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Observational Study

Retrospective Evaluation of Minimally Invasive Lumbar Decompression (mild®) for the Treatment of Neurogenic Claudication: A One-Year Follow-Up Study

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Background: Neurogenic claudication can be a chronic, debilitating disorder and is often hard to treat. Lumbar spinal canal stenosis (LSCS) occasioned by hypertrophy of the ligamentum flavum (HLF) is a common cause of neurogenic claudication, especially in the elderly patient population. These patients can be deemed poor surgical candidates due to the multitude of comorbidities with which they present. Minimally invasive lumbar decompression (mild®, Vertos Medical Inc.) is an alternative to surgery for patients who have neurogenic claudication and do not respond to conservative management. The prevailing literature supports the assertion that the mild® procedure is safe and effective. However, larger, high-powered studies are necessary to definitively establish the role of the mild® procedure in interventional pain treatment paradigms, especially when the effectiveness of conventional injections' utility in reducing pain and improving functioning is called into question.

Objectives: This study aims to assess the safety and efficacy of mild® within a one-year follow-up period, using self-reported pain scores, walking distance, and standing time.

Study Design: This project is a retrospective, observational study using data collected from electronic medical records.

Setting: Procedures were performed between June 11th, 2013, and November 7th, 2024, by a single trained, board-certified anesthesiologist and interventional pain management specialist at the Lahey Hospital and Medical Center, a tertiary academic medical center.

Methods: Variables measured included pain scores on the visual analog scale (VAS), walking distance (in meters), and standing time (in minutes) at intervals of one month, one-6 months, and 6-12 months. Procedure complications were classified as nonexistent (referred to as "none" by the researchers), minor, or major. A major complication was defined as one that required hospital admission. Statistical analysis was carried out using a paired Wilcoxon signed-rank test with a two-tailed hypothesis.

Results: A total of 95 patients underwent mild® in the selected time frame. No patients experienced an intraoperative complication, and 92 (96.8%) experienced no postoperative complications. Postoperative complications were limited to minor issues (e.g., bleeding, nausea, numbness, dizziness). There were significant reductions in VAS pain scores from baseline at one month (7.9 ± 1.2 vs 4.5 ± 2.7, $P < 0.00001$), one-6 months (7.8 ± 1.3 vs 5.2 ± 2.5, $P < 0.00001$), and 6-12 months (7.7 ± 1.2 vs 4.4 ± 3.0, $P < 0.00001$). Significant improvements in walking distance and standing time were also recorded.

Limitations: Limitations include the nature of a single-center, single-provider study. Patient-reported pain scores, walking distance, and standing time are subject to biases in response, recall, and subjectivity. Confounding variables such as epidural steroid injections (ESIs) or changes in enteral medications cannot be taken into consideration.

Conclusions: Patients who have HLF-caused LSCS, are unresponsive to conservative treatment,

and are poor surgical candidates can undergo mild® safely. This study showed significant improvement in VAS pain scores, walking distance, and standing time at intervals of one month, one-6 months, and 6-12 months.

Key words: mild®, spinal stenosis, ligamentum flavum, minimally invasive, low back pain

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Lumbar spinal canal stenosis (LSCS) is estimated to affect over 100 million people worldwide and 11% of older adults within the United States (1). Patients who have LSCS commonly present with intermittent neurogenic claudication, back pain, and/or weakness when the nerves inside the dural sac become compressed (2). These nerves can be compressed by fibrosis due to hypertrophy of the ligamentum flavum (HLF), which is closely associated with mechanical stress and aging (3).

Nonsurgical treatments for HLF-caused LSCS include physical therapy, nonsteroidal anti-inflammatory drugs, acetaminophen, gabapentinoids, and/or lumbar ESIs (4). Progression to open surgical treatment for spinal stenosis implies a risk for complications, and an estimated 30% of LSCS patients do not respond to treatment (5).

The minimally invasive lumbar decompression (mild®, Vertos Medical Inc.) procedure was first developed in 2005 to help treat cancer patients who developed spinal stenosis and likely could not tolerate surgery due to significant comorbidities (6). The treatment is an image-guided percutaneous procedure that aims to debulk hypertrophied ligamentum flavum (7). Preliminary results showed that mild® was safe and produced a clinically significant reduction in pain scores (8). Subsequent studies have reinforced that mild® has a favorable safety profile and can help relieve chronic pain in patients; however, these studies lack large sample sizes (9-12).

