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35 Spinous Process Distractive Devices for Lumbar Spinal Stenosis

Dimitriy Kondrashov, Ken Y. Hsu, and James F. Zucherman
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INTRODUCTION

Lumbar spinal stenosis (LSS) had been first described in 1803 by Portal of France, who observed that narrowed spinal canals were associated with leg pain and atrophy (1). Our understanding of this condition was further enhanced by Verbiest, who described the anatomic changes of hypertrophic articular processes causing spinal canal stenosis (2). Subsequently, Kirkaldy-Willis described the three-joint complex and the pathologic changes found in degenerative spinal stenosis (3). Degenerative processes may start in one, two, or three joint complexes, including the disc anteriorly and the two facet joints posteriorly. With time, all three joints are involved. The degeneration of those joints also causes abnormal motion and abnormal stability, hence the term "mechanical low back pain." The abnormal motion may lead to osteophyte formation, as the body tends to stabilize the motion segment as seen elsewhere in the body (e.g., DJD of the hip, knee). Ultimately the combination of disc protrusion, osteophyte formation, hypertrophy of facet joints and ligamentum flavum result in spinal stenosis, due to the lack of neural element space. Q1

Approximately 1.2 million people in the United States have symptoms related to lumbar spinal stenosis and it is the leading preoperative diagnosis for adults older than 65 years who undergo spine surgery (4). The incidence of degenerative lumbar stenosis ranges from 1.7% to 8%. There does not appear to be gender predominance; however, degenerative spondylolisthesis associated with lumbar spinal stenosis is four times more common among women. Symptoms typically develop in the fifth or sixth decade of life in association with osteoarthritic changes in the lumbar spine. In 1996, almost 90,000 surgeries were performed for LSS (4). Symptoms are exacerbated by the upright posture and walking and include unilateral or bilateral radicular pain, sensory changes, leg muscle weakness and, more rarely, bowel and bladder dysfunction. Symptoms are typically improved or relieved with flexion of the lumbar spine, which increases the cross-sectional diameter of the spinal canal and neuroforamina.

Surgical decompression with or without fusion is the standard surgical treatment for the patients with significant LSS. While offering the potential to improve the quality of life for 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 due to the development of disease at adjacent levels. A 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 (0.32%), dural tears (5.91%), deep infection (1.08%), superficial infection (2.3%), deep vein thrombosis (2.78%), and any complication (12.64%) (5).

Spacers placed between the lumbar spinous processes represent a promising surgical treatment alternative for a variety of spinal pathologies. Intuitively, they provide an unloading distractive force to the stenotic motion segment and have the potential to relieve the symptoms of neurogenic intermittent claudication (NIC) associated with spinal stenosis. The first-generation implant for nonrigid stabilization of lumbar spine was developed in 1986. It included a titanium interspinous blocker and an artificial Dacron ligament. The implant constituted "a floating system" without bony fixation to prevent any loosening. It achieved an increase in the rigidity of destabilized segments beyond normal values. Reportedly, those early implants were efficacious against low back pain (LBP) because of degenerative instability and free of major complications (6).

