Interspinous Distraction Devices (X-Stop) & Interlaminar Spinal Stabilization Devices (Coflex) AHM

Clinical Indications for Procedure

- The use of interspinous decompression implant or distraction devices or interlaminar spinal stabilization devices are considered investigational at this time as insufficient evidence demonstrating the treatment safety and effectiveness.
- Examples: Coflex inter-spinous stabilization spinal implant, Eclipse inter-spinous distraction device, ExtenSure bone allograft inter-spinous spacer, X-stop- (CA), TOPS System, Wallis System- also titanium (France), Interspinous "U"-silicone (France), Minns Device-silicone, Diam- Silicone (TN)

Evidence Summary

Background

- Lumbar spinal stenosis (LSS) refers to narrowing of the lumbar spinal canal, lateral recess, or foramen resulting in neurovascular compression that may lead to pain. Spinal stenosis may be classified by etiology (e.g., congenital or acquired) or symptomatology (e.g., radiculopathy, neurogenic claudication, or mechanical back pain). It can also be classified radiographically, by the location of the stenosis (e.g., central canal, lateral recess, or intervertebral foramen) or by the presence of deformity such as spondylolisthesis or scoliosis. Overlapping in the classification of LSS can occur in that central stenosis with thecal sac compression usually leads to neurogenic claudication, while lateral recess compression is associated with compression of an individual nerve root, thus resulting in radiculopathy. Although symptoms may arise from narrowing of the spinal canal, not all patients with narrowing develop symptoms. The reason why some patients develop symptomatic stenosis and others do not is still unknown. Therefore, LSS does not refer to the pathoanatomical finding of spinal canal narrowing. It is a clinical syndrome of lower extremity pain caused by mechanical compression on neural elements or their vascular supply (Truumees, 2005).
- Non-surgical treatments (e.g., activity modification, medications such as non-steroidal anti-inflammatory drugs, physical therapy that focuses on flexion-based exercises, as well as epidural steroid injections) are usually the first treatment choice for patients suffering
from neurogenic intermittent claudication (NIC) secondary to LSS. If symptoms failed to improve with non-surgical treatments, decompressive surgery (e.g., laminectomy, facetectomy, multi-level laminotomies, fenestration, distraction laminoplasty, and microscopic decompression), with or without fusion, may be necessary. Moreover, several studies reported that surgical treatment produces better outcomes than non-surgical treatment in the short-term; however, the results tend to deteriorate with time (Yuan, et al., 2005).

- While fusion operations have traditionally been used to manage many disorders of the lumbar spine related to instability, pain, or deformity, concern over the long-term effects of fusion on adjacent spinal segments has led to the development of new approaches such as inter-spinous distraction procedures. The X-Stop Inter-Spinous Process Distraction/Decompression System (St. Francis Medical Technologies, Inc., Alameda, CA) was developed to provide an alternative therapeutic. The principal behind the X-Stop (eXtension-Stop) is that by decompressing the affected spinal segment and maintaining it in a slightly flexed position (and also preventing extension) the symptoms of LSS can be relieved. Additionally, it allows the patient to resume their normal posture rather than flex the entire spine. The X-Stop is made of titanium alloy and is available in five sizes -- 6, 8, 10, 12, and 14 mm in diameter. It consists of two major parts: (i) the universal wing, and (ii) the main body (with oval spacer and tissue expander). The wings prevent anterior and lateral movement while the supraspinous ligament prevents posterior displacement. The oval spacer swivels, making it self-aligning relative to the uneven surface of the spinous process. This ensures that no sharp edges come into contact with the spinous process and that compressive loads are distributed equally on the surface of the bone.

- The X-Stop Inter-Spinous Process Distraction/Decompression System gained FDA's PMA in November 2005 for use in alleviating the symptoms of patients with LSS. The X-Stop is intended to be used in patients with symptomatic LSS at one or two levels who have failed at least 6 months of conservative treatment. Under local anesthesia, the implant is inserted between the spinous processes of the affected level(s), and prevents extension at those levels. Talwar, et al. (2005) stated that patients with lower bone mineral density must be approached with more caution during insertion of the inter-spinous process implant.

- According to SFMT Europe B.V., a subsidiary of St. Francis Medical Technologies, the X-Stop is indicated for any of the following conditions:
  - Axial-load induced back pain; or
  - Baastrup's syndrome (also known as kissing spines); or
  - Contained herniated nucleus pulposus; or
  - Degenerative and/or iatrogenic (post-discectomy) disc syndrome; or
  - Facet syndrome; or
  - Neurogenic intermittent claudication due to central and/or lateral-recess LSS; or
  - Spondylolisthesis up to grade 1.5 (of 4) (about 35 %), with NIC; or
  - Unloading of disc adjacent to a lumbar fusion procedure, primary or secondary.

