Percutaneous Decompression Laminotomy (CPT 0275T)

A safe & durable treatment option
for lumbar spinal stenosis

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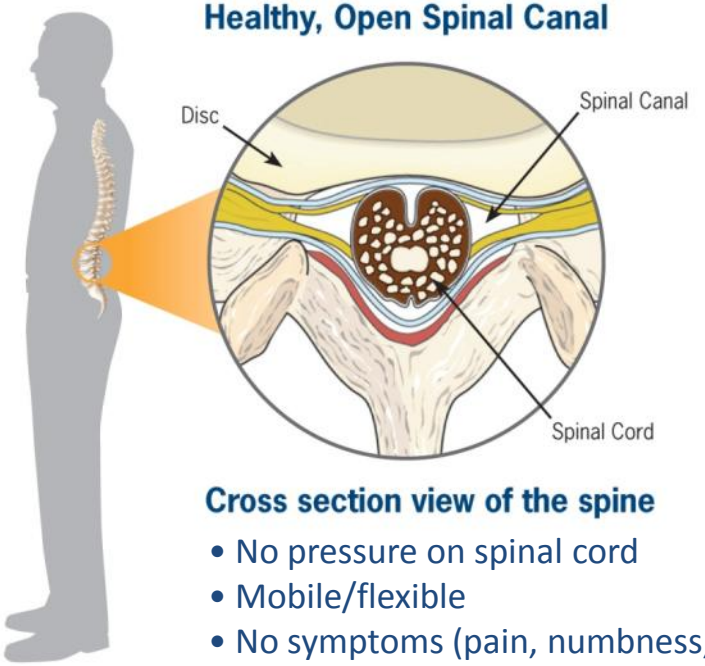
Disclosures

- No financial or ownership relationship to any company involved (currently or future) with product connected to this procedure
- BOD ASIPP
- Ex. Dir. CPS
- President-Elect NANS
- Ex-CAC rep for CT
- Assisted in the development of LCD’s on many occasions
- NANS representative on the MPW

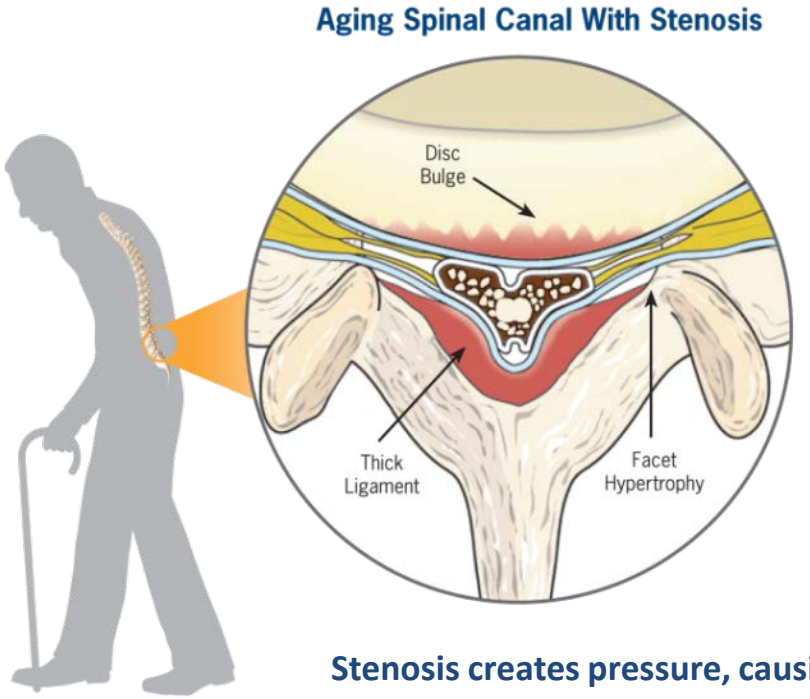
Procedure Overview

Lumbar Spinal Stenosis (LSS)



Cross section view of the spine

- No pressure on spinal cord
- Mobile/flexible
- No symptoms (pain, numbness, tingling)



Stenosis creates pressure, causing:

- Pain, numbness & tingling
- Weakness with activity
- Pain relieved by flexion (sitting, leaning, bending)

- Initial symptom onset generally occurs between 50 – 60 years of age[2]
- Limited therapeutic options, short of open surgery
- Impacts 1.2M[1] Patients in U.S.

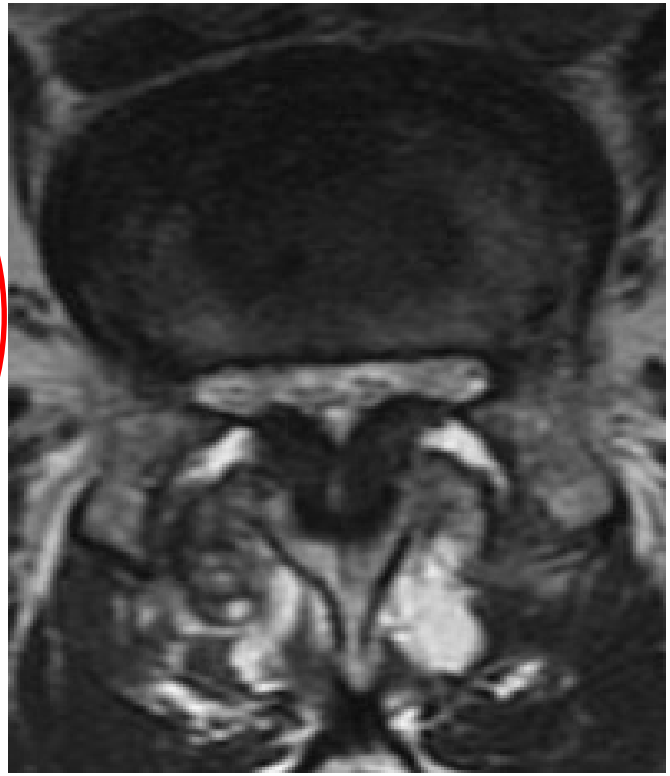
[1]Longitudinal Medicare Database, Quorum Consulting

