

Title: Interspinous Process Decompression with the X-Stop Device for Lumbar Spinal Stenosis: A Retrospective Review.

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## **Introduction:**

Degenerative lumbar spinal stenosis is a common cause of low back and leg pain in individuals in their fifth and sixth decades of life.<sup>1-4</sup> The symptoms specific to intermittent neurogenic claudication include progressive back, buttock or leg pain, and lower extremity numbness or weakness with standing and walking.<sup>2,5,6</sup> In lumbar extension, as with standing, the diameter of the spinal canal is narrowed in the anterior-posterior dimension resulting in compression of the thecal sac and exiting nerve roots.<sup>6</sup> These symptoms are typically relieved by changing to a seated or forward flexed position, as this position increases sagittal spinal canal diameter.<sup>4,6-9</sup> Spinal stenosis is a dynamic process where the diameter of the spinal canal decreases below a critical threshold due to a combination of mechanical factors including degenerative disc disease with resultant disc protrusion, spondylolisthesis, ligamentum flavum hypertrophy, and facet joint arthropathy.<sup>2,4,8</sup> Lumbar spinal stenosis is a progressive disabling condition which compromises an individual's ability to perform their activities of daily living, reduces overall quality of life and ultimately threatens one's independence.<sup>7</sup>

Analgesics, nonsteroidal anti-inflammatories, activity modification, physical therapy and epidural steroid injections are the mainstay of conservative care for spinal stenosis.<sup>6,7</sup> Patients often fail conservative therapy because these treatment options do not alter the anatomic pathology that causes symptoms.<sup>7</sup> Since stenosis is a mechanical problem, surgical intervention in the form of mechanical decompression of the posterior spinal elements is indicated when a patient fails conservative management.<sup>6</sup> The conventional surgical treatment for spinal stenosis is a lumbar laminectomy.<sup>10</sup> The X-Stop is the first interspinous process decompression (IPD) device that provides an alternative surgical option for patients with spinal stenosis.<sup>4</sup> Interspinous process decompression using the X-Stop implant is a relatively new, FDA approved, minimally invasive procedure that increases spinal canal diameter while avoiding exposure of the spinal cord and neural elements. A titanium spacer is placed between adjacent spinous processes of the affected level maintaining distraction of the posterior elements of the vertebral bodies thereby indirectly reducing pressure on the neural elements.<sup>2,4,8,10</sup> The procedure may be performed under a general or local anesthetic in a lateral decubitus or prone position via a midline approach with a minimal hospital stay.<sup>10</sup>

### **Surgical Technique:**

The patient is placed in the right lateral decubitus position and may be slightly sedated. Fluoroscopic imaging is used to localize the appropriate surgical level. Following the administration of a local anesthetic, the skin is incised and the lumbodorsal fascia overlying the adjacent spinous processes is exposed. Longitudinal incisions are then made on each side of the adjacent spinous processes with care taken to preserve the integrity of the supraspinous process ligament running between them. The lumbar paraspinal musculature is then subperiosteally dissected from the adjacent spinous processes out laterally to expose the facet joints. Care is taken to preserve the facet joint capsules. Once dissection is complete and exposure is adequate, attention is turned to the placement of the interspinous process distraction implant (X-STOP). Using lateral fluoroscopic imaging (to verify the correct level), the initial dilator tool is inserted and passed from the right side to the left side of the interspinous space with care taken to remain as anterior or ventral as possible. Then, sequential dilators are used to create maximal distraction and, in doing so, the appropriate size implant is determined. Maximal distraction between the spinous processes can be judged by palpating the tension within the overlying supraspinous process ligament. Once the appropriate implant is chosen, the device is affixed to its insertion tool and passed from the right side to the left side of the interspinous space. The left wing of the implant is then attached under direct visualization and a torque screwdriver is used to tighten the implant into its final position. AP and lateral fluoroscopic imaging is obtained to confirm appropriate positioning of the implant in both planes. The lumbodorsal fascia and skin is closed in the usual fashion. There is no need for placement of a drain as blood loss should be minimal. The procedure is usually performed in less than one hour. Bracing is not needed postoperatively.

### **Materials and Methods:**

Following the Spine Center at Danbury Hospital X-Stop Protocol, the device was implanted at 35 levels in 26 patients (12 males and 14 females; age range 64-90 years; mean, 77 years old) in a fifteen month period. Ten implants were placed at the L3/4 level and 25 implants were placed at the L4/5 level. Implants were single level in 16 patients

and double level in 10 patients. All patients had the classic symptom complex associated with intermittent, neurogenic claudication secondary to spinal stenosis and had failed to respond to non-operative care including non-steroidal anti-inflammatories, physical therapy and the trial of at least one epidural steroid injection. Five patients underwent general endotracheal anesthesia and twenty-one patients received local anesthesia plus sedation. Five patients were operated upon in the prone position and the remainder in a lateral decubitus position. Seven patients had a single level L4/5 spondylolisthesis and one patient had a two-level L3/4 and L4/5 spondylolisthesis. A total of nine 10mm implants, seven 12mm implants and nineteen 14mm implants were placed. The average hospital length of stay was 1.75 days (range 1 to 6 days).

### **Results:**

The data were analyzed for 26 X-Stop patients. As this case study is a retrospective chart and radiograph review, primary outcome is subjective and based on self reported improvement in symptoms and function at postoperative office visits. Twenty-four implantation procedures were successful. There were no treatment related deaths. Eleven patients (42%) were discharged from care by their six or twelve week follow-up visits with resolution of symptoms.

