



mild[®] Lumbar Decompression for the Treatment of Lumbar Spinal Stenosis

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Key words: spine, lumbar, decompression, *mild*[®], stenosis

SUMMARY – *More than 1.2 million people are undergoing treatment for lumbar spinal stenosis (LSS) in the United States. Yet, therapeutic options for these patients are limited to either conservative treatments or highly invasive surgeries. A new image-guided interlaminar decompression procedure, mild[®], offers significant relief for many of these patients by debulking dorsal element hypertrophy while preserving structural stability. mild can be performed without general anesthesia and offers a short recovery period. A meta-analysis of four clinical patient series from multiple institutions in the United States evaluated over 250 patients for safety and clinical efficacy of the mild procedure. Clinical efficacy was evaluated at baseline and at three-month follow-up using validated patient reported outcomes (PRO) instruments including the ten-point Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI). Acute safety and patient outcomes was compared to the Spine Patient Outcomes Research Trial (SPORT). No device or procedure-related serious adverse events (SAEs) have been recorded with the mild procedure. Outcome metrics for patients treated with mild demonstrated statistically significant symptomatic improvement over baseline. When compared to open surgery, mild efficacy results compare favorably, and complication rates are much lower. mild is a safe and effective procedure that decompresses LSS in a minimally invasive manner while preserving the structural stability of the spine.*

Introduction

Lumbar spinal stenosis (LSS) is a serious chronic and progressive degenerative condition of the spine that affects millions of patients worldwide. In 1978, Kirkaldy-Willis¹ recognized the interdependence of the intervertebral discs and zygapophyseal (facet joints) as a tripod like mechanical segment and proposed the concept of a spinal degenerative cascade. Under chronic dynamic mechanical stresses, all elements of the tripod-segments degenerate leading ultimately to intervertebral osteophytosis and facet hypertrophy². Facet hypertrophy can further result in relative lthesis of vertebral segments. Repeated flexion stress on the dorsal soft tissue hypertrophies the ligamentum flavum and alters its elastin: collagen ratio resulting in a

thickened and much less dynamic structure and this seems to preferentially affect the dorsal fibers of this structure, leaving the more ventral fibers relatively normal³⁻⁵. All of these factors contribute to volumetric compromise of the spinal canal, lateral recesses, and neural foramina (Figures 1A and 1B). As the spinal canal narrows, patients develop a host of clinical symptoms that seem to relate directly to the absolute cross sectional diameter of the spinal canal⁶

Therapies for patients with LSS range from conservative management to open surgery. Recent publications however demonstrate better outcomes with surgical decompression over conservative management⁷⁻¹¹. Surgical decompression, while effective, is morbid and has recognized complications. Further, open surgical procedures destabilize the soft tissues that support the spine, often requiring advanced augmentation and instrumentation.

Paper presented at the XIX Symposium Neuroradiologicum, 2010.

