

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

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## 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 is painful and can require several months of low activity and rest.

## Objectives

The purpose of this single-center, randomized, prospective, double-blind, cross-over clinical study is to assess the clinical application, safety and Patient Reported Outcomes (PRO) 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 are aware of the subject's ultimate treatment group. Patients are unblinded at six weeks and allowed to cross over to the other treatment group, if desired. All patients are followed for a period of up to six months after final treatment in order to assess patient outcomes. Enrollment includes up to 40 adult patients at one study center.

Baseline documentation of 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 prior to study treatment. Patient follow-up via telephone survey and office visits includes documentation of the same above measures and any medication changes. Device and procedure-related significant adverse events are documented throughout the study period.

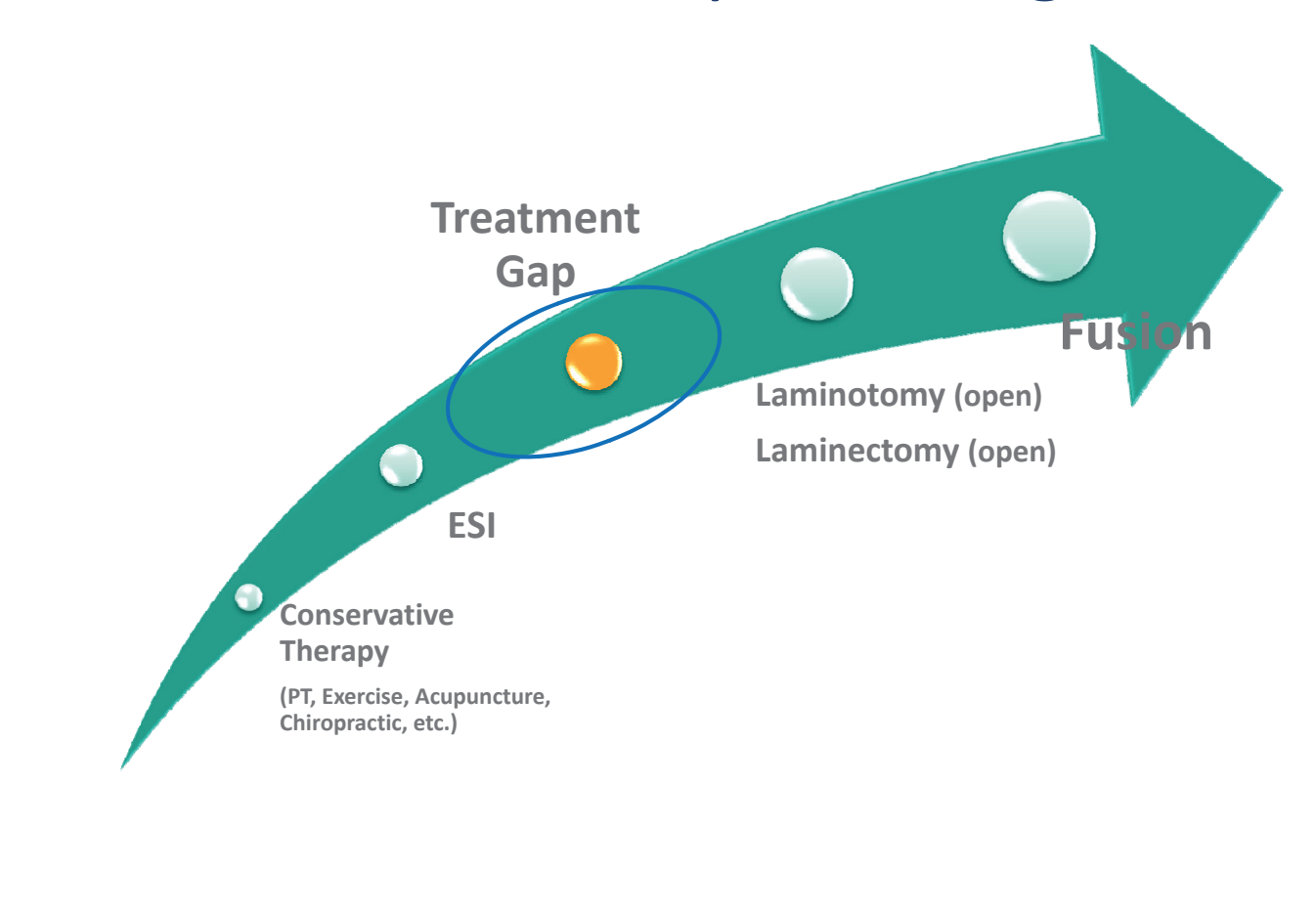
## Results

Enrollment is continuing for this study, and is anticipated to be completed by November 2010. Safety is evaluated for both groups by comprehensive records of both solicited and unsolicited reports of device or procedure-related adverse events. Patient cross-over rate in each group will be monitored.

## Discussion and Conclusion

Thus far, this unique study design has demonstrated comparable safety profiles for the two treatment groups. Device and procedure-related adverse events were absent in both groups, indicating that these procedures are safe. A majority of ESI patients treated to date chose to cross over to *mild* at six weeks, suggesting the need for further treatment in the ESI group. Conversely, none of the *mild* patients have elected to cross over to ESI.

