

Effects of X-Stop Device on Sagittal Lumbar Spine Kinematics in Spinal Stenosis

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Abstract: The X-Stop device is designed to distract the posterior elements of the stenotic segment and place it in flexion to treat neurogenic claudication. Previous biomechanical studies on X Stop have been done in vitro on cadavers looking at disc pressures and segmental range of movements. The objective of this study is to understand the sagittal kinematics in vivo of the lumbar spine at the instrumented and adjacent levels. Twenty-six patients with lumbar spine stenosis underwent 1 or 2 level X-Stop procedure. All had pre- and postoperative positional magnetic resonance imaging (MRI) in standing, supine, and sitting in flexion and extension. Measurements of disc heights, endplate angles, segmental and lumbar range of movement were performed after placement of X Stop at the stenosed level in patients with lumbar spinal stenosis. No significant changes were seen in disc heights, segmental and total lumbar spine movements postoperatively. The X-Stop device does not affect the sagittal kinematics of the lumbar spine in vivo.

Key Words: spinal stenosis, neurogenic intermittent claudication, X Stop, positional MRI

(*J Spinal Disord Tech* 2006;19:328–333)

KEY POINTS

- Prospective observational study
- Using positional MRI
- In vivo study in patients with lumbar spine stenosis

Lumbar spinal stenosis (LSS) is a disabling condition caused by the narrowing of the vertebral canal. Degenerative stenosis¹ is the most common type, usually presenting in the fifth or sixth decade of life with low back and lower extremity pain. The aetiopathogenesis is due to a cascade of degenerative processes starting with degeneration of posterior annulus to disc herniation and dehydration, then to loss of disc height, overriding of the facets,² and/or infolding of ligamentum flavum,³ and ultimately stenosis.

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Neurogenic intermittent claudication, as first described by Verbiest,⁴ is a characteristic feature of LSS 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 area⁵ relieving impingement.

The X-Stop device (Fig. 1) (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 2 adjacent spinous processes of the affected level. 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 2 lateral wings attached to the spacer, the interspinous ligament posteriorly and the bony margins anteriorly, cranially, and caudally. The implant puts the stenotic segment in flexion and restricts extension, but not axial rotation and lateral bending.

In our study, we intend to understand the changes in the disc height, segmental range of movement and total lumbar range of movement before and after X-Stop implantation in vivo in patients with symptomatic spinal stenosis. Previous cadaveric studies⁶ of X Stop have shown a decrease in the segmental range of movement (ROM) at the implanted level without significantly affecting the adjacent levels.

MATERIALS AND METHODS

Ethical approval for this study was sought from and granted by the appropriate local authority (Grampian Ethical Approval Committee).

Patients

Twenty-six patients [14 males and 12 females with age range of 57 to 93 years (mean-71 years)] diagnosed clinically and radiologically with LSS and neurogenic intermittent claudication who had not responded to nonoperative treatment such as bed rest, physiotherapy, anti-inflammatory/analgesic medication, were enrolled in the study. There were 15 single levels [L₂₋₃ (1); L₃₋₄ (3); L₄₋₅ (11)] and 11 double levels [L₃₋₄+L₄₋₅ (10); L₄₋₅+L_{5S1} (1)] operated.

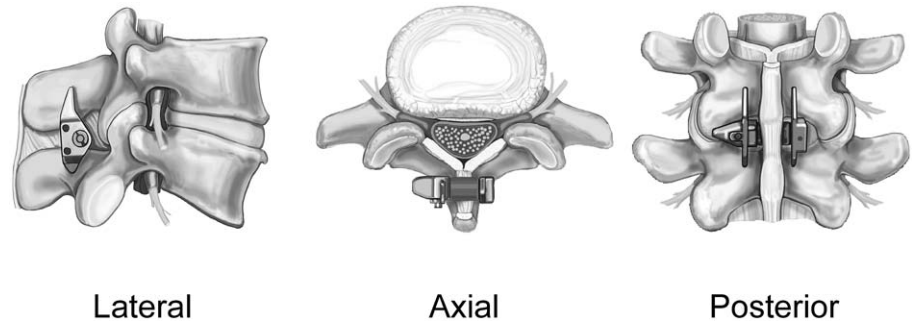


FIGURE 1. Diagrammatic representation of the X-Stop device in situ seen in posterior, lateral and axial views.

