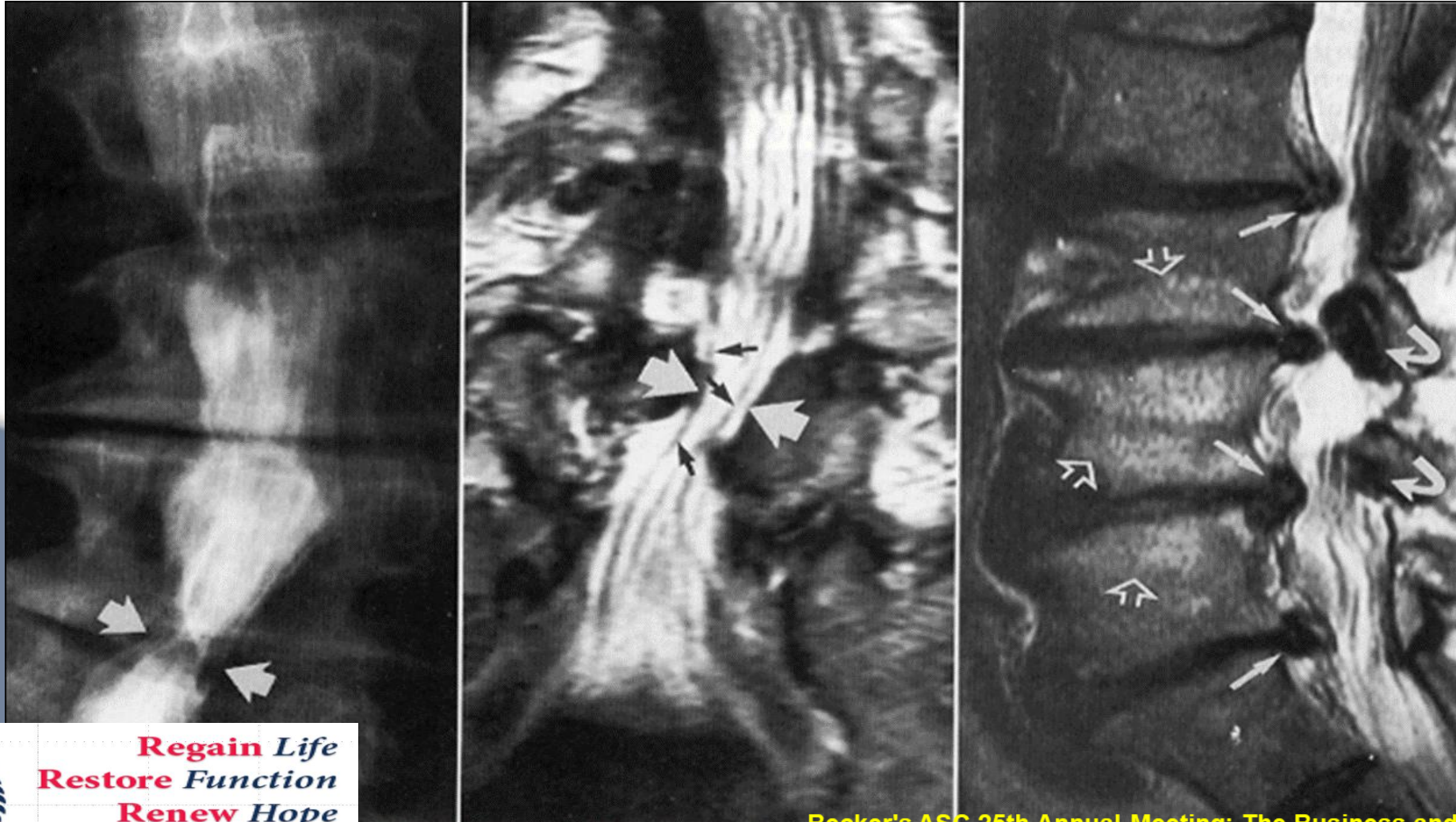


SUPERION: a novel treatment for LSS

Vincent Galan, MD, MBA



VINCENT GALAN, MD, MBA

Founder & CEO of Pain Care

President, Georgia Society of Interventional Pain Physicians (GSIPP)

Diplomate American Board of Anesthesia Subspecialty Certification in Pain Management (DABAPM)

Diplomate American Academy of Pain Medicine (DAAPM)

Diplomate American Board of Interventional Pain Physicians (DABIPP).

Diplomate American Society of Addiction Medicine (DASAM).

- **Consulting & Research Grants:**

MEDTRONIC

NEVRO

NEUROS

SUPERION Learning Objectives

1) LSS

- 1) Prevalence
- 2) Incidence
- 3) Classification
- 4) Pathophysiology

2) What is SUPERION?

3) How does it compares regarding:

- 1) Vs Decompressive Laminectomy
- 2) Complications
- 3) Healthcare utilization

4) SUPERION 5-yr Follow Up

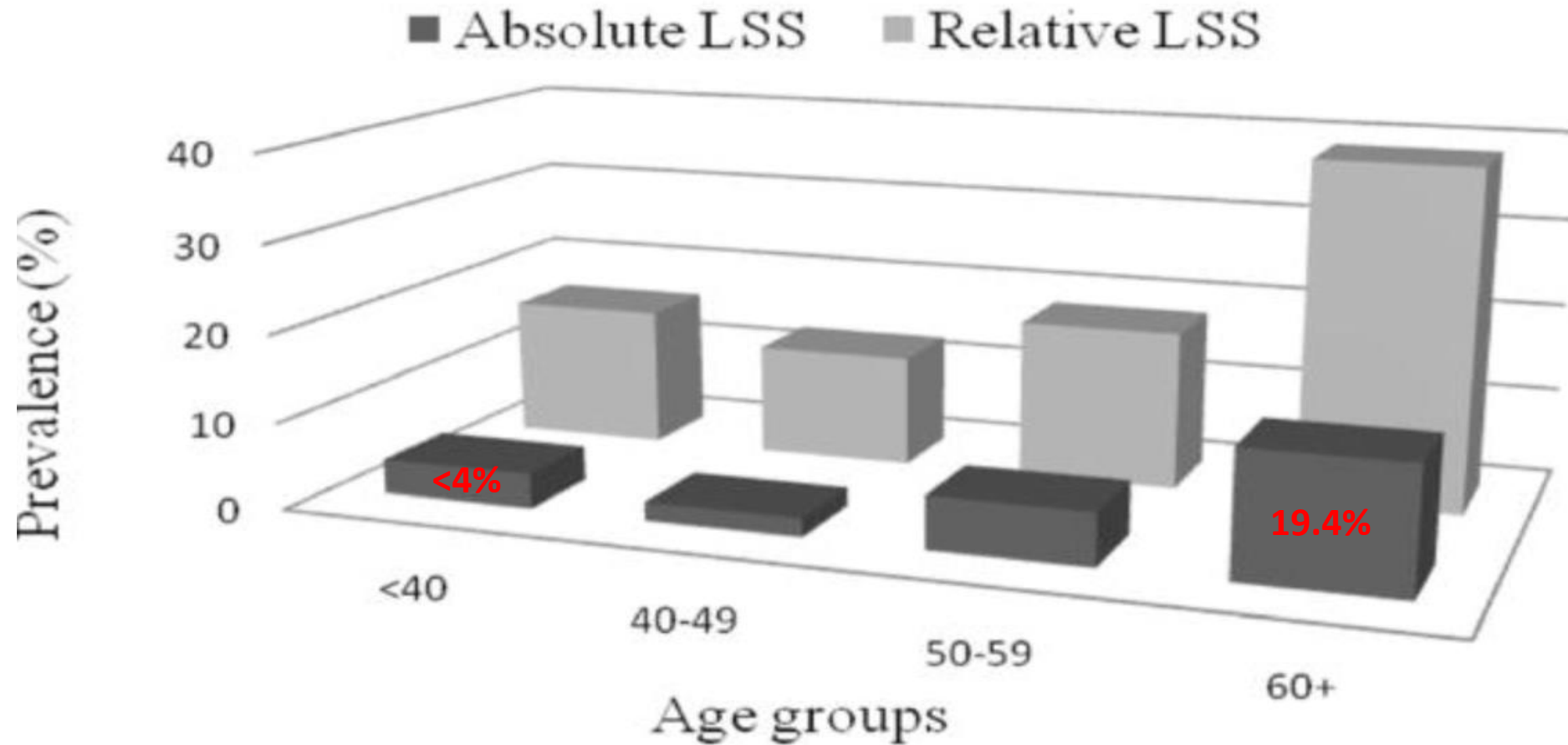
5) MILD vs SUPERION

- 1) When
- 2) Where

Lumbar Spinal Stenosis

- First clinical description of LSS attributed to Verbiest in 1954
- Most frequent indication for lumbar surgery > 65 years population
- Men = Women
- Increases with age
 - annual incidence of LSS is 5 per 100,000 people
 - Asymptomatic > 30 % over 65 yo
 - Absolute LSS is < 10 mm mid-sagittal diameter
- Major cause of pain and disability in the elderly
 - 40% refractory to conservative care w/in 10 years of diagnosis
 - Accounts for +/- 30% ESI done in US
- Clinical manifestation – neurogenic claudication

