Dynamic interspinous process stabilization: review of complications associated with the X-Stop device

CHRISTIAN BOWERS, M.D., AMIN AMINI, M.D., M.Sc., ANDREW T. DAILEY, M.D., AND MEIC H. SCHMIDT, M.D.

Department of Neurosurgery, University of Utah, Salt Lake City, Utah

Object. The X-Stop interspinous device is designed for the treatment of patients with neurogenic intermittent claudication due to lumbar spinal stenosis. It distracts the posterior elements of adjacent vertebral bodies, unloading the intervertebral disc, limiting spinal extension, and improving central canal and neuroforaminal stenosis. In this paper, the authors reviewed the complications and failure/reoperation rates in a small series of patients and compared their results with other reported complication and failure/reoperation rates.

Methods. The medical records of all patients who underwent placement of the X-Stop device for the treatment of NIC at the authors’ institution were retrospectively evaluated, and demographic information, diagnosis, and preoperative pain levels were recorded. Postoperatively, patients subjectively graded the percentage (0–100%) of improvement in pain as well as the amount of residual pain and underwent imaging at 1-, 3-, and 6-month intervals. Approximately 4 years after X-Stop placement, information on long-term outcomes was obtained from patient medical records or additional follow-up.

Results. Thirteen patients (8 men and 5 women) underwent placement of the X-Stop device. Central canal stenosis with bilateral foraminal stenosis was diagnosed in all patients: 9 (69%) of 13 had severe stenosis and 4 (31%) of 13 had moderate stenosis. Five patients (38%) also had associated Grade I spondylolisthesis. Nine patients underwent placement of the X-Stop device at the L4–5 interspinous space and 4 at both the L3–4 and L4–5 levels. The average duration of follow-up was 42.9 months (range 3–48 months). Initially, pain improved an average of 72% (range 50–100%) in these patients; however, preoperative pain returned in 77% of the patients (10 of 13). The overall complication rate was 38%, including 3 spinous process fractures (23%) and 2 instances of new-onset radiculopathy (15%). The ultimate failure rate requiring additional spinal surgery was 85% (11 of 13 patients). These complication and failure rates are much higher than those previously reported.

Conclusions. Overdistraction, poor bone density, poor patient selection, and preexistent adjacent foraminal stenosis may all be factors in the development of the aforementioned complications. Thus, careful attention should be paid preoperatively to adjacent-level disease, bone density, appropriate implant size, and optimal patient selection.

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Key Words • interspinous spacer • X-Stop device • complication • neurogenic claudication

Spinal fusion has been the standard of treatment for spinal instabilities due to degenerative changes in the disc with subsequent spondylolisthesis, ankylosis, and central canal and neuroforaminal stenosis. Although fusion devices have been shown to offer improved outcomes, some long-term clinical data fail to show a correlation between the high rate of fusion and pain improvement. Biomechanical alteration in the load-transferring and stress-shielding effect, causing higher morbidity at the adjacent levels, instrumentation-related osteopenia, and a higher rate of nonunion, has been a growing concern. Recently, new concepts, such as soft stabilization, dynamic stabilization, and motion preservation, have been explored as alternative treatment options to lumbar fusion. Interspinous process spacers have been introduced as a possible alternative to spinal decompression and fusion for the treatment of NIC and discogenic lower back pain. The interspinous devices distract the neuroforamen, unload the intervertebral disc, and limit spinal extension, improving central canal and foraminal stenosis.

The first interspinous device, the Wallis system (Abbott Spine), was developed in 1986 and used in patients with recurrent disc herniation. It was found to improve outcome in patients who underwent a second discectomy incorporating the Wallis device. The second generation of the Wallis implant, made with elastic polyetheretherketone (PEEK), has been shown to reduce pain severity in patients with mild to moderate disc degeneration, lateral recess, central spinal stenosis, and significant lower back pain when used in combination with other surgical interventions. Other interspinous spacers used in Europe but not approved for use in the US include the DIAM...
(Medtronic Sofamor Danek) and the Coflex (Paradigm Spine).17,20

The X-Stop device (St. Francis Medical Technologies) was approved by the US FDA in November 2005 and has been shown to be superior to nonoperative therapy in patients with NIC.27 Biomechanical and radiographic studies have shown that X-Stop increases spinal and neuroforaminal size, limits terminal extension, and reduces intradiscal and facet pressures. Although some large studies have shown very low complication and failure rates with the X-Stop,14,26,27 more recent publications have suggested that these rates may be higher than those previously reported.3,6,21 We used the X-Stop device (Fig. 1) at our institution for a brief period as an alternative to spinal decompression with or without fusion for patients with NIC due to lumbar spinal stenosis.

