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Change in Kinematics of the Spine after Insertion of an Interspinous Spacer for the Treatment of the Lumbar Spinal Stenosis

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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. Three porcine lumbar spines were prepared. On each specimen, an interspinous spacer was inserted at the L4-L5. Flexion-extension moments (0, 2.5, 5.0, 7.5, 10Nm) were applied. 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 15-24% at the surgical level (L4-L5) after insertion of interspinous spacer. At the adjacent levels, the range of motion remained unchanged. In flexion, no significant changes in motion were observed regardless of levels. Therefore, 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 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.

Key words: Interspinous spacer, Degenerative lumbar spinal stenosis (DLSS), Kinematic, Biomechanics, Range of motion (ROM)

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 structures, which manifests leg pain, numbness, and weakness of muscles [2-3]. For management of DLSS, either conservative treatment or surgical interventions are used. But conservative treatments such as bracing can be sometimes ineffective to the patients with severe pain or numbness and often require surgery. Surgical management includes decompression, fusion with pedicle screws and rods, or removal of disc and ligament flavum. However, the removal of laminar and facet joint may induce structural changes and destabilization of spinal column [4]. Moreover, subsequent degenerative changes at the adjacent vertebrae and loss of lumbar spinal curve have been cited as its inherent limitations [5-6]. 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 [7]. In this study, biomechanical effectiveness of the interspinous spacers in terms of limiting extension while maintaining normal spinal kinematics was investigated. For this purpose, changes in motion of each vertebra due to insertion of interspinous spacer were measured in three dimensions using principles of stereophotogrammetry.

MATERIALS AND METHODS

Preparation of the Specimens

Three porcine lumbar (L2-L6) specimens were used in this experiment. They were stored frozen at -20℃.

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Before testing, the specimens were thawed at a room temperature and dissected of muscles and adipose tissues (Fig. 1-A). Resin (Lang Dental Manufacturing Co., Inc., USA) was used to secure the cranial portion of L2 and the caudal portion of L6. To insert interspinous spacer, muscles, adipose and ligamentous soft tissues between the L4 and L5 spinous process were removed. An interspinous spacer (12㎜ in height) that is made of titanium (Interspinous U, Fixano, France) was inserted at L4-L5 (Fig. 1-B, Fig. 2). Lateral wings and spinouses were fixed by a medical wire (□=0.8㎜) to prevent the interspinous spacer from slipping.

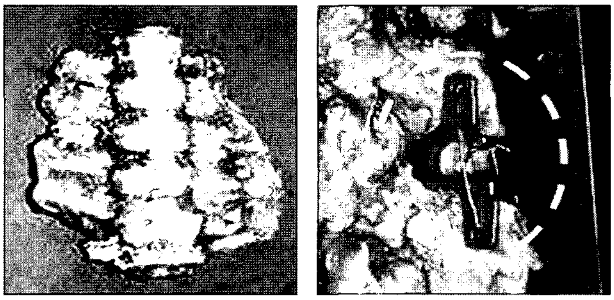
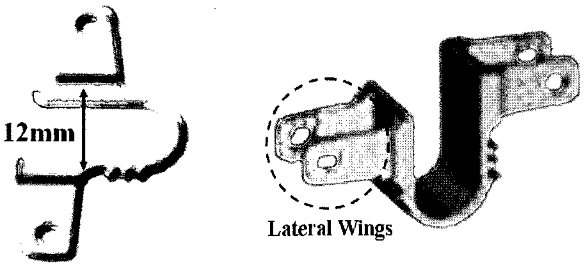

(A) (B)

Fig. 1. Porcine vertebrae used in this study (A) the intact (L2-L6) (B) after insertion of Interspinous U (L4-L5)



(A) (B)

Fig. 2. Interspinous U used in this study (A) saggital view (B) oblique view

Three-Dimensional Measurements

We used algorithm of direct linear transformation (DLT) [8] 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 [8]. 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:

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

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

in which (x, y) are the digitized coordinates of a point, (□x, □y) 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. 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.

