Chapter 32: The X STOP Interspinous Process Decompression System for the Treatment of Lumbar Neurogenic Claudication

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Neurogenic intermittent claudication is the most common and characteristic syndrome of lumbar spinal stenosis. Patients typically obtain relief from sitting and positions of flexion, and exacerbate the pain while standing or walking. The X STOP (St. Francis Medical Technologies Inc., Alameda, California) is an interspinous spacer developed to treat patients with neurogenic intermittent claudication (Figure 1). The implant blocks terminal extension of the stenotic levels of the lumbar spine by means of a spacer placed between the spinous processes. The procedure typically requires no general anesthesia and can be performed in under an hour. The X STOP is an alternative therapy to conservative treatment and decompressive surgery for patients suffering from lumbar spinal stenosis. The X STOP Interspinous Process Distraction (IPD) System (X STOP) is indicated in patients whose symptoms are exacerbated in extension and relieved in flexion. Implanted between the spinous processes, the X STOP reduces extension at the symptomatic level and allows motion in flexion, axial rotation and lateral bending.

Historical Perspective

Although spinal stenosis had been observed in animals and found in Egyptian mummies, it was probably first described in 1803, by Portal of France, who observed that narrowed spinal canals were associated with leg pain and atrophy. Our understanding of this condition was not gained until about fifty years ago when Verbiest described the anatomic changes of hypertrophic articular processes causing spinal canal stenosis. Subsequently, Kirkaldy-Willis wrote about the three-joint complex and the pathologic changes found in degenerative spinal stenosis. 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 the joint also causes abnormal motion, which may
produce osteophyte formation. Ultimately, disc protrusion or osteophyte formation, hypertrophy of facet joints and ligamentum flavum result in spinal stenosis. Medical literature regarding this condition became more available after the mid 1970's. The significant increase in the reported cases of spinal stenosis is related to the introduction of axial imaging provided by CT and MRI scans.

In the United States lumbar spinal stenosis is the leading preoperative diagnosis for adults older than 65 years who undergo spine surgery. In 1996 more almost 90,000 surgeries were performed for lumbar spinal stenosis. Symptoms present with upright posture activity and include unilateral or bilateral radicular pain, sensation disturbance and loss of strength in the lower extremities. Symptoms are typically relieved with flexion the lumbar spine.

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. No known relationship exists between incidence of lumbar spinal stenosis and race. Spinal stenosis did not have the socioeconomic significance that we see today until the 1970’s. The aging of our population is resulting in an increased incidence of degenerative stenosis. In 1900 the life expectancy was 45 years. People older than 65 constituted less than 4% of the population. The estimated life expectancy in 2026 is 86 years with 20% of the population expected to be over 65 years of age. The U.S. Census Bureau projections estimate doubling of the population older than age 64 years to 64 million by 2040.

Current Treatments
Symptoms of spinal stenosis may respond to non-operative management. Conservative measures often begin with a period of rest for one or two days as well as non-steroidal anti-inflammatory medication, physical therapy and sometimes, oral steroids. In physical therapy, trunk stabilization and core muscle strengthening is typically the goal. Epidural steroid injection is often used as an adjunct particularly in those patients with unremitting radiculopathy and neurogenic claudication. There is no clear evidence of long-term efficacy of epidural steroids; however, they can give significant short-term relief and allow participation in physical therapy.

Outcomes with non-operative treatment reported by Hurri et al. showed 44% of patients had at least some improvement in neurologic symptoms. In other studies, Atlas et al. found that 45% percent of patients had improvement in leg pain with non-operative treatment while Johnsson et al reported 32% of patients treated non-operatively considered their condition improved.

Operative treatment is the primary indication for patients with worsening pain that is resistant to conservative treatment. Patients with moderate to severe stenosis that do not improve with non-operative interventions are likely to improve with surgical decompression. Historically, the literature supporting operative treatment has been shown to have methodological flaws with respect to indications for surgery and surgical outcome. However, in the last decade, prospective studies such as the Maine Lumbar Study have shown superior outcomes for operative treatment of symptomatic lumbar stenosis compared to non-operative treatment. Most series report a 64% to 91% rate of improvement following surgery.

