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Review

Application of X STOP Device in the Treatment of Lumbar Spinal Stenosis

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Low back pain is exceptionally ubiquitous, complex, and costly. Nevertheless, lumbar spinal stenosis (LSS) with neurogenic intermittent claudication (NIC) is a frequent cause of low back and lower extremity pain. Although the phenomena and pathophisiology of lumbar spinal stenosis has been described for decades, therapeutic treatment options remain considerably limited.

Current care consists of conservative measures including physical therapy, rest, medications, and epidural steroid injection therapy or invasive surgical treatment including laminectomy with or without fusion. Despite standard of care intervention, many patients are often left inadequately treated and suffer from debilitating low back and lower extremity pain as a result of lumbar spinal stenosis. Interspinous process distraction (IPD) devices were originally described in the 1950s, but technological advances, which have contributed to improved safety and efficacy, have rekindled an interest in IPD implantation. By mimicking lumbar flexion at affected levels of stenosis, it is thought these devices decompress neural structures within the neural foramina and therefore provide pain relief. X-STOP is one such device that is currently approved in the United States for the treatment of mild to moderate NIC resulting from LSS. This manuscript presents a focused review of NIC and LSS and comprehensively presents literature related to the use of the X-STOP IPD device.

Key words: Interspinous process distraction (IPD), X STOP, interspinous spacer (ISS), lumbar spinal stenosis (LSS), neurogenic intermittent claudication (NIC), low back pain, sciatica

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Low back pain is extremely common today. The total costs of low back pain in the United States exceed $100 billion per year (1,2). In 1990 low back pain ranked as the fifth most common reason for all physician visits with nearly 15 million office visits that year (3). Furthermore, a review of the National Ambulatory Medical Care Survey for the years 1989 and 1990 revealed that almost 4% of recorded diagnoses for low back pain were spinal stenosis (3). Evaluation of Medicare Physician Part B claims showed that in 2001 over 2,000 lumbar epidural steroid injections were performed per 100,000 patients and that Medicare expenditures for all lumbosacral injections were over $175 million (4). Further, 23% of these injections were coded for spinal stenosis. Manchikanti et al (5,6) showed that lumbar radiculitis, disc displacement, spinal stenosis, and sciatica accounted for 53% of all epidural injections in 2002 and 54% in 2006. Therapeutic options for patients suffering from neurogenic intermittent claudication (NIC) secondary

to lumbar spinal stenosis (LSS) are relatively limited. The options have conventionally consisted primarily of either conservative management including physical therapy, rest, analgesic or anti-inflammatory medications, and epidural steroid injections or surgical management including laminectomy with or without fusion (7-24).

A relatively new device, however, may provide a third option for patients with symptomatic LSS. Originally available in Europe in June 2002, the X STOP device (Kyphon Inc., Sunnyvale, CA) is an interspinous process implant that was approved for clinical use in the United States by the Food and Drug Administration in November of 2005. Its approved indication is for the treatment of mild to moderate NIC resulting from LSS. This device is based on the observation that LSS with resultant NIC is often relieved when patients bend forward, and accordingly flex their lumbar spine. Upon this premise, the device is designed to fit between the spinous processes at the stenotic lumbar level thereby mimicking lumbar flexion and limiting extension at the localized level. Reportedly, this then widens the neural foramina and decompresses problematic neural structures.

Although interspinous process distraction was originally developed in the 1950s, it was all but abandoned secondary to device dislodgement, poor clinical indication, and hardware malfunction. While a number of interspinous process distraction devices, or IPD devices, have been developed, this paper aims to specifically examine the X STOP device, as it is currently the only FDA-approved IPD device available in the United States. We will highlight the pathophysiology and clinical presentation of NIC caused by LSS and then comprehensively review the literature regarding X STOP utility and effectiveness.

