

X STOP Interspinous Process Distraction for Intermittent Neurogenic Claudication

a report by

St. Francis Medical Technologies, Inc.

Lumbar intermittent neurogenic claudication (INC) secondary to spinal stenosis is a condition that typically affects patients aged 50 years and older and the mean age reported in clinical studies is often 70 years and older. Due to the elderly population that INC affects, treatment options are sometimes limited since conservative care is often ineffective and many patients are unable to undergo general anaesthesia required for a laminectomy procedure. Based on the dynamic nature of the condition, a novel interspinous implant (The X STOP® Interspinous Process Distraction (IPD) System (“X STOP”), St Francis Medical Technologies, Concord, CA, USA, see *Figure 1*) was developed to be implanted using a minimally invasive procedure under local anaesthesia.

The X STOP design was based on clinical findings that patients obtain pain relief from neurogenic claudication symptoms during sitting and flexion and have onset of symptoms during standing, walking and extension. The implant is placed between the spinous processes of the affected level(s) and prevents extension at those levels (see *Figure 2*). Following this design concept, a series of biomechanical studies were performed to test the biomechanical safety and efficacy on such a novel implant.

Biomechanical Findings

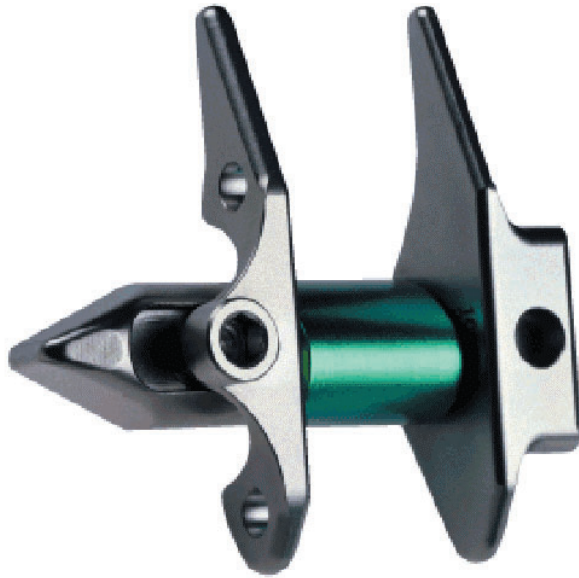
Biomechanical studies concluded that the spinous processes were strong enough to withstand the expected *in situ* loads of daily living. For example, Yerby, et al. reported that the expected load on the implant during extension was 109N, whereas the mean spinous process failure load was between 765 and 1,033N.¹ Other studies showed that the implant

was stable between the spinous processes when loaded in flexion, extension, axial rotation and lateral bending. A study using magnetic resonance imaging (MRI) images to measure spinal canal and foraminal dimensions determined that, during extension, the levels implanted with the X STOP had an increase in canal area, canal diameter and subarticular diameter of 18%, 10% and 50%, respectively; the foraminal area and width increased by 25% and 41%, respectively.² Kinematics studies demonstrated that the X STOP decreases the range of motion in extension, but does not affect axial rotation or lateral bending.³ Also, the kinematics of the adjacent levels are unaffected. Finally, two studies that focused on disc pressure and facet pressure concluded that the disc pressure decreased by 63% in the posterior annulus and 41% in the nucleus during extension,⁴ and the mean facet pressure decreased by 58%.⁵ The disc pressure and facet load were unaffected at the adjacent levels. The biomechanical findings demonstrate that the X STOP:

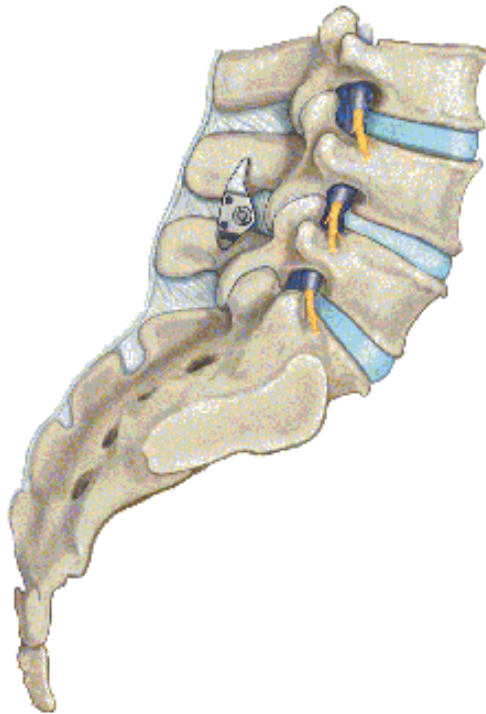
- will not result in spinous process fractures;
- will not dislodge or migrate from the interspinous space;
- is effective in preventing narrowing of the spinal canal and neural foramina;
- allows unrestricted axial rotation and lateral bending;
- reduces disc pressure and facet loads; and
- does not affect the adjacent levels.

