Observational Study

Retrospective Review of the Outcomes of 300 Minimally Invasive Lumbar Decompression® Cases: Real-World Outcomes Compared to Data in Published Literature

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Background: Lumbar spinal stenosis (LSS) is a prevalent cause of pain and disability in elderly individuals, characterized primarily by neurogenic claudication resulting from narrowed spinal canals. Traditional treatment for LSS spans from conservative approaches to decompressive surgery, the latter of which poses significant complication risks. Minimally Invasive Lumbar Decompression® (MILD®, Vertos Medical) offers a less invasive alternative, with its efficacy supported by preliminary studies such as the MiDAS ENCORE.

Objective: This retrospective study evaluates the real-world outcomes of the MILD® procedure in managing LSS accompanied by hypertrophied ligamentum flavum (HLF) in 300 patients who have failed conservative management.

Study Design: A single-center observational study.

Methods: We conducted a retrospective review of 300 patients treated with MILD® at a single center in Northern New Jersey. Patients had documented cases of central LSS with HLF and persistent symptoms despite being treated with conventional therapies. The procedure involved percutaneous lumbar decompression using fluoroscopic guidance. Outcomes measured included scores on the Numeric Pain Rating Scale (NPRS) and patient-reported improvement percentages at intervals of up to one year.

Results: MILD® significantly reduced NPRS scores at all follow-up points, with the most substantial improvements noted within 3 months after the operation and sustained benefits up to a year. The average patient-reported improvement in pain and function was robust, beginning as early as 2 weeks after the procedure. No serious adverse events were reported, affirming the procedure's safety.

Limitations: The absence of a control group and the study's single-center nature might have limited the generalizability of results. These factors highlight the necessity for multicenter controlled trials to validate findings across diverse populations.

Conclusion: The MILD® procedure is a safe and effective treatment for LSS, providing significant and sustained improvements in pain and function, making the technique particularly suitable for patients ineligible for surgery or at higher risk of experiencing complications from it.

Key words: lumbar spinal stenosis, percutaneous image-guided lumbar decompression (PILD) procedure, Minimally Invasive Lumbar Decompression (MILD®) procedure, neurogenic claudication, minimally invasive surgery, retrospective study, real-world outcomes

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Lumbar spinal stenosis (LSS) is a degenerative spinal condition caused by spinal canal narrowing. This condition is especially prevalent in the elderly and can cause significant discomfort that interferes with activities of daily living, which can result in disability. The classic symptom is neurogenic claudication, which is severe back and lower extremity pain that is exacerbated with lumbar extension and relieved with lumbar flexion. Unlike radicular pain, the symptoms of neurogenic claudication do not typically follow a dermatomal pattern.

Patients with neurogenic claudication frequently present with several degenerative spinal conditions, including hypertrophied ligamentum flavum (HLF), disc bulging and herniation, and facet hypertrophy. HLF has been reported to contribute to 50-85% of central canal narrowing (1).

Initial treatment options for patients with LSS begin with conservative measures, which include physical therapy and oral analgesics. If conservative treatments fail, interventional treatment modalities are often considered next, including epidural steroid injections (ESIs) and the Minimally Invasive Lumbar Decompression (MILD®, Vertos Medical) procedure. This procedure provides minimally invasive decompression of the lumbar spinal canal for LSS patients with neurogenic claudication secondary to HLF. The landmark study for the MILD procedure, the MiDAS ENCORE study, provided level I evidence to support the long-term safety and effectiveness of the procedure (2-4). In this study, the procedure had a safety profile comparable to an ESI, with more favorable results (2-4).

This study is a retrospective review of 300 MILD® cases and was designed to reflect real-world practice data by demonstrating the results of patients who were appropriate candidates for MILD®. The objective of this study is to present real-world outcome data for this procedure and compare it to the published literature.

Study Design

This study is a retrospective review of 300 MILD® cases performed by one physician in one practice location in Northern New Jersey.

