

mild® single-center safety results vs. meta-safety

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background

mild is a minimally invasive treatment for pain relief from symptomatic lumbar spinal stenosis (LSS). LSS is a common problem caused by many factors, the most common being ligamentum flavum hypertrophy. The *mild* technique provides removal of small but adequate amounts of ligament and lamina, avoiding the need for aggressive resection of bone and muscle and/or surgical implants. During the *mild* procedure, bone and ligament sculpting devices are passed through a small 6G Portal, under fluoroscopic visualization, to achieve decompression.

objectives

To compare single-center safety results to a broad meta-safety analysis of patients treated with *mild*.

methods

Safety of the *mild* procedure was collected for thirty patients at this institution, and for over 250 patients in the meta-safety analysis used for comparison. The meta-analysis included patients treated at over 20 institutions. Patients were treated with the *mild* procedure for symptomatic lumbar spinal stenosis. Device and procedure-related significant adverse events were documented throughout the study. Patient Reported Outcomes (PRO) are being collected to be presented in future reports. Safety and outcomes were assessed from baseline to six weeks post-treatment.

results

There were no device or procedure-related serious adverse events in either the single center clinical cases, or those included in the meta-analysis. Serious complications are defined as dural tears, nerve root damage, post-op infection requiring surgical intervention, hemodynamic instability and post-op spinal structural instability. Additionally, no reports of blood transfusions, epidural bleeding or hematomas were reported.

conclusion

The *mild* procedure is a safe method for the treatment of LSS. *mild* offers a safe early option for the treatment of LSS following failed conservative therapy, but prior to more invasive surgical treatment.

