MOTION BEHAVIOR OF THE VERTEBRAE AFTER INSERTION OF AN INTERSPINOUS SPACER IMPLANT UNDER VARIOUS CONDITIONS

H.S. Lee*, S.J. Moon*, K.C. Shin**, K.Y. Lee*** and S.J. Lee *, ****

* Biomedical Engineering, Inje University, Gimhae, Korea
** Cheil Orthopaedic Hospital, Seoul, Korea
*** Mechanical Engineering, Sejong University, Seoul, Korea
**** Paik Institute for Clinical Research, Inje University, Busan, Korea

sjl@bme.inje.ac.kr

Abstract: Interspinous spacers have been developed as an alternative surgical treatment for laminectomy or fusion with pedicle screws and rods for the treatment of lumbar spinal stenosis. However, its biomedical efficacies are well not known. In this study, we evaluated kinematic behaviors of the surgical and the adjacent levels before and after inserting interspinous spacers. Five porcine lumbar (L2-L6) spines were prepared. On each specimen, an interspinous spacer was inserted at the L4-L5. A bending moment of 7.5Nm in flexion, extension, lateral bending, and axial rotation were imparted with a compressive force of 700N. A stereophotogrammetric set-up with DLT algorithm was used to assess the three-dimensional motions of the specimen where three markers (≤0.8 ㎜) were attached to each vertebra. Results showed that extension motion decreased by 46.2% at the surgical level (L4-L5) after insertion of interspinous spacer. At the adjacent levels, the range of motion remained unchanged. In other motions, there were no significant changes in ROM. Therefore, our experimental results demonstrated the interspinous spacer can be very effective in limiting the extension motion that may cause narrowing of the spinal canal and vertebral foramen while maintaining kinematic behaviors at the adjacent levels. Further, these results suggested that the use of interspinous spacer may be able to prevent lower back pain at the surgical level and to lower the incidence of degenerative changes at the adjacent levels.

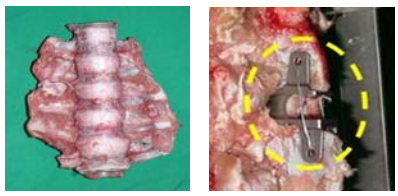
Introduction

Degenerative lumbar spinal stenosis (DLSS) is considered to be one of major causes of lower limb discomfort and disability [1]. Previous studies showed that DLSS causes mechanical compression of the spinal cord and nerve roots as well as compression of vascular structure, which manifests leg pain, numbness and weakness of muscles [2-3]. For surgical management of DLSS, decompression and fusion with pedicle screws and rods are being currently used. However, subsequent degenerative changes at the adjacent vertebrae and loss of lumbar spinal curvature have been cited as inherent limitations. Recently, many types of interspinous spacer have been developed to treat DLSS. They are intended to keep the lumbar spine in a slightly flexed posture to relieve a pain caused by the narrowing of spinal canal and vertebral foramen [4]. In this study, we evaluated the biomechanical effectiveness of the interspinous spacers by measuring ROM of adjacent and operated levels during flexion-extension, lateral bending and axial rotation. For this purpose, changes in motion of each vertebra due to insertion of interspinous spacer were measured in three dimension using principles of stereophotogrammetry.

Materials and Methods

Preparation of Specimens

Five porcine lumbar (L2-L6) specimens were used in this experiment. They were stored frozen at -20°C. Before testing, the specimens were thawed at a room temperature and all muscle and adipose soft tissues were dissected (Figure 1-A). Resin (Lang Dental Manufacturing Co., Inc., USA) was used to secure the cranial portion of L2 and the caudal portion of L6. For surgical model, muscles, adipose and ligamentous soft tissues between L4 and L5 spinous processes were removed. An interspinous spacer (12mm in height) that is made of titanium (Interspinous-U, Fixano, France) was inserted at the spaces between interspinous processes of L4 and L5 (Figures 1-B and 2). Lateral wings and spinous processes were fixed by a medical wire (Φ=0.8mm) to prevent the interspinous spacer from slipping.