Anatomy of the Spine

Composed of 24 vertebrae and the sacrum, the spine is both a durable structure and exquisitely flexible, allowing for motion along a number of axes. Specifically, the lumbar spine is comprised of 5 vertebrae arranged in a lordotic fashion. Each vertebral body is represented by a cancellous core surrounded by a dense cortical rim. Projecting posteriorly at each level is the vertebral arch. From each vertebral arch projects the transverse processes laterally and the spinous process posteriorly. The pedicles, along with the lamina, form the lateral and posterior borders of the spinal canal. Connecting the lamina superiorly and inferiorly is the ligamentum flavum. The vertebral bodies are separated at each level via intervertebral discs made of a gelatinous nucleus pulposus encased in a rigid annulus fibrosis. The pars interarticularis is a region of the lamina bordered by the superior and inferior articular processes. These articular processes form the zygoapophyseal joints. It is the zygoapophyseal, or facet, joints that allow for lumbar stability during flexion, extension and lateral rotation of the spine. The spinous processes are afforded further stability by a dense interspinous ligament and a dorsally bordered supraspinous ligament.

Clinical Presentation, Pathophysiology, and Diagnosis of NIC Secondary to LSS

Verbiest has frequently been credited as first describing the clinical symptoms of posture related NIC secondary to LSS. In 1954 he published a series of 7 case reports of patients complaining of NIC caused by LSS (25). He noted that those patients developed radicular lower extremity pain, often bilaterally, on walking and standing that was relieved immediately with recumbency. In each case, myelography showed a block in the lumbar region, which was confirmed at operation (25). Verbiest also noted that on laminectomies of middle-aged men with characteristic lower extremity radicular pain, the diameter of the lumbar spine was less than that of normal variants (25,26).

The pathophysiology of LSS has been well described by Kirkaldy-Willis and colleagues (27). Their investigations were based on dissection of 50 cadaveric lumbar spines and observations made during laminectomies of 161 patients. They noted that as part of the degenerative process, lumbar spinal stenosis begins with repetitive minor trauma over many years. Likewise, presentation is most common upon or after the fifth or sixth decades of life. Ultimately, LSS is the result of destruction of the posterior joints causing synovial reaction, cartilage destruction, osteophyte formation, and intervertebral disc disruption. These changes ultimately lead to loss of disc height and facet instability often accompanied by buckling of the ligamentum flavum. As a result, the neural foramina and spinal canal are narrowed, impinging upon the structures within them, including the spinal cord, nerve roots, and cauda equina.

Although there is no universally accepted gold standard in the diagnosis of NIC caused by LSS, there are a number of clinical and diagnostic tools that aid in its identification. Unfortunately, findings from radiographic modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) poorly correlate with clinical symptoms (28). Likewise, this can make

concrete diagnosis of LSS challenging and LSS might be easily unrecognized or misdiagnosed by practitioners. Upon expert evaluation of 468 cases of patients aged 20 years or older who presented with primary symptoms of pain or numbness in the legs, Konno et al (29) found the overall prevalence of LSS was 47.4%. Other diagnoses from this study included lumbar disc herniation (17.7%), diabetic neuropathy (2.8%) and peripheral artery disease (8.3%). Furthermore, in spite of specialist evaluation and diagnostic studies, almost one in 4 patients was left with no other diagnosis than "not LSS." In an attempt to develop a clinical diagnosis tool to identify patients with LSS, they determined that characteristics associated with LSS include age greater than 60, absence of diabetes, intermittent claudication, exacerbation of symptoms when standing up with improvement upon bending forward, symptoms with lumbar extension, good peripheral artery circulation, and an abnormal Achilles reflex. Correlating negatively with a diagnosis of LSS included a positive straight leg raise test and symptoms induced with lumbar flexion (29).

X STOP Indications, Contraindications and Placement

The idea of restricting motion in the plane that produces pain, or so-called dynamic stabilization, is not a new concept. In a paper by Bono (30), he mentions that Dr. Fred L. Knowles is often recognized as pioneering interspinous process devices in the 1950s (30). Yet, long-term use of this device was rare as it often became dislodged, which necessitated its removal. Since that time a number of new devices have been developed on the premise of dynamic stabilization with a wide variety of suggested clinical indications. This paper, however, will focus on the FDA approved X STOP interspinous process device. The X STOP device is an all titanium metal, and therefore radiopaque, device. It consists of an oval titanium core that is designed to fit within the interspinous ligament. It is secured within the ligament by 2 lateral wings.