Methods

The medical records of all patients who underwent placement of the X-Stop device for the treatment of NIC were retrospectively evaluated under a protocol approved by the institutional review board. Demographic information, diagnosis, and preoperative pain levels were recorded. Postoperatively, patients were monitored at 1, 3, and 6 months after surgery, and anteroposterior/lateral lumbar spine radiographs (Fig. 2) were obtained to evaluate the position of the device. On follow-up examinations, patients subjectively graded the percentage (0–100%) of improvement in their pain and the amount of residual pain. These data were also collected from the medical records. Approximately 4 years after X-Stop placement, updated long-term clinical data were obtained to determine clinical outcome.

Patient Selection Criteria

All patients who underwent placement of the X-Stop device for the treatment of moderate to severe lumbar spinal stenosis and foraminal stenosis were included in this retrospective review. These patients all had symptoms of lower back pain, neurogenic claudication, and leg pain (unilateral or bilateral) that were evaluated by using MR imaging of the lumbar spine. Only patients with a history of neurogenic claudication with clear symptom amelioration by bending forward were offered treatment with the X-Stop system. After the diagnosis of NIC due to lumbar spinal stenosis, appropriately selected patients underwent placement of the X-Stop device by 1 of 2 different spinal surgeons.

Results

Thirteen patients (8 men and 5 women) underwent placement of the X-Stop interspinous spacers (Table 1): 9 at the L4–5 interspinous space and 4 at both the L3–4 and L4–5 interspinous spaces. Central canal stenosis with bilateral foraminal stenosis had been diagnosed in all of the patients. The degree of stenosis was severe in 9 (69%) of 13 and moderate in 4 (31%) of 13 patients. Five patients (38%) also had Grade I spondylolisthesis at the treated levels, and 1 patient (8%) had a mild degree of scoliosis as well. The average age at the time of surgery was 74.6 years (range 66–84 years).

Except for 1 patient who moved to a different state and was not contacted until the end of the study, all patients were regularly monitored. The average duration of follow-up in the remaining patients was 23.4 months (range 5–48 months), with an accumulative follow-up time of 281 months for all patients. Final follow-up data were obtained after a period ranging from 41 to 48 months postoperatively.
All patients (100%) reported improved symptoms in both lower back and radicular pain immediately after surgery. The average percentage of reported pain improvement was 72% (range 50–100%). However, only 3 patients (23%) did not experience a return of a significant portion of the preoperative pain. One (Case 8) of these 3 patients had adjacent-level radiculopathy due to a herniated disk that produced new back pain necessitating another operation.

Overall, our long-term complication rate was 38%. Three patients (23%) returned with a recurrence of their symptoms due to spinous process fractures of L-4, L-4, and L-5 at 19, 5, and 2 months, respectively (Table 1). These patients were treated using decompressive laminectomy with spinal fusion. Two patients (15%) presented with new L-3 radiculopathies: 1 (Case 13) was at the same level as the X-Stop device and 1 (Case 8) was at the adjacent level above the decompression system. Surgical treatment was recommended for both of these patients, but 1 patient (Case 13) declined because of a desire to avoid open surgery. An additional 6 patients (46%) underwent or were recommended to undergo a laminectomy and/or fusion because of recurrent pain. One of these patients (Case 10) had multiple medical comorbidities that precluded surgery. Another of these patients (Case 5) had only a decompressive laminectomy without subsequent spinal fusion. These additional surgeries occurred anywhere from 4 to 27 months after the initial X-Stop placement. Ultimately, 11 (85%) of 13 patients required additional spine surgery after X-Stop placement.

**Discussion**

**Outcomes Following X-Stop Placement**

The X-Stop implant has been designed with the knowledge that NIC symptoms are relieved by flexion of the lumbar spine. The device is placed between the spinous processes of stenotic levels, limiting extension and increasing the neuroforaminal space to decompress neural tissue (Figs. 3 and 4). Lindsey et al. showed in 7 cadaveric lumbar spines (L2–5) that the interspinous X-Stop implant caused a loss in lumbar lordosis by shifting the neutral position 2° to the flexed position. They found that X-Stop decreased the degree of extension and flexion without affecting lateral bending and axial rotation. The adjacent levels remained unaffected by placement of the X-Stop device. Preclinical data indicated that the X-Stop not only increases spinal canal and neuroforaminal sizes but also unloads the facets and the disk space.