Operative treatment while offering great potential to improve quality of life for individuals has the potential for significant complications. Post-operative complications may include infection, epidural hematoma, instability, non-union, instrumentation failure and the need for
future surgery due to the development of disease at adjacent levels. From a general medical perspective there is also a cardiac and respiratory risk particularly in elderly patients with extensive blood loss procedures. The risk for post-operative infection remains significant despite the practice of antibiotic prophylaxis and strict sterile technique. In a study by Yuan et. al. cohort undergoing lumbar decompression and arthrodesis, with or without internal fixation, revealed and infection rate of 2-3\%. In this same study, the risk of nerve root injury from placement of pedicle screws was 0.4\%. In addition to nerve root injury, dural tears are not uncommon during decompressive procedures. A study by Wang et al. which evaluated 641 patients undergoing lumbar spine surgery, half of which were revisions, revealed 13.7\% incidence of dural tears. A meta-analysis of the literature performed by Turner et al. in 1992 showed the following complication rates for neurogenic claudication surgery: perioperative mortality (0.32\%), dural tears (5.91\%), deep infection (1.08\%), superficial infection (2.3\%), deep vein thrombosis (2.78\%), any complication (12.64\%).

**X STOP Design Rationale and Pre-Clinical Confirmation**

Taking into account the relatively large void of treatment options between the safer, yet less effective conservative care, and the more risky and more effective surgical care, the X STOP was developed to fill this void by providing a safe and effective treatment option. Based on the clinical presentation of LSS patients, 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 of the remaining motion axes of the treated level(s). In addition the implant was designed to be placed using a minimally invasive surgical technique with the patient under local anesthesia. Finally, it was designed to be placed without altering the functional
tissues and allowing very straightforward removal should revision surgery become necessary; in other words X STOP placement does not preclude any further surgery.

Several key design features allow for the implantation of the X STOP between the spinous processes in a straightforward procedure that requires less than one hour of operative time. The oval spacer separates the spinous processes and restricts terminal extension at the implanted level (Figure 2). The two lateral wings prevent the implant from anterior or lateral migration. The supraspinous ligament, which is retained during the procedure, prevents the implant from posterior migration.

Biomechanical studies have shown that the implant significantly prevents narrowing of the spinal canal and neural foramina, limits extension, and reduces intradiscal pressure and facet loading. In an MRI cadaver study, Richards et al. reported that X STOP placement increases the neural foramina area by 26% and the spinal canal area by 18% during extension. In addition, the foraminal width was increased by 41% and the subarticlar canal diameter by 50% in extension. In a kinematics cadaver study, Lindsey et al. reported that 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 posterior annulus and nucleus pulposis pressures were reduced by 63% and 41% respectively during extension, and by 38% and 20% respectively in the neutral, standing position. Finally, Wiseman et al. performed a cadaveric facet loading study and reported that the mean facet force during extension decreased by 68% during extension. In each of these studies, the adjacent level measurements were not significantly changed from the intact specimen state. These pre-clinical studies indicate that the X STOP increases spinal canal and neural foramina space and also produces significant unloading of the disk and facets.
Operative Technique

Patients are placed on a radiolucent table in a right lateral decubitus position after administration of local anesthetic and intravenous sedation (Figure 3). The level to be treated is identified by fluoroscopy. 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 incised to the right and to the left 2cm from the midline. The supraspinous ligament is left intact. Paraspinal musculature is then elevated off the spinous processes and medial lamina bilaterally. Occasionally, hypertrophied facets that block entry into the anterior interspinous space are partially trimmed to enable anterior placement of the implant. The small curved dilator is inserted across the interspinous space abutting the posterior 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 the larger curved dilator is inserted in the same interspinous hole created by the small dilator. After the larger dilator is removed, the sizing instrument is inserted and dilated until the supraspinous ligament becomes just taught. The correct implant size is indicated on the sizing instrument. During the sizing and implant insertion, the patient is asked to maximally flex to open the interspinous space. The appropriately sized X STOP is inserted between the spinous processes to the point where the wing is flush with the right side of the spinous processes. The screw hole for the universal wing on the left side is identified and the universal wing screw is engaged with the main body hole. The two wings are approximated medially and the left sided universal wing screw is secured with a torque-limiting hex driver. Anterior/posterior and lateral fluoroscopy views are taken to verify proper level and position. The incision is then closed. The procedure is typically done within a 24 hour hospitalization.
The X STOP multi-center randomized trial

A multi-center prospective, randomized trial was performed comparing the outcomes of mild to moderate neurogenic intermittent claudication patients treated with the X STOP interspinous distraction system to those treated non-surgically. There were 191 patients treated in a prospective, controlled trial at 9 centers over a 15-month period. Inclusion criteria included age greater than 50 years; leg, buttock, or groin pain with or without back pain that could be relieved during flexion; ability to sit for 50 minutes without pain; walk 50 feet or more; completed at least six months of non-operative therapy; stenosis confirmed by CT or MRI scan at one or two levels; and ability to comply with scheduled clinical and radiographic follow-up evaluations.