The inclusion criteria were: age over 50; leg, buttock or groin pain with or without back pain while standing or walking; 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 positional magnetic resonance imaging (pMRI) scan). Additionally, narrowing of the lumbar spine, nerve root canal, or intervertebral foramina, at one or 2 levels, as demonstrated on the MRI.

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

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

Imaging

The first commercially available upright pMRI scanner is a relatively new imaging tool (Fonar 'Upright', Fonar Corporation, Melville, New York), and 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 degrees head down to vertical (standing) and to move vertically and horizontally enough to place any part of the body in the isocenter 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, (ie standing), and then be compared with the position that relieves the symptoms, (ie sitting). The changes in the disc height, endplate angles, and segmental and total lumbar movement were measured before and after the placement of an X-Stop implant.

Each subject had T2 parasagittal sequences through the 5 lumbar discs in positions of erect, neutral sitting, sitting in flexion, sitting in extension and supine. The

sequence parameters are detailed below (Fig. 2). 4.5-mm slices were taken for the sagittal views.

All the patients were positioned and scanned by the same radiographer. For the erect scan the patients were actually leaning back against a rest at 5 degrees from the vertical surface. 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. Postoperatively, patients were mobilized immediately once they had recovered from the effects of any anesthetic or sedation and discharged within 2 days.

Image Interpretation

The measurements of the pMRI scans were made by 2 researchers using the Osiris 4.17 program (University of Geneva).

Disc heights were measured on the sitting-flexion and extension, supine and erect midline sagittal images. On the images (Fig. 3), distance cursors were used to measure anterior and posterior disc heights to the nearest pixel at the instrumented and adjacent levels. Distances were measured between the most anterior or posterior points on each vertebral body, excluding osteophytes.

Endplate angles and the L1-S1 angles were measured in midline, sagittal, seated-flexion and seated-extension images using angle calipers placed over lines through the endplates from antero-superior or antero-inferior corner to postero-superior or postero-inferior corner, excluding osteophytes (Fig. 4). Endplate angles were measured on the images between adjacent vertebral bodies at the instrumented and adjacent levels. The L1-S1 angles were measured between the superior endplate of L1 and the superior endplate of S1.



FIGURE 2. Fonar upright MRI scanner with the author seen in postures studied.

SPSS version 12.0.1 was used to analyze the data using the Wilcoxon test. The measurements were verified with another observer in the same manner. Scattergraphs showing interobserver variability for disc heights and endplate angles in flexion and extension as shown in Figures 5 and 6. The Pearson correlation coefficient was



FIGURE 3. Anterior and posterior disc height measurement in supine.



FIGURE 4. Endplate and L1-S1 angle measurement in flexion.

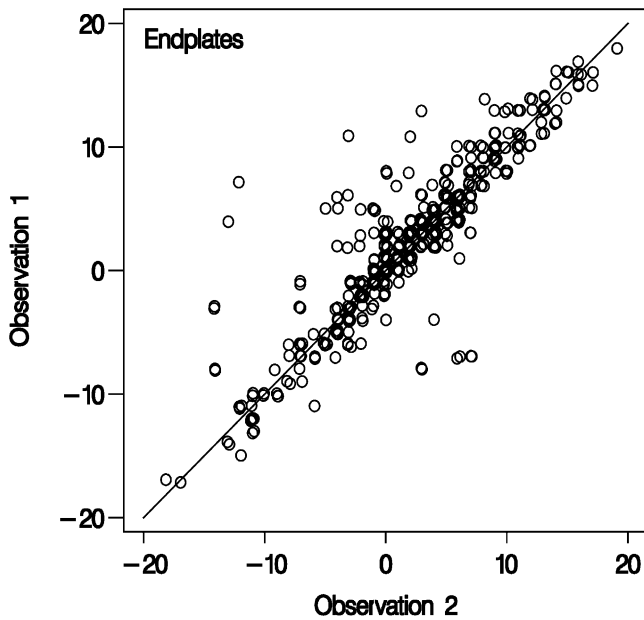


FIGURE 5. Scattergraph—disc height in mm.

