

Long-Term Data on MILD Lumbar Spine Intervention Demonstrate Continued Decreases in Pain

Minimally invasive lumbar decompression (MILD) showed a lasting reduction in pain, with no evidence of spinal instability two years after the procedure in patients with spinal stenosis and neurogenic claudication.

“Reoperation and spinal fracture rates are lower, and safety is higher for MILD versus other lumbar spine interventions,” according to the report (*Reg Anesth Pain Med* 2018;43[7]:789-794).

MILD is simpler and less invasive than fusion or device implantation, according to the report: “MILD does not involve the use of implants, is performed as an outpatient procedure without general anesthesia, requires only a small 5.1-mm port for access, and does not require sutures (although some surgeons elect to place a single suture at the portal site).”

“This is the first well-done controlled study to show that ‘less may be more,’” said Forest Tennant, MD, DrPH, the head of the Arachnoiditis Research and Education Project of the Tennant Foundation, Los Angeles, who did not take part in the research.

“Minimally invasive procedures for the treatment of spinal stenosis are an option for the patient who fails conservative measures, and may be much better than the conventional treatment with epidural steroids,” said Timothy Deer, MD, the president and CEO of the Spine and Nerve Center of the Virginias. Dr. Deer, who is a member of the *Pain Medicine News* editorial advisory board, was not involved in the research.

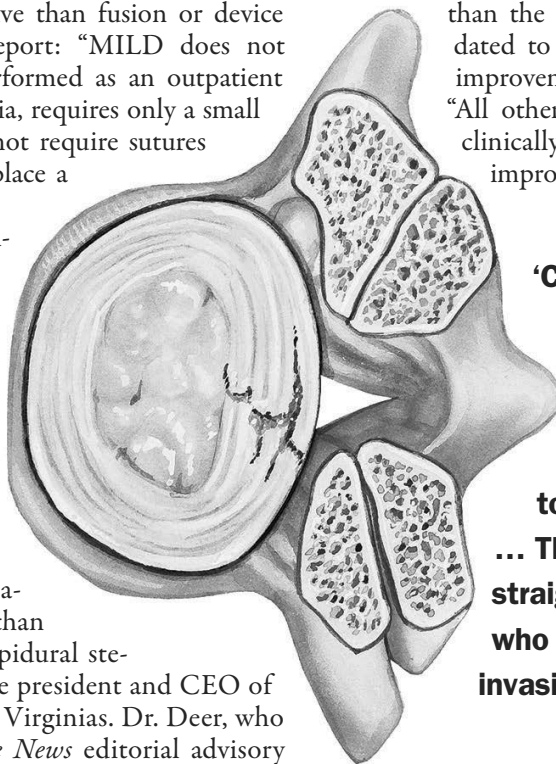
The prospective, multicenter, randomized controlled clinical study compared outcomes in Medicare patients, 143 of whom were treated with MILD, with 131 control patients receiving epidural steroid injections. All patients were evaluated at six months and one year after treatment. MILD patients were evaluated again at two years. The average age of patients was 75.6 years, ranging up to 93. A previous study by the investigators reported on the six-month and one-year evaluations (*Pain Physician* 2016;19[4]:229-242); the current study is the two-year follow-up.

The success rate and durability for MILD were superior to those for patients receiving epidural steroid injections,

according to the report. Additionally, “there was no evidence of spinal instability at [two] years after the MILD procedure.

“All outcome measures demonstrated clinically meaningful and statistically significant improvement from baseline through 6-month, 1-year, and 2-year follow-ups,” according to the report.

At two years, the Oswestry Disability Index (ODI) had risen 22.7 points over baseline, “markedly higher than the 10-point improvement that has been validated to be the threshold for clinically significant improvement for ODI,” according to the report. “All other validated efficacy measures also showed clinically meaningful and statistically significant improvement.”



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—Forest Tennant, MD, DrPH

Concurrently, the numerical pain rating scale had climbed 3.6 points, and scores on the Zurich Claudication Questionnaire symptom severity and physical function domains were up 1.0 and 0.8 points, respectively, according to the report—“really significant and durable pain relief,” said principal investigator Peter S. Staats, MD, MBA, the chief medical officer, National Spine & Pain Centers, and a past president of the North American Neuromodulation Society. He is also a member of the *Pain Medicine News* editorial advisory board. “They also demonstrated significant and durable improvement in their function.”

