EDITORIAL

Interspinous spacers for lumbar stenosis: time for obsolescence?**Marjorie C. Wang, MD, MPH, and Mohammed Y. T. AlGhamdi, MD**

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LUMBAR spinal stenosis (LSS) is the most common indication for spine surgery in the elderly population. This condition is prevalent in approximately 47% of 60- to 69-year-old individuals and increases with age.¹ In the US, rates of surgery for LSS have rapidly increased over time.² Although open laminectomy has traditionally been considered the gold-standard procedure, associated complications, the need for general anesthesia, and resource utilization have led to development of other interventions. Interspinous distraction devices (IDDs) are one example. The X-Stop (Medtronic) was approved in 2005 by the US FDA for use in patients with 1- or 2-level LSS and symptoms that improve with flexion. In one study, results with the X-Stop were favorable at the 1-year outcome compared with those of nonsurgical management; 59% of the X-Stop cohort reported significant improvement in the symptom severity and physical function domains of the Zurich Claudication Questionnaire compared with 12% of the nonsurgical cohort, and the authors reported a 1-year reoperation rate of 6% in the X-Stop cohort.³ Other studies have compared X-Stop with lumbar laminectomy and found improvement in outcomes among both cohorts; however, reoperation rates were consistently noted to be significantly higher among the X-Stop cohort.^{5,6} Since X-Stop can be implanted in an outpatient setting under local anesthesia with shorter procedural times than those required for laminectomy, questions remain regarding whether this device could play a role in the treatment of LSS despite the high reoperation rate.

In this issue of *Journal of Neurosurgery: Spine*, Borg et al.⁴ present results of the United Kingdom Cost-Effectiveness and Quality of Life After Laminectomy or X-Stop (CELAX) open-label, randomized controlled trial. Cost was measured per patient episode and included device, operating time, and admission costs. Quality of life (QOL) was measured using the EQ-5D as the primary outcome. Both the laminectomy and X-Stop cohorts reported im-

provement in QOL compared with baseline, but the laminectomy group showed consistently significant improvement at 6, 12, and 24 months after surgery. In contrast, the X-Stop group showed statistically significant improvement in QOL only at 6 months. In terms of cost, laminectomy was also favorable, mostly driven by the cost of the X-Stop device.

Consistent with prior studies, the mean operative time was significantly longer for laminectomy than for X-Stop (122 minutes for laminectomy vs 66 minutes for X-Stop). These times are comparable to those of Strömqvist et al. (mean 98 minutes for laminectomy vs 62 minutes for X-Stop) and Lønne et al. (mean 113 minutes for minimally invasive laminectomy and 47 minutes for X-Stop).^{5,6} In the current article, the laminectomy procedure was not standardized, and neurosurgeons in training performed some of the procedures in both cohorts. While other publications did not standardize the laminectomy technique or X-Stop training, it would be interesting to note if operative times differed with surgeon experience. Nevertheless, the variety of training and experience in this study setting may more closely reflect real-world practice. Complications were more common in the laminectomy group (19% vs 10% in the X-Stop group), but reoperations were more common in the X-Stop group. Four patients (20%) required reoperation, and 1 patient had an intraoperative spinous process fracture mandating the removal of the device. It is unclear if the X-Stop insertion was performed under local or general anesthesia. This information is also lacking in the literature despite being a proposed advantage of X-Stop.⁴

Randomized controlled trials, while providing the highest level of evidence, are time-consuming and costly to perform. This study is notable for a lengthy recruitment period (2010 to 2014) for a relatively small number of patients: 300 patients were assessed, of whom 49 were randomized.⁴ Specific mention is not made regarding the

inclusion of patients with symptomatic improvement in flexion, an FDA criterion for the insertion of X-Stop. In addition, since multiple conditions that are common in the elderly are listed as exclusions for this device (e.g., osteoporosis and degenerative spondylolisthesis), the lengthy recruitment period may reflect the small number of patients with LSS who qualify for implantation. While the length of stay was not significantly different between the laminectomy and X-Stop groups in this study, it is striking to note that the mean length of stay was 4 days for both the laminectomy and X-Stop cohorts. Again, this may better reflect real-world practice and various protocols for postoperative care and patient expectations in different countries. In comparison, in our query of US Centers for Medicare & Medicaid Services data, approximately 3000 to 4000 ISSD procedures (coded by Current Procedural Terminology [CPT] codes 22867 and 22869) were performed each year on average in 2017 and 2018 (courtesy of Joseph Cheng, MD, personal communication, July 26, 2020).

