Interspinous Process Decompression With the X-STOP Device for Lumbar Spinal Stenosis

A 4-Year Follow-Up Study

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Abstract: X-STOP is the first interspinous process decompression device that was shown to be superior to nonoperative therapy in patients with neurogenic intermittent claudication secondary to spinal stenosis in the multicenter randomized study at 1 and 2 years. We present 4-year follow-up data on the X-STOP patients. Patient records were screened to identify potentially eligible subjects who underwent X-STOP implantation as part of the FDA clinical trial. The inclusion criteria for the trial were age of at least 50 years, leg, buttock, or groin pain with or without back pain relieved during flexion, being able to walk at least 50 feet and sit for at least 50 minutes. The exclusion criteria were fixed motor deficit, cauda equina syndrome, previous lumbar surgery or spondylolisthesis greater than grade I at the affected level. Eighteen X-STOP subjects participated in the study. The average follow-up was 51 months and the average age was 67 years. Twelve patients had the X-STOP implanted at either L3-4 or L4-5 levels. Six patients had the X-STOP implanted at both L3-4 and L4-5 levels. Six patients had a grade I spondylolisthesis. The mean preoperative Oswestry score was 45. The mean postoperative Oswestry score was 15. The mean improvement score was 29. Using a 15-point improvement from baseline Oswestry Disability Index score as a success criterion, 14 out of 18 patients (78%) had successful outcomes. Our results have demonstrated that the success rate in the X-STOP interspinous process decompression group was 78% at an average of 4.2 years postoperatively and are consistent with 2-year results reported by Zucherman et al previously and those reported by Lee et al. Our results suggest that intermediate–term outcomes of X-STOP surgery are stable over time as measured by the Oswestry Disability Index.

Key Words: spinal stenosis, neurogenic claudication, interspinous process decompression, IPD, X-STOP, motion preservation

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Surgical decompression with or without fusion is the standard surgical treatment for patients with moderate to severe lumbar spinal stenosis. While offering the potential to improve the quality of life for the patients, it also has the potential for significant complications, especially when a fusion is performed. Postoperative complications may include the cardiovascular and pulmonary complications of general anesthesia, infection, iatrogenic instability, pseudarthrosis, hardware failure, and the need for future surgery because of the development of new diseases at the same or adjacent levels. An extensive meta-analysis of the literature of spinal stenosis surgery by Turner et al in 1992 showed the following complication rates for lumbar decompressive surgery: perioperative mortality -0.3%, dural tears -5.9%, deep infection -1.1%, superficial infection -2.3%, and deep vein thrombosis -2.7%, for an overall complication rate of 12.6%.[1]

The lumbar interspinous process decompression (IPD) devices represent a promising surgical treatment alternative for a variety of spinal pathologies. Intuitively they provide an unloading distractive force to the stenotic middle column part of the motion segment and have the potential to relieve the symptoms of neurogenic intermittent claudication, associated with spinal stenosis. The first interspinous implant for the lumbar spine was developed in the 1950s by Knowles. Owing to flaws in design, material, surgical technique and applied indications its use was abandoned. Several other IPD devices, with significant differences in designs, materials, surgical techniques and indications have appeared in Europe and South America in the 1990s, some of which are beginning to be evaluated in controlled trials for a host of indications.[2,3] Most of these implants are placed in the interspinous space to improve clinical outcomes after a diskectomy. The first IPD device to be used in the US for the treatment of patients with neurogenic intermittent claudication due to spinal stenosis was the X-STOP device (Fig. 1). It is also the first FDA-approved IPD device. In contrast with other rigid IPD devices, placement of the X-STOP does not violate the supraspinous/interspinous ligamentous complex, which was found to be the largest contributor to resisting applied flexion moments in the lumbar spine in the animal model.[4]

FIGURE 1. The X-STOP device is FDA approved and available in both titanium and PEEK forms.

