

Interspinous Process Decompression – A Dynamic and Minimally Invasive Procedure for Neurogenic Intermittent Claudication

a report by

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Patrick Simons is a neurosurgeon at the MediaPark Klinik in Cologne, Germany, and is primarily involved in the treatment of chronic and acute backache – one of the most common diseases of modern civilisation. In addition to offering the tried and tested decompression methods for treating narrowing of the nerve canal, Dr Simons is also a leader in minimally invasive methods.

Lumbar spinal stenosis (LSS) is a condition that involves the narrowing of either the spinal canal or neural foramina. The stenosis is caused by hypertrophy of the ligament flavum and facet joints, osteophytes, spondylolisthesis and disc protrusion, which results in nerve compression in one or more motion segments.

The most common symptom associated with LSS is intermittent neurogenic claudication (INC) and typically affects patients aged 50 years or older. INC is defined as pain or numbness in the buttocks, thighs and/or legs brought on by either prolonged standing or exercise in an upright position. INC is typically relieved by various manoeuvres that flex the lumbar spine, such as bending forward or sitting, which increases the spinal canal significantly. Decompressive surgery with or without fusion is the current 'gold standard' treatment for moderate to severe symptomatic LSS.

Interspinous Process Decompression

A minimally invasive, stand-alone alternative to conservative and decompressive treatments has been developed – interspinous process decompression (IPD). The interspinous implant (X STOP^{PK}® St. Francis Medical Technologies, Inc.) is placed between the spinous processes to prevent extension of the symptomatic levels, but allows flexion, axial rotation and lateral bending while decompressing the nerves.

Biomechanical studies have shown that, in extension, the implant significantly increases the canal area, the subarticular diameter, the canal diameter, the foraminal area and the foraminal width. These biomechanical results demonstrate the primary mechanism of action of the X STOP implant, the increase of areas that cause nerve compression and accompanying symptoms such as INC. The results have been corroborated by a clinical study in man.

Further studies have demonstrated that the implant significantly reduces pressure on the facets at the implanted level and reduces the pressure in the nucleus pulposus and posterior annulus of the disc. A known

and common side effect of spinal procedures is the influence on the adjacent levels, which may develop degenerative disorders of these adjacent levels. The studies described demonstrated that the X STOP has no significant effect on the adjacent levels, and may prevent the development of disorders at these levels.

Surgical Procedure

Patients may be operated on under local or general anaesthesia and are positioned in a flexed, either prone or lateral decubitus, position. A mid-line incision of between four and eight centimetres is made exposing the spinous processes at the affected disc level, which is confirmed radiographically. The interspinous ligament is pierced, but retained, and the implant is placed between the spinous processes. The spinous processes are not modified to allow implantation but, in cases where hypertrophied facets protrude posteriorly, they should be trimmed without interfering with its integrity in function. The supraspinous ligament is preserved, which is important in preventing post-operative kyphosis, and also serves to stabilise the implant.

X STOP IPD Compared with Conservative Therapy

Early in 1997, 10 patients with symptomatic LSS underwent implantation of the interspinous implant in a clinical pilot study. Eight of the patients showed some level of improvement in symptom severity (SS), physical function (PF), walking distance or all three.

On the basis of these very promising results, a prospective, randomised, multicentre study was conducted in which 191 patients were treated; 100 patients received the X STOP and 91 received conservative (non-operative) treatment. Patients with INC secondary to mild or moderate LSS were eligible for enrolment specified by leg, buttock or groin pain with or without back pain that could be relieved during flexion. At one year, 59% of the patients were successfully treated, compared with 9% of the patients of the group treated with the

conservative method. Two years after surgery, 60% of the patients reported that their symptoms were significantly improved, compared with 18% of the control patients. Regarding PF, 57% of the X STOP patients reported significant improvement, compared with 15% of control patients. Among X STOP patients, 73% were satisfied or very satisfied with their treatment, compared with 36% of the control group patients. Overall, 48% of the patients of the X STOP group were successful, while only 5% of the conservative treatment was successful (see Table 1).

Recently, four-year results were reported for a subgroup of the study population (29 patients) of the study described. The preoperative average Oswestry Disability Index (ODI) score in the X STOP group was 45 versus 37 in the laminectomy group. The four-year post-operative average ODI score in the X STOP group was 15 versus 27 in the laminectomy group. Using a 15-point improvement from baseline ODI score as a success criterion, 14 out of 18 patients (78%) had successful outcomes.

X STOP IPD Compared with Decompressive Surgery

Studies of decompressive laminectomy patients

Table 1: Significant Improvement Rate Two Years After Surgery

	X STOP (n=93)	Control (n=81)	p-value
Symptom severity	60%	19%	<0.001
Physical function	57%	15%	<0.001
Patient satisfaction	73%	36%	<0.001

have shown that 30–70% of patients report significant symptom improvement. A meta-analysis of 74 surgical therapy studies for LSS shows an average rate of 64% with ‘good’ or ‘excellent’ results in the course of the first year.

However, there are significant differences in operative time, estimated blood loss, hospital stay, complication rate and reoperation rates.

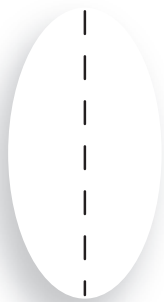
The meta-analysis reported such complications as dural fissures, nerve injuries, deep wound infections, embolism of the lung, epidural haematoma, myocardial infarction and death. For the X STOP device, no complications of this nature were reported during or after the X STOP procedure. ■

A longer version of this article containing references and images can be found in the Reference Section on the website supporting this briefing (www.touchbriefings.com).

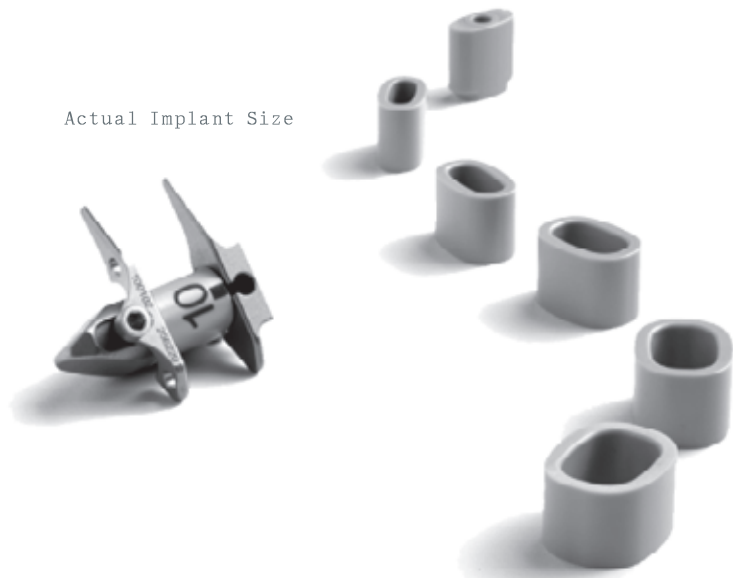
X·STOP^{FX}® IPD System

Interspinous Process Decompression

Actual Incision Size*



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