Evolving Clinical Developments in Interventional Pain Management, The *mild* Procedure

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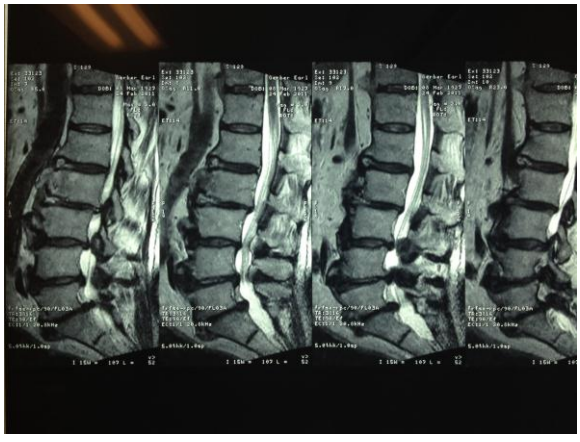
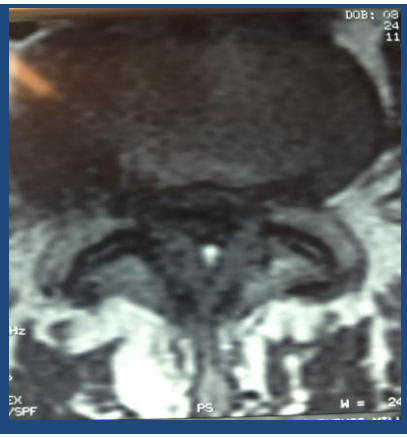
Earl's Story

- 81 y/o male presented 7/1/08 with decreasing ability to walk due to sensation of heaviness and pain from the hamstrings to the ankles.
- Can only walk 30-40 yards before having to stop
- Could mow the entire lawn last year in one session, now it takes him 3 days
- Minimal back pain
- No pain at rest

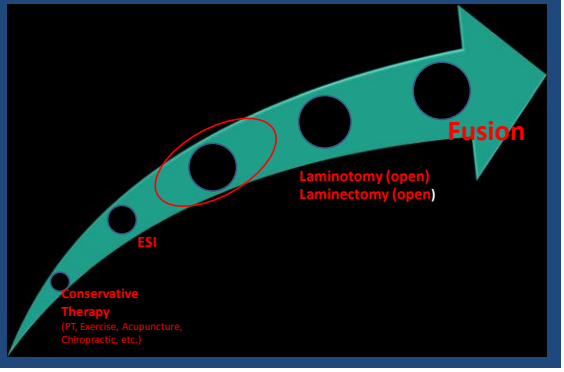




Treatment Timeline

- 8/1/08 Lumbar ESI 100% pain relief for until June 2009
- 9/2009 L4/5 TESI X2 50% pain relief until January 2010
- Patient told to seek surgical opinions L2-L5 Fusion, L3-L5 Fusion.
- Summer 2011 injections stop working.
- Now Takes 3 days to mow the lawn…

Current LSS Therapeutic Algorithm



Revolution in Interventional Pain Management

Imagine a spine procedure that…

- Therapeutically treats the underlying cause of LSS.
- Is performed primarily by the Interventional Pain Physician.
- Is safe by design since the most invasive part of the procedure is the epidurogram.
- Provides long term relief of neurogenic claudication symptoms.
- Has an extremely low complication rate and can be performed in ASC.

mild® Percutaneous Decompression Laminotomy

- FDA cleared
- Treats Lumbar Spinal Stenosis (LSS) caused by neurogenic claudication
- Outpatient procedure
- Fluoroscopically-guided
- No general anesthesia required
- No stitches required
- No implants left behind
- Approx. 10,000 patients treated in over 45 states

Complications & Biomechanical Change

Low Complication Rate & Extremely Low Biomechanical Change	VS.	High Complications Rate & Biomechanical Change
*Physical Therapy *Epidural Steroid Injections *Transcutaneous Electrical *Back Brace *Radio Frequency *Neuromodulation		*Laminectomy *Interspinous Spacers *Fusion

First procedure to treat underlying degenerative process of LSS that has both low complications & extremely low biomechanical change.