[2]Birmeyer NJ, Weinstein JN. Medical versus surgical treatment for low back pain: evidence and clinical practice. Eff Clin Pract. 1999;2:218-227

LSS Symptoms – A Need For Differentiating the Cause

94% of LSS patients[3]

Neurogenic Claudication (NC) = Thecal sac compression / ischemia[1,2]



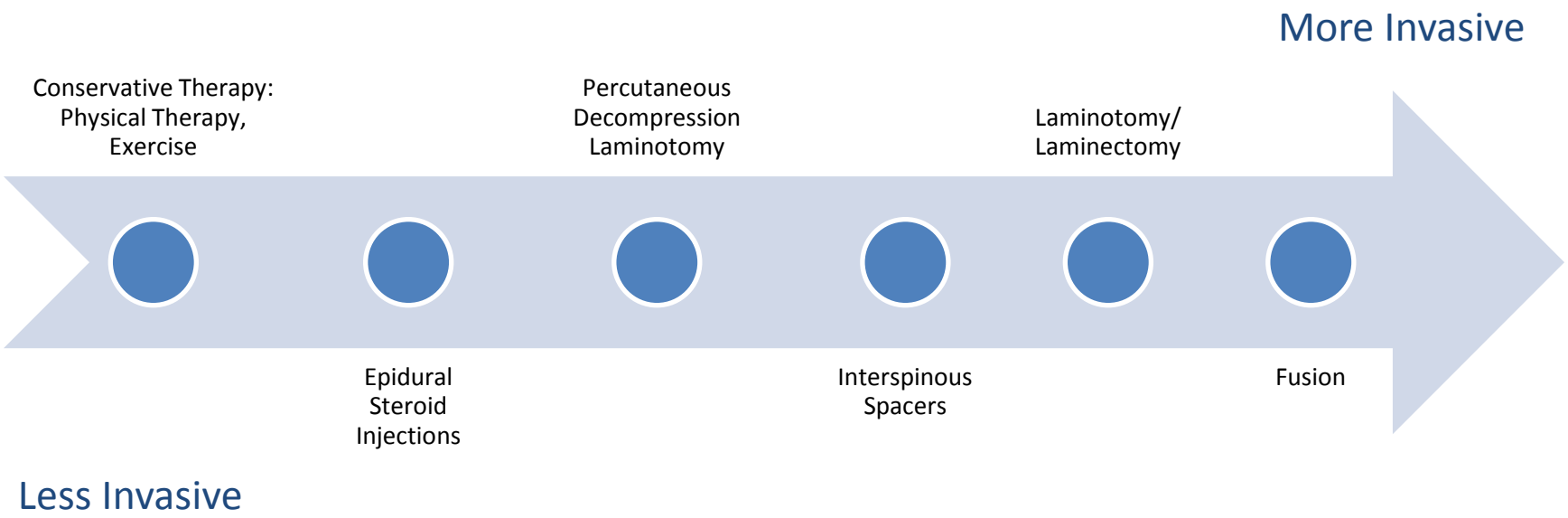
Radicular Pain (RP) = Nerve root inflammation[1]

Different pathophysiological causes[1] require different treatments

- Epidural Steroid Injections treat inflammation…NOT ischemia.
- Decompression is required to treat thecal sac compression/ischemia.

[1]Fukusaki, M et al., Symptoms of Spinal Stenosis Do Not Improve After Epidural Steroid Injection. *Clinical Journal of Pain*: 6/1998;14(2):148-151.
[2]Porter RW, Spinal stenosis & neurogenic claudication. *Spine* 1996 Sep 1; 21(17): 2046-52.
[3]Hall S, Bartleson JD, Onofrio BM, Baker HL, Okazaki H, O'Duffy JD. Lumbar spinal stenosis. Clinical features, diagnostic procedures, and results of surgical treatment in 68 patients. Ann Intern Med 1985;103(2):271-5.

LSS Treatment Options



Percutaneous Decompression Laminotomy achieves the safety profile of conservative treatments with the efficacy of therapeutic treatments.

Neurogenic Claudication Treatments: Percutaneous Decompression Laminotomy Candidate

Percutaneous Decompression Laminotomy Candidate:

- Percutaneous Decompression Laminotomy is an option when hypertrophic ligamentum flavum is a predominant factor of LSS
- Removal of a small amount of tissue, 1-2 mm, can result in a significant increase in the size of the spinal canal sq.area = πr^2

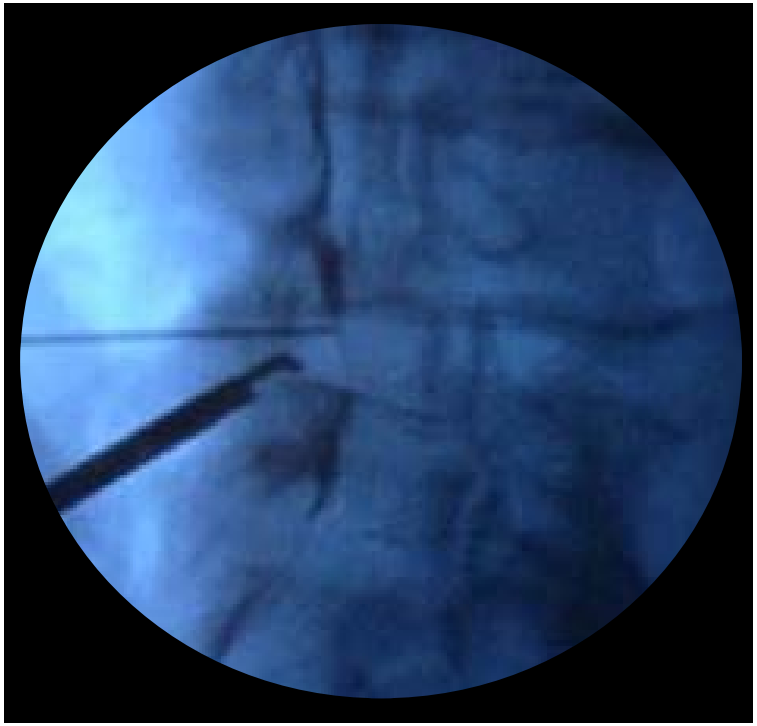
Percutaneous Decompression Laminotomy: Introduction