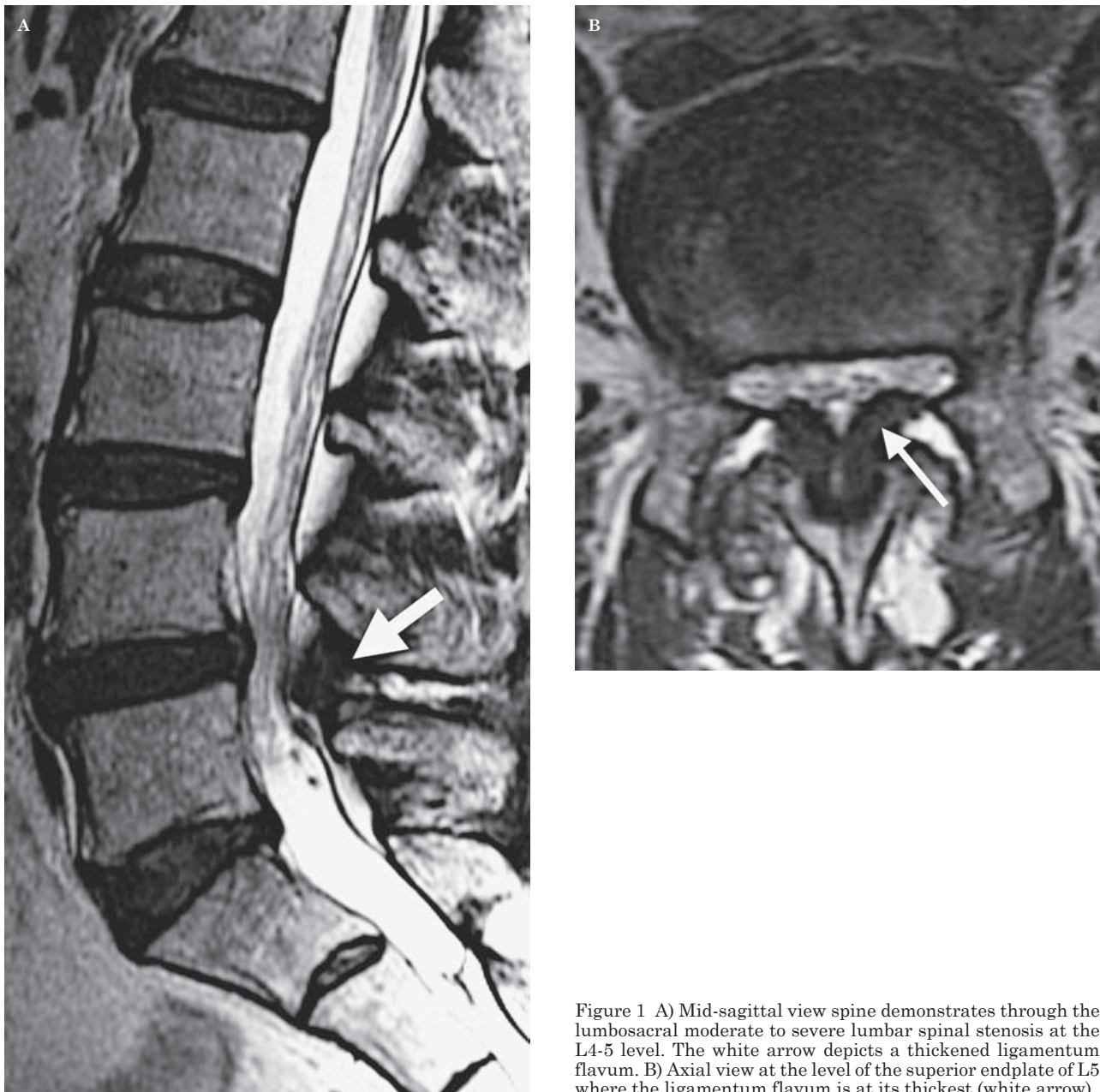


Figure 1 A) Mid-sagittal view spine demonstrates through the lumbosacral moderate to severe lumbar spinal stenosis at the L4-5 level. The white arrow depicts a thickened ligamentum flavum. B) Axial view at the level of the superior endplate of L5 where the ligamentum flavum is at its thickest (white arrow).

A new percutaneous image-guided procedure has been developed, known as *mild*[®] Interlaminar Decompression, to decompress the spinal canal without destabilization of adjacent structures.

The *mild* instruments are used to perform interlaminar decompression of the lumbar spine with image guidance following epidurography. The *mild* procedure is performed by accessing the interlaminar space percutaneously from the posterior lumbar spine, removing small portions of the lamina, and then preferentially re-

secting and debulking the pathologic dorsal tissues of the hypertrophied ligamentum flavum.

The purpose of this report is to present a meta-analysis of acute safety and three-month clinical outcomes of over 250 *mild* patients. These results are compared to the LSS surgical patient cohort of the Spine Patient Outcomes Research Trial (SPORT). The *mild* devices are approved for sale and cleared by the FDA in the United States. Acute safety and six-week functional outcomes of the *mild* procedure has been previously reported^{12,13}. This analysis was

presented in its preliminary form at the XIX Symposium Neuroradiologicum in October 2010. The abstract for this presentation was published in *The Neuroradiology Journal*¹⁴.

Materials and Methods

A meta-analysis was undertaken to compare safety and clinical efficacy of the *mild* interlaminar lumbar decompression procedure with open surgery. Four patient series from multiple institutions in the United States including over 250 patients treated with the *mild* procedure were included in this analysis. Clinical efficacy was evaluated at baseline and at three-month follow-up using validated Patient Reported Outcomes (PRO) instruments including the ten-point Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI). Acute safety and patient outcomes were compared to the SPORT trial.

The *mild* patients were treated from January 2008 through July 2010. Patient cohorts included prospective clinical studies conducted with Institutional Review Board (IRB) approval and patient consent, as well as retrospective surveys of case procedural notes where IRB approval was not required or obtained. All *mild* patients previously failed conservative therapy. All investigators were trained in the appropriate use of the *mild* devices, and associated image guidance procedures, using a cadaver in a standard program.

