

# *mild*<sup>®</sup> procedure for the treatment of lumbar spinal stenosis: procedure description, patient selection and comprehensive safety profile

by: [nagy a. mekhail, m.d., ph.d.](#)  
cleveland clinic, cleveland, oh

## background

*mild* is a minimally invasive treatment for pain relief from symptomatic lumbar spinal stenosis. Lumbar spinal stenosis (LSS) is a common problem that can be caused by many factors including 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, as well as surgical implants.

## objectives

To describe the *mild* procedure, imaging techniques, patient selection and to report on the comprehensive safety profile of this minimally invasive treatment.

## methods

Safety of the *mild* procedure has been collected for approximately 250 *mild* patients. All patients were treated with the *mild* procedure for symptomatic lumbar spinal stenosis utilizing the manufacturer's Instructions for Use. *mild* is performed through a 5.1 mm Portal under fluoroscopic guidance, using light sedation. *mild* decompression can be performed unilaterally or bilaterally, at single or multiple levels. Fluoroscopic imaging in the contralateral oblique view helps position the layer of epidural contrast immediately deep to the inner table of the lamina, providing a visual margin of safety.

## results

Data were collected and reviewed on approximately 250 symptomatic LSS patients treated with the *mild* procedure. To date, there have been no reports of *mild* device or procedure-related serious adverse events (dural tears, nerve root damage, hemodynamic instability, hematomas, blood transfusions or post-op spinal structural instability).

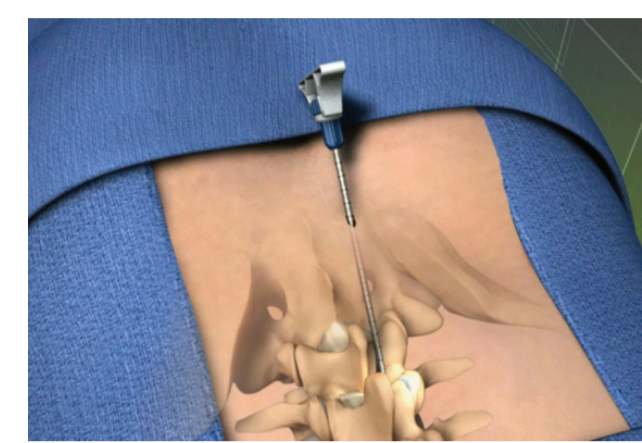
## conclusion

The *mild* procedure is a safe method for the treatment of LSS. No serious device or procedure-related adverse events were reported in over 250 *mild* patients with follow-up ranging from acute to one year. This minimally invasive procedure allows decompression by removing small amounts of bone and tissue, with minor tissue disruption. *mild* offers an early LSS treatment option following failed conservative therapy. For those patients who either cannot tolerate or choose not to proceed to more invasive surgical treatment, *mild* treatment is an option.

## key words

Spine, decompression, fluoroscopy, *mild*, stenosis, ligamentum flavum

## Devices Designed for Safety



**5.1 mm *mild* Portal**  
Minimizes Tissue Disruption  
Leaves Small Wound



***mild* Portal Stabilizer**  
Minimizes Medial & Lateral Movement  
Helps Control Cutting Angle



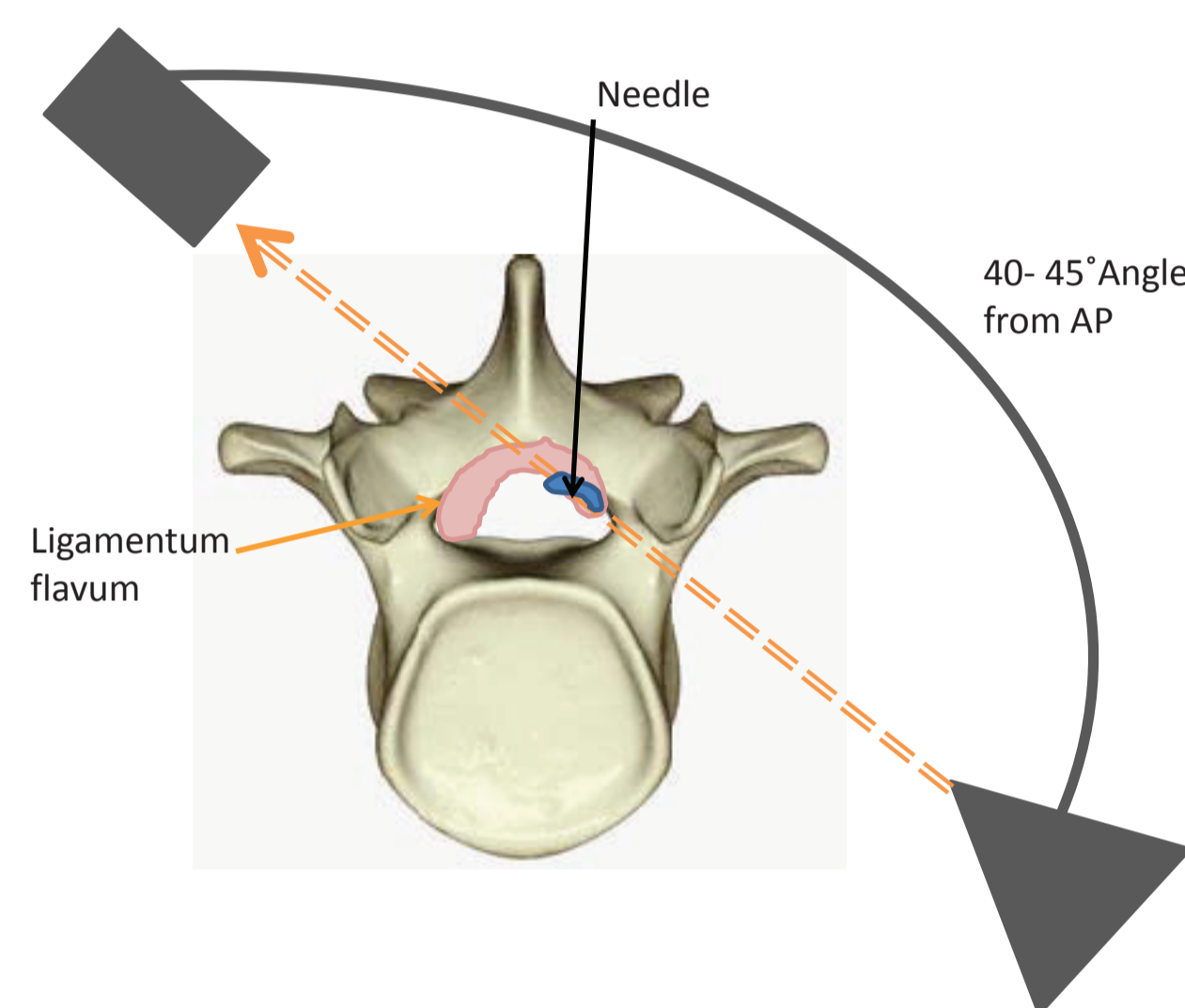
***mild* Depth Guide**  
Ensures Depth of Cutting Instrument