The second-generation implant was made of polyetheretherketone (PEEK) and named the Wallis implant. The proposed indications were: (*i*) following a discectomy for massive HNP leading to substantial loss of disc material, (*ii*) following a second discectomy for a recurrent HNP, (*iii*) following a discectomy for herniation of a transitional disc with sacralized L5, (*iv*) disc degeneration next to a fusion, and (*v*) isolated Modic I lesion associated with chronic LBP (6). Those indications were mostly anecdotal and clinical trials are currently underway in Europe to determine its efficacy. Several other interspinous process decompression (IPD) devices have appeared in Europe and South America in the 1990s: Diam (Medtronic), Interspinous "U" (Fixano), X STOP (St. Francis Medical Technologies Inc., Alameda, California, U.S.A.) and Dynafix (GMReis) (Fig. 1). In general, there has been a paucity of peer-reviewed literature regarding those devices and the reported success as well as the indications for their use was predominantly anecdotal. Some of those implants have been placed in the interspinous space to improve clinical outcomes following a primary surgical procedure, such as a microdiscectomy. Mariottini et al. from Italy have reported on 43 patients with lower extremity pain with back pain, treated by microsurgical nerve root decompression and implantation of a soft intervertebral prosthesis (Diam) (7). Satisfying results were reported in 97% of cases at one- to five-year follow-up and the authors have concluded that the device was a reliable tool for curing LBP and sciatica. The study however lacks control subjects and it is unclear what the contribution of decompression relative to Diam is toward the symptomatic relief. With an increasing variety of these spacers being implanted, several variations in the surgical technique to insert them have evolved. Some spacers require either the supraspinous ligament or interspinous ligament to be significantly altered or removed before they can be inserted, and some spacers require the spinous processes themselves to be either modified or shaped. Several spacers are designed to function as stand alone devices while others incorporate an artificial ligament as an integral part of the design. The artificial ligament helps to maintain function that would otherwise be lost by sacrificing the ligaments, and it may also decrease the laxity of the motion segment, which could be an important component in treating certain pathologies such as degenerative disc disease. Placing the implant in the L5/S1 space represents a particular challenge since the spinous process of the sacrum may not be prominent enough to support some spacers or to secure an artificial ligament. Variations in some of the current implant designs may therefore be necessary to address this level. Since the overwhelming majority of the LSS patients are elderly and are at high risk for osteoporosis, shaping the spinous processes or any bone removal reduces the bone strength and, in general, is best avoided in IPD procedures.

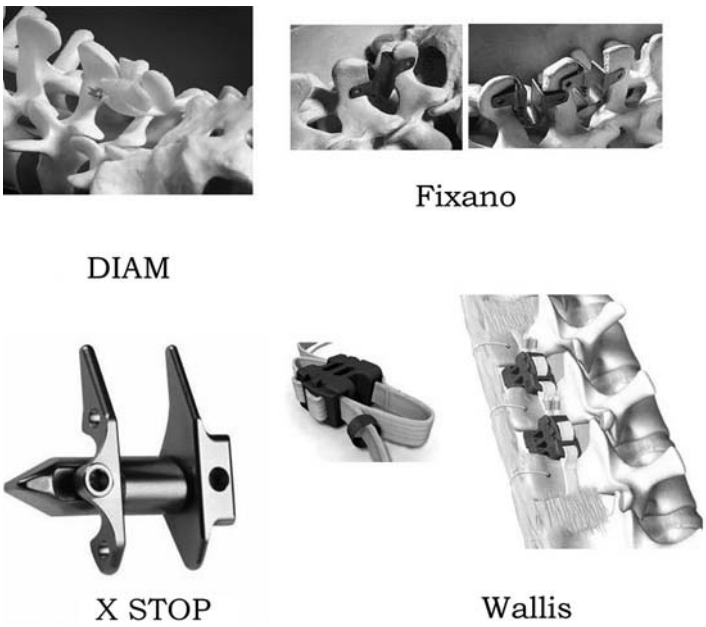


FIGURE 1 Modern interspinous devices.

FIGURE 2 The X STOP device is available in both titanium and PEEK forms.

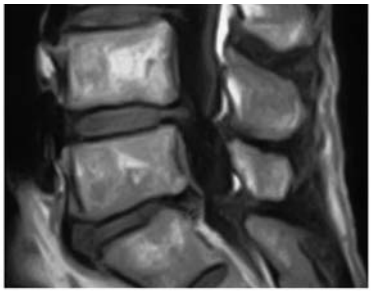
The first IPD device to be used in the United States for the treatment of patients with spinal stenosis was the X STOP device (Fig. 2), which is pending Food and Drug Administration's (FDA) approval at the time of this writing. The X STOP (St. Francis Medical Technologies Inc., Alameda, California, U.S.A.) was developed specifically with the requirements of NIC patients in mind. We will describe in this chapter patient selection, current treatment options, the technique for performing IPD with the X STOP, as well as outcomes from clinical studies.