The X-STOP was designed to limit the terminal extension movement at the individual stenotic level(s) that provokes the symptoms, while allowing unrestricted movement in all the other motion axes of the treated and untreated level(s). Biomechanical studies have shown that the X-STOP significantly increases the spinal canal, subarticular recess and neuroforaminal size, limits terminal extension, and reduces intradiscal pressure and facet loading.[5–7] In a magnetic resonance imaging cadaver study, Richards et al reported that the X-STOP increases the neural foramina area by 26% and the spinal canal area by 18% during extension. In addition, foraminal width was increased by 41% and subarticular diameter by 50% in extension[5] (Fig. 3). In a cadaveric kinematics study, terminal extension at the implant level was reduced by 62% after X-STOP placement, whereas lateral bending and axial rotation range of motion were unchanged. In a cadaveric disc pressure study, Swanson et al reported that the pressures in the posterior annulus and nucleus pulposus were reduced by 63% and 41% respectively during extension, and by 38% and 20% respectively in the neutral, standing position.[6] Finally, Wiseman et al performed a cadaveric facet loading study and reported that the mean facet force during extension decreased by 68% during extension.[7] In each of those studies, the adjacent level measurements were not significantly changed from the intact specimen state. These preclinical studies indicate that the X-STOP increases spinal canal and neural foramina space and also produces significant unloading of the disk and facets.

X-STOP is the only IPD device with class I data and a prospective randomized controlled trial supporting its safety and efficacy compared to the nonoperative treatment.[8,9] We have previously reported on the 12- and 24-month results of the X-STOP patients.[8,9] In the present study, we present 4-year clinical follow-up data on patients implanted with the X-STOP device during the US IDE trial.

METHODS

After obtaining Institutional Review Board approval, eligible subjects were asked to participate in the study and, if willing, to sign an informed consent document. To determine study eligibility, a limited waiver of consent was obtained from the Institutional Review Board to review patient records. Patient records were screened to identify potentially eligible subjects who underwent X-STOP IPD surgery as part of an IDE Pivotal Trial conducted at our hospital from June 2000 to July 2001. Eligibility criteria were as follows:

- Participation in the pivotal study as part of the test group
- availability of preoperative Oswestry Disability Index (ODI) data
- Willingness and ability to provide informed consent
- Willingness and ability to complete an ODI questionnaire

All patients implanted with the X-STOP were screened for eligibility (N = 23). Four patients were disqualified due to lack of preoperative ODI data. One patient died a few weeks before initiation of the study from unrelated causes. An eligible group of 18 X-STOP IPD patients was identified, all of whom elected to participate in the study. The main inclusion criteria for the original IDE pivotal trial were that patients had to be at least 50 years old and have leg, buttock, or groin pain with or without back pain that was relieved during flexion. Patients had to be able to walk at least 50 feet and sit comfortably for 50 minutes.

Main exclusion criteria for the original IDE pivotal trial were that patients should not have had a fixed motor deficit, cauda equina syndrome, previous lumbar surgery of the stenotic level or degenerative spondylolisthesis greater than grade I at the affected level.

SURGICAL TECHNIQUE

The patient is placed on a radiolucent table in a right lateral decubitus position and may be slightly sedated. The level to be treated is identified by fluoroscopy. After administration of a local anesthetic, a midsagittal skin incision of approximately 4 cm is made at the stenotic level(s). This is carried down to the fascia, which is split longitudinally 1 cm to the right and 1 cm to the left of midline. It is of paramount importance to keep the supraspinous ligament intact. The spinal canal is not violated. Removal of any portion of the ligamentum flavum is unnecessary. A small curved dilator is inserted across the interspinous space abutting the posterior border of the facet joints at the most anterior margin of the interspinous space. After the correct level is verified by