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

and the rotation matrix can be written as:

$$[R] = \begin{bmatrix} c_2 c_3 & s_1 s_2 c_3 + c_1 s_3 & s_1 s_3 - c_1 c_3 s_2 \\ -c_2 s_3 & c_1 c_3 - s_1 s_2 s_3 & c_1 s_2 s_3 + s_1 c_3 \\ s_2 & -s_1 c_2 & c_1 c_2 \end{bmatrix}$$

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 [9]:

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} c_2 c_3 & s_1 s_2 c_3 + c_1 s_3 & s_1 s_3 - c_1 c_3 s_2 \\ -c_2 s_3 & c_1 c_3 - s_1 s_2 s_3 & c_1 s_2 s_3 + s_1 c_3 \\ s_2 & -s_1 c_2 & c_1 c_2 \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix}$$

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

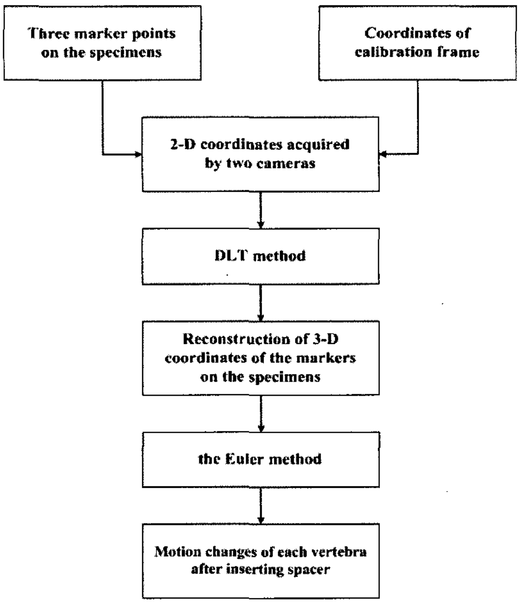


Fig. 3. Schematic diagram for 3-D motion reconstruction using DLT program

Flexibility Test

Three markers (□=0.8㎜) were attached on each vertebra to define its rigid body motion and served as points for the stereophotogrammetry motion measurement. During various types of spinal motion, we could note that the shape of vertebra remained intact to warrant the rigid body assumption of vertebra. Kinematic characteristics of each vertebra was assessed accordingly [10]. The 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. Flexion-extension moments of 0Nm, 2.5Nm, 5Nm, 7.5Nm and 10Nm were imparted with approved weights (Fig. 4). Two dimensional coordinates of each vertebra were taken by two cameras (SONY: DSC F505) (Fig. 5). Two dimensional coordinates were then converted into three dimensional coordinates using DLT algorithm to assess relative 3-D movements of each vertebra from neutral to flexed or extended postures.

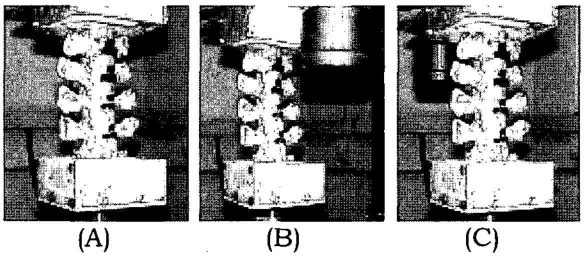

(A) (B) (C)

Fig. 4. Loading conditions (A) neutral (B) flexion moment (C) extension moment

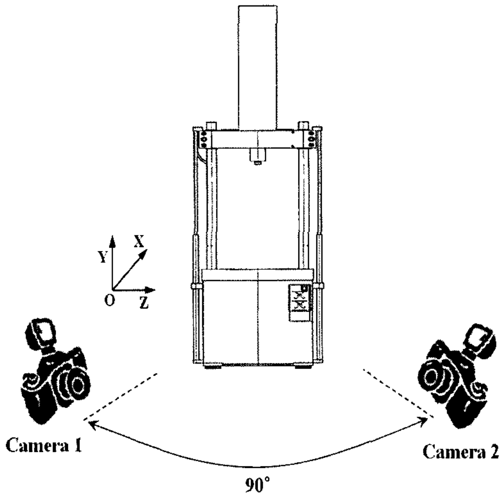


Fig. 5. A stereophotogrammetric set-up that is capable of measuring 3-D motions were built based on direct linear transformation (DLT) algorithm

Statistical Analysis

ANOVA test (SPSS 11.0, 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 flexion-extension moments.