X STOP DESIGN RATIONALE

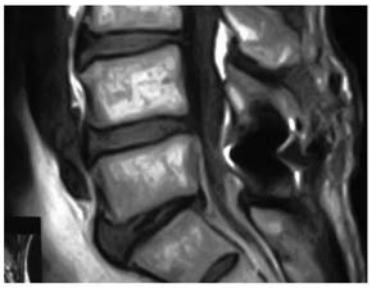
The X STOP was developed to fill the large void of treatment options between the safer, yet less effective conservative care, and the riskier, but more effective surgical decompression. The X STOP was designed specifically to limit the terminal extension movement at only the individual level(s) that provokes symptoms, while allowing unrestricted movement in all the other motion axes of the treated as well as untreated level(s). Because the implant was designed to be placed without removing any bony or soft tissues, the technique is minimally invasive and is usually performed with the patient under local anesthesia.

Several key design features allow for the straightforward implantation of the X STOP. The oval spacer separates the spinous processes and limits extension at the implanted level. The oval spacer helps distribute the load along the generally concave shape of the spinous processes and, by eliminating any sharp edges, reduces the likelihood of damaging the bone. The two lateral wings prevent migration anteriorly or laterally, and the supraspinous ligament, as well as the concave space between the spinous processes, prevents the implant from migrating posteriorly. The tapered tissue expander facilitates lateral insertion, allowing the supraspinous ligament to be preserved. Biomechanical studies have shown that the X STOP significantly prevents narrowing of the spinal canal and neural foramina, limits extension, and reduces intradiscal pressure and facet loading (8–10). In a magnetic resonance imaging (MRI) cadaver study, Richards et al. (8) reported that the X STOP increases the neural foramina area by 26% and the spinal canal area by 18% during extension (Fig. 3). In addition, foraminal width was increased by 41% and subarticular diameter by 50% in extension (8). In a kinematics cadaver study, terminal extension at the implant level was reduced by 62% following X STOP placement, while 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 (Fig. 4) (9). Finally, Wiseman et al. performed a cadaveric facet loading study and reported that the mean facet force during extension decreased by 68% during extension (10). 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 disc and facets.

The requirement to maintain proper sagittal alignment and balance in patients receiving spinal implants is well understood. Lumbar fusion procedures that cause a flat back will



Preoperative MRI of a patient with moderate spinal stenosis at L4-5 and retrolysthesis at L5-S1



Postoperative MRI of the same patient s/p X STOP insertion at L4-5. The claudication symptoms have resolved.

FIGURE 3 The increase in the neuroforaminal and the spinal canal area following rhe X STOP implantation.

overwhelmingly result in unacceptable clinical outcomes. Interspinous spacers are not fusion devices, but given their location posterior to the vertebral body and the axis of rotation, their possible impact on sagittal alignment is potentially significant. Three different radiological studies were therefore undertaken to measure any possible effect of the X STOP on sagittal alignment. In the U.S. study, X-rays were taken at each follow-up visit for both X STOP and

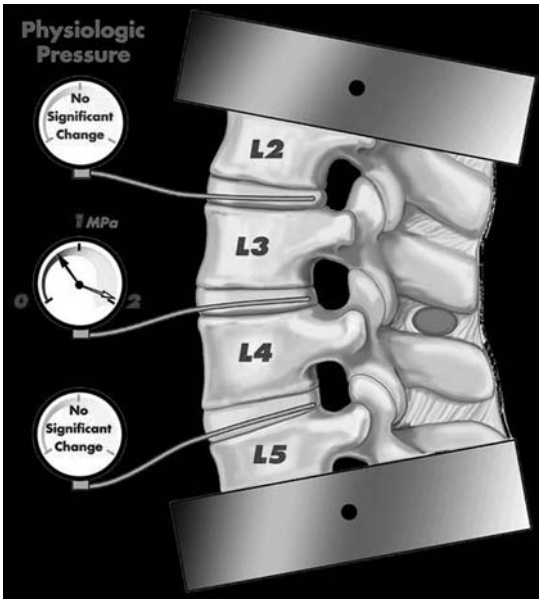


FIGURE 4 After the X STOP implantation into the cadaveric spines, the pressures in the posterior annulus and nucleus pulposus were reduced by 63% and 41%, respectively, during extension, and by 38% and 20%, respectively, in the neutral, standing position.