LSS Prevalence

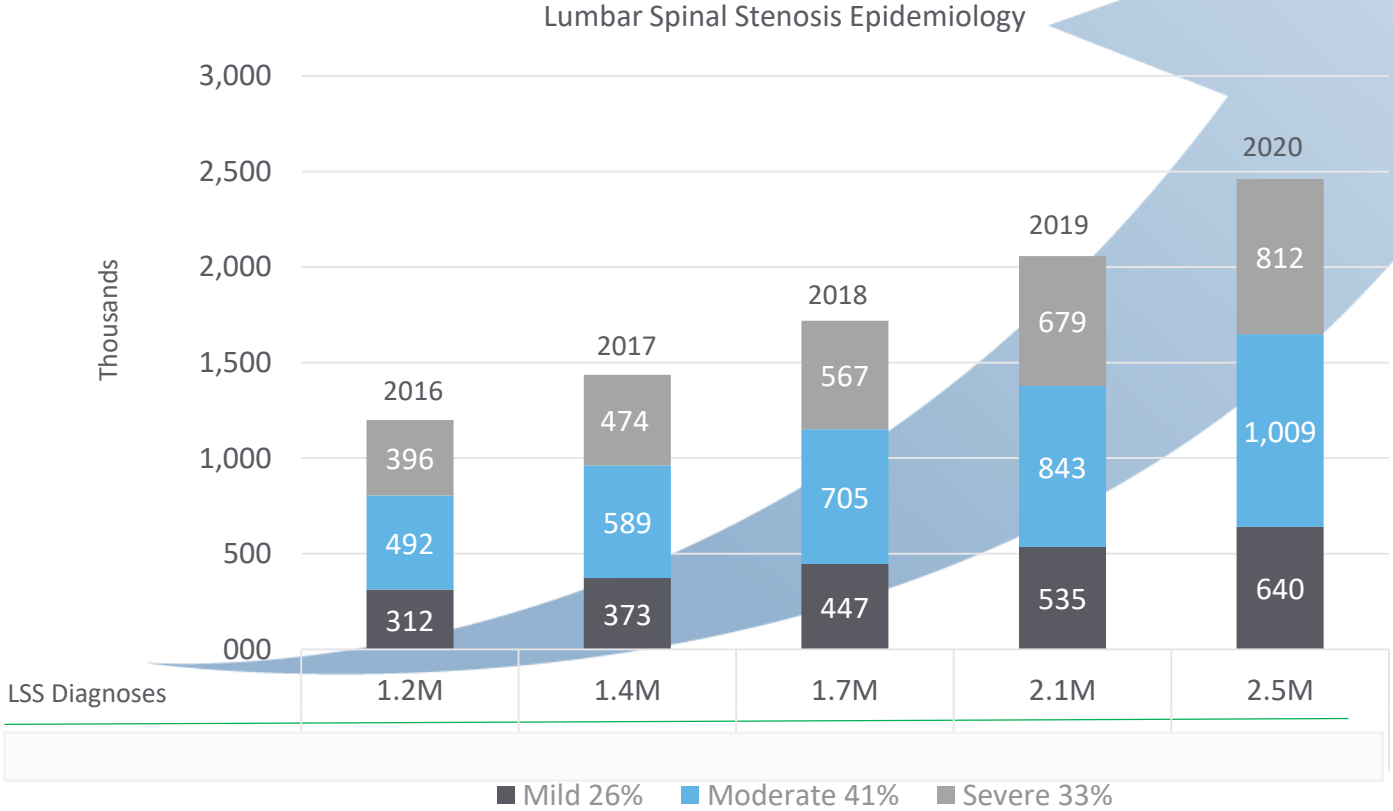


Spinal stenosis prevalence and association with symptoms: The Framingham Study. Leonid Kalichman, Robert Cole, David H. Kim, Ling Li, Pradeep Suri, Ali Guermazi, David J. Hunter. Spine J. 2009 Jul; 9(7): 545-550.

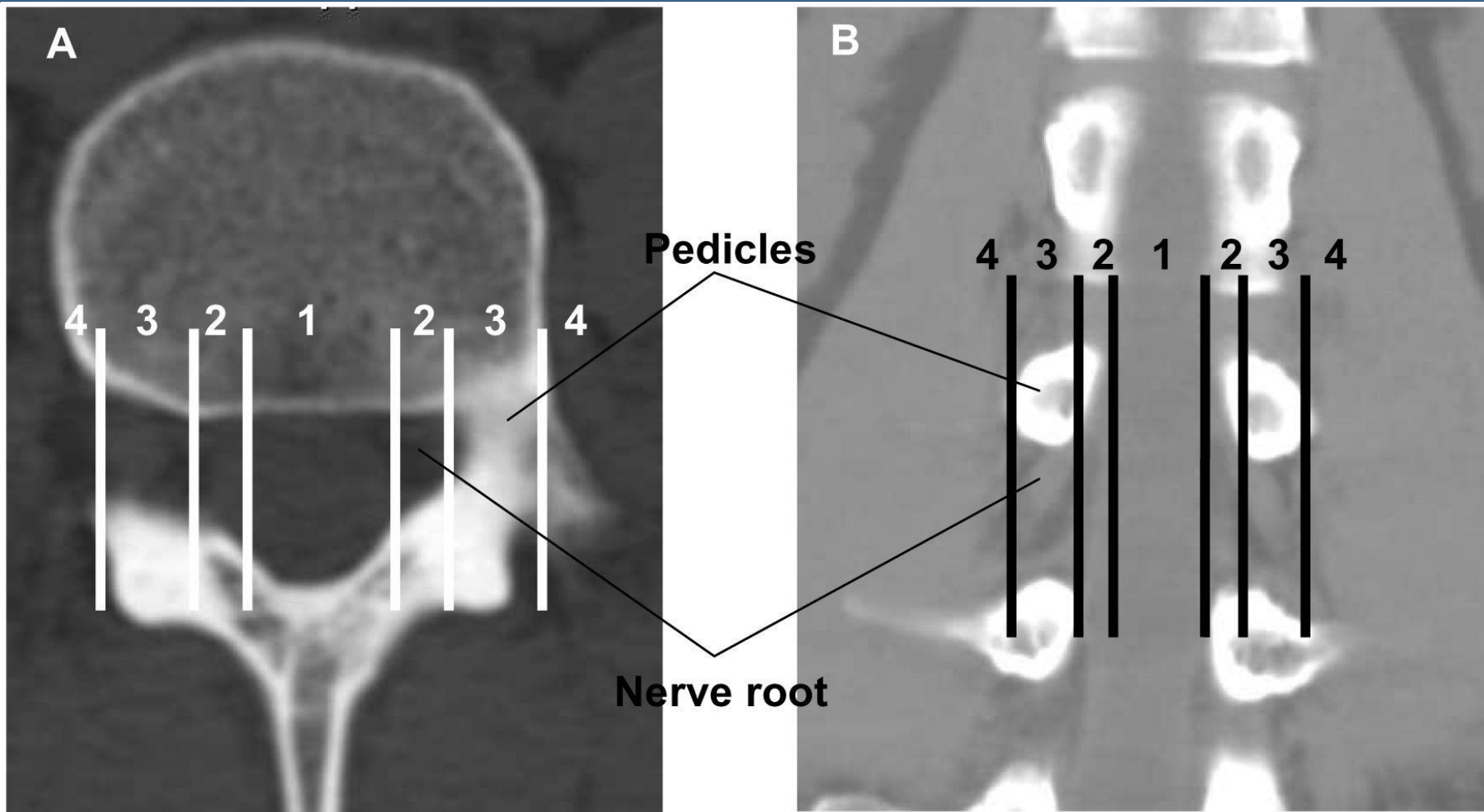
Growth in US Lumbar Spinal Stenosis Patients

Driven by Aging Population

- 20% CAGR 2016-2020



Sources: Qessential Medical Market Research 2015, The Wall Street Journal (Business), Feb 15, 2011, American Association of Neurological Surgeons, Vertiflex ASP business plan



Lumbar vertebrae. Potential regions of contact with nerve roots: 1 central; 2 lateral recess; 3 foramen; 4 extraforaminal

Jenis LG, An HS. Spine update. Lumbar foraminal stenosis. Spine 2000;25(3):389-94.
Genevay S, Atlas SJ. Best Pract Res Clin Rheumatol. 2010 April ; 24(2): 253-265

Lumbar Spinal Stenosis Pathophysiology

- Combination:
 - ligamentum flavum **hypertrophy** or in-folding,
 - loss of disc height - anterior compression from deg. annular **bulges**
 - **facet** joint hypertrophy,
- Signs and Sx's due:
 - **vascular** compromise from vessels supplying the cauda equina (central) or
 - **pressure** upon the **nerve root complex** (lateral stenosis) by degenerative changes.
 - **venous congestion**, or localized inflammatory mediators
- Threshold of approximately **50% reduction cross- sectional area** of the canal appears to be **required for changes are seen in conduction**

Grandmother's Sign



Worse with standing
Pain buttock, groin, ant thigh
Legs: bilateral > unilateral
fatigue, cramps, heaviness,
weakness, paresthesias,
bladder symptoms

Relief by flexion or sitting

Porter RW. Spinal stenosis and neurogenic claudication. Spine 1996 Sep 21(17):2046-52. Review.

