

## Interspinous implant in lumbar spinal stenosis: a prospective cohort

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### Abstract

**Study design** Prospective study on clinical outcome of interspinous process distraction with X-STOP in patients with lumbar spinal stenosis.

**Purpose** To determine the safety and efficacy of X-STOP interspinous distractor.

**Method** A total of 45 patients (24 males, 21 females) with lumbar spinal stenosis were treated with X-STOP system. They had preoperative and postoperative (3, 6 and 12 months) assessments using the Back and Sciatica Questionnaire, the Oswestry Disability Index (ODI) and the SF12 Questionnaire. Patient satisfaction was assessed at each visit.

**Results** The average VAS of back and leg pain was 6.7 and 6.8 preoperatively and improved to 2.7 and 2.8 postoperatively. A total of 68% had improvement in their walking distance following the operation. The average preoperative ODI of 42% improved to 16.38% postoperatively ( $P < 0.0001$ ). A total of 70% of patients had improvement in physical score and 80% in mental score. A total of 82% were very satisfied with the outcome of the operation.

**Conclusion** X-STOP implant is clinically effective with fewer complications and it is a simple procedure.

**Keywords** Lumbar spinal stenosis · Neurogenic claudication · Distractor · Efficacy

### Introduction

Lumbar spinal stenosis is a narrowing of spinal canal or neural foramina producing root ischaemia and neurogenic claudication [1–3]. Both the neural canal and foramen are narrowed with the spine in extension and opened in flexion. Patients are usually 60 years or over and present with unilateral or bilateral leg pain with or without back pain. The pain is worse on walking and if the patient is upright and relieved by sitting or bending forward [1–3]. With increasingly ageing population this is a common problem and difficult to deal with as many of the elderly patients have associated co-morbidities making them unsuitable for conventional decompressive surgery [4, 5]. Although lumbar spinal stenosis is one of the most frequent indications for spinal surgery in patients over 65 years of age [6], deciding the most appropriate procedure is a challenge to the clinicians. X-STOP interspinous implant is a titanium device. It was developed to prevent extension and also increase the dimension of spinal canal and neural foramina [5]. We are reporting the clinical outcome and patient satisfaction following indirect decompression with X-STOP.

### Methods

This is a prospective observational study on clinical outcome and patient satisfaction. A total of 45 patients (24 males, 21 females) with mean age of 61.5 years (range 52–94 years) underwent X-STOP implantation during the period of June 2004–January 2006. All the patients had preoperative X-ray and MRI scan of lumbosacral spine confirming lumbar significant spinal stenosis. Ten patients had three levels implantation, 20 had two levels and 15 had single level done (Table 1).

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**Table 1** Different levels of X-STOP implantation, L4/5 was the commonest level

Level of X-STOP implantation	Number
L 3/4 single level	1
L 4/5 single level	6
L 5/S 1 single level	8
L 2/3, L 4/5 two levels	4
L 3/4, L 4/5 two levels	6
L 4/5, L 5/S 1 two levels	10
L 2/3, L 3/4, L 4/5 three levels	5
L 3/4, L 4/5, L 5/S 1 three levels	5

The inclusion criteria were patients with minimum age of 50 or over, presenting with moderate to severe neurogenic claudication which has not resolved with conservative management like medication, physiotherapy and or caudal epidural injection and also patient's choice.

Patients with motor deficit, cauda equina syndrome, previous spinal surgery at the same level, and spondylolisthesis greater than grade I were excluded.

A total of 70% patients had symptoms of neurogenic claudication for over 2 years and all of them tried conservative management with medication and physiotherapy and or epidural injection but either failed to resolve symptoms or got worse. L4/5 level was the most common site of stenosis (Table 1) and naturally the implantation.

The surgery was performed by two surgeons and the outcome was analysed by an independent member. The clinical outcome and efficacy were assessed using the Back and Sciatica Questionnaire, the Oswestry Disability Index (ODI) and SF12 Questionnaire preoperatively and postoperatively at 3, 6 and 12 months. Visual analogue scale (VAS) of back and leg pain and walking distance were recorded pre- and postoperatively.

Patient's satisfaction was assessed as very satisfied, satisfied or not satisfied. Patient's analgesic requirement was recorded both pre- and postoperatively. A total of 30 patients had minimum follow-up of 24 months (24–30 months) and 15 had minimum of 18 months (18–21 months). Results were analysed using appropriate nonparametric statistical tests, paired 't' test with  $P < 0.05$  as significant.

#### Surgical technique

Patient is placed in prone position. The incision is given along the midline, through paraspinous approach; muscles are distracted to one side preserving supraspinous and interspinous ligaments. A distractor is inserted into the interspinous space and the size of the implant measured. The implant consists of two components—spacer assembly and wing assembly. The spacer assembly is placed in between

the spinous processes. By making another incision about 1 cm lateral to midline, distracting the paraspinous muscles the wing assembly is locked to the spacer assembly. The lateral wings prevent anterior and lateral migration, and the supraspinous ligament prevents posterior migration.

