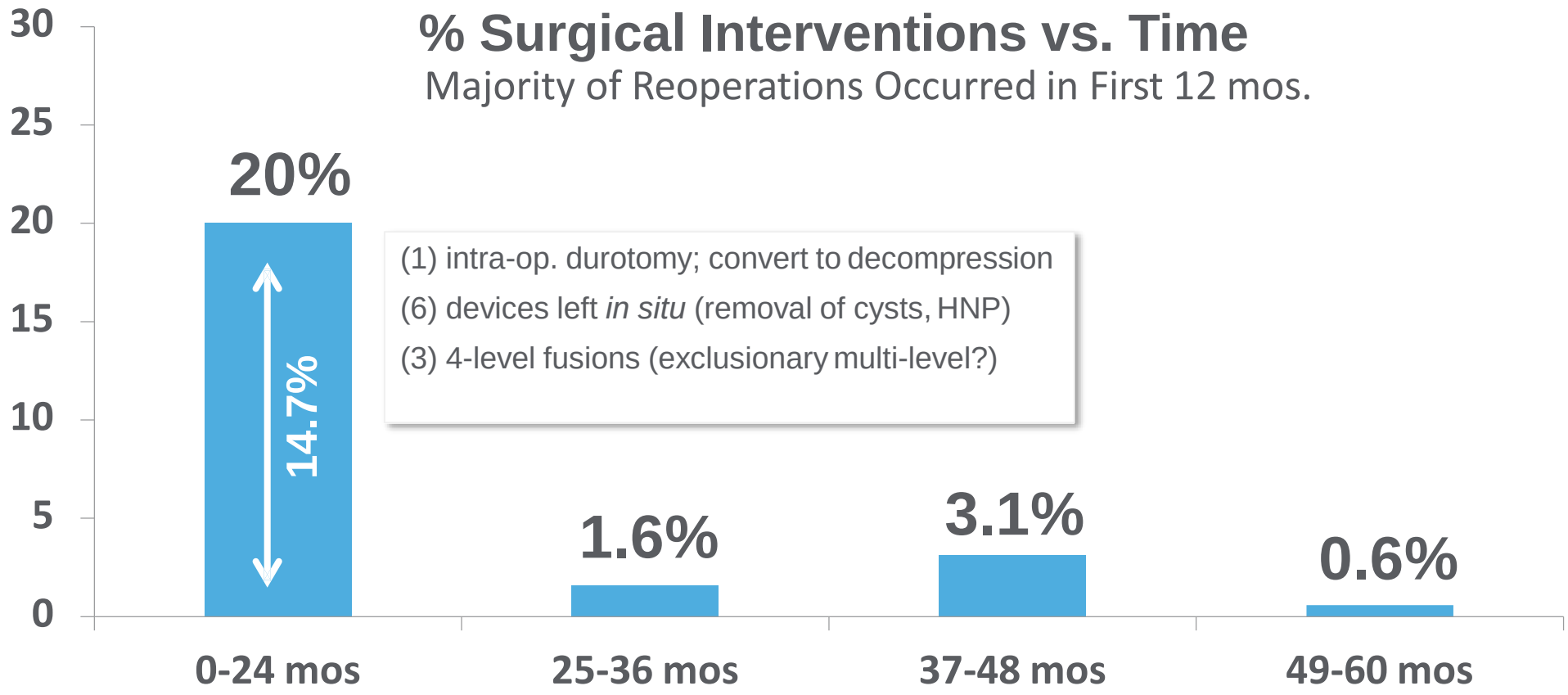
ORIGINAL RESEARCH

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

Time course of results for the Oswestry Disability Index.
Note: Results reported as mean (95% CI).

Safety: Incidence of Reoperations Post-Op



- 14.7% “adjusted” reoperation rate 0-24 mos.; 16.3% at 36 mos., 19.4% @ 48 mos., 20% @ 60 mos.
- Additional interventions associated with *exclusionary* conditions, e.g., unstable spondylolisthesis, spondy >grade 1

Safety: Failures and Mitigations

	Risk	Mitigations
	FAILURE OCCURRENCE	**CONTROLLING RISK FACTORS**
Spinous Process Fracture	• 16% at any time • 8% unhealed • 2% (n=4) required intervention • 0% migration/dislodgement • Majority asymptomatic, and did not affect efficacy outcomes	• **Technique Risk Factor:** 60% of fractures correlated with shallow/dorsal implant placement • **Patient Selection Risk Factors:** Morbid obesity Kissing spine Fragile/thin spinous process Low bone density, steroid therapy
	FAILURE OCCURRENCE	**CONTROLLING PATIENT SELECTION**
Surgical Reintervention	• 20% at ≤ 24 months, all causes • 14.7% “adjusted” for exclusions, non-stenosis-related, multi-level disease	• **Patient Selection Risk Factors:** Exclusionary conditions (e.g., unstable/ hypermobile spondy, spondy >grade 1, non-stenosis comorbidities)

