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X STOP interspinous implant for lumbar spinal decompression

Neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS) is a posture-dependent complaint and it typically affects patients at the age of 50 years or older. NIC is defined as pain or numbness in the buttocks, thighs, and/or legs caused by decrease of the spinal canal and brought on by either prolonged standing or exercise in the erect posture. The symptom is typically relieved by various manoeuvres that flex the lumbar spine, which increases the spinal canal significantly.¹⁻⁹ Decompressive surgery with or without fusion is the current “gold standard” treatment for moderate to severe symptomatic LSS.

Interspinous Process Decompression (IPD)

A new minimally invasive, stand-alone alternative to conservative and standard surgical decompressive treatments has been developed.¹⁰⁻¹³ The interspinous implant (X STOP, St Francis Medical Technologies, Inc.) is placed between the spinous processes to prevent extension of the symptomatic levels, yet allowing flexion, axial rotation and lateral bending.¹⁴

Clinical and pre-clinical studies have shown that the implant significantly increases the dimensions of the neural pathways at the treated segment.¹⁵⁻¹⁷ Studies have also demonstrated that, at the implanted level, the implant significantly reduces the pressure on the facets in the nucleus pulposus and in the posterior annulus of the disc, without influence on adjacent levels.¹⁷⁻¹⁹

Surgical procedure

Patients may be operated on under local anaesthe-

sia with light intravenous sedation, placed in either lateral decubitus or prone position. A 4–8cm mid-line incision is made exposing the spinous processes at the appropriate level, which is confirmed radiographically. The supraspinous ligament is preserved, which is important to prevent postoperative kyphosis, and also serves to stabilise the implant. The interspinous ligament is pierced, but retained, and the implant is placed between the spinous processes (Figure 1).

Clinical results in literature

Prospective multicentre study Based on very promising results of a clinical pilot study of ten symptomatic LSS patients treated with the X STOP, a USA-FDA prospective randomised clinical multicentre study was undertaken that compared the interspinous implant with conservative (non-operative) treatment for the management of NIC. Two year results demonstrated a clinically and statistically significant difference favouring the interspinous implant (Table 1).²⁰

In this study, more than a third of the patients treated with the X STOP implant suffered from a degenerative spondylolisthesis up to grade 1 (out of 4). Spondylolisthesis patients are mostly treated with an instrumented spinal fusion. Analysis of this subgroup showed that the X STOP procedure is as effective as applied on patients without spondylolisthesis.²¹

X STOP versus decompressive laminectomy The success rate of decompressive surgery varies greatly due to a number of factors such as patient selection, surgical technique and outcome measures. An attempted meta-analysis of 74 surgi-

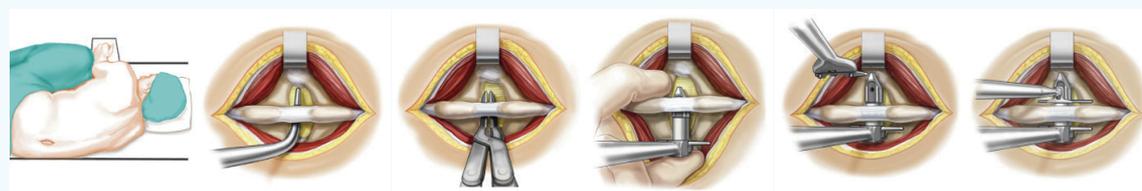


Figure 1. The X STOP IPD implant procedure

Contact

SFMT Europe BV
Hoofdstraat 248
3972 LK Driebergen
The Netherlands
T:+31 34 352 3890
E:info@sfmteurope.com
W:www.sfmt.com

Author

J Timothy FRCS (SN)
Consultant Neurosurgeon
Leeds General Infirmary,
Department of
Neurosurgery
Leeds, UK



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Table 1. ZCQ Success Rates 2 years after surgery

	X STOP (N=93)	Success rates Control (N=81)	P-value
Symptom severity	60%	19%	<0,001
Physical function	57%	15%	<0,001
Patient satisfaction	73%	36%	<0,001