Methods

Patients

Three hundred patients were enrolled in this study from December 2019 through January 2025. Their ages ranged from 59 to 93. All patients had experienced neurogenic claudication for at least 6 months, characterized by pain that manifested predominantly in the lower extremities, numbness, and/or tingling that worsened with standing or walking and improved with forward flexion. Many patients reported needing frequent rest breaks during prolonged standing or ambulation. On examination, patients often displayed a forward-flexed antalgic gait and experienced additional symptomatic relief with further forward bending. All patients had stable neurological exams. Each patient also had an magnetic resonance imaging and/or computed tomography scan of the lumbar spine, which was personally reviewed by the treating physician. Eligible levels displayed central LSS with HLF thickness of at least 2.5 mm on axial imaging. The imaging study was then correlated with physical examination findings to verify that the observed stenosis accounted for the patient's symptoms. Every patient had multilevel (2 or more contiguous levels) disease, and none had undergone the MILD® procedure previously. All patients had previously undergone an interlaminar or transforaminal ESI that did not provide relief of symptoms past 3 months. Every patient had an NPRS score > 4 before the procedure. Exclusion criteria included patients with spondylolisthesis that exceeded grade I, progressive neurological deficits, and/or high suspicion for cauda equina syndrome and other serious spinal pathologies.

Intervention

MILD® was performed under light sedation and percutaneously through a 5.1 mm port, limiting trauma to the tissue. During the procedure, the interlaminar space was accessed from the posterior lumbar spine, under fluoroscopic guidance. Small amounts of lamina and HLF were selectively removed, achieving lumbar decompression. Visualization of an epidurogram contrast flow confirmed the amount of decompression. Once adequate decompression was achieved, the devices were removed, and the procedure was completed. All procedures involved multilevel decompressions; most were 2-level cases, and no procedure addressed more than 4 levels.

Outcome Measures

NPRS scores and percentages of improvement were reported at the following time frames: 2 weeks, 3 months, 6 months, 9 months, and one year after the procedure. The percentages of improvement were evaluated by asking patients to estimate the percentage by which they had improved in both pain and func-

tion after the surgery. Safety was evaluated by assessing the incidence of procedure-related adverse events at follow-up visits.

Statistics

The means and standard deviations of the groups, divided by time frame, were summarized. A paired t-test with a 0.05 significance level was used to determine if statistical significance was reached for the NPRS before and after the procedure at different time points. A one-sample t-test with a 0.05 significance level was used to determine whether the mean percentage improvement differed significantly from zero. Clinical significance was defined as an improvement of over 30% in the NPRS score. Adverse events were summarized by using frequency counts and percentages.

Results

Patients demonstrated remarkable improvements in NPRS after MILD® at all time points (Fig. 1, Table 1). The NRPS scores showed a gradual decline over the 12-month study period. Preoperatively, the average score was 7.75 (95% CI: 7.62–7.87). At 2 weeks after the procedure, the average score decreased to 4.16 (95% CI: 3.97–4.35), with further reductions to 3.53 at 3 months (95% CI: 3.37–3.69), 3.35 at 6 months (95% CI: 3.22–3.49), 3.27 at 9 months (95% CI: 3.14–3.40) and 3.35 at 12 months (95% CI: 3.22–3.48). These results indicate a substantial decrease in NRPS scores within the first 3 postoperative months, followed by a stabilization in the subsequent months. Additionally, most patients demonstrated clinically significant improvements in pain, starting immediately at 2 weeks after the procedure. About 77% of patients exhibited a 30% or greater improvement in their NPRS scores, while 54% exhibited a 50% or greater improvement in those scores. The proportion of patients responding to MILD® continued to increase to the 6-month mark, at which point 94% of patients achieved a 30% or greater improvement in NPRS scores, and 74% achieved an improvement of 50% or greater (Fig. 2). Those values stabilized after 6 months.

In terms of percentage improvement, patients reported significant gains in both pain relief and function following the procedure (Fig. 3, Table 2). At 2 postoperative weeks, the average improvement was 56.2% (95% CI: 53.1–59.2). This percentage increased to 80.1% at 3 months (95% CI: 78.4–81.8). By 6 months, the average improvement was 73.3% (95% CI: 71.3–75.3), a level that remained consistent at both 9 months and 12 months.

Both of those outcome measures achieved statistical and clinical significance at all follow-up intervals. No serious procedure-related adverse events were reported. No patients were lost to follow-up.

Discussion

Neurogenic claudication secondary to LSS is a prevalent condition in the adult population, often leading to significant disability and a reduced quality of life. Traditionally, decompressive surgery has been the primary treatment for LSS; however, it carries risks, long recovery times, and high health care costs. Conservative treatments, such as physical therapy, NSAIDs, and other pharmacological agents, have demonstrated limited effectiveness (5). While ESIs may provide short-term relief, their benefits may be limited and decrease over time (6). In contrast, the MILD® procedure has emerged as a safe and effective treatment option for patients with LSS.