control patients and measurements were made of the lumbosacral angle (L1 to S1) and the intervertebral angle. At two-year follow-up, there were no significant differences in the mean scores between the two groups of patients (11). In the second study, preoperative X-rays from a subset of X STOP patients were digitally analyzed by digital metrics and compared to the standing films taken at two-year follow-up. In 23 patients with single level implants, the change in the intervertebral angle was only 0.5° (±2.0°) and the change in the lumbosacral angle was 0.1° (±3.8°). Similar values were recorded for 18 patients with double level implants. Interim data from an ongoing study by Dr. Douglas Wardlaw at the University of Aberdeen in Scotland have been recently presented, in which standing flexion/extension preoperative images were compared to postoperative images obtained in a positional MRI scanner. In addition to confirming in vivo the increases in the area of the foramen and canal that were measured in the preclinical in vitro cadaver study, results of this study confirm a change in angulation for both the lumbosacral angle and intervertebral angle of between 1° and 2°. These three studies confirm that the X STOP results in only minimal changes to sagittal alignment and this may be attributed at least in part to preserving the supraspinous ligament. This ligament is a substantial structure and its presence and the preservation of its original osseous insertion help prevent overdistraction of the segment. Its importance has been highlighted by several recent studies. The ultimate load and tensile strength of the interspinous/supraspinous ligament complex are 203 N and 1.2 Mpa, respectively (12). In another biomechanical study, the supraspinous/interspinous ligament complex was the largest contributor to resisting applied flexion moments in the porcine lumbar spine (13).

INDICATIONS

The ideal patient for the X STOP implantation has predominantly lower extremity complaints with or without LBP secondary to lumbar spinal stenosis at one or two levels. The clinical diagnosis of spinal stenosis should be confirmed with either MRI or computed tomography (CT) scan with or without a myelogram. The symptoms must be relieved with flexion. AS sitting places the lumbar spine in relative flexion, patients should be able to sit for about an hour without the pain. X STOP would be particularly indicated for the patients unable to undergo general anesthesia. The X STOP in its current design appears to be suitable for implantation at the L5/S1 levels in most patients, although in the clinical study conducted in the United States, patients with symptomatic stenosis at L5/S1 were excluded. In Europe, the X STOP is being successfully implanted at the L5/S1 level. Approximately one-third of patients in the United States have received implants at two levels, while triple levels procedures were not allowed in the U.S. study. As with L5/S1 procedures, triple level procedures are performed in Europe, but infrequently. Based on experience gained from more than 3000 X STOP procedures that have been performed worldwide, there appears to be a considerable amount of overlap in patients indicated for surgical decompression and patients indicated for the X STOP.

Patients with previous spinal surgery at the stenotic level are relatively contraindicated for the IPD. Theoretically those patients who have had prior microdiscectomy still have intact interspionous ligament and spinous processes and might me considered for the procedure. Grade 1 degenerative spondylolisthesis is not a contraindication for the X STOP. Patients with isthmic spondylolisthesis, however, are contraindicated. The presence of osteoporosis is not a contraindication. The presence of severe osteoporosis, as evidenced by a history of fragility fractures, may indicate insufficient bone quality to support the spacer and is a contraindication. Patients with grade 2 or higher degenerative spondylolysthesis, lateral lysthesis, or lumbar/thoracolumbar scoliosis with a Cobb angle greater than 25° are relatively contraindicated for the X STOP. Cauda equina syndrome is an absolute contraindication as these patients require emergent comprehensive surgical decompression.

