X STOP Interspinous Process Decompression for Lumbar Spinal Stenosis

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Key Points

- The X STOP, FDA approved November 2005, can be used for neurogenic intermittent claudication (NIC) at one or 2 level lumbar spinal stenosis.
- The X STOP preserves the interspinous and supraspinous ligaments.
- The X STOP preferred approach is with local anesthesia as an outpatient procedure.
- One, two, and four year outcomes are at least as good as laminectomy with less cost and less surgical risk.
- The X STOP can be used in low grade spondylolisthesis.

INTRODUCTION

The X STOP, an interspinous process spacer, is a promising surgical treatment alternative for intermittent neurogenic claudication caused by lumbar spinal stenosis. The device provides an unloading distractive force to the stenotic middle column of the motion segment and can relieve claudicatory symptoms of central, lateral, and foraminal stenosis. Other devices currently being tested are suggested for degenerative disk disease, adjacent level syndromes, lumbar spinal stenosis, and herniated disk. 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. Some 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 limit flexion and it may also decrease the laxity of the motion segment, which could be an important component in
treated certain pathologies such as degenerative disc disease. NIC is the most common symptom seen in lumbar spinal stenosis. Patients typically obtain relief with sitting or positions of flexion and are exacerbated with standing or walking. Moreover, elderly patients tend to be osteopenic and at risk for osteoporosis, any shaping or remodeling the spinous process would reduce the strength and should be avoided. In fact, care should be taken to avoid decorticating or damaging any bone surrounding the spinous process.

The first interspinous process decompression device approved in the United States by the FDA for general use (November 21, 2005) was the X STOP (St Francis Medical Technologies, Inc. Alameda, CA). It was approved for use in Europe July 2002. Since then, over 10,000 devices have been implanted. Placement of this device requires preservation of the spinous process, interspinous and supraspinous ligaments. This chapter will describe current treatment options, patient selection, biomechanical studies, the technique for performing Interspinous Process Decompression (IPD) with the X STOP, as well as outcomes from all clinical, biomechanical and radiographic studies published to date.

Current Treatment

Treatment for NIC involves conservative or operative measures. Conservative treatment usually begins with activity management as well as non-steroidal anti-inflammatory medications, physical therapy and/or a short course of oral steroids. Trunk stabilization and core muscle strengthening is typically the goal in physical therapy. However, bracing and physical therapy alone have little proven efficacy. Hurri et al showed 44% had some improvement with non-operative treatment. Atlas et al found that
45% of patients had improvement in leg pain and Johnsson et al reported 32% considered their symptoms improved with conservative treatment.

Epidural steroid injections are often used as an adjunct in those patients with severe or unremitting radiculopathy and/or NIC. In about one third of cases, this treatment can result in enough relief to avoid surgery for a short period of time. However, long term relief is less likely.

If conservative treatment fails to provide relief or is worsening, operative treatment is indicated. Traditionally, the surgeries include decompressive laminectomy, laminotomy or foramenotomy depending on the anatomic region of the stenosis. Moreover, fusion may be indicated where the motion segment is unstable. The success of these surgeries varies with severity, surgical technique, patient selection and outcomes measures. A meta-analysis of 74 studies related to surgery for spinal stenosis reveals a rate of good to excellent results of 64% at one year. Prospective studies such as the Maine Lumbar Study have shown superior outcomes for operative treatments of symptomatic lumbar stenosis compared to non-operative treatment.

Surgical decompression, while offering the potential to improve the quality of life for the patients, also has the potential for significant complications, especially when a fusion is performed and in revision surgery. Post-operative 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%), any complication (12.64%). In a study by Yuan et al., 2-3% of patients undergoing lumbar decompression and arthrodesis with or without internal fixation, suffered an infection and the risk of nerve root injury from placement of pedicle screws was 0.4%.

