Development and Evaluation of a System for Intraoperative Measurement of Spinal Rotational Mobility *

Ko KITAHARA**, Kazuhiro HASEGAWA*** and Toshiaki HARA****

**Venture Business Laboratory, Niigata University, 8050 Ikarashi Ninochou, Nishiku, Niigata City, Niigata, Japan, 950-2181
E-mail: kitahara@gs.niigata-u.ac.jp

***Niigata Spine Surgery Center, 2-5-22 Nishi-machi, Kounanku, Niigata City, Niigata, Japan, 950-0165

****Faculty of Engineering, Niigata University, 8050 Ikarashi Ninochou, Nishiku, Niigata City, Niigata, Japan, 950-2181

Abstract

Quantitative measurement of spinal rotational mobility is critical in assessing spinal instability. We have developed a system for intraoperative measurement of spinal mobility. The system consists of a motor-driven mechanical apparatus with a computerized controller, load cell, optical displacement transducer, and spinous process holders that allow handling of the spinal process without damaging the ligaments. In this study, we examined the ability of this measurement system to detect mobility and corresponding clinical instability of a destabilized model spine comprised of porcine lumbar segments. From the load–displacement curve, we determined three motion parameters: stiffness, neutral zone (NZ), and absorption energy (AE). To demonstrate the potential of the measurement system for clinical application, we applied five cycles of axial rotation to the segment ten times. The measurements were highly reproducible. To verify the utility of the measurement system, we tested destabilized functional spinal units in vitro. In this setting, stiffness and AE decreased and NZ increased with progressive destabilization of the model spine. Significant relationships were observed between the destabilized model and the biomechanical data.

Key words: Spine, Biomechanics, Instability, Intraoperative Measurement, Stiffness, Neutral Zone, Absorption Energy

1. Introduction

Low back pain due to spinal segmental instability is common in lumbar degenerative diseases. In this context, “instability” is not used as mechanical engineering term; rather, it is a clinical term used to describe the loss of the spine’s ability to maintain its pattern of motion under normal physiologic loads without neurological deficit, major deformity, or incapacitating pain1). Spinal instability occurs when the ligaments, discs, and facet joints of the spinal segments are damaged, such that they can no longer support the segments sufficiently to protect the neural elements2).

Lumbar segmental instability is difficult to define. Although radiographic evaluation of degenerative lumbar spines is widely performed3)-10), its usefulness in the diagnosis of lumbar segmental instability remains controversial. In previous studies, flexion-extension X-rays showed a large range of normal motion with a significant overlap of underlying...
pathologic conditions\textsuperscript{11},\textsuperscript{12}. Although biplanar, cineradiographic, and fluoroscopic measurements provide some additional information about the disordered motion patterns\textsuperscript{13}-\textsuperscript{18}, these dynamic approaches cannot be used to draw a biomechanical conclusion about instability because no information about the load-deformation relationship can be extracted from the images.

Intraoperative biomechanical measurements assess motion properties that are essential for estimating segmental instability. Ebara et al. developed a method of measuring spinal stiffness that used a spinal spreader and measured the tensile stiffness of a mobile segment; they concluded that tensile stiffness depends on disc degeneration, decompression, and interbody fusion\textsuperscript{19}. Brown et al. developed a motor-driven vertebrae distractor to measure motion segment stiffness. They concluded that the vertebral distractor allows objective and quantitative intraoperative measurement of the stiffness of a mobile lumbar spine segment\textsuperscript{20},\textsuperscript{21}.

In the above studies, spinal segmental mobility was evaluated using the stiffness in flexion. However, from a biomechanical perspective, estimates of additional parameters, such as the neutral zone (NZ), are needed to assess spinal mobility\textsuperscript{22}. Clinical instability cannot be estimated by measuring mobility in flexion only, and measuring the rotational mobility of the spinal segments is also important\textsuperscript{23}.

In 1997, we began ongoing efforts to develop and test a new and safe intraoperative measurement system for determining segmental properties by measuring multiple biomechanical parameters. After performing several ex-vivo studies\textsuperscript{24},\textsuperscript{25}, we launched the clinical application of the measurement system for sagittal plane (flexion-extension) motion properties\textsuperscript{26}. Measuring the relationship between load and displacement during spinal rotation with this system allows evaluation of spinal mobility and detection of spinal instability.

Instability of the spinal segment can occur in any motion direction\textsuperscript{27}-\textsuperscript{34}. In particular, torsional instability has been implicated in the pathogenesis of low back pain\textsuperscript{34}. Therefore, multidirectional measurement of the target segment is desirable. In the study described here, we developed and tested another system for measuring spinal mobility. This system, which measures rotational mobility in the axial plane, was evaluated for its ability to detect segmental mobility corresponding to clinical instability in destabilized porcine lumbar segments.

