

mild[®]

*Minimally Invasive
Lumbar Decompression*

*clinical
experience
report*

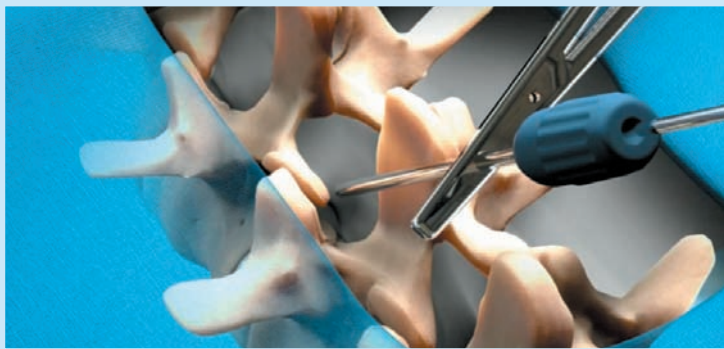


Vertos | *mild*[®]
MEDICAL | Minimally Invasive
Lumbar Decompression

the proof is in the results

mild clinical experience: n=30

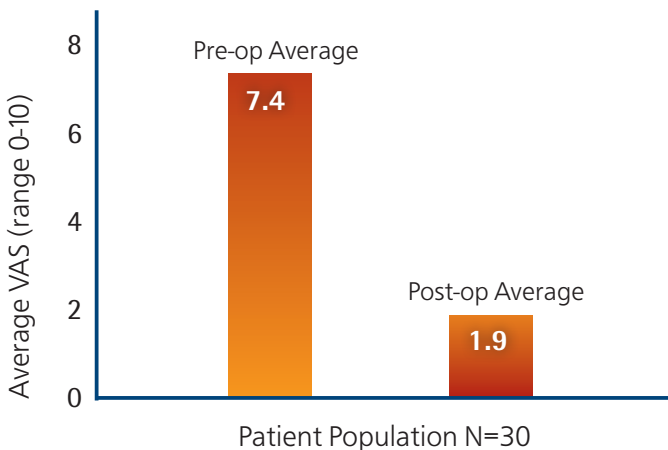
This Clinical Experience Report is intended to provide you with a summary of the early patients treated using the *mild* procedure. Though not part of a controlled clinical trial, we believe the data reflect the positive benefits of this unique approach. No device-related adverse events were reported in the nearly 100 patients as of January, 2009.



“early results indicate that patients treated with the mild procedure have experienced greater than a 74% reduction in pain and greater than a 70% improvement in mobility.”

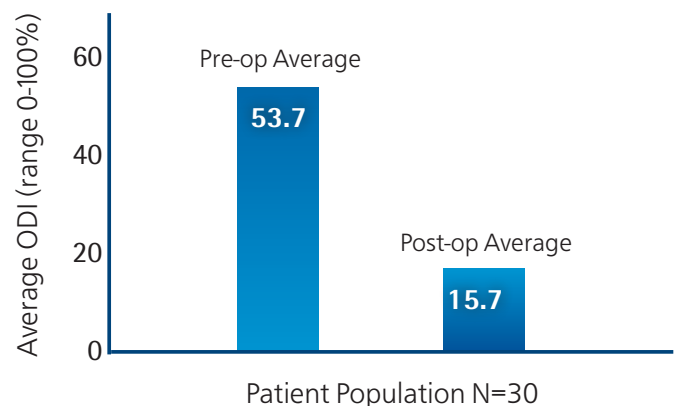
physician self-reported patient demographic information— 6 weeks postoperatively

- Information consists of a 30-patient population that had physician-monitored VAS and ODI scores preoperatively and postoperatively.
- Five physicians at five different facilities contributed this information.
- Post-op scores that were entered into the calculations are the latest information obtained at least 6 weeks post-procedure.



VAS COMPARISON

Pre-op Average vs. Post-op Average (6 weeks or >)



ODI COMPARISON

Pre-op Average vs. Post-op Average (6 weeks or >)

less pain, more mobility continues

This chart shows data for 8 patients from the original group at one year postoperatively.

