Received: 17.12.2013 / **Accepted:** 02.02.2014
DOI: 10.5137/1019-5149.JTN.10135-13.0

Original Investigation

X-Stop® Implantation Effectively Limits Segmental Lumbar Extension in-vivo without Altering the Kinematics of the Adjacent Levels

X-Stop® İmplantasyonu Komşu Seviyelerde Kinematik Özellikleri Değiştirmeden in-vivo Segmental Lumbar Ekstansiyonu Etkin Şekilde Sınırlar

Zongmiao WAN[1], Guoan LI[2]

[1]The First Affiliated Hospital of Nanchang University, Orthopaedic Department, JiangXi Province, China
[2]Massachusetts General Hospital, Harvard Medical School, Bioengineering Laboratory, Department of Orthopaedics, Boston, USA

Corresponding Author: Zongmiao WAN / E-mail: zongmiao2008@gmail.com

ABSTRACT

AIM: To evaluate the in-vivo three-dimensional (3D) vertebral kinematics of the implanted and adjacent segments after implantation of the interspinous process distracting (ISP) device during various functional activities.

MATERIAL and METHODS: Eight patients with lumbar spinal stenosis (LSS) scheduled for X-Stop® surgery were recruited. Prior to surgery, patients were scanned with computed tomography/ magnetic resonance imaging (CT/MRI) in order to construct 3D L2 to S1 vertebral models. The lumbar spines of the patients were then imaged using two fluoroscopes while they performed seven functional activities before and after X-Stop® surgeries. The in-vivo 3D vertebral positions were determined in the dual fluoroscopic images using an established 2D-3D matching method. The vertebral 3D ranges of motion (ROM) of the implanted and cranial-caudal adjacent levels were then measured.

RESULTS: Primary ROMs of the implanted segments were significantly decreased ($p<0.05$) by 50.2% only at torso extension, from preoperative 2.5±1.4° to postoperative 1.1±0.5°, but not significantly ($p>0.05$) at flexion, twisting and lateral bending. Primary ROM and the coupled translations and rotations of the implanted and the adjacent levels were not significantly changed during each posture.

CONCLUSION: X-Stop® implantation reduced the in-vivo range of extension by 50.2% at the implanted segment without disturbing 3D kinematics at the adjacent segments.

KEYWORDS: Interspinous process distracting device, In-vivo, Kinematics, Adjacent segments

ÖZ

AMAÇ: Çeşitli işlevsel aktiviteler sırasında, interspinöz proses distraksiyon (ISP) cihazı implantasyonu sonrasında, implantasyonun yapıldığı segmentte ve komşu segmentlerde in vivo üç boyutlu (3D) vertebral kinematik özellikleri değerlendirmek.

YÖNTEM ve GEREÇLER: X-Stop® cerrahisi planlanan sekiz lomber spinal stennoz (LSS) hastası çalışmaya alındı. Cerrahiden önce hastalar 3D L2-S1 vertebra modelleri oluşturmak üzere bilgisayarlı tomografi/manyetik rezonans görüntüleme (BT/MRG) ile tarandı. Hastaların lomber omurgaları daha sonra X-Stop® cerrahisi öncesi ve sonrasında yedi işlevsel aktivite gerçekleştirirken, iki floroskop kullanılarak görüntülendi. İn vivo 3D vertebra pozisyonları, yerleşmiş bir 2D-3D eşleştirme yöntemi kullanılarak ikili floroskopik görüntülerde belirlendi. İmplantasyon yapılan ve kraniyal-kaudal komşu seviyelerde sonra 3D hareket aralıkları (ROM) ölçüldü.

BULGULAR: İmplantasyon yapılan segmentlerde primer ROM sadece gövde ekstansiyonunda preoperatif 2,5±1,4° değerinden postoperatif 1,1±0,5° değerine %50,2 şeklinde önemli ölçüde azaldı ($p<0,05$) ama fleksiyon, bükülme ve lateral eğilmede önemli fark yoktu ($p>0,05$). İmplantasyon yapılan ve komşu seviyelerde primer ROM ve kuplaj yapılmış translasyonlar ve rotasyonlar her postür sırasında önemli değişiklik göstermedi.