Lumbar Spinal Stenosis

	Points
Age: 60–70	1
>70	2
Absence of diabetes	1
Intermittent claudication	3
Exacerbation of symptoms when standing up	2
Symptom improvement when bending forward	3
Symptoms induced by having patients bend forward	-1
Symptoms induced by having patients bend backward	1
Good peripheral artery circulation	3
Abnormal Achilles tendon reflex	1
Straight leg raise test positive	-2

A clinical diagnosis support tool to identify patients with lumbar spinal stenosis. The total score range from -2 to 16. A score equal or greater than 7 has a sensitivity of 92.8% and a specificity of 72.0% for the diagnosis of symptomatic LSS.

Konno S, Hayashino Y, Fukuhara S, Kikuchi S, Kaneda K, Seichi A, et al. Development of a clinical diagnosis support tool to identify patients with lumbar spinal stenosis. *European spine journal* 2007;16(11):1951–7.

Lumbar Spinal Stenosis Continuum of Care

superion[®]
Indirect Decompression System

CONSERVATIVE
TREATMENT

TRADITIONAL
TREATMENT

MILD
STENOSIS

MODERATE
STENOSIS

SEVERE
STENOSIS

NSAID
ESI - Level II
OPIOIDS

Racz procedure – Level III

**SUPERION[®] BRIDGES
THE MIS GAP**



LAMINECTOMY
FUSION

: success 45 - 72%

- ✓ Non-surgical patient; retains virgin back
- ✓ Treats central canal, lateral recess, and foraminal stenosis

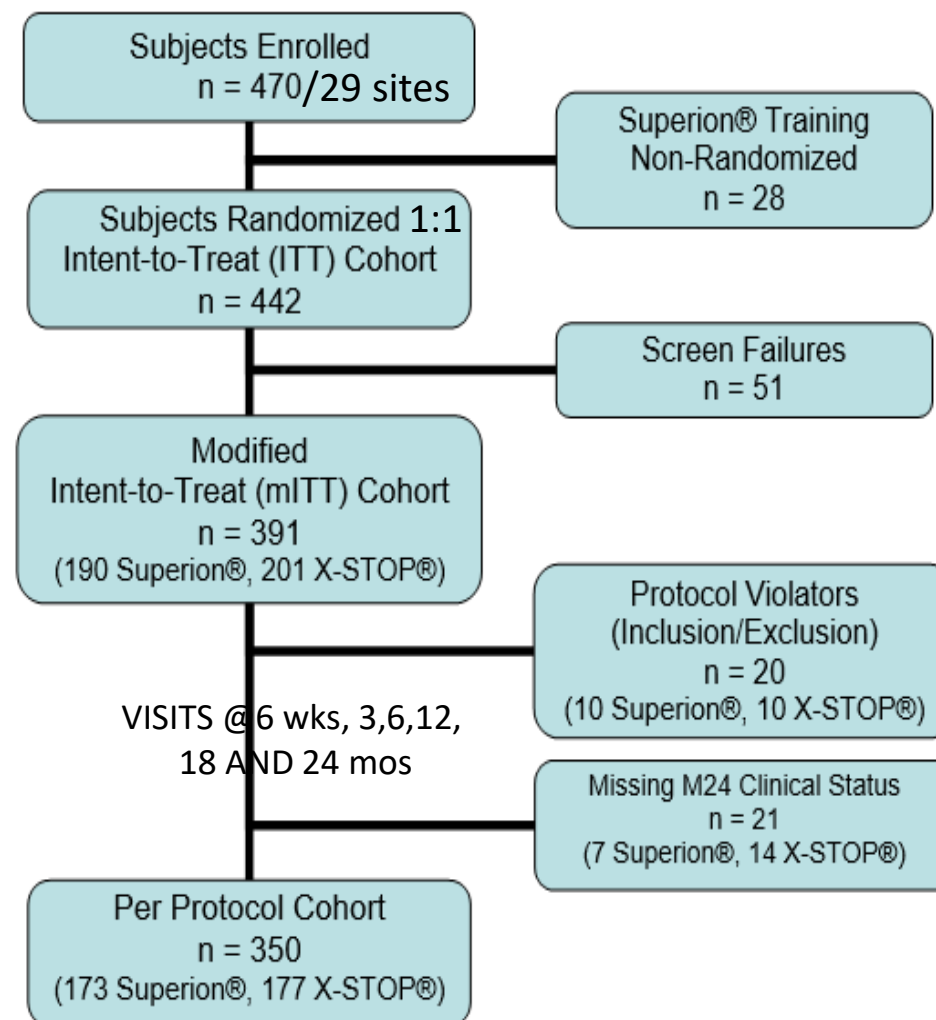
Superion[®] Clinical Trial Design

Key Inclusion Criteria

- Persistent leg, buttock, or groin pain, with or without back pain, that was relieved by lumbar flexion
- **unsuccessful** response **> 6 months** of conservative treatment
- **Moderate** spinal **stenosis** at one or **two levels** from L1-L5,
- **Zurich** Claudication Questionnaire **Physical Function** score **≥ 2.0**
- Able to sit for 50 minutes without pain and to walk ≥ 50 feet

Key Exclusion Criteria

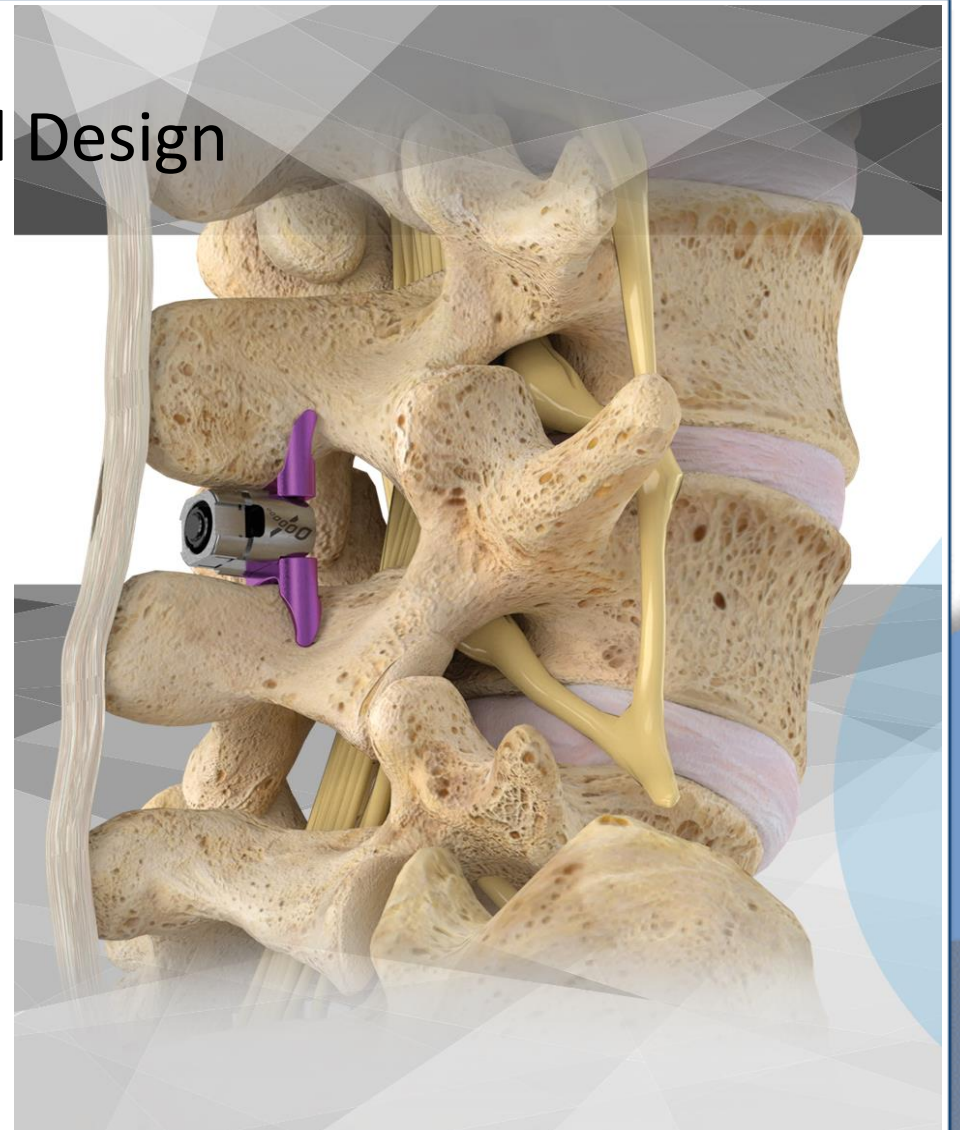
- Fixed motor deficit
- Concomitant surgical procedure required
- Grade II or greater spondylolisthesis
- Unremitting back pain in any spinal position
- Significant lumbar instability, defined as ≥ 3 mm translation or ≥ 5° angulation
- Vertebral osteopenia, osteoporosis, or history of vertebral fracture
- Previous lumbar spine surgery
- Cauda equine syndrome



Patel et al. Superion Interspinous Process Spacer for Intermittent Neurogenic Claudication Secondary to Moderate Lumbar Spinal Stenosis. SPINE (2015) Volume 40, Number 5, pp 275-282

