

Minimally Invasive Lumbar Decompression for Spinal Stenosis

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Abstract: Over 1.2 million patients are diagnosed with, and in active treatment for lumbar spinal stenosis (LSS) at any given time. Typically, these patients experience discomfort while walking or standing, for any length of time. The LSS treatment algorithm contains a gap of under-treated patients between epidural steroid injections (ESI) and open surgery. With the introduction of a minimally invasive lumbar decompression, or *mild*[®], procedure (Vertos Medical) for spinal stenosis, the LSS patient no longer needs to suffer under-treatment or undergo major lumbar surgery. *mild*[®] makes it possible to address this progressive disease with a progressive option.

Keywords: Decompression, lumbar, MiDAS, mild[®], percutaneous, stenosis.

INTRODUCTION

The current treatment algorithm for LSS consists of conservative management (physical therapy, rest, medications, exercise, etc.), followed by epidural steroid injections (ESI), and finally opens surgical decompression and fusion (Fig. 1). The *mild*[®] procedure (Vertos Medical) is a minimally invasive alternative to open or endoscopic surgery for lumbar decompression in the treatment of lumbar spinal stenosis (LSS). *mild* is typically performed using intravenous (IV) sedation monitored anesthesia care (MAC) and consists of partial removal of inter-laminar bone (laminotomy), and partial excision (debulking) of the ipsilateral ligamentum flavum and fatty tissue from the posterior aspect the lumbar spinal canal.

Decompression procedures primarily differ according to the access and guidance components. For example, a percutaneous approach is defined by a 5-10 mm surgical incision, an endoscopic approach requires a 15-20 mm incision, and a typical open laminotomy requires a 4-6 cm incision. The *mild* procedure utilizes a 5.1 mm portal for percutaneous approach and employs continuous epidurographic lateral oblique fluoroscopic image guidance throughout the procedure [2].

METHODS

LSS is generally described as compression of the neural elements related to a variety of degenerative changes including: facet hypertrophy, hypertrophic ligamentum flavum, and bulging of the intervertebral disc. In LSS, the space within the spinal canal narrows, which leads to asymptomatic compression of nerves and ultimately symptomatic neurogenic claudication. The goal of any surgical treatment of LSS is relief of symptoms by adequate neural decompression while preserving as much of the anatomy, stability, and biomechanics of the lum-

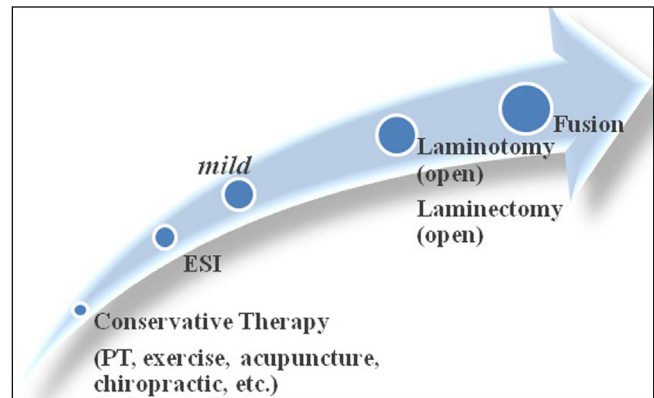


Figure 1. Current Treatment Algorithm.

bar spine as possible. Endoscopic and traditional open surgical treatment of LSS may not only require the 1.5-6 cm incisions mentioned above, but also involve a wide laminectomy and undercutting of the medial facet with foraminotomy; leading to local tissue trauma, scarring, and potential postoperative spinal instability [1].

The *mild* procedure offers a minimally invasive alternative to a standard laminotomy-laminectomy. Typically, *mild* is performed using local anesthesia and IV sedation to keep the patient comfortable. This procedure treats LSS by removing small, but adequate, portions of laminar bone and debulking the ligamentum flavum.

