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Influence of X Stop on Neural Foramina and Spinal Canal Area in Spinal Stenosis

Manal Siddiqui, FRCS,* Efthimios Karadimas, MD,* Malcolm Nicol, MRCS,*
Francis W. Smith, FRCR,† and Douglas Wardlaw, FRCS ChM*

Study Design. Measurements of cross sections of exit foramen and spinal canal were performed before and after placement of X Stop in physiologic postures using positional MR scanner at the stenosed level in patients with lumbar spinal stenosis.

Objective. To quantify the effect of the implant *in vivo* on the lumbar spine at the instrumented levels in various postures.

Summary of Background Data. Dimensions of the spinal canal and neural foramen decrease from flexion to extension. Symptoms of spinal stenosis occur typically in standing or extension. The X Stop device is designed to distract the posterior elements of the stenotic segment and place it in flexion to treat neurogenic claudication. We think that the device will improve the dimension of the canal in standing and extension.

Methods. Twenty-six patients with lumbar spine stenosis underwent a one- or two-level X Stop procedure. All had preoperative and postoperative positional MRI in standing, supine, and sitting flexion and extension. Measurements were carried out on the images acquired.

Results. Significant increase in the dimensions of the neural foramen and canal area were demonstrated after surgery.

Conclusions. The X Stop device improves the degree of central and foraminal stenosis *in vivo*.

Key words: spinal stenosis, neurogenic intermittent claudication, X Stop, positional MRI. **Spine 2006;31: 2958–2962**

Lumbar spinal stenosis is a disabling condition caused by narrowing of the vertebral canal. Portal of France may have been the first to study this condition in humans.[1] The etiopathogenesis has been well described by Kirkaldy-Willis *et al.*[2] It usually presents in the fifth or sixth decade of life with low back and lower extremity pain. It is due to a cascade of degenerative processes starting with degeneration of posterior anulus to disc herniation and dehydration, then to loss of disc height, overriding of the facets[3] and/or infolding of ligamentum flavum,[4] and ultimately to stenosis.

Verbiest[5] first described neurogenic intermittent claudication, which is a characteristic feature of lumbar spinal stenosis. It is characterized by pain, altered sensation and weakness in the lower extremity during standing and walking, and relieved on resting or sitting. Standing narrows the neural foraminal and canal area resulting in impingement, whereas flexing as seen in sitting increases the area[6] relieving impingement.

The X Stop device (SFMT, Concord, CA) has been designed to treat patients with neurogenic intermittent claudication who obtain relief on sitting and/or flexion. It is a titanium oval spacer placed between the two adjacent spinous processes of the affected level (Figure 1). The procedure is done under general or local anesthetic in lateral decubitus position *via* a midline approach. The supraspinous and interspinous ligaments are preserved. The paraspinal muscles are stripped off the spinous processes. The migration of the implant is prevented by two lateral wings attached to the spacer, the interspinous ligament posteriorly and the bony margins anteriorly, cranially, and caudally. The implant put the stenotic segment in flexion and restricts extension but not axial rotation and lateral bending.

Previous cadaveric studies[7] of X Stop have shown a significant increase in the dural sac and exit foraminal area at the implanted level. Prospective, randomized, multicentric clinical study on X Stop showed that 59% of patients were considered as having a successful outcome as compared with 12% of those who were managed nonoperatively at 1 year.[8] This gave us reason to study this treatment in our patients. In this study, we intended to observe the changes in the cross-sectional area of the exit foramen and spinal canal before and after X Stop implantation *in vivo* in patients with symptomatic spinal stenosis.

