

mild[®] 50-Patient Single-Center Six-Month Clinical Outcomes Study Report

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Background

Neurogenic claudication is a common symptom in the patient presenting with Lumbar Spinal Stenosis. *mild* is a commercially available treatment for pain relief from symptomatic lumbar spinal stenosis. Using a dorsal approach under fluoroscopic imaging, space is created as bone and tissue are resected during the minimally invasive *mild* procedure, with minimal surrounding structure disturbance.

Objectives

To present *mild* patient safety and efficacy outcomes achieved in a Single-Center Study on all available patients through six-months following treatment of symptomatic LSS.

Methods

Fifty patients have been treated in this Single-Center Study using the *mild* procedure for lumbar decompression. Appropriate patient selection is emphasized and comprehensive safety and pain and mobility outcomes are reported. Outcomes are assessed using validated outcomes instruments including Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire, and SF-12v2[®] Health Survey.

Results

Six week results showed significant reduction of pain as measured by VAS. Improvement in physical function and mobility as measured by ODI was significant and clinically relevant. These patient outcomes demonstrated safe, favorable responses to *mild* therapeutic LSS treatment for all available patients through Week 26.

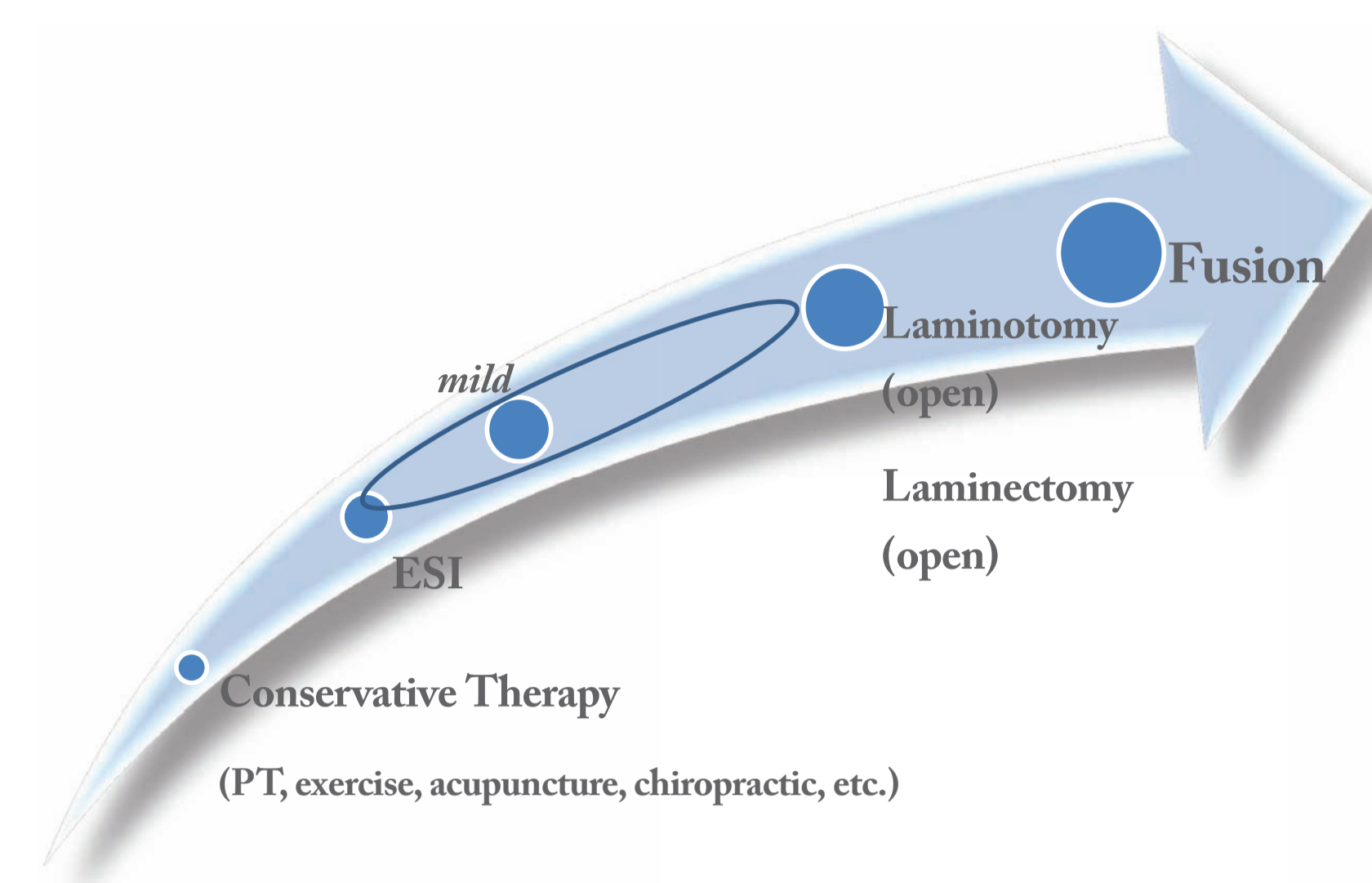
Conclusions

The *mild* procedure has proven to be a safe method for pain reduction and improved mobility in the symptomatic lumbar spinal stenosis patient. These results were achieved in a population presenting with multiple LSS co-morbidities such as disc protrusion, facet hypertrophy and osteophyte formation. The profile for *mild* candidates includes those patients having symptomatic neurogenic claudication resulting from multiple co-morbidities, one of which is hypertrophic ligamentum flavum. Post-study follow-up of this patient population will continue for up to two years post-treatment.