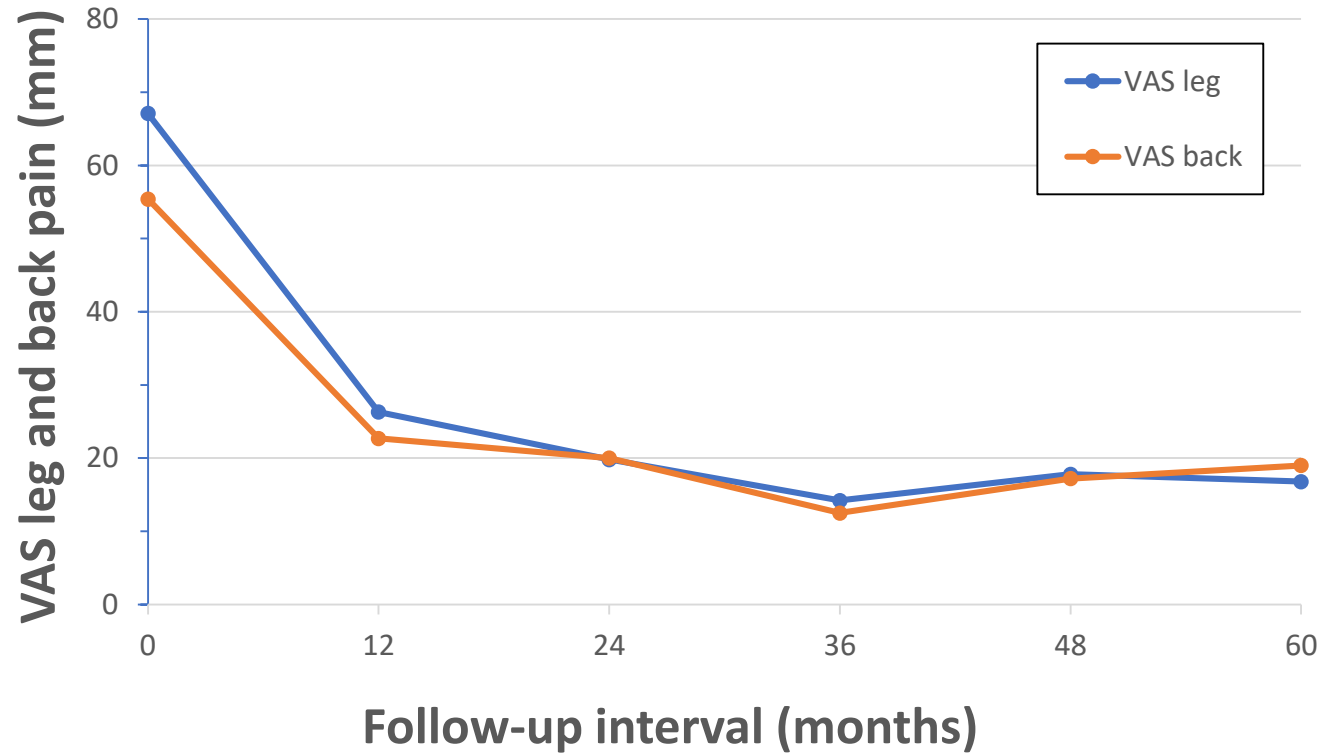
Superion® Clinical Trial Design

- FDA-Imposed Multiple Outcomes Measures
- **Primary Outcomes**
 - Zurich Claudication Questionnaire (ZCQ)
 - Clinically improvement in 2 out of 3
 - Physical Function > 0.5point decrease
 - Symptom Severity > 0.5 point decrease
 - Patient Satisfaction < 2.5 decrease
 - NO ESI at the index level
 - NO re-operation, revision, removal at index level
 - NO RFTC or SCS
 - NO major-implant or procedure related complication
- **Secondary Outcomes**
 - Visual Analog Scale (VAS) – leg and back
 - Oswestry Disability Index (ODI)
 - Patient Satisfaction questions
 - Adverse events



Patel et al. Superior Interspinous Process Spacer for Intermittent Neurogenic Claudication Secondary to Moderate Lumbar Spinal Stenosis. SPINE (2015) Volume 40, Number 5, pp 275-282

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.

Clinical Interventions in Aging

 Open Access Full Text Article

Dovepress

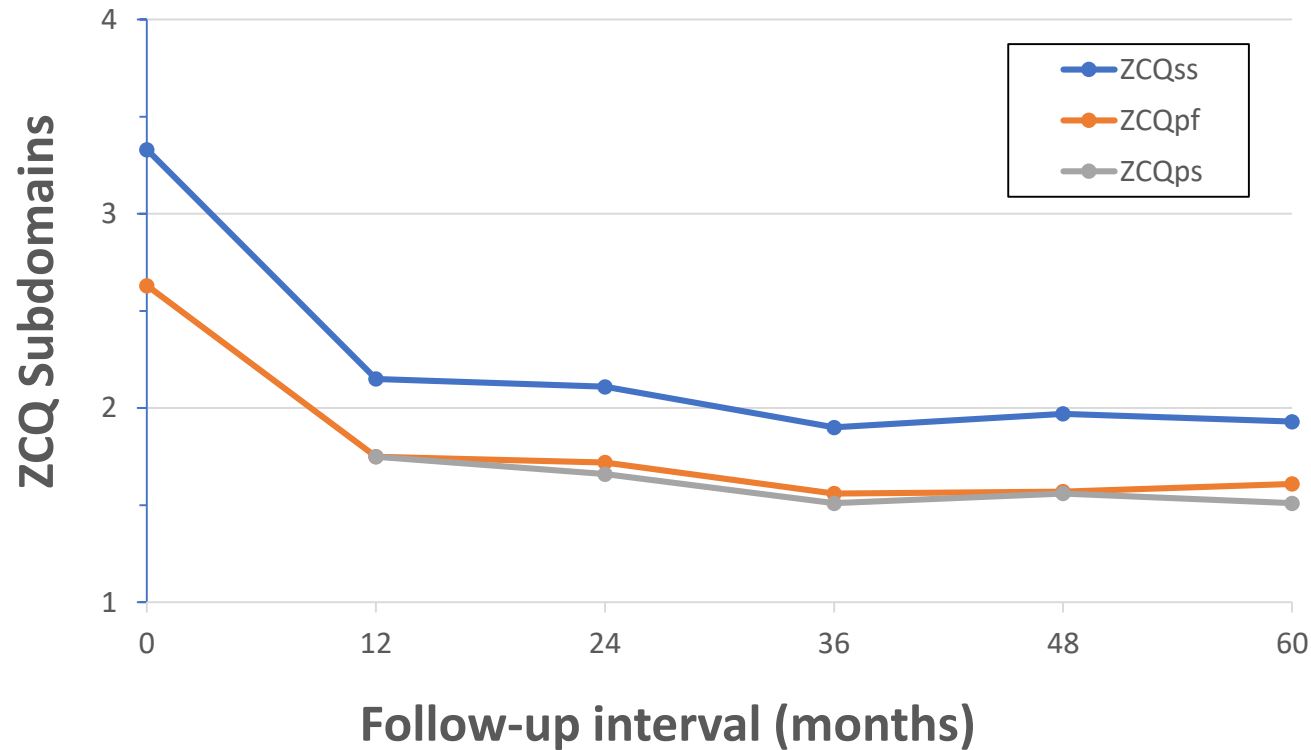
open access to scientific and medical research

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](#)

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: **ss**, symptom severity; **pf**, physical function; **ps**, patient satisfaction; ZCQ, Zurich Claudication Questionnaire.

Clinical Interventions in Aging

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Dovepress

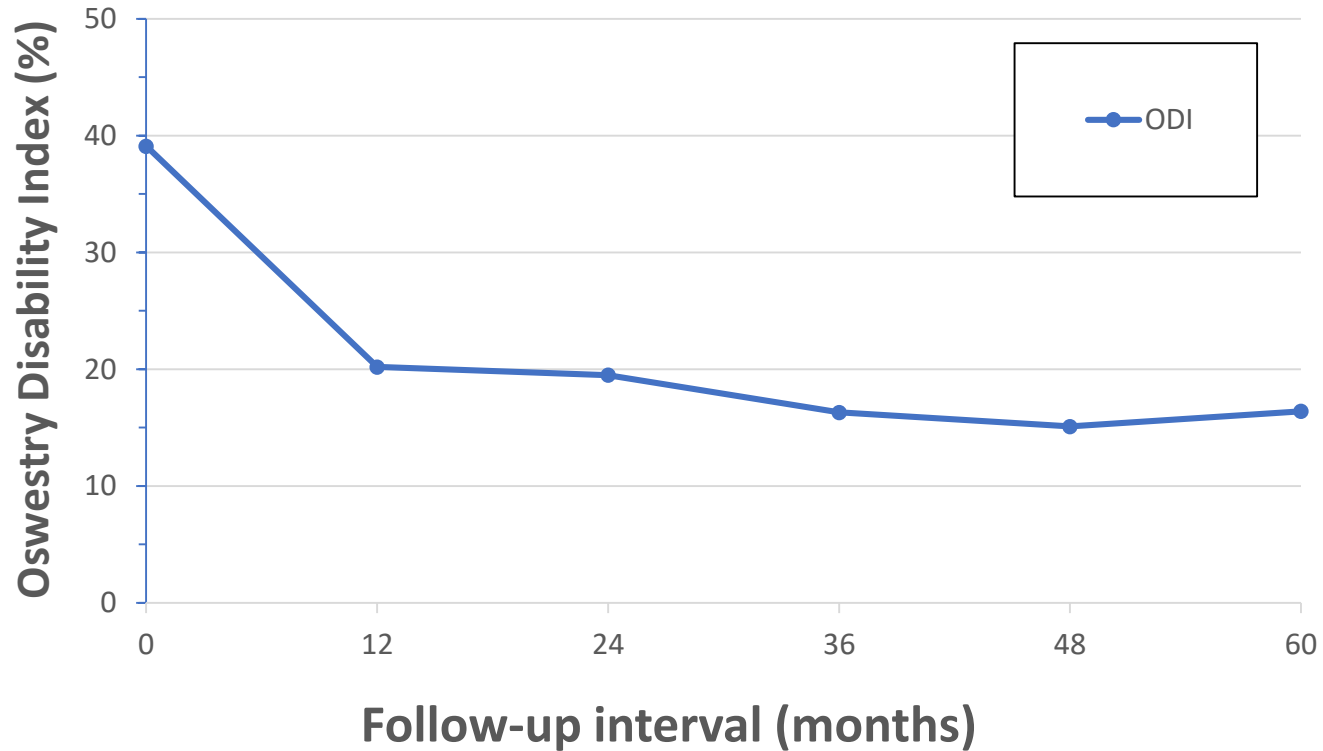
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Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis

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6 September 2017
[Number of times this article has been viewed](#)

Oswestry Disability Index




>50%
improvement
in scores
from baseline
at 5 years

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

Clinical Interventions in Aging

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ORIGINAL RESEARCH

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

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Lumbar Spinal Stenosis

Baseline Characteristics

Characteristic	CC *	SUPERION	DS No Fusion	Comparison p-value§		
				CC v Spacer	CC v DS	Spacer v DS
Number of patients	100	189	129	NA	NA	NA
Age, mean (SD)	58 (12)	66 (9)	64 (11)	<0.05	<0.05	NS
Male, %	40	58	59	<0.05	<0.05	NS
ODI , mean (SD)	57 (19)	39 (13)	47 (14)	<0.05	<0.05	<0.05
SF-12 PCS , mean (SD)	31.4 -8.1	29.2 -8.4	26.7 -9.4	<0.05	<0.05	<0.05
SF-12 MCS, mean (SD)	49.2 -12.1	49.9 -13.1	48.2 -11.2	NS	NS	NS
1 Level treated, %	NA	52	45			
2 Levels treated, %	NA	48	55	NS	NS	NS

SD: Standard deviation. *CC: Conservative Care, from Parker et al. 2014. Results from spondylolisthesis and stenosis patients were combined.

†Spacer: from ISISS trial, Superior patients. ‡DS: Decompressive Surgery without fusion, from institutional registry. §For continuous variables, a two sample Z-test was used for the pairwise comparisons. For categorical variables, Fisher's exact test was used. A p-value of 0.05 was considered statistically significant. No corrections for multiplicity were applied.

Parker et al. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superior interspinous spacer. Intl Journal of Spine 2015; 9(28).

	Treatments		
	Conservative Care	SUPERION	Decompressive Surgery
Variable	Base Case	Base Case	Base Case
Hospital Readmission*	NA	0.00%	5.40%
D/C Inpatient rehabilitation	NA	0.00%	3.90%
Probability of utilization - Qtr of Procedure			
Healthcare	94.00%	13.10%	12.90%
Medications	100.00%	64.30%	64.30%
Diagnostics	86.00%	8.80%	8.80%

*Adverse Events (AE) that generate additional reimbursement outside of the global payment.

Healthcare includes non-surgeon physician visits, physical therapy, chiropractic care, acupuncture.

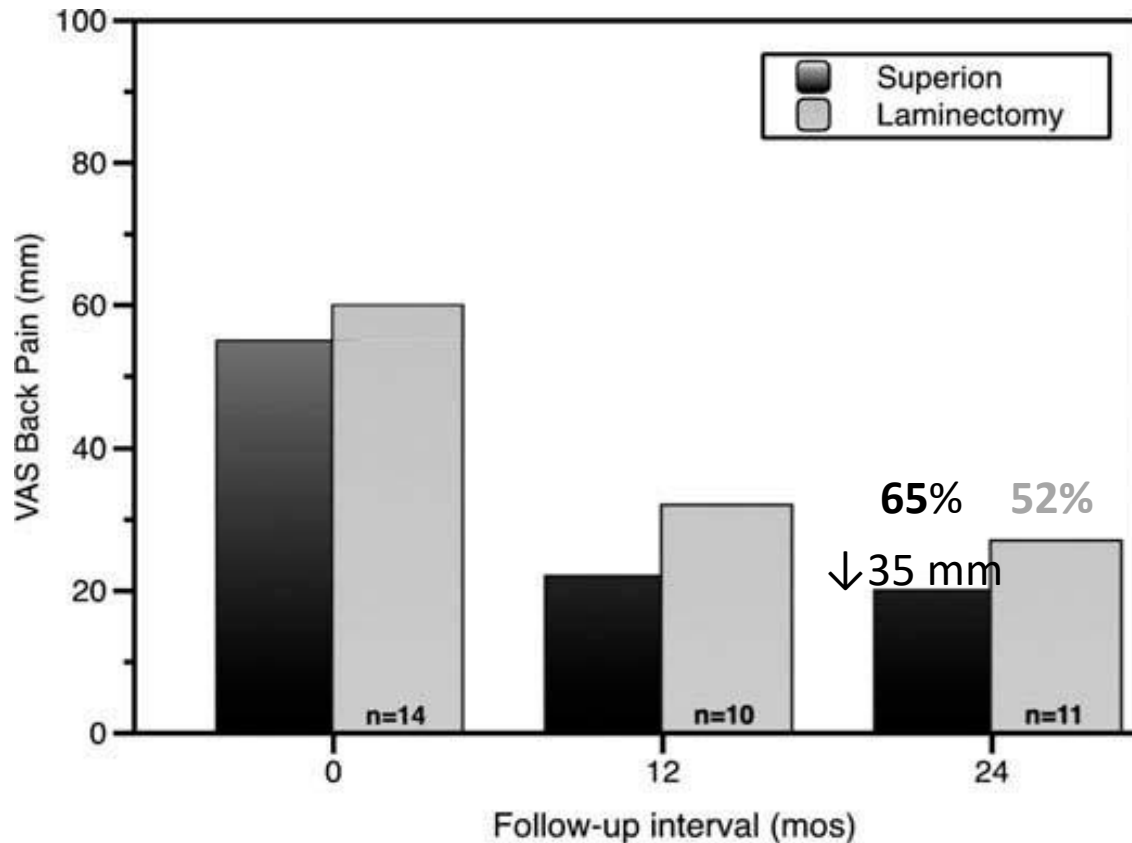
Medications include narcotics, muscle relaxants, NSAIDs, and oral steroids.

Diagnostics include MRI scans, CT scans, x-rays, spine injections, and EMGs.

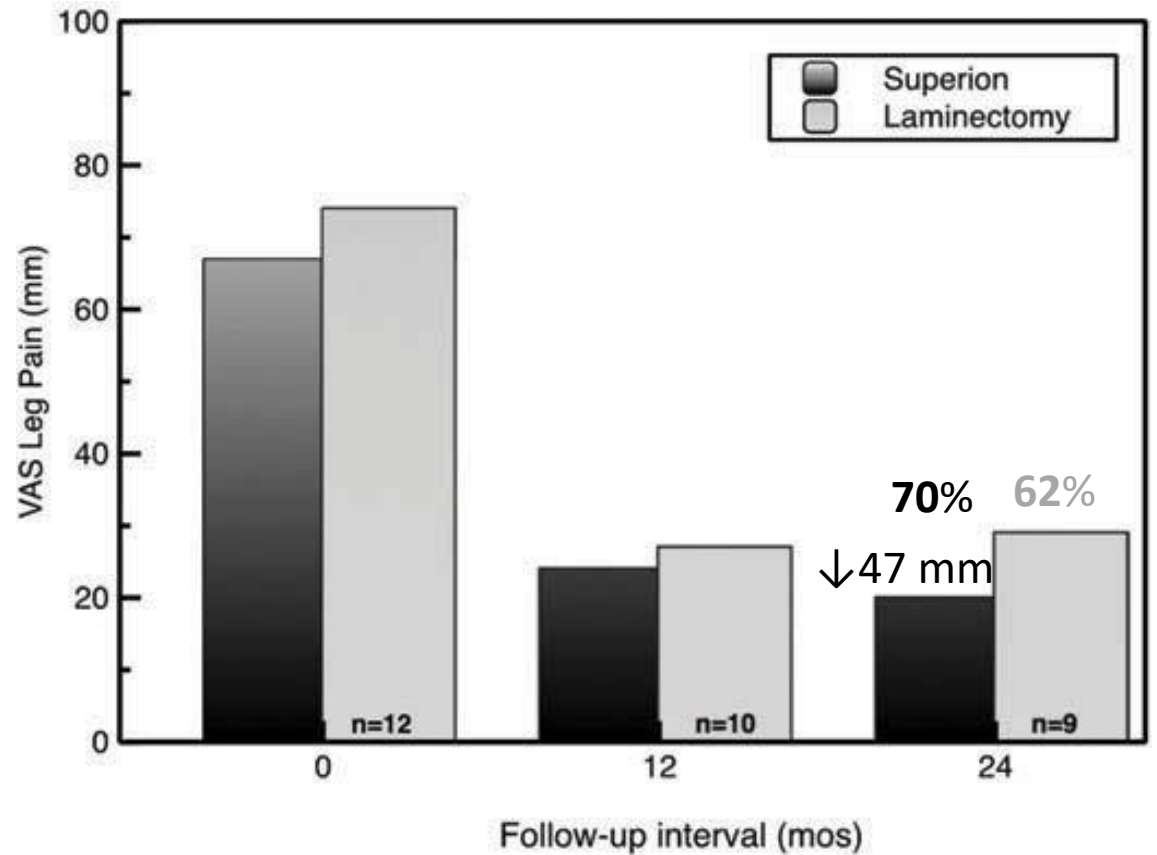
Superion patients assumed to have the same level of utilization for non-surgeon physician visits, medications, and diagnostics as decompressive surgery patients.