References

- Porter RW. *Spine* 1996;21:2046-2052.
- Schonstrom N, et al. *J Orthop Res* 1989;7:115-21.
- Verbiest H. *J Bone Joint Surg* 1954;36B:230-7.
- Willen J, et al. *Spine* 1997;22:2968-76.
- Blau JN, Logue V. *Brain* 1978;101:211-222.
- Chung SS, et al. *Skeletal Radiol* 2000;29:217-223.
- Dong G, Porter RW. *Spine* 1989;14:965-969.
- Inufusa A, et al. *Spine* 1996;21:2412-2420.
- Penning L, Wilmink JT. *Spine* 1987;12:488-500.
- Zucherman JF, et al. *Eur Spine J* 2004;13:22-31.
- Zucherman JF, et al. In: *Trans Int Meeting on Advanced Spine Techniques* 2002; Montreux.
- Zucherman JF, et al. In: *Trans North American Spine Society* 2002; Montreal.
- Zucherman JF, et al. In: *Trans Eurospine* 2002; Nantes, France.
- Lindsey DP, et al. *Spine* 2003;28:2192-2197.
- Smith FW, et al. In: *Trans ASSR* 2005; San Juan, Puerto Rico.
- Siddiqui M, et al. In: *Trans World Spine* 2005; Rio de Janeiro, Brazil.
- Richards JC, et al. *Spine* 2005;30:744-9.
- Wiseman CM, et al. *Spine* 2005;30:903-7.
- Swanson KE, et al. *Spine* 2003;28:26-32.
- Zucherman JF, et al. *Spine* 2005;30:1351-8.
- Anderson PA. In: *Trans ISSLS* 2005 New York, USA.

cal LSS studies reported a mean rate of good to excellent outcomes of 64% in the first year. The most definitive finding of this literature analysis was the poor scientific quality of the published studies. None of the 74 studies were randomised and just three studies were clearly prospective.²²

Compared to literature-reported outcomes of decompressive surgery there are significant differences in operative time, estimated blood loss, hospital stay, complication rate and re-operation rates, favouring the X STOP IPD (Table 2).²³⁻³⁵

Both the multicentre study in the USA and Strömquist et al, as part of the Swedish national register of lumbar surgery, used the SF-36 to evaluate general health outcomes after surgical treatment.³⁶ A comparison between two matched subsets of patients, 90 each, showed that the post-operative scores were improved for both groups in all domains except for general health one year after surgery.³⁷

Mean postoperative scores in the two physical and emotional domains improved more markedly for the X STOP group.

Okumu and Hannibal evaluated the cost and effectiveness of X STOP and laminectomy surgery during index hospitalisation for the treatment of 33 patients with LSS in the USA.³⁸ Patients were matched for age, number of levels treated and pre-operative disability. It was shown that X STOP is significantly more cost effective than laminectomy for the treatment of single and double level LSS (Table 3).

Turner et al reported on complications such as

dural tears, neural injuries, deep wound infections, pulmonary embolism, myocardial infarction and death in their meta-analysis of 74 LSS surgery studies.²² To date, with the exception of a death that occurred three days postoperatively and was determined to

be unrelated to the X STOP implant, there were no complications of this nature reported during or after the X STOP procedure.

European clinical experience Timothy et al reported on preliminary experience of the X STOP implant in 10 patients with LSS.³⁵ Six months after surgery all patients reported an improvement in symptoms.

A prospective clinical evaluation of 15 patients with three and six month follow-up was carried out by Wardlaw et al in conjunction with pre- and postoperative positional MRI scan measurements.³⁹ All cases demonstrated clinical improvement and the X STOP implant increased the cross-sectional area of the dural sac and exit foramina without affecting the overall movement of the lumbar spine.

Heijen and Kramer reported on the satisfaction of 14 patients with NIC, who were treated with the X STOP implant.⁴⁰ 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.

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 Zurich Claudication Questionnaire (ZCQ). This is the only validated, LSS specific outcomes measure.^{41,42} The questionnaire consists of three domains: Symptom Severity (SS), Physical Function (PF), and Patient

Table 2. X STOP decompression vs laminectomy

Operative and hospitalisation details	X STOP	Laminectomy
Average OR time (minutes)	27-54	104-224
Average blood loss (cc)	46	120-1040
Average length of hospital stay	< 24 hours - 2 days	7-8 days
Operative or device related complications	7%	20% (with arthrodesis) 14% (without arthrodesis)
Re-operation rate	6%	10-23%



Table 3. X STOP vs laminectomy: Average hospital costs for single and double level LSS

	Laminectomy 1 level	Laminectomy 2 levels	X STOP 1 level	X STOP 2 levels
Hospital Charges	\$10,446	\$9,797	\$561	\$412
Lab/EKG	\$1,314	\$1,531	\$481	\$673
OR/OR supplies	\$23,605	\$22,768	\$6,588	\$7,105
X-Rays	\$1,366	\$847	\$2,106	\$3,347
Pharmaceuticals	\$4,764	\$4,935	\$1,153	\$1,254
Anesthesia	\$2,184	\$2,228	\$356	\$229
Other	\$1,652	\$3,632	\$314	\$332
Sub-total	\$45,331	\$45,739	\$11,559	\$13,353
Hardware (est)			\$5,500	\$11,000
Total	\$45,302	\$45,739	\$17,059	\$24,353

Satisfaction (PS). To date 58 of 111 patients have been evaluated one year after surgery with good results (Table 4). Two patients had a re-operation because of lack of efficacy and one because of dislocation of the implant.