- **A safe procedure that can help LSS patients stand longer & walk farther with less pain[1]**
- **Treats lumbar spinal stenosis (LSS) with neurogenic claudication**
- **Approximately 13,000 patients treated in over 45 states**
- **FDA 510(k) Cleared Devices**
  - "Intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions"
- **CPT Category III: 0275T**
  - **Percutaneous laminotomy**/laminectomy (interlaminar approach) for **decompression** of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

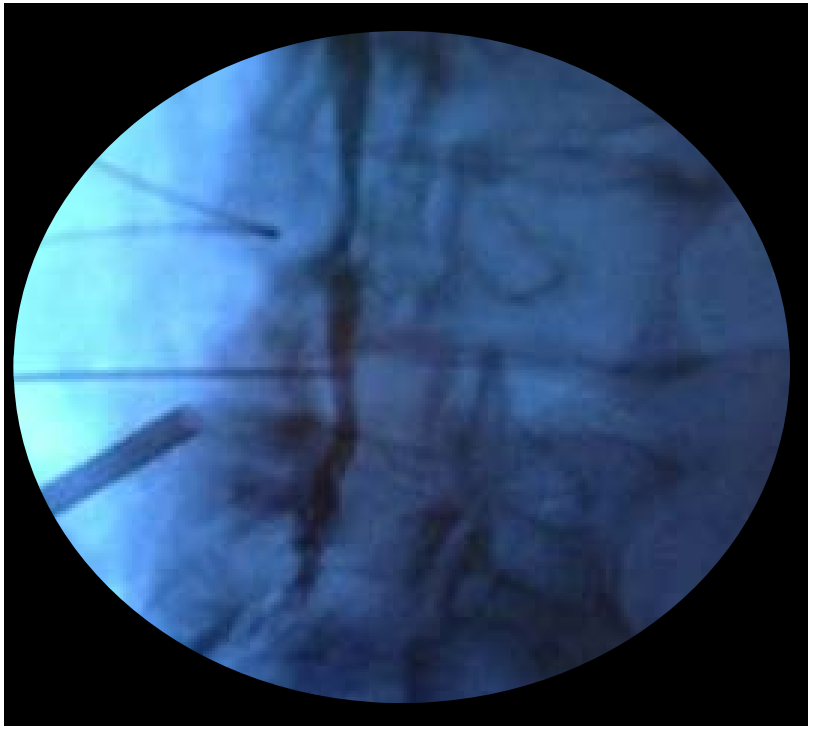
[1]Mekhail, Nagy, et al. (2012) Functional and Patient-Reported Outcomes in Symptomatic Lumbar Spinal Stenosis Following Percutaneous Decompression. Pain Practice, 12(6): 417–425. doi: 10.1111/j.1533-2500.2012.00565.

Percutaneous Decompression Laminotomy: Procedure Description

- FDA cleared devices, fluoroscopically guided, safe, outpatient procedure for the treatment of LSS:
  - Performed through a small portal (5.1 mm)
  - Requires NO general anesthesia, NO stitches, & NO overnight hospital stay
- Limited tissue available to be removed (minimal return of ligament in Tissue Sculpter)
- Changes noted in epidurogram (improved / easier flow, thicker / straighter line)
- Epidurogram reveals space restoration in debulked / previously stenosed area