There were two intra-operative related complications which represent treatment failures. One patient was noted to have an L4 spinous process fracture prior to closure requiring removal of the two adjacent implants prior to leaving the operating room. A second patient also sustained an L4 spinous process fracture and therefore, the procedure was aborted and no implant was placed. Two patients, each of which had a single level implant at L4/5 continued to have persistent symptoms postoperatively. Their cases are considered to reflect treatment failures as both patients ultimately required delayed implant removal and formal laminectomy less than one year from the initial procedure. No difficulties were noted when removing the implant when they subsequently underwent laminectomy.

There was one device related adverse event. At a routine two week postop check, one patient (who underwent a two level implant) was noted to have a dislodged L4/5 implant detected on follow-up radiographic exam. Although she continues to be

symptomatic (persistent radicular left leg pain), she has an intact neurological exam and has refused additional treatment to date. Her case is also considered to represent a treatment failure.

Postoperatively, one patient (who had received a local anesthetic) developed hypoxic respiratory failure, was found to have a right lower lobe infiltrate on radiograph and was presumed to have developed aspiration pneumonia. She received seven days of intravenous antibiotics along with an oral prednisone taper and was ultimately discharged home with home oxygen therapy. Her preoperative symptoms have resolved.

Three patients in this series had stenosis at the L2/3 level that was not addressed as the device is not indicated for implantation at the L2/3 level. One patient was discharged to long-term pain management at twelve weeks post-operatively. One patient with an L4/5 implant developed recurrent radicular left leg pain with a new foot drop at ten months post-op at which time an L4/5 laminectomy was recommended. Although considered to be a minimally invasive procedure, five patients in our series required transfer to an extended care facility upon discharge from the hospital for additional rehabilitation.

### **Discussion:**

As with any spinal procedure, peri and post-operative complications include the risk of cardiovascular and pulmonary complications related to a general anesthetic, infection, blood loss, iatrogenic instability and hardware failure.<sup>10</sup> Other considerations specific to the X-Stop include the risk of spinous process fracture which may result in failure to place the device, implant removal and or need to abort the procedure. Additional risks include device expulsion, migration or displacement and incomplete decompression resulting in inadequate pain relief and ultimate need for a subsequent laminectomy.

The advantages of this minimally invasive procedure include the ability to perform it under a local rather than a general anesthetic<sup>7</sup> (although in our series 5 patients received general anesthesia). While the literature suggests that it can be performed on an out-patient basis that has not been our clinical experience.<sup>4</sup> There is minimal risk of dural tear or spinal cord injury since the neural elements are not exposed. Additionally, the supraspinous and interspinous ligaments are preserved so spinal stability is not sacrificed

and it may obviate the need for spinal fusion in some patients. In theory, length of stay should be shorter than that of patients who have undergone a conventional lumbar laminectomy and fewer patients should require nursing home care or rehabilitation. However, five patients in our series (19%) required transfer to short term rehabilitation facilities upon discharge from the hospital.

**Conclusion:**

Despite its limitations, this study shows that the X-Stop device can effectively treat spinal stenosis in approximately one-third of patients. The study by Hsu et al. demonstrated that treatment with the X-Stop device was superior to conservative care alone and comparable to the benefit of lumbar decompression.<sup>1,8</sup> This new technology offers an alternative, low risk, minimally invasive treatment option when compared to laminectomy with or without fusion. As with all new technology, clear indications need to be defined in order to have predictable surgical outcomes. While IPD may be superior to conservative care, conventional lumbar laminectomy still provides the most definitive treatment option. Long term data are still lacking and time will reveal how many patients will deteriorate and ultimately go on to require decompressive laminectomy. IPD with the X-Stop implant is not indicated for stenosis at the L2/3 and L5-S1 levels and therefore, open decompressive laminectomy may still provide more predictable outcomes for patients with multi-level stenosis.

Spine specialists must put clinical success into perspective. The X-Stop device can be placed under a local anesthetic, with a shorter length of stay, and allows for immediate postoperative mobilization and quicker return to function. Complications are relatively few when compared to laminectomy with or without fusion. If treatment with the X-Stop does not meet the patient's expectation, the implant can easily be removed and a laminectomy can still be performed. A return to the operating room, however, drives up health care costs when one considers a second hospitalization and utilization of additional resources such as visiting nurse services and extended care facilities. Therefore, clinicians must question whether the cost of this new technology (or lack of reimbursement) is justified when studies so far have failed to show a statistically significant difference in long term outcomes.

Perhaps the greatest value in this procedure is its ability to obviate the need for concomitant spinal fusion when spinal stenosis is associated with a spondylolisthesis. In elderly patients with significant medical co-morbidities including diabetes, autoimmune diseases, osteoporosis and history of tobacco use, adding a fusion to address the potential instability suggested by the existence of a spondylolisthesis adds significant morbidity to the decompression. IPD with the X-Stop device may also prove to be the more appropriate intervention for the high risk, symptomatic candidate with moderate stenosis whose multiple medical co-morbidities preclude them from being medically cleared to undergo a general anesthetic. Clearly, proper patient selection is essential for optimal clinical results. Historically, surgical intervention has been limited to a choice between decompressive lumbar laminectomy with or without fusion. This new technology provides another potential treatment option.<sup>9</sup>

The authors recognize the limitations of this study in that no objective preoperative questionnaire was obtained, Furthermore; it was not a prospective, randomized multi-center controlled study. It would be beneficial to compare patients undergoing IPD with the X-Stop implant with those undergoing decompressive laminectomy so that definitive conclusions can be ascertained with respect to clinical improvement of symptoms.

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