One year* after *mild* treatment, N=8

Pt. #	Baseline VAS	One Yr. VAS	Baseline ODI (%)	One Yr. ODI (%)
1	8	2	60	15
2	4	5	78	26
3	4	0	44	0
4	6	2	40	22
5	9	0	41	20
6	7	0	58	0
7 ^A	7	7	54	32
8	5	1	18	10
Average	6.2	2.1	42.4 ^B	15.6 ^B

*Average 10 months post-procedure

Note A: Pt. #7 VAS Score at 6 months negatively impacted by knee problem

Note B: ODI Baseline Average (42.4%) = Severe Disability; ODI F/U Average (15.6%) = Minimal Disability

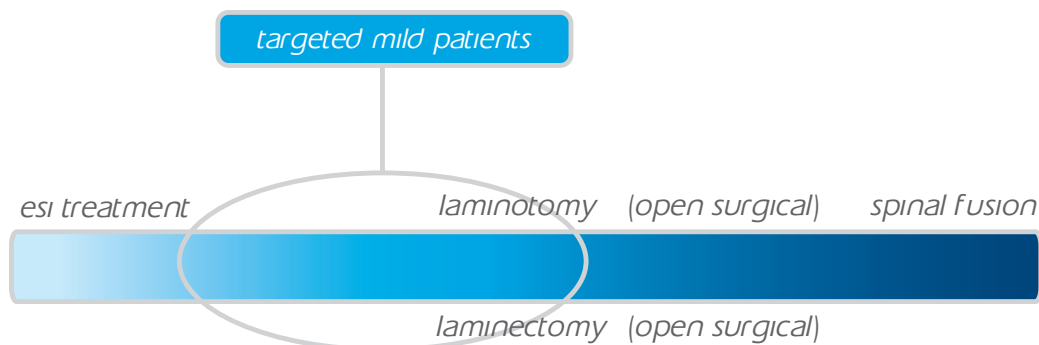
the *mild* procedure

The *mild* procedure allows percutaneous, image-guided treatment of LSS by accessing the interlaminar space, concurrently removing tissue and bone to decompress the spine, and thereby potentially alleviating the symptoms associated with LSS.

The minimally invasive nature of the *mild* procedure enables shorter in-patient therapy and recovery in contrast to other treatment options such as Laminotomy (open surgical), Laminectomy (open surgical) and Spinal Fusion. Patients undergoing a *mild* procedure are typically discharged the following day.

the *mild* opportunity

mild fills an important void along the LSS treatment continuum, providing a viable option for failed ESI patients and those concerned about the invasiveness of Laminotomy and Laminectomy.



Indication For Use – The Vertos *mild* Devices are specialized surgical instruments intended to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. Contraindications – The Vertos *mild* Devices are not intended for disc procedures, rather, tissue resection at the perilaminar space, within the interlaminar space and at the ventral aspect of the lamina. The Vertos *mild* Devices are not intended to be used near the lateral neural elements and remain dorsal to the dura using image guidance and anatomical landmarks. United States Regulatory Status – The Vertos *mild* Devices have received 510(k) marketing clearance from the United States Food and Drug Administration.

we are currently enrolling patients in this trial and seeking additional investigators to reach our goal of 30 sites. for more information please contact us.

clinical strategy

Vertos Medical, Inc. is committed to the safety and effectiveness of the *mild* procedure and to building clinically and scientifically relevant data collected through Institutional Review Board (IRB) governed clinical trials. The company is currently enrolling the first phase of what we anticipate to be a four-phased clinical trial. Phase I is expected to enroll 75 patients at up to 30 study centers. Adult patients with symptomatic LSS who meet the study enrollment criteria will be offered the *mild* procedure as an alternative to surgery or continued standard non-surgical medical management. These patients may continue on the medical management considered appropriate by their physician/investigator. Specific inclusion criteria for the study are detailed below. A fully detailed protocol including all inclusion and exclusion information is available upon request.

inclusion criteria:

All patients must meet the following criteria to be enrolled into the study:

1. Symptomatic and LSS primarily caused by dorsal element hypertrophy.
2. Prior failure of conservative therapy.
3. Radiologic evidence of LSS (L3-L5), Ligamentum flavum > 2.5 mm, confirmed by pre-op MRI and/or CT.
4. Central canal cross sectional area $\leq 100 \text{ mm}^2$.
5. Anterior listhesis $\leq 5.0 \text{ mm}$.
6. Able to walk at least 10 feet unaided before being limited by pain.
7. Available to complete 26 weeks of follow-up.
8. Consistent with the intended labeling statement for use.
9. Able to use all package components to perform the procedure.
10. A signed Informed Consent Form is obtained from the patient.

company overview

Vertos Medical, Inc., is a privately held medical device company pioneering the development of percutaneous interventional devices used in the treatment of common spinal diseases, such as lumbar spinal stenosis (LSS). Using our proprietary *mild* (Minimally Invasive Lumbar Decompression) procedure, we obtained treatment results in patients with moderate-to-severe LSS, demonstrating both improved mobility and decreased pain. A summary of our success to date is detailed in this first quarterly Clinical Experience Report.

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