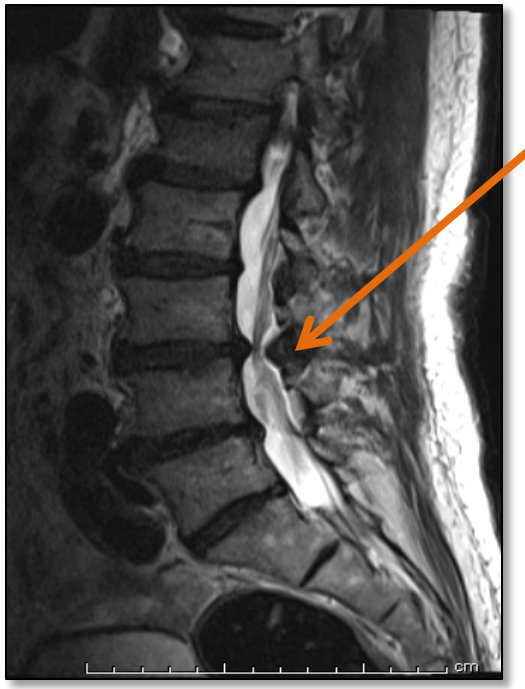


Pre-procedure



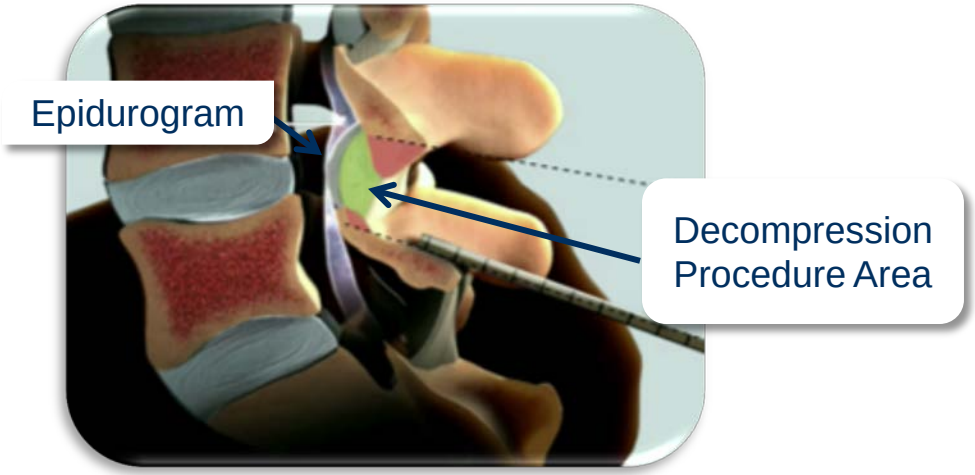
Post-procedure

Percutaneous Decompression Through a 5.1 mm Portal



Debulk the Ligamentum Flavum

- Debulking restores space in the spinal canal
- Access minimizes tissue disruption
- Removal of a small portion of lamina
- Removal of excess ligamentum flavum
- Leaves anterior ventral fibers of the ligament intact
- Supporting structures remain intact
  (spinous process, facets, & majority of lamina)



Percutaneous Decompression Laminotomy & Open Surgery Comparison

	Laminotomy/ Laminectomy (with or without Fusion)	Percutaneous Decompression Laminotomy	Benefits of Percutaneous Decompression Laminotomy
Procedure Setting/ Anesthesia	Inpatient: General Anesthesia	Outpatient: MAC	
Incision Length	2–5 Inches Stitches	5.1 Millimeters No Stitches	**Safe by Design**
Days in Hospital	3–5[2]	< 1	
Complication Rate Dural Tear / Blood Loss Requiring Transfusion	23.5%[3]	0.06% Commercial Cases 0% In All Clinical Trials[1]	**Low Complication Risk**
Responder Rate	60–80%[4]	70 –80%[1]	**Comparable Efficacy**
Average Medicare Reimbursement	$20 –80K[4]	$4,760[5]	**Low Cost**

[1]Based on procedure data collected in all clinical trials.
[2]Deyo, Mizra, Martin, Kreuter, Goodman, Jarvik. Trends, Major Medical Complications, & Charges Associated With Surgery for Lumbar Spinal Stenosis in Older Adults. JAMA, Vol. 303 No. 13.
[3]Weinstein, et al., for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794–810. 9.2% dural tear & 14.3% blood loss requiring transfusion reported.
[4]Weinstein, et al., for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794–810
[5]2013 Medicare National Average Reimbursement for APC 0208 is $3,760, Physician Fees are Carrier priced and average at $1000 per procedure

Clinical Data Overview

Robust Clinical Research

- 16 Published Peer-Reviewed Journal Articles
- 11 Clinical Trials, including 542 Patients:
  - Safety Series
  - MiDAS I
  - MiDAS II
  - MiDAS ECO
  - Surgery Intolerant
  - Percutaneous Decompression Laminotomy vs. ESI
  - Single-Site Series
  - Cleveland Clinic Study
  - Single-Site Long Term Series
  - Independent Case Series with 1 Year Follow-up
  - Prospective Single-Site Month 6 Report

Peer Reviewed Clinical Literature Demonstrates Safety & Improved Patient Outcomes

Study Author/ Abbreviated Title	# PLD Patients Milestone	Study Design Summary	Outcomes -VAS improvement -ODI improvement	ZCQ Outcomes -Symptom (S) -Function (F) -Satisfaction	Post PLD improvement -SF 12v2® Physical Component Score (PCS) -Others
Mekhail et al/ Functional Outcomes Long Term	N=40 Year 1	Prospective single center Endpoints: VAS, Roland Morris (RM), PDI (Pain Disability Index), Standing Time (ST), Walking Distance (WD)	VAS 3.5 (p<0.0001, ANOVA)		RM 7.7 (54% improvement), p<0.0001 ANOVA PDI 22.6 (55% improvement), p<0.0001 ANOVA ST 56 min (570% improvement), p<0.0001 ANOVA WD 3710 ft (1510% improvement), p<0.0001 ANOVA
Chopko & Caraway/ MiDAS Phase I	N=75 Week 6	Prospective 14 study centers Endpoints VAS, ODI, ZCQ. SF-12v2®	VAS 3.6 (p<0.0001, t-test) ODI 17.9 (p<0.0001, t-test)	S2.35(p<0.0001, t-test) F1.96(p<0.001, t-test) Satisfaction 2.0	PCS = 9.0 (95% CI ± 3.02)
Lingreen & Grider/ Post-mild Report	N=42 Month 1	Retrospective Single Center Endpoints: VAS, Standing Time, Walking Time, Satisfaction	VAS 3.8 (p<0.05, Mann-Whitney U-test)		59% of patients stand longer 57% of patients walk longer 86% of patients recommended mild to other patients
Mekhail, et al./mild Long Term Results	N=58 Year 1	Prospective, 11 study centers Endpoints: VAS, ODI, ZCQ, SF-12v2	VAS 2.9 (p<0.0001, t-test) ODI 11.9 (p<0.0001, t-test)	S 1.16(p<0.001, t-test) F 0.58(p<0.002, t-test) Satisfaction 2.2	PCS = 6.1 (95% CI + 2.99)
Chopko/High Risk Patients	N=14 >Month 8	Prospective controlled single center Endpoints: VAS, ODI	VAS 3.9 (p=0.05, ANOVA) ODI 17.2 (p=0.05, ANOVA)		
Brown / RCT ESI vs mild	N=38 Month 3	Prospective controlled single center Endpoints: VAS, ODI, ZCQ Satisfaction	VAS 2.9 (p<0.01 Tukey HSD) ODI 18.6(p<0.01Tukey HSD)	Satisfaction 1.8	
Basu /Single Site Series	N=27 Month 6	Prospective controlled single center Endpoints: VAS, ODI, ZCQ	VAS 5.2 (p<0.0001, t-test) ODI 24.0 (p<0.0004,t-test)	S 1.71(p<0.001, t-test) F 1.17(p<0.001, t-test) Satisfaction 1.8	
Schomer/mild lumbar Decompression	N=253 Month 3	Meta-analysis, 17 study centers Endpoints: VAS, ODI	VAS 3.5 (p<0.0001, t-test) ODI 17.1 (p<0.0001 t-test)		
Wong/ Interlaminar Decompression Long Term Outcomes	N=17 Year 1	Prospective controlled single center Endpoints: VAS, ODI	VAS 5.4 (95% CI + 1.5) ODI 26.6 (95% CI + 8.8)		
Deer, et al. / Single Site Long Term mild Results	N=35 Year 1	Prospective controlled, single center Endpoints: VAS, ODI, ZCQ	VAS 2.9 (p<0.0001,ANOVA) ODI 17.4(p<0.0001,ANOVA)	S 1.2(p<0.0001,t-test) F 0.8(p<0.0001,t-test) Satisfaction 1.86	
Levy, et al./ Systematic Review & Meta-Analysis	N=109 Year 1	Systematic Review & Meta-analysis Endpoints: VAS, ODI	VAS 3.9 (95% CI +0.42) ODI 16.0 (95% CI + 3.35)		
Chopko/ Long-term Results – Two Year Outcomes	N=45 Year 2	Prospective 11 study centers Endpoints VAS, ODI, ZCQ.	VAS 2.4 (p<0.0001,ANOVA) ODI 8.6 (p<0.0001,ANOVA)	S 0.9(95% CI +0.2) F 0.4(95% CI +0.2) Satisfaction 2.2	