In addition to the German results presented here, Katz et al reported outcomes with two year follow-up on 197 NIC patients treated with a lumbar laminectomy using the same success criteria in a patient population similar to those enrolled in the registry.³⁰ The German X STOP patients show higher ZCQ-success rates compared to the scores of the laminectomy patients (Figure 2).

Conclusion

The decompression of the lumbar spine with X STOP IPD implant 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 anaesthetic and many patients can return home within 24 hours of surgery.

In brief, regarding X STOP decompression of the lumbar spine:

- It is clinically well proven as an effective treatment for symptoms of LSS with or without

Table 4. ZCQ success rates 1 year after surgery

	ZCQ Success rates
Symptom Severity	84%
Physical Function	78%
Patient Satisfaction	81%

out degenerative spondylolisthesis.

- It is safe.
- It has a short surgery time and can be made under local anaesthesia.
- It is minimally invasive.
- It can be implanted during a short stationary or ambulatory stay.
- There is an immediate and subsistent relief of pain.
- It is cost-effective.

The X STOP implant offers the benefits of decompression, yet with a low risk profile, for NIC patients.

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.

However, mainly due to flaws in studies on decompressive laminectomy, no definitive conclusions can be drawn. ■

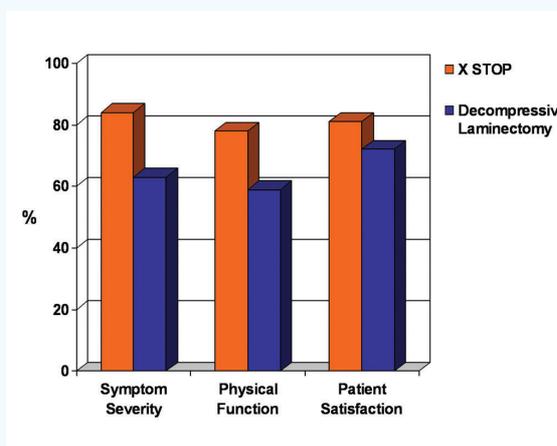


Figure 2. ZCQ-success rates: X STOP versus laminectomy patients reported by Katz et al

References

- Turner JA, et al. *Spine* 1992;17:1-8.
- Benz RJ, et al. *Clin Orthop* 2001;384:116-121.
- Deyo RA, et al. *J Bone Joint Surg* 1992;74A:536-43.
- Iguchi T, et al. *Spine* 2000;25:1754-1759.
- Postacchini F, et al. *J Bone Joint Surg Br* 1993;75:386-92.
- Hu RW, et al. *Spine* 1997;22:2265-71.
- Jonsson B, et al. *Spine* 1997;22:2938-44.
- Katz JN, et al. *J Bone Joint Surg Am* 1991;73:809-16.
- Katz JN, et al. *Spine* 1996;21:92-8.
- Hu RW, et al. *Spine* 1997;22:2265-71.
- Jonsson B, et al. *Spine* 1997;22:2938-44.
- Katz JN, et al. *J Bone Joint Surg Am* 1991;73:809-16.
- Katz JN, et al. *Spine* 1996;21:92-98.
- Timothy J, et al. *Br J Neurosurgery* 2005; abstract, in press.
- Strömquist B, et al. *Acta Orthop Scand* 2001;72:99-106.
- Strömquist B, et al. In: *Trans Eurospine* 2004; Porto, Portugal.
- Okuma K, Hannibal M. In: *Trans ISSLS* 2005; New York, USA.
- Wardlaw D. In: *Trans ISMISS* 2004; Zurich, Switzerland.
- Heijen SAF, Kramer FJK. *Ned Tijdschrift voor Orthopaedie* 11(4):199-203.
- Stucki G, et al. *J Clin Epidemiol* 1995;48:1369-78.
- Stucki G, et al. *Spine* 1996;21:796-803.