INDICATIONS AND CONTRAINDICATIONS

Patient selection criteria include leg, buttock, or groin pain with or without back pain which is relieved with sitting or flexion. Once the diagnosis is confirmed with either MRI or CT, at one or two levels, and a trial of conservative management (typically up to 6 months), placement of the device can be considered. Moreover, patients should be able to sit for at least 50 minutes without pain. Contraindications include cauda equina syndrome, scoliotic Cobb angle >25 degrees, gross instability at the motion segment, fragility compression fracture or severe osteoporosis, Paget’s disease, metastasis to the vertebrae, ankylosis at the affected segment, spinal anatomy that would cause the device to become unstable (such as aplastic spinous process or spina bifida occulta), isthmic spondylolisthesis, olisthesis, and degenerative spondylolysis > Meyerding Grade I. Spondylolisthesis up to Grade I is indicated and described in more detail later. Patients with prior spinal surgery were excluded from the study trials, however, patients who have had prior laminotomy from a microdiskectomy may be considered, assuming the interspinous and supraspinous ligaments are intact. Although, extensive prior laminectomy would be a contraindication. X STOP may also be indicated for the patients unable to undergo general anesthesia.
Although in the clinical study conducted in the U.S., patients with symptomatic stenosis at L5/S1 were excluded, the X STOP has been successfully implanted at the L5/S1 level in Europe in patients with sufficiently sized S1 spinous processes. Approximately one third of patients in the US have received implants at two levels, while three level procedures were not performed in the U.S. study. As with L5/S1 procedures, triple level procedures are performed in Europe, but less frequently.

DESCRIPTION OF THE DEVICE

The X STOP was developed to provide a safer, less invasive treatment option for those who fail conservative management and those needing the riskier decompression surgery. The X STOP was designed specifically to reduce extension only at the individual level(s) that provokes symptoms, while allowing unrestricted movement in flexion, axial rotation and lateral bending 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.

Thickened lamina, hypertrophied ligamentum flavum, spondylolisthesis, disk bulges, and facet hypertrophy can concomitantly lead to canal, foraminal, and lateral recess stenosis. NIC is often position dependant where symptoms such as pain, numbness, tingling, and weakness are elicited with extension of the lumbar spine and relieved in flexion or sitting. The level affected primarily is L4-L5, followed by L3-L4, L5-S1, L2-L3, L1-L2.
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 (Figure 1). 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 cortical bone. The two lateral wings prevent migration laterally, the lamina prevents migration anteriorly, 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, from right to left allowing the supraspinous ligament and its insertions to be preserved (Figure 2).

The L5-S1 level may present a difficult challenge. Most people lack an S1 spinous process large enough to support the device. Those who do have a large S1 spinous process usually are those who have a lumbarized S1 segment. In these cases, the X STOP can be placed in the same manner as the proximal segments.

BACKGROUND OF SCIENTIFIC TESTING/CLINICAL OUTCOMES

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. In an MRI 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. In a kinematics cadaver study, Lindsey, et al showed 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. Rohlman et al performed a similar study and from a slight increase in intradiskal pressure which reduced dramatically with extension at the implanted segment. This finding, however only occurred when the interspinous space was distracted more than 6mm\textsuperscript{37}. They recommend not placing an implant much larger than the interspinous space. 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 those 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.

In a six month clinical f/u MRI study, Wardlaw et al. and Siddiqui et al reported equal results in their clinical study evaluating positional magnetic resonance imaging (MRI) changes after X STOP implantation\textsuperscript{38,39}. Siddiqui found in 17 levels an increase in the dural sac from 77.8 to 93.4mm squared (p=0.006). In a later study, Siddiqui et al found in 26 patients, no differences in disc heights, endplate angles, and segmental and lumbar range of movement\textsuperscript{40}.