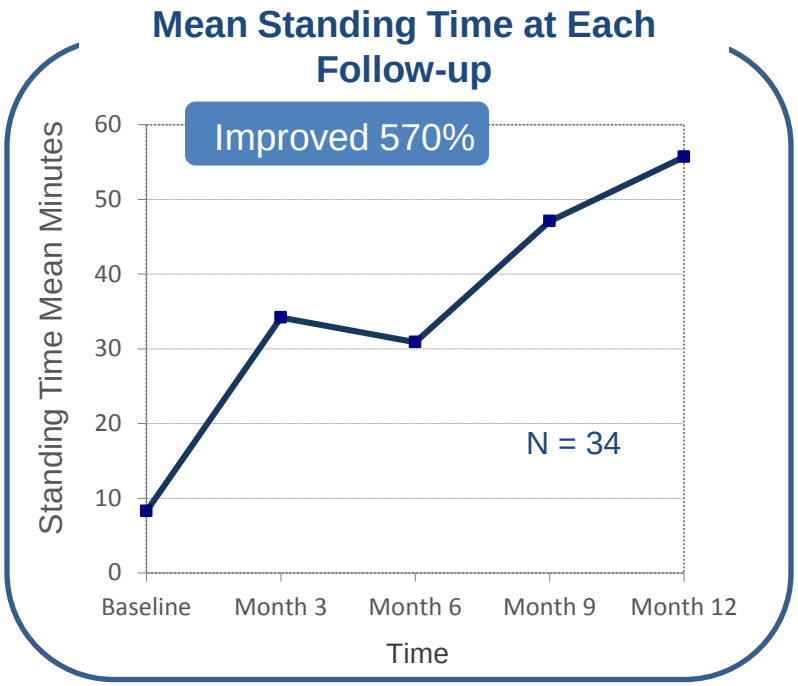
Note: Clinical relevance was also established in all validated outcomes measures: VAS >2, ODI >6, ZCQ Domains >0.5< Satisfaction <2.5, SF-12v2 PCS > 3 points.

Dramatic Functional Improvement at 1 Year[1]

Cleveland Clinic, Prospective, Single-Center Study

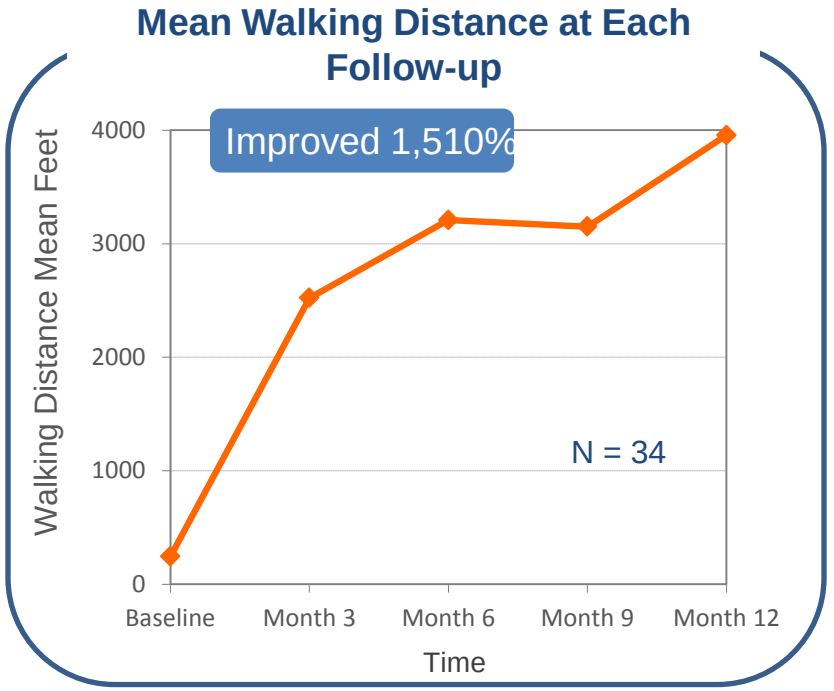
Standing time: 8 to 56 minutes

Improvement allows patients to perform activities of daily living: washing dishes, cooking, grocery shopping



Walking distance: 246' to 3,956'

To the mailbox → Around the mall



[1]Mekhail, Nagy, et al. (2012) Functional and Patient-Reported Outcomes in Symptomatic Lumbar Spinal Stenosis Following Percutaneous Decompression. Pain Practice, 12(6): 417–425. doi: 10.1111/j.1533-2500.2012.00565.x

Study Background

MiDAS I[1]

- Prospective
  - Year 1 follow-up
- Multi-center
  - 11 U.S. study centers
- Safety
  - Comprehensive solicited & unsolicited
- Patient-Reported Outcomes
  - VAS: 10-point Visual Analog Scale
  - ODI: Oswestry Disability Index
  - SF-12v2®: Health Survey
  - ZCQ: Zurich Claudication Questionnaire

[1]Mekhail N, Vallejo R, Coleman MH, Benyamin RM. Long-term results of percutaneous lumbar decompression *mild*® for spinal stenosis. *Pain Pract* 2012;12(3):184-193.