This meta-analysis includes 253 patients treated with *mild* interlaminar decompression. Safety information related to device or procedure-related adverse events occurring at the time of treatment was available for all patients. Three-month efficacy follow-up was reported as available for a subset of these patients.

mild Procedure

The *mild* procedure has been previously described^{12,13}. The *mild* procedure is conducted under fluoroscopic guidance, and is performed through a 6g port (*mild* Portal), with a separate port placement at each hemi-laminar level. The patient is placed prone on a radiolucent operative table and a ventral bolster is used to flex the spine forward, thus opening the interlaminar space. The procedure is typically conducted using local anesthetic and light sedation.

An epidurogram is performed ipsilateral to the intended treatment level, providing a

fluoroscopic visual landmark. The contralateral oblique fluoroscopic view is the primary working view for the procedure, as the contrast media highlights the epidural space, allowing for identification of the hypertrophic ligamentum flavum (Figure 2A). Proper placement of the Portal can be verified by frequently observing in both lateral and anterior/posterior views with C-arm fluoroscopy.

The contralateral oblique fluoroscopic view also provides visualization orthogonal to the major axis of the lamina, creating a fluoroscopic posterior working zone. The epidurogram localizes the anterior margin of the working zone and instruments should not be placed beyond this visual landmark, thereby preventing inadvertent penetration into the thecal sac. Additional contrast media can be added as needed throughout the procedure to assist in maintaining visualization of the working zone, and to assess the amount of decompression achieved.

Following epidurography, the *mild* Trocar and Portal are inserted percutaneously, under fluoroscopic guidance, along the desired trajectory. The Trocar is then removed leaving the hollow *mild* Portal in the interlaminar space. The Portal angle is maintained at the skin surface using the Portal Stabilizer, and the Depth Guide is placed over the Portal limiting forward motion of the working instruments. This Portal allows percutaneous access to the lamina and the ligamentum flavum.

First, the *mild* Bone Sculpter Rongeur is advanced through the Portal to the lamina where the laminotomy is performed (Figure 2B). Removal of only a small amount of bone improves access to the interlaminar space, and partially releases the hypertrophic ligamentum flavum. The *mild* Tissue Sculpter is then advanced under the lamina into the dorsal aspect of the hypertrophic ligamentum flavum (Figure 2C). The unique design of the Tissue Sculpter tip allows for debulking of the ligamentum flavum by removal of the fibrotic collagen-laden posterior portion of the ligament, while leaving the more healthy ventral fibers intact. These ventral ligamentum fibers remain as a protective zone to the epidural space. Decompression is confirmed through visual changes in the ventral contour that is depicted by the dorsal margin of the epidurogram, which appears thicker and straighter due to less deformation of the epidural space by the debulked ligamentum flavum.

After confirmation of adequate decompression, the Depth Guide, Portal Stabilizer and Portal are removed, leaving no implants be-