SONUÇ: X-Stop® implantasyonu, in vivo ekstansiyon aralığını komşu segmentlerde 3D kinematik özellikleri bozmadan %50,2 azalttı.

ANAHTAR SÖZCÜKLER: İnterspinöz proses distraksiyon cihazı, İn-vivo, Kinematik özellikler, Komşu segmentler

INTRODUCTION

Interspinous process (ISP) distraction devices such as X-Stop® have been used as an alternative solution to conventional laminectomy or fusion surgery for elderly patients suffered from lumbar spinal stenosis (LSS), although there were relatively controversial outcomes in medium-long term (11, 15, 18, 26). When the interspinous process device is placed at interspinous process by mini-invasive operation, theoretically the posterior part of vertebrae should be distracted more than the anterior part of vertebrae on the sagittal plane, which is called "flexion effect" caused by IPD implantation. ISP device application is hypothesized to create a sustained "flexion effect" via distracting the posterior elements of the stenotic segment, which like that patient can relieve neural symptoms while leaning forward (2, 14, 19).

Previous studies (6, 8, 10, 23) have suggested a possible relation between the increased vertebral motion and adjacent segment diseases (ASD). Therefore it is also important to evaluate the vertebral kinematics at the adjacent segments. Many efforts have been made to quantify the effect of ISP device implantation on the vertebral kinematics (14, 16, 17, 21). However, the in-vivo effect of ISP device on the 6 degree of freedom (6 DOF) vertebral kinematics is still not clear, although previous studies have evaluated the vertebral kinematics using in-vitro (14, 17) experiments and 2D in-vivo techniques (16, 21).

In in-vitro studies, Lindsey et al. (14) reported that X-Stop® insertion significantly reduced ROM from flexion to neutral, but not from neutral to extension; the vertebral kinematics at the adjacent levels were not significantly affected. Park et al. (17) reported that the ROM of extension and flexion of the operated segment as significantly reduced by 33% and 28% respectively; the ROM of extension and flexion at the cranial-caudal adjacent levels was also significantly increased.

In in-vivo studies, Siddiqui et al. (21) and Nandakumar et al. (16) found the X-Stop® implantation did not significantly affect the in-vivo segmental sagittal ROM at the X-Stop® implanted and adjacent levels using 2D MR techniques.

In this current study, we provide detailed in vivo 3-D kinematics data, while the previous studies only described in vitro or 2-D kinematics data; we also used a relatively new technique called the "dual-fluoroscopy imaging system combined with 2D-3D matching method".

MATERIAL and METHODS

Subject Recruitment and Demographics

Ten patients with LSS who were scheduled to undergo X-Stop® surgery were enrolled at the Bioengineering Laboratory of Massachusetts General Hospital/Harvard Medical School. Approval of the experimental design by the authors' institutional review board (IRB) was obtained prior to the initiation of the study and a signed consent form was obtained from each patient before testing. The inclusion criteria included: age over 50 and leg, buttock, or groin pain with or without back pain that was relieved by flexion. The subjects had to be able to stand for at least 20 minutes (duration of dual-fluoroscopic imaging). The exclusion criteria included: presence of active infection in the lumbar spine, cauda equina syndrome, previous lumbar surgery at the stenotic level, spondylolisthesis grade 2 or more (according to Meyerding classification), other pathological anatomy such as vertebral fracture, and more than slight scoliosis (Cobb angel ≥25º).

Of the 10 recruited patients, two failed to complete the study: one opted out of the surgery, and the other refused to undergo the follow-up visit. Eight patients completed the study (4 males and 4 females; mean age 78.8 years, range from 66 to 86 years old). The average follow-up time was 7.4 months (Table I). The X-Stop® devices were implanted at a total of 10 segments in the 8 patients (seven at L4-5, two at L3-4 and one at L5-S1). The study focused on both the operated and the cranial-caudal adjacent segments, which resulted 10 operated segments, 8 cranial adjacent segments and 8 caudal adjacent segments. At the post-operative follow up, there were no X-Stop® related complications.