The device is indicated for use in patients aged 50 years or older who are experiencing moderately impaired physical function secondary to NIC as a result of LSS. The X STOP may be implanted at one or 2 stenotic lumbar levels. Most importantly, candidates for placement must report alleviation of claudication with lumbar flexion, with or without back pain, and have undergone at least 6 months of failed non-surgical treatment (31). Contraindications to placement of the X STOP device include:

1. allergy to titanium
2. spinal anatomy or disease that would prevent implantation or cause instability
3. cauda equina syndrome
4. severe osteoporosis
5. active systemic infection or localized infection at the site of implantation.

Placement of the X STOP device has been well documented by Zucherman et al (32). It is typically performed under local anesthetic with the patient in the right lateral decubitus position. Patients are required to maintain a flexed position in order to aid in distraction of the spinous processes and facilitate device placement. Surgical levels are first correctly identified with fluoroscopy. A 4 to 5 centimeter mid-saggital incision is then made over the appropriate spinous processes. The soft tissue is dissected to the fascia at which point the fascia is incised longitudinally to the right and left of midline. Great care is taken to maintain the integrity of the supraspinous ligament. A curved dilator is then advanced through the interspinous ligament at its most anterior margin. The appropriate surgical level is then re-verified with fluoroscopy. The small dilator is removed and a larger dilator is placed. The larger dilator is then removed and a sizing distractor is placed with the patient maintaining spinal flexion. The spinous processes are then distracted until the supraspinous ligament becomes taut. The proper X STOP implant size is then determined by an indicator on the distraction instrument. The distractor is removed and the X STOP device of indicated size is placed through the interspinous process until the right lateral wing rests against the right side of the spinous processes. At this point, the left lateral wing is attached and fastened securely against the left side of the spinous processes with the 2 wings approximated at midline. Proper positioning of the X STOP device is verified with anteroposterior and lateral fluoroscopy prior to closure. Procedural time is generally less than one hour and blood loss is usually less than 100 mL. Patients are typically discharged home within 24 hours of surgery with many patients returning home on the same day as surgery.

Validity of X STOP Mechanism of Action

IPDs including X STOP have been reported to be effective in relieving low back pain and lower extremity radicular pain in appropriately selected patients with disc height loss and significant pain relief during flexion (33). The mechanism of X STOP for pain relief is

still under investigation. Theoretically, X STOP implantation supports the diseased lumbar spine segments in a more flexed position, but close to neutral alignment; it also reduces pathological mobility. Potential mechanisms of pain relief include widening the lumbar spinal canal, diminishing neuroforaminal narrowing, reducing facet loads at implanted levels, decreasing intradiscal pressure, and increasing anterior and posterior disc heights.

As mentioned above, the X STOP device is designed to distract the interspinous processes and limit extension at the affected level(s). In doing so, the neural foramina are allegedly spread and maintained open, decompressing neural elements and relieving claudication. Lee et al (34) was the first to report changes in neural canal and foramen dimensions following the placement of the X STOP interspinous device. Ten patients had 11 X STOP devices placed and were evaluated using MRI both pre- and post-operatively. From their study, they note that the mean dural sac area increased by 23% (73.6 vs. 90.2 mm²) after X STOP placement. Intervertebral foraminal area also improved by 36% (60.3 vs. 82.3 mm²) with the X STOP device. In another study, Richards et al (35) examined 8 cadaveric lumbar spines from L2-L5. These cadaveric spines were cemented in a stabilizing brace and neural foraminal measurements were made at 15 degrees of flexion and extension with and without X STOP implantation. While maintained in extension with the interspinous device, the mean canal area increased by 18% (273 vs. 231 mm²) with canal diameter increasing 10% (19.5 vs. 17.8 mm). Subarticular diameter of the implanted spines was 48% greater (3.7 vs. 2.5 mm). Foraminal area increased 25% (106 vs. 133 mm²) and foraminal width was 41% greater (3.4 vs. 4.8 mm) among implanted specimens.

On in vivo examination, Siddiqui and colleagues (36) compared 6-month pre- and 6-month post-X STOP implantation lumbar MRI dimensions. This study included 12 patients who underwent implantation at a total of 17 levels. In lumbar extension, left exit foramen dimensions increased by 34% (77.25 vs. 103.73 mm²) and right exit foramen dimensions increased 25.4% (90.67 vs 113.7 mm2). On spinal cross section examination of standing patients the mean canal dimension increased 20% (77.78 vs. 93.39 mm²), 16% in neutral (93.17 vs. 108.29 mm²) and 27% in extension (84.56 vs. 107.35 mm²) with X STOP implantation. Furthermore, no change in overall lumbar posture was observed (36). This suggests that while placement of the X STOP device changes localized vertebral dimensions at implanted level(s), the overall lordotic orientation of the lumbar spine might be unaffected. Siddiqui et al (37) later examined 26 patients undergoing implantation of X STOP at a total of 15 single levels and 11 double levels for LSS with NIC. They again noted significant improvement in spinal canal dimension and the neural foraminal area after implantation.

