New Device for Relief of Lumbar Spinal Stenosis Draws Mixed Reviews

By Stephanie Cajigal

A new device may make it easier and safer to relieve symptoms of lumbar spinal stenosis in a select group of patients, according to some neurosurgeons and orthopedic surgeons. But whether the development poses a breakthrough for people with back pain is a matter for debate.

The X-STOP Interspinous Process Decompression System (X-STOP-IPD) was approved by the FDA in November 2005. To date, about 5,000 to 8,000 people in the US and about 30,000 people worldwide have received the implant, said James F. Zucherman, MD, who along with Kenneth Hsu, MD, invented the device in 1996. [Both inventors — of St. Mary's Spine Center in San Francisco — were stockholders in St. Francis Medical Technologies, Inc., the company that manufactured the X-STOP, and which was bought last year by Kyphon, Inc.]

Lumbar spinal stenosis is caused by arthritis-related degenerative changes — bones and ligaments of the spinal facet joints thicken or enlarge. These changes narrow the lumbar spinal canal, putting pressure on the nerves and spinal cord. Patients usually have back pain, numb feet, and, often, walking-induced claudication in the back and legs that is relieved by standing still or flexing at the waist.

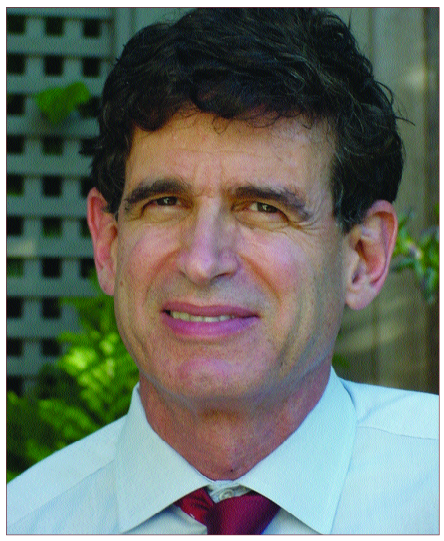
Surgeons place the X-STOP — a titanium implant — between the spinous processes of the lumbar spine to limit the spinal extension in the area causing the pain. It is designed to keep the space between the spinous processes open, so that posterior nerve roots will not be compressed and cause pain. Unlike the traditional surgical approaches of laminectomy and spinal fusion, no bone or cartilage is removed.

The X-STOP is a titanium metal implant. The oval spacer fits between the spinous processes and the wings are designed to prevent the implant from moving.

Dr. Zucherman described the X-STOP procedure as minimally invasive and lasting less than an hour. It requires a brief recovery time — one to two weeks compared with five to six months after spinal fusion — and is usually done with local anesthesia.

Dimitriy G. Kondrashov, MD, who has co-authored studies on X-STOP with Dr. Zucherman and colleagues, likened the effects to that of an elderly woman who leans over her grocery cart while shopping for relief of back pain or discomfort. Once patients have the procedure, they don't need to lean forward for pain relief, he explained. The X-STOP enables the cross-sectional area of the spine to decrease in extension and increase in flexion, causing the posture to straighten to a neutral and less painful position, he added.

The inventors wanted to create an alternative — a middle ground — between limited treatment such as epidermal steroid injections, and more aggressive surgery, such as laminectomy and fusion, said Dr. Kondrashov, attending orthopedic spine surgeon at St. Mary's and St. Francis Spine Centers in San Francisco.



Dr. James F. Zucherman said the X-STOP procedure is minimally invasive — lasting less than an hour — is usually done with local anesthesia, and requires one to two weeks for recovery.

The FDA based its approval on a 2005 study that randomized 191 patients to receive either the X-STOP implant or conservative nonsurgical treatment for 15 months (*Spine* 30:1351-1358). Conservative treatments included at least one epidural steroid injection following enrollment, nonsteroidal anti-inflammatory medications, analgesics, and physical