3-Dimensional CT/ MRI-Based Vertebral Model

The lumbosacral spines of seven subjects were CT scanned (Light-Speed Pro16, GE, Waukesha, WI) using high-resolution axial plane images in a relaxed, supine position. Images were obtained with a thickness of 0.625 mm, and with a resolution of 512×512 pixels. The spine of one patient was MRI scanned using a 3 Tesla scanner (Siemens, Malvern, Pa) with a spine surface coil and a T2–weighted fat suppressed 3D SPGR sequence. Parallel sagittal images were obtained with a thickness of 1 mm without gap, and with a voxel size of 0.3×0.3 mm.

Table I: Patient Demographics

No.	Sex	Age	Diagnosis	BMI (kg/m^2)	Implanted Segment	Cranial Segment	Caudal Segment	Follow-up (months)	X-Stop Related Complications
1	F	74	LSS	22.4	L4/5	L3/4	L5/S1	3	No
2	F	86	LSS	19.1	L4/5	L3/4	L5/S1	5	No
3	M	78	LSS	27.5	L3/4,L4/5	L2/3	L5/S1	12	No
4	M	81	LSS	21.1	L4/5	L3/4	L5/S1	10	No
5	M	66	LSS	39.4	L4/5, L5/S1	L3/4	N/A	8	No
6	F	84	LSS	31.2	L4/5	L3/4	L5/S1	3	No
7	M	76	LSS	26.6	L3/4	L2/3	L4/5	8	No
8	F	85	LSS	27	L4/5	L3/4	L5/S1	10	No

Notes: LSS: *lumbar spinal stenosis;* ***BMI:*** *body mass index;* ***N/A:*** *not available;* ***X-Stop® device-related complications*** *included: spinous process fracture, X-Stop® dislocation;* ***F:*** *female;* ***M:*** *male.*

The CT and MRI images of the spinal segments were imported into a solid modeling software (Rhinoceros® version 4.0, Robert McNeel & Associates, Seattle, WA) in order to construct 3D anatomical vertebral models of L2, L3, L4, L5 and S1 using an established, validated protocol (12, 13, 22). Both the CT and MRI techniques yield accurate vertebral 3-D models that can be used interchangeably (22).

Dual Fluoroscopic Imaging and 3D-2D Matching Technique

Before and after X-Stop® implantation, the lumbar spines of the subjects were imaged two times using a dual orthogonal fluoroscopic image system (BV Pulsera, Phillips, Bothell, WA) at seven functional postures of the torso: upright standing, maximum extension, flexion, left-twisting, right-twisting, left-bending, and right-bending (Figure 1). The in-vivo positions of the lumbar vertebrae were then reproduced in the solid modeling software by matching the 3D models of the vertebrae to the calibrated dual fluoroscopic images (12, 13, 22). The 3D models of the vertebrae were independently translated and rotated in 6DOF until their projection outlines matched the osseous contours captured on the two fluoroscopic images (Figure 2). The method can reproduce in-vivo human spine 6DOF kinematics within accuracy of 0.2 mm and repeatability of 0.3 mm in translations and 0.7° in orientations (22).

Range of Vertebral Motion Measurement

The relationship between the adjacent vertebrae at different torso postures was directly measured from the coordinate systems established on the models (Figure 3). Right-hand Cartesian coordinate systems were constructed at the endplates of each vertebra. The origin of the coordinate system was at the geometric center of the endplate. The X-axis was set in the frontal plane to represent the medial-lateral direction of the vertebrae and pointed to the left direction; the Y-axis was set in sagittal plane to represent the anterior-

Figure 1: Experimental setup of the dual fluoroscopic imaging system (DFIS) for capture of the in vivo lumbar spine positions at 7 functional postures.