Exclusion criteria included fixed motor deficit; cauda-equina syndrome, significant lumbar instability; previous lumbar surgery; significant peripheral neuropathy or acute denervation secondary to radiculopathy; scoliotic Cobb angle greater than 25 degrees; spondylolisthesis greater than grade 1 (on a scale of 1 to 4) at the affected level(s); sustained pathologic fractures or severe osteoporosis of the vertebrae and/or hips; obesity; active infection or systemic disease; Paget's disease or metastasis to the vertebrae or steroid use for more than one month within 12 months preceding the study. Patients were also excluded who had anatomy that would prevent implantation of the device, such as an ankylosed segment, or spinal anatomy that would cause the device to be unstable after implantation.

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 non-steroidal anti-inflammatory medications (NSAIDs), analgesics, and
physical therapy. Physical therapy consisted of back school and modalities such as ice packs, heat packs, massage, stabilization exercises, and pool therapy. Those randomized to the X STOP group underwent surgery.

Assessments were made at baseline (prior to initial treatment), and at 6 weeks, 6 months, 1 year, and 2 years following the initial treatment. Assessments were based on data collected using a validated, patient-completed outcomes measure specific to neurogenic claudication, the Zurich Claudication Questionnaire (ZCQ) as well as the SF-36. The ZCQ has three domains focused on symptom severity, physical function, and patient satisfaction.

There were 100 patients randomized to the X STOP group and 91 patients to the control group. There were no significant differences in age, height, or weight between the two groups (Table 1). Also, there were no significant differences in baseline Symptom Severity and Physical Function scores. All 91 patients in the control group received an epidural steroid injection at baseline. An additional 125 injections were administered to control group patients over the course of the study, for a total of 216 injections.

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 procedures took an average of 58 minutes. The average blood loss was 40 ml for a one-level procedure and 58 ml for a two-level procedure. 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. The procedure was performed under local anesthesia in 97 patients and under general in 3 patients. The X STOP was typically implanted in an acute care hospital where patients stayed less than 24 hours.
At 2-years follow-up, data from 93 of the 100 X STOP patients and 81 of the 91 control patients were available for analysis. In the X STOP group, seven patients were lost to follow-up; four patients died, two patients failed to complete the ZCQ, and one patient withdrew. In the control group, ten patients were lost to follow-up; three patients died, one patient could not tolerate the initial epidural steroid injection which was aborted, and six patients withdrew. During the course of the study, six patients in the X STOP group and 24 patients in the control group underwent decompressive surgery (laminectomy) for relief of their stenosis symptoms during the 2-year follow-up period. Post-laminectomy outcomes were available for 28 of these patients (6 X STOP and 22 controls). The mean follow-up time for the laminectomy group was 12.8 months (range 2.5 to 26.9 months).

Study Results

The X STOP group had a significantly greater percentage of patients with an improvement in Symptom Severity than did the control group at each post-treatment visit. At the 24-month evaluation, 56/93 patients (60.2%) reported a clinically significant reduction in the severity of symptoms compared to 15/81 patients (18.5%) in the control group (Figure 4). The X STOP group also had a significantly greater percentage of patients with an improvement in Physical Function than did the control group at each post-treatment visit. At the 24-month evaluation, 53/93 patients (57.0%) reported a clinically significant improvement in their physical function compared to 12/81 patients (14.8%) in the control group. The X STOP group had a significantly greater percentage of patients who were at least "somewhat satisfied" in the Patient Satisfaction domain than did the control group at each post-treatment visit. At the 24-month evaluation, 68/93 patients (73.1%) were at least "somewhat satisfied" compared to only 28/78
patients (35.9%) in the control group. Sixteen of 28 (57.1%) patients undergoing laminectomy had clinically significant improvement in Symptom Severity, 18/28 (64.3%) had clinically significantly improvement in Physical Function, and 15/28 (53.6%) were satisfied with the outcome of their treatment.

