

# One-Year Results of X STOP Interspinous Implant for the Treatment of Lumbar Spinal Stenosis

Manal Siddiqui, FRCS,\* Francis W. Smith, MD,† and Douglas Wardlaw, FRCS, ChM\*

**Study Design.** Prospective observational study.

**Objective.** To prospectively assess the clinical outcome of patients with symptomatic lumbar spinal stenosis before and at periodic intervals after X Stop implantation and to compare the data with previous studies.

**Summary of Background Data.** The X Stop Interspinous Process Distraction Device is a relatively new interspinous implant designed for patients with symptomatic spinal stenosis particularly neurogenic claudication. Previously, a randomized study has shown a 75% improvement in symptoms and physical function at 1-year post-X Stop implantation for lumbar spinal stenosis. The only other study is a preliminary report of only 10 patients with variable intervals of clinical outcome assessment.

**Method.** 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. They were clinically evaluated at the preoperative, 3-month, 6-month, and 1-year stage with clinical questionnaires (Zurich Claudication Questionnaire, Oswestry Disability Index, and SF-36).

**Results.** Sixteen patients failed to complete all the questionnaires at all time intervals and hence were excluded, leaving 24 patients who had completed all questionnaire at all time interval. By 12 months, 54% of these 24 patients reported clinically significant improvement in their symptoms, 33% reported clinically significant improvement in physical function, and 71% expressed satisfaction with the procedure. 29% of the patients required caudal epidural after 12 months after surgery for recurrence of their symptoms of neurogenic claudication.

**Conclusion.** The results of this prospective observational study indicate that X Stop offers significant short-term improvement over a 1-year period. It is a safe, effective, and less invasive alternative for treatment of lumbar spinal stenosis. Our results, however, are less favorable than the previous multicenter, randomized study.

**Key words:** X Stop, lumbar spinal stenosis, prospective study. *Spine* 2007;32:1345–1348

Since the time of Verbiest,<sup>1,2</sup> lumbar spinal stenosis and neurogenic claudication have been well described in the literature.<sup>3–8</sup> The pathology lies in the compression of the neural elements at the motion segment by herniated nucleus pulposus, infolding of ligamentum flavum, thickened lamina, spondylolisthesis, or facet arthrosis leading to central, lateral, or foraminal stenosis.<sup>9–11</sup>

Symptoms of spinal stenosis are often postural with standing and lumbar extension exacerbating and flexion relieving leg pain, tingling, and weakness.<sup>4,5,12–15</sup> The treatment options may vary from activity modification, nonsteroidal anti-inflammatory drugs, physiotherapy, and epidural injection for those with mild symptoms or unfit for surgery to surgical decompression with or without fusion in patients who fail to respond to conservative measures.

Previous biomechanical studies in cadavera have shown the device to increase the dimensions of the canal and neural foramina, reduce extension, and allow flexion and unrestricted axial rotation and lateral bending at the level of implantation.<sup>16,17</sup> Zucherman *et al*, in a prospective, multicenter trial,<sup>18,19</sup> randomized patients into those being offered X Stop and those prescribed nonoperative therapy for symptoms of spinal stenosis. At 1- and 2-year follow-up, their clinical results have shown this device to offer significant improvement over conservative care and be a suitable alternative to surgical decompression in patients with lumbar spinal stenosis and postural exacerbation of symptoms.<sup>18,19</sup>

Based on the results of the above study, we designed this prospective study, which evaluates the 1-year clinical results of X Stop in symptomatic lumbar spinal stenosis.

## ■ Methods

Ethical approval for this project was sought from and granted by the appropriate local authority (Grampian Ethical Approval Committee). Forty consecutive patients over a 36-month-period were enrolled in the study. There were equal number of males and females. Our inclusion criteria were age of 50 years or older with leg or buttock pain with or without back pain while standing or walking, which is at least partly relieved on sitting. Also, patients should have had a failed trial of conservative treatment with analgesics, physiotherapy, and caudal epidural. All 24 patients in the study had undergone caudal epidural injections for symptomatic relief that lasted from a few weeks to a few months. Additionally, MRI confirmed diagnosis of stenosis at 1 or 2 levels. All patients underwent a preoperative and a 6-month postoperative positional upright MRI scan in standing and sitting in flexed and extended postures. The exclusion criteria were as follows: unremitting spinal pain in any position; cauda equina syndrome, defined as neurocompression causing bowel or bladder incontinence or reten-

From the Departments of \*Orthopaedics and †Radiology, Woodend Hospital, Aberdeen, Scotland.