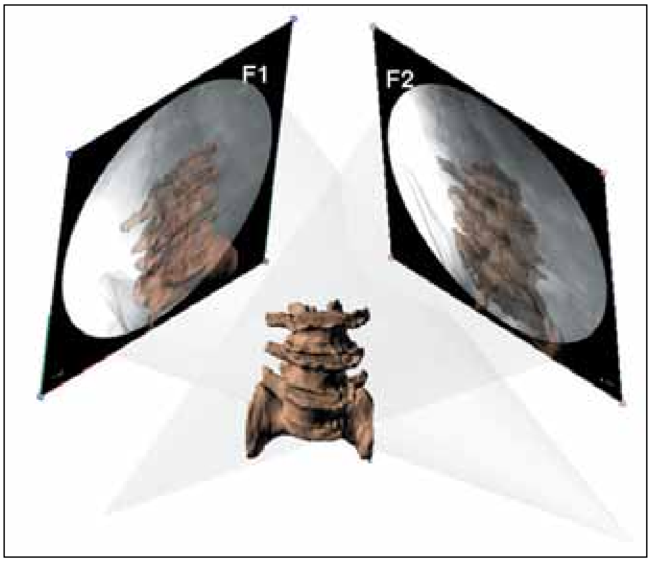

Figure 2: In the solid modeling software (Rhinoceros 4.0), the in vivo positions of the lumbar vertebrae were reproduced by matching the 3D vertebral models to the bony outlines on the dual-fluoroscopic images.

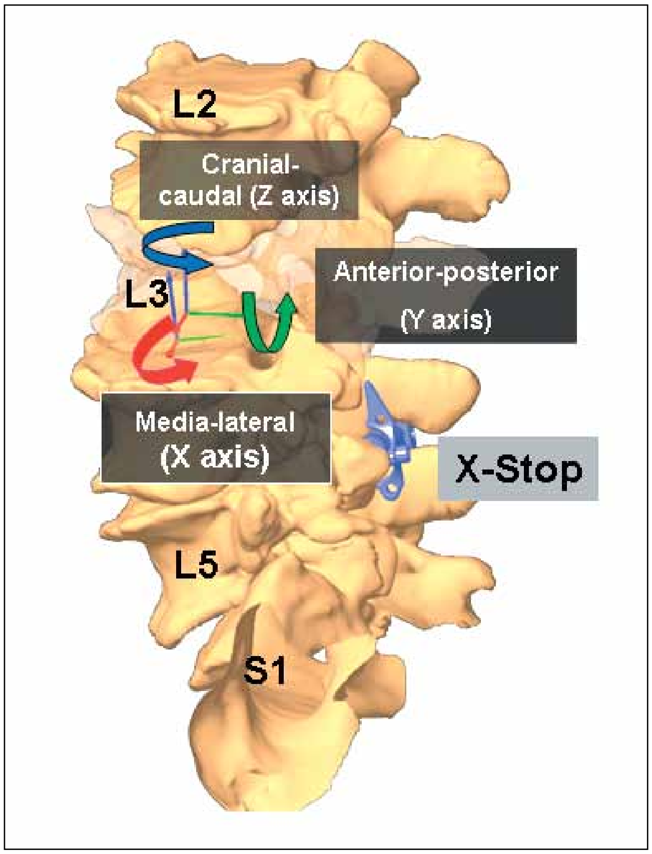

Figure 3: 3D anatomic vertebral models from L2 to S1 were constructed using the CT/MRI scans. The local coordinate system was at the anatomic center of each endplate in order to calculate the relative 6DOF kinematics of the cranial vertebra with respect to caudal vertebra.

posterior direction and pointed to the posterior direction; and the Z-axis was perpendicular to the X-Y plane to represent the cranial-caudal direction and pointed to the cranial direction. The relative motions of the cranial vertebrae body with respect to the caudal vertebral body were calculated at the X-Stop® implanted and the cranial-caudal adjacent segments. The 6DOF kinematics was expressed as three translations along media-lateral, anterior-posterior and cranial-caudal axes, and three rotations (Euler angles in x-y-z sequence). For each functional posture, the ROM data consisted of the primary rotations and the coupled translations and rotations in all 6DOF.

Statistical Analysis

Multiway repeated measures ANOVA was used to analyze the vertebral 3D ROM during physiologically weight-bearing standing, flexion-extension, lateral bending and twisting before and after X-Stop® implantation. 6DOF kinematics were the dependent variables, including three parameters of displacement and three parameters of degrees on the x-y-z axles of coordinate system; the vertebral level and postures were the independent variables. When a statistically significant difference was detected, the post hoc Newman-Keuls test was performed. The Statistical significance was set at $p<0.05$. The statistical analysis was performed using commercially available software (Statistica version 8.0, Statsoft, Tulsa, OK).

