

# Comparative Study of Epidural Steroid Injection versus *mild*<sup>®</sup> Procedure in Patients Diagnosed with Symptomatic Moderate to Severe Lumbar Spinal Stenosis

## Background

Various minimally invasive and surgical options are used to perform lumbar decompressive procedures. The goal of the *mild* procedure is to effect a decompression with minimal surrounding tissue disruption. The standard medical therapy widely used to treat symptomatic lumbar spinal stenosis is a combination of pain medicine, epidural steroids (ESI) and/or physical therapy. Where conservative therapy fails, the common surgical procedures involve various techniques that range from an insertion of an interspinous decompression implant to moderate endoscopic or major open surgery. These all may result in various amounts of damage to large areas of tissue, muscle, ligaments and bone in the back. Recovery from the major surgical procedures in painful and can require several months of low activity and rest.

## Objectives

The purpose of this single-center, randomized, prospective, double-blind clinical study is to assess the clinical application and outcomes with *mild* devices versus epidural steroid injection in patients with symptomatic moderate to severe lumbar spinal stenosis.

## Methods

Patients with symptomatic lumbar spinal stenosis who meet the study enrollment criteria are randomized to either ESI or the *mild* procedure. Patients are treated with the *mild* procedure under radiographic image guidance as described in the *mild* product labeling, or with ESI. Neither the enrolling physician nor the subject is aware of the subject's ultimate treatment group. These patients are followed for a period of up to 6 months in order to assess patient outcomes. Complete enrollment will include 40 adult patients at one study center.

Documentation of concomitant and pain medication usage, neurological examination, Visual Analog Score (VAS), Quality of Life (SF-12), Oswestry Disability Index (ODI), and Zurich Claudication Questionnaire (ZCQ) are made during the scheduled screening/baseline physical examination prior to study treatment. Patient follow-up via telephone survey and office visits include documentation of the same above measures and any medication changes. Device-related and significant adverse events are documented throughout the study period.

## Results

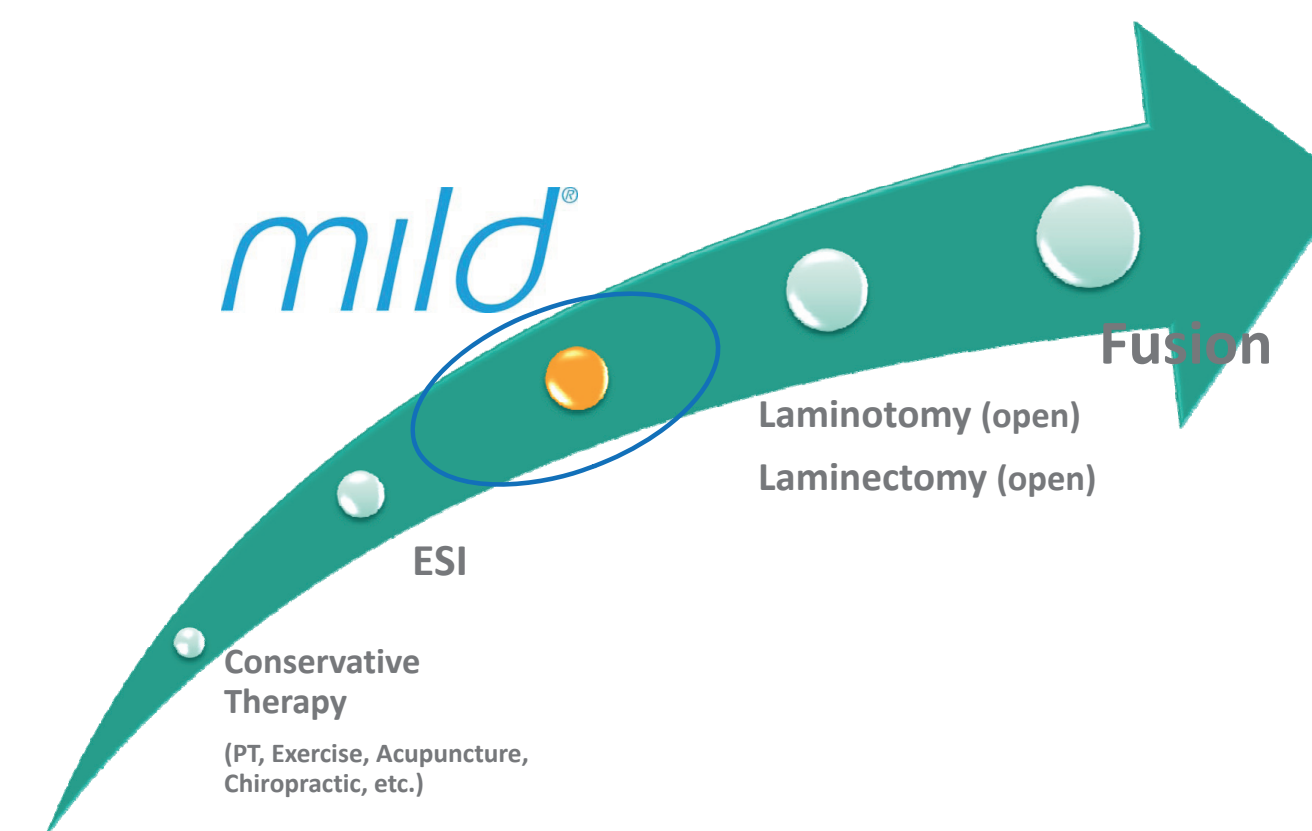
Enrollment is under way for this study, and is anticipated to be completed in 2010. The *mild* and traditional injection therapy groups will be analyzed separately for safety and effectiveness, and the two groups will be compared. Outcome measures to be evaluated include:

- Ability to perform treatments as planned free of technical complications
- Acceptable safety, consistent with other similar procedures
- Subject success, supported by procedure completion and effectiveness
- Changes in back pain as measured by a 10-point VAS and pain medication requirements
- Function as measured subjectively by the ODI and ZCQ patient questionnaires
- Quality of Life Physical Component Score (PCS) as measured by the SF-12 short form survey
- Changes in Neurological status as determined through physical examination
- Changes in pain medication requirements

## Discussion and Conclusion

The Discussion will compare comprehensive safety of the two study groups. The Conclusion will summarize and assess the study findings.

## LSS Therapeutic Algorithm



## Study Methodology

- Prospective, randomized, double-blind, x-over
  - 20 *mild* LSS patients
  - 20 ESI LSS patients
- Single center
- Procedures performed similarly
- Patient & examining physician blinded to Week 6
- Safety & efficacy data collection up to 2 years

## *mild*/ESI Procedure Candidates

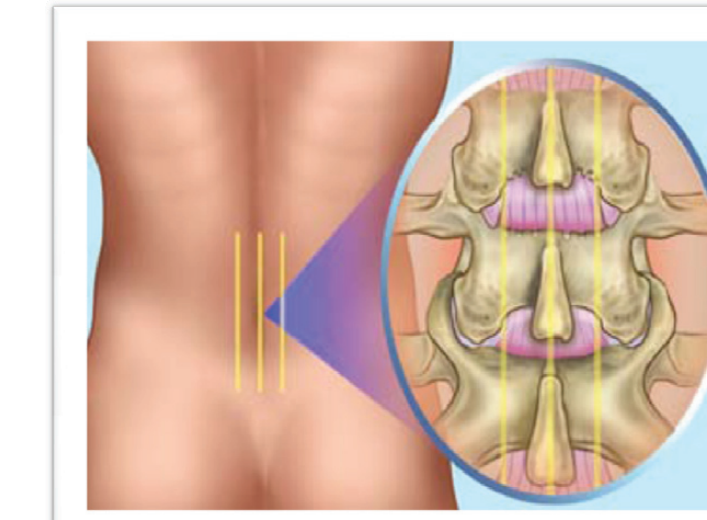
- Symptomatic LSS with radiologic evidence of LSS
- Reduced dural sac cross sectional area, requiring intervention to restore space
- Co-morbidities such as moderate osteophytes, facet hypertrophy and disc protrusion expected and acceptable
- Hypertrophic ligamentum flavum present
- No prior surgery/spinal fracture at tx level