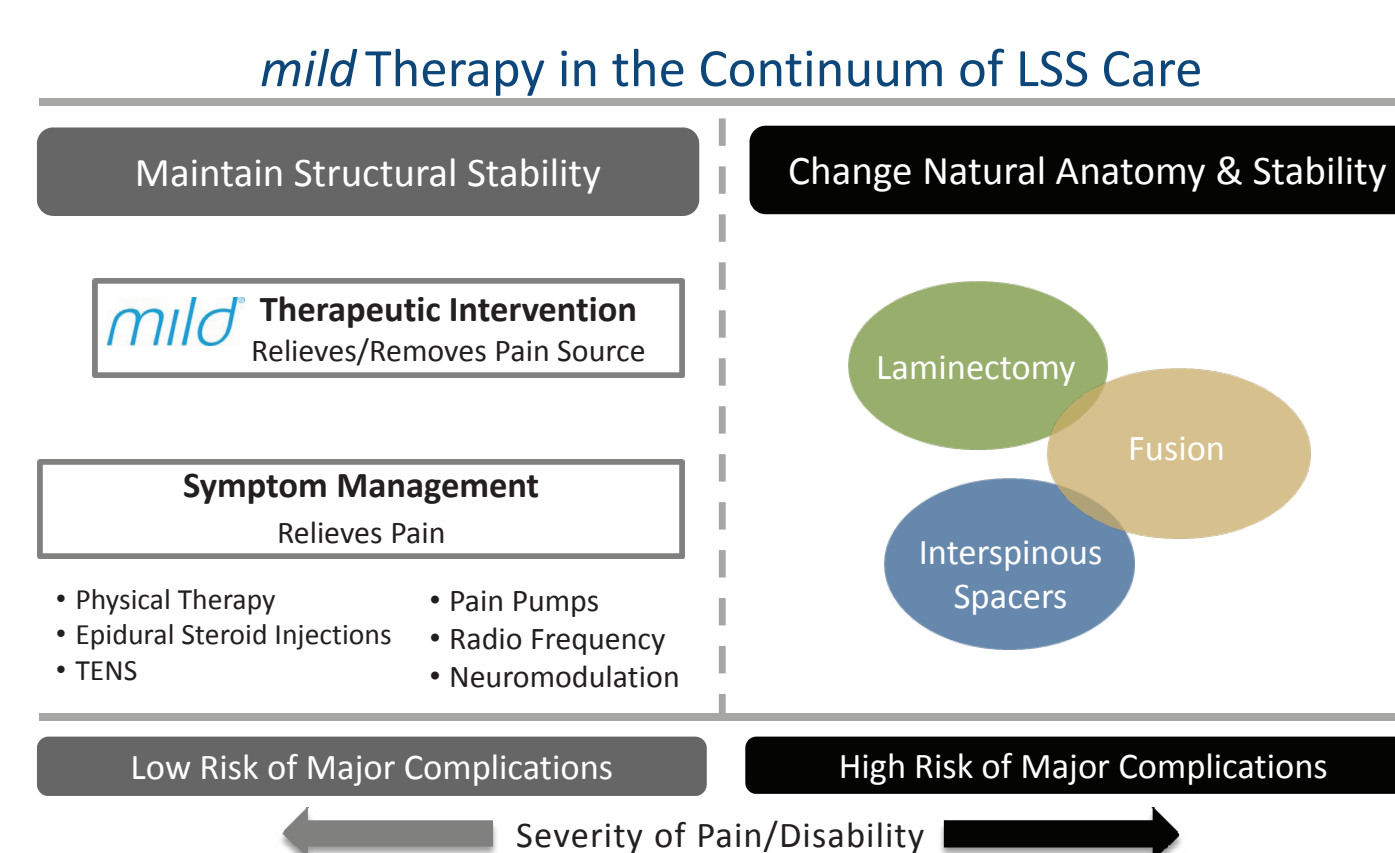
mild Procedure Description

- Posterior approach
- Fluoroscopic imaging
- Small *mild* Portal access (6 G, 5.1 mm)
- General anesthesia not required
- No removal of major spinal support structures
- No implants left behind
- Bilateral one-level operative time ~one hour

mild Devices/Procedure Benefits

- Posterior approach – Lower risk & easier access, treating away from epidural space, nerve roots & vascular structure
- Epidurogram-enabled visualization
- Safe instrument design controls depth & cutting angle
- Treatment through 5.1 mm portal, minimal tissue disruption, small wound, rapid healing time
- Local anesthesia with conscious sedation – no general anesthesia risk, patient returns home quickly
- No implants to deteriorate/dislodge/destabilize