RESULTS

Primary Rotations

At the implanted segments, the primary range of extension was significantly decreased from 2.5±1.4° to 1.0±0.5° (p=0.044) after X-Stop® device implantation. In average, reduced range of extension was 50.2%. However, during flexion, left-right bending and left-right twisting, the primary rotations showed no significant differences, which were from1.8 ±1.4° to 1.4±1.1° (p=0.702), from 3.1±2.1° to 2.4±1.1° (p=0.856), from 3.4 ±2.7° to 3.7±2.3° (p=0.777) respectively (Figure 4A-C). At the cranial adjacent segments, the primary range of extension, flexion, left-right bending and left-right twisting showed no significant difference, which were from1.5 ±1.7° to 1.5±0.9° (p=0.994), from 1.1±0.9° to 1.3±0.8° (p=0.748), from 2.5 ±3.0° to 2.2±1.3° (p=0.951), from 1.8 ±1.4° to 1.8±1.4° (p=0.998) respectively, before and after X-Stop® implantation.

At the caudal adjacent segments, the primary range of extension, flexion, left-right bending and left-right twisting also showed no significant difference, which were from 2.4 ±1.0° to 2.3±1.5° (p=0.994), from 2.3±1.2° to 2.5±1.6° (p=0.963), from 1.9 ±1.0° to 2.3±1.3° (p=0.619), from 2.8 ±1.9° to 3.7±3.5° (p=0.996) respectively, before and after X-Stop® implantation.

Coupled Translations and Rotations

The coupled translations (including left-right translation, anterior-posterior translation, cranial-caudal translation) and the coupled rotations were not significantly affected (p>0.05) at the implanted segments and the adjacent segments during all studied positions, i.e. extension, flexion, lateral bending and twisting, after the X-Stop® implantation.

DISCUSSION

We have showed that only the ROM during extension was significantly (p<0.05) decreased by 50.2%, while the other primary rotations ranges were not significantly (p>0.05) changed after X-Stop® implantation. In line with our data, others (14, 17, 24) have also found a significant decrease in the range of extension following X-Stop® implantation. Park et al. (17) reported a significant (p<0.05) decrease to 67% (from 2.72° to 1.89°); Lindsey et al. (14) reported a decrease from 1.3° to 0.5° (p=0.052). Wilke et al. (24) evaluated the kinematics of human cadaver specimens with bilateral hemifacetectomy after ISP spacers implantation and observed the range of extension was only 50% of the ROM of the intact state, but the ranges of flexion, lateral bending and axial rotation were not significantly affected.

In contrast, Park et al. (17) observed that the range of flexion was significantly (p<0.05) decreased from 4.35° to 3.11° and Lindsey et al. (14) also reported a significant (p<0.05) decrease in flexion from 6.3° to 2.5°. In our study, the range of flexion at the implanted segment was not significantly (p>0.05) affected by the X-Stop® implantation from preoperative 1.8 ±1.4° to postoperative 1.4±1.1° (P=0.702), although the post-operative segment had in average a small range in flexion. The inconsistency of these findings may be due to the different loading conditions between our in-vivo and previous in-vitro study designs. In-vitro testing is limited by the alteration of the normal soft tissue stiffness and lacks normal physical conditions (9). In-vivo studies by Siddiqui et al. (21) and Nandakumar et al. (16) reported that the range of whole extension-flexion motion was not affected significantly (p>0.05) using a positional MRI technique in LSS patients; however, they did not separate extension from flexion and treated the two motions as a whole.

Comparing our ROM value at the implanted level with the previous studies, we found that our in-vivo ROM is relatively smaller than the cadaveric experiment data (14, 17, 24), which was probably due to different study metrics. The range of vertebral motion is also affected by segment level (13), age (1, 3), body mass index (BMI) (1, 3) (1) and pathology such as degeneration and LSS (3, 20) which can also account for the different ROM values between the studies. Our data were similar to the data of Siddiqui et al. (21) and Nandakumar et al. (16) who used the positional MRI machines.