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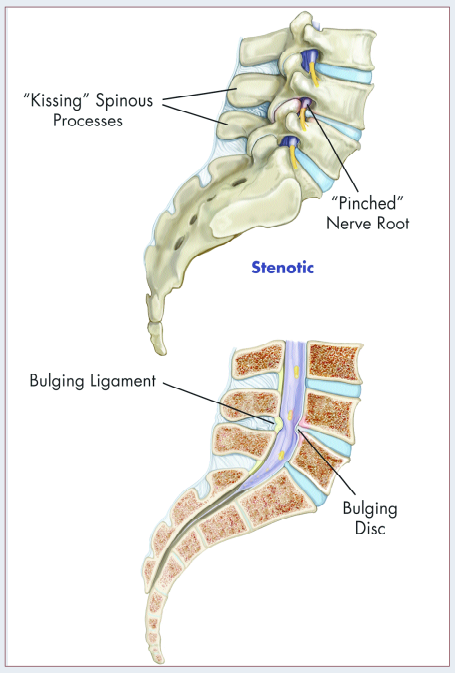


During surgery, the X-STOP IPD [titanium] implant is placed between two bones called spinous processes in the back of the spine.

therapy. Patients were at least 50 years old, and had leg, buttock, and groin pain with or without back pain that was relieved by flexion. In addition, the patients had to be able to walk at least 50 feet.

Patient outcome was defined by the Zurich Claudication Questionnaire, which surveys symptom severity, physical function, and satisfaction with the outcome of the procedure. At two years, the X-STOP group reported a 45.4 percent improvement over the mean baseline symptom severity score, compared with 7.4 percent reported by the controls. On the physical function score, the X-STOP patients improved by 44.3 percent compared to -0.4 percent for controls; and 73.1 percent of the X-STOP patients reported that they were satisfied with their treatment compared with 35.9 percent of controls.

PATIENT SELECTION FOR DEVICE

The FDA has approved the X-STOP for people age 50 and older with moderately impaired physical function who experience relief in flexion and have had at least six months of nonoperative treatment. Patients with osteoporosis are eligible unless they have had fragility fractures; one study that tested interspinous implants on cadavers found a correlation between load failure (the load on the bone that causes the bone to break or collapse) and lower bone-mineral density (*Eur Spine J* 2006;15(6):908-912). Dr. Zucherman said his group has been experimenting with the insertion of cement into the vertebral bodies above and below the device. "That has doubled the strength in our laboratory studies and may be a way to compensate for that," he said.

But Michael Y. Wang, MD, who has performed several X-STOP procedures and is associate professor of clinical neurological surgery at the University of Miami, said that problems may arise as the device wears against the vertebral bones over time. "This may cause skeletal erosion or local inflammation, but the prevalence and severity of this is unknown and there have been no long-term evaluation or studies to date."

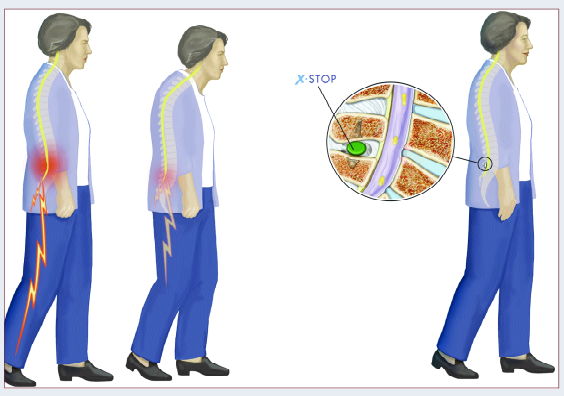
In fact, experts told *Neurology Today* that patient selection is the most important factor in determining the X-STOP's effectiveness.

"The potential danger with any new technology is that surgeons will start doing this for everything — for people with pathology that this wouldn't be appropriate for," said Kurt M. Eichholz, MD, who along with Richard G. Fessler, MD, PhD, described the benefits of the X-STOP in an editorial published in *Nature Clinical Practice Neurology* (2006;2(1):22-23). "I think this is a unique and less invasive alternative for people who have the right type of pathology. …The results are determined not in the operating room but by picking the right procedure for the right patient."

According to Dr. Kondrashov, "the right patient" includes people who haven't responded well to conservative treatments but at the same time are at risk of complications from general anesthesia.

Dr. Eichholz, assistant professor of neurological surgery at Vanderbilt University, said the X-STOP would not work for patients who have a misalignment of the bones or a slipped disc.

He said many patients have inquired about the device after learning about it through reports in the lay media. "This [one] story made it sound like 'I went to the hospital, I was there for a half-hour, and now I'm perfect,'" he said. "When patients see that, they come in with these magnificent expectations of having a half-hour procedure and feeling like a 12-year-old kid. I take all those things with a grain of salt and try to be realistic and make sure that it is appropriate for them."