![Fig. 3. Postoperative midsagittal CT myelograms demonstrating an L-4 (A) and L-5 (B) spinous process fracture.](image-url)
ings. In a prospective randomized trial of 191 patients with pain arising from neurogenic claudication, Zucherman et al.\textsuperscript{26,27} reported that patients who were treated with the X-Stop had significantly greater pain relief than those treated with epidural steroid injections (control group) after 1 and 2 years. However, these data could be misleading because the control group was treated with epidural steroid injection, which is not the therapy of choice for lumbar stenosis. Although these results are comparable with reported outcomes in patients treated with decompressive laminectomy, a better study would compare the outcome in patients following X-Stop placement with the outcome in patients following laminectomy.

Kondrashov et al.\textsuperscript{13} described a study that included a 4-year follow-up in 18 patients with central canal stenosis who had received an X-Stop device and noted that 78\% of the patients had a $\geq 15$-point improvement from the baseline Oswestry Disability Index. Initially, 100\% of the patients in our series reported improved symptoms, a rate better than the previously reported success rates of 70 and 73.1\%.\textsuperscript{15,26} The mean symptom severity improved by 72\%, which compares favorably with the 45.4\% reported previously.\textsuperscript{26} However, after a 4-year follow-up, only 2 of our patients (15\%) did not experience a return of the preoperative or the occurrence of new back symptoms requiring further surgery. One possible explanation for the wide discrepancy in long-term pain relief in our analysis compared with that in the Kondrashov et al.\textsuperscript{11} study is that they may have had more patients with milder canal stenosis. Another plausible explanation is that there is a very steep learning curve associated with X-Stop use, and it takes a large number of cases to reach the high success rates often cited in the literature. In fact, most of the large randomized controlled trials demonstrating high success rates with X-Stop placement have been done in high-volume centers where the device is used with great frequency.\textsuperscript{13,14,26,27}

Our results correspond with those in other recent series described in the literature (Table 2). The authors of a study based on patient responses to the Zurich Questionnaire, quantifying patient satisfaction after X-Stop placement, demonstrated a “good outcome” in only 31.3\% of patients in a follow-up of $< 24$ months.\textsuperscript{4} Furthermore, Siddiqui et al.\textsuperscript{22} demonstrated that 7 (29.2\%) of 24 patients with a 1-year follow-up after X-Stop placement had recurrent pain requiring caudal epidural steroid injections. Only 54\% of these patients had significant improvement.

**TABLE 2: Recent publications on X-Stop device complications and failures**

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>No. of Patients Treated</th>
<th>No. of Patients w/ Recurrent Pain (%)</th>
<th>FU (mos)</th>
<th>No. of Patients w/ Complication (%)</th>
<th>Patients w/ Additional Surgery Recommended/Performed (%)</th>
<th>No. of Patients w/ Good Outcome/Preop Goal Met (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>current study</td>
<td>13</td>
<td>10 (77)</td>
<td>41–48</td>
<td>3 spinous process fracture (23); 2 radiculopathy (15)</td>
<td>11 (85)</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Barbagallo et al., 2009</td>
<td>69</td>
<td>NA</td>
<td>23</td>
<td>4 spinous process fracture (6); 4 device dislocation (6)</td>
<td>(7)</td>
<td>NA</td>
</tr>
<tr>
<td>Brussee et al., 2008</td>
<td>65</td>
<td>1 (2)</td>
<td>12 ± 9</td>
<td>0</td>
<td>6 (9)</td>
<td>(31)</td>
</tr>
<tr>
<td>Verhoof et al., 2008</td>
<td>12</td>
<td>7 (58)</td>
<td>30.3</td>
<td>0</td>
<td>7 (58)</td>
<td>5 (42)</td>
</tr>
<tr>
<td>Siddiqui et al., 2007</td>
<td>39 (24 w/ full FU)</td>
<td>7 (29) (received caudal epidural steroid injection)</td>
<td>12</td>
<td>2 intraop spinous process fracture (5)</td>
<td>2 (8)</td>
<td>significant improvement in pain (54); physical function improvement (33)</td>
</tr>
</tbody>
</table>

* NA = not applicable.
Dynamic interspinous decompression and stabilization

in their pain, and only 33% had improvement in physical function after a 1-year follow-up.\textsuperscript{22}