SURGICAL TECHNIQUE

The patient is placed on a radiolucent table in a right lateral decubitus position and may be slightly sedated (Fig. 5). No general anesthesia is used. While patients can be treated in the prone position, this may prevent them from completely flexing their spines during the procedure and could result **F5**

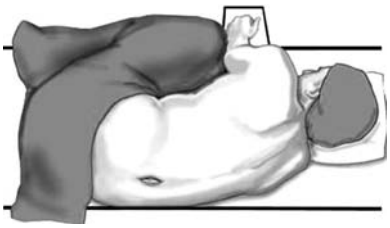


FIGURE 5 The patient is placed on a radiolucent table in a right lateral decubitus position and a midline 4 cm incision is made over the spinous processes of the stenotic level(s).

in a less than optimal amount of distraction and an implant that is too small. The level to be treated is identified by fluoroscopy. After administration of a local anesthetic, a mid-sagittal incision of approximately 4 cm is made over the spinous processes of the stenotic level(s). This is carried down to the fascia which is split longitudinally 2 cm to the right and to the left of midline. It is of paramount importance to keep the supraspinous ligament intact. The paraspinal musculature is then elevated off the spinous processes and medial lamina bilaterally in the subperiosteal fashion using electrocautery and a Cobb elevator. Occasionally hypertrophied facets that block access to the interspinous space are partially trimmed with a rongeur to enable proper anterior placement of the implant. The spinal canal is not violated and neither laminotomy, nor laminectomy, nor foraminotomy is performed. 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, the small dilator is removed and a larger curved dilator is inserted (Fig. 6). The interspinous and supraspinous ligaments are left fully intact. After the larger dilator is removed, the sizing distractor 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. The appropriately sized X STOP device is inserted between the spinous processes until being flushed to the right side of the spinous processes (Fig. 7). The screw hole for the universal wing on the left side is visualized and the universal wing screw is engaged (Fig. 8). The two wings are approximated towards the midline and the left sided universal wing screw is secured with a torque-limiting hexagonal screwdriver (Fig. 9). Anteroposterior (AP) 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. The procedure is typically performed in less than an hour, and patients are discharged from the hospital within 24 hours.

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COMPLICATIONS

Reported complications related to the IPD have been minor and transient. No procedures were converted to laminectomy during X STOP implantation. Four percent (4 out of 100) of the

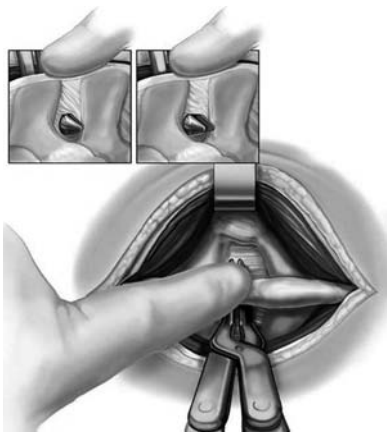

FIGURE 6 The interspinous space is sequentially dilated. The interspinous and supraspinous ligaments are left fully intact.

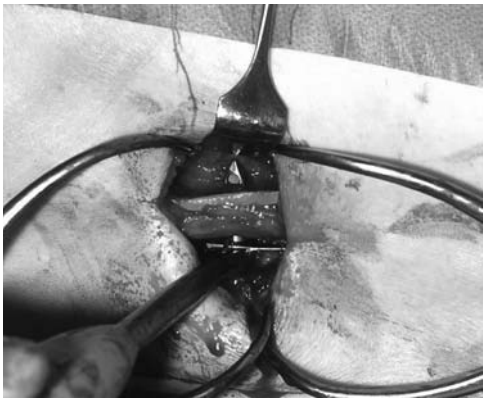

FIGURE 7 The appropriately sized X STOP device is inserted between the spinous processes until being flush with the right side of the spinous processes.

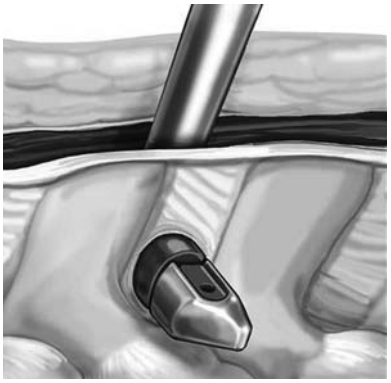

FIGURE 8 The screw hole for the universal wing on the left side is visualized and the universal wing screw is engaged.

