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## The X STOP May Reduce Neurogenic Claudication in Lumbar Spinal Stenosis **CME**

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June 23, 2005 — The X STOP, an interspinous process decompression system, is successful in reducing symptoms of neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS), according to the results of a multicenter, prospective, randomized study published in the June 15 issue of *Spine*.

"X STOP provides an alternative therapy to conservative treatment and decompressive surgery for patients suffering from NIC," write James F. Zucherman, MD, from St Mary's Hospital in San Francisco, California, and colleagues. "The X STOP is implanted between the spinous processes and reduces pathologic extension at the symptomatic level(s), while allowing flexion and unrestricted axial rotation and lateral bending. Biomechanical studies have shown that the implant significantly reduces intradiscal pressure and facet load and prevents narrowing of the spinal canal and neural foramens."

Of 191 patients treated, 100 received X STOP and 91 received conservative care. The Zurich Claudication Questionnaire, a patient-completed, validated instrument for NIC, was the primary outcome measure.

In each domain of the questionnaire, X STOP patients had significantly better outcomes than conservatively treated patients at every follow-up visit. At two years, improvement from the mean baseline Symptom Severity score was 45.4% in the X STOP patients and 7.4% in the control group. Improvement means in the Physical Function domain were 44.3% and -0.4%, respectively. Patient satisfaction with treatment was 73.1% in the X STOP group and 35.9% in the control group.

Compared with the incidence and severity of laminectomy complications cited in the literature, the complications associated with the X STOP procedure suggest that the procedure is at least as safe as a decompressive laminectomy, and probably safer, according to the authors.

"The X STOP provides a conservative yet effective treatment for patients suffering from lumbar spinal stenosis," the authors write. "In the continuum of treatment options, the X STOP offers an attractive alternative to both conservative care and decompressive surgery."

The X-STOP device is being evaluated as part of an ongoing investigational protocol approved by

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*Spine*. 2005;30:1351-1358

## Learning Objectives for This Educational Activity

Upon completion of this activity, participants will be able to:

- Describe the clinical presentation and management of NIC.
- Compare X STOP vs conservative therapy in the management of NIC.

## Clinical Context

LSS complicated by NIC is a common problem that can be difficult to treat. Patients with NIC usually complain of back and leg pain, numbness, and lower extremity weakness that are exacerbated by activities of lumbar extension such as standing and walking. In contrast, flexion of the lumbar spine frequently relieves symptoms. The most common spinal level affected by NIC is L4–L5.

Conservative management is generally the initial choice of therapy for NIC and consists of analgesics, physical therapy, and epidural steroid injections. For those patients who fail these modalities, spinal decompression surgery may be indicated. However, this surgery can have a variable success rate and carries the risk of intra- and postoperative complications. The X STOP is a device implanted between the spinal processes that prevents extension of the lumbar spine while maintaining other spinal range of motion. It could represent an alternative means to treat patients with NIC in whom conservative therapy fails. The authors of the current study compare X STOP with conservative therapy in a cohort of older patients with moderate NIC.

## Study Highlights

- Patients eligible for study participation were at least 50 years old and had leg, buttock, or groin pain. All were able to walk at least 50 feet. Patients with a fixed motor deficit, cauda equina syndrome, previous lumbar surgery, or spondylolisthesis of more than grade 1 were excluded from the research protocol.
- Patients were randomized to receive either conservative therapy or X STOP. Those in the conservative therapy group all received at least 1 steroid injection along with analgesics and physical therapy as necessary.
- Study participants were examined at 6 weeks, 6 months, 1 year, and 2 years for the main study outcomes. Outcomes were drawn from the Zurich Claudication Questionnaire and included measurements of symptoms and physical function. Patient satisfaction and radiographic changes were also assessed.
- 191 patients were randomized from 9 U.S. centers. The mean age was 69 years, and baseline symptoms and physical function were similar between the 2 treatment groups. Spondylolisthesis of grade 1 or less was present in approximately one third of the cohort.
- In the X STOP group, 100 patients received implants at 136 levels. The average procedure time was 54 minutes, and 97 of the procedures were completed under local anesthesia. The control group received a total of 216 epidural steroid injections during the study period.
- The X STOP group performed significantly better in the main study outcomes. This improvement was evident at 6 weeks and remained static during the rest of the trial period. At 2 years, the mean improvement in symptom severity was 45.4% in the X STOP group, compared with 7.4% in the conservative management group. Improvements in physical function were 44.3% and -0.4%, respectively.
- Rates of clinically significant improvement in symptoms and physical function in the X STOP cohort were 60.2% and 57%, respectively. The respective values for the conservative management group were 18.5% and 14.8%.
- 73.1% of participants in the X STOP group reported being at least somewhat satisfied with treatment, compared with 35.9% of the conservative therapy group. This difference was also significant.
- Factors associated with a better outcome with X STOP were the absence of comorbid conditions and lower surgical blood loss. In contrast, a positive femoral stretch test was associated with worse outcomes in the X STOP cohort.

- Rates of decompressive surgery were 26.4% in the conservative therapy group and 6% in the X STOP group.
- Radiographic measurements were similar between groups at 12 and 24 months.
- No device-related intraoperative complications were reported with X STOP. There were 3 reports of complications associated with X STOP surgery, and 3 participants reported device-related complications during the follow-up period. In comparison, there were 5 complications associated with epidural injection.

## Pearls for Practice

- NIC associated with LSS results in pain and neurologic symptoms that are frequently exacerbated by lumbar extension and decreased with lumbar flexion. Patients are generally initially treated with conservative therapy.
- Compared with conservative therapy in older patients with moderate NIC, X STOP is associated with superior outcomes in terms of symptoms, physical function, and patient satisfaction. However, radiographic measurements are similar with both forms of therapy.

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