Advancing Technique for Lumbar Spinal Stenosis

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Relievechronicpainnow.org

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The Problem: A Carousel of Pain

- Our population is aging – enter 73 million baby boomers!
- 6.3M moderate LSS patients secondary to Neurogenic Intermittent Claudication
- 380K New patients added annually
- Patients are on a carousel of pain, looking for long-term relief

Source: data on file
WHAT IS LUMBAR SPINAL STENOSIS (LSS)?

A gradual narrowing of the space in the spine where nerves pass through. The narrowing can cause a “pinching” on the lower back nerves resulting in tingling, numbness, weakness and/or pain in one or both legs and/or lower back. Relief can be experienced when bending forward slightly or sitting.
The Problem: Neurogenic Intermittent Claudication Symptomatology

<table>
<thead>
<tr>
<th>CENTRAL</th>
<th>LATERAL RECESS</th>
<th>FORAMINAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudication</td>
<td>Claudication</td>
<td>Claudication</td>
</tr>
<tr>
<td>Back, Buttocks, and Leg Pain</td>
<td>Radicular Pain</td>
<td>Radicular Pain</td>
</tr>
<tr>
<td>Very Positional</td>
<td>Weakness</td>
<td>More</td>
</tr>
<tr>
<td>Possible Weakness</td>
<td>Is Rare</td>
<td>Dermatomal</td>
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<tr>
<td></td>
<td></td>
<td>Burning/Tingling</td>
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</tbody>
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Radicular Pain is stenosis moving laterally to the peripheral elements

Lack of symptom relief with flexion is exclusionary for Vertiflex Procedure patient selection
The Vertiflex Procedure: 
Brace the Space

For Patients with Neurogenic Intermittent Claudication Secondary to LSS

Canal and foraminal space for nerves increase in FLEXION

Canal and foraminal space for nerves decrease in EXTENSION

The Vertiflex Procedure limits EXTENSION

Limiting extension reduces or eliminates the compression of nerves at the implanted level(s)
The Vertiflex Procedure is a simple, minimally invasive treatment which can provide effective, long-term relief.

- FDA approved
- Small incision
- Same-day procedure
- Does not require removal of bone or tissue
- Speedy recovery time
- Low risk of infection or complications
- Can provide long-term relief
- More than 10,000 patients treated since 2016

BEFORE VERTIFLEX PROCEDURE
Pinched nerves causing pain

AFTER VERTIFLEX PROCEDURE
Spacer provides relief off the pinched nerves

*Superior Indirect Decompression System (IDS)"

The Vertiflex Procedure

HOW IT’S DONE

The Vertiflex Procedure uses a small spacer designed to relieve pressure on the nerves.

Your physician will place the spacer between the spinous processes (bony projections off the back of the vertebra) through a small tube that is approximately the size of a dime.

Once the spacer is placed, it is intended to relieve pressure off the nerves, and reduce the pain, without having to lean forward or sit down.
Indirect decompression achieved by restriction of extension

MRI: Pre & Post Vertiflex Imaging

Pre-op

Post-op

The Vertiflex Procedure
L3/4
Clinical Data: IDE RCT- Opioid Use

85% decrease in the proportion of subjects using opioids compared to baseline at 5 years\(^*\)

Figure 1 Opioid-medication prevalence (%) by follow-up interval for all study subjects (n=190).

Note: Sample sizes were 190 (prestudy, baseline), 181 (week 6), 173 (month 3), 174 (month 6), 163 (month 12), 150 (month 18), 150 (month 24), 125 (month 36), 106 (month 48), and 107 (month 60).

*Study completers

Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis
Patient Selection: Clinical Presentation

- Lack of symptom relief with flexion is exclusionary for the Vertiflex Procedure patient selection
- Extension provokes symptoms, pain / weakness in legs
- "Shopping Cart" Sign: Leaning forward while walking to ambulate more comfortably
- Flexion: Sitting relieves symptoms*

*Lack of symptom relief with flexion is exclusionary for the Vertiflex Procedure patient selection*
Helping Existing Patients

Consider Vertiflex if the Patient Record Includes:

• Pain, Cramping, Weakness, or Tingling in the Back, Buttocks, and Legs
• Spinal Stenosis Diagnosis
• Lumbar Radiculopathy Diagnosis
• Difficulty Walking/Standing without Rest

• Reduced Function
• Repeated ESI treatment
• RFA Treatment
• Suggested Referral to Surgeon
• Failing Spinal Cord Stimulator
THE RESULTS ARE REAL

The Vertiflex Procedure has collected 5 years of clinical data proving that it is effective for LSS patients.³

9/10³ PATIENTS Are satisfied with the Vertiflex Procedure

85%⁴ Drop in patients using opioids

81%³ Improvement in physical function

75%³ Reduction in leg pain symptoms

*Among study completers at 5 years

REAL PATIENTS. REAL RESULTS.

GLORIA, 75
“The day of my procedure, I went to visit the butterfly park in Scottsdale. I felt happy and walked around without any problems!”

BILL, 77
“I have no more leg pain which was killing me before, from my hip to my ankle. That is completely gone!”
Clinical Data: Overview

Significant Clinical Improvement Maintained Over 5 Years in the IDE Randomized Control Trial

- **66%** improvement in back pain scores from baseline at 5 years[^4]
- **75%** improvement in leg pain scores from baseline at 5 years[^4]
- **85%** decrease in the proportion of patients using opioids compared to baseline at 5 yrs[^5]
- **90%** Patient Satisfaction at 5 years[^4]

[^4]: Study Completers
[^5]: Study Completers
• In order to best meet the needs of your patient and to maximize efficiency, it is ideal for your patient to have a recent MRI & Flex-Ex Films prior to the Vertiflex eval/consult.

• Patients have multiple pain generators. Vertiflex is one of many exciting minimally invasive procedures Interventional Spine and Pain have to offer.
Thank you!

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Questions?

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