## Current LSS Therapeutic Algorithm



## *mild* Procedure Description

- Posterior approach
- Fluoroscopic imaging
- Small *mild* Portal access (6 G, 5.1 mm)
- Local anesthesia with conscious sedation
- No removal of major spinal support structures
- Bilateral one-level operative time ~one hour

## *mild*/ESI Procedure Candidates

- Primary Inclusion Criteria
  - Symptomatic LSS with radiologic evidence of LSS
  - Hypertrophic ligamentum flavum is contributing factor
  - Prior failure of conservative therapy
  - Reduced dural sac cross sectional area, requiring intervention to restore space
  - Able to walk at least 10 feet unaided
  - Co-morbidities such as moderate osteophytes, facet hypertrophy and disc protrusion expected and acceptable

## *mild*/ESI Procedure Candidates

- Primary Exclusion Criteria
  - Prior surgery at intended treatment level
  - History of recent spinal fractures
  - Disabling back or leg pain from causes other than LSS
  - Significant/symptomatic disc protrusion or osteophyte formation
  - Excessive/symptomatic facet hypertrophy

## Study Methodology

- Prospective, randomized, double-blind, cross-over
  - 20 *mild* patients
  - 20 ESI patients
- Single center
- Block randomization – groups of 4
- Patients all treated for symptomatic LSS
- Procedures performed similarly
- Patient and examining physician blinded to Week 6
- ESI/*mild* related SAEs solicited/unsolicited
- Data collection up to 2 years
- 4 Validated PROs utilized (future reporting)

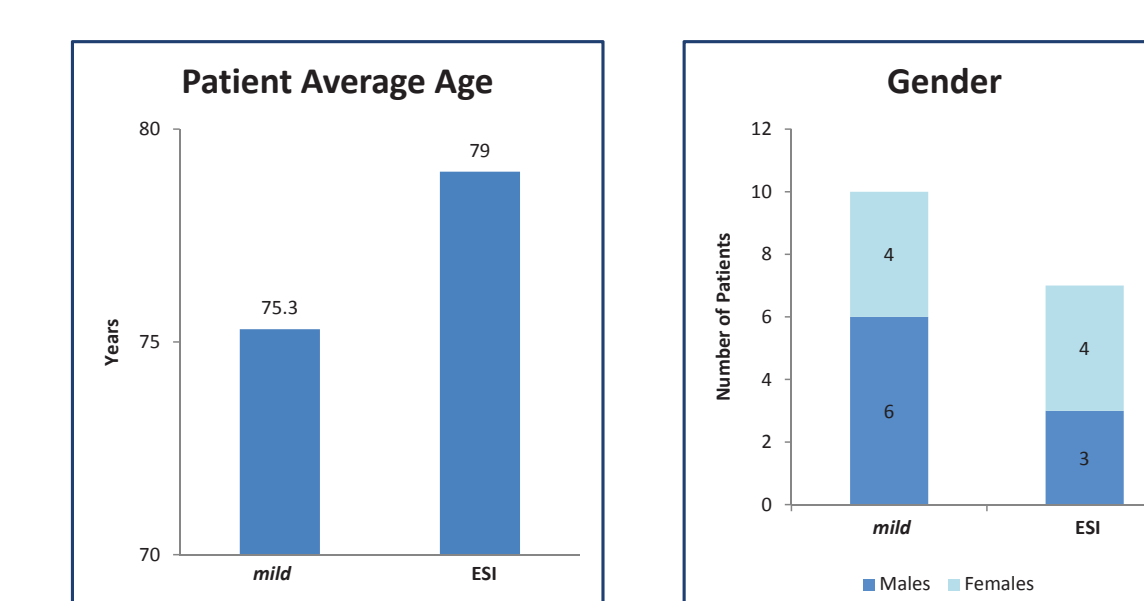
## Intraoperative Safety Success Measures

