

X-Stop vs Laminectomy for lumbar spinal stenosis: Quality of life and cost-effectiveness

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Researchers in the United Kingdom (UK) conducted a randomized controlled trial in 47 patients with lumbar spinal stenosis to compare treatment outcomes and costs of two competing surgical procedures: insertion of the X-Stop (Medtronic) interspinous distractor device and open decompression surgery with laminectomy. Both procedures improved the patients' quality of life; however, overall, laminectomy gave patients a better quality of life and was also more cost-effective.

Detailed findings of this study can be found in a new article, "A <u>randomized controlled trial</u> of the X-Stop interspinous distractor device versus laminectomy for <u>lumbar spinal stenosis</u> with 2-year <u>quality-of-life</u> and cost-effectiveness outcomes," published today in the *Journal of Neurosurgery: Spine*.

Background

Lumbar spinal stenosis is the term used to describe narrowing of the spinal canal within the lower lumbar spine. This narrowing, often a sign of aging, may be due to bone spurs resulting from arthritis, a bulging spinal disc, or thickened ligaments. As the spinal canal narrows, spinal nerves passing through it can become compressed and inflamed, leading to weakness, numbness, and/or pain in the lower back and legs, and, occasionally, bladder or bowel dysfunction.

In many cases, lumbar spinal stenosis can be managed nonsurgically by



use of medicines to reduce swelling and pain, physical therapy, and specific exercises. However, in some cases, these are ineffective and spinal surgery is recommended. Most often, laminectomy is performed by removing a portion of bone on the back of the lumbar vertebra at the site of compression, allowing the spinal canal to expand and relieving pressure on the spinal nerves.

Traditional laminectomy is open surgery usually requiring general anesthesia and a few days in the hospital. X-Stop surgery is less invasive. Often placed after administration of a local anesthetic agent, the X-Stop Interspinous Process Decompression System (Medtronic), composed of a titanium alloy, is inserted at the back of lumbar vertebrae, between the spinous processes of adjacent vertebrae at the site of spinal canal narrowing. Once there, the device prevents the spine from bending too far backward, compressing spinal nerves and causing discomfort.

Present Study

In this article, the authors describe a prospective, open-label, randomized controlled trial, "Cost-Effectiveness and Quality of Life After Laminectomy or X-Stop (CELAX)," in which open laminectomy and use of the X-Stop device for the treatment of lumbar spinal stenosis were compared. The primary outcomes investigated were cost-effectiveness and long-term quality of life. The study was conducted at three medical centers in the UK.

Between 2010 and 2014, 47 patients who experienced neurogenic caudication from lumbar spinal stenosis and whose symptoms improved on forward flexion were randomized into one of two treatment groups: 26 patients underwent laminectomy and 21 patients received the X-Stop device. The surgical procedures were performed by consulting and attending surgeons as well as by residents. General anesthesia was used in all cases.



Eighteen women and 29 men, ranging in age from 47 to 86 years, participated fully in the clinical trial. During the course of the study, five patients in the X-Stop group crossed over into the laminectomy group.

Quality of life for the patients was measured using EQ-5D instruments (EuroQuol Group) before the procedure and again at 6 months, 1 year, and 2 years post-procedure. Costs per patient were based on the cost of time in the operating room plus the cost of the hospital stay.

Six months after treatment, the mean quality of life in both the laminectomy and X-Stop groups was significantly better than that measured at baseline (pretreatment). At 1 and 2 years post-treatment, the improved quality of life demonstrated in the laminectomy group continued to be significantly better than baseline; in the X-Stop group, quality of life remained improved but not significantly so.

In this clinical study, the mean cost for a laminectomy was £2712 (\$3316) and that for the X-Stop procedure was £5148 (\$6295). Surgery took nearly twice as long when laminectomy was performed (mean 122 minutes compared with 66 minutes for X-Stop insertion). The mean length of hospital stay was comparable: 4.3 days in the laminectomy group and 4.2 days in the X-Stop group. The increase in the cost of the X-Stop procedure was due in large part to the cost of the device.

There were four complications in the laminectomy group, although only one required a return to the operating room. There were two complications in the X-Stop group, both of which necessitated removal of the device and a switch to laminectomy. Treatment with the X-Stop device was later found to be inadequate in three patients, who then also underwent surgery for laminectomy and removal of the device.

Additional data on primary and secondary outcomes are provided in the article and in a supplemental file online.



The authors conclude that laminectomy is more cost-effective than the X-Stop device for the treatment of lumbar spinal stenosis. The X-Stop device improved quality of life but less so than laminectomy. Nevertheless, the interspinous distractor device still provides a service. The authors suggest that the X-Stop "should be reserved for cases in which a less-invasive procedure is required. There is no justification for its regular use as an alternative to decompressive surgery."

When asked about the findings of this study, Dr. Anouk Borg, first author of the paper, responded, "It is very encouraging that both treatments resulted in an improvement in the quality of life for our patients. The X-Stop device is an attractive option as it is less invasive than standard open surgery. It is also a faster procedure and it is reversible. The device can be removed if required. However, we found that open laminectomy is a more cost-effective procedure in the UK, with sustained improvement in quality of life up to the trial endpoint at 2 years."

More information: Journal of Neurosurgery: Spine (2021). DOI: 10.3171/2020.7.SPINE20880, the jns.org/doi/10.3171/2020.7.SPINE20880

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