While neurosurgeons and orthopedic surgeons predominated in billing for CPT 22867 and 38.5% of the procedures were performed in an inpatient setting, interventional pain, pain management, anesthesia, and physical medicine and rehabilitation providers accounted for the majority of billing for CPT 22869, and the majority of the procedures were performed in an ambulatory surgery center (80.5%) and outpatient setting (17.4%). These differences in practice likely lead to wide variations in cost and would impact cost-effectiveness calculations.

Is it time for IDD's to be obsolete? Are there still patients who might benefit from this surgical technique? While Borg et al.⁴ add strong evidence that X-Stop is not cost-effective in the United Kingdom (UK), the long inpatient stay seems contrary to the intended purpose of this device. Since the finding of cost-effectiveness was sensitive to the X-Stop device cost, there may still be a role for less costly interspinous distractor devices. Finally, since there may also be a learning curve for the implantation of IDD's, standardized training may reduce procedural times and early complications such as spinous process fractures. A North American Spine Society evidence review of lumbar stenosis suggested that future study should compare cost and outcomes among LSS patients treated by interspinous distractor devices, microlaminectomy decompression surgery, or well-defined medical treatment.⁷ A study designed to evaluate all three groups with a standardized surgical treatment and anesthesia regimen in an outpatient setting would likely definitively answer this question. Nevertheless, Borg et al.⁴ strengthen the current evidence that clearly shows that IDD's should not be used as an alternative to laminectomy in the general population with symptomatic LSS.

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Disclosures

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Response

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We thank Drs. Wang and AlGhamadi for their comments addressing the results of the CELAX trial. We screened patients with symptoms typical of neurogenic claudication, which includes symptomatic improvement on forward spinal flexion. These patients were offered participation in the trial if MRI supported the diagnosis and all inclusion criteria were met. The study arms were open lumbar laminectomy and X-Stop insertion. The procedures were not standardized, so as to reflect the variability in real practice. Patients randomized for X-Stop insertion provided consent for conversion to laminectomy in case of complications. Although the X-Stop can be inserted under local anesthesia, all surgeons opted to carry out the procedure under general anesthesia. The reasons for these decisions were not explored in this trial. Of note, patients who

could not tolerate general anesthesia would not have been eligible to participate, as they could not be randomized to a laminectomy.

Quality of life, measured with the EQ-5D, improved in both groups. In the laminectomy group, there was improvement at every time point; however, in the X-Stop group, improvement plateaued after 6 months. We report intention-to-treat analysis, and thus at 24 months, the X-Stop group included 5 patients who crossed over to laminectomy. The as-treated analysis showed that at 24 months, both groups would have shown a statistically significant improvement.

Surgeon experience varied, reflecting real practice. Most X-Stop insertions (76%) were performed by a consultant or attending surgeon, whereas most laminectomies (69%) were performed by neurosurgeons in training. The mean length of consultant operations was 81 minutes, versus 110 minutes when performed by a resident. However, since laminectomies are longer operations, this may account for some of that difference.

Although a large number of patients were screened, only a small proportion met all the inclusion criteria and were willing to undergo randomization. Often, patients did not like the idea of their operation being chosen at random and preferred to make a conscious decision about

which procedure to undergo. One might expect the length of stay to be shorter for the X-Stop cohort. However, in this study, both groups had the same mean length of stay (4 days). This may relate to preexisting poor mobility requiring therapy input and home assessments prior to discharge and unfamiliarity of staff with the X-Stop procedure, resulting in a longer period of observation. All X-Stop insertions were performed in an inpatient setting. This may negate the potential advantage of the X-Stop device having a shorter hospital stay and affect the cost-effectiveness analysis.

The CELAX trial showed that in a real-life UK setting, laminectomy was more cost-effective than X-Stop insertion for the treatment of lumbar spinal stenosis. However, patients showed some improvement in both QOL and disease-specific outcome measures in both groups. This suggests that there may still be a role for the X-Stop device, particularly in patients in whom a less-invasive procedure is required and if the costs could be offset by reducing device costs or moving to a higher rate of ambulatory care with earlier discharge.

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