Although these studies agree with the mechanistic fundamentals of interspinous technology, they are limited in number and evaluate dimensions at a maximum of 6 months postoperatively. It is difficult to say whether these measured improvements in canal and foraminal area will be maintained over the long-term. Furthermore, the clinical significance of these changes in spinal and foraminal dimensions is uncertain.

Previous studies have shown that spinal fusion can result in instability at adjacent levels and that this abnormal motion might accelerate adjacent segment degeneration (34). In order to study lumbar kinematics after X STOP placement, Lindsey et al (38) examined 7 cadaveric lumbar spines from L2-L5. The X STOP device was implanted at the L2-3 level and 2 CCD cameras were used to record the angle of implanted steel pins in flexion-extension, lateral bending, and axial rotation. As discussed, the X STOP device is designed to limit extension at implanted levels. Accordingly, flexion-extension range of motion at the implanted level was significantly reduced in this study. Axial rotation and lateral bending at the implanted level, however, were not significantly affected. Furthermore, with the exception of a decreased L4-L5 neutral to extension position, the kinematics of the adjacent levels was not significantly altered. This study also showed an overall decrease in flexion to extension range of motion for the entire lumbar specimen (Non-implant 25.8° vs. Implanted 20.8°) and a 2° decrease in L2-L5 lordosis.

X STOP device implantation effects on in vivo sagittal kinematics was later studied by Siddiqui et al (39). Pre-operative and 6 month post-operative MRIs were obtained on 26 patients who had a total of 15 single level and 11 double level X STOP implantations. In order to quantify the kinematic effect of X STOP implantation, height, endplate angles, segmental and lumbar range of motion, and L1S1 angle were recorded. In this study, the X STOP device did not affect lumbar spine sagittal kinematics.

It has also been argued that X STOP implantation might offset compressive forces at the localized level and in doing so increase facet joint pressure at adjacent levels. As a result of a potentially increased burden at

adjacent lumbar levels, this could conceivably accelerate or promote degeneration. Wiseman et al (40) examined 7 cadaveric lumbar spines loaded with 700 N of compression in 15 Nm of extension. Pressure-sensitive film was inserted into the facet joints at the X STOP implanted level (L2-L3 level in all specimens) and adjacent levels. At the implanted level peak pressure of the facet joint was reduced 55% (3.73 MPa vs. 1.68 MPa), mean pressure decreased by 39% (0.93 MPa vs. 0.57 MPa), contact area was reduced 46% (0.79 cm^2 vs. 0.42 cm^2), and the mean force was reduced by 67% (83.2N vs. 26.8N) (40). The results, however, did not reveal a significant change in facet loading measurements at adjacent levels. Although these are encouraging results, the affects of loading pressures in vivo remain to be investigated.

Lazoro et al (41) examined the kinematics on the L1-2 segment before and after implantation with a novel minimally invasive lumbar interspinous spacer (Synthes USA, LLC, West Chester, PA) in 7 human cadaveric specimens. With interspinous spacer (ISS) in place, the range of motion and stiff zone during extension were significantly improved with less reduced foraminal height. This study also showed more than 50% reduction of facet loading during full extension after implantation. However, the clinical value of this study is relatively limited due to a small data sampling and lack of clinical investigation in elderly patients with LSS at usual lumbar levels.

Although the exact functional mechanism of pain relief is not fully know, it is most likely that by distracting adjacent spinous processes the X STOP device expands the neural foramina and spinal canal and may unbuckle redundant tissue within the canal, such as the ligamentum flavum. Although modest, this overall expansion of the neural and spinal canal diameter may decompress the neural structures within. By decompressing these structures the X STOP device is thought to alleviate pain associated with NIC.