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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tion; pathologic fractures of the vertebrae; severe osteoporosis of the spine; body mass index greater than 40 kg/m<sup>2</sup>; presence of active infection; Paget's disease at the involved segments or spinal metastases; and spinal anatomy such as ankylosing spondylitis or fusion at the affected level.

Patients were asked to complete Zurich Claudication Questionnaire (ZCQ), Oswestry Disability Index (ODI), and SF-36 before surgery, at 3 months, 6 months, and 1 year. ZCQ has been validated as a tool to assess outcome in lumbar spinal stenosis.<sup>20-22</sup> The ZCQ has 3 sections: symptom severity, physical function, and post-treatment patient satisfaction. The symptom severity section has 7 questions that can receive a score from 1 to 5; the physical function section has 5 questions that can receive a score from 1 to 4; and the patient satisfaction section has 6 questions that can receive a score from 1 to 4. Scores of each section are averaged, and the lower the score; the better the outcome. A minimum difference of 0.5 between 2 time intervals is regarded as clinically significant.

The surgical technique for implantation of the interspinous device was as follows: the patients were administered local anesthetic with sedation after placing them in right lateral decubitus posture with their spines flexed on a radiolucent table. General anesthetic was needed in only a few patients. All patients received a single preoperative and 2 doses after surgery of Augmentin. The surgical levels were identified using fluoroscopy. 0.5% of bupivacaine with adrenaline was also infiltrated in the area of the planned incision for hemostasis. A midsagittal incision was made over the stenotic segment and the musculature elevated off the laminae and facets. A curved dilator was inserted as far anteriorly as possible in the interspinous space piercing the interspinous ligament. Then a sizing distractor was inserted in the same area to determine the implant size. Next the X Stop device was inserted into the interspinous space using an insertion instrument as far anteriorly and as close to the posterior aspect of the lamina as possible. An adjustable wing was fastened to the implant, and the incision closed. No bony or ligamentous resection is carried out, and the spinal canal is not breached, thereby preserving the anatomy of the operated segment and eliminating the risk of neural surgery that occurs infrequently with formal surgical decompression. Blood loss was minimal. Patients were admitted a day before surgery. Patients were allowed to mobilize independently either the same day as the operation or the next day and discharged home as soon as clinical and social/domestic circumstances would allow.

## ■ Results

Forty consecutive patients over a 36-month period (January 2003 through December 2006) were enrolled in the study. Two patients (5%) were excluded from the study because intraoperative fracture of spinous processes during the X Stop procedure led to conversion to a formal surgical decompression. One patient was declared unfit for surgery due to exacerbation of preexisting medical comorbidities.

Of the remaining 37 patients, 8 had either incompletely finished or not completed their SF-36 questionnaires, 10 had not or incompletely filled in the ZCQ Questionnaire, and 11 had ODI questionnaires lacking at 1 or more follow-up times.

**Table 1. Coexisting Comorbidities (n = 24)**

Illness	% of Patients
Coronary artery disease	33
Hypertension	12
Peripheral vascular disease	4
Diabetes mellitus	8
Chronic obstructive airway disease	25
Lower limb arthroplasty	17

We were left with 24 patients having a full set of all the questionnaires completed. There were equal numbers of both sexes. The median age was 71.5 years (males 71 years; females 72.5 years). 34 levels were operated of which 14 were single levels and 10 double levels (L<sub>2-3</sub>-2; L<sub>3-4</sub>-9; L<sub>4-5</sub>-22; L<sub>5</sub>S<sub>1</sub>-1). The duration of the symptoms varied from 18 months to 25 years. 3 patients had received caudal epidural in the past and 1 patient had had laminectomy and discectomy 27 years previously. 7 patients were noted to have Grade 1 degenerative spondylolisthesis. The median weight was 75 kg. The average length of stay in the hospital was 3 days including the day of the surgery. One patient had a stroke 3 weeks after surgery, but recovered well from it with independent mobility at 3 months. The commonest comorbidities were coronary artery disease and chronic obstructive airway disease (Table 1).