## *mild* Procedure Description

- Posterior approach
- Fluoroscopic imaging
- Small 1.5 mm *mild* Portal access
- Local anesthesia with conscious sedation
- Bilateral one-level operative time ~one hour
- No removal of major spinal support structures

## Structural Stability Maintained in Both Treatment Groups

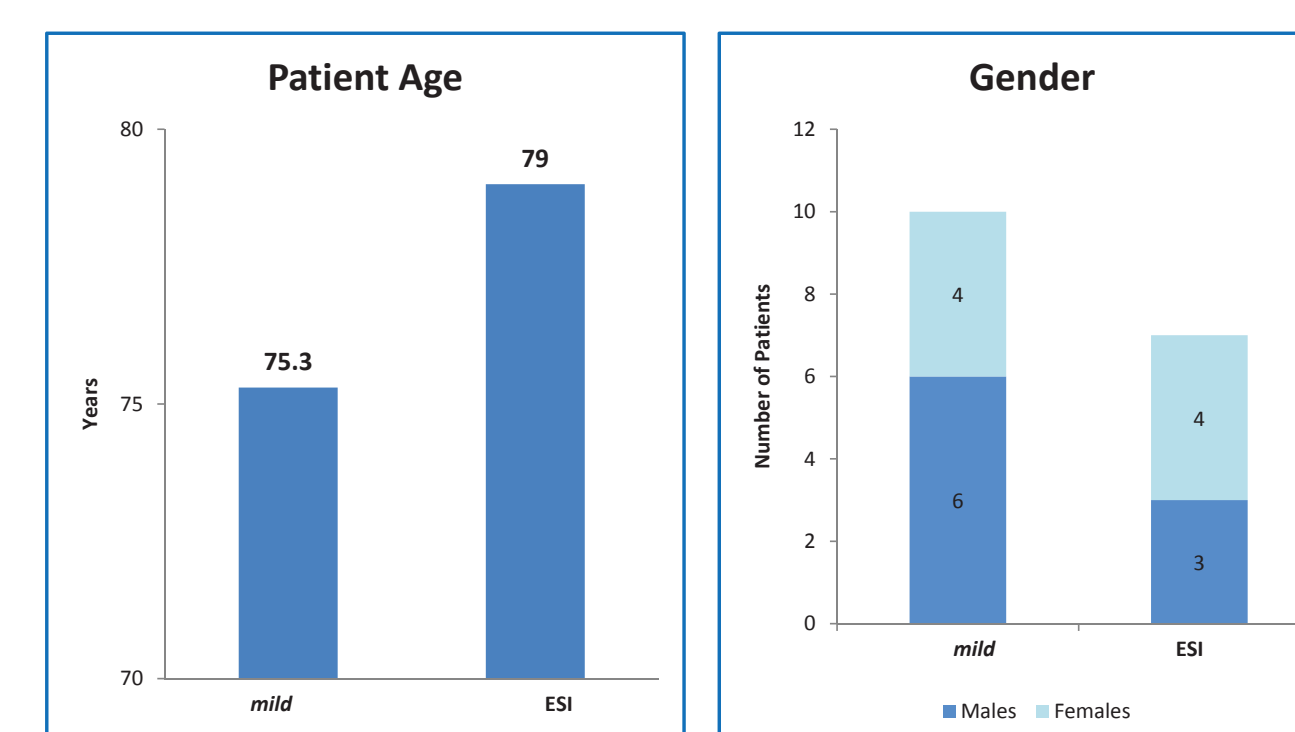
- The *mild* procedure and ESI relieve pain while leaving the ventral fibers of the ligament and the spinous process intact without an implant. This enables continued natural stability.