1. S Yerby, D Lindsey and J Kreshak, “Failure load of the lumbar spinous process”, International Society for the Study of the Lumbar Spine (2001), Edinburgh.
2. J Richards, S Majumdar and D Lindsey, et al., “Quantitative changes in the lumbar spinal canal with an interspinous implant”, International Meeting on Advanced Spine Techniques (2002), Montreux, Switzerland.
3. S Yerby, D Lindsey and K Swanson, et al., “Influence of an interspinous spacer on the kinematics of the lumbar spine”, Eurospine (2002), Nantes, France.
4. K E Swanson, D P Lindsey and K Y Hsu, et al., “The effects of an interspinous implant on intervertebral disc pressures”, Spine, 28(1) (2003), pp. 26–32.
5. C Wiseman, D Lindsey and S Yerby, “The effect of an interspinous spacer on facet load during extension”, International Society for the Study of the Lumbar Spine (2003), Vancouver, Canada.



Figure 1: An Orthogonal View of the X STOP Implant (left)

The tissue expander allows for ease of insertion in the interspinous space and the spacer resists extension of the stenotic level. The wings prevent lateral and anterior migration, and the supraspinous ligament prevents posterior migration. The X STOP is placed between the spinous processes of the affected level.

Figure 2: The implant is placed between the spinous processes of the affected level(s) and prevents extension at those levels.

Clinical Findings

A randomised, prospective, multicentre study of the X STOP was performed in the US.⁶⁻⁸ One hundred patients 50 years or older were randomised to the X STOP group, and 100 patients were randomised to a control group of patients who received non-operative therapy that included at least one epidural steroid injection. Patients were followed for two years after treatment and, at each follow-up visit of six weeks, six months, one year and two years, patients completed a Zurich Claudication Questionnaire (ZCQ) that assessed the patients' symptoms and function specific to INC.^{9,10} The ZCQ is a validated outcomes measure that quantifies a patient's clinical success in symptom severity, physical function and satisfaction. The mean age of the patients in both groups was approximately 70 years. The mean operative time for the X STOP procedure was 51 minutes for a single level and 59 minutes for a double level and there was less than 60cc of blood loss in either case. All cases but three were performed under local anaesthesia and 95% of the patients returned home in less than 24 hours. At 24 months, 65% of the patients had clinical improvement in symptom severity, 64% had clinical improvement in physical function and 77% were satisfied. On the other hand, in the control group, 34% had clinical improvement in symptom severity, 30% had clinical improvement in physical function and 53% were satisfied.

During the study, nine X STOP patients and 26 control patients elected to undergo a laminectomy procedure due to lack of pain relief and completed a ZCQ following their laminectomy. Following the laminectomy, 63% of the patients had clinical improvement in symptom severity, 69% had clinical improvement in physical function and 63% were satisfied.