At 1 year, 7 patients had recurrence of their symptoms severe enough to warrant a caudal epidural injection. Two of these patients continued to be symptomatic and underwent removal of X Stop device followed by decompression and fusion at the same sitting. Only these 2 patients were noted to have their X Stop device "slipped" dorsally on radiographs at 1 year.

We calculated a mean preoperative symptom severity score of 3.37 (range, 2.14-4.86). We noted that all but 2 patients improved 3 months after surgery, and in 71% this improvement was clinically significant. Maximal improvement occurred at 3 months with a 0.95 drop in the symptom severity score. In the subsequent follow-up visits, the score gradually increased but continued to show clinically significant improvement (0.54 reduction) from preoperative values up to the 12-month visit. However, only 54% of the patients were significantly improved (Tables 2, 3).

The mean preoperative physical function score of 2.45 (range, 1.20-3.80) was calculated; 67% of patients' physical function scores improved at 3 months, but only in 46% was this clinically significant. Overall,

**Table 2. Mean Zurich Claudication Scores**

Domain	Time Period Relative to Surgery			
	Preoperative	3 Months	6 Months	12 Months
Symptom severity	3.37	2.42	2.65	2.83
Physical function	2.45	2.05	2.16	2.19
Patient satisfaction		1.90	1.91	2.12

**Table 3. Clinically Significant Improvement Expressed as Percentage of Patient Population**

ZCQ Domain	Time Period of Follow-up Visit		
	3 Months	6 Months	12 Months
Symptom severity (%)	71	54	54
Physical function (%)	45	42	33
Patient satisfaction (%)	79	79	71

however, at the 3-month visit, the measured 0.40 point drop in the physical function score was not clinically significant. Again, a gradual increase in the score was noted in the subsequent 6- and 12-month visits. The difference in the scores at 6 and 12 months, compared from preoperative score, was not clinically significant. Only 33% of the patients showed significant improvement in physical function at 1 year.

The mean patient satisfaction score at 3- and 6-month visit was 1.91 (range 1.00–3.83) and marginally increased, *i.e.*, less satisfaction at 1 year (mean, 2.12; range, 1.00–3.17).

The mean ODI score showed maximal improvement at the 3-month visit (preoperative: 48%; range, 24%–62%; 3 months: 35%; range, 4%–64%) with very little change subsequently (Table 4).

The mean physical function, bodily pain, and physical cumulative scores of the SF-36 showed maximal increase in the first 3 months after surgery. Unlike these 3 parameters, the role-physical score continued to improve up to the 1-year visit (Figure 1).

**Discussion**

Based on previous biomechanical, radiographic,<sup>13–15</sup> and clinical studies,<sup>12</sup> which have shown that flexion increases spinal canal and foraminal dimensions and relieves symptoms of lumbar spinal stenosis, the X Stop has been designed to hold the stenotic level in flexion and thus mechanically providing pain relief.

*In vitro* studies of X Stop have shown increased foraminal and spinal canal dimensions at the implanted level in extension,<sup>16</sup> a reduction in the pressures in the posterior anulus in extension and neutral,<sup>23</sup> and off-loading of the facet joints<sup>24</sup> without altering the dimensions or pressures in the adjacent nonoperated levels.

*In vivo*, it is suggested that these biomechanical effects bring about clinical improvement in patients with lumbar spinal stenosis treated with X Stop.<sup>17</sup> Zucherman *et al* have shown that 75% of patients improved in symptoms and physical function and 70% in satisfaction at 1

**Table 4. Oswestry Disability Index (mean scores)**

Time Period Relative to Surgery	Time Period of Follow-up Visit		
	3 Months	6 Months	12 Months
Preoperative			
48	35	36	37