2. Methods

2-1. Measurement device

To detect spinal segmental instability, we developed a new system for measuring spinal mobility during lumbar spine surgery (Figure 1). The system consisted of spinous process holders (Gi-5; Mizuhoikakikai, Niigata, Japan), a motion generator, and a personal computer. The spinous process holders were designed to handle the spinal processes without damaging the supra- and interspinous ligaments. The motion generator consisted of a computerized linear actuator, an optical displacement transducer (LB-080; Keyence, Tokyo, Japan), a load cell (LUR-A-200NSAI; Kyowa Dengyo, Tokyo, Japan), and a multidirectional ball joint that connected the motion generator to the spinous process holders. The motion generator was attached through the ball joint to two spinous process holders, which gripped the adjacent spinous processes firmly. The linear actuator (RC-RSW-L-50-S; IAI, Shizuoka, Japan) generated continuous displacement applied to the spinous process holders at speeds of 1.00 to 100 mm/sec. The mobile segment was displaced from the neutral position and rotated right and left cyclically. The neutral position was defined as the segment position when no load was applied. In the experiments, the load and displacement at the tip of the caudal spinous process holder were measured using a load...
cell and an optical displacement transducer, respectively, and the load–displacement curves were plotted on a computer screen.

![Fig. 1  Schematic diagram of a new system developed to measure spinal rotational mobility. An actuator is used to move the caudal spinous process holders. Load is measured with a load cell, and displacement is measured using an optical displacement transducer.](image)

2-2. Specimen preparation

In vitro experiments were performed using fresh-frozen porcine lumbar spines to demonstrate the potential of the measurement system, and the specimens consisting of functional spinal units (FSUs) were harvested from mature porcine lumbar spines. The FSUs were dissected to remove all muscles and fatty tissues, while the ligamentous tissues (supraspinal, interspinous, anterior longitudinal, anterior longitudinal, posterior longitudinal, transverse ligament, and flavum), discs, facet joints, and osseous structures were left in place. During the experiments, six FSUs (two each of T12/L1, L2/L3, and L4/L5) were used to demonstrate the potential of the system, and eight FSUs (two each of T12/L1 and L2/L3, and one each of L1/L2, L3/L4, L4/L5, and L5/L6) were used to assess destabilized segments, as shown Table 1. During the tests, the specimens were maintained at a constant temperature and humidity to prevent deterioration.

2-3. Data analysis

From the load–displacement curves, we determined three motion parameters to evaluate the spinal motion: the stiffness, NZ, and absorption energy (AE) (Figure 2). Stiffness describes the relationship between the load and displacement of the spinal segment while rotation is applied. In this study, the stiffness was defined as the slope of the line fitting the load–displacement curve from 1 to 2 mm on right rotation and from –1 to –2 mm on left rotation. The NZ is the flat region of the load–displacement curve around the neutral position. This indicates that the passive spinal column offers little resistance. The NZ was defined as the displacement that occurs while the load is reduced from 1 N to –1 N. The load–displacement curve showed hysteresis, as the load lagged behind the change in displacement. The area inside the load–displacement curve has units of energy. This energy is absorbed by the discs, ligaments, and other soft tissues around the spinal segment while the segment is moving. The AE was defined as the area surrounded by the load–displacement curve during one cycle of spinal motion.
Fig. 2 Determination of each parameter from the third load–displacement curve. The left and right stiffness (N/mm) values were defined as the slopes of the lines fitting the load-displacement curve from –1 to –2 mm and from 1 to 2 mm, respectively. The neutral zone (mm) was defined as the displacement that occurred while the load was reduced from 1 N to –1 N along the load-displacement curve. Absorption energy (J) was defined as the area of the resulting hysteresis loop.

Fig. 3 Models of destabilized porcine lumbar spines. A: Intact. B: Supraspinal and interspinous ligament desmotomy (SID). C: Unilateral total facetectomy (UF). A portion of the left facet joint was removed. D: Unilateral incision of the posterior annulus fibrosus (IAF). The left posterior annulus fibrosus was incised.

2-4. Experimental procedure

We developed a system to measure spinal mobility during lumbar spine surgery to
evaluate spinal instability. Our goal was to establish methods for measuring and evaluating clinical instability intraoperatively. Before making clinical measurements intraoperatively, it is essential to demonstrate the potential of the measurement system.

Repeatability test

The repeatability test was performed to demonstrate the potential of the measurement system. In this test, each FSU was assessed while intact. Displacement generated by the actuator at a speed of 1.0 mm/sec was applied to the tip of the holders with a maximum displacement of 4.0 mm from the neutral position for five cycles of axial rotation. After 5 min, the same specimen was retested for five more cycles of axial rotation, and this process was repeated ten times. In total, this test generated 50 load–displacement curves for each specimen. We determined three motion parameters from each cycle for every load–displacement curve and calculated the coefficients of variation (CVs) by dividing the standard deviation by the mean of each parameter and converting it to a percentage.