Objectives

The objective of this current study is to add to the growing evidence that supports the use of mild® as a nonsurgical approach to HLF-caused LSCS. The researchers sought to evaluate the safety and efficacy of mild® procedures performed at a tertiary academic medical center.

Study Design

This project is a retrospective observational study using data collected from electronic medical records (EMRs). The study received approval from the Institutional Review Board (IRB) at the Lahey Hospital and Medical Center and was given the approval number 20213092. Copies of written informed consent were not obtained due to the retrospective nature of this study. There were no conflicts of interest to report, and the researchers received no financial support. The manuscript was formulated using the Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE) checklist.

Setting

All mild® procedures were performed between June 11th, 2013, and November 7th, 2024, by a single trained, board-certified anesthesiologist and interventional pain management specialist at the Lahey Hospital and Medical Center.

Methods

Patients

Data collection was completed between June 2021 and February 2025. Eligibility criteria included any patients who underwent mild® and completed at least one clinic follow-up appointment within one year. Patients who did not respond to conservative nonsurgical management were selected to undergo mild® if they carried a diagnosis of LSCS with neurogenic claudication and showed the presence of HLF (at least 2.5 mm) on magnetic resonance imaging (MRI). Patients with spondylolisthesis of grade II or higher were excluded.

Intervention

The goal of mild® is to remove small portions of lamina and ligamentum flavum through a percutaneous approach. These interventions can be performed bilaterally and at multiple levels. All procedures were performed under a complete aseptic technique, and the patients received moderate sedation with intravenous fentanyl and/or midazolam. The board-certified interventional pain specialist in our study created a 5.1 mm treatment portal in which he inserted a trocar with a portal stabilizer and depth guide. Instruments,

including a bone sculptor rongeur and tissue sculptor, were passed through the treatment portal. Epidurograms with contrast material were utilized throughout the procedure to improve visualization and ensure the instrumentation was posterior to the dura at all times. At the end of the procedure, devices were removed, and the patients' skin was closed with Steri-Strips™ (3M™). See Fig. 1 for an example of an epidurogram.

Measurement

After a query of patients' medical-record numbers was secured, baseline patient characteristics were acquired from the EMR. These characteristics included age, body mass index (BMI), gender, ethnicity, and comorbidities. Comorbidities of interest for this study included hypertension, coronary artery disease, atrial fibrillation, history of coronary artery bypass grafts, history of percutaneous coronary interventions, Parkinson's disease, congestive heart failure, asthma, chronic obstructive pulmonary disease, diabetes mellitus, chronic kidney disease, history of cancer, and history of cerebrovascular accidents. Those comorbidities were selected because they placed patients at higher risk for postoperative complications if patients who had said comorbidities pursued open spine surgery (13).

Procedure-specific variables include the vertebral levels and the number thereof for each patient. All intraoperative and postoperative complications were recorded. Postoperative complications were divided into categories labeled none, minor, or major. Major complications were defined as any complications that required admission to the hospital. Additionally, the incidence of ESIs, transforaminal epidural steroid injections, medial branch blocks, radiofrequency denervation, intrathecal pumps, spinal cord stimulator placement, or spine surgery within one year after the mild® procedure was recorded for each patient.

Baseline visual analog scale (VAS) pain scores, walking distance in meters (m), and standing time in minutes (min) were recorded in the EMR at the initial pain clinic visit. Patients were then asked to return to the pain clinic after their mild® at intervals of one month, one-6 months, and 6-12 months to assess changes in VAS pain scores, walking distance, and standing time. Potential reporting bias was addressed by having nursing staff assess and record patient responses at clinic visits.

Statistical evaluation of nonparametric data was performed using the paired Wilcoxon signed-rank test with a two-tailed hypothesis and a preselected significance level of 0.05 (14). Other data were reported descriptively as mean ± SD (symmetric distributions) or median ± interquartile range (skewed distributions). All of the individual patient data collected during the trial will be shared after de-identification. These data will be available to any individual who makes such a request to the authors, at the discretion of the principal investigator of the study.