Opportunity

- **1.2M+** LSS patients diagnosed & in active treatment.[1]
- Painful, degenerative, age-related narrowing of the lumbar spinal canal.
- Patients are limited due to pain & immobility.
- Limited therapeutic options, short of open surgery.
- No existing surgical procedures to treat neurogenic claudication in the outpatient setting except *mild.*
- 94% of LSS patients have neurogenic claudication.[2]

[1]Longitudinal Medicare Database, Quorum Consulting.
[2]Hall S, Bartleson JD, Onofrio BM, Baker HL, Okazaki H, O'Duffy JD. Lumbar spinal stenosis. Clinical features, diagnostic procedures, & results of surgical treatment in 68 patients. Ann Intern Med 1985;103(2):271-5.

Identifying Neurogenic Claudication

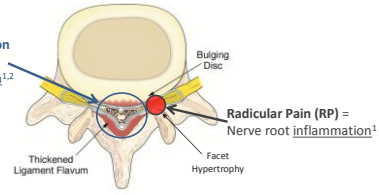
Clinical Presentation

- Uni or bilateral lower extremity pain post walking short distance or standing

- Relieved by short rest and forward flexion (reduces ligament compression)

LSS Causes

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



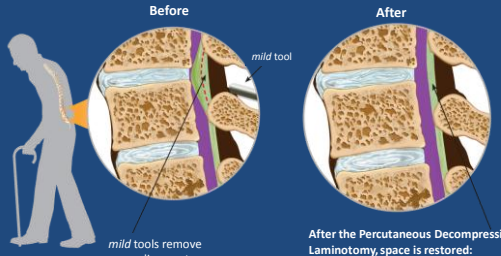
Different pathophysiological causes[1] require different treatments

- 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, & results of surgical treatment in 68 patients. Ann Intern Med 1985;103(2):271-5.

mild Treats LSS Through a 5.1mm Portal

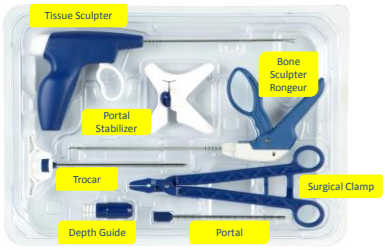
"Removing a Kink in a Drinking Straw"



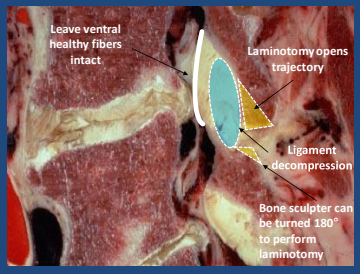
After the Percutaneous Decompression Laminotomy, space is restored:

- Reducing pressure in the spinal canal
- Reducing pain & numbness
- Restoring mobility

mild Device Kit

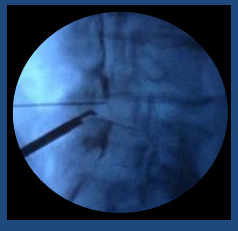


mild Procedure Steps

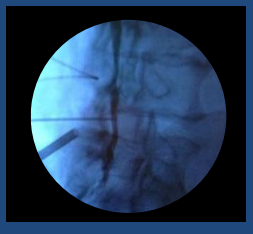


Visual Confirmation of Decompression

Pre *mild*



Post *mild*



Robust Clinical Research

8 Clinical Trials

1 Study Enrolling
100 Patients
•MiDAS ECO

7 Studies Completed
331 Patients
- Initial IRB 10 Series
- Safety Series
- MiDAS I
- MiDAS II
- Surgery Intolerant
- *mild*® vs. ESI
- Single-Site Series

431 Total Patients

No Major Complications Reported[1]
-No re-hospitalization ≤ 30 days
-No dural tear
-No blood transfusion

8 Published Peer-Reviewed Journal Articles

2012
- Pain Practice Journal- A Double-blind, Randomized, Prospective Study of Epidural Steroid Injection vs. The *mild*® Procedure in Patients with Symptomatic Lumbar Spinal Stenosis

2011
- Clinical Journal of Pain- *mild*® Procedure: Single-site Prospective IRB Study
- The Neuroradiology Journal- *mild*® Lumbar Decompression for the Treatment of Lumbar Spinal Stenosis
- Journal of Neurosurgical Review- Minimally Invasive Lumbar Decompression for Spinal Stenosis.
- Pain Practice Journal- Long-Term Results of Percutaneous Lumbar Decompression mild for Spinal Stenosis.