Results of the SF-36 scores show there were no significant differences in the pre-treatment enrollment scores between the X STOP and NO-OP groups for any SF-36 domain (Figure 5). At the 6-week, 6-month, and 1-year post-treatment follow-up time points, the X STOP group scored significantly better than the NON OP group in every physical domain. In addition, at each time point, the mean scores in each category for the X STOP group were significantly better than the respective pretreatment scores, whereas in the NON OP group, none of the mean scores was significantly better.

Three complications occurred intra-operatively or within 72 hours following surgery in the X STOP group. There was one episode of respiratory distress and one ischemic coronary episode which resolved without clinical sequelae. One X STOP patient with a history of cardiovascular disease developed pulmonary edema two days following device implantation. There were four minor operative site-related complications in the immediate post-operative period: one wound dehiscence, one swollen wound that was aspirated, one hematoma, and one report of incisional pain. There were three device-related complications in the X STOP group. One X STOP patient suffered a fall which caused the implant to dislodge. The dislodged implant was removed without sequelae. An asymptomatic spinous process fracture was diagnosed in another patient on routine 6-month follow-up radiographs, which required no further medical treatment or surgical intervention. One patient reported worsening pain 382 days following
treatment, which was determined to be possibly related to the implant. Finally, one implant was placed posterior enough to be considered malpositioned.

Case Examples

Radigraphic Study Images for single level with degenerative spondylolisthesis. Images show improvement in disk-height, intervertebral angle, listhesis and foraminal dimension

Images from a two level procedure, pre-operative and one year post-operative.

MRI images of degenerative stenosis. Images at 6 weeks post-op show improved foraminal space.

Discussion

A simple clinical observation that neurogenic intermittent claudication patients get symptom relief from flexion and symptom exacerbation from extension led to the idea that restricting extension at the symptomatic level(s) would likely relieve the patients’ symptoms as well. The concept developed into the X STOP interspinous process implant.

To date no randomized, prospective, multi-center study has been performed for either conservative treatment or a decompressive laminectomy. The ZCQ outcomes measure used in the above study provides a validated instrument to quantify a change in the symptoms, physical function and patient satisfaction following an intervention for neurogenic intermittent claudication.\textsuperscript{21,22} Using the definition developed by Stucki \textit{et al.} of a 0.5 change in both the Symptom Severity and Physical Function domains as representing a clinically significant change,
the results of the present study demonstrate that the X STOP improves symptoms and function significantly compared to epidural steroid injections and conservative therapy in patients with mild to moderate symptoms of NIC after 6 weeks, 6 months, 12 months and 24 months post-treatment.

Approximately 44% of control patients in the present study experienced some improvement in their pain symptoms, and 43% experienced some improvement in their physical function. In addition, 24 of 91 (26%) patients in the control group elected to undergo a laminectomy compared to 6% in the X STOP group. This crossover rate in the control group is consistent with those reported in the literature.\(^{12,13,15,23,24}\)

The outcomes assessed by the ZCQ scores in the present study for patients who underwent a decompressive laminectomy are consistent with the findings from the prospective study reported by Katz et al. as well as data reported by others.\(^{25-27}\) The comparable outcomes for the X STOP group and patients who underwent a laminectomy in the current study provide a basis against which to compare the outcomes of the X STOP group in similar patient populations, using the same outcomes measure and success criteria. The results for X STOP patients and laminectomy patients reported by Katz et al. at two-year follow-up are very similar, as are the mean improvement scores for both Symptom Severity and Physical Function (Figure 6). In the study by Katz et al., 63% of the patients were significantly improved in Symptom Severity, 59% were improved in Physical Function and 72% were satisfied.\(^{26,27}\) Comparing these results to results for X STOP patients, 59.8% were improved in Symptom Severity, 56.5% were improved in Physical Function, and 72.8% were satisfied. Similar values are present for the 28 patients who went onto a decompressive laminectomy in the above study.
In light of similar outcomes between the X STOP and surgical decompression procedures, there are important differences between the two surgical procedures. The procedural aspects of X STOP implantation compare favorably to those reported in the literature for decompressive surgery. The mean operative time for the X STOP procedure was 51.2 minutes for a single-level procedure and 58.1 minutes for a two-level procedure, which was considerably less than the range of 72 to 278 minutes reported for laminectomy procedures. In addition, the mean blood loss of 40.1 mL to 57.9 mL during the X STOP procedure was less than the range of 115 to 1040 mL reported for decompressive surgery. Additionally, the ability to perform a majority of the X STOP procedures under local anesthesia significantly reduces the risks associated with the administration of general anesthesia.

