

**Title:** New 5 Year Data Demonstrates *mild* as a Long-term Solution and Helps Patients Avoid Open Surgery

Most *mild* providers are very familiar with the study conducted by Dr. Nagy Mekhail (MD, PhD) who, along with a team of investigators from the Department of Pain Management at the Cleveland Clinic, examined the real-world benefit of the *mild* Procedure: functional improvement. The 1-year outcomes demonstrated significant functional improvement for patients in both walking distance and standing time, with continuous mean improvement at each follow-up point. The study results are remarkable, as can be viewed in Figures 1 and 2 below. Patients clearly benefited from this type of treatment with a notable increase in function; this shows the difference in patients who previously were not able to complete simple, everyday tasks to being able to get out and enjoy life—without having to sit down and rest as frequently as they did before having the *mild* Procedure.

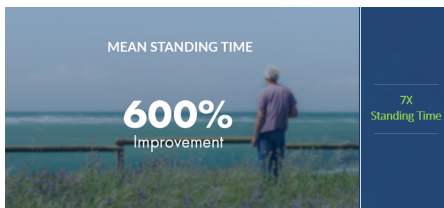


Fig. 1 Mean

Standing Time in patients after the *mild* Procedure.

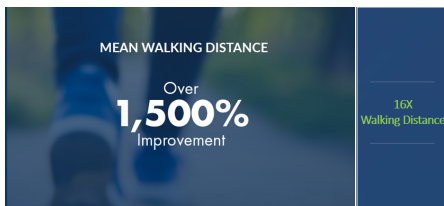


Fig. 2 Mean Walking

Distance in patients after the *mild* Procedure.

The investigators continued to study this patient population to further explore the long-term durability of *mild* as measured by the incidence of open lumbar decompression surgery at the same level(s) as the *mild* procedure during 5-year follow-up.

The recently published paper (name, pub) explores the demand for minimally invasive procedures like *mild* for this growing patient population who desire, and often require, a safe and low-cost solution that may help them avoid surgery. Authors cite-- "Given the large and growing elderly population who are either unwilling or unable to tolerate general anesthesia and the potential adverse effects associated with open decompression procedures, it is necessary to consider less invasive options, especially if the cost differential and complication profile greatly favor the minimally invasive option. [...] as the longevity of this aging population increases, the demand for sustenance of active quality of life and reduced cost of health care is rising."

*mild* can be a straightforward and safe solution for patients, addressing a major root cause of their stenosis without having to undergo an invasive open surgery. "Proper patient screening and differential

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diagnosis play key roles in treating the large lumbar spinal stenosis (LSS) population. It is well-known that LSS is multifactorial. However, as was previously reported in clinical studies, positive outcomes are achieved with the removal of very small amounts of bone and hypertrophic ligament using the *mild* Procedure in patients having a combination of facet hypertrophy, osteophytes, disk bulge, spondylosis, and/or foraminal stenosis.<sup>14,16-19</sup> Clearly, it is not necessary to correct every causal factor in a large population of the LSS patients.”

So, is the *mild* procedure durable over 5 years, and will it allow elderly patients with symptomatic LSS to avoid lumbar decompression surgery (while providing significant symptomatic relief)? The investigators believe so. Here are 3 key takeaways from the article, and a link to access the full peer-reviewed article from (journal name):

Strong Safety Profile	<p>“The <i>mild</i> Procedure allows debulking of the hypertrophic ligamentum flavum without interfering with the integrity of the bony spine, and does not require implants. This supports the robust safety profile of the <i>mild</i> procedure as compared with open decompression spine surgery as well as interspinous process decompression.”</p> <p>“There were no major complications recorded.”</p>
Early Treatment Option	<p>“Since the <i>mild</i> Procedure demonstrated durability up to 5 years, it might also be concluded with caution, that appropriate patients should be encouraged to undergo the <i>mild</i> Procedure as early as needed, rather than waiting until these patients are at an advanced age.”</p>
<i>mild</i> saved 88% of patients from open lumbar decompression surgery for at least 5 years	<p>“... report demonstrates a low percentage of patients resorting to open surgical decompression options after undergoing the <i>mild</i> Procedure; 9.3% at 2 years and 12.0% at 5-year follow-up. This represents an annual incidence rate of open lumbar surgical decompression of only 2.4%.”</p> <p>Only 12% of patients required lumbar surgical decompression during the 5-year follow-up period. <i>mild</i> saved 88% of patients with symptomatic LSS from open lumbar decompression surgery for at least 5 years.</p>

**Commented [HY1]:** ID a way to make these statements infographics or something easy to collect key takeaways from & use quotes from the paper to support it

[button] Access full article to learn more

**Acknowledgements:** A special thank you to the investigator and author team from the Evidence-Based Pain Management Research Group at the Cleveland Clinic: Nagy Mekhail, MD, PhD; Shrif Costandi, MD; George Nageeb, BS; Catherine Ekladios, MD; Ogena Saied, MS. Vertos and the *mild* patients across the country who benefit from this procedure are grateful for your care and attention in advancing the data around the safety, functional improvement, and long term durability of *mild*.