The MiDAS 1 study, a prospective multicenter trial,

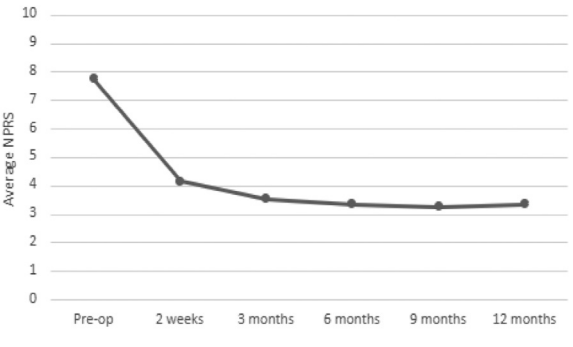


Fig. 1. *Average self-reported Numeric Pain Rating Scale (NPRS) before and after the MILD® procedure over a 12-month period.*

Table 1. *Summary statistics for Numeric Pain Rating Scale (NPRS) scores at baseline and at serial follow-up after the MILD® procedure.*

	Pre-Op	2 Weeks	3 Months	6 Months	9 Months	12 Months
Average	7.7	4.2	3.5	3.4	3.3	3.4
95% CI	(7.6, 7.9)	(4.0, 4.3)	(3.4, 3.7)	(3.2, 3.5)	(3.1, 3.4)	(3.2, 3.5)
P-value		$P < .001$	$P < .001$	$P < .001$	$P < .001$	$P < .001$

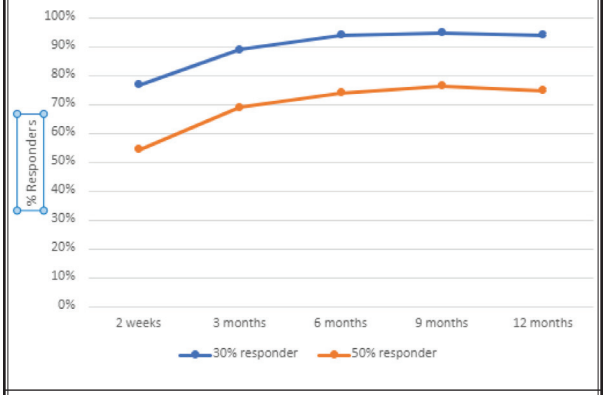


Fig. 2. *Percentage of patients achieving clinically significant reductions in NPRS scores, defined as at least 30% and 50% reductions, after the MILD® procedure over a 12-month period.*

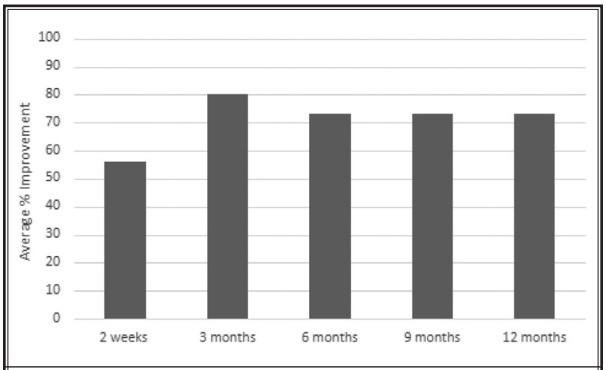


Fig. 3. *Average self-reported percentage improvement in pain and function after the MILD® procedure over a 12-month period.*

Table 2. *Summary statistics for percentage improvement in pain and function relative to baseline at serial follow-up after the MILD® procedure.*

	2 Weeks	3 Months	6 Months	9 Months	12 Months
Average	56%	80%	73%	73%	73%
95% CI	(53%, 59%)	(78%, 82%)	(71%, 75%)	(71%, 75%)	(71%, 75%)
P-value	*P* <.001	*P* <.001	*P* <.001	*P* <.001	*P* <.001

evaluated 78 patients who had undergone MILD® to treat their LSS. Statistically and clinically significant improvements were observed in pain reduction, mobility, and physical function at the 6-week follow-up. Visual analog scale (VAS) scores improved from 7.3 to 3.7, and Oswestry Disability Index (ODI) scores improved from 47.4 to 29.5, with both *P*-values < 0.0001. Additionally, Zurich Claudication Questionnaire (ZCQ) results showed significant improvements in physical function and symptom severity. Short-Form 12-item (SF-12v2®) Health Survey scores improved in all summary measures and health domain scales, with statistical significance for all scales except the general scale. Patients reported high satisfaction with their outcomes, and no major device- or procedure-related complications were noted (7).