Results

In total, 95 individual patients received a mild® procedure in the selected time frame and were included in the initial data query. Only the patients who ultimately had a follow-up visit were included in the

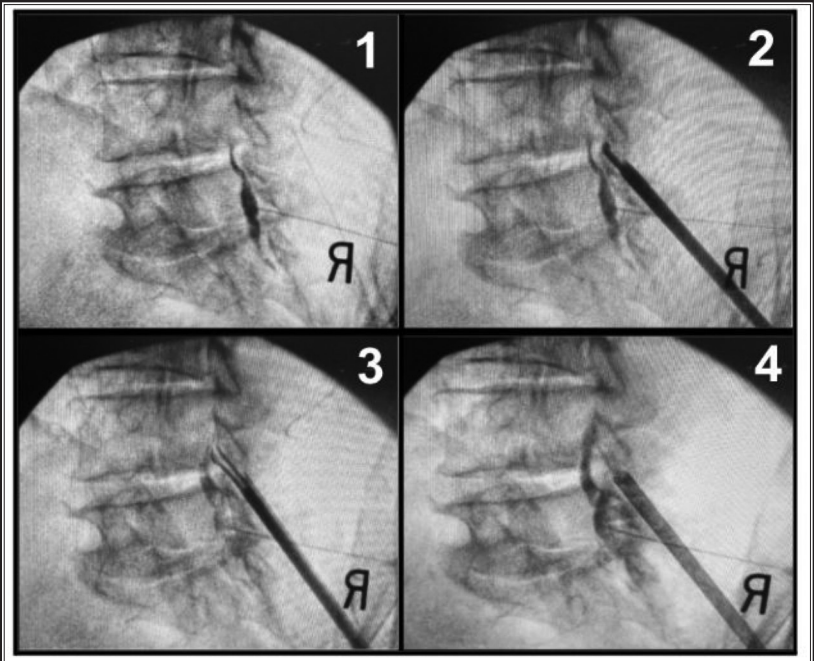

Fig. 1. *Epidurogram before decompression (1) and after decompression (4). Note the significant improvement in the cephalad spread of contrast dye in the epidural space posterior to the L4 vertebrae following decompression. Image 2 shows the bone sculptor rongeur removing pieces of superior lamina. Image 3 shows the tissue sculptor used to debulk ligamentum flavum from the posterior intralaminar space.*

statistical analysis for each respective follow-up period. Patients had an average age of 81.1 ± 6.6 (years ± SD) and an average BMI of 28.9 ± 4.7 (mean kg/m^2 ± SD). Most of the patients were Caucasian (93.7%), and the ratio of men to women was close (51.6% to 48.4%, respectively). Common comorbidities included hypertension (88.4%), coronary artery disease (32.6%), history of cancer (30.5%), diabetes mellitus (27.4%), and atrial fibrillation (26.3%). Characteristics of the patients are displayed in Table 1.

Most patients received mild® at L4-L5 (98.9%), followed by L3-L4 (51.6%) and L2-L3 (4.2%). Approximately half of the patients received mild® at a single vertebral level (48.4%), whereas slightly over half were given the procedure at multiple vertebral levels (51.6%). Specific vertebral levels for each patient are included in Table 2. No complications occurred during any of the mild® procedures. Postoperative complications were limited to minor issues, including serosanguinous discharge (2.1%), nausea (1.1%), self-limited hand numbness (1.1%), and dizziness (1.1%). None of the patients required overnight hospital admission. Complications are summarized in Table 3.

There were significant reductions in VAS pain scores, walking distance, and standing time at the intervals of one month, one-6 months, and 6-12 months. At one month, patients' pain scores on the VAS were 4.5 ± 2.7 (mean ± SD), in contrast to the baseline scores of 7.9 ± 1.2 (mean ± SD), with a *P*-value of < 0.00001. There were also significant reductions in pain scores at one-6 months (7.8 ± 1.3 vs 5.2 ± 2.5, $P < 0.00001$) and 6-12 months (7.7 ± 1.2 vs 4.4 ± 3.0, $P < 0.0001$) (Table 4).

Walking distance improved from a median of 15.2 m at baseline to 71.5 m at the one-month mark. This trend continued during the periods of one-6 months (15.2 m vs 126.2 m, $P < 0.00001$) and 6-12 months (30.2 m vs 401.2 m, $P = 0.0002$). In addition to walking distance, there were minor improvements in standing time. Standing time improved from a median of 5 min at baseline to a median of 15 min at one month ($P < 0.0001$), one-6 months ($P < 0.00001$), and 6-12 months ($P = 0.0018$). Comprehensive data on walking