fluoroscopy, a small dilator is removed and a larger curved dilator is inserted. The interspinous and supraspinous ligaments are left fully intact. After the larger dilator is removed, a sizing distraction instrument is inserted. During the procedure, patients are able to assist by bringing their knees up against their chest and opening the interspinous space, which is distracted until the supraspinous ligament becomes taught. The correct implant size is indicated on the sizing instrument. An appropriately sized X-STOP device is inserted between the spinous processes until it is flush with the right side of the spinous processes. The screw hole for the universal wing on the left side is visualized and the universal wing screw is engaged. The 2 wings are approximated toward the midline and the left-sided universal wing screw is secured with a torque-limiting hexagonal screwdriver (Fig. 2). Anteroposterior and lateral fluoroscopy views are taken to verify the proper position. The incision is closed in the usual fashion. The drain is not routinely utilized. The use of a postoperative brace is unnecessary.
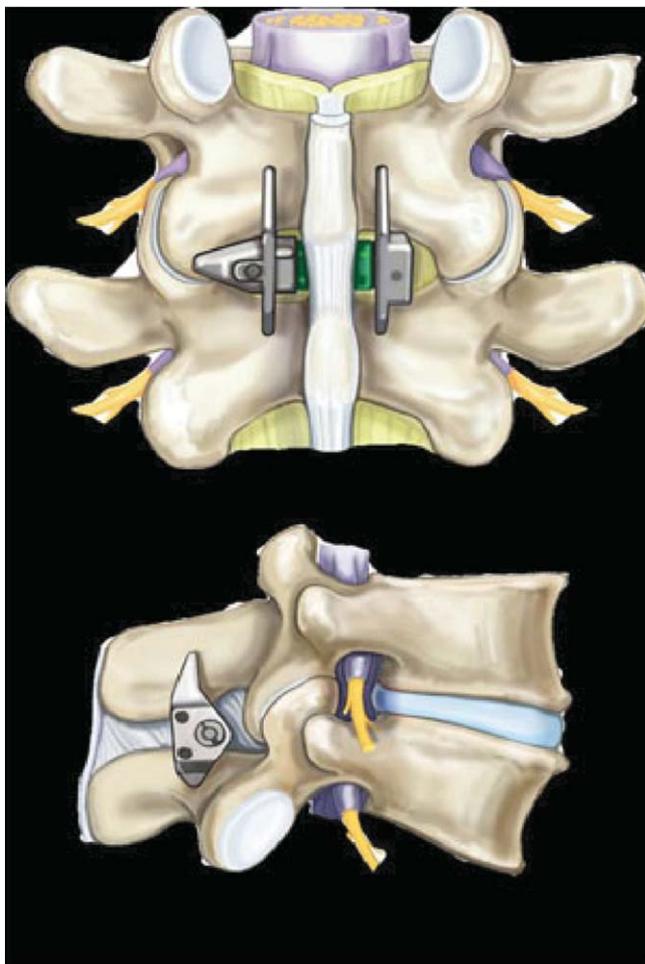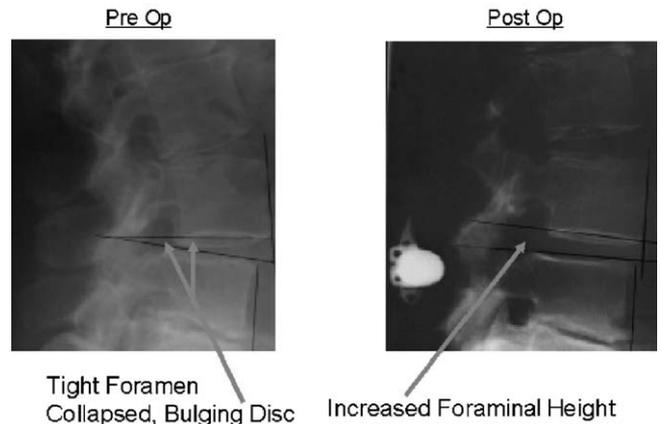

FIGURE 3. An X-STOP case example.

The procedure is typically performed in less than an hour, and patients are discharged from the hospital within 24 hours.

RESULTS

Eighteen X-STOP IPD subjects participated in the study. The average length of follow-up was 51 months (range 45 to 61) and the average age at the time of the operation was 67 years. Twelve out of 18 patients had the X-STOP implanted at 1 level (either L3-4 or L4-5). Six out of 18 patients had the X-STOP implanted at 2 levels (L3-4 and L4-5). There were no implantations at the L5-S1 level in the US study. Six out of 18 patients in the study had a grade I degenerative spondylolisthesis. The mean preoperative ODI score was 45 (range 20 to 80). The mean postoperative ODI score was 15 (range 0 to 36), and the mean improvement score was 29. Using a 15-point improvement from baseline ODI score as a success criterion, 14 out of 18 patients (78%) had successful outcomes at long–term follow-up. Pre- and postoperative ODI scores, ODI changes, number of levels treated and the presence or absence of grade I degenerative spondylolisthesis at the treated level for each patient are listed in Table 1.