The MiDAS Encore study followed 99 patients who underwent MILD® over a 2-year period, demonstrating sustained, clinically meaningful, and statistically significant improvements in all primary and secondary efficacy outcome measures. At the 2-year mark, patients showed notable improvements, including a 22.7-point reduction in ODI scores, a 3.6-point improvement in NPRS scores, and significant decreases in symptom severity and gains in physical functioning as measured on the ZCQ. Importantly, no patients required a subsequent MILD® procedure, and the occurrence of adverse events was minimal, with no serious device- or procedure-related complications (2-4).

The results of our study demonstrated that MILD® led to significant improvements in patient-reported pain and functioning, as evidenced by reductions in the NPRS scores at all follow-up time points. On average, patients reported substantial improvements in both pain levels and functional capacity following the procedure. These changes were not only statistically significant but also clinically meaningful, further supporting the effectiveness of MILD® in managing pain and improving function. Importantly, no serious adverse events were observed, indicating that the procedure was safe for patients. These findings align with previous research suggesting that minimally invasive interventions can offer substantial benefits without significant risk of complications (2). Our study adds robust, real-world evidence to support the efficacy and safety of MILD®, reinforcing findings from other previous research (2-4,7-15). Moreover, the large sample size of 300 patients also strengthens the statistical validity of the results. These outcomes are essential, since they demonstrate outcomes observed in clinical practice, confirming the practical utility of MILD®. In the future, we plan to continue assessing these patients over multiple years to better evaluate the long-term success rate and safety of MILD®.

While surgical interventions remain an option for certain individuals with LSS, MILD® has emerged

as a compelling alternative, particularly for those who may not be ideal candidates for surgery. Supported by data indicating that traditional surgical decompression carries about a 12% rate of intraoperative and postoperative complications (16), MILD® offers a safer option with a considerably lower risk profile. This information is especially relevant for patients who are at a higher risk of complications from more invasive procedures. Importantly, opting for MILD® does not preclude patients from considering future surgical interventions if necessary. These factors advocate for the inclusion of MILD® within treatment algorithms for neurogenic claudication due to LSS with HLF, enhancing both the options available to patients and their overall safety.

Given the strong outcomes demonstrated in this study and the comparative safety of MILD®, future management and therapeutic guidelines should consider it a primary treatment modality for suitable patients who have not responded to conservative management. To further substantiate the efficacy and safety of MILD® relative to surgical interventions, we recommend that future randomized controlled trials directly compare the outcomes of MILD® with those of traditional surgical decompression techniques. This approach can help establish whether MILD® should always be considered prior to surgical intervention and guide clinical decision-making for patients who are good candidates for both procedures. This study represents an advancement in the therapeutic landscape for managing LSS with HLF and paves the way for continued research to expand upon these encouraging results.

Limitations

The absence of a control group presents a potential limitation in this study. Incorporating a control group proved challenging, since the patients had already exhausted conventional medical management, including ESIs. However, many previous studies have already demonstrated the superiority of MILD® over conventional management and/or ESIs (2-4,13). Despite this factor, the lack of a control group makes it difficult to distinctly attribute the observed improvements to MILD®, independent of external factors.

Additionally, this study's single-center design poses another limitation. The study sourced its patients exclusively from Northern New Jersey and its surrounding areas. Thus, the results are particularly reflective of this region's demographic, including its ethnic composition, socioeconomic status, and regional health policies. This element may limit the applicability of the findings to populations outside this geographic area. Furthermore, outcomes could differ in other locations where variations in medical practice, physician expertise, and available health care resources might influence the outcome of MILD®. These factors underscore the need for further multicenter randomized control trials to validate these findings across diverse settings and enhance the generalizability of the study's conclusions.

Conclusion

Our retrospective study aimed to evaluate the real-world outcomes of MILD®, providing valuable insight into the effectiveness and safety of this procedure beyond the controlled environment of clinical trials. The results demonstrate significant and sustained improvements in pain relief, as well as self-reported mobility and function, supporting the growing body of evidence that MILD® is a safe and effective treatment. This study highlights MILD® as a viable alternative to traditional surgery, especially for patients at higher risk of complications who have not achieved sufficient relief from conservative treatments.

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