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mild Procedure Device Kit



Figure 2. *mild* Devices: **a.** *mild* Tissue Sculpter; **b.** *mild* Portal Stabilizer; **c.** *mild* Bone Sculpter Rongeur; **d.** *mild* Surgical Clamp; **e.** *mild* Portal; **f.** *mild* Depth Guide; **g.** *mild* Trocar and Handle.

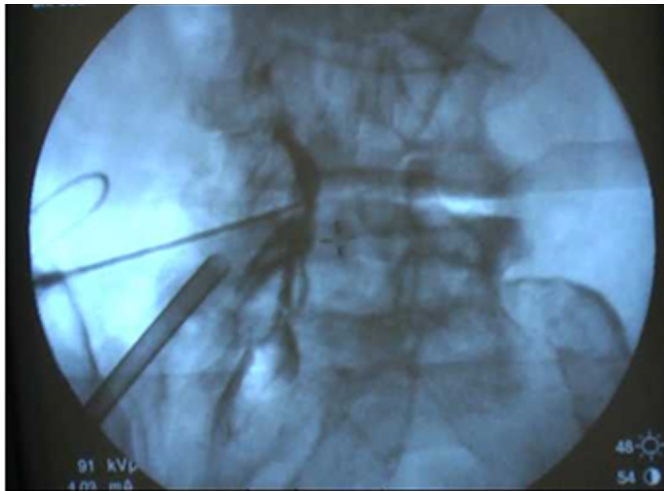


Figure 3. Epidurogram allows visualization for safe and adequate decompression of the target area.

This improves the space in the spinal canal while minimizing trauma to the surrounding tissue and bony structures. The restoration of space is confirmed during the procedure utilizing the continuous contralateral oblique epidurogram (Fig. 2).

Purposeful design elements of the surgical instruments used in the *mild* procedure include built-in safety features such as blunt tips to protect structures at the posterior approach and special top cutting surfaces for precision cutting at the desired angle (Fig. 3). The disposable *mild* kit also includes a portal stabilizer to minimize medial and lateral movement during the procedure, and an instrument depth guide.

The typical *mild* patient is elderly, often 65 years of age or older, and presents with lumbar spine neurogenic claudication symptoms thought to be concordant with findings of lumbar stenosis verified through imaging (MRI or CT) studies. Conservative measures have not alleviated symptoms satisfactorily. Neurogenic claudication is triggered by axial loading activities and unlike intermittent



Figure 4. Patient is kept comfortable in prone position with appropriate bolstering to open interlaminar space exposing target hemilaminar region.

or vascular claudication, is relieved by flexion and not by mere cessation of walking as in vascular claudications. Use of a simple standing test or, historically the Van Gelderen bicycle test, can assist when distinguishing between vascular and neurogenic claudication. The clinical symptoms from LSS result from a constrained cross sectional area of the canal either due to direct compression of the nerve roots that comprise the cauda equina, or due to reduction of venous outflow resulting in nerve root ischemia (or some combination of the two). The presence of a hypertrophied ligamentum flavum, compromising the anterior-posterior and lateral dimensions of the spinal canal identifies optimal candidates for the procedure [2, 3].

At the beginning of the procedure the patient is placed in the prone position on a radiolucent operating table, draped, and sterilely prepped. Appropriate bolstering is used as needed (Fig. 4). An epidurogram is then performed for the purpose of identifying the hypertrophic ligament flavum. Utilization of the contralateral oblique view presents the thickest cross-section of the lamina, providing optimal ligamentum infolding imaging. Next, the interlaminar space is identified through fluoroscopic visualization (Fig. 5). After the trajectory has been planned and the patient's skin marked, the *mild* 6G portal and 7G trocar are inserted percutaneously. These devices are advanced along the desired trajectory under fluoroscopic guidance. Once positioned, the trocar is removed, leaving the access portal in the interlaminar space (Figs. 6, 7). The *mild* Bone Sculptor Rongeur is



Figure 5. Epidurogram is performed with low volume intermittent injections using flow patterns to determine decompression and stopping point.