The supraspinous ligament is a substantial structure and its presence as well as the preservation of its original osseous insertion prevents over distraction of the segment. The ultimate load and tensile strength of the interspinous/supraspinous ligament complex are 203 N and 1.2 Mpa, respectively\textsuperscript{41}. In another biomechanical study, the supraspinous/
interspinous ligament complex was the largest contributor to resisting applied flexion moments in the porcine lumbar spine\textsuperscript{42}.

A relative contraindication for its use is in a patient with severe osteoporosis. Talwar, et al showed that the spinous process is significantly weaker in those with low bone mineral densities and therefore care must be taken when implanting the X STOP in patients with lower bone mineral density\textsuperscript{43}.

\textit{Clinical Outcomes}

A multi-center prospective, randomized controlled trial was performed in the U.S. comparing the outcomes of mild to moderate neurogenic intermittent claudication patients treated with the X STOP interspinous process decompression system with patients treated non-surgically\textsuperscript{44}. There were 191 patients treated at 9 centers. Inclusion criteria included: patients older than 50 years old; leg, buttock, or groin pain with or without back pain while walking and relieved with forward flexion and able to sit for at least 50 minutes pain free. Exclusion criteria includes a fixed motor deficit, cauda equina syndrome, significant instability, previous lumbar surgery, dense peripheral neuropathy, scoliosis with Cobb angle >25 degrees, spondylolisthesis greater than Grade I (25\% slip or less), history of pathologic compression fractures including fragility fractures, severe osteoporosis, obesity (BMI >40), and active infection.

Eligible patients were randomized to either the X STOP group or the conservative care group. Those randomized to the conservative care group received one or more epidural steroid injection and had the option to receive NSAID’s, analgesics, and physical
therapy and additional injections as needed. Physical therapy consisted of back school which included, stabilization exercises, pool therapy, massage, and cold/hot packs. Assessments were based on baseline (prior to initial treatment) and at 6 weeks, 6 months, 1 year, 2 year, and later 4 yr. Assessment data were based on outcomes measure specific for neurogenic claudication, the Zurich Claudication Questionnaire (ZCQ) , as well as the SF-36.

One hundred patients received the X STOP and 91 patients were treated non-operatively. 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 5 X STOP sizes available during the trial, ranging from 6mm to 14mm. The procedure was performed under local anesthesia in 97 patients and under general in 3 patients. The length of stay was, on the average, less than 24 hours.

At 2-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 2-year follow-up, 56/93 (60.2%) of the patients reported a clinically significant reduction in the severity of symptoms compared to the 15/81 (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 2-year follow-up, 73% of the patients were at least “somewhat satisfied” compared to 36% of the controls. Interestingly, patients with 2 level X STOPs had greater symptom relief than the single level, although not significantly so. This is opposite the trend seen in laminectomy and fusion cases where multilevel procedures tend to have less favorable outcomes.

Results of the SF-36 scores showed no significant differences in the pre-treatment 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 including the mean scores, whereas in the control group, none of the mean scores were better.

More recently, based on the original 18 patient FDA pilot study group who all received X STOP, Kondrashov et al showed 78% had successful outcomes at 4 years follow-up. They used a 15 point improvement in Oswestry Disability Index compared with the baseline (Table 1).

German Registry

In Germany, a registry is being maintained to gather prospective data on NIC patients, who are treated with the X STOP implant in general practice. Patients are assessed pre-and postoperatively using the validated, condition-specific ZCQ. The ZCQ is the only validated LSS-specific outcomes measure. The questionnaire consists of three domains: Symptom Severity (SS), Physical Function (PF), and Patient Satisfaction (PS). To date, 212 patients have been evaluated 1 year after surgery with very good
results (Table 2). Two patients had a reoperation because of lack of efficacy and one because of dislocation of the implant.

**European Clinical Experience**

A prospective clinical evaluation of 15 patients with 3- and 6-month follow-up was carried out by Wardlaw et al in conjunction with pre- and postoperative positional MRI scan measurements. All cases demonstrated clinical improvement and the X STOP implant increased the cross-sectional area of the dural sac and exit foramina without affecting overall movement of the lumbar spine.