Materials and Methods

Patients. Twenty-six patients (14 males and 12 females; age range, 57–93 years; mean, 71 years) diagnosed clinically and radiologically with lumbar spinal stenosis and neurogenic intermittent claudication who have not responded to nonoperative treatment, such as bed rest, physiotherapy, anti-inflammatory/analgesic medication, were enrolled in the study. Ethical committee approval for the position MRI scans was received. Based on the good clinical results of 1-year prospective randomized controlled trial,[8] the X Stop device had been given the CE Mark and the Grampian University Hospitals

From the Departments of *Orthopaedics and †Radiology, Woodend Hospital, Aberdeen, Scotland.
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The medical device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.
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Address correspondence to Douglas Wardlaw, FRCS, Department of Orthopaedics, Woodend Hospital, Eday Road, Aberdeen, Scotland AB15 6XS U.K.; E-mail: manalsiddiquis@yahoo.co.uk or doug.wardlaw@arh.grampian.scot.nhs.uk

Figure 1. X Stop device.

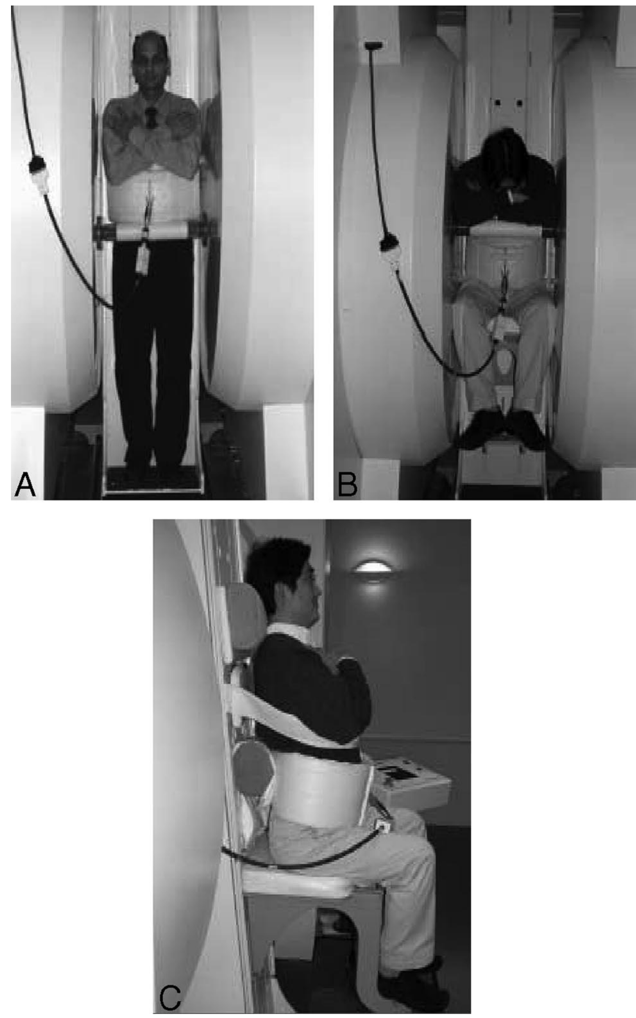

Figure 2. 0.6T upright MRI scanner with subjects in various postures.

NHS Trust's approval had been received for the X Stop procedure. There were 15 single levels (L2–L3[1]; L3–L4 (3); L4–L5 [11]) and 11 double levels (L3–L4 + L4–L5 [10]; L4–L5 + L5–S1 [1]) operated.

The inclusion criteria were: age over 50 years; leg, buttock, or groin pain with or without back pain while standing or walking; and rest must relieve the leg pain when the spine is flexed such as when sitting or stooping forwards. The patient must be able to sit comfortably for at least 50 minutes (duration of pMRI scan). Additionally, narrowing of the lumbar spine, nerve root canal, or intervertebral foramen, at one or two levels, should be demonstrated on MRI.

The exclusion criteria were: unremitting spinal pain in any position; cauda equina syndrome, defined as neurocompression causing bowel or bladder incontinence or retention; pathologic fractures of the vertebrae; severe osteoporosis of the spine; body mass index greater than 40 kg/m^2; presence of active infection; Paget's disease at the involved segments or spinal metastases; spinal anatomy such as ankylosing spondylitis; or fusion at the affected level.