(A) (B)

Figure 1: Porcine vertebrae used in this study, (A) the intact (L2-L6), (B) after insertion on interspinous-U (L4-L5)

ISSN: 1727-1983 © 2005 IFMBE

(A) (B)

Figure 2: Interspinous-U used in this study, (A) sagittal view, (B) oblique view

3-D Motion Measurement

We used algorithm of direct linear transformation (DLT) and the Euler angles to measure kinematic characteristics of each vertebra before and after inserting an interspinous spacer. The DLT method allows the determination of the three dimensional coordinates of a point in space from two or more planar images (i.e., two-dimensional images). Its algorithm is commonly used in kinematic analysis of human and animal movement [5]. Advantages of DLT method are the accuracy of the results obtained and the great flexibility in camera set-up.

The Direct Linear Transformation equations are:

$$x + \delta x = \frac{L_1 X + L_2 Y + L_3 Z + L_4}{L_9 X + L_{10} Y + L_{11} Z + 1}$$

$$x + \delta x = \frac{L_5 X + L_6 Y + L_7 Z + L_8}{L_9 X + L_{10} Y + L_{11} Z + 1}$$

in which (x, y) are the digitized coordinates of a point, (δx, δy) are the errors associated with the coordinates, and (L_1, L_2, L_3,…, L_{11}) are the unknown DLT parameters of each camera.

After reconstructing three dimensional coordinates by DLT method, we used the Euler angle method to calculate angle changes of vertebrae between the motions. The coordinate transformation matrix in terms of x, y, z (i.e., the local coordinate system that defines the each vertebra) with respect the global coordinate system of X, Y, Z was defined from the dot product of unit vectors that were constructed from each three points on the rigid body. The coordinated transformation matrix was 3×3 matrix by three unit vectors and three axes.

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} i \bullet i' & i \bullet j' & i \bullet k' \\ j \bullet i' & j \bullet j' & j \bullet k' \\ k \bullet i' & k \bullet j' & k \bullet k' \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix}$$

and the rotation matrix can be written as:

$$[R] = \begin{bmatrix} C_2C_3 & S_1S_2S_3 + C_1S_3 & S_1S_3 - C_1C_3S_2 \\ -C_2S_3 & C_1C_3 - S_1S_2S_3 & C_1S_2S_3 + S_1C_3 \\ S_2 & -S_1C_2 & C_1C_2 \end{bmatrix}$$

where, c = cosine, s = sine, and 1, 2, and 3 denote the rotation angles about x, y, and z, respectively. Therefore, coordinate transformation with Euler angles can be written as [6]:

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} C_2C_3 & S_1S_2S_3 + C_1S_3 & S_1S_3 - C_1C_3S_2 \\ -C_2S_3 & C_1C_3 - S_1S_2S_3 & C_1S_2S_3 + S_1C_3 \\ S_2 & -S_1C_2 & C_1C_2 \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix}$$

Euler angles are most commonly used to describe flexion/ extension, lateral bending, and axial rotation of the joint body motion in space. Figure 3 shows schematic diagram for 3-D motion measurements.

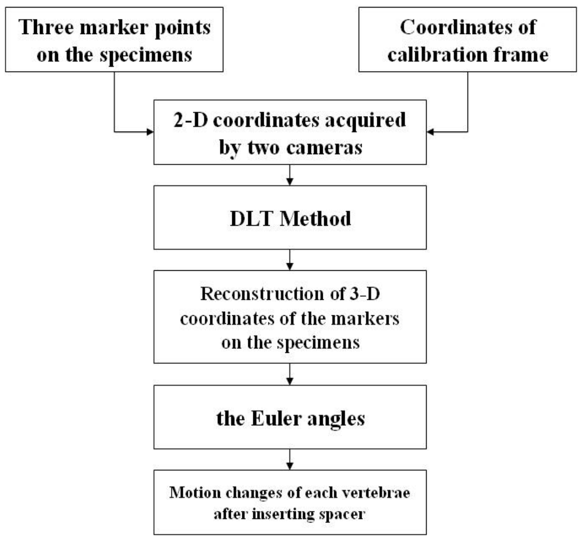


Figure 3: Schematic diagram for 3-D motion reconstruction using DLT algorithm and Euler angles