Parker et al. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superior interspinous spacer. Intl Journal of Spine 2015; 9(28).

Superior vs Laminectomy

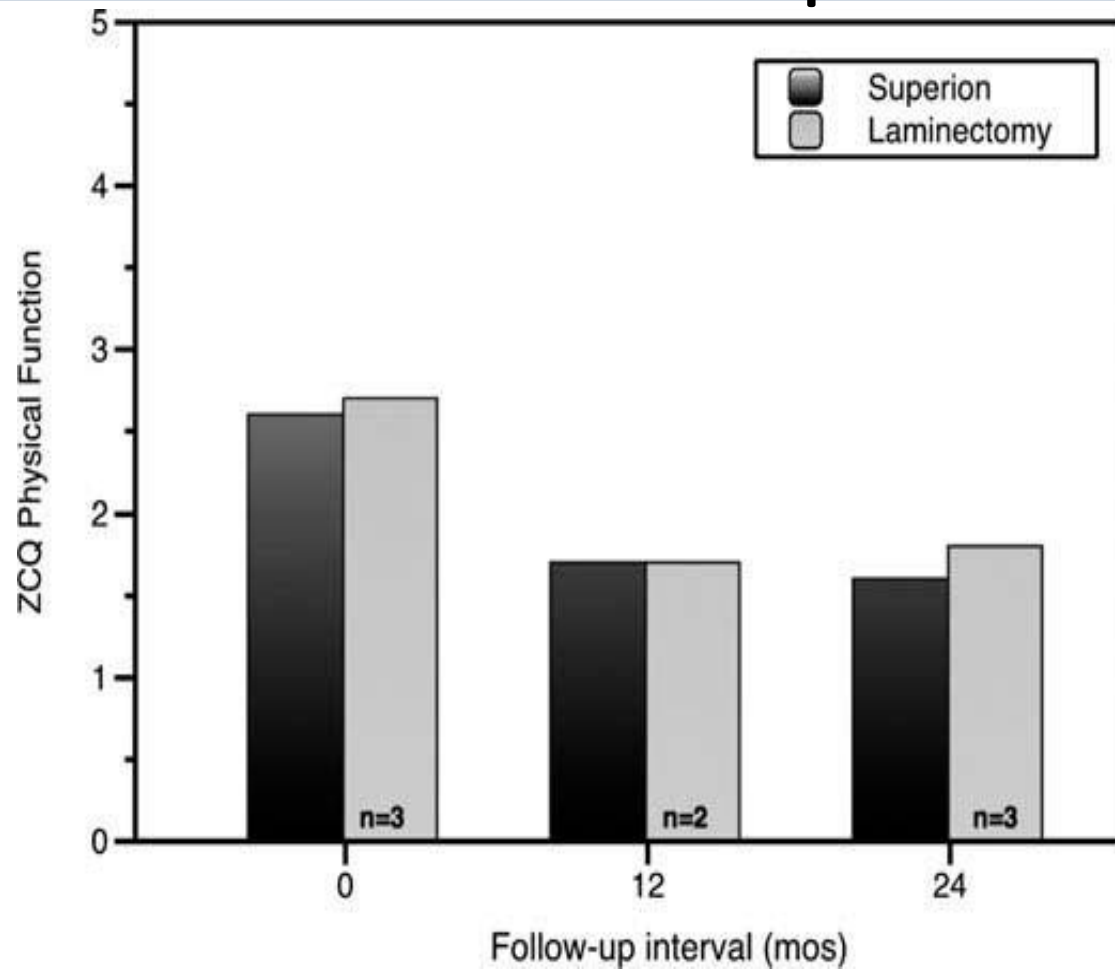


BACK PAIN severity. Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.

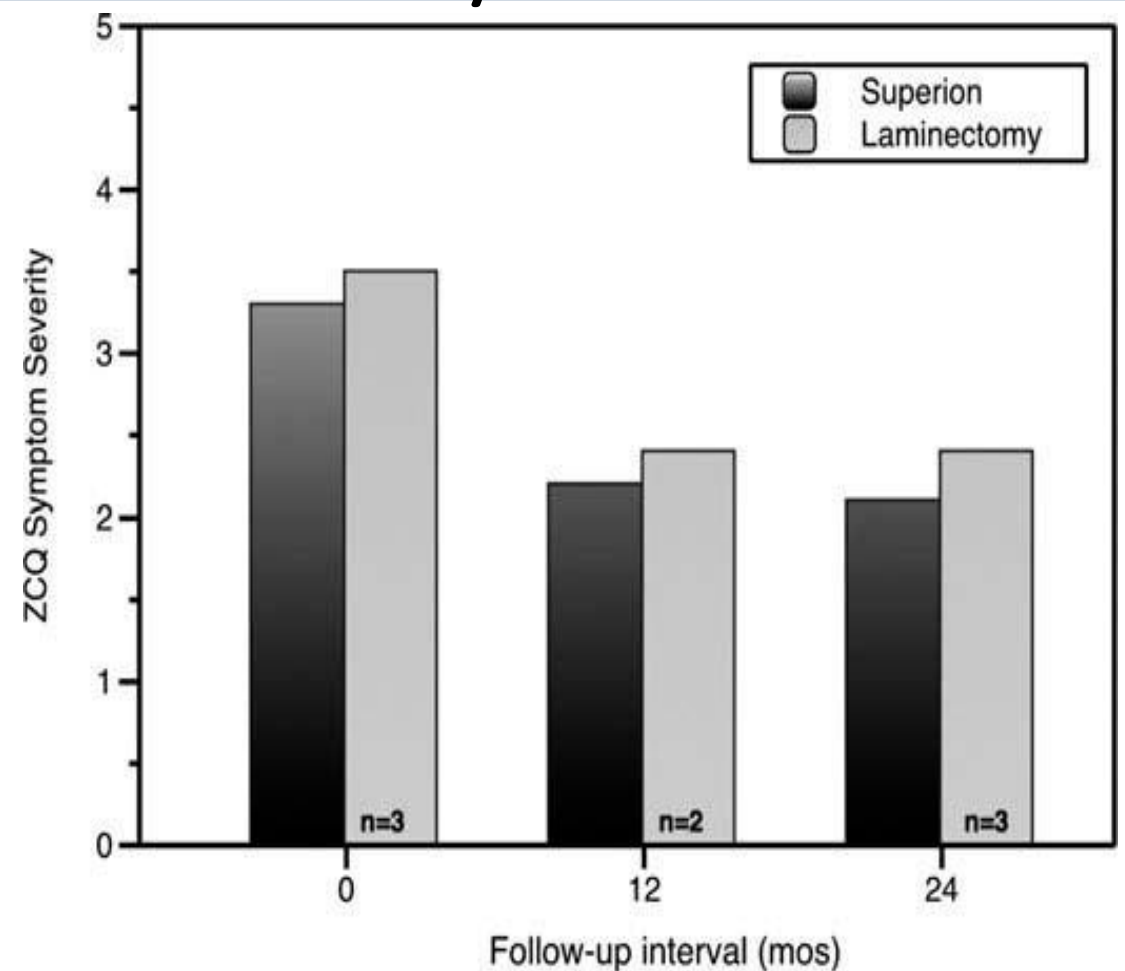


LEG PAIN severity. Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies.