0.966 $P < 0.001$ between the 2 observers for the disc height measurements and 0.886 $P < 0.001$ for the endplate angles.

RESULTS

1. Endplate Angles: As seen in Table 1 (A, B), in neither flexion nor extension was there any significant difference in the change in endplate angles after the

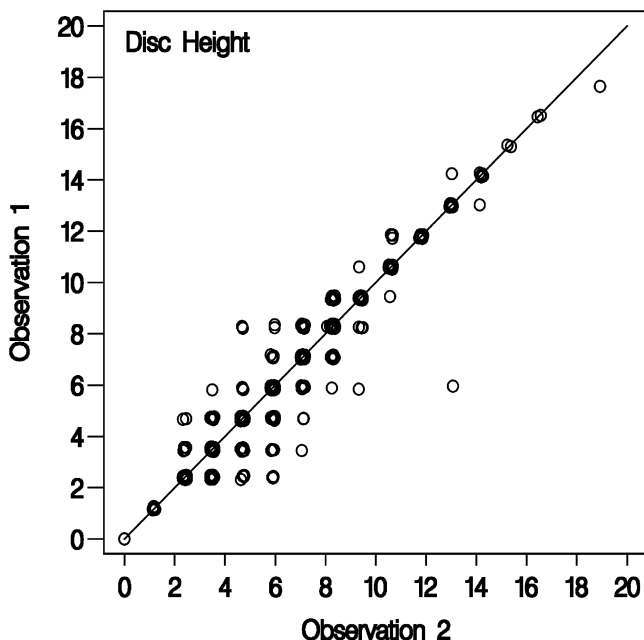


FIGURE 6. Scattergraph—endplate angles.

- procedure. No difference was seen above, below or at single or double level procedure.
2. Segmental ROM: Although, no difference was noted in the single-level procedure postoperatively, however, the caudad level of the double level implantation did show significant reduction in the range of movement Table 1.
3. Disc Height: Table 2 (A–H) showed no significant changes after the procedure in both anterior and posterior disc heights comparing flexion and extension and supine and erect postures.
4. L1S1 Angle: No appreciable change was seen in flexion or extension after the procedure, and thus no change was seen in the total lumbar range of movement in both single and double levels. Table 3 (A, B).

DISCUSSION

Assessment of mobility of the lumbar spine plays an important part in assessing the symptomatic spine. Previous studies have looked at assessing segmental movement of the lumbar spine using plain radiography aided by other devices.^{7–9} These studies have been conducted in asymptomatic young volunteers and thus have shown a larger segmental range of movement (7 to 14 degrees) than that seen in our study where the mean age was 71 years.

Changes in intervertebral angles with posture have also been reported using plain radiographs.^{10–12} In these studies, the intervertebral angles were measured in supine and standing. A slight increase in the angles toward lordosis was noted in the erect posture from supine.

The advent of MRI offered the advantage of no radiation exposure, better definition of neural structures, and axial and parasagittal slices. Kimura et al¹³ showed the effect of axial loading in supine posture using 1.5 T (Magnetom Symphony, Siemens, Munchen, Germany) scanner and DynaWell (DynaMed, Mahopac, NY) loading harness. The changes observed after loading were: increased lordosis at L3-4, kyphosis at L5-S1, overall increase in lordosis of lumbar spine (from 53 to 57 degrees), and decreased disc height at L4-5 only. Cadaveric study by Hasegwa et al¹⁴ has shown that below the critical limit of 4 mm of the posterior disc height, foraminal stenosis is significant. In our study, the posterior disc height remained between 4.3 to 5.5 mm preoperatively in all postures. The posterior disc height did show an increase irrespective of posture and number of operated levels, but these changes were not statistically significant. Postoperatively, the anterior disc height appeared to increase, albeit minimally, in single-level implantation. In double levels, the disc height expectedly reduced postoperatively.