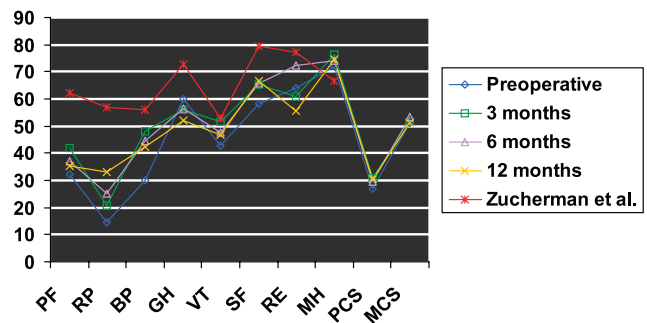


Figure 1. SF-36 scores.

year following X Stop in a prospective randomized multicenter study.<sup>18</sup> Lee *et al* have shown similar satisfaction rates, but only 40% of their patients improved in symptom severity at a variable follow-up time between 9 and 18 months.<sup>25</sup>

Our study, although with a smaller number, had similar age and gender distribution to previous X Stop studies with comparable mean preoperative scores for each of the ZCQ domains and physical function, role-physical, and bodily pain domains of SF-36. In spite of this, our results don't show as much an improvement as noted earlier (Table 5).

We note that maximal clinical improvement, whether significant or not, occurs by 3 months and then gradually declines; 29% of our patients by 12 months underwent caudal epidural injection for the recurrence of their symptoms of leg pain and neurogenic claudication. The decision for repeating caudal epidurals was made after discussion with the patients the options of repeating a course of nonsteroidal anti-inflammatory drugs and/or caudal epidural injections or undergoing surgical decompression. All opted for caudal epidural injection rather than surgical decompression. The temporal deterioration of symptoms has not been noted before in the previous X Stop studies. The cross section of the X Stop device used is circular, and it distracts the relatively flat edges of the adjacent spinous processes. Thus, point loading may occur at the operated level. We hypothesize that, perhaps with cyclical loading *in vivo*, bony indentations occur where the implant abuts the spinous processes of the operated level that with time lead to a reduction in the degree of distraction initially achieved. This would lead to encroachment on the neural structures leading to recurrence of symptoms. After evaluating our own results, we have now decided to use

**Table 5. Clinically Significant Improvements at 1 Year**

Study	ZCQ Domains		
	Symptom Severity (%)	Physical Function (%)	Patient Satisfaction (%)
Lee <i>et al</i> <sup>25</sup>	40	10	70
Zucherman <i>et al</i> <sup>18,19</sup>	75	75	70
Current study	54	33	71

XSTOP<sup>PK</sup>, which has on a cross-sectional view a flatter surface that rests against the spinous processes; 17% of our patients also had had previous lower limb arthroplasty, and 4% had had peripheral vascular disease noted and treated previously the symptoms from which may also influence the patients' responses to the questionnaires. There may also be progression of spinal stenosis, which would contribute to the reduction in the clinically significant improvement achieved in the first 3 months after surgery.

Complications were observed in our study. Two of the early patients in our study had spinous process fracture at the time of the operation and subsequently underwent formal surgical decompression. We think that this is because the operating surgeon was unfamiliar with the force needed to distract the stenotic segment. We would caution surgeons unfamiliar with this device against overzealous distraction of the surgical segments. Two patients were noted to have a dorsally slipped implant at 1 year with symptoms of neurogenic claudication and underwent removal of the implant with decompression and fusion.

We recognize that there are limitations in our study. This is not a randomized controlled trial comparing X Stop with surgical decompression, and the numbers of patients in this study are relatively small as is the follow-up period of 12 months. We are in the process of collecting data for 2-year follow-up.

Despite the limitations, we have shown that implantation of the X Stop device is relatively safe and effective, short-term treatment for patients with lumbar spinal stenosis and other significant comorbidities.

### ■ Key Points

- X Stop is a safe and effective short-term treatment option for patients with symptomatic lumbar spinal stenosis.
- Symptomatic benefit derived is maximal at 3 months but remains clinically significant up to 12 months after surgery in 54% of the patients.
- Although physical function improves maximally at 3 months after surgery, it is clinically significant in only 33% of the patients at 12 months.
- A total of 71% of the patients are somewhat to very satisfied with the procedure at 1 year.
- Our results are less favorable than the previously published randomized study on X Stop.

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