Accuracy test using a destabilizing model

To verify the ability of the measurement system to assess spinal instability, destabilized FSUs were tested in vitro. Each specimen was first tested intact and then destabilized before retesting. Subsequently, the specimen was destabilized further and again retested. The same FSU was destabilized sequentially as follows: intact, supraspinous and interspinous ligament desmotomy (SID), unilateral total facetectomy (UF), and unilateral incision of the posterior annulus fibrosus (IAF) (Figure 3). The specimens were subjected to five cyclic displacements at a speed of 1.0 mm/sec with a maximum displacement of 2.0 mm. We analyzed the load–displacement curve of the third cycle of spinal axial rotation to evaluate the influence of destabilization on the segmental motion and mobility. We then compared the three motion parameters calculated from the load–displacement curves with the destabilized models. Statistical analyses were performed with STATISTICA version 6 (StatSoft, USA), using one-factor repeated measures ANOVA to reveal differences within each injury model. P-values of less than 0.05 were considered to be significant.

Table 1  Coefficient of variation (CV) for each mechanical parameter.

<table>
<thead>
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<th>Right Stiffness</th>
<th>Left Stiffness</th>
<th>Neutral Zone</th>
<th>Absorption Energy</th>
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<td>T12/L1</td>
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<td>L2/L3</td>
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<tr>
<td>T12/L1</td>
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<td>4.98%</td>
<td>5.92%</td>
<td>6.88%</td>
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<tr>
<td>L2/L3</td>
<td>2.28%</td>
<td>2.10%</td>
<td>4.44%</td>
<td>6.26%</td>
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<tr>
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<tr>
<td>Mean</td>
<td>4.57%</td>
<td>4.30%</td>
<td>6.20%</td>
<td>8.57%</td>
</tr>
</tbody>
</table>

3. Results

3-1. Repeatability test

To determine the repeatability of the spinal mobility measurement, we calculated the CV of each mechanical parameter determined from the load–displacement curve. The CV is a statistical measure of the dispersion of a probability distribution and is defined as the ratio of the standard deviation to the mean. The CVs were as follows: right rotational stiffness 2.28–5.75% (mean 4.57%), left rotational stiffness 2.10–5.50% (4.30%), NZ 4.44–7.75% (6.20%), and AE 6.28–12.78% (8.57%). The small CVs for each parameter measured
reflected the high repeatability of the load–displacement curves (Table 1).

![Graph showing load-displacement curves for different injury models](image)

Fig. 4 Typical third load–displacement curve for each injury model. Hysteresis loops occurred in all cases and the area inside the hysteresis loops decreased gradually as the destabilization increased.

![Graph showing stiffness, neutral zone, and absorption energy for different injury models](image)

Fig. 5 Left and right stiffness, neutral zone (NZ), and absorption energy (AE) for each injury model. A: The right rotational stiffness was significantly smaller for UF than for SID, and was significantly smaller for IAF than for SID or UF. For the left rotational stiffness, significant differences were detected among SID, UF, and IAF, as with right rotation. B: As destabilization progressed, NZ gradually increased and AE gradually decreased. Significant differences were observed among NZ values for SID, UF, and IAF. C: Statistically significant differences were observed among the AE values for SID, UF, and IAF.

3-2. Accuracy test using a destabilizing model

Segmental mobility is characterized by the relationship between the applied displacement and the load opposing the displacement. Figure 4 shows the typical load–displacement curves obtained using the spinal mobility measurement system; hysteresis loops occurred in all cases and the area inside the hysteresis loops decreased gradually as the destabilization increased.

Spinal mobility was evaluated using three motion parameters: stiffness, NZ, and AE. Because individual differences existed in the three motion parameters, the motion
parameters of the destabilized models were compared to those of the intact specimen. The right rotational stiffness rate was defined as the stiffness of each destabilized model divided by the stiffness of the intact specimen, which was 94.74±8.77% for SID, 43.14±7.81% for UF, and 26.46±13.69% for IAF (mean±standard deviation). The right rotational stiffness rate for UF was significantly smaller than for SID, and the rate for IAF was significantly smaller than for SID and UF. The left rotational stiffness rate was 92.89±5.51% for SID, 81.14±5.91% for UF, and 68.64±11.53% for IAF. Significant differences were detected among SID, UF, and IAF, as with right rotation (Figure 5A). The NZ rate increased gradually as destabilization progressed. As shown Figure 5B, the NZ rate was 113.23±14.17% for SID, 171.58±56.62% for UF, and 221.11±49.60% for IAF. The NZ rate increased remarkably for UF and IAF, and significant differences were observed among SID, UF, and IAF. The AE rate decreased gradually as destabilization progressed. The AE rate was 94.72±8.03% for SID, 62.87±15.29% for UF, and 49.27±6.98% for IAF. Statistically significant differences were observed among SID, UF, and IAF (Figure 5C).