Studies using MRI scanner^{15,16} have been done to look at the total lumbar range of movement in asymptomatic population. The mean ROM varied from 36 to 44 degrees. However, these studies were done in the lateral

TABLE 1. Endplate Angles

	Flexion				Extension				Segmental ROM			
	Preop.	Postop.	Diff.	P Value	Preop.	Postop.	Diff.	P Value	Preop.	Postop.	Diff.	P Value
(A) Endplate Angles (°)—Single Level												
Above	-2.7	-3.1	-0.4	0.655	7.7	7.2	-0.5	0.112	5.0	4.1	-0.9	0.310
At	2.0	1.4	-0.6	0.407	0.3	0.9	0.6	0.197	2.3	2.4	0.1	0.475
Below	-2.9	-2.5	0.4	0.277	5.3	5.4	0.1	0.916	2.4	2.9	0.5	0.502
(B) Endplate Angles (°)—Double Level												
Above	-0.2	0.1	0.3	0.720	5.4	7.3	1.9	0.472	6.3	5.7	-0.6	0.283
Level 1	-0.6	-0.3	0.3	0.859	4.0	2.9	-1.1	0.440	5.3	3.0	-2.3	0.064
Level 2	-1.0	-1.7	-0.7	0.201	4.8	4.1	-0.7	0.442	4.4	2.4	-2.0	0.035
Below	-6.0	-6.6	-0.6	0.319	10.0	9.9	-0.1	0.953	6.4	4.3	-2.1	0.072

recumbent or supine posture in young volunteers. Our results, which show a much lower ROM, may be due to the population being older, who in addition had significant degenerative changes in the majority of their lumbar discs.

The biomechanical study done with the X-Stop device⁶ used 7 human cadavera lumbar spines. Changes were measured in the segmental ROM at the level of instrumentation and adjacent levels after single-level

implantation of the device at L3-4. There was a significant decrease in ROM at the level of the device (from 7.6 to 3.1 degrees $P < 0.05$). The level above and below the implantation did not show any significant change. In our study, we did see a reduction in segmental ROM at the caudad operated level when 2 devices were inserted, but this was not significant. As expected, no changes were seen in the adjacent levels. The X Stop cadaveric study is not directly comparable to ours because the cadavers

