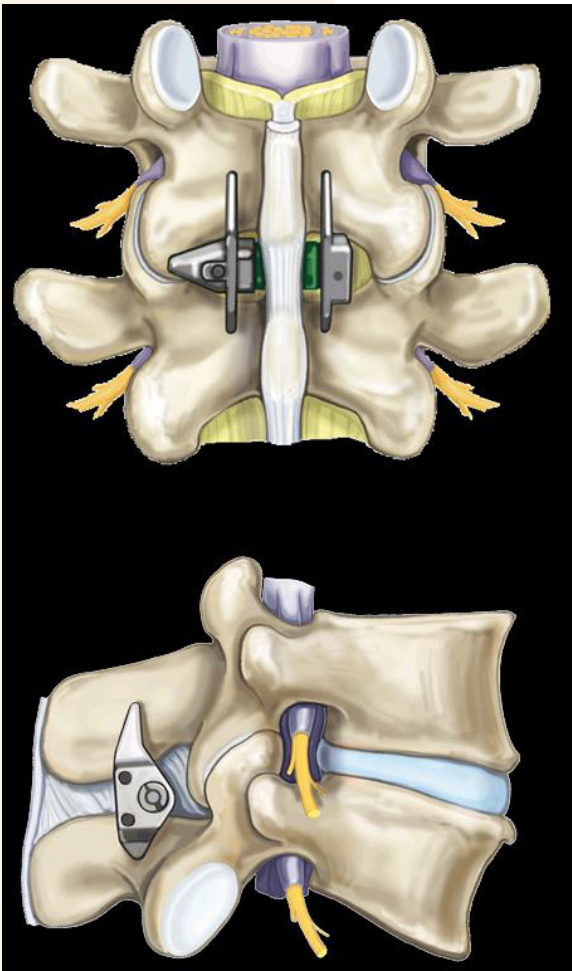


Titanium spacer takes off as treatment for lumbar spinal stenosis

UCH SPINE CENTER GETTING GOOD SHORT-TERM OUT- COMES WITH AN “X” FACTOR

The many indignities of aging include a gradual thickening of ligaments and degeneration of cartilage and bone, which for most contributes to a general sense of being less flexible and more creaky than in the flower of youth. But in the spine – in particular the lower back, which bears a disproportionate burden of maintaining an upright posture – the process can cause a great deal of pain.



Inserted between lumbar vertebra, the spacer relieves pinched nerve roots that can lead to spinal stenosis.

Approved in the United States to treat lumbar spinal stenosis in November 2005, about 10,000 X-Stop interspinous spacers have been implanted in patients.

A new medical device, called the X-Stop interspinous spacer, is helping ease that pain for a growing number of patients at UCH’s Spine Center and elsewhere.

Lumbar spinal stenosis, or LSS, is diagnosed roughly 700,000 times a year in the United States. It is a result of expanding bone spurs and disc cartilage between vertebra, which narrow the spinal canal. This narrowing, or stenosis, can impinge on the spinal cord as well as nerve roots exiting to the legs.

Aching backs. LSS symptoms include dull or aching back pain spreading to the legs; numbness and “pins and needles” in the legs, calves and rump; weakness and degraded physical balance and even lessened physical endurance. They tend to flare when a person is in a standing position. Such symptoms, in turn, can limit a patient’s physical activity and contribute to obesity, depression and other psychological issues and general physical deterioration, physicians say.

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Studies have shown that roughly one in 10 people end up with such symptoms, making lumbar spinal stenosis the most common reason for spine surgery among older people in the United States.

Knowledge Enterprises, Inc. estimates that the malady costs the U.S. economy billions a year in lost work hours alone.

“If we all lived long enough, we would all eventually get this,” said Vikas Patel, MD, a UCH Spine Center surgeon. “Just like arthritis of the hip or the knee, it’s the deterioration of the joints that leads to it.”

A third way. There have traditionally been two main avenues for treating LSS. One focused on physical therapy, anti-inflammatory drugs and epidural injections. The other involved major surgery called a laminectomy, or “unroofing” of the vertebral bone and ligaments to take pressure off the spinal cord and nerves.

Surgery also often involved fusing vertebra with titanium screws to add stability. The X-stop interspinous spacer provides a third option, Patel said.

The titanium device, approved by the U.S. Food and Drug Administration in November 2005 for use in LSS patients aged 50 or older, consists of two flanking “wings” connected by a central bar, giving the loose impression of an automotive spoiler.

Surgeons remove one wing, insert the bar between two spinous processes (the protrusions making up the “bumps” in the backbone), and lock the second wing down. The bar then prevents the vertebra from pressing as closely together.

A patient can have one, two or even three X-stop spacers inserted, said Patel, who has done about 50 such procedures in the past two years. Unlike a laminectomy, it’s an outpatient procedure, and can be done under local or general anesthetic, he said. Within about 10 days – the time it takes the incision to heal – the patient has no medical restrictions, he added.

“I think it’s a great technique for the right patients,” Patel said. “It allows them a

“It allows patients a minimally invasive alternative that does not require general anesthesia, and it offers an alternative for patients who would otherwise be too sick or medically compromised to have surgery.”

minimally invasive alternative that does not require general anesthesia, and it's an option for patients who would otherwise be too sick or medically compromised to have surgery.”

Competition and questions. James Butler, district manager for Colorado and Wyoming for Medtronic, Inc., which sells the X-Stop spacer, said the device was developed by two San Francisco spine surgeons, James Zucherman, MD, and Ken Hsu, MD. It remains the lone FDA-approved interspinous spacer. About 10,000 have been implemented worldwide.

But it could have some competition soon. UCH is among a few hospitals participating in a Phase III clinical trial for a similar medical implant, said Evalina Burger, vice chair of the University of Colorado Denver School of Medicine's Department of Orthopedics and a senior orthopedic spine surgeon at the Spine Center.

UCH has been implanting X-Stop spacers in patients aged 70 or older, Burger said. She said that fact and the device's newness still leaves open questions of its longevity.

“Are we treating them effectively so they're not going to come back or are we buying them some time?” she asked. “We haven't had this [device] for 10 or 15 years, so we don't know the long-term outcome.”

Burger, an expert in metals used for spine surgery, said she was initially skeptical of the device.

“I truly could not figure out how this device could make that big of a difference,” she said.

But, she said, intuition often clashes with medical reality, with devices that seem like sure bets flopping – and vice-versa.

With the X-Stop spacer, she said, “I was pretty amazed by the amount of relief patients got. I'm still wary about long-term outcomes, but it seems to make a significant difference in terms of immediate relief that I cannot explain at all.”

UCH Spine Center surgeons are offering a free public presentation on the X-Stop interspinous spacer from 6:30-8 p.m. on Thursday, May 28, in conference room 2007/2133 of the Anschutz Inpatient Pavilion. Call 303-231-6711 for reservations.