Superion vs Laminectomy

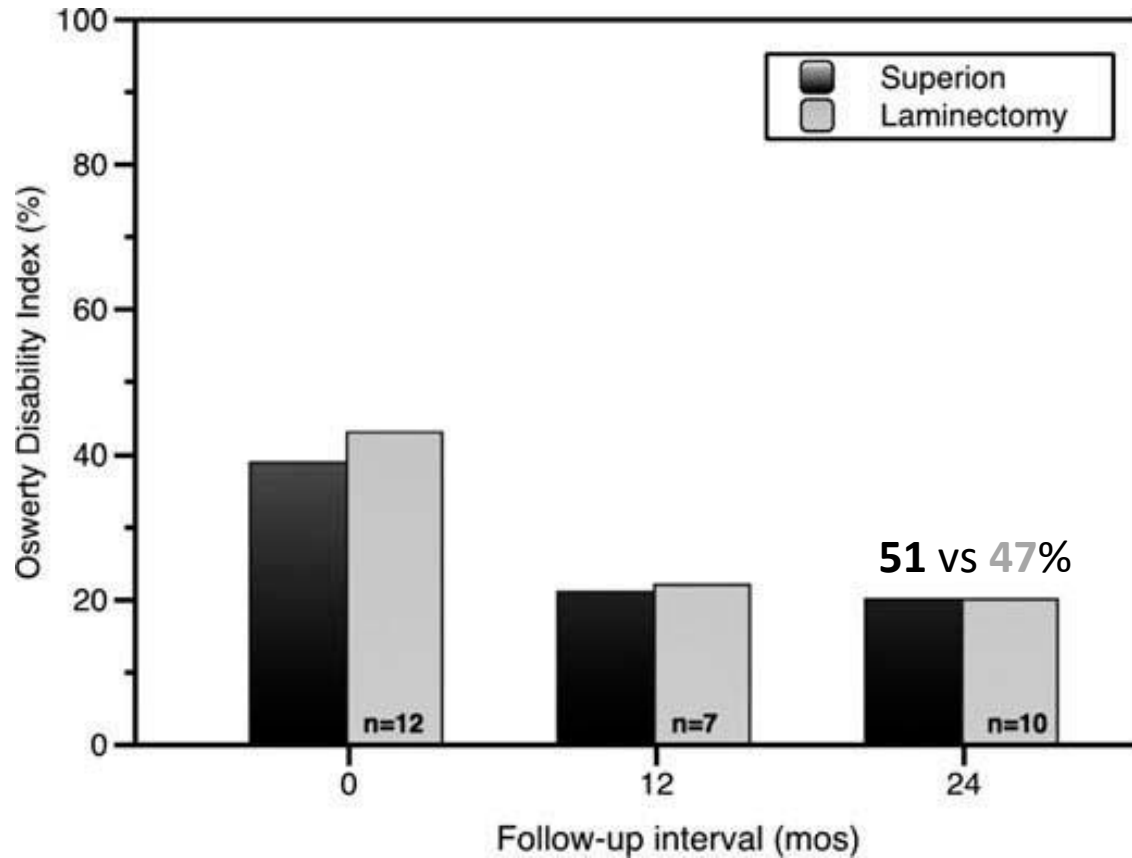


ZCQ physical function. Preoperative, 12 and 24 month scores for spacer (mean) and laminectomy (median); n refers to number of included studies

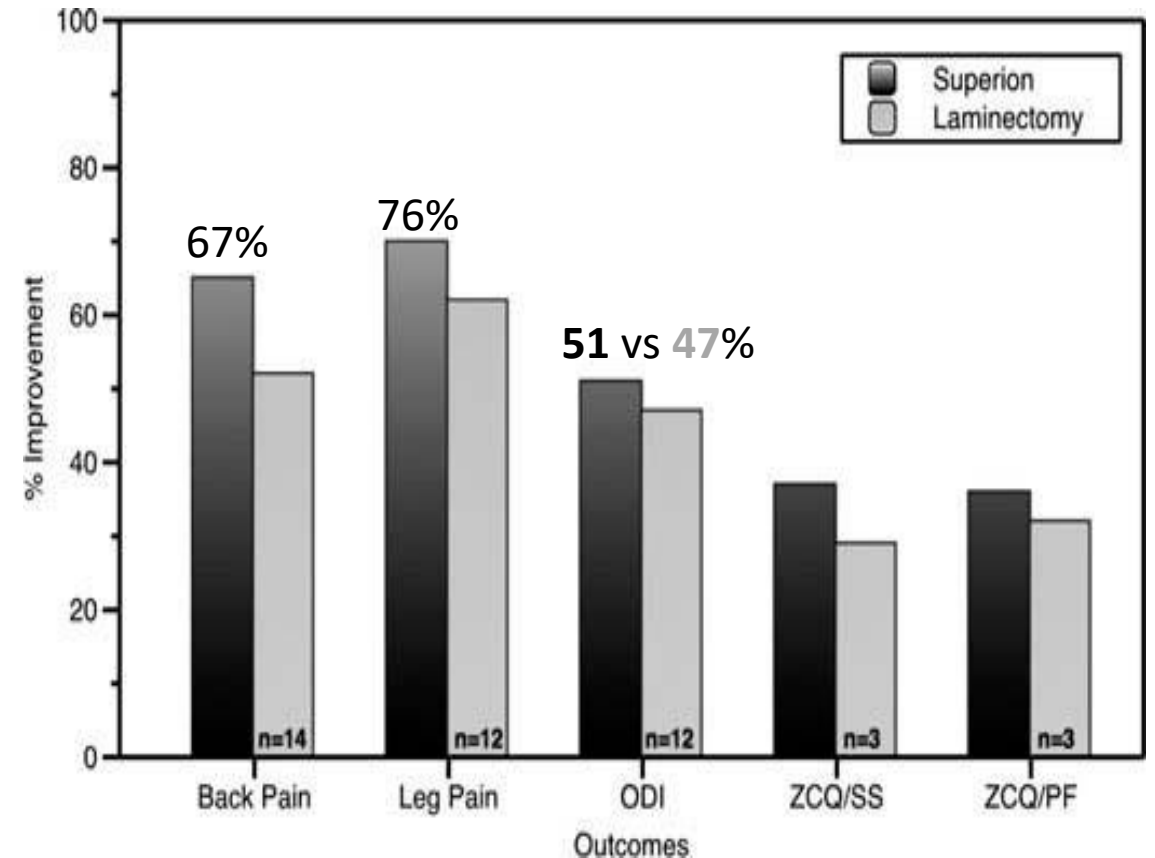


ZCQ symptom severity. Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies

Superior vs Laminectomy



Oswestry disability index. Preoperative, 12- and 24-month scores for spacer (mean) and laminectomy (median); n refers to number of included studies



Percentage improvement by outcome measurement.

ODI, Oswestry disability index; ZCQ/SS, Zurich Claudication Questionnaire Symptom Severity domain; ZCQ/PF, Zurich Claudication Questionnaire Physical Function domain. n refers to number of included studies

Major medical complications, wound complications, and mortality following surgery for lumbar spinal stenosis, patients aged 66 years or older, 2007

	<u>n</u>	<u>Cardiopulmonary complications or stroke</u> n (percent)	<u>Wound complication</u> , n (percent)	<u>Mortality 30- days</u> , n (percent)
Overall	32,152	984 (3.1%)	398 (1.2%)	128 (0.4%)
Age Category	66–70 (8,554)	215 (2.5)*	98 (1.1)	27 (0.3)*
	71–74 (7,383)	208 (2.8)	87 (1.2)	22 (0.3)
	75–79 (8,667)	286 (3.3)	120 (1.4)	32 (0.4)
	80+ (7,548)	275 (3.6)	93 (1.2)	47 (0.6)
Chronic Pulmonary disease	Yes (5,525)	272 (4.9)*	77 (1.4)	35 (0.6)*
	No (26,627)	712 (2.7)	321 (1.2)	93 (0.3)
Previous spine surgery	Yes (2,196)	87 (4.0)*	101 (4.6)*	--**
	No (29,956)	897 (3.0)	297 (1.0)	121 (0.4)
Type of surgical procedure	Decompression (21,474)	458 (2.1)*	196 (0.9)*	72 (0.3)*
	Simple fusion 6,082	285 (4.7)	100 (1.6)	28 (0.5)
	Complex fusion 4,596	241 (5.2)	102 (2.2)	28 (0.6)
Number of disc levels fused	None or unknown (21,960)	508 (2.3)*	216 (1.0)*	77 (0.4)*
	1–2 (8,386)	356 (4.2)	133 (1.6)	31 (0.4)

Healthcare Utilization: Surgery LSS

Measures of health care utilization related to surgery for lumbar spinal stenosis, patients aged 66 years or older, 2007

Mean n Length of		N	Mean hospital charges, \$ (SE)	30 days, n (percent)
Overall		32,152	\$38,476 (123)	2,936 (9.1)
Type of Surgical procedure	Decompression	21,474	\$23,724 (129)*	1,667 (7.8)*
	Simple fusion	6,082	58,511 (506)	673 (11.1)
	Complex fusion	4,596	\$80,888 (753)	596 (13.0)
Number of Disc levels fused	None or unknown	21,960	\$25,026 (158)*	1,738 (7.9)*
	1–2	8,386	\$63,506 (429)	910 (10.9)
	3 or more	1,806	\$85,793 (1,384)	288 (15.9)

Deyo et al. JAMA. 2010 April 7; 303(13): 1259–1265

5 Year Efficacy and Durability

Superior Clinically Successful in Each Category

Responder Success at	2 years	3 Years	4 Years	5 Years
ZCQ Physical Function	72.5%	79.6%	80.0%	80.7%
ZCQ Symptom Severity	77.1%	84.3%	83.4%	75.0%
ZCQ Patient Satisfaction	84.0%	91.7%	86.7%	89.8%
ODI	63.4%	67.6%	61.1%	64.8%
VAS – Back Pain	67.2%	76.6%	66.7%	64.7%
VAS – Leg Pain	75.6%	82.8%	78.2%	80.0%
No Reoperations	80.0%	78.4%	75.3%	74.7%
No Revisions				

- SP fractures: 16% - Majority asymptomatic, and did not affect efficacy outcomes
 - Rate of fracture in commercial use: <1%
- No migrations & no dislodgements throughout the IDE trial and commercialization

