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)

Initial symptom onset generally occurs between 50 – 60 years of age

Limited therapeutic options, short of open surgery

Impacts 1.2M Patients in U.S.

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)

¹Longitudinal Medicare Database, Quorum Consulting
Different pathophysiologic causes\textsuperscript{1} require different treatments

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


LSS Treatment Options

More Invasive

Conservative Therapy: Physical Therapy, Exercise
Percutaneous Decompression Laminotomy
Laminotomy/Laminectomy
Epidural Steroid Injections
Interspinous Spacers
Fusion

Less Invasive

Percutaneous Decompression Laminotomy achieves the safety profile of conservative treatments with the efficacy of therapeutic treatments.
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.
  \[ \text{sq.area} = \pi r^2 \]
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

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

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

1Based on procedure data collected in all clinical trials.
52013 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

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

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

Study Background

MiDAS I

- 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

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

Length of Stay
100 Patients = Less than 24 Hours

Total Levels / Patient
89% of levels were treated bilaterally
Reduced Pain & Improved Mobility
Durable at Year 1

Clinically Relevant
• 79% of all Year 1 Patients were Responders¹
• Mean Pain – 53% Reduction

Statistically Significant
• p<0.0001, t-test

Clinically Relevant
• Mean Mobility – 34% Increase
Statistically Significant
• p<0.0001, t-test

¹Responders defined as VAS reductions ≥ 1.
²The 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).
³Year 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

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

**ESI**

<table>
<thead>
<tr>
<th>Time</th>
<th>Week 1</th>
<th>Week 6</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS Score</td>
<td>2.4</td>
<td>6.2</td>
<td>*</td>
</tr>
</tbody>
</table>

\[N=17\]

**PLD**

<table>
<thead>
<tr>
<th>Time</th>
<th>Week 1</th>
<th>Week 6</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS Score</td>
<td>4.1</td>
<td>3.8</td>
<td>2.5</td>
</tr>
</tbody>
</table>

\[N=21\]

- **Only** 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.}
\(^2^{n=2 as all other patients had crossed over to mild. These 2 patients crossed over to mild after week 12.}
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

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>2 Year</th>
<th>Mean Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean VAS (Responders)</strong></td>
<td>7.9</td>
<td>4.1</td>
<td>3.8 points</td>
</tr>
<tr>
<td><strong>Mean ODI (Responders)</strong></td>
<td>50.5</td>
<td>38.9</td>
<td>11.6 points</td>
</tr>
</tbody>
</table>

2Responders defined as VAS reductions > 1. Response rate 71.1%.
**Procedure Safety in Clinical Trials:**
**Percutaneous Decompression Laminotomy vs. Open Surgery**

<table>
<thead>
<tr>
<th></th>
<th>Percutaneous Decompression Procedure*</th>
<th>OPEN SURGERY(^2) Laminotomy/Laminectomy with or without Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Patients</strong></td>
<td>389(^1)</td>
<td>394</td>
</tr>
<tr>
<td><strong>Dural Tear</strong></td>
<td>0%</td>
<td>9.2%</td>
</tr>
<tr>
<td><strong>Blood Transfusion</strong></td>
<td>0%</td>
<td>14.3%</td>
</tr>
<tr>
<td><strong>Overall Adverse Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intraoperative</strong></td>
<td>0%</td>
<td>9.9%</td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td>0%</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

*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%.

\(^1\) 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)

Health Care System Burden
# Health Care System Impact

<table>
<thead>
<tr>
<th>Hospital Stay</th>
<th>Percutaneous Decompression Procedure: &lt;1 Day&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Traditional Open Decompression Surgery: 3-5 Days&lt;sup&gt;4&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication Rate</td>
<td>&lt;0.06% Commercial&lt;sup&gt;2&lt;/sup&gt; (13,000 cases in 45 states)</td>
<td>23.5%&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>– Dural Tear / Blood Loss Requiring Transfusion</td>
<td>0% all clinical trials&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Anesthesia</td>
<td>MAC/Light</td>
<td>General</td>
</tr>
<tr>
<td>Average Medicare Reimbursement</td>
<td>$4,760&lt;sup&gt;6&lt;/sup&gt;</td>
<td>$23,724&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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

**Medicare cost savings = $18,964 or 80%**

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<sup>1</sup> 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.

<sup>2</sup> Based on mild® procedure data collected in all reported commercial cases.

<sup>3</sup> Based on mild® procedure data collected in all clinical trials.


<sup>6</sup> 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:

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

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