Interspinous Process Decompression: What's the state of the evidence?

OR leaders are striving to make evidence-based decisions on new technology. OR Manager and ECRI Institute have joined in a collaboration to bring quarterly supplements with summaries of the Institute's technology assessment reports to OR Manager readers. ECRI Institute is an independent nonprofit organization that researches best approaches to improving patient care. They do their work by analyzing the research literature and data on clinical procedures, medical devices, and drug therapies.

An implant recently FDA-approved for marketing to treat spinal stenosis may be a minimally invasive alternative to conventional procedures such as laminectomy and foraminotomy. This is an excerpt from ECRI Institute's evidence report on interspinous process decompression to treat spinal stenosis.

Technology Description
Interspinous process decompression is a minimally invasive surgical procedure used to treat lumbar spinal stenosis when conservative, nonoperative treatments have failed to relieve symptoms. The procedure involves surgically implanting an interspinous process spacer between the affected spinous processes at 1 or 2 lumbar levels. The implant is designed to block lumbar extension, which aggravates symptoms caused by spinal stenosis. The potential to relieve pain while preserving natural biomechanics of the lumbar spine may make this procedure an appealing alternative to conventional procedures.

Although several interspinous process implants are available worldwide and several others are under investigation, the X STOP Interspinous Process Decompression System made by Kyphon Inc (Sunnyvale, CA) is the only interspinous process implant approved for marketing by the Food and Drug Administration (FDA). The X STOP implant consists of two titanium components: a spacer assembly and a wing assembly. After the patient receives local anesthesia with intravenous sedation, the surgeon inserts the implant through a 1- to 2-in midline incision under the supraspinous ligament and through the interspinous ligament, attaching the wing assembly, adjusting the width, and tightening the set screw. The procedure typically takes less than an hour. The patient may have the surgery on an outpatient basis or be admitted for a 24-hour stay. Discharge instructions include some limitations, but normal activity usually can be resumed within 2 to 6 weeks.
Indications/contraindications
According to the FDA-approved labeling, the X STOP implant is indicated for patients age 50 years and older who have:

- neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis
- moderately impaired physical function and experience relief in flexion of leg/buttock/groin pain with or without back pain
- undergone a regimen of at least 6 months of nonoperative treatment.

The X STOP implant may be placed at 1 or 2 levels in patients in whom operative treatment is indicated at no more than two levels.

Labeled contraindications for the implant include:

- an allergy to titanium or titanium alloy
- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ
- cauda equina syndrome
- diagnosis of severe osteoporosis
- active systemic infection or infection localized to the site of implantation.

Costs
The cost of one X STOP implant is $5,500. On average, 1.6 implants are used per case, making the mean total implant cost per procedure $8,800.

Procedure charges
Estimated total procedure charges are $22,878. The ICD-9 code 84.58 describes the procedure. The implant is currently assigned to DRG 499/500.

Reimbursement
Medicare does not have a national coverage determination for this technology. Coverage is left to the discretion of local Medicare carriers.

Effective October 2006, CMS provided a new technology add-on payment maximum of $4,400 for the X STOP implant for an inpatient procedure. These supplemental payments provide additional funding for new technologies that meet a cost threshold and demonstrate a substantial improvement over existing treatment options. Add-on payments may remain in effect for 2 to 3 years. Medicare also approved a pass-through payment for this procedure when performed in a hospital outpatient setting. Effective January 2007, practitioners can use the pass-through device code, C1821, for single- and double-level treatments. Procedural costs are reimbursed at $1,456 per treated level under APC 0050.

A search of 3rd party payers that make their coverage policies available found that as of August 6, 2006, 3 US private third-party payers with specific medical policies deny coverage for interspinous process decompression—Aetna, Cigna, and Blue Cross Blue Shield of CA.

Two temporary CPT codes have been assigned for insertion of spinous process decompression implants.

Clinical trials
The FDA premarket approval (PMA) randomized clinical trial (RCT) of the X STOP included 191 patients 50 years of age or older with symptomatic lumbar spinal stenosis. The patients were randomly assigned to treatment with the X STOP implant or nonoperative therapy. Study patients had completed at least 6 months of conservative therapy, had leg, buttock, groin, and/or back pain that could be completely relieved by flexion, had CT or MRI evidence of lumbar canal narrowing, and were required to sit for 50 minutes without pain and walk at least 50 feet.
Ongoing clinical trials
Conditions of FDA marketing approval included postapproval studies to obtain 5-year follow-up data from all patients in the PMA clinical trial who received the X STOP implant plus a new cohort of lumbar spinal stenosis patients. This study is expected to include 240 patients at 8 clinical sites.