Our data also indicated that neither the primary rotation nor the coupled translations and rotations at the adjacent segments were significantly affected (p>0.05) during functional postures by the X-Stop® implantation. These results confirm the results of the previous in-vitro (14, 17) and in-vivo studies (16, 21). Lindsey et al. (14) and Park et al. (17) reported that the primary range of motion in flexion-extension, axial

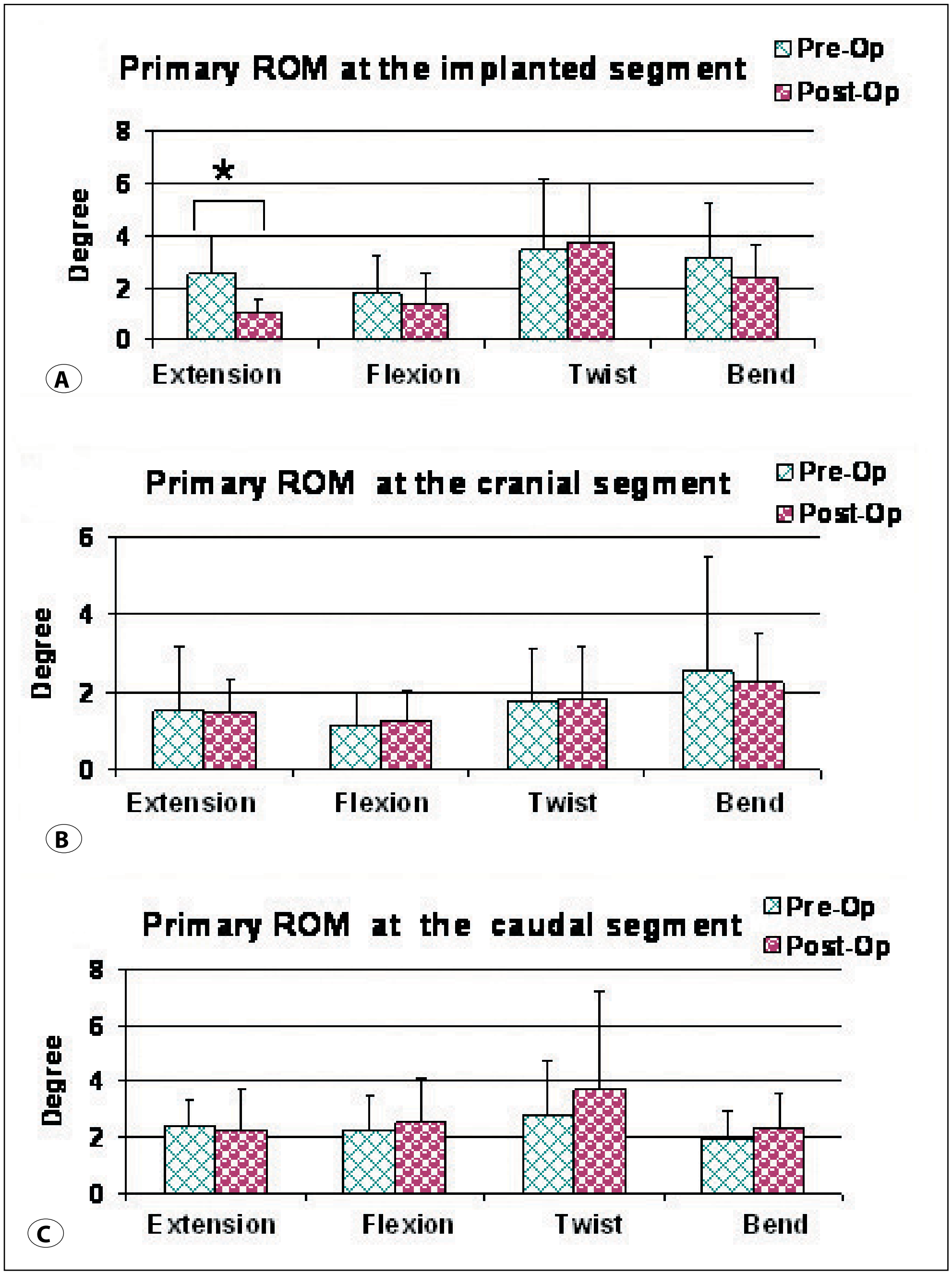

Figure 4: Primary ranges of motion (ROM) during extension (from upright standing to maximum extension), flexion (from upright standing to maximum flexion), twist (left-right twisting) and bend (left-right bending), **A)** at the implanted segment, **B)** at the cranial adjacent segment, **C)** at the caudal adjacent segment.