Table 1. *Patient characteristics (n = 95).*

Variable	Value
Age (mean years ± SD)	81.1 ± 6.6
Body mass index (mean kg/m^2 ± SD)	28.9 ± 4.7
Gender; n (%)	
Male	49 (51.6%)
Female	46 (48.4%)
Ethnicity; n (%)	
Caucasian	89 (93.7%)
Asian	4 (4.2%)
African American	1 (1.1%)
Hispanic	1 (1.1%)
Comorbidities; n (%)	
Hypertension	84 (88.4%)
Coronary artery disease	31 (32.6%)
Atrial fibrillation	25 (26.3%)
History of CABG or PCI	17 (17.9%)
Parkinson's disease	5 (5.3%)
Congestive heart failure	18 (18.9%)
Asthma	13 (13.7%)
Chronic obstructive pulmonary disease	16 (16.8%)
Diabetes mellitus	26 (27.4%)
Chronic kidney disease	12 (12.6%)
History of cancer	29 (30.5%)
History of cerebrovascular accident	21 (22.1%)

Abbreviations: CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention

Table 2. *mild® procedure levels.*

Specific Procedure Levels	n (%)
L3-L4 & L4-L5	45 (47.4%)
L4-L5	45 (47.4%)
L2-L3, L3-L4, & L4-L5	3 (3.2%)
L3-L4	1 (1.1%)
L2-L3 & L4-L5	1 (1.1%)
Total Procedure Levels	n (%)
L2-L3	4 (4.2%)
L3-L4	49 (51.6%)
L4-L5	94 (98.9%)

Table 3. *mild® procedure complications.*

Complications	n (%)
Intraoperative complications	
No	95 (100%)
Yes	0 (0%)
Postoperative complications	
None	92 (96.8%)
Minor	
Serosanguinous discharge	2 (2.1%)
Nausea	1 (1.1%)
Self-limiting hand numbness	1 (1.1%)
Dizziness	1 (1.1%)
Major	0 (0%)

distance and standing time are shown in Tables 5 and 6, respectively.

The incidence of patients who received additional pain interventions one year after undergoing mild® can be seen in Table 7. None of the patients received an intrathecal pump, spinal cord stimulator, or spine surgery. Lumbar ESIs were performed for refractory pain relief in a respective 7 (7.4%) and 6 (6.3%) patients between one-6 months and 6-12 months. A smaller number of patients received a transforaminal ESI, or diagnostic medial branch block, with or without radiofrequency denervation.

Limitations

The major limitation of this study was that all the mild® procedures were performed by one trained interventional pain physician at a single institution. Hospital practices or provider techniques are likely to vary from one another, which may result in different experiences for patients undergoing mild®. Therefore, the generalizability, or external validity, of the study is limited. External validity is also limited by low diversity, since a large majority of patients were Caucasian. There was not enough variability to perform sensitivity analyses between different races. Reporting bias was at least partially attenuated by having nursing staff assess the patients. Ultimately, several factors confounded the study, such as the small proportion of patients who underwent other interventional pain procedures within a year of their mild® surgery. Additionally, there might have been variability in pharmacological pain regimens, varying levels of engagement with physical therapy, or comorbidities such as obesity and other chronic pain issues that impacted pain scores and functional capacity. These confounders were not accounted for in this study.

Future studies evaluating mild® would benefit from using the Oswestry Disability Index (ODI), a widely employed standardized tool used for measuring a patient's functional disability caused by low back pain (15). ODI scores were recorded infrequently in this study and could not be utilized for statistical analysis. Also, wearable technologies such as accelerometers may provide a more accurate representation of walking distance and standing time.

Conclusion

Data from this study support the use of mild® to treat instances of neurogenic claudication resulting from spinal stenosis caused by HLF. As discussed previously, elderly patients with chronic low back pain are likely to also have significant comorbidities, thus potentiating the risk that these patients will experience complications during open spine surgery (16). Patients in this study were most likely to have hypertension (88.4%) and a greater than 25% chance of having coronary artery disease, atrial fibrillation, diabetes mellitus, and/or a history of cancer. Although they were higher-risk surgical patients, no intraoperative

Table 4. *Changes in pain scores.*

Comparison Group	n in Paired Comparison	Baseline Pain Score (mean ± SD[b])	Follow-Up Pain Score (mean ± SD)	*P*-value[a]
one month	85	7.9 ± 1.2	4.5 ± 2.7	< 0.00001
one-6 months	67	7.8 ± 1.3	5.2 ± 2.5	< 0.00001
6-12 months	42	7.7 ± 1.2	4.4 ± 3.0	< 0.00001

a: paired Wilcoxon signed-rank test with two-tailed hypothesis and selected significance level of 0.05; b: SD, standard deviation

