

mild

Procedure,
Intense
Satisfaction

Minimally Invasive Approach to Lumbar Spinal Stenosis Relieves Pain and Increases Mobility

Patients with moderate to severe lumbar spinal stenosis (LSS) often can't stand longer than a few minutes or walk more than a few hundred feet without developing severe pain. This significantly limits their activities and quality of life. Until a few years ago, the only treatment options available for patients with LSS were conservative therapies or open spine surgery.



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For patients who don't respond to conservative treatment and are unable or unwilling to undergo open spine surgery, Cleveland Clinic's Department of Pain Management now offers a novel X-ray-guided percutaneous outpatient treatment called *mild*[®], which stands for minimally invasive lumbar decompression.

"The *mild* procedure decreases pain and increases mobility while maintaining the structural integrity of the spine," says Nagy Mekhail, MD, PhD, Director of Evidence-Based Medicine in the Department of Pain Management.

The average age of patients presenting with LSS is 73 years. Medicare began covering the *mild* procedure in July 2012, and a number of private insurers cover it as well.

WHO'S A CANDIDATE?

LSS may be due to a bulging disk and/or hypertrophy of the ligamentum flavum, which lines the back of the spinal canal. Narrowing of the spinal canal causes nerve compression. When someone with LSS stands or walks, the spinal canal narrows even more, causing neurogenic claudication, or low back and leg pain that is relieved with sitting or bending forward.

Patients with moderate to severe LSS may be candidates for *mild* if they complain of neurogenic claudication and if MRI shows that a thickened ligamentum flavum, not a bulging disk, is the major cause of the spinal stenosis, Dr. Mekhail says.

TRADITIONAL OPTIONS CAN FALL SHORT

Nonsurgical treatment for LSS includes NSAIDs, physical therapy and/or epidural injections to relieve inflammation and swelling. These treatments are effective in only a small percentage of patients, and their chances of efficacy decrease with the duration of LSS. If they do work, the effect may not be sustained, and they need to be repeated.

"Epidural steroid injections tend to have limited effectiveness because LSS pain is ischemic rather than inflammatory in origin, as in radicular pain due to a herniated lumbar disk," Dr. Mekhail explains.

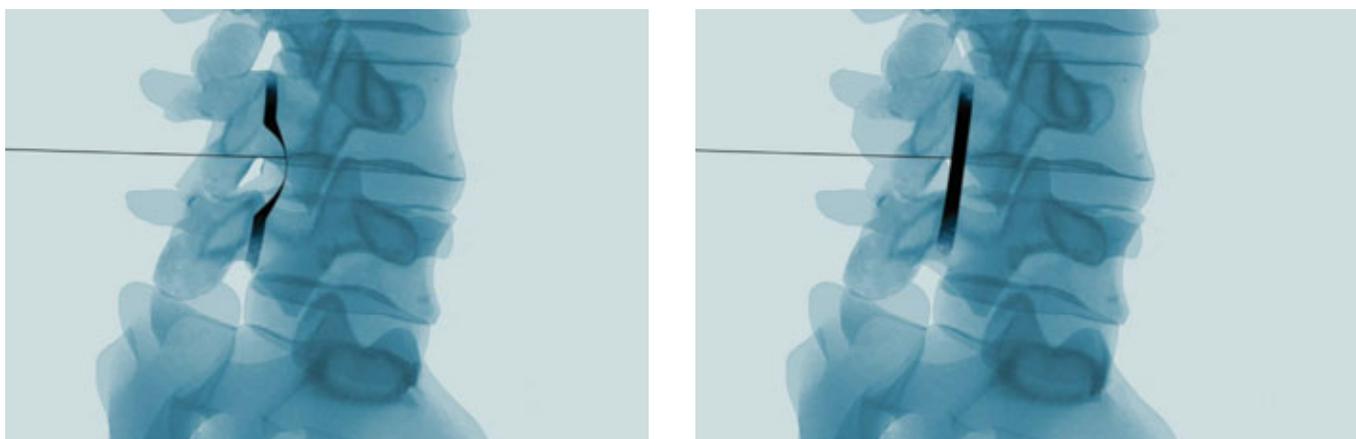
Some patients who have LSS can benefit from open spine surgery, in which the laminae are removed to relieve pressure on the spinal nerves. However, not all patients are candidates for open spine surgery, especially since surgery and anesthesia carry a higher risk in the older patients who account for the bulk of LSS cases.

The *mild* procedure offers a new treatment option for these patients. "With more than 10,000 baby boomers turning 65 every day, more and more patients are seeking innovative treatments such as *mild* to stay active and maintain their quality of life," Dr. Mekhail says.