- There is a scarcity of randomized controlled studies on the clinical value of the X-Stop for the indications listed above, especially its long-term (over 2 years) benefits.
Currently, available evidence on this device is mainly from J.F. Zucherman and K.Y. Hsu (developers of this technology), and their associates.

- Verhoof and colleagues (2008) stated that the X-Stop inter-spinous distraction device has been reported to be an alternative to conventional surgical procedures in the treatment of symptomatic degenerative lumbar spinal stenosis. However, the effectiveness of the X-Stop in symptomatic degenerative lumbar spinal stenosis caused by degenerative spondylolisthesis is not known. A cohort of 12 consecutive patients with symptomatic lumbar spinal stenosis caused by degenerative spondylolisthesis were treated with the X-Stop inter-spinous distraction device. All patients had LBP, neurogenic claudication and radiculopathy. Pre-operative radiographs revealed an average slip of 19.6%. Magnetic resonance imaging of the lumbo-sacral spine showed a severe stenosis. In 10 patients, the X-Stop was placed at the L4 to L5 level, whereas 2 patients were treated at both, L3 to L4 and L4 to L5 level. The mean follow-up was 30.3 months. In 8 patients, a complete relief of symptoms was observed post-operatively, whereas the remaining 4 patients experienced no relief of symptoms. Recurrence of pain, neurogenic claudication, and worsening of neurological symptoms was observed in 3 patients within 24 months. Post-operative radiographs and MRI did not show any changes in the percentage of slip or spinal dimensions. Finally, secondary surgical treatment by decompression with posterolateral fusion was performed in 7 patients (58%) within 24 months. The authors concluded that the X-Stop inter-spinous distraction device showed an extremely high failure rate, defined as surgical re-intervention, after short term follow-up in patients with spinal stenosis caused by degenerative spondylolisthesis. They do not recommend the X-Stop for the treatment of spinal stenosis complicating degenerative spondylolisthesis.

- Lindsey, et al. (2003) examined the kinematics of the instrumented lumbar spine and adjacent levels due to the insertion of the X-Stop. Seven lumbar spines (L2 - L5) were tested in flexion-extension, lateral bending, and axial rotation. Images were taken during each test to determine the kinematics of each motion segment. The X-Stop was inserted at the L3 - L4 level, and the test protocol was repeated. These researchers found that the X-Stop does not significantly alter the kinematics of the motion segments adjacent to the instrumented level.

- In a study using 7 cadaveric spines (L2 - L5), Fuchs, et al. (2005) noted that the X-Stop may be used in conjunction with a unilateral medial facetectomy or unilateral total facetectomy. However, it should not be used in conjunction with bilateral total facetectomy. In another cadaveric L2 - L5 spine study (n = 7), Wiseman, et al. (2005) reported that inter-spinous process decompression by placing the X-Stop between the L3 - L4 spinous processes will unlikely cause adjacent level facet pain or accelerated facet joint degeneration. Furthermore, pain induced from pressure originating in the facets and/or posterior anulus of the lumbar spine may be relieved by inter-spinous process decompression. Richards, et al. (2005) quantified the effect of the X-Stop on the dimensions of the spinal canal and neural foramina during flexion and extension. By means of a positioning frame, 8 specimens (L2 - L5) were positioned to 15 degrees of flexion and 15 degrees of extension. Each specimen was assessed singing magnetic resonance imaging (MRI), with and without the X-Stop, placed between the L3 - L4 spinous processes. Canal and foramina dimensions were compared between the intact and
implanted specimens. These investigators concluded that the X-Stop prevents narrowing of the spinal canal and foramina in extension.

- Lee and colleagues (2004) reported their preliminary findings on the use of the X-Stop for LSS in elderly patients (n = 10). Subjects were evaluated post-operatively by MRI and the Swiss Spinal Stenosis Questionnaire. Cross-sectional areas of the dural sac and intervertebral foramina at the stenotic level were measured post-operatively and compared with the pre-operative values. After implantation of the X-Stop, the cross-sectional area of the dural sac increased 16.6 mm² (22.3 %) and intervertebral foramina increased 22 mm² (36.5 %). The intervertebral angle as well as the posterior disc height changed significantly. A total of 70 % of the patients stated that they were satisfied with the surgical outcome.