Credentialing/training issues
The manufacturer offers either a training program using cadavers or an internet-based program. Surgeons may also be mentored by certified OR nurses who have received training in this technology.

Impact on hospital operations
Patients with spinal stenosis who have failed medical management may be seeking a minimally invasive alternative to conventional surgery, which could give hospitals that offer the X STOP a competitive advantage.

Cautions and complications
The package insert of the X STOP implant includes warnings and potential adverse events. The X STOP must be placed properly to avoid dislodgment, particularly if the patient experiences a traumatic event. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure. Other potential adverse events include fracture of the spinous process, foreign body reaction, and mechanical failure. Potential complications related to the surgery itself include, among others, reactions to anesthesia, myocardial infarction, and infection.

Two-year results of the RCT found that compared to the nonoperative group, the X STOP group reported fewer adverse events (36.3% vs 17.0%).

Intraoperative or postoperative complications in the X STOP group included one episode each of respiratory distress, ischemic coronary episode, or pulmonary edema in a patient with cardiovascular disease who subsequently died. Specific implant-related adverse events included one each of implant migration/dislodgment, malpositioned implant, or spinous process fracture.

Effect on other technologies
Currently, clinical studies have not compared the outcomes of X STOP implantation with other decompression surgeries. If data emerge showing the X STOP has comparable outcomes to conventional surgery, it is likely conventional procedures will decrease. However, if data emerge suggesting that X STOP provides adequate pain relief, but only for a limited time, rates of conventional surgery may decline initially but rise again.

Because it is minimally invasive, this technology may prompt a broadening of patient selection criteria, and patients who may have deferred or declined conventional procedures might opt for interspinous process decompression.

Reported results/outcomes
Investigators measured primary outcomes by changes in the Zurich Claudication Questionnaire, a validated outcomes measure specific to lumbar spinal stenosis that captures data on symptom severity, physical function, and posttreatment patient satisfaction. The primary effectiveness endpoint of the study was the difference in overall treatment success between the two study groups at 2-year follow-up. Success was reported in 45 of 96 patients (47%) in the X STOP group and 4 of 87 (5%) in the nonoperative group (p < 0.001). Patients most likely to have treatment success were those with moderately impaired physical function at baseline.

At 24 months, 84% in the X-STOP group maintained distraction, 6% of patients underwent a laminectomy with removal of the implant because of continued stenosis symptoms, and one patient had implant removal alone. In the nonoperative group, 26% of patients subsequently underwent a laminectomy.

Cost considerations
Overall long-term cost savings are possible if interspinous process decompression provides a durable alternative to conventional surgical approaches.
Conclusions
The key clinical questions regarding this technology are:

- Is it more effective than nonoperative treatment in reducing pain and improving function?
- Is it as effective or more effective than conventional surgical procedures in reducing pain and improving function?

The published evidence consists of one RCT. Data from this 2-year trial suggest that, compared to nonoperative management, the X STOP spacer resulted in improved pain, improved function, and higher patient satisfaction. Implanting the spacer also appeared to reduce the need for a laminectomy over a 2-year period. Longer follow-up is needed to assess implant-related complications. A significant unknown is whether the spacer will interfere with the success of subsequent laminectomy. Trials comparing interspinous process decompressive implants with lumbar fusion are ongoing.

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SELECTED SOURCES


Quantitative evidence base (Low)
The evidence base consists of 1 multicenter randomized controlled trial that compares implantation of the X STOP spacer to nonoperative treatment in 191 patients with spinal stenosis.

Quality of evidence base (Low)
Weaknesses of this evidence base include its small size, lack of blinding, and limited long-term follow-up. Also, the current clinical trial compares the X STOP to nonoperative treatment. Comparison to conventional surgical decompression procedures will be required to clarify where the X STOP procedure lies in the hierarchy of treatment options for spinal stenosis.

Consistency of evidence base (Low)
Having only one study prevents assessment of the consistency of results.

Robustness of evidence base (Low)
New data could easily change the reported results.