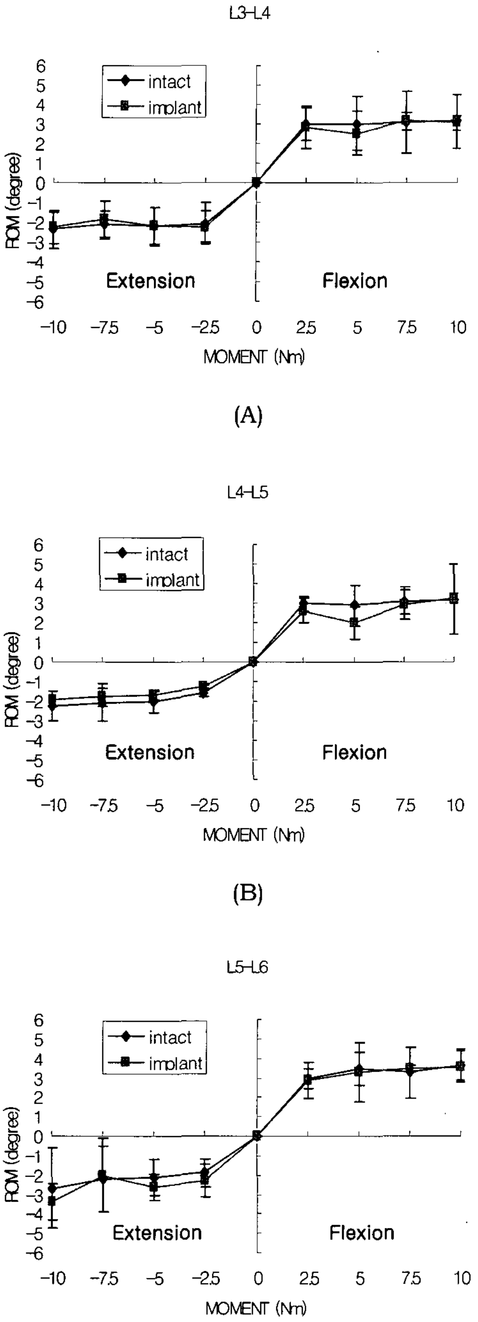
RESULTS

Accuracy of the Measurements

A rigid body with three vertebral markers was used to estimate the accuracy of the motion measurement system. The rigid body Euler angles were calculated from two 2-D stereophotogrammetry images. The accuracy was rotations and translations within 0.54 degrees and 0.15㎜, respectively.

Flexion-Extension Moment Loading

In extension moment, at the surgical level (L4-L5), the range of motion (ROM) decreased by 24%, 22%, 15%, and 17% respectively as the extension moments increased. On the other hand, the ROM increased with extensive moment at the inferiorly adjacent level (L5-L6) except at 7.5Nm of extension. However, it was not statistically significant ($p>0.05$). At the superiorly adjacent levels (L3-L4), the ROM remained relatively unchanged. In flexion, the surgery did not cause any statistically significant changes in ROM regardless of motion segment locations ($p>0.05$).



(A)

(B)

(C)

Fig. 6. Mean values of each vertebral range of motion (ROM) with each moment step (0Nm, 2.5Nm, 5Nm, 7.5Nm, and 10Nm) (A) L3-L4 level (B) L4-L5 level (C) L5-L6 level

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.[10] 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.

Previous studies [4, 6] showed that the ROM at the level above the surgery increased more than the ROM at the below. But our study showed the opposite. That is mainly because we used weights instead of pulley to apply the moment loads. To use the weights, the cranial portion of a loading apparatus was fixed to a testing machine so that amount of the pure moments could be converted to the translation motions. On the other hand, the most cephalic vertebra was unconstrained to allow natural physiological movements of the spine in response to the applied load [11].

Precautions were taken not to injure the specimen and to maintain physiological movements during the experiment. The magnitude of moment in our experiment ranged from 0 to 10 N-m as they are commonly found in literatures. Yamamoto et al.[12] reported that pure moments of a maximum of 10Nm is sufficient to produce maximum physiologic motions and not to injure spine while using human cadaveric spine. Although there are inherent differences between the porcine vertebra and the human's, we applied the moment loads of 0, 2.5, 5.0, 7.5, and 10Nm knowing that the porcine vertebrae are far stronger than the human's. Apparently, no damages were found with our specimen while specimen was undergoing physiologically-relevant flexion and extension.

Lindsey et al.[7] 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. Our study showed that insertion of the interspinous spacer resulted in ROM decrease at the surgical levels by 15% 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 remained relatively unchanged except at 7.5Nm of flexion while preserving normal kinematics of the motion segments.

Chow et al.[6] 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. Rao et al.[4] reported that both laminectomy and laminotomy caused destabilization of a spinal motion segment, which may require an additional surgery to reinforce affected segments. In our results, both the superiorly (L3-L4) and inferiorly (L5-L6) adjacent levels exhibited relatively unchanged ROM on the sagittal plane. Therefore, a new treatment using interspinous spacers is likely to preserve kinematic behaviors at the adjacent levels.

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 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.

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