Heijnen and Kramer reported on the satisfaction of 14 patients with NIC, who were treated with the X STOP implant. One patient died of a non-back related disorder. Eleven of the other 13 patients expressed a great satisfaction. They are free of NIC symptoms and all but one would undergo the surgery again, if the choice had to be made again.

**Patients with Degenerative Spondylolisthesis**

Of interest, 39 patients in the US FDA study with grade I degenerative spondylolisthesis were treated with the X STOP and 22 patients were treated non-operatively. Using 15-point improvement over baseline scores in the ZCQ as the criterion of clinical success, 69% of the 39 X STOP patients had a successful outcome at 2-year follow-up, compared to 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 2-year.
follow-up. Spondylolisthesis patients are often treated with spinal fusion and decompression. Moreover, Anderson et al. in a cohort of 75 patients, 42 X STOP and 33 non-operative controls at 2 years follow-up, showed statistically significant clinical success in 63.4% of X STOP and 12.9% of controls using ZCQ and SF-36 outcome measures. Sagittal balance (listhesis and kyphosis) remained unaltered. The X STOP represents a significantly less invasive alternative therapy for these patients, resulting in very good clinical outcomes and most importantly, no evidence that the implant results in any instability of the motion segment.

**Sagittal Balance**

The requirement to maintain proper sagittal alignment and balance in patients receiving spinal implants is well understood. Experience with lumbar fusion procedures that cause a flat back has overwhelmingly resulted in unacceptable clinical outcomes. Three different radiologic 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 control patients and measurements were made of the lumbosacral angle (L1 to S1) and the treated intervertebral angle. At 2-year follow-up, there were no significant differences in the mean angles between the two groups of patients. Preoperative x-rays from a subset of X STOP patients were also compared to standing films taken at 2-year follow-up. In 23 patients with single-level implants, the change in the intervertebral angle was only 0.5 degree, and the change in the lumbosacral angle was 0.1 degree.
Interim data from an ongoing study being conducted by Wardlaw, Smith, and Siddiqui have been recently presented, in which preoperative images were compared to post implant 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 minor change in angulation for both the lumbosacral angle and intervertebral angle of approximately 1 degree. These three studies confirm that the X STOP results in only minimal changes to sagittal alignment. This due is to preserving the supraspinous ligament and its original insertions. This ligament is a very robust structure receiving the confluence of the lumbodorsal fascia and its preservation prevents overdistraction of the segment.

X STOP Versus Decompressive Laminectomy

It is not easy to interpret X STOP clinical results in the context of published outcomes of surgical treatment for stenosis. To date, no randomized controlled multicenter study has been performed for X STOP versus laminectomy. The X STOP was clearly superior to conservative treatment in the US study, but it does not permit a comprehensive comparison between the X STOP and laminectomy.

Hannibal compared patients from the US FDA Pivotal X STOP Trial (June 2000 – July 2001) with those who received laminectomy during the same time period, at the same institution, and using the same criteria used in that trial in a non-random manner. At 4 years post surgery and using a 15 point improvement from baseline ODI score as a success criterion, 80% (12/15) of X STOP patients and 38% (5/13) laminectomy patients had successful outcomes.48
Compared to literature-reported outcomes of decompressive surgery there are significant differences in operative time, estimated blood loss, hospital stay, complication rate, and reoperation rates, favoring the X STOP.\(^{49-51,52-54,55,56,57}\)

The results of the X STOP patients showed 59.8% were statistically significantly improved in Symptom Severity, 56.5% improved in Physical Function and 72.8% were satisfied. 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. Sixty-four percent had clinically significant improvement in Symptom Severity Domain of ZCQ, 68.2% had clinically significantly improvement in Physical Function Domain of ZCQ, and 59.1% were satisfied with the outcome of their treatment. Furthermore, Katz et al.\(^{(1999)}\) published a large series of surgically treated spinal stenosis patients also using the ZCQ outcomes tool at 2 years follow-up. In that study, 63% of the patients were significantly improved in Symptom severity, 59% improved in Physical Function and 72% were satisfied. Fokter et al looked at pre and post laminectomy ZCQ scores at 12-54 months in 58 patients, 63.8% of the patients had significant clinical improvement in Symptom Severity, 55.2 had significant clinical improvement in Physical Function, and 58.6% of the patients were at least somewhat satisfied (Table 3)\(^{58}\).