Key Words

Decompression, fluoroscopy, ligamentum flavum, lumbar, *mild*, minimally invasive, spine, stenosis

LSS Therapeutic Algorithm



mild Therapeutic Intervention

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

LOW Complication Rate & No Biomechanical Change	VS.	HIGH Complication Rate & Biomechanical Change
<ul style="list-style-type: none"> Physical Therapy Epidural Steroid Injections Transcutaneous Electrical Nerve Stimulation (TENS) Pain Pumps Radio Frequency Neuromodulation 		<ul style="list-style-type: none"> Laminectomy Interspinous Spacers Fusion

mild Pre-Treatment Clinical Findings

- Patients generally > 60 years old
- Primary complaint leg pain, numbness &/or weakness
- Symptoms occur while walking or prolonged standing
- Symptoms relieved by bending forward, sitting, or lying down
- Neurogenic back pain radiates to buttocks with ambulation
- Patient history of lumbar neurogenic claudication, confirmed via imaging studies

mild Procedure Description

- General anesthesia not required
- Posterior approach with fluoroscopic imaging
- Small *mild* Portal access (6 G, 5.1 mm)
- Minor resection of laminar bone
- No removal of major spinal support structures
- Debulk hypertrophic ligamentum flavum
- Bilateral one-level operative time < 1 hour
- Wound closed with sterile adhesive strip
- No implants left behind

Study Methodology

- Single-center analysis = Center for Pain Relief
 - 50 prospective, consecutive study patients
- Patients all tx with *mild* for symptomatic LSS
- Planned follow-up 2 years
- Device/procedure-related Serious Adverse Events
 - Comprehensive to 6 months, N= 50
- Patient reported outcomes (VAS & ODI)
 - Week 6, n=22 this report

Key Study Success Goals

- *mild* procedure completed as planned (typically < 1 hour and patient comfortable with light sedation)
- No *mild* device/procedure Significant Adverse Events (SAEs)
- Mobility improvement 15 points on ODI (An FDA panel has suggested a 15-point change from baseline in ODI score is clinically significant)
- VAS pain score improves ≥ 2 points on 10- point scale