2010
- Pain Physician Journal- Retrospective Review of Patient Self-Reported Improvement & Post-Procedure Findings for *mild*®
- Pain Physician Journal- MIDAS I (*mild*® Decompression Alternative to Open Surgery): A Preliminary Report of a Prospective, Multi-Center Clinical Study
- Physician Journal - New Image Guided Ultra-Minimally Invasive Lumbar Decompression Method: The *mild*® Procedure

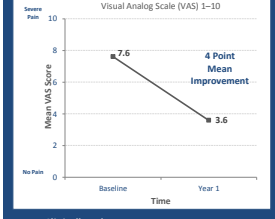
[1]No major intraoperative or postoperative mild Device or procedure-related adverse events (blood loss requiring transfusion, dural tear, hematoma, nerve root damage) reported in any clinical studies.

Proven Efficacy

MiDAS I Clinical Trial

Reduced Pain

VAS Over Time (Responders[1])
Visual Analog Scale (VAS) 1–10

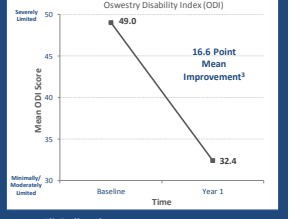


Clinically Relevant
- **79%** of all Year 1 Patients were Responders[1]
- Mean Pain – **53% Reduction**

Statistically Significant
- *p<0.0001, t-test*

Improved Mobility

ODI Over Time (Responders[2])
Oswestry Disability Index (ODI)

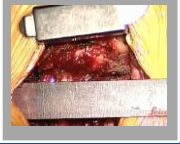


Clinically Relevant
- Mean Mobility – **34% Increase**

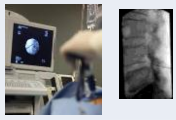
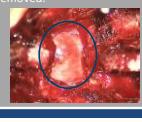
Statistically Significant
- *p<0.0001, t-test*

[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 Febr uary 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).

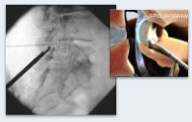
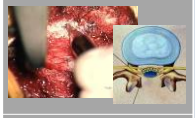
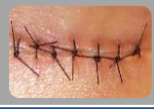
mild vs. Open Surgery

	Percutaneous Decompression Laminotomy	vs.	Traditional Decompression Surgery
Anesthesia	MAC/Light		General
Incision Length	5.1 mm (No stretching)		2-3" (Plus stretch) 

mild vs. Open Surgery

	Percutaneous Decompression Laminotomy	vs.	Traditional Decompression Surgery
Visualization	Fluoroscopic guidance 		Direct posterior 
Working Area in Relation to the Dura	Fluoroscopic visualization provides depth to accurately view location of the of dura. 		No direct visualization of dura until tissue/bone has been removed. 

mild vs. Open Surgery

	Percutaneous Decompression Laminotomy	vs.	Traditional Decompression Surgery
Bone & Tissue Removal	Minimal removal to achieved improved flow only. 		No feedback mechanism to identify adequate bone/tissue removal. 
Incision Closure	Adhesive bandage  5.1 mm		Stitches 

mild vs. Open Surgery

	Percutaneous Decompression Laminotomy	vs.	Traditional Decompression Surgery
Hospital Stay	Less than 24 hours[1]		3-5 Days[4]
Complication Rate – Dural Tear / Blood Loss Requiring Transfusion	▪ <0.03% Commercial[2] (10,000 cases in 45+ states) ▪ Zero all clinical trials[1]		23.5%[5]
Responder Rate	70-80%[3]		60-80%[5]

[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, Mirza, 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.