4. Discussion and Conclusions

After a half-century of controversy, a clear definition of clinical instability of the spine has yet to be established, partly because facts elicited from ex-vivo or animal studies 28)-38) appear inconsistent with those from patients with mechanical low back pain or motion-induced radiculopathy. Although conventional radiographic measurements are still popular for the clinical diagnosis of instability, radiographic examinations 3)-10) are limited to still measurements with a large range of values, so that normal angular motion cannot be precisely defined 25). In addition, these radiographic measures demonstrate some kinematics, but they do not yield biomechanical data concerning the load–deformation relationship, which is necessary to determine the segmental instability. Thus, no clinically convenient and biomechanically accurate tools that yield results correlating with those of extensive basic studies have been available.

Our approach constitutes an attempt to bridge the gap between the basic biomechanical data and the clinical symptoms observed to arise from instability. The final goals of our intraoperative measurement for segmental instability are to determine distinct criteria based on the biomechanical data and to certify a rationale for lumbar fusion, the gold-standard therapy for segmental instability, from a biomechanical point of view. We have already launched the clinical application of the measurement system for sagittal plane (flexion-extension) motion properties 26) following several ex-vivo studies 24),25). However, since instability of the spinal segment can occur in any motion direction 8),28)-34), multidirectional measurement of the target segment is desirable. This study provides a basic confirmation of the potential of our new measurement system for quantitating clinical motion properties in the axial plane.

The measurement had sufficiently high repeatability for clinical use, as indicated by the low CV for each motion parameter. The computerized motor-driven measurement system, which was able to accurately rotate the segment at a constant speed, and the specially designed spinous process holder, contributed to the excellent repeatability.

Our spinal mobility tester can evaluate stiffness, NZ, and AE as new parameters for defining spinal mobility. In this study, as destabilization of the spine increased, stiffness and AE decreased progressively, while NZ increased. Because stiffness is the relationship between the load and deformation of the spinal segment, a segment having a high stiffness value can resist a large external force in the normal range of motion (ROM), while a segment with a low stiffness value can deviate from the normal ROM when an external force is applied. Because AE is the energy that is absorbed or lost through the intervertebral discs, ligaments, and other soft tissue around the spinal segment, a spinal segment with a
large AE can relieve external forces, acting as a dashpot. NZ describes the ROM through which the spine moves easily with a minimal load, and it gradually increases as the spinal segment becomes too loose. A relationship between these three parameters and progressive destabilization of the spine is probable, and these parameters can be used to distinguish the destabilized model. A study on intraoperative measurements reported that stiffness was not correlated with the clinical results of surgery\(^{39}\). We suggest that the use of multiple biomechanical parameters, including NZ, is necessary to clarify segmental instability.

This study has certain limitations. The specimens were functional spinal units harvested from porcine lumbar spines, and although porcine lumbar spines are similar to those of humans in size and shape, the clinical measurement of human spinal mobility does not always yield results similar to those obtained in this study. Furthermore, the mechanical behavior of an FSU in vitro is not necessarily the same as its behavior in vivo. Nevertheless, the objective of this study was to assess the potential of the measurement system, and porcine FSUs provide a reasonable model for pre-clinical testing. The biggest limitation, however, was the lack of standardization for individual differences. In an attempt to achieve standardization for individual differences, we compared the parameters of each specimen in its destabilized states to those of the same specimen in the intact state. However, clinical measurements are intended to assess a degenerate segment, and it was not possible to measure the motion parameters of the intact state to standardize the parameters of the degenerate segment. If we were to measure normal segments in various groups, or establish a database for various forms of degeneration, we could quantitatively define the instability of spinal segments.

Although several spinal mobility testing devices have been reported, none can estimate lumbar spine mobility with all the ligamentous structures intact\(^{19–22,40}\). Existing measurement devices were placed between the adjacent spinous processes of a spinal segment, a maneuver requiring incision of the ligament. By incorporating our spinous process holder, our spinal mobility tester allows measurement of the mobility of intact specimens without desmotomy. Of course, the measurement must be performed in a safe manner for clinical use. During our measurements, we observed no adverse events, such as fracture, ligament rupture, nerve injury, or injury of any other structure. In addition, segment mobility measurement took less than 3 min. These results suggest that our motion measurement system is sufficiently safe for intraoperative measurements. This study demonstrated the potential utility of our system for obtaining useful data on spinal mobility for the diagnosis of spinal instability.

**References**