MILD showed excellent safety, “with no device- or procedure-related serious adverse events,” according to the report. “Further, there was no evidence of spinal instability through 2-year follow-up.”

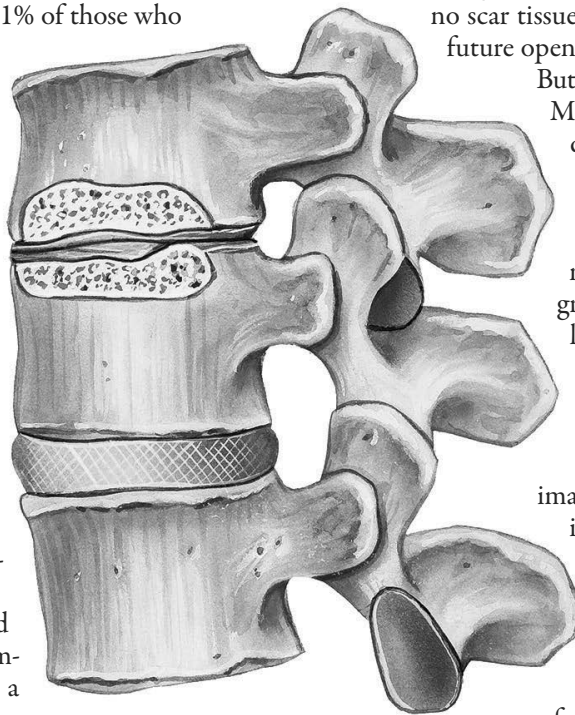
At six-month and one-year follow-up, results had already proven superior for MILD patients compared with those receiving epidural steroid injections, according to the report. At one-year follow-up, 58% of MILD patients showed improvement on the ODI, compared with 27.1% of those who had received epidural steroid injections. MILD patients also showed significantly greater improvement than those who had received epidural steroid injections.

Low Rates of Reoperation

Only 5.6% (8/143) patients needed reoperation at two years, according to the study. This compares favorably to studies that found reoperation rates two years after spinal fusion to range from 12.5% to 16.9%, and from 14.4% to 26.0% after implantation of interspinous distraction devices, or “spacers,” which are designed to restrict painful movements while enabling normal motion.

The investigators also compared MILD with adverse events and complications from other studies of a variety of surgical treatments for lumbar spinal stenosis. In SPORT (Spine Patient Outcomes Research Trial), following surgical decompression, intraoperative complications occurred in 9.9% of cases while postoperative complications occurred in 12.3% of cases (*JAMA* 2006;296[20]:2441-2450).

“Spinal fusion studies have reported related complication rates as high as 23.3% through two years,” the investigators wrote.



MILD Doesn't Foreclose Other Options

“MILD ... has a unique role as a solution when conservative therapies have failed, and the risks of more invasive approaches may not be warranted,” according to the report. “It is important to note that MILD does not affect surgical options for the few patients who do not respond to this treatment. Because of the very minimally invasive approach and targeted subtle decompressing, there is minimal or no scar tissue that would increase the risk of possible future open spine surgery.”

But other approaches might foreclose MILD. “Patients undergoing open surgical decompression are no longer candidates for less invasive approaches,” the authors wrote.

The report noted that the study's major limitations were lack of a control group for the two-year follow-up, and lack of direct comparison of efficacy with open surgical approaches. Nonetheless, Dr. Tennant praised the study for its high quality.

“Clinicians need to know that minimally invasive surgery for spinal stenosis is not only here, but it has equal or better outcomes compared to old standard interventions. And there are few complications, such as adhesive arachnoiditis,” Dr. Tennant said. “The message for clinicians is straightforward: Search out surgeons who will use the new, minimally invasive procedures.”

Dr. Staats said, “In an era of an opioid crisis, but also of continued and persistent uncontrolled pain, having very cost-effective therapy with long-term durability is very important.”

—David C. Holzman

Dr. Deer reported serving as a consultant to Comorloc, Vertiflex and Vertos. Drs. Staats and Tennant reported no relevant financial disclosures.