Surgical operation was simulated on the specimen by inserting interspinous spacer (Interspinous-U®, Fixano Co., France) between the L4-L5 spinous processes. At each motion, the 2-D images of each vertebra from two digital cameras (SONY: DSC F505) were obtained simultaneously. For analyzing 3-D motion changes of each vertebra, DLT algorithm and Euler angle are used. The 3-D motions of both the intact and the operated specimens were calculated at the superiorly adjacent (L3-4), the operated (L4-5), and the inferiorly adjacent (L5-6) motion segments at each loading condition.

Flexibility Test

Three markers (Φ=0.8mm) were attached on each vertebra to define the rigid body motion of the vertebral body. The porcine specimens were placed in a testing machine that has been calibrated for stereophotogrammetry measurements. L2 and L6 of the specimens were fixed on a loading apparatus capable of applying bending moments. To simulate physiologically relevant loading conditions, a bending moment of 7.5Nm in flexion, extension, lateral bending, and axial rotation were imparted with a compressive force of 700N as found in literature [7]. The 2-D coordinates of each vertebra were taken by two cameras (SONY: DSC F505) and were then converted into 3-D coordinates using Direct Linear Transformation (DLT) algorithm. Euler angles were calculated to assess relative range of motion of each vertebra in three dimensions before and after insertion of the interspinous-U.

Statistical Analysis

ANOVA test (SPSS 10.0, SPSS Inc., IL, USA) with a level of significance of 0.05 was used to analyze the motion changes at the surgical and the adjacent levels after inserting spacer during various loading conditions.

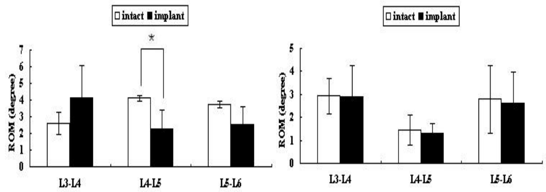
Results

Accuracy of the Measurements

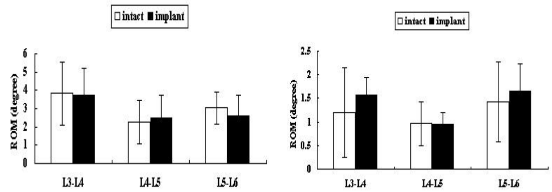
For 3-D motion measurement of each vertebra, the accuracy was rotations and translations within 0.54 degrees and 0.15mm, respectively.

Flexibility Test

In extension, insertion of the interspinous spacers resulted in statistically significant decrease with a drop of 46.2% at the operated level. There were considerable changes in range of motion (ROM) at the adjacent levels, but statistically insignificant, which indicated the preservation of the normal motion after surgery. In other motions, there were no significant changes in ROM (Figure 4) as well regardless of levels.



(A) Extension (B) Flexion



(C) Lateral Bending (D) Axial Rotation

Figure 4: The mean ROM of the adjacent and implanted levels before and after insertion of interspinous spacer during flexion-extension, lateral bending, and axial rotation (* : $p < 0.05$).

Discussion

We evaluated the biomechanical effectiveness of the interspinous spacers in terms of spinal kinematics of the porcine lumbar spine before and after insertion of the implant. In this study, porcine lumbar spines were used for *in vitro* biomechanical testing due to the limited availability of human cadaver specimens. Despite apparent differences in anatomical structure such as size, shape, spinal curves, orientation of the spinous and transverse processes, and the facet joint, Dickey et al.[8] suggested that the porcine lumbar spine may be a potential model for the human lumbar spine for *in vitro* mechanical test including comparisons between spinal fixation constructs. Lindsey et al.[4] reported that degenerative lumbar spinal stenosis could be relieved by flexing the stenotic segment, which decreases epidural pressure, increases the cross sectional area of the spinal canal, increases the area of intervertebral foramens, and decreases nerve root compression. Chow et al.[9] reported redistribution of the mobility of the unfused (i.e., adjacent) levels after either a single level L4-5 or a double level L4-5-S1 fusion. Loss of lumbar lordosis after fusion has been suggested to be a reason for the degeneration of the adjacent levels [10].