TABLE 2. Disk Heights

	Flexion				Extension				Change in Height (Flexion-Extension)			
	Preop.	Postop.	Diff.	P Value	Preop.	Postop.	Diff.	P Value	Preop.	Postop.	Diff.	P Value
(A) Anterior Disc Heights (mm)—Single Level (15 patients)												
Above	7.2	7.9	0.7	0.037	9.0	9.2	0.2	0.328	1.8	1.3	-0.5	0.437
At	5.1	5.6	0.5	0.309	6.1	6.1	0	0.856	1.0	0.5	-0.5	0.365
Below	6.5	7.0	0.5	0.182	7.1	7.7	0.6	0.056	0.6	0.7	0.1	0.964
(B) Anterior Disc Heights (mm)—Double Level (11 patients)												
Above	5.7	6.3	0.6	0.059	7.5	8.2	0.7	0.098	1.8	1.9	0.1	0.777
Level 1	5.4	5.7	0.3	0.398	7.0	6.8	-0.2	0.670	1.6	1.1	-0.5	0.326
Level 2	6.1	6.4	0.3	0.436	7.8	7.4	-0.4	0.290	1.7	1.0	-0.7	0.182
Below	9.2	10.1	0.9	0.235	9.9	11.4	1.5	0.034	0.7	1.3	0.6	0.574
(C) Posterior Disc Heights (mm)—Single Level (15 patients)												
Above	5.7	5.6	-0.1	0.547	4.8	5.7	0.9	0.039	-0.9	0.1	1.0	0.120
At	5.0	5.3	0.3	0.360	4.6	4.8	0.2	0.527	-0.4	-0.5	-0.1	0.713
Below	5.0	5.4	0.4	0.232	4.5	5.4	0.9	0.007	-0.5	0	0.5	0.181
(D) Posterior Disc Heights (mm)—Double Level (11 patients)												
Above	5.1	5.4	0.3	0.774	4.2	4.8	0.6	0.204	-0.9	-0.6	0.3	0.547
Level 1	5.1	5.7	0.6	0.098	4.5	5.0	0.5	0.028	-0.6	-0.7	-0.1	0.864
Level 2	5.5	5.7	0.2	0.750	4.8	4.9	0.1	0.902	-0.7	-0.8	-0.1	0.719
Below	7.0	7.4	0.4	0.336	5.9	6.8	0.9	0.071	-1.1	-0.6	0.5	0.389
(E) Anterior Disc Heights (mm)—Single Level (15 patients)												
Above	9.7	10.4	0.7	0.079	8.7	9.2	0.5	0.016	-1.0	-1.2	-0.2	0.720
At	6.7	7.0	0.3	0.627	5.3	5.7	0.4	0.052	-1.4	-1.3	0.1	0.201
Below	8.4	8.8	0.4	0.590	8.2	7.9	-0.3	0.454	-0.4	-0.9	-0.5	0.151
(F) Anterior Disc Height (mm)—Double Level (11 patients)												
Above	8.1	9.7	1.6	0.118	7.5	7.9	0.4	0.586	-0.6	-1.8	-1.2	0.119
Level 1	7.6	7.9	0.3	0.340	7.2	6.7	-0.5	0.288	-0.4	-1.2	-0.8	0.319
Level 2	8.7	8.4	-0.3	0.473	8.4	7.3	-1.1	0.136	-0.3	-1.1	-0.8	0.865
Below	11.7	13.5	1.8	0.056	11.4	12.0	0.6	0.461	-0.3	-1.5	-1.2	0.161
(G) Posterior Disc Height (mm)—Single Level (15 patients)												
Above	4.9	5.5	0.6	0.219	4.7	4.6	-0.1	0.590	-0.2	-0.9	-0.7	0.229
At	4.8	4.9	0.1	0.365	4.3	4.3	0.0	1.000	-0.5	-0.6	-0.1	0.478
Below	4.3	5.0	0.7	0.018	4.7	4.5	-0.2	0.141	0.4	-0.5	-0.9	0.005
(H) Posterior Disc Height (mm)—Double Level (11 patients)												
Above	4.5	5.5	1.0	0.096	4.2	4.3	0.1	0.276	-0.3	-1.2	-0.9	0.149
Level 1	4.2	5.2	1.0	0.041	4.4	5.0	0.6	0.172	0.2	-0.2	-0.4	0.279
Level 2	5.0	5.4	0.4	0.252	4.8	5.2	0.4	0.350	-0.2	-0.2	0.0	0.669
Below	5.5	6.4	0.9	0.102	5.2	5.6	0.4	0.461	-0.3	-1.1	-0.8	0.066

TABLE 3. Total Lumbar ROM

	Preop.	Postop.	Diff.	P Value
(A) L1-S1 Angle (°)—Single Level				
Flexion	-12	-14	-2	0.441
Extension	33	32	-1	0.779
ROM	20	16	-4	0.139
(B) L1-S1 Angle (°)—Double Level				
Flexion	-15	-14	1	0.609
Extension	38	35	-3	0.092
ROM	23	21	-2	0.759

were not screened for spinal stenosis or degenerative change. Hence the results of our study are similar to the cadaveric study, but our values are much smaller.

This prospective observational study investigated the effects of the X-Stop interspinous implant in vivo on the movement in the lumbar spine in patients with LSS. We utilized an upright MRI scanner that allows us to physiologically load the lumbar spine in different postures. The implant in vivo does not significantly affect the sagittal lumbar spine kinematics.

ACKNOWLEDGMENT

The authors would like to thank Dr Diana Villegas at the St. Francis Medical Technologies for her support.

Conflicts of Interest: Benefits have been received by the authors, but are solely directed towards this research.

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