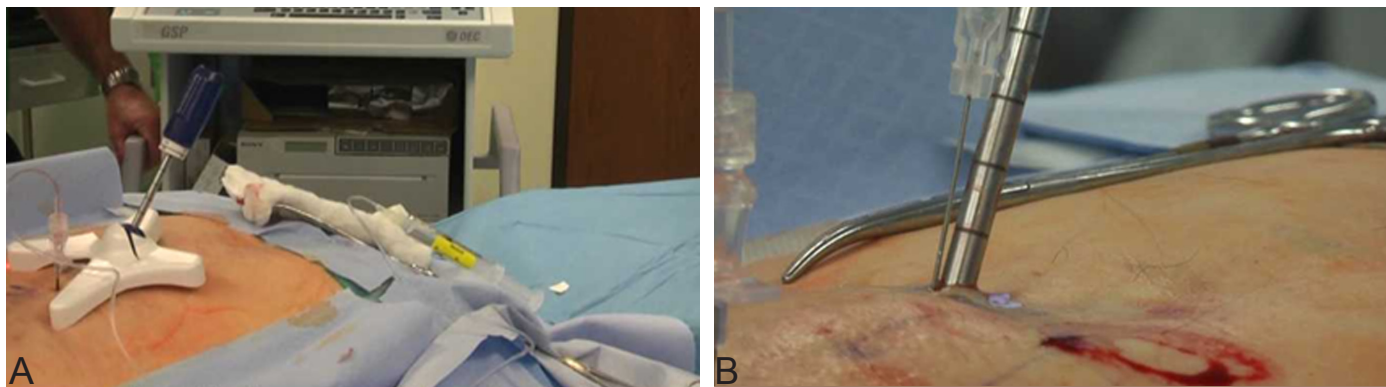


Figure 6. A. Portal stabilizer and depth guide are employed to avoid medial/lateral port movement and to avoid reaching unintentional instrument progression into the dural structures. **B.** A percutaneously placed 6G portal in the interlaminar space abuts the laminae providing access for laminotomy and tissue removal.

placed through the access portal to the lamina. The physician carefully rotates this device, which precisely cuts and then removes small pieces of bone. Once sufficient access is obtained, the Rongeur is removed and the *mild* Tissue Sculptor is advanced through the portal under the lamina into the dorsal aspect of the hypertrophic ligamentum flavum. Debulking of the ligamentum flavum is accomplished by removing the collagen laden posterior portion of the ligament, while leaving the ventral fibers of the ligament intact. An improved/easier contrast flow (reduction of infolding), along with limited availability of tissue to be removed, are clear indicators of the decompression endpoint on epidurogram. The procedure can be performed bilaterally and on multiple vertebral levels at one or more settings. It should be noted that the angle of the cutting tip on the instrumentation requires a new incision and instrument insertion when the procedure is being performed bilaterally or at another level.

Once adequate decompression has been achieved at the final operative level, the portal is removed and the wound typically closed with a sterile adhesive bandage. Since there is minimal soft tissue trauma, patients are usually observed for two hours after the procedure (or per facility standard protocol used for light sedation and local anesthetic) and subsequently discharged as clinically indicated. Patients are allowed to ambulate as tolerated and instructed to increase activities slowly. No implants are left behind and future treatment is not impeded by the *mild* procedure.