rotation and lateral bending at the adjacent segments was not significantly altered by the X-Stop® device in human cadaver experiments. Siddiqui et al. (21) and Nadakumar et al. (16) also reported that the X-Stop® device did not significantly ($p>0.05$) affect the in-vivo primary ranges of segmental motion in 2D sagittal planes at the adjacent segments using the positional MRI technique.

In a lumbar cadaveric experiment, Chow et al. (4) confirmed hypermobility of adjacent segments following fusion. Frymoyer et al. (5) also noted a compensatory increase in the range of lumbar motion in adjacent levels following lumbar fusions using flexion-extension radiographs. Since we have noted that the kinematics of the adjacent level has been significantly increased, our hypothesis is that X-Stop® implantation would not increase the adjacent degeneration.

In line with our data, multicenter, prospective, randomized trials carried out by Zucherman et al. (7, 25, 26), have shown that the X-Stop® device implantation can effectively relieve neural symptoms in patients with LSS when compared to conservative treatments. The outcome is similar to the laminectomy surgery at 1-year and 2- year follow-up intervals. However, the long-term biomechanical and clinical efficacy of the X-Stop® implantation is still unknown and should be investigated in future.

There are some limitations that should be noted in the current study. First, the X-Stop® device was implanted at different segments (2 subjects at L3-4, 7 subjects at L4-5, 1 subject at L5-S1). We mixed the ROMs of different levels together since the aim of this current study was to compare the preoperative and postoperative data, and the data showed a similar trend for L3-4, L4-5 and L5-S1. Finally, the sample size was relatively small (8 subjects). Even so, we were able to obtain significant findings using the sensitive experiment techniques.

CONCLUSION

X-Stop® implantation reduced in-vivo range of extension by 50.2% at the implanted segment without disturbing kinematics of the adjacent segments during the postoperative follow-up period. These data may be useful for surgeons who choose to implant interspinous process devices in treatment of stenosis patients.