Superior 5 –Yr Outcomes

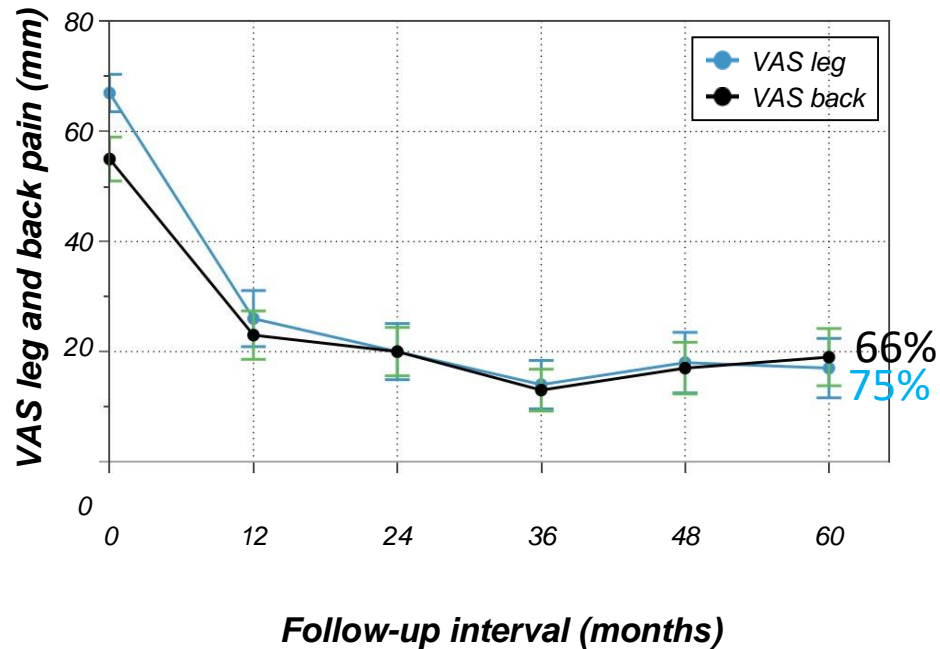
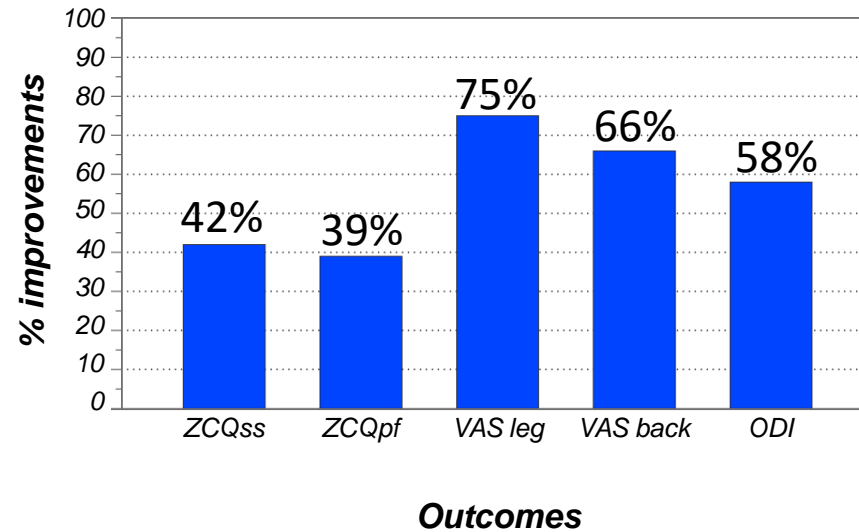


Figure 2 Time course of results for leg and back pain severity by VAs.

Note: results reported as mean (95% CI).

Abbreviation: VAs, visual analog scale.



Percentage improvement for each outcome at 5 years compared to preoperative levels.

Note: All changes were statistically significant ($P,0.001$).

Abbreviations: ZCQ, Zurich Claudication Questionnaire.pf, physical function; ss, symptom severity; VAs, visual analog scale; ODI, Oswestry Disability Index

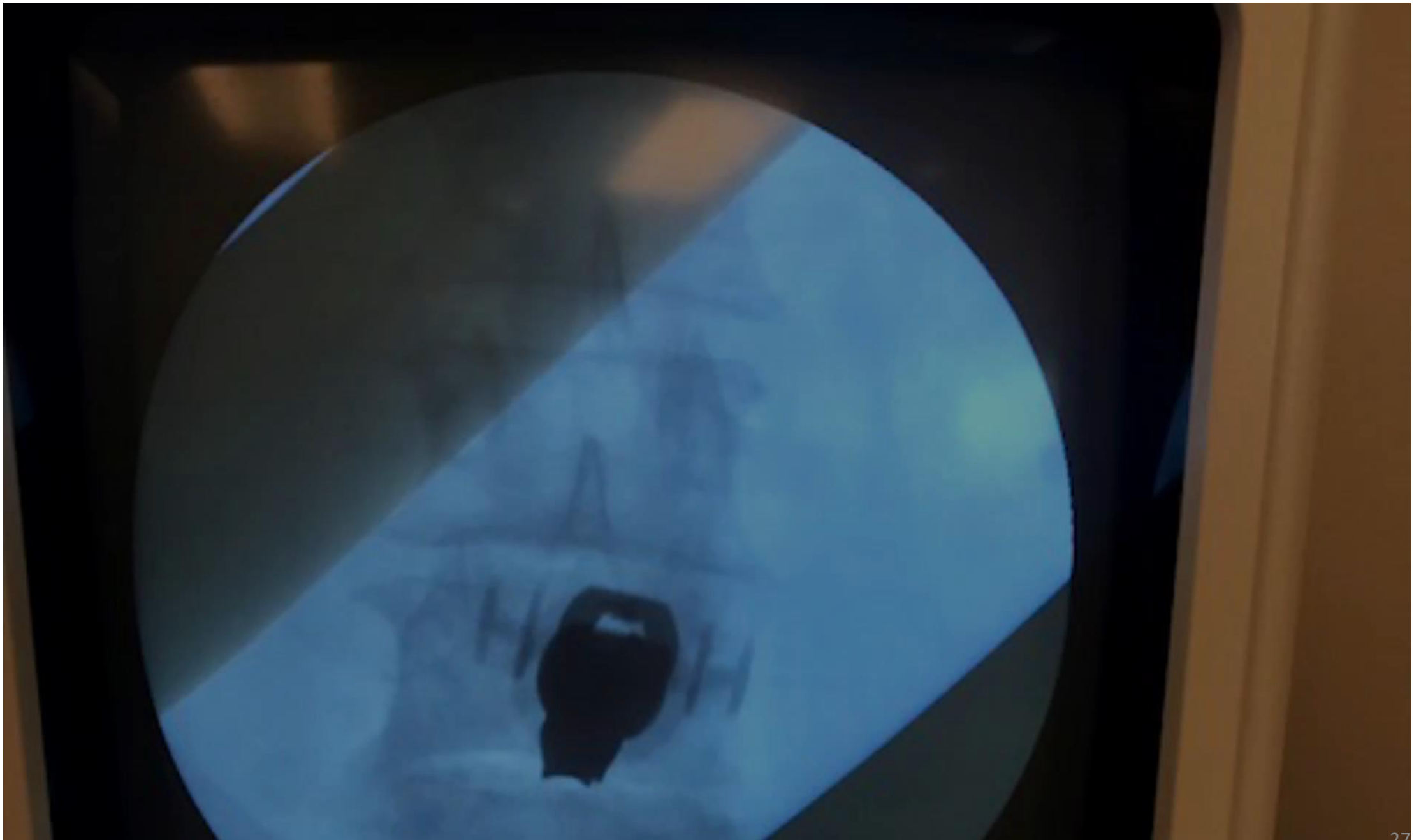
Nunley PD, Patel VV, Gorndorff D, Lavelle WF, Block JE, Geisler FH.
Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. *Clinical Interventions in Aging*, 2017:12.

Conclusion

- Minimally Invasive
- Minor Anatomic Disruption,
 - full range of surgical options remains available if a revision becomes necessary to manage re-emergence of LSS
- Simple
 - 30-50 mins
- Rapid Recovery
 - ASC setting
- Low Surgical Risk of Complications,
 - Minimal EBL
- Long-term Clinical Durability,
- **SUPERION - a viable treatment option for LSS.**

Nunley PD, Patel VV, Gorndorff D, Lavelle WF, Block JE, Geisler FH.

Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. Clinical Interventions in Aging, 2017:12.



Lumbar Spinal Stenosis

MILD

- 1) LSS at L5-S1
- 2) Osteoporosis/ compression fractures
- 3) Scoliosis >10% Cobb Angle
- 4) Surgery w/ partial spinous process resection
 - 1) Previous laminectomy 1-level below LSS level
 - L3-L5 fusion with L2-3 LSS, laminectomy may weaken the SP
 - MILD safer
- 5) Excellent LSS central decompression
- 6) Less Cost, but less ASC Reimbursement
- 7) High fluoro exposure

SUPERION

- 1) Works well for Central/Latera/Foraminal LSS
- 2) Faster 25-50 mins, technically easier
 - 1) NO epidurogram
 - 2) NO need for bilateral decompression approach
- 3) Pro fees Reimbursement for 2 levels
- 4) Very good ASC reimbursement
- 5) Good 5-year data
- 6) Less fluoro exposure

Thank you