Decompressive laminectomy is a relatively invasive surgical procedure and entails significant risks for NIC patients with potential complications that include paralysis, myocardial infarction, pulmonary embolism, pneumonia, hematoma, deep vein thrombosis, neurological deficit, deep infection, superficial infection, dural tears, implant failure (when accompanied by a fusion) and pseudarthrosis. None of these complications were observed during or after the X STOP procedure. Since the X STOP surgical technique is not performed adjacent to the nerve roots or spinal cord, the risk of neurologic deficit or paralysis may be considered minimal. No incidence of either complication was reported in this study. Compared to the incidence and severity of complications cited in the laminectomy literature, the X STOP represents a much safer procedure.

Because non-operative therapy served as a control in the above study, definitive comparisons between the X STOP and decompressive laminectomy cannot be made. Turner et al. conducted a meta-analysis of 74 stenosis studies, in which the authors note that no
randomized trials comparing surgery to conservative treatment had been conducted. Few studies were prospective, the follow-up data collection methods were unclear, rarely was the data analyzed by someone other than the physician, and the outcomes were not assessed at consistent time intervals. Subsequent clinical studies have somewhat rectified these shortcomings. Medical therapy was selected as a control, both because it is a common treatment for patients with mild to moderate NIC, and because implantation of the X STOP, like non-operative care, does not require the patient to undergo a highly invasive procedure.

Summary

Implantation of the X STOP is an alternative to laminectomy, with clinical outcomes that are comparable to and consistent with results reported for decompressive surgery. Results of a randomized, prospective trial show that the X STOP improves symptoms and function significantly compared to epidural steroid injections and conservative therapy in patients with mild to moderate symptoms. The absence of any major complications demonstrated that the X STOP is relatively safe.

The X STOP provides an effective treatment option for patients suffering from mild to moderate symptoms of lumbar spinal stenosis.

References


8. Verbiest H. Chapter 16. Neurogenic intermittent claudication in cases with absolute and relative stenosis of the lumbar vertebral canal (ASLC and RSLC), in cases with narrow lumbar intervertebral foramina, and in cases with both entities. Clin Neurosurg 1973;20:204-14


Figure Legends

Figure 1. An image of the X STOP depicting the adjustable universal wing, tissue expander, fixed wing, and spacer. The tapered tissue expander allows for easier insertion between the spinous processes. The universal and fixed wings limit anterior and lateral migration. The spacer limits extension of the treated spinous processes.

Figure 2. A) posterior, B) lateral, and C) axial views of a lumbar motion segment with an implanted X STOP. The implant is placed posterior to the lamina and away for the nerve roots and spinal cord. The supraspinous ligament is retained to prevent posterior migration. The implant is not fixed to any bony structures.

Figure 3. Surgical Technique. A) Patients are placed in a right lateral decubitus position and mid-sagittal incision of approximately 4 cm is made over the spinous processes of the stenotic level(s). B) The small curved dilator is inserted at the most anterior margin of the interspinous space. C) The sizing instrument is inserted and dilated. D) The X STOP is inserted between the spinous processes. E) The universal wing is attached to the tissue expander.

Figure 4. A bar chart depicting the percent of patients in the X STOP and Control groups who had significant clinical improvement in the Symptom Severity and Physical Function domains and those who were satisfied with the treatment. The X STOP outcomes are significantly greater that those of the Control group for each domain.
Figure 5. There were no significant differences between the baseline pre-treatment scores of the X STOP and Control groups. At 24 months, the X STOP group had significantly greater SF-36 scores in all domains except the GH, RE, and MCS domains. Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Function SF), Role Emotional (RE), Mental Health (MH), Physical Component Summary (PCS), Mental Component Summary (MCS).

Figure 6. A comparison of the ZCQ domain outcomes for the 197 patients reported by Katz et al., the X STOP patients, and 6 X STOP and 22 Control patients who underwent a laminectomy. The outcomes are similar for each group in each domain.
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<th>X STOP</th>
<th>Control</th>
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Symptom Severity (SS), Physical Function (PF)
Adjustable Wing

Tissue Expander

Fixed Wing

Oval Spacer