Mitigations effective: Rate of fracture in commercial use <1%

Complications

Safety established by low rate of significant complications

Complication	Rate of Occurrence
Reoperation rate @ ≤2 years	14.7%[1]
All cause early rehospitalization	0%
Early cardiopulmonary / stroke	0%
Early wound complications	0%
Neural injury	0%
Bleeding requiring transfusion	0%
Infections	0%
Dural tear	0.5%

[1]Excludes pts. revised due to unrelated pathologies (e.g., cyst removal, HNP), unrelated surgeries, and those deemed retrospectively to have been ineligible for enrollment due to, e.g., significant instability, spondy >grade 1. Unadjusted reoperation/revision rate 20% at 2 years.

Clinical Summary

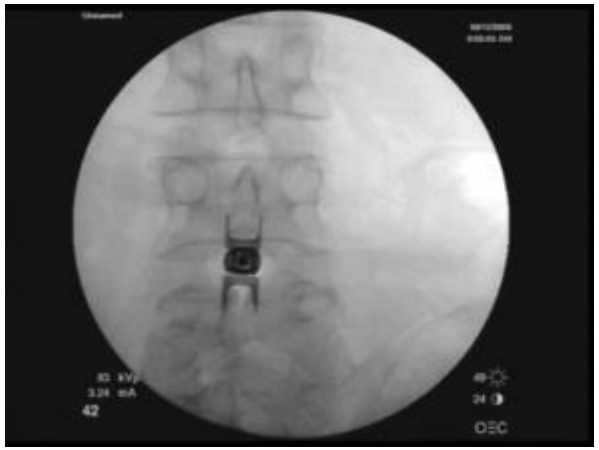
- **BENEFITS OF SUPERION**
  - Less invasive/traumatic approach; no anatomical “burned bridges” which may compromise future surgical treatment options
  - Fewer/lesser post-operative complications
  - Treats central, lateral recess, *and* foraminal stenosis
  - Durable clinical benefit through 24, 36, 48, and 60 months
- **RISKS**
  - Reoperation rate (>75% of patients did not require a re-operation)
  - Spinous process facture (majority asymptomatic; 32% healing rate at 24 months, 55% at 60 months; no impact upon outcomes)
- **RISK MITIGATION**
  - Labeling disclosures identify and mitigate risks
  - Physician training to optimize patient selection and technique

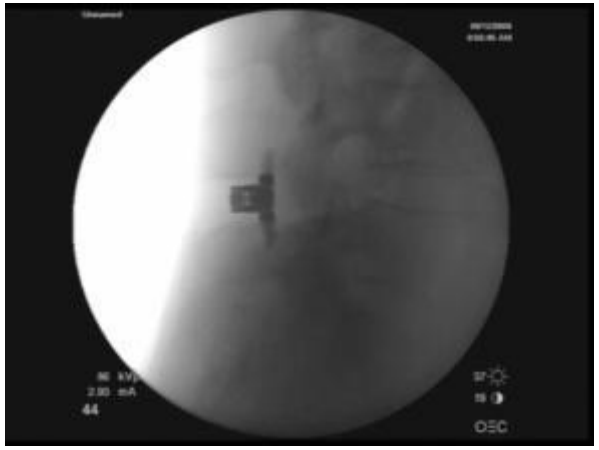
Small percutaneous 12-15mm skin incision