- In a multi-center, prospective, randomized, controlled trial, Zucherman and colleagues (2005) compared the outcomes of X-Stop treated NIC patients (n = 100) with their non-operatively treated counterparts (n = 91). The primary outcomes measure was the Zurich Claudication Questionnaire (ZCQ) -- a patient-completed, validated instrument for NIC. At every follow-up visit, X-Stop treated patients had significantly better outcomes in each domain of the ZCQ. At 2 years, the X-Stop treated patients improved by 45.4 % over the mean baseline Symptom Severity score compared with 7.4 % in the control group; the mean improvement in the Physical Function domain was 44.3 % in the X-Stop group and -0.4 % in the control group. In the X-Stop group, 73.1 % patients were satisfied with their treatment compared with 35.9 % of control patients.

- Siddiqui, et al. (2007) reported on the one year results of a prospective observational study of the X Stop interspinous implant for the treatment of lumbar spinal stenosis. Forty consecutive patients were enrolled and surgically treated with X Stop implantation. The X Stop device was implanted at the stenotic segment, which was either at 1 or 2 levels in each patient. Sixteen of 40 patients failed to complete all clinical questionnaires at each of the specified time intervals and were excluded from the study. The investigators reported that, by 12 months after surgery, 54 percent of the 24 remaining patients reported clinically significant improvement in their symptoms, 33 reported clinically significant improvement in their physical function, and 71 percent expressed satisfaction with the procedure. Twenty-nine percent of patients required caudal epidural after 12 months for recurrence of their symptoms of neurogenic claudication. The investigators noted that, although this study indicates that the X Stop offers significant short-term improvement, these results were less favorable than the previous randomized clinical study. Limitations of this study include the lack of a control group, short duration of follow-up and high proportion of dropouts.

- In a literature review, Christie, et al. (2005) evaluated the mechanisms of action and effectiveness of inter-spinous distraction devices in managing symptomatic lumbar spinal pathology. They stated that these devices continue to be evaluated in clinical trials; and that although the use of inter-spinous implants is still experimental, the early results are promising, and it is likely that future studies will establish a niche for them in the management of lumbar spinal pathology.

- Bono and Vacarro (2007) reviewed interspinous process devices for the lumbar spine, and stated that, although some clinical data exist for some of these devices, defining the
indications for these minimally invasive procedures will be crucial. "Indications should emerge from thoughtful consideration of data from randomized controlled studies."

- Based upon a systematic evidence review on inter-spinous distraction procedures for spinal stenosis causing neurogenic claudication in the lumbar spine, the National Institute for Health and Clinical Excellence (NICE, 2006) concluded that "evidence of efficacy is limited and is confined to the medium and short term. These procedures should only be used in the context of special arrangements for consent, audit and research". Additionally, the specialist advisors to the Institute's Interventional Procedures Advisory Committee noted that given the fluctuating symptoms associated with this condition, the assessment of outcomes in clinical studies may be unreliable. Furthermore, some advisors questioned the long-term effectiveness of the procedure.

- The questions regarding the long-term effectiveness of the X-Stop raised by Christie, et al. (2005) as well as some specialist advisors of the National Institute for Health and Clinical Excellence's Interventional Procedures Advisory Committee (2006) are congruous with those raised by documents released by the FDA in 2004 prior to a public hearing on the product. The FDA's PMA review stated that "although the device can be inserted with a minimally invasive operative technique as an outpatient procedure with generally a local anesthetic a decision as to the safety and effectiveness of this device is based solely on 24 month data because information on the patient outcomes after 24 months is not available. This information becomes important when looking at pain relief and return to function. Even though the goal of the study was accomplished showing a significant, statistical difference between the investigational and control groups, more patients report improvement at 12 months than at 24 months. Contrary to what has been observed in spinal fusion studies, in this study, a percentage of patients whose symptoms improved at 6 and 12 months show a trend of regression of pain and function symptoms toward baseline levels. There appears to be a trend with early pain relief but the data suggests that in about 15% of patients initially successfully treated by the X-stop had only temporary relief".

- On August 31, 2004, the FDA's Orthopaedic and Rehabilitation Devices Panel voted 5 to 3 to recommend a "not approvable" decision on the PMA for the X-Stop. The Panel cited concern with the need to identify the patient population that is most likely to benefit from the device, noting that overall effectiveness was not demonstrated in a majority of the clinical study population. The Panel also cited concerns with the longer term effectiveness of the device (longer than two years), with potential bias in the clinical study, and with the need for radiographic or other objective evidence of the device's mechanism of effect on the spine in patients.

- As a condition of approval, the FDA has required the manufacturer to conduct a postmarketing study of the long-term safety and effectiveness of the X-Stop in patients who received the X-Stop under the Investigational Device Exemption (IDE). The FDA has required the manufacturer to conduct an additional post-approval study involving 240 patients at up to 8 clinical sites.

