Evolving Clinical Developments in Interventional Pain Management, The mild Procedure

Mark Coleman, M.D.
Director of Advanced Therapies
National Spine and Pain Centers, LLC
Baltimore, MD

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

Conservative Therapy
PT/Exercise, Acupuncture, Chiropractic, etc.
ESI
Laminotomy (open)
Laminectomy (open)
Fusion
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

<table>
<thead>
<tr>
<th>Low Complication Rate &amp; Extremely Low Biomechanical Change</th>
<th>High Complications Rate &amp; Biomechanical Change</th>
</tr>
</thead>
</table>
| *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

¹Longitudinal Medicare Database, Quorum Consulting.
**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
- **Radicular Pain (RP)** = Nerve root inflammation

Different pathophysiological causes require different treatments

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

**mild** Treats LSS Through a 5.1mm Portal

“Removing a Kink in a Drinking Straw”

- Before
- After

mild tool removes excess ligament

After the Percutaneous Decompression Laminotomy, space is restored
- Reducing pressure in the spinal canal
- Reducing pain & numbness
- Restoring mobility
**mild Device Kit**

- Tissue Sculpter
- Portal Stabilizer
- Trocar
- Bone Sculptor Reversal
- Portal
- Depth Guide
- Rongeur
- Surgical Clamp

**mild Procedure Steps**

1. Laminotomy opens trauma.
2. Leave ventral healthy fibers intact.
3. Bone sculptor can be turned 180° to perform laminotomy.

**Visual Confirmation of Decompression**

- Pre mild
- Post mild
Robust Clinical Research

8 Clinical Trials
1 Study Enrolling 100 Patients (MIDAS ECO)
1 Study Completed
431 Total Patients
No Major Complications Reported
- No rehospitalization
- No death

8 Published Peer-Reviewed Journal Articles

2012
• Pain Practice Journal - Minimally Invasive Percutaneous Interventional Therapy in the Treatment of Lumbar Spinal Stenosis and Pain
• Clinical Journal of Pain - Mild Procedure: Single-Site Prospective IRB Study

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

2010
• Pain Practice Journal - Long-Term Results of Percutaneous Lumbar Decompression Mild® for Spinal Stenosis.

Proven Efficacy
MiDAS I Clinical Trial

Reduced Pain
Visual Analog Scale (VAS) 0-10

Improved Mobility
Oswestry Disability Index (ODI)

Clinically Relevant
Mean Pain - 53% Reduction
Statistically Significant
p<0.0001, t-test

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

mild vs. Open Surgery

| Percutaneous Decompression Laminotomy vs. Traditional Decompression Surgery |
|---|---|
| **Anesthesia** | **General** |
| MAC/Light | **2-3” (Plus stretch)** |
| **Incision Length** | **5.1 mm (No stretching)** |
### mild vs. Open Surgery

#### Percutaneous Decompression Laminotomy vs. Traditional Decompression Surgery

**Visualization**
- Fluoroscopic guidance
- Fluoroscopic visualization provides depth to accurately view location of the dura.

**Working Area in Relation to the Dura**
- No direct visualization of dura until tissue/bone has been removed.

#### Bone & Tissue Removal
- Minimal removal to achieve improved flow only.
- No feedback mechanism to identify adequate bone/tissue removal.

#### Incision Closure
- Adhesive bandage
  - 5.1 mm
- Stitches

#### Hospital Stay
- Less than 24 hours
- 3-5 Days

#### Complication Rate
- Dural Tear / Blood Loss Requiring Transfusion
  - <0.03% Commercial (10,000 cases in 45 states)
  - Zero all clinical trials

#### Responder Rate
- 70-80%
Greater Cost Savings & Lower Utilization of Health Care Resources

| Percutaneous Decompression Laminotomy vs. Traditional Decompression Surgery |
|-------------------------------------------------|-------------------------------------------------|
| **Hospital Stay**                               | **Traditional Decompression Surgery**            |
| Less than 24 hours                              | 3-5 Days                                        |
| **Anesthesia**                                  | **Anesthesia**                                  |
| MAC/Light                                       | General                                         |
| **Procedure Cost**                              | **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%


*2011 Medicare National Average Reimbursement for APC 0208 is $3,536.
**2011 Medicare National Average Reimbursement for APC 0208 is $23,724.

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., fluoroscopy, CTS), 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 not 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?

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Code</th>
<th>Description</th>
<th>Time (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0056T</td>
<td>Computer-assisted musculoskeletal surgical navigational orthopedic procedure</td>
<td>20985</td>
<td>Jan - 08</td>
<td>4.5</td>
</tr>
<tr>
<td>0065T</td>
<td>Ocular photoscreening, with interpretation and report, bilateral</td>
<td>99174</td>
<td>Jan - 08</td>
<td>3.5</td>
</tr>
<tr>
<td>0082T</td>
<td>Stereotactic body radiation therapy, treatment delivery, one or more treatment areas, per day</td>
<td>77373</td>
<td>Jan - 07</td>
<td>2.5</td>
</tr>
<tr>
<td>0084T</td>
<td>Insertion of a temporary prostatic urethral stent</td>
<td>53855</td>
<td>Jan - 10</td>
<td>5.5</td>
</tr>
<tr>
<td>0090T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression) cervical; single interspace</td>
<td>22856</td>
<td>Jan - 09</td>
<td>4.0</td>
</tr>
<tr>
<td>0093T</td>
<td>Removal of total disc arthroplasty, anterior approach cervical; single interspace</td>
<td>22864</td>
<td>Jan - 09</td>
<td>4.0</td>
</tr>
<tr>
<td>0096T</td>
<td>Revision of total disc arthroplasty, anterior approach cervical; single interspace</td>
<td>22861</td>
<td>Jan - 09</td>
<td>4.0</td>
</tr>
<tr>
<td>0115T</td>
<td>Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention,</td>
<td>99605</td>
<td>Jan - 08</td>
<td>2.5</td>
</tr>
<tr>
<td>0120T</td>
<td>Cryoablation of breast fibroadenomas</td>
<td>19105</td>
<td>Jan - 07</td>
<td>1.5</td>
</tr>
<tr>
<td>0135T</td>
<td>Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy</td>
<td>50593</td>
<td>Jan - 08</td>
<td>2.5</td>
</tr>
<tr>
<td>0140T</td>
<td>Exhaled breath condensate pH</td>
<td>83987</td>
<td>Jan - 10</td>
<td>4.5</td>
</tr>
<tr>
<td>0144T</td>
<td>Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium</td>
<td>75571</td>
<td>Jan - 10</td>
<td>4.5</td>
</tr>
<tr>
<td>0153T</td>
<td>Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation and instrument calibration</td>
<td>34806</td>
<td>Jan - 08</td>
<td>2.5</td>
</tr>
<tr>
<td>0154T</td>
<td>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</td>
<td>93982</td>
<td>Jan - 08</td>
<td>2.5</td>
</tr>
<tr>
<td>0162T</td>
<td>Electronic analysis and programming, reprogramming of gastric neurostimulator (i.e., morbid obesity)</td>
<td>95980</td>
<td>Jan - 08</td>
<td>3.0</td>
</tr>
<tr>
<td>0170T</td>
<td>Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])</td>
<td>46707</td>
<td>Jan - 10</td>
<td>3.5</td>
</tr>
<tr>
<td>0194T</td>
<td>Procalcitonin (PCT)</td>
<td>84145</td>
<td>Jan - 10</td>
<td>1.5</td>
</tr>
</tbody>
</table>

*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