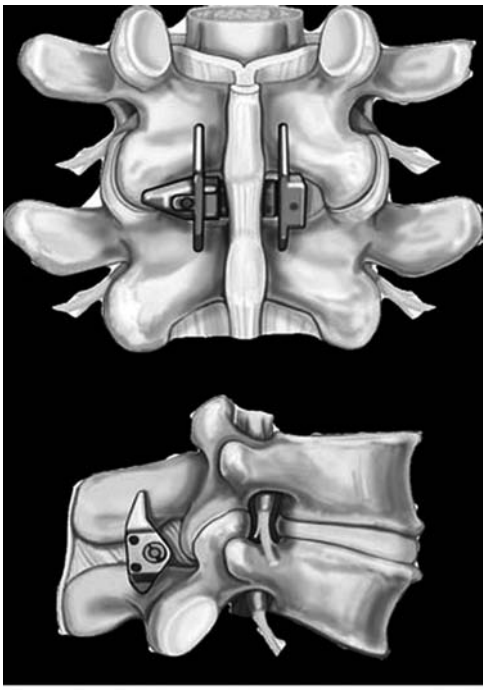

FIGURE 9 The implanted X STOP device. Note the preservation of the supra-/ interspinous ligament complex.

X STOP patients in the U.S. clinical study developed some minor operative site-related complications: one wound dehiscence, one seroma, one hematoma, and one report of incisional pain (11,14). There have been no reports of either vascular or neurological complications, which is anticipated since the laminae are left intact and the spinal canal and neuoforamina are not entered. Four percent (4 out of 100) of the patients developed device-related complications. One X STOP patient fell, causing the implant to dislodge, which was removed without any sequelae. A review of the patient's radiographs showed a very prominent facet that prevented the implant from being positioned properly. In retrospect, it could have been trimmed to allow more anterior placement of the X STOP. One patient reported worsening pain about one year after the procedure, which was determined to be possibly related to the implant. One implant was placed too posterior and was considered to be malpositioned. An asymptomatic spinous process fracture was diagnosed in another patient on routine six-month follow-up radiographs. This required no further medical treatment or surgical intervention and the patient's stenosis symptoms were eliminated from the time of the procedure onward despite the fracture. While unlikely, it is possible to fracture the spinous process during the surgical procedure, either by applying too much force to the sizing distractor, or by applying too much lateral force against the spinous process while attempting to insert the implant. Fracturing the spinous process would require the patient to be converted to laminectomy as the X STOP design completely relies on the support of the intact cephalad and caudad spinous processes.

X STOP OUTCOMES

A multicenter prospective, randomized controlled trial was performed in the United States comparing the outcomes of mild with moderate neurogenic intermittent claudication patients treated with the X STOP interspinous process decompression system to patients treated nonsurgically (11,14). There were 191 patients treated at nine centers. Eligible patients were randomized to either the X STOP group or the control group. Those randomized to the control group received at least one epidural steroid injection and had the option to receive nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, and physical therapy and additional injections as needed. Assessments were based on the Zurich Claudication Questionnaire (ZCQ), a validated, patient-completed outcomes measure specific to neurogenic claudication (15,16), as well as the SF-36.

One hundred patients received the X STOP and 91 patients were treated nonoperatively. A total of 136 levels were implanted in 100 patients: 64 single levels and 36 double levels. One-level procedures took an average of 51 minutes and two-level—58 minutes. Blood loss was negligible: 40 ml for one-level procedures and 58 ml for two-level procedures. The most common level implanted was L4–L5 (89/136) and the second most common level was L3–L4 (43/136). The most common implant size was 12 mm. There were five X STOP sizes available during the trial, ranging from 6 mm to 14 mm. The procedure was performed under local anesthesia in 97 patients and under general in three patients. The length of stay was, on the average, less than 24 hours.