Insertion Loads

LSS is a degenerative process and likewise primarily a disease of an older patient population. As a result, many candidates for interspinous placement also have lower bone mineral density. Placement of the X STOP device necessarily requires a degree of lateral loading pressure. This loading pressure, however, may place the spinous processes at risk. Talwar et al (42) examined ten lumbar segments from 4 cadavera. The specimens were cleaned and fixed in an axial loading frame. The average age of the specimens was 64 years. In this study, the mean lateral insertion load of the X STOP was 65.6 N with a range of 10.5 to 150.2 N versus a mean spinous process failure load of 316.9 N with a range of 94.7 to 786.4 N. Although it is evident that the mean lateral insertion load during implantation of the X STOP device is over 4 times greater than the spinous process failure load, it is not without some overlap. Therefore it is conceivable that implantation might pose a risk to some patients with particularly brittle spinous processes. Additionally, in this same study the authors demonstrate a positive correlation between bone mineral density and lateral failure load of the spinous process. As a result, patients with even mild osteoporosis might not be ideal candidates for X STOP placement.

Recently, a novel technique of posterior element vertebroplasty to augment the spinous process strength has been reported by Idler et al (43). This cadaveric study suggests that intraspinous process injection of Poly(methyl methacrylate) (PMMA) could increase spinous process strength, reduce the risk of posterior element fracture, and therefore expand the safety and success of implantation for patients with severe osteoprosis seeking the X STOP procedure. In vivo practice, however, remains to be investigated.

Clinical Data

In May of 2000 a Food and Drug Administration investigational trial on the efficacy of X STOP began. This study was designed to compare X STOP placement versus non-operative (NON OP) treatment for NIC secondary to LSS. Nine centers enrolled 200 randomized patients in a prospective, controlled trial. A total of 191 patients were treated with a total of 136 X STOP implantations. Eligible patients were 50 years of age or older with leg, buttock, or groin pain, regardless of back pain, that could be relieved with flexion. Patients were required to be able to sit for 50 minutes without pain, already undergone at least 6 months of non-operative therapy, and be able to walk a minimum of 50 feet. Patients were excluded if they had cauda-equina syndrome, previous lumbar surgery at the levels of stenosis, greater than grade I spondylolisthesis, or a fixed motor deficit. LSS was confirmed at one or 2 levels on CT or MRI. Patients were evaluated to primary outcomes using the Zurich Claudication Questionnaire (ZCQ). This questionnaire evaluates patient satisfaction, physical function, and symptom severity. Treatment qualified as a success if the patient was at least "somewhat satisfied" and had at least a 0.5 improvement in physical function and symptom severity. Patients also completed

the Medical Outcomes Study Short Form-36 (SF-36). In the X STOP group 64 single level devices and 36 double levels were placed. At one year the success of the X STOP device was 59% versus 12% in the NON OP group (32). Furthermore, X STOP patients also reported significantly higher success rates at 6-week and 6-month follow-up periods. In a follow-up study of these same patients reported at 2 years post treatment, patient satisfaction rates were 73.1% in the X STOP group compared to 35.9% in the NON OP group (44). These results are comparable to that of a small study by Lee et al (34) who reported patient satisfaction rates of 70% among X STOP implanted patients at a minimum follow-up period of 9 months. Regarding symptom severity, at 2 years X STOP patients reported a 45.4% improvement over baseline compared to 7.4% in the NON OP group and physical function improvement of 44.3% versus –0.4% in the NON OP group (44). Of the 136 X STOP devices placed there were no reported intraoperative complications and none of the procedures was converted to decompressive surgery at the time of placement. Six patients in the X STOP group and 24 patients in the NON OP group, however, did eventually undergo decompressive surgery at some point during the 2-year period due to unresolved stenosis. Three complications were noted intraoperatively or within 72 hours postoperatively including one ischemic coronary episode, one respiratory distress event, and one episode of pulmonary edema. Three device related complications were documented including an implant dislodgment after a fall, an asymptomatic spinous process fracture discovered on 6 month follow up imaging, and one patient who complained of worsening pain 382 days after placement of the X STOP device. Upon evaluation of all radiographic images at 6 weeks and 2 years postoperatively, 96% of implanted levels had maintained distraction of the spinous processes (44).