mild- A Therapeutic Treatment Alternative for LSS



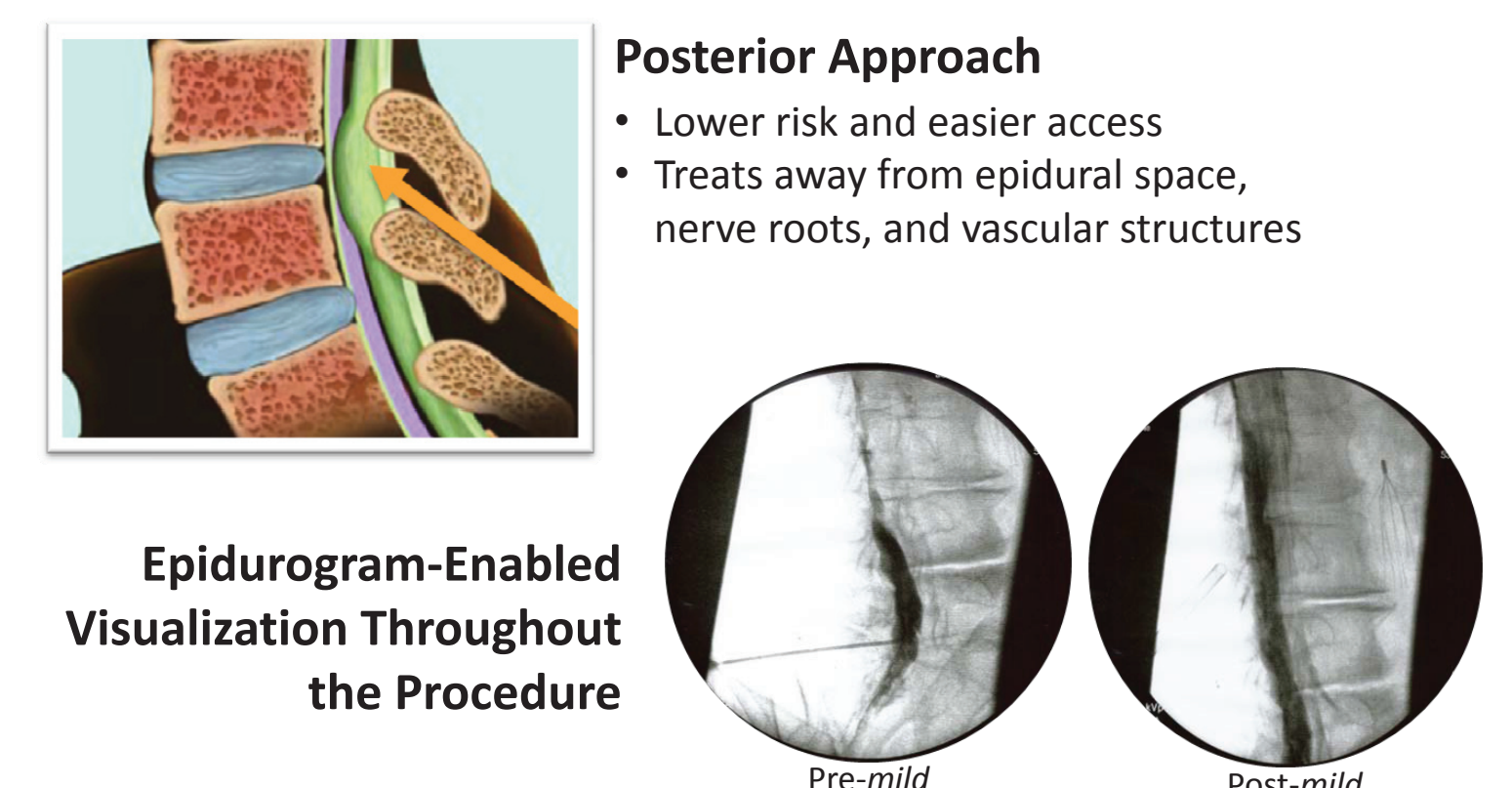
Study Methodology

- Single center analysis = 30 *mild* study cases – Center for Pain Relief
- Multi-center *mild* meta-analysis = 234 cases – 20 institutions
- Patients all tx with *mild* for symptomatic LSS
- Device/procedure-related SAEs tracked to date – Up to 12 weeks for single-center – Up to 1 year for meta-analysis

mild Procedure Candidates

- Primary Criteria
 - Symptomatic LSS with radiologic LSS evidence
 - Co-morbidities such as osteophytes, facet hypertrophy and disc protrusion included
 - Ligamentum flavum hypertrophy present
 - Dural sac cross sectional area reduced, requiring intervention to restore space

mild is a Safe Procedure With Built-in Procedure Safety



Demographics

Meta	Single Center
All cases performed in North America Sites geographically distributed Number of sites = 20	All cases performed in North America Sites geographically distributed Number of sites = 1
Patient number = 234	Patient number = 30
Follow-up range = up to 1 year	Follow-up range = up to 12 weeks

mild Safety Analysis Meta N=234; Single Site N=30

Study (# <i>mild</i> Patients/Max. Time Post-Treatment) Meta Data	SAEs	Single-Site	SAEs
MIDAS I (n = 78/1 year)	None	Deer (n=30/12 weeks)	None
Canada IRB study (n =10/Week 26)	None		
Safety Study (n=90/Acute)	None		
MIDAS II (n = 36/Week 12)	None		
Randomized Studies <i>mild</i> Cases (n=20/Week 12)	None		
TOTAL = 234	None		

Note: Minor complications such as headache and tenderness at wound site were not collected.

Discussion of Results

- Safety in meta AND single-center
 - No dural tears
 - No blood transfusions
 - No nerve root damage
 - No hematomas
- Overall, with no major device or procedure-related complications, the *mild* procedure compares favorably with reports of both open surgical and minimally-invasive series.

Conclusions

- *mild* provides a safe solution for the treatment of LSS.
- *mild* offers an early therapeutic LSS treatment option prior to more invasive surgical treatment.