At two-year follow-up, data from 93 of the 100 X STOP patients and 81 of the 91 control patients were available for analysis. 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 post-treatment visit. At two-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 post-treatment visit. At the 24-month evaluation, 57% of the patients reported a clinically significant improvement in their physical function compared to 15% of the controls. At two-year follow-up, 73% of the patients were at least "somewhat satisfied" compared with 36% of the controls.

Results of the SF-36 scores showed no significant differences in the pretreatment enrollment scores between the X STOP and control groups for any SF-36 domain. At all follow-up time points, the X STOP group scored significantly better than the control group in every physical domain.

It is not easy to interpret X STOP clinical results in the context of published outcomes of surgical treatment for stenosis, given the generally poor quality of that literature. To date, no

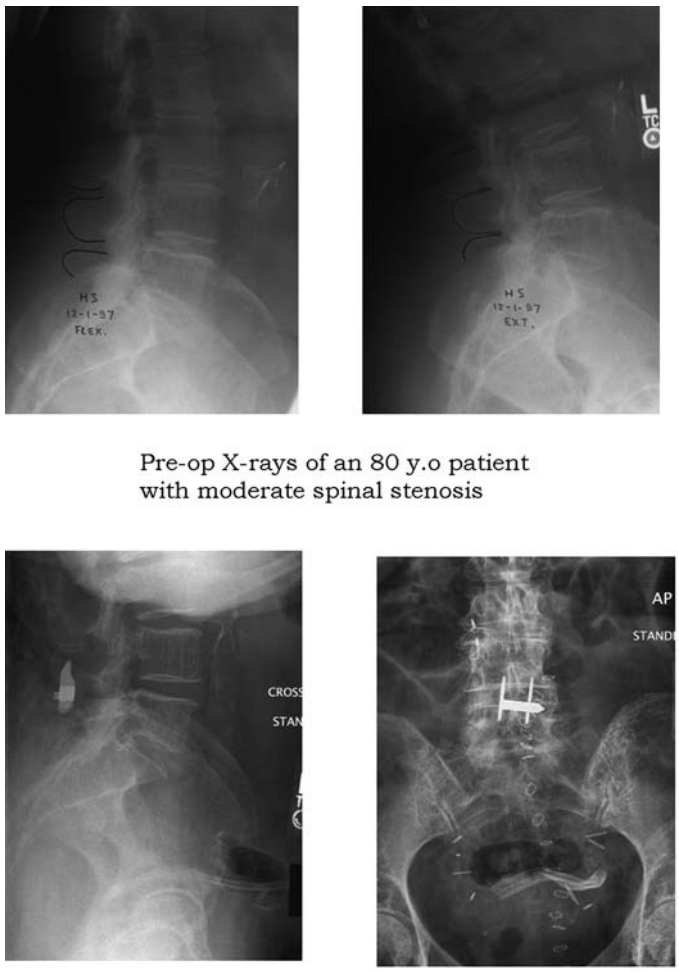

FIGURE 10 A case example from the X STOP pilot study with seven-year follow-up. Q4

randomized, prospective, multi-center study has been performed for either conservative treatment or a decompressive surgery in the treatment of LSS. The X STOP was clearly superior to nonoperative therapy in the randomized study conducted in the U.S. study, but it does not allow a direct comparison between the X STOP and laminectomy to be made.

During the course of the U.S. study, 24 patients in the control group underwent decompressive laminectomy for the relief of their stenosis symptoms and outcomes are available for 22 patients. At a mean follow-up time of 12.8 months outcomes for these patients were very similar to outcomes of the X STOP patients at two-year follow-up. Sixty-four percent had clinically significant improvement in symptom severity domain of ZCQ, 68% had clinically significantly improvement in physical function domain of ZCQ, and 60% were satisfied with the outcome of their treatment.