Year 1 Cohort (N = 58)

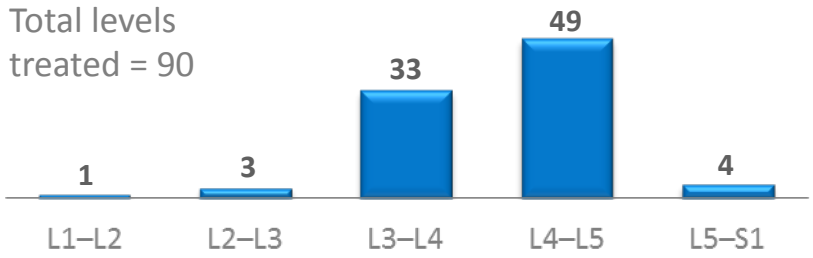
MiDAS I

Demographics

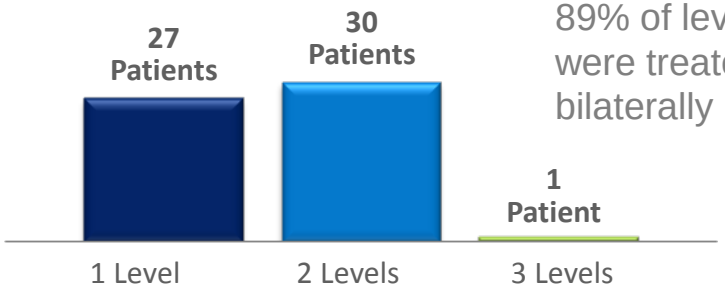
Average Age:
70 Years
Female 65.5%
Male 34.5%

Patients Treated / Level

Total levels treated = 90



Total Levels / Patient



89% of levels were treated bilaterally

Length of Stay

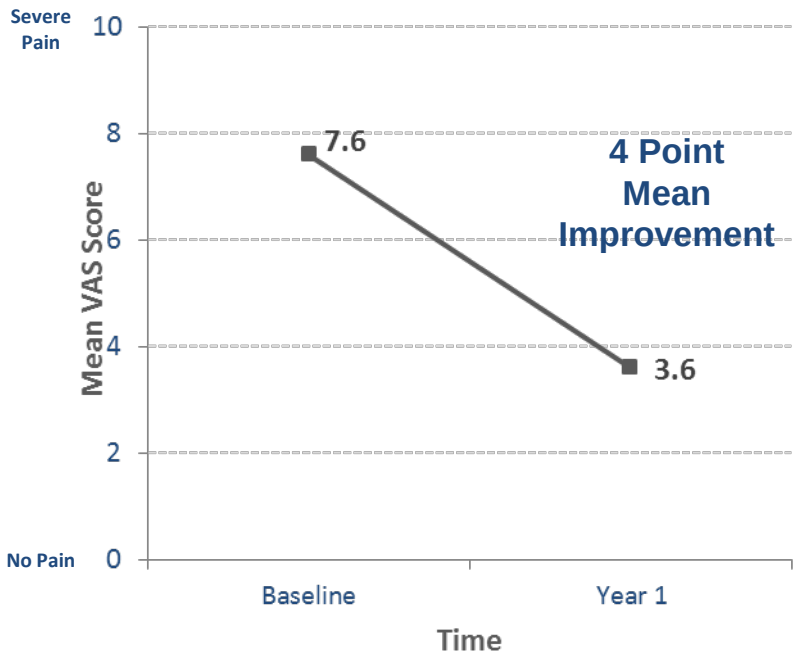
100 Patients = Less than 24 Hours

Reduced Pain & Improved Mobility

Durable at Year 1

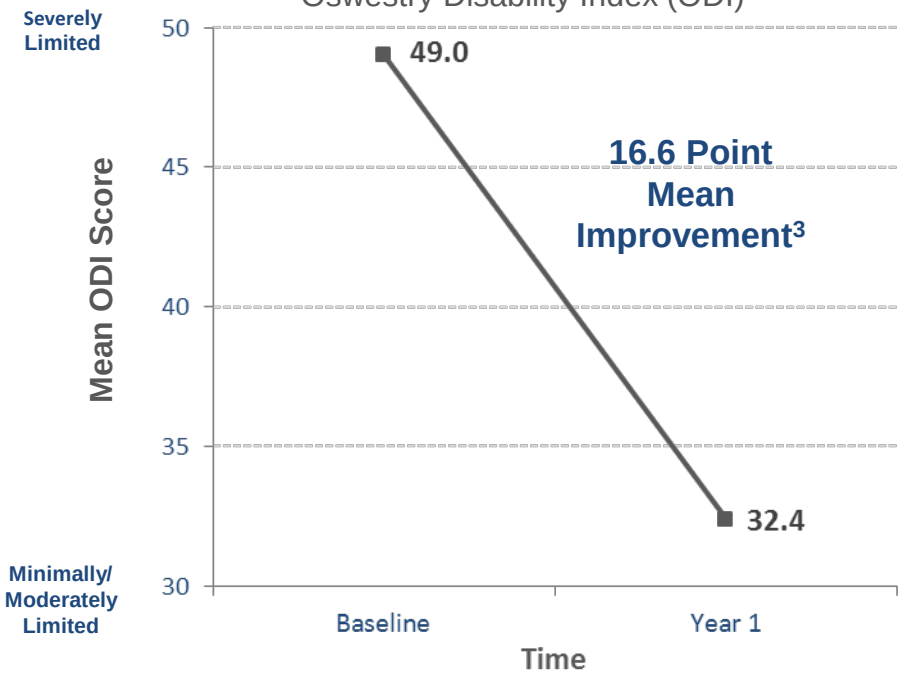
VAS Over Time (Responders[1])