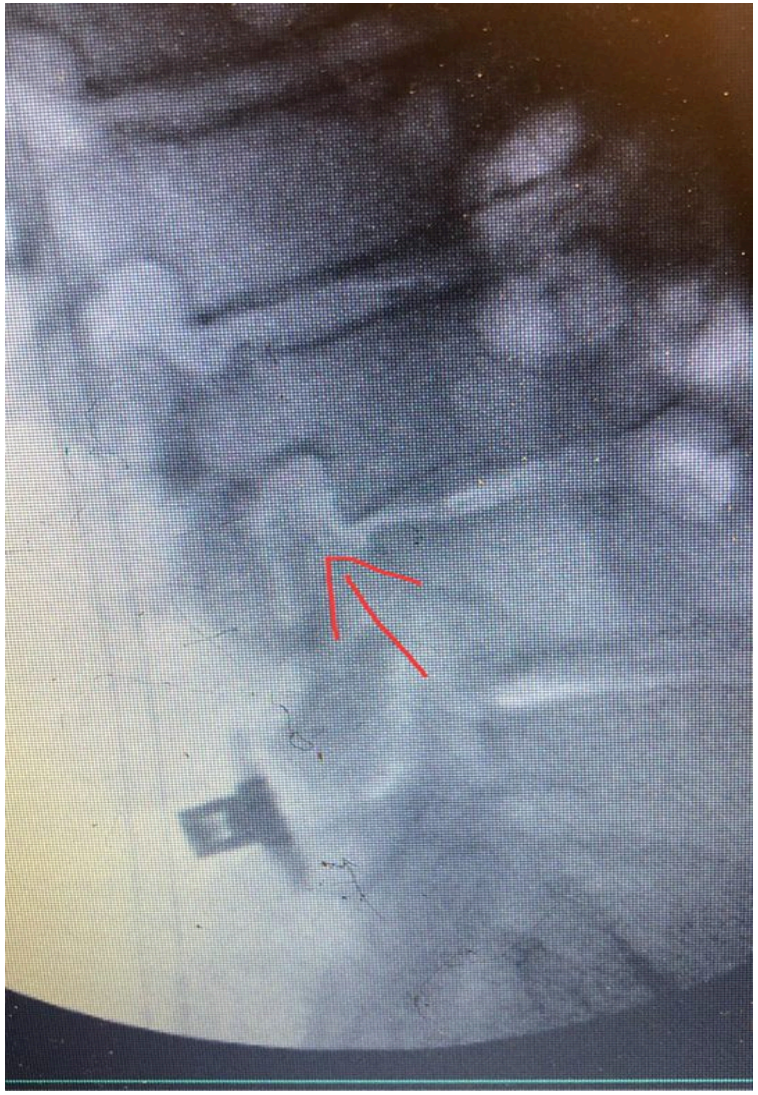
Preserves the anatomical structures Minimal operative time

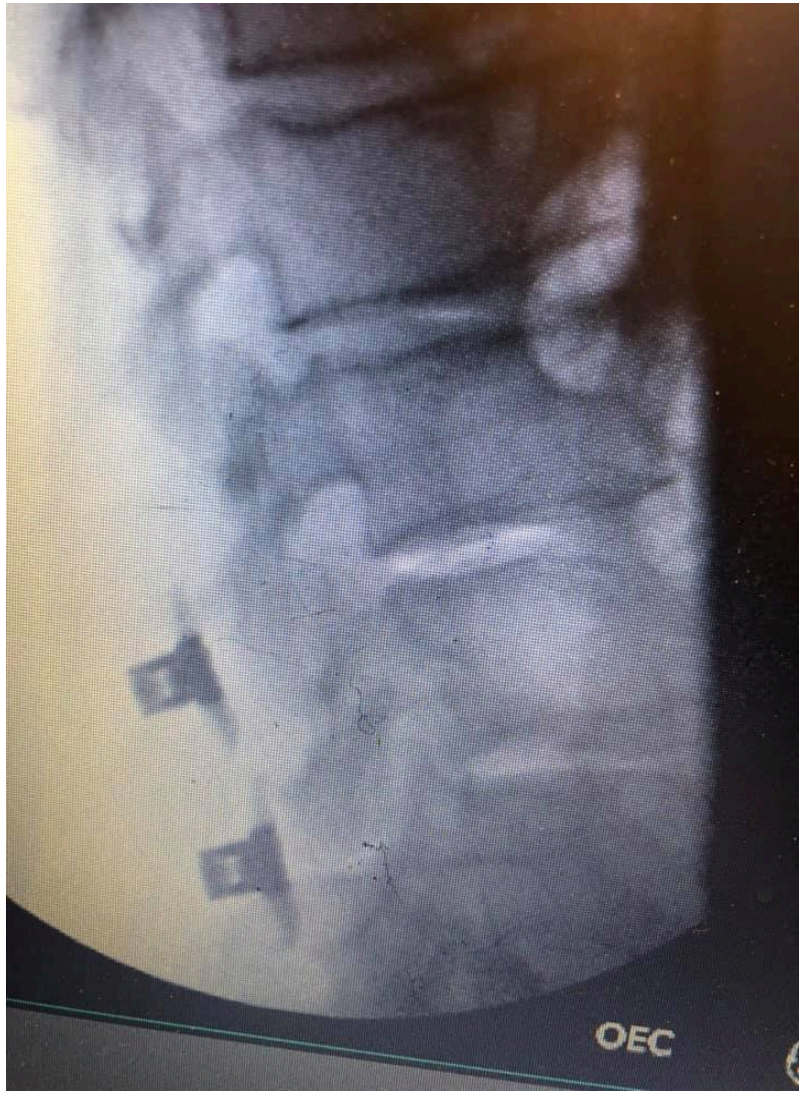
Reversible procedure

Local w/conscious sedation option





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Questions?