Of interest, 39 patients with grade I degenerative spondylolisthesis were treated in the U.S. study with the X STOP and 22 patients were treated nonoperatively. Using 15-point improvement over baseline scores in the ZCQ as the criterion of clinical success, 69% of the IPD patients had a successful outcome at two-year follow-up, compared with 9% of the control patients. The mean improvement score for the 39 X STOP patients was 26 points. There were no significant differences in the mean percentage of slip between X STOP and control patients at baseline or at two-year follow-up. The X STOP represents a significantly less invasive alternative

therapy for these patients, resulting in very good clinical outcomes and most importantly, and no evidence that the implant results in any instability of the motion segment.

SUMMARY

IPD is a relatively new motion-preserving spinal procedure. There is a great deal yet to be learned regarding its possible application in a variety of degenerative spinal conditions. Thus far, X STOP is the only IPD device with the class I clinical data to support its efficacy. Similar to indirect fracture reduction techniques, the IPD utilizes ligamentotaxis to indirectly increase the foraminal and canal dimensions by reconstituting tension in the posterior ligamentous structures. Compared to most other developments in the motion-preservation field, such as disc arthroplasty, the apparent advantages of IPD compared with regular decompression include the following:

- No need for general anesthesia.
- Ease of application via the familiar posterior approach.
- Ease of revision.
- No opening of the spinal canal and, therefore, a minimal risk of injury to the neural elements.
- Being able to salvage with regular procedures (laminectomy alone or laminectomy with fusion).

The concerns regarding the procedure are mostly theoretical and extrapolated from other orthopedic disciplines, such as the total joint arthroplasty. They include the following:

- Wear debris generation owing to the implant and its clinical significance (should be minor because the articulation is bone-on-metal and unlikely to generate metal debris. In addition, any generated debris would not be likely to enter the spinal canal, since the canal is not violated during the X STOP placement).
- Longevity of the implants (a relatively minor concern because the metal is the strongest in compression, which is a predominant mode of loading of the implanted X STOP).

Future Developments

- Combining IPD with some degree of laminectomy/laminotomy at the same/adjacent levels (similar to the way some other IPD devices have been utilized).
- Performing IPD adjacent to a fusion or an artificial disc.
- Performing multilevel IPD (based on encouraging preliminary European results).
- Exploring the role of IPD in modulation of discogenic LBP (based on the reduction of intradiscal pressure observed with IPD application in the laboratory) and facet syndrome (based on the reduction of facet loading demonstrated in the laboratory).
- Investigating the role of IPD in patients with severe LSS and higher-grade degenerative slips.
- Performing a clinical randomized side-by-side comparison of IPD versus laminectomy.
- Perfecting the patient selection criteria for X STOP (symptomatic relief with standardized flexion-based test).
- Elucidating the role of bone densitometry prior to implantation to potentially include the subset of patients with severe osteoporosis.

In summary, X STOP interspinous process decompression is indicated for the elderly patients with one- or two-level mild-to-moderate lumbar spinal stenosis with predominantly lower extremity complaints which are relieved in flexion or sitting. X STOP outcomes have been demonstrated to be vastly superior to nonoperative therapy in the U.S. multicenter prospective randomized trial in LSS patients with mild-to-moderate symptoms. The patients with grade I degenerative spondylolysthesis seem to do at least as well after the X STOP implantation as the patients without the instability. The X STOP clinical outcomes are comparable to the results previously reported for patients who have undergone laminectomy.

Complications of IPD are relatively minor and uncommon. Placement of the X STOP device would not significantly complicate future laminectomy and/or fusion. Being a minimally invasive procedure, IPD helps avoid the major risks of laminectomy such as the risks of general anesthesia, direct neural injury, dural tears, and iatrogenic instability. In patients with grade I degenerative spondylolysthesis who are frequently treated with fusion, IPD also prevents the risks of pedicle screw placement and pseudarthrosis. Most importantly, being a motion-sparing device, X STOP does not increase the adjacent segment stresses and does not contribute to the adjacent segment degeneration and adjacent segment disease. X STOP and possibly other interspinous decompression devices will likely be a useful adjunct to the currently available surgical armamentarium for the successful treatment of spinal stenosis.

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