Our study showed that insertion of the interspinous spacer resulted in ROM decrease at the surgical levels by 46.2% under extension. Thus, the limited extension motion at the surgery levels (L4-L5) could be effective for treatment of DLSS by reducing nerve root compression. In addition, the ROM of the adjacent levels remained relatively unchanged while preserving normal kinematics of the motion segments. In terms of flexion, lateral bending and axial rotation, there are no significant changes in ROM. Therefore, use of interspinous spacer can effectively preserve the normal motion behavior at the adjacent level while effectively reducing the ROM in extension.

Conclusions

Our experimental results demonstrated the interspinous spacer is very effective in limiting the extension motion that may cause narrowing of the spinal canal and vertebral foramens while maintaining kinematic behaviors at the

 ISSN: 1727-1983

adjacent levels. These results suggested that the use of interspinous spacer may be able to prevent lower back pain at the surgical level and to lower the incidence of degenerative changes at the adjacent levels.

Acknowledgement

This study was supported by the Korea Science and Engineering Foundation Grant (R01-2005-000-10116-0)

References

[1] AMASHITA K., HAYASHI J., OHZONO K., and HIROSHIMA K. (2003): 'Correlation of Patient Satisfaction with Symptom Severity and Walking Ability after Surgical Treatment for Degenerative Lumbar Spinal Stenosis', *Spine*, **28**, pp. 2477-2481

[2] GILES G. (2000): 'Mechanisms of Neurovascular Compression within the Spinal and Intervertebral Canals', *JMPT*, **23**, pp. 107-111

[3] INUI Y., DOITA M., OUCHI K., TSUKUDA M., FUJITA N., and KUROSAKA M. (2004): 'Clinical and Radiologic Features of Lumbar Spinal Stenosis and Disc Herniation With Neuropathic Bladder', *Spine*, **29**, pp. 869-873

[4] LINDSEY D., SWANSON K., FUCHS P., HSU K., ZUCHERMAN J., and YERBY S. (2003): 'The effects of an interspinous implant on the kinematic of the instrumented and adjacent levels in the lumbar spine', *Spine*, **28**, pp. 2192-2197

[5] BOURCELOT P., AUDIGIEI F., DEGUEURCE C., GEIGER D., and DENOIX J. (2000): 'A Method to Synchronise Cameras Using the Direct Linear Transformation Technique', *J. Biomechanics*, **33**, pp. 1751-1754

[6] CRAWFORD N., YAMGUCHI G., and DICKMAN C. (1996): 'Methods for Determining Spinal Flexion/ Extension, Lateral Bending, and Axial Rotation from Marker Coordinate Data: Analysis and Refinement', *Human Movement Science*, **15**, pp. 55-78

[7] YAMAMOTO I., PANJABI M., CRISCO R., and OXLAND T. (1989): 'Three-Dimensional Movements of the Whole Lumbar Spine and Lumbosacral Joint', *Spine*, **14**, pp. 1256-1260

[8] DICKEY J., DAMUS G., and BENDER D. (2003): 'Comparison of Porcine and Human Lumabr Spine flexion Mechanics', *Vet. Comp. Orthop. Traumatol*, **16**, pp. 44-49

[9] CHOW D., LUK K., EVANS J., and LEONG J. (1996): 'Effects of Short Anterior Lumbar Interbody Fusion on Biomechanics of Neighboring Unfused Segments', *Spine,* **21**, pp. 549-555

[10] UMEHARA S., ZINDRICK M., PATWARDHAN A., and ea al. (2000): 'the Biomechanical Effect of Postoperative Hypolordosis in Instrument Lumbar Fusion on Instrumented and Adjacent Spinal Segments', *Spine,* **25**, pp. 1617-1624

ISSN: 1727-1983 © 2005 IFMBE