There is striking similarity in outcomes between the X STOP and laminectomy groups. However, there are some important differences between these procedures. The mean operative time for the X STOP was less than an hour for two levels, compared with 72-278 minutes reported for laminectomies. Mean blood loss 40.1-58ml during the X STOP was negligible compared with 115-1040ml reported for decompression.\(^{59-60}\)
Moreover, the X STOP procedure can be performed under local anesthesia, thus nearly eliminating the risk associated with general anesthesia. Finally, the incidence and severity of complications cited in the laminectomy literature compared with the X STOP indicates that the X STOP is a much safer procedure.

**OPERATIVE TECHNIQUE**

The patient is placed in the right lateral decubitus position on a radiolucent table (Figure 3). The level(s) to be treated is identified by fluoroscopy using an 18 ga needle taped to the skin. An indelible ink mark is made at the appropriate level. The site is prepped with usual sterile technique and draped using shower curtain type drape. Two 22 ga spinal needles can be placed at the caudal and cephalad most extent of the proposed incision to accurately identify the level(s) and length of the incision. The spinal needles may be used to instill local anesthetic with epinephrine to block the posterior rami bilaterally. A mid-sagittal incision about 4 cm is made over the spinous process to the dorsal fascia. A Cobb elevator is used to sweep the subcutaneous tissue from the dorsal fascia. After further local anesthesia to the dorsal fascia, two longitudinal incisions are made through both layers of the dorsal fascia about 1 cm from the lateral aspect of the spinous processes. The paraspinal musculature is then subperiosteally elevated from the spinous processes and medial lamina bilaterally using a large Cobb elevator. A large Cobb is appropriate to ensure that the canal is protected, especially in cases with prior laminotomy. The spinal canal should never be violated and neither laminectomy nor laminotomy is performed. Removal of any portion of the ligamentum flavum is unnecessary.
If the facets are hypertrophied, they may block proper insertion of the devise causing them to be placed too posterior, thus, they may be partially trimmed medially with a rongeur to ensure adequate anterior placement. Fuchs et al found in a cadaveric biomechanical study that the facets can be safely trimmed without destabilizing the motion segment while using the X STOP. However, one should avoid aggressive bilateral facetectomies.

Prior to starting the insertion process, the patient is asked to curl-up and flex their back by trying to place their chin to their knee. A small curved dialator is inserted across the interspinous space at the most anterior margin of the interspinous space. After the correct level is verified by fluoroscopy, the small dilator is removed and replaced with a larger curved one. A finger is placed on the left side at the point where the small dilator is removed to ensure placement of the large dilator as well as the sizing distractor which are placed at the same location. The interspinous ligament is dilated, not excised. After the larger dilator is removed the sizing distractor is inserted. Since the patient is in the flexed, pain free position, the sizing distractor should be opened until it contacts the spinous process and slightly distracts the interspinous space. If the interspinous space is sized between two available X STOP sizes, choose the next smallest size. The X STOP is then implanted from right to left, again with a finger on the left side to help guide the beveled tip of the device through the appropriate point. The right wing should be flush against the side of the spinous process. The screw hole for the universal wing on the left side is directly visualized and the wing screw is engaged. The two wings are approximated medially and the universal wing screw is secured using a torque-limiting screwdriver. Anterior/posterior and lateral fluoroscopy views are obtained to ensure proper placement.
The two fascia incisions are closed separately along with subcutaneous and skin. A drain is rarely indicated. The procedure can typically be performed in less than an hour and most patients can be released from the hospital within 24 hours. (Figure 4)

POSTOPERATIVE CARE

Patients are encouraged to get-up and ambulate as soon as they feel comfortable. They should avoid hyperextension activities for 2 to 6 months.