Visual Analog Scale (VAS) 1–10



ODI Over Time (Responders[2])

Oswestry Disability Index (ODI)



Clinically Relevant

- **79%** of all Year 1 Patients were Responders[1]
- Mean Pain – **53% Reduction**

Statistically Significant

- *p<0.0001, t-test*

Clinically Relevant

- Mean Mobility – **34% Increase**

Statistically Significant

- *p<0.0001, t-test*

[1]Responders defined as VAS reductions ≥ 1.

[2]The published approximate MCID for the ODI version utilized in this study is 6.0 (JM Fritz, JJ Irrgang, Physical Therapy February 2001 vol. 81 no. 2 776–788).

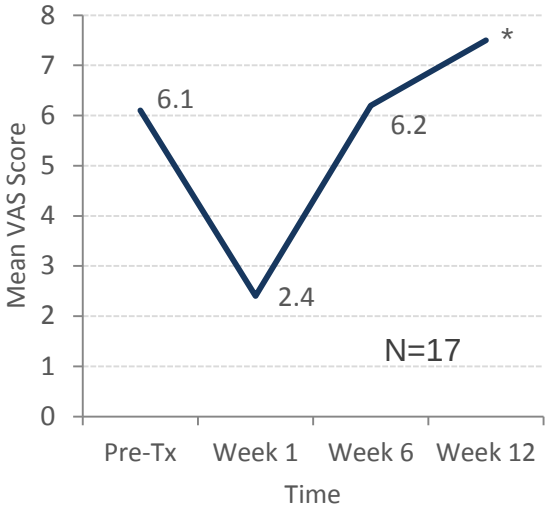
[3]Year 1 mean ODI improvement of 16.6 points represents 79% of all year 1 patients (responders).

Decompression Required to Treat NC

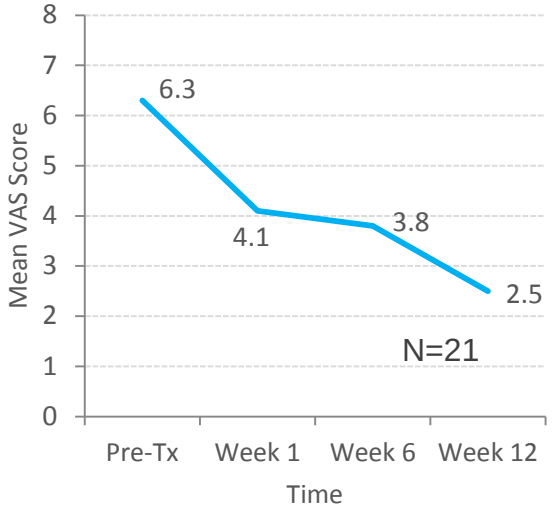
ESI vs. Percutaneous Laminotomy Decompression[1]

- Prospective, randomized, double-blind, single-center study
- 100% of patients had Neurogenic Claudication Symptoms

ESI



PLD



- **<u>Only</u>** patients treated with PLD experienced long term pain relief from NC symptoms
- After 6 weeks, patients were unblinded & 100% of patients treated with ESI crossed over to PLD
  - Crossover patients experienced similar improvement as PLD cohort

[1]Brown, L. A Double-blind, Randomized, Prospective Study of Epidural Steroid Injection vs. The *mild* Procedure in Patients with Symptomatic Lumbar Spinal Stenosis. *Pain Practice*, 2012.
*n=2 as all other patients had crossed over to *mild*. These 2 patients crossed over to *mild* after week 12.

Two-Year Outcomes[1]

- Approx. 75% of 1 Year Patients have reported outcomes at 2 years
- Findings are consistent with 1 year outcomes
- Published in *Clinical Journal of Pain* on Feb 26th 2013

	Baseline	2 Year	Mean Improvement
Mean VAS (Responders[2])	7.9	4.1	3.8 points
Mean ODI (Responders[2])	50.5	38.9	11.6 points

[1]Chopko, B. Long-term Results of Percutaneous Lumbar Decompression for LSS Two-Year Outcomes. *Clin J Pain* 2013; DOI. 10.1097/AJP.0b013e31827fb803 [Epub ahead of print].
[2]Responders defined as VAS reductions $\geq$ 1. Response rate 71.1%.

Procedure Safety in Clinical Trials:

Percutaneous Decompression Laminotomy vs. Open Surgery

	Percutaneous Decompression Procedure*	OPEN SURGERY[2] Laminotomy/Laminectomy with or without Fusion
Number of Patients	389[1]	394
Dural Tear	0%	9.2%
Blood Transfusion	0%	14.3%
Overall Adverse Events		
Intraoperative	0%	9.9%
Postoperative	0%	12.3%

***No major intraoperative or postoperative Percutaneous Decompression Laminotomy device or procedure-related adverse events (blood loss requiring transfusion, dural tear, hematoma, nerve root damage) reported in any clinical studies. A total of 7 adverse events have been reported in over 13,000 commercial cases, a rate of 0.06%.**

[1]1. MiDAS I (78 Patients) 2. Single-Site Series (42 Patients) 3. *mild* vs. ESI (38 Patients) 4. Safety Series (90 Patients) 5. Single-Site Long Term Series (46 Patients) 6. MiDAS II (55 Patients) 7. Cleveland Clinic Study (40 Patients) (see bibliography)

[2]Weinstein, et al., for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794–810.