- Recently published guidelines from the North American Spine Society (NASS, 2007) concluded that there was insufficient evidence to support the use of the XSTOP in persons with lumbar spinal stenosis. The NASS guidelines noted: "Although the study
cited in support of this recommendation is a level I study, it is a single study. Therefore, until further evidence is published there remains insufficient evidence to make a recommendation [about the use of the XSTOP in lumbar spinal stenosis].

- In summary, the clinical value of X-Stop for patients with LSS is still uncertain. In particular, whether its reported benefit will decline over time will require more research with longer-term evaluation. Additionally, further randomized controlled studies are needed to compare these inter-spinous process implants with traditional surgical interventions such as laminectomy and/or fusion.

- In December 2004, the FDA granted 510(k) approval for ExtenSure bone allograft inter-spinous spacer device, which is a cylindrically fashioned piece of allograft bone intended to effect distraction, restore and maintain the space between 2 adjacent spinous processes and indirectly decompress a stenotic spinal canal at 1 or 2 levels. The procedure promotes fusion of the allograft to the spinous process above, while allowing motion between the allograft and the spinous process below. It is thought that this would provide a long-term solution to implant stability while retaining segmental motion. It may also be used to facilitate fusion between 2 or more adjacent spinous processes. This is similar to the action of the X-Stop device. However, there is a lack of clinical studies demonstrating effectiveness of the ExtenSure device.

- The TOPS System, a total posterior arthroplasty implant, is an alternative to spinal fusion that is designed to stabilize but not fuse the affected vertebral level following decompression surgery to alleviate pain stemming from lumbar spinal stenosis while maintaining range of motion. It is indicated for patients with lower back and leg pain resulting from moderate-to-severe lumbar spinal stenosis at a single level between L3 and L5 that may be accompanied by facet arthrosis or degenerative spondylolisthesis. The TOPS System is not available for commercial use in the United States. Enrollment for an FDA investigational device exemption study commenced in May 2008.

- In a review of the evidence on surgery for LBP for the American Pain Society's clinical practice guideline, Chou et al (2009) concluded that surgery for radiculopathy with herniated lumbar disc and symptomatic spinal stenosis is associated with short-term benefits compared to non-surgical therapy, though benefits diminish with long-term follow-up in some trials. For non-radicular back pain with common degenerative changes, fusion is no more effective than intensive rehabilitation, but associated with small-to-moderate benefits compared to standard non-surgical therapy. Moreover, they stated that although there is fair evidence that an inter-spinous spacer device is moderately more effective than non-surgical therapy for 1- or 2-level spinous stenosis, there are insufficient data to evaluate long-term benefits and harms.

- The Coflex (Paradigm Spine) is an interlaminar spinal stabilization device for persons with lumbar stenosis that is implanted following laminectomy and decompression. The device is intended to provide benefits over fusion, including durable pain relief, maintenance of spinal motion, reduced hypermobility of adjacent segments resulting in reduced degeneration at adjacent levels. A pivotal randomized controlled clinical trial is pending publication evaluating the noninferiority of the Coflex interlaminar stabilization with instrumented posterolateral spinal fusion (pedicle screw fixation) in subjects with back pain and spinal stenosis and no or mild instability (up to grade 1 spondylolisthesis).
who had failed conservative management. The primary outcome of the study is improvements in Oswestry Disability Index (ODI) score, and secondary outcomes include the Visual Analog Scale (VAS) back and leg pain, and the Zurich Claudication Questionnaire (ZCQ) score.

- Other endpoints measured include range of motion at the level adjacent to the procedure, as range of motion has been found to be related to the development of adjacent level degeneration and disease. Subjects were followed over a two-year period. Limitations of the study include the lack of blinding and the intermediate duration of the study. In addition, the study compared the effectiveness of the Coflex device with spinal fusion in spinal stenosis subjects with no instability; however, the benefits of spinal fusion in this group of subjects are uncertain.

- In a prospective, randomized, multi-center, FDA IDE trial, Davis et al (2013a) evaluated the safety and effectiveness of Coflex interlaminar stabilization compared with posterior spinal fusion (PSF) in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. A total of 322 patients (215 Coflex and 107 fusions) from 21 sites in the U.S. were enrolled between 2006 and 2010. Subjects were randomized to receive laminectomy and Coflex interlaminar stabilization or laminectomy and postero-lateral spinal fusion with spinal instrumentation in a 2:1 ratio. Overall device success required a 15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. Patient follow-up at minimum 2 years was 95.3 % and 97.2 % in the Coflex and fusion control groups, respectively. Patients taking Coflex experienced significantly shorter operative times (p < 0.0001), blood loss (p < 0.0001), and length of stay (p < 0.0001).