COMPLICATIONS & AVOIDANCE

Reported complications related to the X STOP have been minor and resolved easily without further sequelae. In the US clinical study, there was one wound dehiscence, one seroma which was aspirated, one hematoma, and one report of incisional pain. No spinous process fractures occurred during X STOP implantation. There have been no reports of either vascular or neurological complications, which is anticipated since the lamina are left intact and the spinal canal and neuroforamina are not entered. Device-related complications included one patient who 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 properly positioned anteriorly. One patient reported worsening pain about 1 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 6-month follow-up radiographs.

Revising the implant is rather uncomplicated. Once the set screw on the wing is
removed, the implant can be easily removed or replaced. Should an adjacent level need to be instrumented with the XSTOP, there would be little added difficulty. Placement of the X-STOP adjacent to a prior fusion remains a subject for further testing.

Cost Analysis

Kondrashov et al recently evaluated the cost effectiveness of X STOP treated patients versus those patients treated with laminectomy in a European hospital setting. They found X STOP to be significantly more cost effective. There were 18 X STOP and 11 laminectomy patients. Average hospital costs for 1 level X STOP and 1 level laminectomy group were $17,059 and $45,302 respectively. Average hospital costs for 2 level X STOP and 2 level laminectomy groups were $24,353 and $45,739 respectively. The main savings in the X STOP group (cost drivers) were in OR costs (shorter operative time), hospital charges (X STOP is an outpatient procedure) and anesthesia charges (X STOP is placed under local/ MAC anesthesia). The cost of the X STOP implant and higher radiology charges due to use of fluoroscopy during X STOP placement were significantly offset by those savings.

ADVANTAGES

➢ It is clinically well proven as an effective treatment for symptoms of LSS with or without degenerative spondylolisthesis.

➢ It is safe.

➢ It has a short surgery time and can be made under local anesthesia.

➢ It is minimally invasive.
- It can be implanted during a short stay as an outpatient.
- There is an immediate relief of NIC.
- It is cost-effective.
- It can easily be revised to other procedures.
- There is no violation of the spinal canal.
- There is no tissue removal.

DISADVANTAGES
- Can not be used with lytic spondylolisthesis.
- There is no published prospective controlled studies comparing X STOP with laminectomy.

CONCLUSIONS/DISCUSSION
Decompression of the lumbar spine with the X STOP offers a well-proven, safe, effective, and cost-effective treatment of patients suffering from NIC secondary to LSS. The X STOP can be implanted with local anesthetic, and many patients can return home within hours after surgery. The X STOP implant offers the benefits of decompression, yet with a low-risk profile, for NIC patients. It utilizes ligamentotaxis to indirectly increase the foraminal and canal dimensions by reconstituting tension in the posterior ligamentous structures.

The comparative analyses suggest that the outcomes of the X STOP decompression may at least be comparable to outcomes reported in the literature for decompressive laminectomy.
The X STOP interspinous process decompression is indicated for 50 year or older patients with 1 or 2-level mild-to-moderate lumbar spinal stenosis symptoms with back and lower extremity complaints which are relieved in flexion. X STOP outcomes have been demonstrated to be vastly superior to non-operative therapy in the US multicenter prospective randomized trial in LSS patients with mild to moderate symptoms.

Complications with the X STOP are relatively minor and uncommon. X STOP 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 probably does not contribute to the adjacent segment degeneration and adjacent segment disease.

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. Posterior and lateral 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 then sizing instrument is inserted at the most anterior margin of the interspinous space. C) The universal wing is attached.
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