***mild* Tissue Sculpter**  
Allows Resection & Retraction of Ligamentous Tissue  
***mild* Bone Sculpter Rongeur**  
Allows Resection & Retraction of Laminar Bone

## Contralateral Oblique View Needle Placement & Epidurogram

- Best imaging view
- Presents the thickest cross-section of the lamina
- Positions the layer of epidural contrast immediately deep to the inner table of the lamina



## *mild* Safety Analysis

### Demographics

All cases performed in North America  
Sites geographically distributed  
Number of sites = 22 US; 1 Canada

*mild* patient number = 264

Follow-up range = up to 2 years

## *mild* Safety Comparison

Outcomes	<sup>1</sup> Simple Decompression Surgery	<sup>1</sup> Complex Fusion Surgery	<sup>2</sup> <i>mild</i>
Major Medical Complications	2.1 %	5.2 %	None
Life-threatening Complications	2.3 %	5.6 %	None
Wound Complications	0.9 %	2.2 %	None
Re-hospitalization within 30 Days	7.8 %	13.0 %	None
30-Day Mortality	0.3 %	0.6 %	None

1. Deys, Richard, JAMA, April 7, 2010-Vol 303, No. 13  
2. *mild* comprehensive data from MIDAS I & MIDAS II studies, Canadian study, Deer patient series and Deer/Kapur safety study (N= 264)

## *mild* Procedure

- Local anesthesia with conscious sedation
- Epidurogram and fluoroscopic image guidance
- Posterior approach treats away from epidural space, nerve roots & vascular structures
- Small portal access
- One-level bilateral completed in about an hour
- No implants/no major structural disruption
- Sterile adhesive strip closure

## *mild* Patient Selection

- LSS patients exhibiting neurogenic claudication
  - Back and/or leg pain, numbness (unilateral or bilateral)
  - Occurs with axial loading, especially when walking or prolonged standing
  - Relieved when flexing by bending forward, sitting, raising foot or lying down
- Ligamentum flavum hypertrophy confirmed with imaging studies (MRI)
- Thecal sac cross sectional area reduced, requiring intervention to restore space
- Facet hypertrophy and disc protrusion are among common accepted co-factors

## *mild* Comprehensive Safety Profile Study data N=264

Study	# <i>mild</i> Patients	Max. Time Post-tx Meta Data	Serious Complications
MIDAS I	n = 78	2 Years	None
Canadian IRB Study	n = 10	6 Months	None
Deer/Kapur Safety Study	n = 90	Acute	None
MIDAS II	n = 55	6 Months	None
Deer Series	n = 31	6 Months	None
<b>Total Patients</b>	<b>N = 264</b>	Range: Acute to 2 Years	None

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

## Specific Complication Rates Reported in Literature\* for LSS Surgical Series

	Procedure Type		
	Open Surgery	Minimally Invasive Surgery	<i>mild</i> Procedure
Blood Transfusions	1.1-76.9%	0%	0%
Dural Tears or Spinal Fluid Leaks	2.0-20%	1.1-12.5%	0%
Hematomas	0-5%	0-5%	0%
Post-op Infections	0-5.7%	0-4%	0%

\*List of references on file at Vertos Medical, provided by Canopy Medical, LLC

## Discussion of Results

- *mild* safety analysis:
  - No major medical complications
    - No dural tears
    - No blood transfusions
    - No nerve root damage
    - No hematomas
  - No life-threatening events & no deaths ≤ 30 days of tx
  - No wound complications or ≤ 30-day re-hospitalizations
- Overall, with no major device or procedure-related complications, the *mild* procedure compares favorably with reports of both simple and complex surgical decompression procedures

## Conclusions

- *mild* devices provide safe, minimally invasive access for removal of small amounts of bone and tissue
- No serious device or procedure-related adverse events were reported in over 250 *mild* patients
- *mild* dorsal approach and visual guidance yielded a consistently safe procedure
- *mild* safety profile is better than open surgical series safety profile as reported in current literature
- *mild* is a therapeutic LSS treatment option for patients exhibiting neurogenic claudication