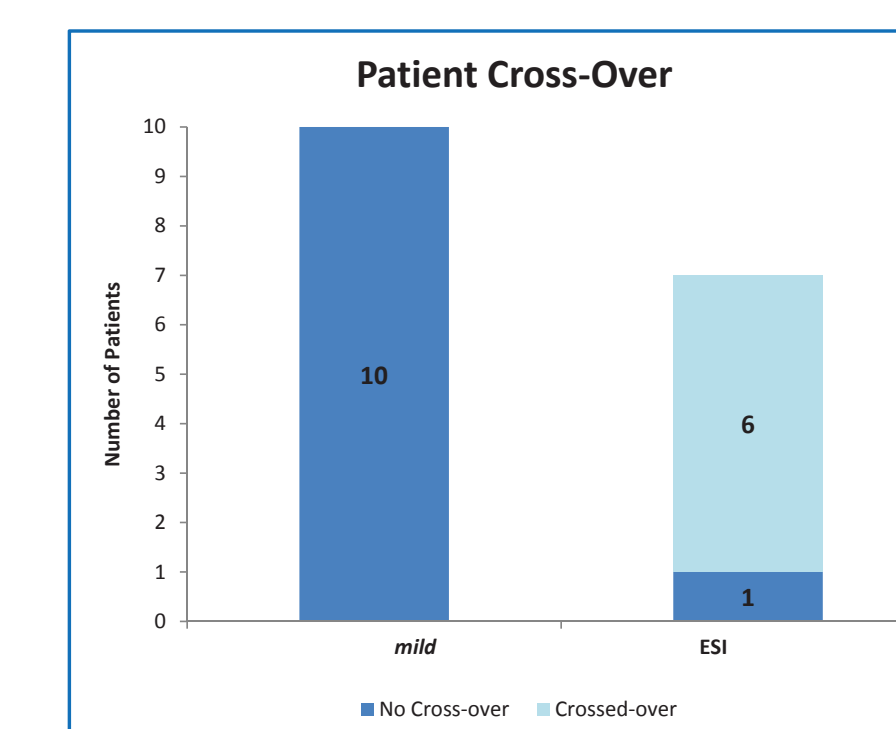
## Safety Success Measures

- *mild* or ESI procedure completed as planned
- Patient comfortable with light sedation / local anesthetic
- No changes in neurological status intra or post-tx
- Safety - consistent with other similar procedures
- Patient success - supported by validated questionnaires
  - No safety-related decrease in physical function
- No *mild* or ESI device/procedure Serious Adverse Events
  - Such as blood transfusions, dural tears, nerve root damage

## Demographics



## Patient Cross-Over



## Safety Comparisons

	<i>mild</i> Patients MIDAS I (78) & Single Site (10)	Single Site ESI Patients	Deer/Kapural Publication on <i>mild</i> Patients	SPORT*
Number of Patients	88	7	90	394
Dural Tears	0%	0%	0%	9.2%
Blood Transfusions	0%	0%	0%	14.3%
<b>Overall Serious Adverse Events</b>				
Intraoperative Complications:	0%	0%	0%	9.9%
Postoperative Complications:	0%	0%	0%	12.3%

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

## Discussion of Results

- Safety
  - No dural tears in either treatment group
  - No blood transfusions in either treatment group
  - No nerve root damage in either treatment group
  - No hematomas in either treatment group
- Overall, with no major device or procedure-related complications reported, *mild* safety compares favorably with ESI.

## Conclusions

- *mild* and ESI provide safe solutions for the treatment of LSS.
- *mild* and ESI offer early therapeutic LSS treatment options prior to more invasive surgical treatment.
- ESI offers a choice that treats the symptom while *mild* offers a therapeutic choice that removes the symptom source.

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