RESULTS

mild® EFFECTIVENESS

The MiDAS I (*mild* decompression alternative to open surgery) prospective clinical study was conducted at 14 US spine specialist practices and designed to assess the safety and functional outcomes of *mild* in the treatment of LSS. Patient selection criteria included: prior failure of conservative therapy; a hypertrophic ligamentum flavum (>2.5 mm); and a reduced thecal sac cross-section. Pa-

tients were assessed according to a Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ) and SF-12v2® Health Survey. A total of 78 patients were treated, 55 of these patients were over 65 years old. Twenty of the procedures were performed in an ambulatory surgical center (ASC) and 58 were performed at a hospital. Fifty-one percent of patients were treated at two levels, resulting in 115 total treated levels, for a total of 170 procedures with some levels treated bilaterally [2]. There were no major device or procedure related complications in this patient cohort with major complications defined as: dural tears, nerve root injury, hematomas, and infections. At week 6 follow-up, there were significant improvements in all clinical outcomes: VAS pain score ($p < 0.0001$); ODI functional mobility ($p < 0.0001$); ZCQ pain and function ($p < 0.001$); and the SF-12v2® quality of life physical and mental component scores.

Lingreen et al. conducted a retrospective review of 42 consecutive patients undergoing the *mild* procedure [5]. Patients ranged in age from 52 to 86 years old and all had failed prior conservative therapy for LSS. The majority of patients underwent two levels of bilateral decompression. There were no major adverse events. The most significant minor event was soreness lasting for a few days. No patient required overnight observation.

mild® SAFETY

Given that the decompression component of the *mild* procedure is similar to open laminotomy, the safety of the *mild* procedure emerges as the key unique outcome. As noted above, neither Chopko [2] nor Lingreen [5] reported major adverse events in a total of 120 patients. Further, Deer et al. reported the safety data of a manual and electronic chart review for 90 additional patients treated by 14 physicians in 9 American states [3]. Again, there were no significant complications with the *mild* procedure including no incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, hematoma, or infections reported. None of the procedures was aborted. No patients required re-admission to the hospi-

tal within 30 days of the mild procedure in these studies. Of the 210 procedures published in the peer reviewed literature, the reported incidence of major adverse events was 0%, thus confirming the excellent safety record of the *mild* procedure.

Deyo et al. recently reviewed the safety and effectiveness of the *mild* procedure when indirectly compared to open or endoscopic laminectomy [4]. The review was a retrospective cohort analysis of Medicare claims from 2002-2007 for patients undergoing surgery for spinal stenosis. Among the 21,474 patients undergoing open or endoscopic decompression only (i.e. without fusion), there was a 2.1% incidence of medical complications and a 30 day mortality of 0.6%. The length of stay was 2.7 days with 7.8% of patients re-hospitalized within 30 days for any reason. These statistics underscore the safety advantage of the *mild* procedure.

PROCEDURE SETTING

Though most commonly performed in the hospital outpatient setting, the *mild* procedure can be conducted safely and effectively in an ASC [2]. The procedure is performed by a trained physician in an operating room with surgical support staff in attendance. Typically, patient recovery is accomplished in a recovery room with appropriately trained nursing staff and does not require overnight observation; this is consistent with *mild* being an outpatient procedure [5].

DISCUSSION

Minimally invasive lumbar decompression for spinal stenosis (presented here as the *mild*® procedure) is indicated for those LSS patients exhibiting neurogenic claudication with hypertrophic ligamentum flavum. The *mild* procedure is similar to standard open or endoscopic lumbar laminotomy in terms of the anatomic structures undergoing decompression. The most significant difference between these procedures is that *mild* is a minimally invasive therapy that relies on fluoroscopic guidance, thus providing a clear procedural safety margin. Typically performed with local anesthesia and conscious sedation, the *mild* procedure can be performed in the outpatient setting. In multiple studies, patients reported significant

improvements in all clinical outcomes without any reported safety issues [3, 5]. The results of these studies compare favorably when contrasted to the Medicare database which indicates that 2.1% of patients undergoing simple decompression experience medical complications and 7.8% are re-hospitalized within 30 days [4].

CONCLUSION

Using a minimally invasive lumbar decompression (*mild*) for spinal stenosis, one can safely, and effectively reduce pain, improve functionality, and minimally change spinal biomechanics and stability in LSS patients who have failed conservative treatment and who are not yet in need of, or who do not desire more invasive open surgical decompression procedures.

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