Once enrolled, patients underwent a preoperative pMRI. Patients were reviewed in clinic at 6 and 12 weeks after surgery and underwent a second pMRI scan at 6 months.

Imaging. Positional MRI is a relatively new imaging tool. The first commercially available upright pMRI scanner (Fonar "Upright," Fonar Corp., Melville, NY) has only been available since October 2000. The pMRI scanner has an open configuration with the magnetic field generated between the vertically mounted poles of a resistive magnet. This gives enough space for the scanning table to rotate from 15° head down to vertical (standing) and to move vertically and horizontally enough to place any part of the body in the iso-center of the magnet with the patient in any position. With pMRI, it is possible to compare the relative positions of the lumbar vertebrae throughout the full range of movement. By using pMRI, the patient can be studied in the very position that exacerbates the symptoms, (*i.e.*, standing), and then compared with the position that relieves the symptoms (*i.e.*, sitting). The changes in the cross-sectional area of the exit foramen and spinal canal were measured before and after the placement of an X Stop implant.

Each subject had T2 axial and parasagittal sequences through the five lumbar discs in positions of erect, neutral sitting, sitting in flexion, and sitting in extension (Figure 2). The sequence parameters are detailed below; 4.5-mm slices were taken for the axial and sagittal views.

All patients were positioned and scanned by the same radiographer. For the erect scan, the patients were actually leaning back against a rest at 5° from the vertical. This was necessary because we have found, from previous studies, that no subject was able to stand absolutely still for the time needed for the study. By having the patient leaning against an almost vertical surface, this problem was eliminated. For the positions where the patient sat in flexion and extension, support rests were placed once the patient had taken up the posture. Patients were asked to flex and extend only to the degree that they found comfortable for the duration of the scan.

Procedure. The devices were implanted by, or under the direct supervision of a single surgeon. The patients had the procedure either under local anesthetic with or without sedation, or under a light general anesthetic. After surgery, patients were mobi-

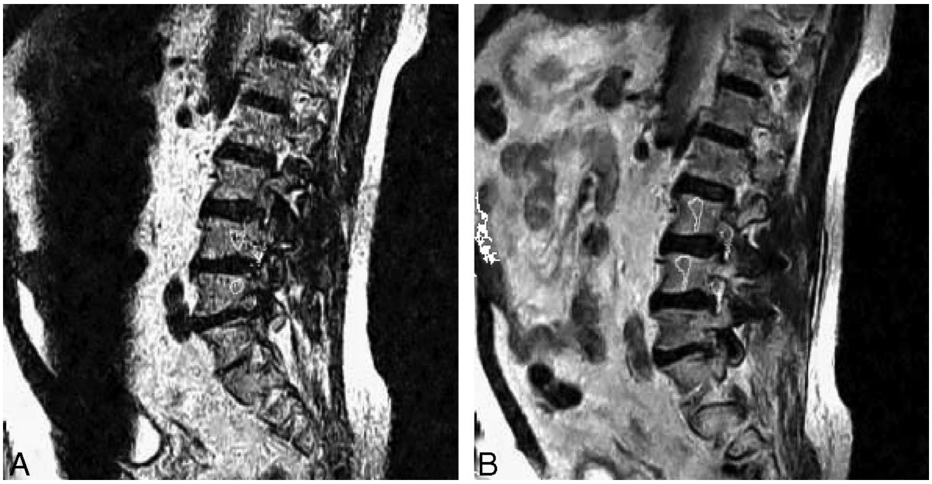

Figure 3. Preoperative (A) and postoperative (B) cross-sectional area of the neural foramen in extension posture.

lized immediately once they had recovered from the effects of any anesthetic or sedation and discharged within 2 days.

Image Interpretation. On the parasagittal images (Figure 3), the surface area of the exit foramen at instrumented levels were measured using the region of interest (ROI) cursor. This cursor gives a surface area within a drawn boundary. The same tool was used on the axial images to measure the surface area of the dural sac.