- There was a trend toward greater improvement in mean ODI scores in the Coflex cohort (p = 0.075). Both groups demonstrated significant improvement from baseline in all VAS back and leg parameters. Patients taking Coflex experienced greater improvement in Short-Form 12 physical health outcomes (p = 0.050) and equivalent mental health outcomes. Coflex subjects experienced significant improvement in all ZCQ outcomes measures compared with fusion (symptom severity [p = 0.023]; physical function [p = 0.008]; satisfaction [p = 0.006]). Based on the FDA composite for overall success, 66.2 % of Coflex and 57.7 % of fusions succeeded (p = 0.999), thus demonstrating non-inferiority.

- The overall adverse event rate was similar between the groups, but Coflex had a higher re-operation rate (10.7 % versus 7.5 %, p = 0.426). At 2 years, fusions exhibited increased angulation (p = 0.002) and a trend toward increased translation (p = 0.083) at the superior adjacent level, whereas Coflex maintained normal operative and adjacent level motion. The authors concluded that Coflex interlaminar stabilization is a safe and effective alternative, with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low-grade spondylolisthesis.

- In a prospective, randomized, multi-center FDA IDE trial, Davis et al (2013b) evaluated the safety and effectiveness of Coflex Interlaminar Stabilization compared with PSF to treat low-grade spondylolisthesis with spinal stenosis. A total of 322 patients from 21 sites in the U.S. were enrolled between 2006 and 2008 for the IDE trial. The current study evaluated only the subset of patients from this overall cohort with Grade 1
spondylolisthesis (99 in the Coflex group and 51 in the fusion group). Subjects were randomized 2:1 to receive decompression and Coflex interlaminar stabilization or decompression and PSF with spinal instrumentation. Data collected included peri-operative outcomes, ODI, back and worse leg VAS scores, 12-Item Short Form Health Survey, ZCQ, and radiographic outcomes at a minimum of 2 years.

- The FDA criteria for overall device success required the following to be met: 15-point reduction in ODI, no re-operations, no major device-related complications, and no post-operative epidural injections. At a minimum of 2 years, patient follow-up was 94.9 % and 94.1 % in the Coflex and fusion control groups, respectively. There were no group differences at baseline for any demographic, clinical, or radiographic parameter. The average age was 63 years in the Coflex cohort and 65 years in the fusion cohort. Coflex subjects experienced significantly shorter operative times (p < 0.0001), less estimated blood loss (p < 0.0001), and shorter length of stay (p < 0.0001) than fusion controls. Both groups experienced significant improvements from baseline at 2 years in ODI, VAS back, VAS leg, and ZCQ, with no significant group differences, with the exception of significantly greater ZCQ satisfaction with Coflex at 2 years.

- The FDA overall success was achieved in 62.8 % of Coflex subjects (59 of 94) and 62.5 % of fusion controls (30 of 48) (p = 1.000). The re-operation rate was higher in the Coflex cohort (14 [14.1 %] of 99) compared with fusion (3 [5.9 %] of 51, p = 0.18), although this difference was not statistically significant. Fusion was associated with significantly greater angulation and translation at the superior and inferior adjacent levels compared with baseline, while Coflex showed no significant radiographic changes at the operative or index levels. The authors concluded that low-grade spondylolisthesis was effectively stabilized by Coflex and led to similar clinical outcomes, with improved peri-operative outcomes, compared with PSF at 2 years.

- Re-operation rates, however, were higher in the Coflex cohort. Patients in the fusion cohort experienced significantly increased superior and inferior level angulation and translation, while those in the Coflex cohort experienced no significant adjacent or index level radiographic changes from baseline. Coflex Interlaminar Stabilization is a less invasive, safe, and equally effective clinical solution to PSF to treat low-grade spondylolisthesis, and it appears to reduce stresses at the adjacent levels.

- The major drawback associated with these 2 studies were: (i) lack of patient blinding, (ii) these studies did not assess the effectiveness of a fusion group consisting of lumbar intervertebral cages or BMP, and (iii) it is possible a subset of patients with a stable slip and with minimal back pain may benefit from decompression only, without the need for stabilization. Furthermore, long-term data are needed to ascertain if motion preservation with the Coflex device will lead to lower re-operation rates for adjacent level disease compared with fusion.

- Also, an UpToDate review on "Subacute and chronic low back pain: Surgical treatment" (Chou, 2013) does not mention Coflex/interlaminar stabilization as a therapeutic option.

References


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