Conclusion

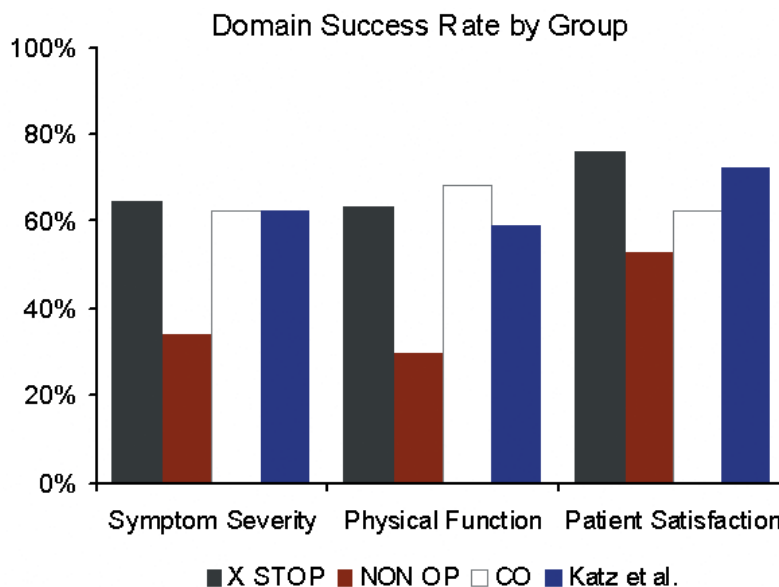
The X STOP Interspinous Process Distraction System has been demonstrated to be safe and effective from both a biomechanical and clinical

6. K Hsu, J Zucherman and C Hartjen, et al., "Symptom severity outcomes in lumbar stenosis patients treated with the X STOP interspinous process spacer and non-operative treatment", *Spine Across the Sea (2003)*, Maui, Hawaii.
7. K Hsu, J Zucherman and C Hartjen, et al., "The X STOP interspinous implant improves physical function in lumbar spinal stenosis patients", *International Society for the Study of the Lumbar Spine (2003)*, Vancouver, Canada.
8. J Zucherman, K Hsu and C Hartjen, et al., "Multicenter randomized prospective trial for treatment of lumbar neurogenic claudication with an interspinous device: one-year results", *International Society for the Study of the Lumbar Spine (2002)*, Cleveland, OH.
9. G Stucki, L Daltroy and M H Liang, et al., "Measurement properties of a self-administered outcome measure in lumbar spinal stenosis", *Spine*, 21(7) (1996), pp. 796-803.
10. G Stucki, M H Liang and A H Fossel, et al., "Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar spinal stenosis", *J. Clin. Epidemiol.*, 48(11) (1995), pp. 1,369-78.

point of view. The supporting studies show that the X STOP is significantly more effective than non-operative treatment and as effective as a laminectomy in treating patients with lumbar INC. In addition to the results presented in the current study, Katz, et al. reported on 199 INC patients treated with a lumbar laminectomy.¹¹ The patients were assessed using the same ZCQ presented in the current study; however, not all of the same results were reported by Katz, et al. Unpublished data of this patient population, however, demonstrates that 63% of the patients had clinical improvement in symptom severity, 59% had clinical improvement in physical function and 72% were satisfied. These values are similar to those of the X STOP patients and laminectomy patients in the current study (see Figure 3) and suggest that the X STOP IPD system is as effective as a laminectomy.

In addition, there were no major intraoperative or post-operative complications that occurred as a result of the procedure. The complications that occurred included a posteriorly dislodged implant in one patient following a traumatic fall, an asymptomatic spinous process fracture occurred between the six-week and six-month visits, one haematoma and one wound dehiscence. The dislodged implant was removed without sequale and the spinous process fracture healed without affecting the patient's clinical success. These complications are relatively minor compared with those associated with a laminectomy such as dural tears, neural injury, deep wound infection, pulmonary embolism, myocardial infarction and death. This suggests that the X STOP procedure is a much safer treatment for INC than a laminectomy that requires general anaesthesia and is performed directly adjacent to the neural structures.

Figure 3: ZCQ Success Rates for the X STOP, Control, Laminectomy Patients in the Current Study and Laminectomy Patients Reported by Katz, et al.



SS: symptom severity, PF: physical function, PS: patient satisfaction

In the continuum of the treatment options for patients with INC, the X STOP offers the immediate and long-lasting effectiveness of a laminectomy with the safety of conservative care. In summary, the X STOP IPD procedure:

- can be performed under local anaesthesia on an out-patient basis;
- does not require removal of bone or soft tissue;
- is safe and effective;
- is less costly than a laminectomy; and
- is clinically proven. ■

11. J N Katz, G Stucki and S J Lipson, et al., "Predictors of surgical outcome in degenerative lumbar spinal stenosis", Spine, 24(21) (1999), pp. 2,229-33.