While the results of this study are favorable, criteria for inclusion included at least 6 months of prior conservative therapy for LSS. The control or NON OP group was then relegated to conservative treatment, a treatment which they have presumably already had limited success as evidenced by their ongoing clinical symptoms of LSS. The authors also fail to report the SF-36 scores in the 2-year follow up study making one- and 2-year follow-up comparison difficult. In a separate study, however, the mean SF-36 scores from this patient pool are reported at 2-year follow. The results from that study illustrated that the X STOP group had significantly better outcomes than the NON OP group in the domains of bodily pain, mental health, physical component summary, physical functioning, quality of life, role physical, and social function (45). Further, the authors point out that these SF-36 scores are comparable to published outcomes of laminectomy. Yet, of the 200 patients originally enrolled in the pilot study, only 82 X STOP and 53 NON OP patients were included in this 2-year follow-up study of SF-36 outcomes.

A 4-year follow-up study was also published in July of 2006 using the same patient pool from the FDA investigational trial (46). In this study the Oswestry Disability Index (ODI) was used to evaluate outcomes at an average of 4.2 years postoperatively. Yet only 18 patients were included in this follow-up study despite initial enrollment of 200. Of the 18 patients with X STOP device placement, the mean preoperative score was 45 compared to a mean postoperative score of 15 at the 4-year follow-up (46). The authors qualified device success as an improvement of 15 points. Using this criteria, 14 of 18 patients, or 78%, had successful outcomes (46). This study, however, is limited to only 18 patients and reports the Oswestry Disability Index, an index not previously reported in the one or 2-year follow-up studies. The study also fails to compare the clinical outcomes to those of a control or NON OP group. While the overall data from these studies is encouraging, it is limited to a maximum of 4.2 years and inconsistent index reporting and patient follow up makes comparison and outcome determination difficult.

In a separate study, Siddiqui et al (33) enrolled 40 patients who were surgically treated with the X STOP device and examined ZCQ, ODI, and SF-36 scores preoperatively and at 3, 6 and 12 month postoperative intervals. At 12 months, 54% of patients reported significant symptom improvement, 33% reported improvement in physical function, and 71% reported satisfaction with the procedure (33). Yet of the 40 enrolled patients in this study, 16 were excluded, leaving a study group of only 24 patients. Although the results were favorable, the outcomes did not show as significant of an improvement as the results from the larger FDA pilot study.

A clinical evaluation study showed X STOP does improve pain score and daily function in patients with neurogenic claudication, but a good outcome is achieved less often than previously reported (47). Complications associated with the X STOP procedure have been documented, although available data are limited. Negative results of this treatment might be underreported (48). Reported complications include dislocation of device, spinous process fracture (49), and foot drop

(50). Barbagallo et al (49) consider underlying causes of these complications are related to the anatomic variants of the spinous process and interspinous areas of the patients including markedly decreased interspinous distance, abnormal shape of the spinous process, and facet hypertrophy.

X STOP Versus Decompressive Surgery

While the X STOP device has been compared to non-operative therapy for NIC secondary to LSS in a number of studies, there is little data regarding its effectiveness when compared to lumbar decompression surgery. Kondrashov et al (51) compared 18 patients who received X STOP implants to 12 patients who underwent laminectomy without fusion. Of the 18 X STOP patients, 12 were treated at one level and 6 at 2 levels. This compares to 3 of the 12 laminectomy patients who were treated at one level and 9 who were treated at 2 levels. In this study an improvement of 15 Oswestry Disability Index points defined patient success. Based on the success criteria outlined, they concluded that 78% of the X STOP group, versus only 33% of the laminectomy group, had successful outcomes at 4 years follow-up (51). Although this data illustrates a striking contrast in success, the pre-operative average ODI scores in the X STOP group are 25% greater (45 vs. 36). Previous studies have demonstrated that patients with more severe physical limitation might have better measurable success rates than those with less disability (52). Further, this is a retrospective analysis and not randomized nor double-blinded. The study also included economic analysis, comparing direct hospital charges of X STOP placement to that of laminectomy without fusion. The average direct hospital costs for one level X STOP placement was $15,980 versus a laminectomy average of $45,302 for one level. Two level X STOP placement cost was $25,618 compared to a 2-level laminectomy cost of $46,752 (51). Hospital charges, operative time, and anesthesia charges were cited as the main factors underlying the greater expense of laminectomy. As already discussed, the X STOP device is typically implanted solely with local anesthetic and patients are normally discharged within 24 hours of surgery. Yet, as the authors point out, the analysis only considers the direct hospital charges, and a short recovery period after X STOP placement might translate into a substantial additional savings in indirect costs.