- *mild* or ESI procedure completed as planned
- Treatment completed in reasonable time
- Patient comfortable with conscious sedation and local anesthetic
- No *mild* or ESI device/procedure Serious Adverse Events
  - Such as blood transfusions, dural tears, nerve root damage
- No re-operations, additional LSS-directed treatments or other interventions required day of procedure

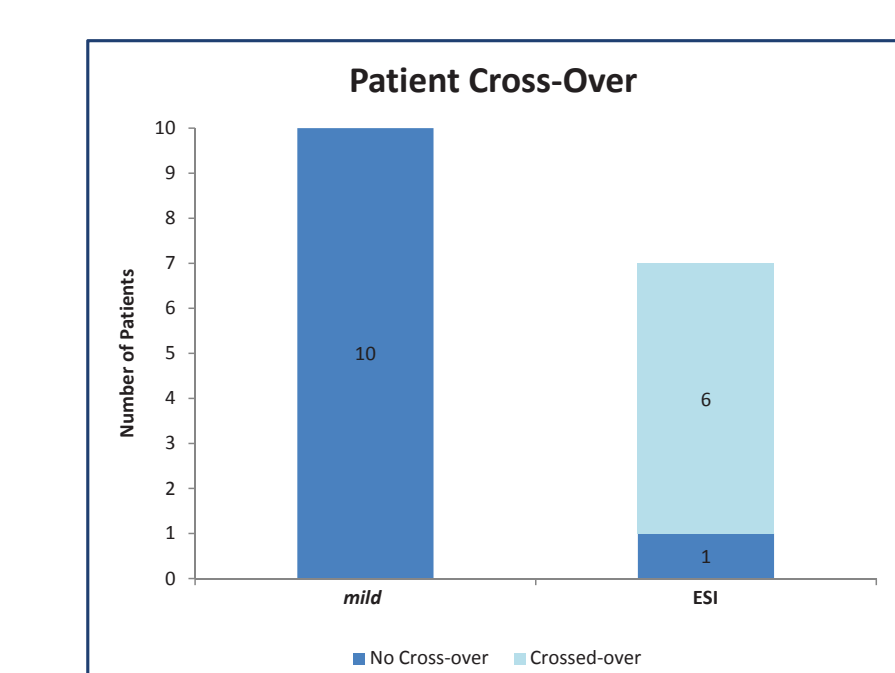
## Postoperative Safety Success Measures

- No post-op *mild*/ESI related serious adverse events
- Acceptable safety - consistent with other similar procedures
- Patient success - supported by validated questionnaires
  - No safety-related decrease in physical function
- No changes in neurological status - determined by physical examination

## Demographics



## Patient Cross-Over



## Safety Comparisons

|                        | Meta Analysis<br><i>mild</i> Patients | Single-Site<br>ESI Patients | Deer / Kapural<br>Publication on<br><i>mild</i> Patients | SPORT *  |
|------------------------|---------------------------------------|-----------------------------|--|--|
| Number of Patients     | 202                                   | 7                           | 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%<br>Postoperative Complications: 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