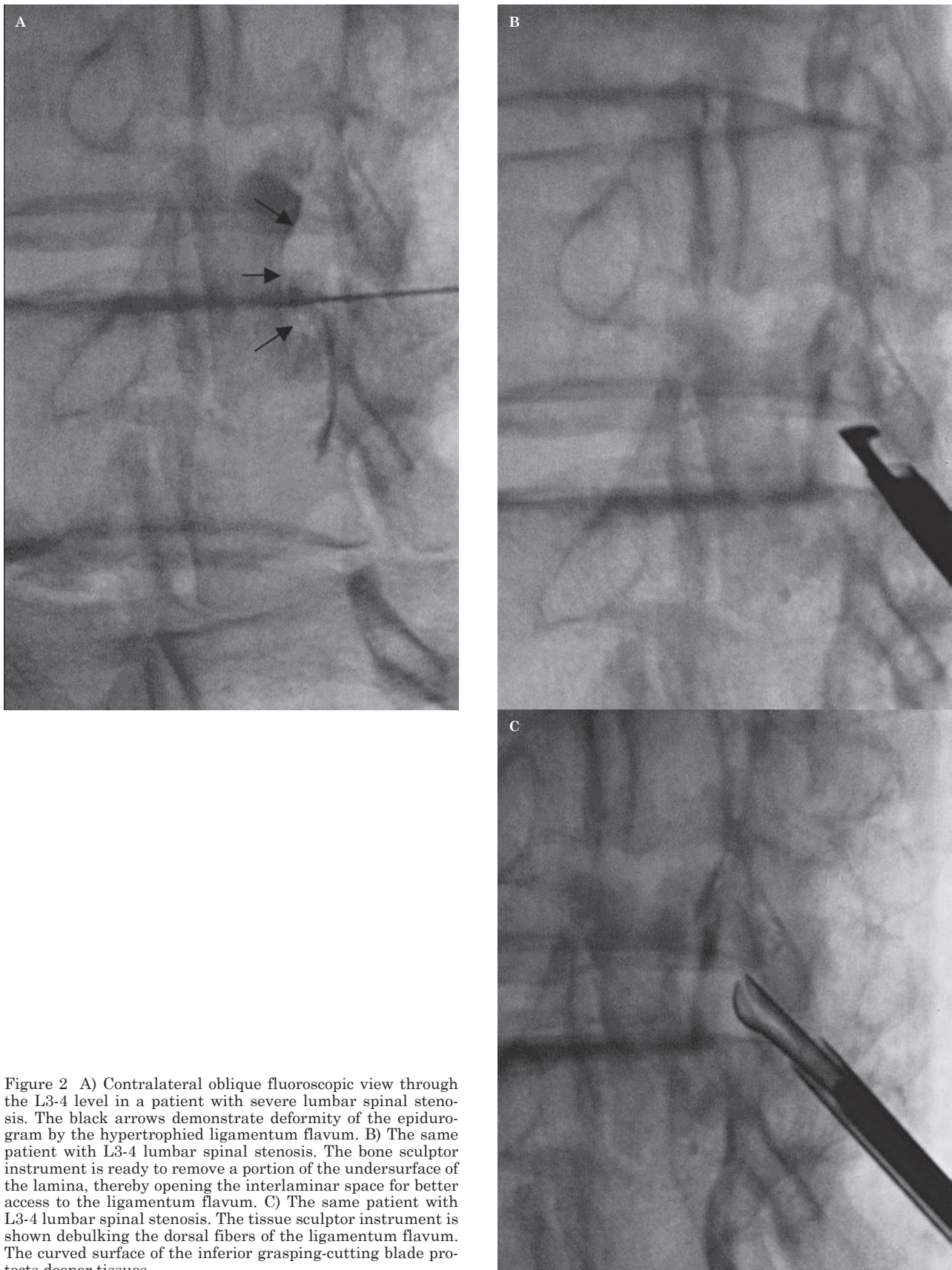


Figure 2 A) Contralateral oblique fluoroscopic view through the L3-4 level in a patient with severe lumbar spinal stenosis. The black arrows demonstrate deformity of the epidurogram by the hypertrophied ligamentum flavum. B) The same patient with L3-4 lumbar spinal stenosis. The bone sculptor instrument is ready to remove a portion of the undersurface of the lamina, thereby opening the interlaminar space for better access to the ligamentum flavum. C) The same patient with L3-4 lumbar spinal stenosis. The tissue sculptor instrument is shown debulking the dorsal fibers of the ligamentum flavum. The curved surface of the inferior grasping-cutting blade protects deeper tissues.

hind. The Portal site is closed with a sterile adhesive strip, with no need for sutures. The mild decompression procedure may be repeated on the contralateral side and at multiple levels.

Results

Demographic and procedural data were available for 163 *mild* patients in this meta-analysis. For these patients, mean patient age was 68.8 years, and gender was 40.5% male and 59.5% female. Approximate duration of the *mild* procedure from patient entry to departure from the OR was one hour. A total of 237 levels were decompressed, of which 199 were treated bilaterally and 38 were treated unilaterally.

Of 163 patients, 109 patients (66.9%) were discharged from the hospital on the same day as the procedure, and 54 patients (33.1%) stayed for one night only. None of the patients stayed longer than 24 hours.

Acute safety data were available for all 253 patients included in this meta-analysis, and there were no reports of major *mild* device or procedure-related complications. Major complications were defined as dural tears, nerve root injury, post-op infection, hemodynamic instability, and post-op spinal structural instability.

Patient Reported Outcomes (PRO) data were available at baseline and three-month follow-up for 107 patients. Patients experienced a statistically significant ($p < 0.0001$, t-test for correlated samples) pain score improvement from baseline to three-months post-*mild* procedure. The average baseline VAS was 7.4, and average VAS at three-month follow-up was 3.9, an improvement of 3.5 points. Further, patients experienced a statistically significant ($p < 0.0001$, t-test for correlated samples) mobility improvement from baseline to three-month follow-up. Average baseline ODI was 48.0, and average ODI at three-month follow-up was 30.9, an improvement of 17.1 points.