#### Radiography

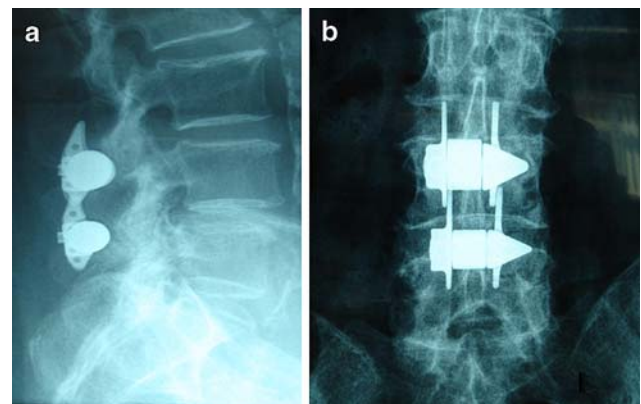
All patients underwent an anteroposterior and lateral plain radiographs of the lumbar spine in the neutral or standing position. The distance between the spinous processes, anterior and posterior disc height and angle at the implanted level of the implanted levels of X-STOP was compared between the 6-week, 1 and 2-year radiographs using the sagittal radiographs (Fig. 1a, b).

#### Results

None of the patients was lost during the follow up. The surgeons were able to complete implantation in all the patients and there was no major per operative complication. The average duration of multi-level implantation was 50 min. The average hospital stay was 2 days (range 1.5–3 days). The mean blood loss for multilevel implantation was 50 (SD 15) ml.

A total of 68% had significant improvement in the walking distance following the operation. Preoperatively 20% of patients could walk less than 100 yards before they had to rest, 43% less than 0.5 mile, 20% between 0.5 and 1 mile and only 17% could walk more than 1 mile at a stretch. This improved postoperatively to only 0.03% in the less than 100 yards group, 17% less than 0.5 mile, 23% between 0.5 and 1 mile and encouraging 59% being able to walk more than a mile at a stretch.

The mean VAS of back and leg pain improved from 6.7 and 6.8 preoperatively to 2.7 and 2.8 postoperatively.

**Fig. 1 a, b** Postoperative lateral and anteroposterior X-ray of lumbosacral spine and confirming the satisfactory position of implants

Improvement in the ODI score by 12% or more was taken as significant. A total of 90% patient had improvement in their ODI score ( $P < 0.0001$ ) with average preoperative score of 42% (range 10–82%) and postoperative score of 16.4% (range 0–58%) respectively (Table 2).

With the SF12 questionnaire the mean preoperative physical and mental subscore was 11.31 and 16.54, respectively and improved to 16.04 and 22.76 postoperatively (Table 2). A total of 70% patients had significant improvement in physical score ( $P = 0.0003$ ) and 80% in the mental score ( $P = 0.005$ ). The SF12 preoperative average pain score of 2.04 improved to 3.95 following the operation.

Consumption of nonsteroidal anti-inflammatory drugs and morphine derivatives had significantly decreased. Before the surgery all patients took analgesic regularly (at least twice a day). At follow-up 55% stopped taking any analgesic and another 35% took occasionally (less than once a day) and 10% regularly.

A total of 82% were very satisfied or satisfied with the operation.

Distraction was maintained in 97% of the levels implanted with the X-STOP, defined as no measurable change in the distance between the spinous processes when radiographs taken at the 6 week follow-up were compared with radiographs taken at the 1 and 2-year follow-up. The angle at the implanted level was also maintained during the follow up (Table 3).

The MRI scan (Figs. 2a, b; 3a, b) postoperatively confirmed improvement in the canal diameter on axial view and widening of neural foramina on coronal view.

**Complications**

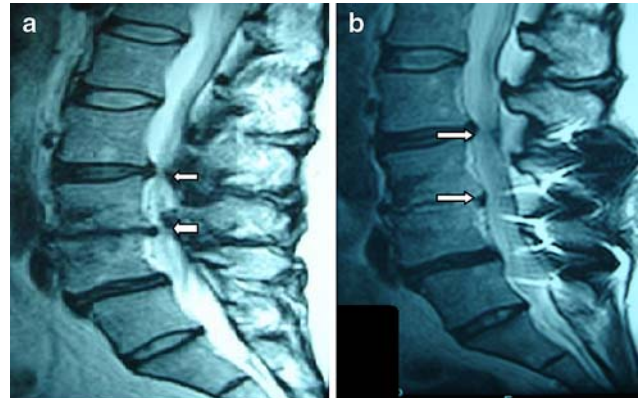
Two (6.6%) patients had superficial wound infection which settled down with oral antibiotic. One had revision surgery as his symptoms persisted even after 9 months following the operation and further MRI scan of lumbosacral spine confirmed significant central disc prolapse and eventually he had microdiscectomy for the same level.