Table 5. *Changes in walking distance.*

Comparison Group	n in Paired Comparison	Baseline Distance in Meters (Median [IQR[b]])	Follow-Up Distance in Meters (Median [IQR])	*P*-value[a]
one month	59	15.2 [15.0 - 30.5]	71.5 [30.6 - 402.3]	< 0.00001
one-6 months	44	15.2 [15.0 - 30.5]	126.2 [46.3 - 600.0]	< 0.00001
6-12 months	24	30.2 [15.2 - 30.5]	401.2 [30.5 - 804.7]	0.0002

a: paired Wilcoxon signed-rank test with two-tailed hypothesis and selected significance level of 0.05; b: IQR, interquartile range

Table 6. *Changes in standing time.*

Comparison Group	n in Paired Comparison	Baseline Standing Minutes (Median [IQR[b]])	Follow-Up Standing Minutes (Median [IQR])	*P*-value[a]
one month	62	5.0 [5.0 - 5.0]	15.0 [10.0 - 15.0]	< 0.00001
one-6 months	44	5.0 [5.0 - 5.0]	15.0 [10.0 - 30.0]	< 0.00001
6-12 months	24	5.0 [4.5 - 5.0]	15.0 [10.0 - 20.0]	0.00018

a: paired Wilcoxon signed-rank test with two-tailed hypothesis and selected significance level of 0.05; b: IQR, interquartile range

Table 7. *Incidence of pain intervention post-mild® procedure.*

Type of intervention	One Month n (%)	One-6 Months n (%)	6-12 Months n (%)
Lumbar epidural steroid injection	0 (0%)	7 (7.4%)	6 (6.3%)
Transforaminal epidural steroid injection	0 (0%)	1 (1.1%)	2 (2.1%)
Medial branch block	0 (0%)	5 (5.3%)	7 (7.4%)
Radiofrequency denervation	0 (0%)	3 (3.2%)	3 (3.2%)
Intrathecal pump	0 (0%)	0 (0%)	0 (0%)
Spinal cord stimulator	0 (0%)	0 (0%)	0 (0%)
Spine surgery	0 (0%)	0 (0%)	0 (0%)

complications ensued, supporting the observation that mild® was a safe alternative to open spinal decompression surgery. Complications were self-limited, and no patients required overnight hospital admission. Safaee et al studied 354 patients at a tertiary academic medical center and found that minimally invasive decompressive surgeries were associated with decreased total costs due to a shorter length of stay when compared to those that followed open lumbar decompressions (17). However, the average age of the patients in the Safee et al (17) study was 55 years, which was much younger than the average age of 81 years in our study. Larger studies are needed to determine if mild® procedures are associated with a greater cost benefit than their open counterparts for elderly patients.

Our study is not the first to show a significant reduction in elderly patients' VAS pain scores after mild®. Shahi et al followed 345 patients after they underwent minimally invasive spinal surgeries and found that elderly patients (> 80 years old) had significant reductions in back and leg pain from the baseline scores (18). Although there were significant changes from baseline, elderly patients showed less improvement than did the younger individuals. This result may suggest that minimally invasive procedures are effective alternatives to open surgeries for younger, healthier patients as well. Also, it may be argued that mild® is safe and effective to perform at multiple vertebral levels simultaneously, which has been shown in previous assessments of minimally invasive spine surgeries (19). Future sensitivity analyses of larger sample sizes are needed to confirm or refute these claims.

Although mild® has been shown to be a safe, effective procedure with a similar safety profile to that of a classic ESI, there are significant risks to the former technique (20). The epidural and intrathecal spaces adjacent to the ligamentum flavum are prone to serious complications. In December 2023, Tenhoeve et al described a case report of a 76-year-old woman who underwent mild® and presented to the emergency department following hospital discharge with worsening pain, weakness, and numbness in her legs (21). Imaging studies revealed an acute lumbar epidural hematoma that required surgical intervention. Any institution that implements mild® as an ambulatory procedure must retain providers trained in early recognition of complications related to neuraxial procedures, and these same providers must educate their patients about the risks and parameters that should prompt return to the hospital or emergency department.

The results of this study support the growing evidence that mild® is a safe alternative to open spine surgery for treating patients who have neurogenic claudication derived from HLF-caused LSCS. Patients in this single-center, single-provider study showed clinically significant improvements in VAS pain scores, walking distance, and standing time at intervals of one month, one-6 months, and 6-12 months. Future high-power, multicenter studies are still needed to assess the longer-term functional improvements in patients who receive mild®.

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