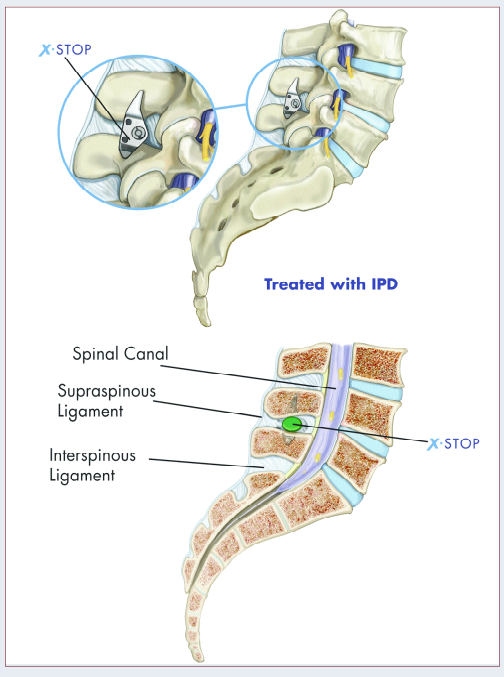


The X-STOP is designed to keep the space between the spinous processes open, so that when the patient stands upright the nerves in the back will not be pinched or cause pain.

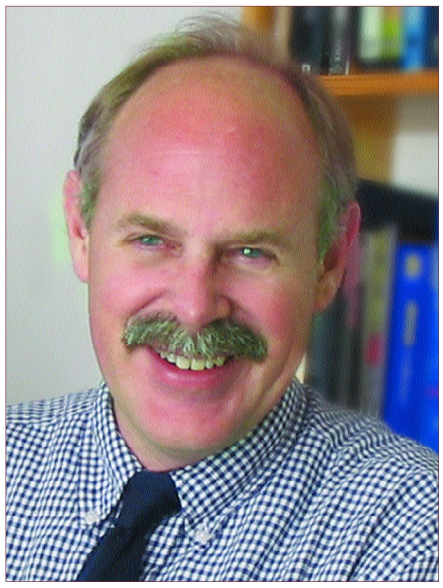
NOT A 'ONE-STOP SOLUTION'

It's also important that the procedure not be viewed as a one-stop solution to back pain, said John C. Chiu, MD, medical director of the California Spine Institute for Minimally Invasive Spine Surgery, who wrote a review paper of the X-STOP for *Surgical Technology International* (2006;15:265-275). Since about one-third of older adults have more than one back complication, surgeons should combine the X-STOP with other techniques. For example, they should remove calcified discs that protrude into the spinal canal because stretching the spinal process will do nothing to move the disc, he said.

Richard Deyo, MD, professor of medicine and health services at the University of Washington in Seattle, where he also co-directs the Center for Cost and Outcomes Research, said it will be difficult to draw conclusions on the X-STOP until studies compare it to laminectomy. "We don't know — and the FDA couldn't know — the long-term results of this [X-STOP] and how it compares to other alternatives… I think the FDA was too quick to approve this and is generally too quick to approve new devices."



There is no removal of bone or soft tissue during the X-STOP procedure. The implant is not positioned close to nerves or the spinal cord, but rather behind the spinal cord between the bony spinous process.



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But Dr. Chiu sees minimally invasive procedures like the X-STOP as the future of back surgery and even as a way to cut health-care costs. Patients — and ultimately, society — he said, will face fewer costs through improved functioning and dramatically reduced tissue trauma resulting in speedier recoveries. "I think this type of procedure should be encouraged by all specialists including neurologists, neurosurgeons, and orthopedic surgeons," he said. ■

To see a video of an X-STOP surgery visit: **www.globalortho.com.au/index.php?option=com_content&task=view&id=120&Itemid=305**.

CORRECTION

In "First Large Review of Childhood-onset MS Reveals More Severe Disabilitiy Occurs Earlier Than It Would For Adult-onset Disease" (July 17, p. 1), the article incorrectly stated that the April 2007 *Neurology* supplement on pediatric multiple sclerosis was not peer-reviewed by the Neurology editors; in fact it was.

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