Demographics- Study & Procedure

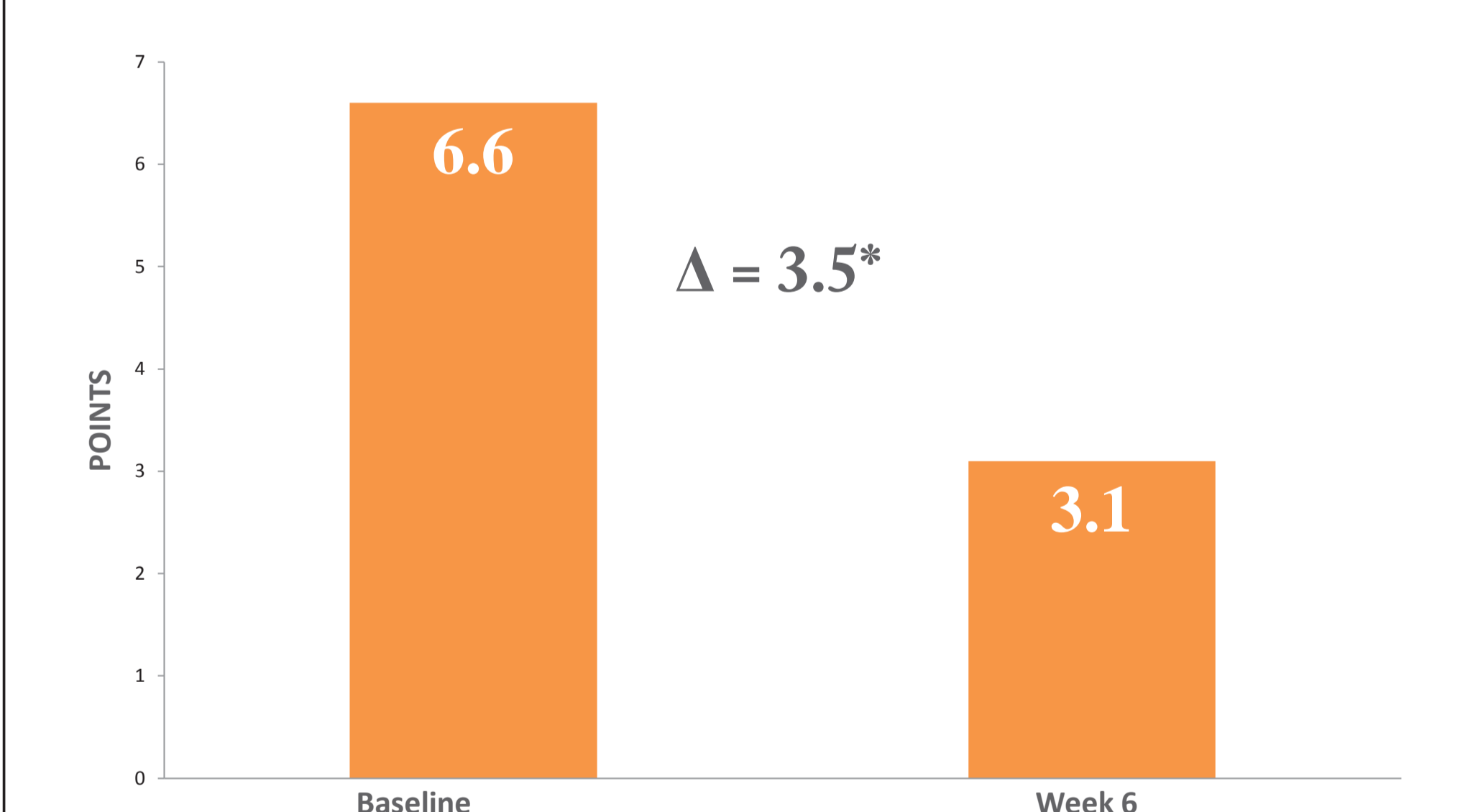
Single US Study Center	
Mean Age	67 Years
Patient Gender	Majority (64%) Female
Follow-up Range	Up to 6 months (Safety) Week 6 (Efficacy)
Length of Stay	All patients discharged the same day
Procedure Time (Mean)	< 1 hour duration

mild Single-Center Safety Comparisons

	Meta Analysis <i>mild</i> Study Patients	Single-Center <i>mild</i> Patients	Deer / Kapural Publication on <i>mild</i> Patients	SPORT* LSS Surgical Patients
Number of Patients	303	50	90	394
Dural Tears	0%	0%	0%	9.2%
Blood Transfusions	0%	0%	0%	14.3%
Overall Adverse Events	0%	0%	0%	Intraoperative Complications: 9.9% Postoperative Complications: 12.3%