Reported Complications

Previously reported complications associated with the use of X-Stop primarily include device dislocation/malposition, spinous process fractures, erosion of the spinous process, infection, hematoma, and even neurological sequelae such as foot drop.\textsuperscript{1,3,18} The randomized prospective trial conducted by Zucherman et al.\textsuperscript{26} is one of the most oft-cited early papers documenting high effectiveness and low complication/failure rates of the X-Stop device, with a complication rate of only 4% and a failure/reoperation rate of 6% in 100 patients. Recently, however, there have been reports\textsuperscript{3,4,22,24} of higher postoperative X-Stop complication rates than those demonstrated in many of the earlier publications (Table 2). There has also been a plea for the submission and publication of more X-Stop studies showing negative results.\textsuperscript{7} Our complication and failure/reoperation rates were much higher than those reported by Zucherman et al.: 38 and 85%, respectively. We observed a higher rate of spinous process fractures (23%) than previously reported (Table 1). In addition, 2 patients (15%) presented with new-onset radicular pain, a complication that to our knowledge has not been reported in the literature. Perhaps most concerning was the relatively high rate of failure/reoperation (85%) in our own analysis. The authors of a recent study\textsuperscript{24} describing the outcome of X-Stop placement in a small group of patients with Grade I spondylolisthesis also documented a high rate (58%) of failure/reoperation. This result led to the recommendation that X-Stop not be used in patients with spondylolisthesis, and spondylolisthesis is now a defined contraindication to X-Stop placement.\textsuperscript{14,24} The data from our study support this recommendation since 80% of the patients (4 of 5) with Grade I spondylolisthesis required additional surgery.

The 3 patients in our study with spinous process fractures had successful clinical outcomes up until their spinous process fractures, which occurred at 2, 4, and 19 months posttreatment. The patient with the delayed spinous process fracture at 19 months had what has recently been referred to as a "sandwich phenomenon" fracture of the middle spinous process in adjacent double-level X-Stop placement.\textsuperscript{2} The onset of symptoms in these patients was immediate and similar to preoperative symptoms. The reasons for the spinous process fractures were unknown, although possible factors include each patient's degree of osteoporosis and possible overdistraction/overdilation of the interspinous space with a large X-Stop device. Hence, the bone density of each patient and the size of the implant should be carefully evaluated preoperatively. A moderately sized device and modest distraction may be needed to avoid spinous process fractures, especially in patients with poor bone quality and osteoporosis.

Overdistraction may also account for the new-onset radiculopathy at 1 level above the treated level. Wiseman et al.\textsuperscript{25} showed that the X-Stop device unloads the facet joints of the affected levels; however, they also found that the adjacent facet peak pressure is increased up to 19%. A combination of increased pressure on the adjacent facet, a moderate level of adjacent foraminal stenosis, and larger than appropriate implant may induce severe adjacent-level foraminal stenosis causing adjacent-level radiculopathy. Thus, a lesser degree of distraction may be required in patients with mild to moderate adjacent-level foraminal stenosis.

In addition to the previously noted steep learning curve, the selection of patients less likely to suffer from complications or failure/reoperation due to X-Stop placement may explain the low complication/failure/reoperation rates seen in earlier studies. It has been suggested that higher success rates will be achieved by avoiding patients with Grade I spondylolisthesis and implanting the device in patients with only mild to moderate spinal stenosis instead of severe spinal stenosis.\textsuperscript{9} Recent data show that the most important factor in selecting the proper patient for X-Stop placement may be the clinical demonstration of positional-dependent claudication relieved by flexion.\textsuperscript{14} Although all of our patients met this criterion, other factors can affect success. For example, some believe that certain spinal anatomical variants predispose patients to X-Stop failure and suggest using this information as a guide to determine which patients receive X-Stop treatment.\textsuperscript{3}

Conclusions

Although the X-Stop device has been shown in some studies to serve as a viable, minimally invasive treatment option for patients with NIC due to lumbar spinal stenosis, our small series demonstrated a high rate of complications and the need for further spinal surgery (85%). We found an increasing number of recent publications suggesting that the X-Stop device may not be as free of complications and failures/reoperations as has been traditionally reported. Additional areas of X-Stop investigation include appropriate in vitro assessments and a larger group of long-term clinical outcomes with several years of follow-up.\textsuperscript{23} Further clinical studies are needed to evaluate the X-Stop system compared with our current standards of treatment—laminectomy or interlaminar decompression. Moreover, further randomized studies are needed to help identify the patient subset most likely to experience long-term benefit from X-Stop placement. Our data would seem to support the previously noted fact that patients with moderate to severe spinal stenosis are poorer candidates than those with mild to moderate stenosis. Furthermore, there may be a very steep initial learning curve for success with X-Stop placement. Careful preoperative evaluation of adjacent-level disease, bone density, appropriate implant size, and degree of spinal stenosis leading to optimal patient selection will provide the best chance of X-Stop placement success and avoid the aforementioned complications.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: MH Schmidt,

References


Manuscript submitted February 12, 2010. Accepted March 25, 2010. Address correspondence to: Meic H. Schmidt, M.D., Department of Neurosurgery, University of Utah, 175 North Medical Drive East, Salt Lake City, Utah 84132. email: neuropub@hsc.utah.edu.