DISCUSSION

IPD is a relatively new, but already well-documented motion-preserving spinal procedure. Thus far, X-STOP is the only IPD device with class I clinical data to support its efficacy, whereby the differences with other devices do not allow extrapolation of these data to other IPD devices. It was shown to be superior to nonoperative therapy in the randomized study at 1 and 2 years.[8,9] A multicenter prospective, randomized controlled trial was performed in the US comparing the outcomes of mild-to-moderate neurogenic intermittent claudication patients treated with the X-STOP IPD system to patients treated nonsurgically.[8,9] Those randomized to the control group received at least 1 epidural steroid injection and had the option to receive NSAIDs, analgesics, physical therapy

FIGURE 2. The X-STOP device in place.

TABLE 1. Pre & Postoperative Oswestry (ODI) Scores – 18 X-STOP Patients

Patient	Preoperative ODI	Postoperative ODI	Absolute Δ in ODI	Relative Δ in ODI (%)	Levels Treated	Grade I Spondylolysthesis at Treated Level	F/U (MO)
1	65	16	49	76	1	Yes	45
2	80	33	47	58	2	Yes	45
3	20	0	20	100	1	Yes	46
4	40	32	8	20	2	No	53
5	32	0	32	100	1	No	57
6	34	10	24	71	2	No	49
7	38	0	38	100	1	No	58
8	24	18	6	25	1	No	45
9	43	28	15	35	1	No	45
10	51	11	40	78	2	Yes	46
11	58	10	48	83	1	No	50
12	42	14	28	67	1	Yes	48
13	56	22	34	61	2	No	53
14	28	24	4	14	1	Yes	51
15	28	0	28	100	2	No	54
16	36	36	0	0	1	No	59
17	62	22	40	65	1	No	61
18	67	0	67	100	1	No	48
Average	45	15	29	64	—	—	51
SD	16.8	12.0	18.2	—	—	—	5

and additional injections as needed. Assessments were based on the Zurich Claudication Questionnaire (ZCQ), a validated, patient-completed outcomes measure specific to neurogenic claudication,[10,11] and the SF-36. A total of 136 devices were implanted in 100 patients. The X-STOP group had a significantly greater percentage of patients with an improvement in symptom severity domain of ZCQ than did the control group at each posttreatment visit. At the 2-year follow-up, 60% of the patients reported a clinically significant reduction in the severity of symptoms compared to the 18% of the controls. The X-STOP group also had a significantly greater percentage of patients with an improvement in physical function domain of ZCQ than did the control group at each posttreatment visit. At the 2-year follow-up, 57% of the patients reported a clinically significant improvement in their physical function compared to 15% of the controls and 73% of the patients were at least "somewhat satisfied" compared to 36% of the controls. At all follow-up time points, the X-STOP group scored significantly better than the control group in every physical domain. Following those reports it was, however, still unclear whether the superior results in the X-STOP group would deteriorate with time, as was the case with some other lumbar surgical procedures (ie, microdiskectomy and laminectomy). For example, Katz et al[12] and Johnson et al[13] have noted deterioration of the early results of decompressive surgery over time. In Katz's series, 17% of patients ultimately underwent a second procedure for instability or recurrent stenosis. The current study has utilized a slightly different outcome tool—ODI—as opposed to ZCQ for determination of success. These outcome tools have been shown to be closely correlated in spinal stenosis patients by Pratt et al.[14] Our results have demonstrated that the success rate in the X-STOP

IPD group was 78% at an average of 4.2 years postoperatively, and is consistent with the 2–year results reported for X-STOP treatment arm of the pivotal trial (85%) and the results from Japan reported by Lee et al (70%).[15] Our results suggest that intermediate–term clinical outcomes of X-STOP IPD surgery are stable over time as measured by the ODI. In our study, all patients but one had some improvement (17 out of 18). The 4 patients that were classified as failures (ODI improvement of less than 15 points) had relatively low preoperative ODI scores: 24, 28, 36 and 40. Lower disability at the start makes it more difficult to achieve the 15-point ODI success criteria. This is especially so in older age-groups with frequent comorbidities, which can impact the postoperative ODI scores independent of the improvement of the spinal symptoms.

Though this series has limitations of a smaller sample size, it nevertheless confirms the satisfactory longevity of its effect. We will continue to follow the patients enrolled in the US IDE X-STOP trial and will report on the longer follow-up.

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