MINIMALLY INVASIVE, MAXIMALLY QUICK RECOVERY

The *mild* procedure is performed under deep sedation through a 1-cm incision. The clinician uses a special sculpting tool that glides through a portal with a diameter of 5 mm, about the size of a pen cap, to go between the bones, scrape out the ligaments and widen the spinal canal to reduce nerve compression (see images below). X-ray fluoroscopy and repeated injection of contrast material into the epidural space are used to assess positioning and assist with visualization throughout the procedure.

Because the architecture of the spine remains intact, spinal mechanics are not disrupted and patients typically recover quickly. They are discharged home after a couple of hours and are able to begin walking within the first 24 hours after the procedure. Patients are encouraged to walk regularly and/or participate in physical therapy following the procedure.



Radiographic views of a spine before (left) and after (right) the *mild* procedure. Widening of the spinal canal decompresses nerves, relieving chronic pain from lumbar spinal stenosis.

ENCOURAGING AND ENDURING RESULTS

Results with *mild* to date have been encouraging. Dr. Mekhail and colleagues recently published one-year outcomes among dozens of patients who underwent the *mild* procedure (see Suggested Reading). Highlights include:

- No major device- or procedure-related complications
- Significant reduction in pain at one-year follow-up
- Improvement in physical functionality and mobility as measured by change (before vs. after procedure) in walking distance and standing time
- Decreased disability secondary to neurogenic claudication

Results are no less impressive at the individual patient level, as illustrated in the sidebar. “Patients are able to get back to more normal lives and the activities they enjoy — everything from grocery shopping to golfing,” Dr. Mekhail notes.

To refer an LSS patient for evaluation for the mild procedure, call 216.444.9114.

SUGGESTED READING

Mekhail N, Costandi S, Abraham B, Samuel SW. Functional and patient-reported outcomes in symptomatic lumbar spinal stenosis following percutaneous decompression. *Pain Pract.* 2012;12(6):417-425.

Mekhail N, Vallejo R, Coleman M, Benjamin RM. Long-term results of percutaneous lumbar decompression *mild*[®] for spinal stenosis. *Pain Pract.* 2012;12(3):184-193.

PATIENTS PLEASED WITH QUALITY-OF-LIFE PAYOFFS

Enthusiastic testimonials are common among patients who have had the *mild* procedure for LSS. Here are profiles of several patients who underwent the procedure in Cleveland Clinic’s Department of Pain Management.

Frances Robinson, 70, had the procedure in January 2012. She had previously received epidural injections to control her LSS-related pain, but the effectiveness would eventually wear off. “I couldn’t walk too far or I would get pain down my leg and would have to stop,” she says. She also couldn’t stand longer than five or six minutes without having to sit or lie down.

Since the procedure, Mrs. Robinson has been able to run errands and do chores around the house that had become increasingly difficult. On a recent trip to Florida, she was able to enjoy water aerobics, shop at flea markets and outlet stores, and comfortably walk on the beach with her husband for 40 to 50 minutes at a time.

“I call the *mild* procedure my miracle,” Mrs. Robinson says. “I would certainly advise others to consider this procedure, as it made such a big difference to my life.”

Michael O’Malley, 71, used to experience LSS-related pain that “felt like an electric shock that started at the hip and went all the way down to the knee.” That pain is a distant memory since he underwent the *mild* procedure in November 2012. Despite unrelated hip pain for which he is seeking treatment, Mr. O’Malley has been regularly walking a quarter of a mile a day for exercise.

He says he was impressed that *mild* was done on an outpatient basis and he was able to get back to his normal activities so quickly. “The procedure was amazing, especially the fact that you could go to the hospital at 8 a.m. and be back home by 4 p.m. The doctors and everyone there were excellent. I walked the same day I had the procedure.”

Nagy Youssef, 67, a one-time international-level track and field athlete from Egypt, could walk no farther than 500 feet and had to sit after five minutes of standing when he first saw Dr. Mekhail for LSS-related pain. The pain forced Mr. Youssef to significantly scale back his work coaching Egyptian track and field teams. He was also unable to mentor his grandchildren in their athletic pursuits or grocery shop with his wife.

“The back pain decreased significantly after the *mild* procedure, and I can now stand for more than 30 minutes and walk four miles,” says Mr. Youssef, who was known as Nagui Assad when he competed in the Olympics in the 1970s and ’80s. He’s now back at work as a coach, active with his grandchildren and once again able to help his wife with shopping.

“I feel that my life clock has been wound back to before the year 2000, when the pain started,” Mr. Youssef says.