Greater Cost Savings & Lower Utilization of Health Care Resources

	Percutaneous Decompression Laminotomy	vs.	Traditional Decompression Surgery
Hospital Stay	Less than 24 hours		3-5 Days
Anesthesia	MAC/Light		General
Procedure Cost	$3,536*		$23,724**

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

Cost savings= $20,188 or 85.1%

** 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.
* 2011 Medicare National Average Reimbursement for APC 0208 is $3,536.

Current Status of Medicare Coverage & Payment

- **AMA CPT® Category III code 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.
- Current coverage is dependent on local Medicare Administrative Contractors (MAC) decision. Some are covering the procedure and some are not.
- The code is <u>not</u> currently approved for Medicare reimbursement in the ASC
- Facility payment maps to APC 0208, which averages $3,536
- Physician payment: The clinical work associated with mild would be most clinically-similar to that of CPT code 63030, which had a national average payment of $962 in 2011
- *mild* has been performed in ASC for cash pay patients

What is Next for Coverage & Payment?

- Coverage in all MAC Jurisdictions
- Code modification to allow for modifiers
  - Category III code changes are announced every July and January and implemented 6 months later
- Request for an ASC ready code
  - Would be the first ASC ready laminotomy procedure
  - Time to achieve an ASC ready code is variable
- Category I
  - Earliest approval would be in 2013 with implementation in 2014 based on CPT cycle
- Widespread commercial insurance coverage

How Long Does It Take to Get From Category III to Category I?

Category III			Category I		Cat III Release to Cat I Effective (Years)
Code	Release Date	Descriptor	Code	Effective Date	
0056T	Jul-03	Computer-assisted musculoskeletal surgical navigational orthopedic procedure	20985	Jan-08	4.5
0066T	Jul-04	Ocular photoscreening, with interpretation and report, bilateral	99174	Jan-08	3.5
0082T	Jul-04	Stereotactic body radiation therapy, treatment delivery, one or more treatment areas, per day	77373	Jan-07	2.5
0084T	Jul-04	Insertion of a temporary prostatic urethral stent	53855	Jan-10	5.5
0090T	Jan-05	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression) cervical, single interspace	22856	Jan-09	4.0
0093T	Jan-05	Removal of total disc arthroplasty, anterior approach cervical; single interspace	22864	Jan-09	4.0
0096T	Jan-05	Revision of total disc arthroplasty, anterior approach cervical; single interspace	22861	Jan-09	4.0
0115T-0117T	Jul-05	Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention,	99605-99607	Jan-08	2.5
0120T	Jul-05	Cryoablation of breast fibroadenomas	19105	Jan-07	1.5
0123T	Jul-05	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy	50593	Jan-08	2.5
0140T	Jul-05	Exhaled breath condensate ph	83987	Jan-10	4.5
0144T-0151T	Jul-05	Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium	75571-75574	Jan-10	4.5
0152T	Jul-05	Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation and instrument calibration	34806	Jan-08	2.5
0154T	Jul-05	Noninvasive physiologic study of implanted wireless pressure sensor in aneurysmal sac following endovascular repair, complete study including recording, analysis of and waveform tracings, interpretation and report pressure	93982	Jan-08	2.5
0162T	Jan-05	Electronic analysis and programming, reprogramming of gastric neurostimulator (i.e., morbid obesity)	95980-82	Jan-08	3.0
0170T	Jul-06	Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])	46707	Jan-10	3.5
0194T	Jul-08	Procalcitonin (PCT)	84145	Jan-10	1.5

Time May Vary Dramatically. Median of Sample = 3.5 Years From Category III Code Release to Category I Effective

Therapeutically Treat LSS in the ASC

mild perfect fit for ASC

- Favorable safety profile & low complication rates
- High efficacy & patient satisfaction
- Lower utilization of health care resources
- Outpatient procedure with no general anesthesia

ASC Market Opportunity

- LSS patients:
  - Elderly population with multiple co-morbidities
  - High users of healthcare
- Patient satisfaction generates repeat customers and positive referrals to the ASC.
- Only decompression procedure on the horizon to treat LSS that has potential to be performed in ASC.

Success

- 10/2011 L3/4 and L4/5 Mild procedure
- Complete relief of pain, leg fatigue
- Regular 2-3 mile walks
- Back to mowing the lawn

Earl
May 2012

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