On axial images (Figure 4), the spinal canal area at the instrumented levels was measured using the ROI cursor where the canal is at the narrowest. The measurement included the extradural fat pad, but excluded disc, ligament flavum, and facet joint. Laterally, the measurement was taken up to the subarticular diameter.

The measurements of the pMRI scans images were made by two researchers using the Osiris 4.17 program (University of Geneva). SPSS version 12.0.1 was used to analyze the data using Wilcoxon test. The measurements were verified with another observer in the same manner. Pearson correlation coefficient for interobserver reliability was 0.96 ($P < 0.0001$) for the spinal canal and 0.82 ($P < 0.0001$) for the foraminal measurements.

Results

Spinal Canal Area

We demonstrated a similar reduction in the canal dimension before surgery as the spine moves from flexion into extension as seen in normal spines. However, the narrowest dimension was noted in the standing erect posture at both, single-level (74.4 mm^2) and double-level (94.8 mm^2 cranial; 91.3 mm^2 caudal) stenotic segments.

The X Stop device increased the dimensions of the spinal canal in all postures. At single-level implantation, this increase was, however, only significant in seated-neutral (21%, $P = 0.011$) and erect (23%, $P = 0.003$) postures. In double-level surgeries, significant increase was noted in erect (cranial segment, 19%; $P = 0.005$; caudal segment, 21%; $P = 0.003$) and seated-extension postures (cranial segment, 18%; $P = 0.041$; caudal segment, 15%; $P = 0.007$) (Tables 1, 2).

Neural Foramen Area. Our results show similar reduction in the neural foraminal area before surgery on extension as seen in the normal spines. The X Stop device increased the dimension of the neural foramen in both seated-flexion and seated-extension.

At single-level implantation, this increase was, however, only significant in extension on the left side (20% increase, $P = 0.027$) and on flexion on the left side (19% increase, $P = 0.023$). In double-level surgeries, significant increase was noted in the right cranial (27%, $P =$

Figure 4. Preoperative (A) and postoperative (B) cross-sectional area of the spinal canal in erect posture.

Table 1. Canal Area at Single-Level Implantation (mm^2)

Posture	Preoperative	Postoperative	Difference	P
Flexion	97.7	99.8	2.1	0.820
Neutral	76.8	93.2	16.4	0.011
Standing	74.4	91.7	17.3	0.003
Extension	84.4	92.4	8.0	0.363

0.005) and caudal levels (20%, $P = 0.037$), and left cranial level (32%, $P = 0.009$) on extension (Tables 3, 4).

■ Discussion

In one of the first studies in the English literature on lumbar spine kinematics, Panjabi *et al*[9] showed greater changes in the intervertebral foraminal area of the degenerated segments than those not affected. Mayoux-Benhamou *et al*[10] also have described the decrease in lumbar foraminal diameter and heights as the spine moved from flexion to extension.

Cadaveric biomechanical studies, such as that by Schönström *et al*,[11] have reported a reduction in the spinal canal by 40 mm^2 when the spine moves from flexion to extension. Infusa *et al*[12] have shown a 24% reduction in foraminal cross section and a 16% reduction in spinal canal from flexion to extension, whereas Fujiwara *et al*[13] have shown a 21% reduction in foraminal cross section.

Schmid *et al*[14] studied 12 asymptomatic volunteers in a 0.5T open-configuration MR scanner. They reported a significant postural reduction in cross section of the spinal canal at L4–L5 by 16% ($P < 0.001$) and neural foramen by 35% ($P < 0.001$). Chung *et al*[6] studied 20 asymptomatic volunteers in 1.5T MR scanner. They found 68 mm^2 reduction in the area of the spinal canal at L3–L4 and 61 mm^2 reduction at L4–L5 as the spine was put into extension from flexion. The scans were done in supine posture with bolsters to put spine in flexion or extension.

