Procedure Offers Alternative for Spinal Stenosis

BY AMY ROTHMAN SCHONFELD
Contributing Writer

Olympic Valley, Calif. — A new minimally invasive procedure dramatically reduced pain and disability for a small group of patients with lumbar spinal stenosis. No complications or adverse events were reported, and patients were discharged the same day or the next day.

The procedure is performed using the MILD (minimally invasive lumbar decompression) device that allows practitioners to perform a lumbar decompression to remove bone to access the area of stenosis under fluoroscopic guidance, and then widen and decompress the canal by thinning or sculpting the bone and enlarged ligaments that compress the nerve roots. Low back pain, leg fatigue and pain, and physical impairments are attributed to this compression, according to Dr. Joshua A. Hirsch.

"I view the MILD procedure as part of a broadening array of treatments that minimally invasive spine specialists can offer patients with lumbar spinal stenosis," said Dr. Hirsch, director of interventional neuroradiology/endovascular neurosurgery and chief of minimally invasive spine surgery at Massachusetts General Hospital, Boston.

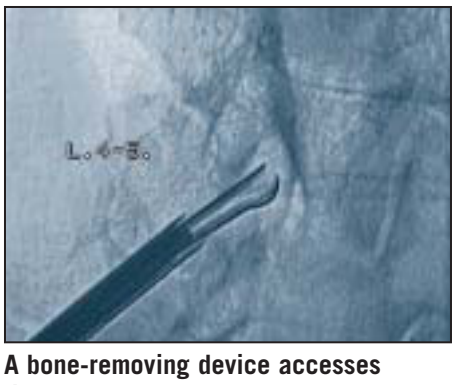
As of July 2008, 42 patients with severe spinal stenosis underwent the MILD procedure. Ten patients were followed under an institutional review board–approved protocol designed to assess improvement in pain using a Visual Analog Scale (VAS), and disability using the Oswestry Disability Index (ODI). Preoperatively, these patients had ODI scores of 60%-80%, indicating that they were crippled by their condition, and VAS pain scores of 6-10.

At 6 weeks post treatment, the mean disability score improved by 84% compared with baseline (ODI 0%-20%) and the mean pain score decreased by 90% (VAS scores at 1). All 10 patients had discontinued narcotics use for pain by 6 weeks post op and were discharged from the hospital on the same day or the day following the procedure. "These are phenomenal results," said Dr. Hirsch, who noted that these initial promising results must be validated by further study.

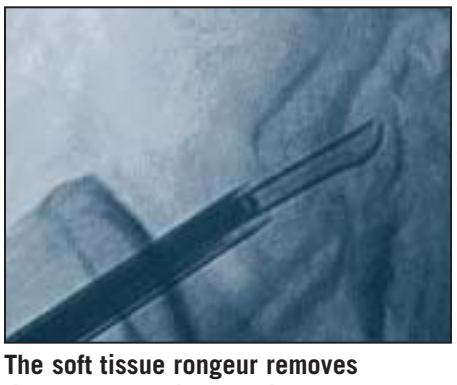
No complications have been reported from the procedure. Other advantages of the procedure are that it requires only local sedation, allows patients to recover quickly, and offers the possibility of delaying or preventing more invasive surgery. The incisions are smaller than a dime, said Dr. Hirsch, who presented his findings at the annual meeting of the Society of Neurointerventional Surgery and received travel support from the device's manufacturer, Vertos Medical Inc., of San Jose, Calif.

During an interview, Dr. Allan L. Brook, director of interventional neuroradiology at Montefiore Medical Center, New York,

In the first step, the bone rongeur is utilized to remove posterior bone.



A bone-removing device accesses ligamentum flavum.



The soft tissue rongeur removes ligament posterior to epidural space.

Photos courtesy Dr. Allan L. Brook

said he has used the MILD device in three cases. Montefiore is 1 of 10 sites participating in the Vertos-sponsored MILD Preliminary Patient Evaluation Study, a multicenter, prospective clinical study to assess the clinical application and outcomes of minimally invasive lumbar decompression with the devices in patients who have symptomatic spinal stenosis.

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DR. HIRSH

"These patients have had dramatic pain relief. The majority of these patients have exhausted standard medical therapies, as well as numerous other less invasive injections. I believe many patients could benefit from this minimally invasive posterior lumbar decompression," said Dr. Brook. He noted that there are no other percutaneous procedures that attempt to remove the soft tissue that impinges from behind the nerves; most aim to remove the disk or rely upon open surgical techniques, with their known risks.

Dr. Brooks reported that he has no financial relationship with Vertos Medical.

"Lumbar spinal stenosis is a huge problem which really impacts people's quality of life. Approximately 1.5 million people in the U.S. are diagnosed with it every year—about twice the number of those who have vertebral compression fractures," said Dr. Hirsch. "The MILD device allows us to provide a minimally invasive alternative to traditional laminectomy/laminotomy." ■

COX-2s Work By Week 2 Or Not at All

BY BRUCE JANCIN
Denver Bureau

PARIS — The overwhelming majority of osteoarthritis patients who will respond favorably to a given cyclooxygenase-2 selective NSAID will do so within the first 2 weeks, a pooled analysis of two placebo-controlled clinical trials has shown.

Thus, the 2-week mark is a reasonable time in which to consider whether to switch a patient to a different NSAID, Dr. Steven S. Smugar said at the annual European Congress of Rheumatology.

However, a case also can be made for using a more conservative decision point at 4 weeks. That's because 28% of nonresponders after 2 weeks became responders by week 4 in this post hoc pooled analysis. But the absolute number of patients who fell into this delayed-responder subgroup was small, added Dr. Smugar of Merck & Co., West Point, Pa.

Overall, 84% of responders at week 2 were responders at week 12. Of 360 nonresponders at week 2, 60% remained nonresponders at week 12.

He reported on 1,207 patients with knee or hip osteoarthritis who were randomized to 12 weeks of once-daily etoricoxib (Arcoxia, not available in United States) at 30 mg, celecoxib (Celebrex) at 200 mg, or placebo in two identical double-blind clinical trials sponsored by Merck.

After 12 weeks, 66% of patients in the etoricoxib group, 64% in the celecoxib group, and 43% on placebo had a favorable response as defined primarily by at least a 50% improvement in pain or function and an absolute change of 20 mm or more on a 100-mm visual analog scale.

Eighty-four percent of responders at week 2 remained responders at week 12. The durability of response was good, demonstrated by the fact that, among responders, 74% were consistent responders at all four of the study assessment points at 2, 4, 8, and 12 weeks, according to Dr. Smugar.

Of 360 nonresponders at week 2, 60% remained nonresponders at week 12. ■