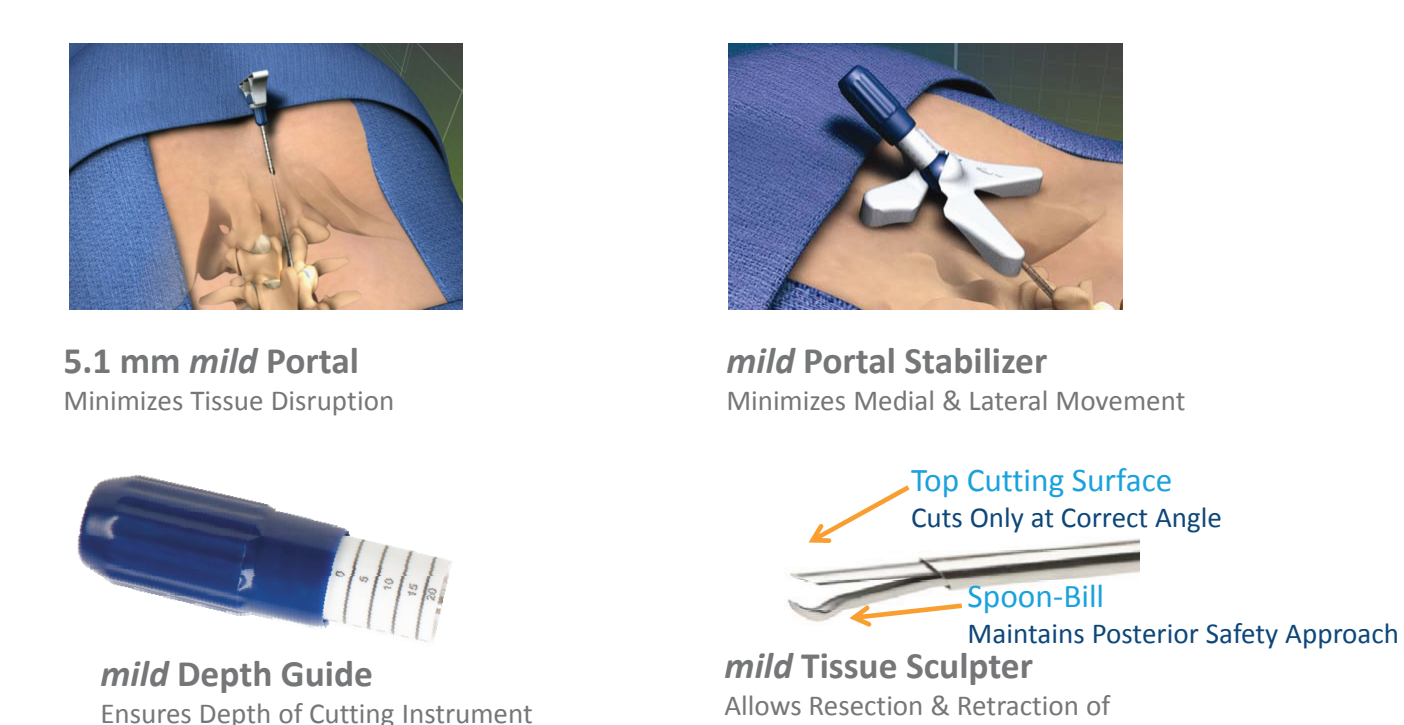
- *mild* and ESI provide safe solutions for the treatment of LSS.
- *mild* and ESI offer early therapeutic LSS treatment options prior to more invasive surgical treatment.
- ESI offers a choice that treats the symptom while *mild* offers a therapeutic choice that removes the symptom source.

## *mild* Device Kit



## *mild* is a Safe Procedure

With Specially Designed Devices



## Structural Stability Maintained in Both Treatment Groups

- The *mild* procedure allows for decompression while leaving the ventral fibers of the ligament, the spinous process and the majority of the lamina intact without an implant. This enables continued natural stability.