**Discussion**

This study evaluates the clinical outcome, safety and efficacy of X-STOP in the treatment of lumbar spinal steno-

**Table 3** Preoperative and follow up radiographic analysis

	6 weeks postop	1 year postop	2 years postop
Spinous process distance (mm)	52.4 (7.2)	52.2 (7.4)	51.7 (7.2)
Anterior disc height (mm)	9.6 (4.3)	9.2 (4.1)	9.0 (4.1)
Posterior disc height (mm)	5.4 (2.5)	5.3 (2.3)	4.9 (2.3)
Implanted level angle (°)	14 (7.3)	14.6 (7.1)	14.6 (7)



**Fig. 2** a Preoperative, b Postoperative. a, b Sagittal MRI (T2 weighted) of lumbosacral spine showing degenerative disc at multiple levels and foraminal narrowing at L3/4, 4/5, L5/S1 with L3/4 being the worst (a). Postoperative scan (b) shows foraminal widening and X-STOP in situ at the same levels

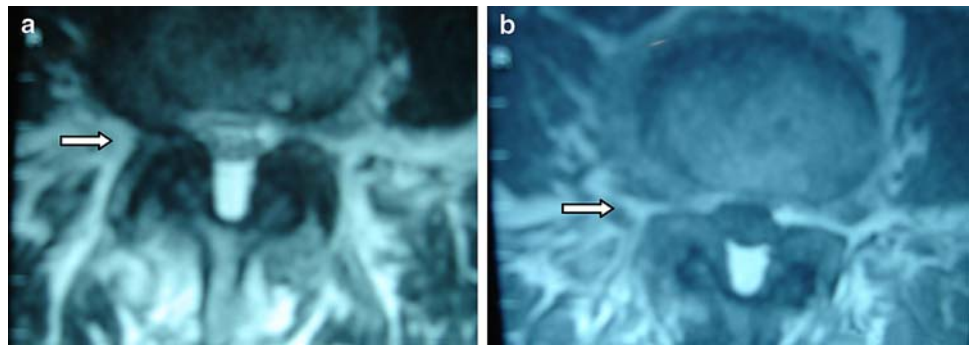
sis specially in elderly patients. With increasingly ageing population and more advanced diagnostic choices [7] for back pain surgeons are facing more challenging job of deciding the nature of surgery. Several studies have reported that the presence of co-morbidities is associated with worse symptoms, function, satisfaction and over all worse scores in most of the outcome measurements [8–10].

We have done literature search to compare the outcome of our study with those on the safety and efficacy of decompressive laminectomy. Johosson et al. [11] reported 60% of patients with LSS treated surgically as improved. In a study by Katz et al. [8] 63% patients significantly improved in symptoms severity, 59% were improved in physical function. Gunzburg et al. [12] reported that 58% had improvement in three of four outcome measures (VAS, ODI, Waddell Disability Index, Low back outcome score). Airaksinen et al. [10] reported that 88% of their patients had improvement in the ODI score. The outcome in our

**Table 2** Pre and postoperative pain and SF12 scores

	VAS leg pain	VAS back pain	ODI	SF12 physical score	SF12 mental score
Preop	6.7 (0–10)	6.8 (1–9)	42% (10–82)	11.31 (6–15)	16.54 (6–24)
Postop	2.7 (0–7)	2.8 (0–5)	16.4% (0–58)	16.04 (10–20)	22.76 (11–27)

**Fig. 3** **a** Preoperative, **b** Post-operative. **a**, **b** showing axial MRI (T2 weighted) of lumbar spine. **b** Shows decompression of right L4 nerve root shown (white arrow)



series (90% improved in ODI score, 70% in physical score, 80% in mental score) is comparable or better.

Despite comparable outcome of X-STOP and other surgical decompressions reported in the literature there is significant difference in associated complications [20]. The mean operative time (50 min for multilevel implantation) and blood loss (50 ml) with X-STOP were considerably less than that reported for decompressive surgery [13–15]. Major complication reported for laminectomy with or without fusion includes paralysis, myocardial infarction, pulmonary embolism, haematoma, deep vein thrombosis, neurodeficit, deep infection, implant failure [15–17]. None of these complication happened in our series. So the X-STOP procedure is simple, minimally invasive [19] and likely safer.

Patient satisfaction is one of the most important indicators of good outcome of any procedure. Katz et al. [6] reported 75% patients were satisfied with decompressive surgery. Galliano et al. [18] reported that 65% patients had a general satisfaction after surgery. The satisfaction rate in patients undergoing X-STOP (80%) is comparable to the above groups of decompression surgery.

Our results are consistent with the data already published by Zucheman et al. [20] with a 2 year follow up.

There are limitations to the study. The cohort of operated patients is small and longer follow-up is needed. There is also lack of control groups. We will be continuing to collect data for bigger cohort and longer duration, but the short term clinical outcome with X-STOP is encouraging.

## Conclusion

Interspinous process distraction with X-STOP is simple but effective and safe procedure without significant morbidity. In the elderly patients with associated co-morbidities X-STOP is a good choice with comparable results to decompressive surgery.

**Conflict of interest statement** No funds were received in support of this study.

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