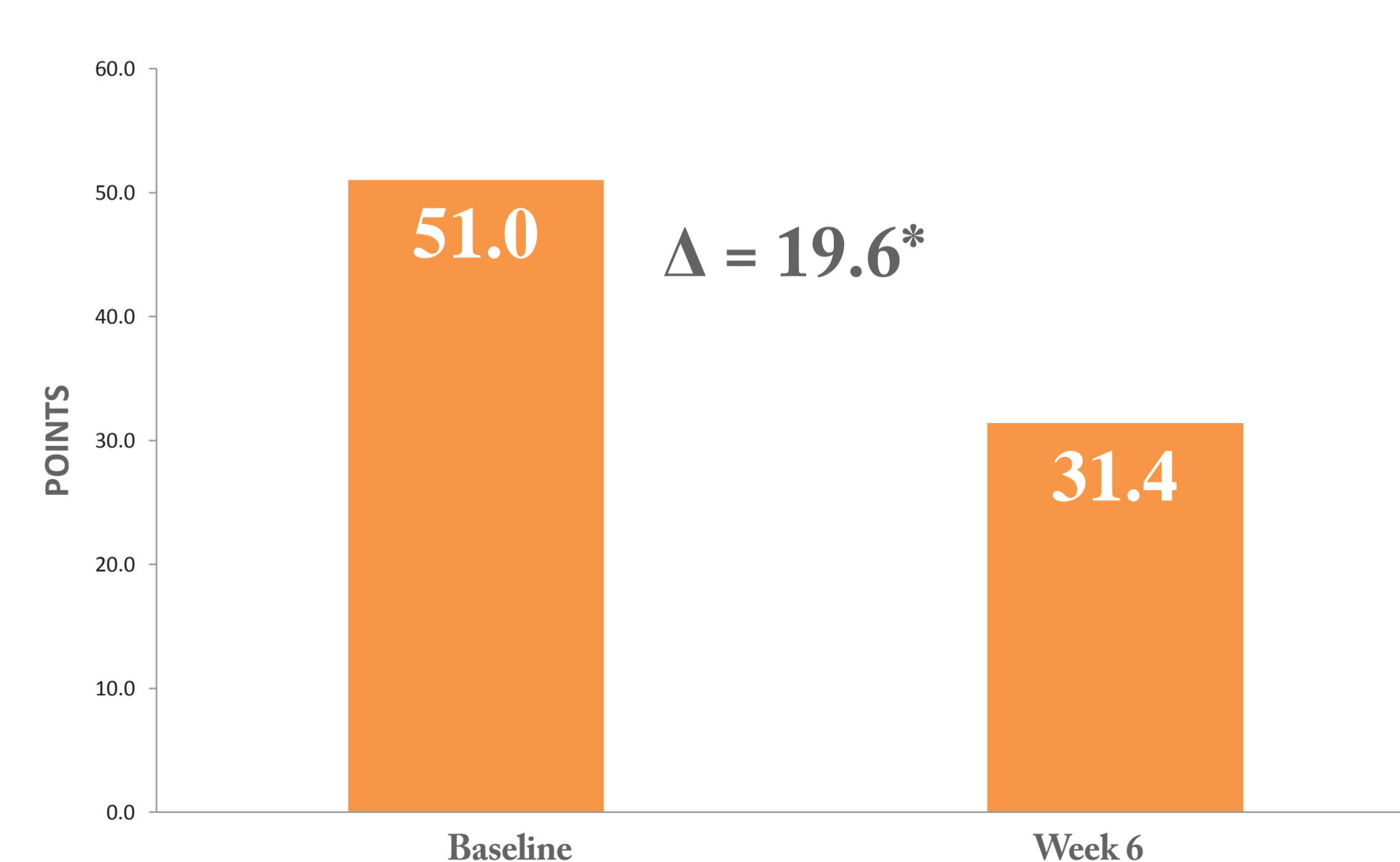
* Weinstein, et al, for the SPORT Investigators. Surgical versus Nonsurgical Therapy for LSS. NEJM 2008;358:794-810.

Mean VAS Improvement



* Clinical significance demonstrated by 2 point improvement; non-responders included = 2.2 point improvement.

Mean ODI Improvement



* Clinical significance demonstrated by 15-point ODI improvement (FDA Panel Guidance); non-responders included = 17 point improvement.

Conclusions

- *mild* provides a safe solution for LSS treatment
- Majority of *mild* patients experience clinically significant improvement in pain and mobility
- Patients are treated using local anesthesia
- Same day discharged is routine with *mild* procedure
- *mild* offers a new addition to standard treatment options for patients needing more than conservative symptom management, but less than potentially structurally destabilizing surgery