Commentary on:
Evaluation of Interspinous Process Distraction Device (X-STOP) in a Representative Patient Cohort
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Efficacy of Surgical Treatment for Lumbar Stenosis with the X-STOP: An Issue in Need of Closer Inspection

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Lumbar spinal stenosis (LSS) is the most frequent diagnosis in patients more than 65 years who require spinal surgery (4, 9). The condition is characterized by anatomic narrowing of the spinal canal leading to thecal sac and nerve root compression. The classic clinical presentation of LSS is neurogenic claudication with pain that radiates into the buttocks and lower extremities and that is exacerbated by standing or walking. However, patients will also often report that flexion of their lower back or sitting alleviate their symptoms. The anatomic basis for these complaints is that lumbar extension is associated with buckling of the ligamentum flavum into the spinal canal resulting in exacerbation of spinal canal narrowing. On the other hand, flexion of the lumbar spine lengthens the posterior spinal column, rendering the ligamentum flavum in taut position and in effect opens up the spinal canal (11, 16).

Surgical treatment is indicated in patients with LSS who have persistent debilitating symptoms and failed conservative treatments. Although decompressive laminectomy is considered to be the traditional surgical treatment for LSS, there are several concerns with that procedure. First, surgical morbidity is associated with laminectomy, particularly in elderly patients with multiple medical co-morbidities. Second, the rate of recurrent back pain that can lead to reoperation ranges from 10%–23% at 7–10 years (13). Finally, there is significant variability in the surgical outcomes for treatment of LSS with laminectomy in the published literature. In a meta-analysis by Turner et al. (13), they found that an average of 64% of patients reported good-to-excellent outcomes after laminectomy for LSS, but the rate of successful outcome ranged from 26%–100% in 74 reports. Those concerns have led surgeons to search for alternative surgical treatments to laminectomy, particularly treatments that are less invasive to the patients.

During the past two decades, minimally invasive spine surgery (MIS) techniques have been developed to decrease the surgical morbidity. The fundamental tenet of MIS is to minimize the degree of unnecessary iatrogenic injury to the spine during treatment and still achieving the expected goals of surgery. A traditional open laminectomy requires relatively extensive detachment of the paraspinal musculatures away from the spine along with removal of ligamentous structures that inherently weakens the structural integrity of the spine. Although most patients will tolerate the biomechanical alteration of the spine after a traditional laminectomy, a subset of the patients can suffer persistent pain from the muscle injury or spinal instability from surgery. During the past decade, emerging data from clinical experiences with MIS in spine support that decreased blood loss and infection rate with speedier recovery can result from minimizing surgically related soft tissue injuries (5, 7, 8, 10). However, high-quality randomized prospective controlled studies comparing MIS to open spine surgery is still lacking.

An innovative MIS treatment developed for LSS in the past two decades is the interspinous distraction device. The concept of treating LSS with interspinous distraction originated from the clinical observation that lumbar flexion widens the spinal canal and the neuroforamen anatomically while it relieves neurogenic claudication pain clinically. A number of interspinous devices were designed, but the X-STOP device (Medtronic, Inc., Minneapolis, Minnesota, USA) is the most extensively studied and widely used in the United States. The Food and Drug Administration (FDA) approved the X-STOP device for treatment of one- or two-level symptomatic LSS in the United States in November 2005. Zucherman et al. (16, 17) conducted the initial prospective multicenter randomized controlled study comparing the X-STOP to the nonoperative treatment for LSS that provided the pivotal

Key words
- Interspinous device
- Neurogenic intermittent claudication
- Spinal stenosis
- X-STOP

Abbreviations and Acronyms
FDA: Food and Drug Administration
LSS: Lumbar spinal stenosis
MIS: Minimally invasive spine surgery
ZCQ: Zurich claudication questionnaire

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Table 1. Inclusion and Exclusion Criteria from the Zucherman et al. (17) Prospective Controlled Trial on X-STOP versus Nonoperative Treatment of Lumbar Stenosis