Schönström *et al*[15] did a retrospective study on CT scans of 34 patients with central lumbar stenosis. They reported the L3–L4 to be the commonest site of stenosis in this group and encroaching soft tissue to be the commonest cause. They also proposed that the critical diameter of dural sac is 100 mm^2. Danielson *et al*[16] have shown a significant reduction in the spinal canal cross section in patient with lumbar spine stenosis when axially loaded in supine posture. This was seen in 46% of sites or 76% of patients. In 8 of the 34 patients, the cross-sectional area reduced below the critical value of 100 mm^2.

The concept of an interspinous implant is not a new one. Indeed, since 1958, interspinous implant have been designed to treat disc or nucleus pulposus herniation and segmental instability.[17–19] X Stop interspinous device has been specifically designed to distract the instrumented segment, putting it into flexion and stretching the soft tissues such as ligamentum flavum and/or disc encroaching on the canal. Thereby, there is an increase in the dimension of the canal and an alleviation of symptoms.

In our study, we observed that the postural changes in the dimension of the degenerate spine were similar to those found in the literature mentioned above. Before surgery, in extension, a lesser reduction was noted at the neural foramen (14%–18%) at single-level disease than double-level disease (13%–39%). This finding is similar to that of Panjabi *et al*.[9] The X Stop device, once *in situ*, did limit the reduction in dimensions of the foramen. Perhaps because of the varying degrees of foraminal stenosis, we did not get a uniform increase in the values after surgery, comparing right to left side. We think that this difference is due to varying anatomy rather that measurement differences.

We found that the spinal canal area was characteristically narrowest in the erect posture for both single- and double-level stenosis before surgery. The standing erect postoperative dimensions were similar to that of seated-flexed preoperative dimensions. It is of note that these values are lower than the critical value suggested by Schönström *et al*[11] who based this finding on tracings of CT scans. MRI offers better delineation of soft tissues.

■ Conclusion

The X Stop interspinous decompression device did significantly improve the canal dimension, and at least on

Table 2. Canal Area at Double-Level Implantation (mm^2)

Posture	Site	Preoperative	Postoperative	Difference	P
Flexion	Cranial	122.0	135.0	13.0	0.203
	Caudal	114.5	125.7	11.2	0.213
Neutral	Cranial	115.2	126.8	11.6	0.059
	Caudal	105.8	110.6	4.8	0.424
Standing	Cranial	94.8	112.5	17.7	0.005
	Caudal	91.3	110.0	18.7	0.003
Extension	Cranial	104.9	123.7	18.8	0.041
	Caudal	104.6	120.8	16.2	0.007

Table 3. Foraminal Area at Single-Level Implantation (mm^2)

Posture	Side	Preoperative	Postoperative	Difference	P
Flexion	Right	95.6	111.4	15.8	0.233
	Left	100.0	118.7	18.7	0.023
Extension	Right	82.3	93.1	10.8	0.090
	Left	82.3	98.4	16.1	0.027

Table 4. Foraminal Area at Double-Level Implantation (mm^2)

Posture	Side	Site	Preoperative	Postoperative	Difference	P
Flexion	Right	Cranial	92.8	107.6	14.8	0.022
		Caudal	86.5	93.7	7.2	0.131
	Left	Cranial	122.8	121.3	−1.5	0.646
		Caudal	84.1	89.5	5.4	0.286
Extension	Right	Cranial	70.7	90.1	19.4	0.005
		Caudal	75.4	90.2	14.8	0.037
	Left	Cranial	75.4	99.6	24.2	0.009
		Caudal	63.0	77.7	14.7	0.213

one side, the neural foraminal area. This *in vivo* study provides evidence of mechanism of action of the implant from patients with spinal stenosis.

■ Key Points

- This is a prospective observational *in vivo* study of the X Stop device.
- We measured changes in neural foramen and spinal canal in lumbar spinal stenosis before and after the procedure.
- We used positional MRI to see the effect of posture in patients with spinal stenosis.

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