Discussion

Patients undergoing lumbar decompression surgery for the treatment of lumbar spinal stenosis have been reported to have better outcomes than patients treated nonsurgically⁹⁻¹¹. Most recently, the Spine Patient Outcomes Research Trial (SPORT) showed a significant outcome advantage for surgery over nonsurgical treatment at three months, and these changes

remained significant at four year follow-up^{7,8}. The comparative design of SPORT, which included both randomized and observational cohorts, focused on the disparity of patient outcomes between surgery and nonsurgical treatment. Safety, as well as Operative Time, Mean Blood Loss, and Hospital Stay, were reported for patients in the SPORT surgical cohort.

All patients enrolled in SPORT had neurogenic claudication and/or radicular leg pain with ongoing symptoms for at least 12 weeks, and were judged by the investigators to be surgical candidates. SPORT surgical patients underwent standard posterior decompressive laminectomy. The SPORT surgical population had a mean age of 63.6 years and was 61.4% male. This compares to a mean age of 68.8 years for the mild patients and 40.5% male gender (see Table).

Reported mean operative time for a SPORT surgical laminectomy was 128 minutes, compared to approximately one hour for a *mild* procedure. SPORT surgical mean blood loss was 314 ml as compared to the negligible amount reported for *mild* procedures. Hospital stays were significantly shorter for *mild* patients at less than one day on average, compared to over three days for SPORT surgical patients.

A comparison of patient safety with the *mild* procedure versus SPORT surgical patients undergoing standard decompressive laminectomy is remarkable. To date, there have been no reports of serious complications associated with the *mild* devices or procedure, and there have been no blood transfusions required for *mild* patients, either intraoperatively or postoperatively. In comparison, 9.9% of patients in the SPORT surgical cohort experienced complications, including the most common surgical complication, dural tear, in 9.2% of patients. Further, 9.5% of SPORT surgical patients required an intraoperative blood transfusion, and 4.9% required a postoperative transfusion.

Patient Reported Outcomes related to pain were reported for *mild* patients using the ten-point Visual Analog Scale (VAS). At three-month follow-up, *mild* patients experienced a statistically significant ($p < 0.0001$, t-test for correlated samples) decrease in pain of 3.5 points on the VAS scale, which represents a 35.0% improvement (47.3% improvement from baseline). In SPORT, pain was recorded through the Low Back Pain Bothersomeness Scale, a secondary outcome measure in the Study. The Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms. SPORT surgical patients reported

Table *mild*[®] Procedures versus SPORT LSS Surgical Cohort

	<i>mild</i> [®] Procedures	<i>SPORT LSS Surgical Cohort</i>
<i>Demographics and Procedure:</i>		
Patients	163	394
Mean Age	68.8 Years	63.6 Years
Male % / Female %	40.5% / 59.5%	61.4% / 38.6%
Operative Time	One hour	128 minutes
Mean Blood Loss	Negligible	314 ml
Hospital Stay	< 1 day	3.0-3.5 days
<i>Safety:</i>		
Patients	253	394
Dural Tear	0%	9.2%
Blood Replacement		
Intraoperative Transfusion	0%	9.5%
Postoperative Transfusion	0%	4.9%
Overall Complication Rate	0%	9.9%
<i>Efficacy:</i>		
Patients	107	378
Pain:		
Scale	Visual Analog Scale	Low Back Pain Bothersomeness*
Baseline	7.4	4.1
3-Month Follow-up	3.9	2.1
Improvement (%)	-3.5 (-35.5%)	-2.0 (-33.3%)
Mobility:		
Scale	Oswestry Disability Index	Oswestry Disability Index
Baseline	48.0	43.2
3-Month Follow-up	30.9	21.8
Improvement	-17.1	-21.4

*Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

a decrease in pain of 2.0 points on this Scale, which indicates a 33.3% improvement at three-months (48.8% improvement from baseline).

Changes in mobility were recorded for both mild patients and SPORT surgical patients using the Oswestry Disability Index (ODI). *mild* patients reported a statistically significant ($p < 0.0001$, t-test for correlated samples) mobility improvement of 17.1 points from baseline ODI to three-month follow-up. This can be compared to the SPORT surgical cohort with a reported mobility improvement of 21.4 points from baseline to three-months. The difference in ODI improvement between these two groups is not statistically significant.

Conclusion

As a less-invasive alternative to decompression surgery, *mild* Lumbar Decompression has demonstrated comparable patient outcomes to standard decompressive laminectomy, with shorter procedure times, less blood loss, shorter hospital stays, and significantly better safety. *mild* is a safe and effective procedure that offers a valuable treatment option for the large number of symptomatic LSS patients who have failed conservative therapy. The *mild* procedure is primarily performed using local anesthesia, requires no implants and preserves the structural stability of the spine.

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