Recently a clinical investigation by Kutcha and colleagues (53) indicated that X STOP implantation in 175 patients with LSS provided short-term as well as long-term satisfactory outcome. The Visual Analog Scale score of leg pain in the patients was reduced from 6.0 preoperatively to 3.9 at 6 weeks and 3.9 at 2 years postoperatively; Oswestry scores were 32.6, 22.7 and 20.3 respectively. In 8 patients, however, implanted X STOP devices had to be explanted with subsequent microsurgical decompression due to poor pain control. The authors pointed out that the interspinous device does not replace microsurgical decompression in patients with massive stenosis and continuous claudication, but offers a safe, effective, and less invasive alternative in selected patients with spinal stenosis (53). Similarly, Nardi et al (54) reports another interspinous device, Aperius perc LID system offers an easy, safe and effective treatment for patients with lumbar degenerative stenosis and neurogenic intermittent claudication which did not respond to conservative treatment and this device system can represent a valid alternative to the traditional surgical techniques However, Asperius perc LID system is not available in USA at this time.

Other Possible Indications for X STOP Implantation

Although the X STOP device is approved for NIC secondary to LSS, it might lend itself to other applications. Two studies (55,56) have examined the outcomes of X STOP placement for LSS caused by degenerative spondylolisthesis. In a study by Anderson et al (55), a cohort of 75 patients, 42 treated with X STOP and 33 treated non-operatively, with spondylolisthesis ranging from 5-25% reported a clinical success rate of 63.4% in the X STOP group compared to 12.9% in the non-operative treated patients at 2 years follow-up. This success contrasts, however, with a later study by Verhoof and colleagues (56) who performed a retrospective chart review of 12 consecutive patients who had an average spondylolisthesis slippage of 19.6%. In this study, 7 of 12, or 58%, required decompression with posterolateral fusion within 24 months of X STOP placement for degenerative spondylolisthesis. Furthermore, MRI results from this study failed to demonstrate any improvement of the axial or sagittal diameter of the central canal after placement of the X STOP device (56).

As discussed above, the X STOP device is currently FDA approved for placement at a maximum of 2 stenotic levels. It might, however, offer utility for patients with stenosis at multiple levels. Although the device might not be independently beneficial in this patient population, Fuchs et al (57) have suggested that it could possibly be used as an adjunct during decompressive

procedures, such as unilateral medial facetectomy for the treatment of subarticular stenosis or unilateral total facetectomy for the treatment of foraminal stenosis. The advantage, they argue, is that by decompressing neural structures, adjunct X STOP implantation might minimize the invasiveness of decompressive surgery by lessening the amount of tissue needing to be resected. To this end, Fuchs et al (57) prepared 7 cadaveric spines in order to investigate the effects of X STOP placement on the kinematics of the lumbar spine with graded facetectomy. Results from this study showed that although the implant decreased range of motion during flexion and extension with graded facetectomy, it did not alter axial rotation kinematics (57). The clinical outcome and significance of in vivo X STOP placement as an adjunct to facetectomy remains to be investigated.

Summary

The X STOP interspinous process distraction device is a relatively new apparatus approved by the FDA for the treatment of mild to moderate LSS resulting in NIC. As outlined above, a number of studies, both with cadaveric specimens and in vivo, have shown improvement in lumbar spinal and neural foraminal dimensions after implantation. Furthermore, the above investigations into the clinical outcomes of X STOP implantation have thus far yielded encouraging results regarding the overall safety and efficacy of this device. Nevertheless, the future of the X STOP device in treating patients with LES and NIC is not yet entirely clear. Large, randomized, and truly long-term studies with consistent outcome measures and follow up are currently lacking. As a result, the definitive efficacy and safety of this implant still remains debatable.

Conclusion

Current treatment of LSS with NIC has to this point traditionally consisted of either conservative therapy or invasive decompressive surgery. The X STOP device might offer an intermediately invasive, clinically beneficial, and cost effective third option.

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