Inclusion criteria
1. >50 years
2. Have buttocks, leg, and groin pain with or without back pain that is relieved with flexion
3. Able to walk for at least 50 feet
4. Able to sit 50 minutes without pain
5. Lumbar stenosis confirmed by computerized tomography or magnetic resonance imaging at one or two levels
Exclusion criteria
1. Fixed motor
2. Cauda equina syndrome
3. Previous lumbar surgery at the stenotic level
4. Greater than grade 1 spondylolisthesis
5. Significant peripheral neuropathy
6. Acute denervation secondary to radiculopathy
7. Scoliosis with Cobb angle more than 25 degrees
8. Pathologic fractures
9. Severe osteoporosis of vertebrae and/or hips
10. Significant lumbar instability
11. Active infection or systemic disease
12 Paget's disease
13. Spinal metastasis
14. Steroid use for more than 1 month within 12 months before the study

data, which led to the FDA approval of X-STOP. The study enrolled 191 patients at 9 U.S. centers from May 2000 to July 2001. The inclusion and exclusion of the study are listed in **Table 1** (16). At both 1-year and 2-year follow-up, the patients treated with X-STOP had clinically significant improvement compared to the patients treated with conservative treatment (16, 17). Using the Zurich claudication questionnaire (ZCQ) as the primary outcomes measurement with the definition of clinical success as patients who achieved significant improvements in all three components of ZCQ (physical function, symptom severity, and satisfaction), they achieved a success rate of 48.4% in patients treated with X-STOP and only 4.9% in patients treated with nonoperative treatment (17). The investigators concluded that the X-STOP provides a conservative, yet effective, alternative treatment to laminectomy for patients suffering from LSS.

Although the FDA approved the X-STOP, they identified several concerns about the Zucherman study that many clinicians may not be aware of (6, 15). First, randomization was not performed in the traditional manner. Instead, patients were randomized in blocks of two patients with one treatment and one control patient assigned per pair. Therefore, the investigators could determine the treatment assignment of the second patient in each pair and potentially bias the selection of the patients into the second slot. Second, one study center had a disproportionally higher clinical success rate than all other sites, and it was also the highest enrolling site. The particular site enrolled 20 patients and reported an 85% success rate. However, the next three highest enrolling sites had clinical success rates at only 27.8%, 14.3%, and 45.5%. The FDA also highlighted that the principle investigators from the most successful site had a significant equity interest in the device company, raising the concern for conflict of interest (6). It is unclear how the FDA managed this significant conflict of interest and ultimately approved the device under those circumstances. Finally, there was a trend for more adverse events in the X-STOP treatment group compared to the nonsurgical group that did not reach statistically significance. Although the sponsor claimed the adverse events were unrelated to the device, they occurred far more frequently in the X-STOP group and many of them were related to the back, hip, and lower extremity (**Table 2**) (6).

Since the initial publication of the Zucherman et al. study, others clinicians have published their experience with the X-STOP for treatment of LSS or low grade spondylolisthesis with significantly less favorable results. In a prospective observational study of 24 patients, Siddiqui et al. (12) reported that only 54% of their patients had significant improvement in their symptom severity and 33% of their patients had significant improvement in physical function at 12 months compared to 75% reported by Zucherman et al. (12). In a retrospective study of 12 consecutive patients who underwent treatment of LSS with degenerative spondylolisthesis using X-STOP, Verhoof et al. (14) reported that four patients (33.3%) had no clinical improvement immediately after surgery. At 12-week follow-up, two additional patients had recurrent symptoms, and a third patient had recurrence of symptoms by the 24-month follow-up. In total, 58% of their patients failed their treatment of spondylolisthesis with LSS using X-STOP within a relatively short 24 months follow-up period. Brussee et al. (3) also performed a prospective observational study of 62 LSS patients treated with X-STOP, including patients with grade I spondylolisthesis. They found that only 30.6% of their patients reported good result in their overall satisfaction and only 31.1% of their patients reach good outcome in all three domains of ZCQ compared to the 48.1% reported in Zucherman et al. study. In addition to poor outcomes, other studies have reported higher complication rates associated with X-STOP treatment than reported in the Zucherman et al. study. Barbagallo et al. (1) reported 8 complications (11.6%) related to device dislodgement and spinous process fracture in a study of 69 patients. Bowers et al. (2) reported a retrospective analysis of 13 patients with LSS that underwent treatment with X-STOP. They found that 77% of their patients had recurrence of their preoperative pain after X-STOP implant, and they had a 38% overall complication rate related to spinous process fractures, device dislodgement, and new radiculopathy. In total, 85% of their patients required additional surgery.

In the current issue, in a retrospective study, Patil et al. reports their experience with treatment of LSS using the X-STOP. They hypothesize that clinical efficacy can be achieved with the X-STOP treatment in patients with LSS who do not meet the stringent inclusion and exclusion criteria defined by the Zucherman et al. trial. Although they intended to study 31 patients initially, only 21 patients ultimately met their defined study criteria for a 2-year outcome analysis. In this study, there was a device-related complication rate of 28.6% (6 of 21 patients). In addition, they only found clinical success in 38.1% of their