Health Care System Burden

Health Care System Impact

	Percutaneous Decompression Procedure	vs.	Traditional Open Decompression Surgery
Hospital Stay	<1 Day[1]		3-5 Days[4]
Complication Rate – Dural Tear / Blood Loss Requiring Transfusion	<0.06% Commercial[2] (13,000 cases in 45 states) 0% all clinical trials[1]		23.5%[5]
Anesthesia	MAC/Light		General
Average Medicare Reimbursement	$4,760[6]		$23,724[4]

Lack of overnight hospital stay & no general anesthesia equates to much lower hospital charges.

Medicare cost savings= $18,964 or 80%

[1] Based on *mild*® procedure data collected in all clinical trials. No major intraoperative or postoperative *mild* Device or procedure-related adverse events (blood loss requiring transfusion, dural tear, hematoma, nerve root damage) reported in any clinical studies.
[2] Based on *mild*® procedure data collected in all reported commercial cases.
[3] Based on *mild*® procedure data collected in all clinical trials.
[4] Deyo, Mizra, Martin, Kreuter, Goodman, Jarvik. Trends, Major Medical Complications, & Charges Associated With Surgery for Lumbar Spinal Stenosis in Older Adults. JAMA, Vol. 303 No. 13.
[5] Weinstein, et al., for the SPORT Investigators. Surgical vs. Nonsurgical Therapy for LSS. New Engl J Med. 2008;358:794–810.
[6] 2013 Medicare National Average Reimbursement for APC 0208 is $3,760, Physician Fees are Carrier priced and average at $1000 per procedure

The Case for Coverage

Percutaneous Decompression Laminotomy fulfills Medicare Coverage Criteria

- Percutaneous Decompression Laminotomy satisfies Medically Necessary & Reasonable criteria as defined in the Medicare Program Integrity Manual
  - FDA Cleared for "performing lumbar decompressive procedures"
  - 13,000 patients treated in 45 States
  - Robust clinical studies demonstrating efficacy & safety
  - Positive Medicare Coverage established in 23 states
  - "Reasonable & Necessary" affirmed by 132 ALJ decisions
- Medically necessary services must have been established as safe and effective and must be:
  - Consistent with the symptoms or diagnosis of the illness or injury under treatment
  - Necessary and consistent with generally accepted professional medical standards (e.g., not experimental or investigational)
  - Furnished by qualified personnel
  - At least as beneficial as an existing and available medically appropriate alternative

The Case for Coverage

- **Health Care System Burden Minimization:**
  - Outpatient/ASC (No overnight hospital stay required)
  - No general anesthesia required
  - 80% cost savings over reported simple open surgery decompression procedures
  - Unique code designed to track procedure results
- **Proven Safety & Efficacy:**
  - 11 Independent Clinical Trials & 16 Peer Reviewed Publications
    - Body of evidence contains Levels I, II and III clinical trial evidence
    - Statistically significant & clinically relevant pain & mobility improvement in all studies
    - Per SORT & other systems as presented in AHRQ = Grade A Recommendation
  - Extremely low complication rate = low risk (0% in clinical trials, <0.06% in commercial cases)
  - CMS included procedure on the ASC approved procedure list for 2013 based on safety profile

Current Medicare (MAC) Coverage: Percutaneous Decompression Laminotomy, CPT 0275T

Total number of states & MACs (Medicare Administrative Contractors) with positive coverage:

MAC	States Covered	Total States
CGS (Cigna Government Services)	KY, OH	2
Palmetto	NC, SC, VA, VW	4
Palmetto	CA, NV, HI	3
NHIC (National Heritage Ins Co)	MA, RI, NH, VT, ME	5
WPS (Wisconsin Physician Services)	IA, KS, NE, IA	4
WPS (Wisconsin Physician Services)	MI, IN	2
WPS (Wisconsin Physician Services)	MN, WI, IL	3
Total		23

Published Coverage Criteria

Coverage criteria published by WPS (Wisconsin Physician Services):

- "Lumbar canal stenosis is a common cause of chronic LBP and leg pain. Minimally invasive lumbar decompression (MILD) is a new procedure for pain relief from symptomatic central lumbar canal stenosis. It entails limited percutaneous laminotomy and thinning of the ligamentum flavum in order to increase the critical diameter of the stenosed spinal canal. WPS Medicare has concluded that clinical literature supports that the MILD procedure, when medically indicated, appears to be a safe and a likely effective option for treatment of neurogenic claudication in patients who have failed conservative therapy and have ligamentum flavum hypertrophy as the primary distinguishing component of the stenosis."

Thank You

Strength of Evidence: Evaluation of the Percutaneous Decompression Laminotomy Body of Evidence

Key elements in systems used to assess strength of evidence:

- **Quality:** Study design and minimization of opportunity for bias
- **Quantity:** Total number of studies, sample size or power, magnitude of treatment effect/mean change from baseline
- **Consistency:** Similar findings between similar and different study designs or populations on a given topic/reproducibility of the results across studies

Systems useful to assess strength of body of evidence:

- SORT[1] (*Strength of Recommendation Taxonomy* – Journal of Family Practice,) assesses strength as Grade A, B, or C
- Multiple systems presented in Agency for Health and Research Quality[2] (AHRQ Publication 02-E016) such as CEBM (Center for Evidence Based Medicine)
- Evaluating the body of evidence for Percutaneous Decompression Laminotomy using SORT or CEBM type systems:
  - Grade A recommendation

[1]Ebell MH, Siwek J, Weiss BD, et al. Strength of Recommendation Taxonomy (SORT): A patient-centered approach to grading evidence in the medical literature. *J Fam Pract* 2004;53(2):111-117.
[2]West S, King V, Carey TS, et al. Systems to rate the strength of scientific evidence. Agency for Healthcare Research and Quality (AHRQ) Publication No. 02-E016. *Evid Rep Technol Assess* 2002;47:1-204.