REFERENCES

1. Bible JE, Simpson AK, Emerson JW, Biswas D, Grauer JN: Quantifying the effects of degeneration and other patient factors on lumbar segmental range of motion using multivariate analysis. Spine (Phila Pa 1976) 33(16):1793-1799,2008
2. Bono CM, Vaccaro AR: Interspinous process devices in the lumbar spine. J Spinal Disord Tech 20 (3):255-261,2007
3. Burton AK, Battie MC, Gibbons L, Videman T, Tillotson KM: Lumbar disc degeneration and sagittal flexibility. J Spinal Disord 9 (5):418-424,1996
4. Chow DH, Luk KD, Evans JH, Leong JC: Effects of short anterior lumbar interbody fusion on biomechanics of neighboring unfused segments. Spine (Phila Pa 1976) 21(5):549-555,1996
5. Frymoyer JW, Hanley EN Jr, Howe J, Kuhlmann D, Matteri RE: A comparison of radiographic findings in fusion and nonfusion patients ten or more years following lumbar disc surgery. Spine (Phila Pa 1976) 4(5):435-440,1979
6. Ha KY, Schendel MJ, Lewis JL, Ogilvie JW: Effect of immobilization and configuration on lumbar adjacent-segment biomechanics. J Spinal Disord 6(2):99-105,1993
7. Hsu KY, Zucherman JF, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, et al: Quality of life of lumbar stenosis-treated patients in whom the X STOP interspinous device was implanted. J Neurosurg Spine 5(6):500-507,2006
8. Kahmann RD, Buttermann GR, Lewis JL, Bradford DS: Facet loads in the canine lumbar spine before and after disc alteration. Spine (Phila Pa 1976) 15 (9):971-978,1990
9. Keller TS, Holm SH, Hansson TH, Spengler DM: 1990 Volvo Award in experimental studies. The dependence of intervertebral disc mechanical properties on physiologic conditions. Spine (Phila Pa 1976) 15(8):751-761,1990
10. Keorochana G, Taghavi CE, Lee KB, Yoo JH, Liao JC, Fei Z, et al: Effect of sagittal alignment on kinematic changes and degree of disc degeneration in the lumbar spine: an analysis using positional MRI. Spine (Phila Pa 1976) 36(11):893-898,2011
11. Kondrashov DG, Hannibal M, Hsu KY, Zucherman JF: Interspinous process decompression with the X-STOP device for lumbar spinal stenosis: A 4-year follow-up study. J Spinal Disord Tech 19 (5):323-327,2006
12. Kozanek M, Wang S, Passias PG, Xia Q, Li G, Bono CM, et al: Range of motion and orientation of the lumbar facet joints in vivo. Spine (Phila Pa 1976). 34 (19):E689-696,2009
13. Li G, Wang S, Passias P, Xia Q, Wood K: Segmental in vivo vertebral motion during functional human lumbar spine activities. Eur Spine J 18 (7):1013-1021,2009
14. Lindsey DP, Swanson KE, Fuchs P, Hsu KY, Zucherman JF, Yerby SA: The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine. Spine (Phila Pa 1976) 28 (19):2192-2197,2003
15. Moojen WA, Arts MP, Bartels RH, Jacobs WC, Peul WC: Effectiveness of interspinous implant surgery in patients with intermittent neurogenic claudication: A systematic review and meta-analysis. Eur Spine J 20 (10):1596-1606,2013
16. Nandakumar A, Clark NA, Peehal JP, Bilolikar N, Wardlaw D, Smith FW: The increase in dural sac area is maintained at 2 years after X-stop implantation for the treatment of spinal stenosis with no significant alteration in lumbar spine range of movement. Spine J 10 (9):762-768,2010
17. Park SW, Lim TJ, Park J: A biomechanical study of the instrumented and adjacent lumbar levels after In-Space interspinous spacer insertion. J Neurosurg Spine 12 (5):560-569,2010
18. Patil S, Burton M, Storey C, Glenn C, Marino A, Nanda A: Evaluation of interspinous process distraction device (X-STOP) in a representative patient cohort. World Neurosurg 80(1-2):213-217,2013
19. Richards JC, Majumdar S, Lindsey DP, Beaupre GS, Yerby SA: The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication. Spine (Phila Pa 1976) 30 (7):744-749,2005
20. Schmoelz W, Huber JF, Nydegger T, Dipl I, Claes L, Wilke HJ: Dynamic stabilization of the lumbar spine and its effects on adjacent segments: An in vitro experiment. J Spinal Disord Tech 16 (4):418-423,2003
21. Siddiqui M, Karadimas E, Nicol M, Smith FW, Wardlaw D: Effects of X-STOP device on sagittal lumbar spine kinematics in spinal stenosis. J Spinal Disord Tech 19 (5):328-333,2006
22. Wang S, Passias P, Li G, Wood K: Measurement of vertebral kinematics using noninvasive image matching method-validation and application. Spine (Phila Pa 1976) 33(11):E355-361,2008
23. Wang S, Xia Q, Passias P, Li W, Wood K, Li G: How does lumbar degenerative disc disease affect the disc deformation at the cephalic levels in vivo? Spine (Phila Pa 1976) 36 (9):E574-581,2011
24. Wilke HJ, Drumm J, Haussler K, Mack C, Steudel WI, Kettler A: Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure. Eur Spine J 17 (8):1049-1056,2008
25. Zucherman JF, Hsu KY, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, et al: A prospective randomized multi-center study for the treatment of lumbar spinal stenosis with the X STOP interspinous implant: 1-year results. Eur Spine J 13(1):22-31,2004
26. Zucherman JF, Hsu KY, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, et al: A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: Two-year follow-up results. Spine (Phila Pa 1976) 30(12):1351-1358,2005