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Is the X STOP® interspinous implant a safe and effective treatment for neurogenic intermittent claudication?

GLOSSARY

NEUROGENIC INTERMITTENT CLAUDICATION
Back pain, leg pain, or both, caused by lumbar stenosis, which limits the distance a patient is able to walk

ZURICH CLAUDICATION QUESTIONNAIRE
A validated patient self-assessment questionnaire, used to measure lumbar spinal stenosis treatment outcomes

Original article Zucherman JF *et al.* (2005) A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine* **30:** 1351–1358

SYNOPSIS

KEYWORDS interspinous process decompression and spacer, lumbar laminectomy, lumbar spinal stenosis, neurogenic claudication

BACKGROUND

Patients with NEUROGENIC INTERMITTENT CLAUDICATION secondary to lumbar spinal stenosis are managed conservatively, or undergo decompressive surgery with or without fusion. Widely varying success rates have been reported following surgical decompression. The X STOP® (St Francis Medical Technologies, Inc., Concord, CA) interspinous process decompression system is a potential alternative treatment for these patients.

OBJECTIVE

To compare the efficacy of the X STOP® implant with that of conservative treatment for neurogenic intermittent claudication.

DESIGN AND INTERVENTION

The X STOP® system was implanted at 136 levels (including 89 implants at L4–L5 and 43 at L3–L4) in 100 patients aged 50 years or above. Patients were included if they had buttock, leg, or groin pain, in the presence or absence of back pain, and relief of pain during flexion. Exclusion criteria included fixed motor deficit and cauda equina syndrome. Implants were single level in 64 patients and double level in 36 patients. Control patients ($n=91$) all received an epidural steroid injection at baseline, and were given further steroid injections, nonsteroidal anti-inflammatory drugs, analgesics, and physical therapy, as required. Outcomes were assessed at baseline and at 6 weeks, 6 months, 1 year, and 2 years after treatment.

OUTCOME MEASURE

The primary outcome was percentage improvement following treatment, based on symptom severity and physical function scores from the ZURICH CLAUDICATION QUESTIONNAIRE (ZCQ).

RESULTS

Data were analyzed for 93 X STOP® patients and 81 controls who completed 2-year follow-up. The groups were demographically similar and had similar mean ZCQ symptom severity and physical function scores at baseline. There was significantly greater improvement in mean ZCQ scores in the X STOP® group (symptom severity 45.4%, physical function 44.3%) than in the control group (symptom severity 7.4%, physical function –0.4%) at 2 years from baseline ($P<0.001$). The mean relative changes in ZCQ score from baseline were consistent in both groups at all time points in the study. At 2 years, clinically significant improvement in symptom severity was reported by 56/93 patients in the surgical group (60.2%) compared with 15/81 patients in the control group (18.5%; $P<0.001$). Clinically significant improvement in physical function was reported by 53/93 patients in the surgical group (57.0%), compared with 12/81 control patients (14.8%; $P<0.001$). There were no device-related intra-operative complications or treatment-related deaths, and all implantation procedures were successful. Subsequent decompressive laminectomy was carried out in 6 patients in the X STOP® group, and in 24 patients in the control group. One patient's X STOP® implant was dislodged during a fall, and was subsequently removed. Another patient had an asymptomatic spinous process fracture, which did not require treatment. Increasing pain was reported by one patient, 382 days after surgery. One patient had a malpositioned implant, which had been inserted too far posteriorly.

CONCLUSION

The X STOP® implant can safely and effectively treat the symptoms of lumbar stenosis in a percentage of patients. Therefore, the X STOP® implant provides an alternative to conservative treatment or lumbar decompression surgery.

COMMENTARY

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Lumbar stenosis is one of the most frequent indications for spinal surgery. Hypertrophy of the lumbar facets and the ligamentum flavum, as well as degeneration of the intervertebral disks, contribute to a decrease in the caliber of the central canal. This causes compression of the thecal sac and symptoms of back pain, leg pain, and neurogenic claudication, which can severely limit a patient's ability to perform daily activities. Frequently, patients experience relief from their symptoms with flexion of the lumbar spine, which widens the central canal.

Treatment for lumbar stenosis has historically involved conservative therapy, or surgical decompression. The mainstays of conservative therapy involve analgesics, nonsteroidal anti-inflammatory drugs, physical therapy, and epidural steroid injections. These treatments do not treat the anatomical pathology that causes the symptoms, so conservative therapy is frequently unsuccessful.[1–3] Surgical intervention involves a decompressive laminectomy, a surgical procedure in which the posterior elements of the vertebral column, including the spinous process, laminae, interspinous ligaments and the ligamentum flavum, are removed. This allows decompression of the central spinal canal. In some cases, however, removal of these elements combined with degenerative changes already present can cause instability of the spinal column that necessitates a fusion.

Zucherman *et al.* describe a novel surgical intervention that allows relief of symptoms with minimal destabilization of the spine. The X STOP® interspinous spacer device maintains a mild degree of flexion at the level to which it is applied. In this way, it maintains the diameter of the central canal in extension.[4] The advantages of this procedure are that it is done without removal of the interspinous ligament or other posterior elements, and that it can be done under local anesthetic rather than general anesthetic. Using a prospective, randomized study comparing 100 patients undergoing placement of the X STOP® with 91 patients undergoing conservative therapy, Zucherman *et al.* showed that patients who received the X STOP® had significant improvement in symptoms compared with those undergoing conservative therapy, on the basis of preoperative and postoperative ZCQ scores. Symptom severity and physical function scores improved by 45% at 6 weeks in those receiving the X STOP®, and this improvement was maintained at 2-year follow-up. Long-term follow-up data are not available, and time will show how many patients go on to require open surgical decompression.

In the future, it would be beneficial to compare patients undergoing placement of this type of device with those undergoing decompressive laminectomy, with regard to complications and improvement of symptoms, especially back pain. As with any surgical procedure, proper patient selection is essential. Such interspinous devices are likely to be more effective in patients with moderate canal stenosis than in those with severe stenosis. In patients who have severe lumbar stenosis that is not relieved by sitting or standing in a flexed position, the efficacy of such devices might not be as great. It is clear, however, that interspinous devices such as the X STOP® might present a less invasive surgical option for patients suffering from neurogenic claudication secondary to moderate lumbar stenosis.

References

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3 Katz JN *et al.* (1999) Predictors of surgical outcome in degenerative lumbar spinal stenosis. *Spine* **21:** 2229–2233

4 Richards JC *et al.* (2005) The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. *Spine* **30:** 744–749

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Competing interests
RG Fessler declared competing interests; go to the article online for details. KM Eichholz declared he has no competing interests.

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PRACTICE POINT
Interspinous implants might offer a less invasive surgical alternative to decompressive laminectomy for patients with moderate symptoms of lumbar stenosis, allowing improvement in claudication, back pain, and leg pain