Evaluation of lumbar segmental instability in degenerative diseases by using a new intraoperative measurement system

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Object. In vivo quantitative measurement of lumbar segmental stability has not been established. The authors developed a new measurement system to determine intraoperative lumbar stability. The objective of this study was to clarify the biomechanical properties of degenerative lumbar segments by using the new method.

Methods. Twenty-two patients with a degenerative symptomatic segment were studied and their measurements compared with those obtained in normal or asymptomatic degenerative segments (Normal group). The measurement system produces cyclic flexion–extension through spinous process holders by using a computer-controlled motion generator with all ligamentous structures intact. The following biomechanical parameters were determined: stiffness, absorption energy (AE), and neutral zone (NZ). Discs with degeneration were divided into 2 groups based on magnetic resonance imaging grading: degeneration without collapse (Collapse[−]) and degeneration with collapse (Collapse[+]). Biomechanical parameters were compared among the groups. Relationships among the biomechanical parameters and age, diagnosis, or radiographic parameters were analyzed.

Results. The mean stiffness value in the Normal group was significantly greater than that in Collapse[−] or Collapse[+] group. There was no significant difference in the average AE value among the Normal, Collapse[−], and Collapse[+] groups. The NZ in the Collapse[−] was significantly higher than in the Normal or Collapse[+] groups. Stiffness was negatively and NZ was positively correlated with age. Stiffness demonstrated a significant negative and NZ a significant positive relationship with disc height, however.

Conclusions. There were no significant differences in stiffness between spines in the Collapse[−] and Collapse[+] groups. The values of a more sensitive parameter, NZ, were higher in Collapse[−] than in Collapse[+] groups, demonstrating that degenerative segments with preserved disc height have a latent instability compared to segments with collapsed discs. (DOI: 10.3171/SPI/2008/8/3/255)

KEY WORDS • intraoperative measurement • lumbar degenerative disease • segmental instability

LUMBAR segmental instability is difficult to define. Although radiographic evaluation of degenerative lumbar spines is extensively performed,6,7,13,20,23,34 its usefulness in the diagnosis of lumbar segmental instability remains controversial. Previous studies reported that flexion–extension x-ray films show a large range of normal motion with a significant overlap of underlying pathological conditions.8,14 Biplanar, cineradiographic, or fluoroscopic measurements provide some additional information on the disordered motion patterns.11,16,27,33,37,39 These dynamic approaches, however, cannot be used to draw a biomechanical conclusion about the instability, because no information about the load–deformation relationship can be determined from the images. Direct spinal motion measurements using pins placed directly in the spinous process have been performed, with promising results because of the detailed kinematic information obtained.10,30,36 This measurement method has not been developed for routine clinical use, however, probably because of the invasiveness of the procedure.
Intraoperative measurements of a cervical or lumbar segment are occasionally performed to determine instability. Common limitations of the previously used measurements include damage to the ligamentous or bone structures due to the fixation of pins, screws, or a spreader to the vertebrae, and also the fact that data about the stiffness of only a single loading direction (flexion or extension) can be obtained. From a biomechanical viewpoint, segmental properties of the spine cannot be verified by stiffness alone. Measurements of multiple parameters, including the NZ, are necessary. Since 1997, we have been developing a new, safe intraoperative measurement system to determine segmental properties by measuring multiple biomechanical parameters. After performing several ex vivo studies, we have now launched the clinical application of the measurement system. The final goal of this project is to establish a reliable system to obtain the biomechanical data that can be referred to for decision-making about lumbar fusion, which is the gold standard therapy for segmental instability.

The purpose of this study was to clarify the biomechanical properties of lumbar segments in patients with degenerative disc disease by using the new intraoperative measurement system.

Clinical Material and Methods

Equipment Used

This new intraoperative measurement system consists of spinous process holders (Gi-5, Mizuhoikikikai), a motion generator (RC-RSW-L-50-S, IAI Corp.), and a personal computer. The 2 holders firmly grip adjacent spinous processes. A cyclic displacement in a single direction at a speed of 2 mm/second is generated to the tips of the holders, with a maximum displacement of 15 mm from the neutral position (defined as the position in which no load is recorded between the tips of the holders). The load at the tip of the caudal spinous process holder is measured with a load cell (LUR-A-200NSAI, Kyowadengyo Corp.), and displacement is measured using an optical displacement transducer (LB-080, Keyence). Real-time load–displacement data are obtained using a personal computer. The spinous process holder is connected to the motion generator through a multidirectional ball joint, producing flexion–extension of the segment (Fig. 1).

If a center of the segmental rotation is supposed to be at the center of the nucleus pulposus, the length of the lever arm is ~190 mm. In this setting, the 15-mm translation of the holder’s tips is equivalent to an ~3.75-mm translation.

Fig. 1. Schematic and photograph illustrating the setup for a new intraoperative measurement system consisting of spinous process holders, a motion generator, an optical displacement transducer, and a personal computer.
Biomechanical evaluation of lumbar segmental instability

of the spinous processes. This distance is not hazardous. In addition, the real segmental motion (× [degrees of rotation]) induced by a 15-mm translation of the tips of the spinous process holders can be approximately calculated as follows (Fig. 2A):

\[
x = 360 \times (15/2\pi) (°) \\
= 360 \times (15/2 \times 3.14 \times 190) \\
= 4.526°.
\]

Therefore, the ROM is \(\approx 4.5 \times 2 = 9°\). This value is equivalent to the ROM measured intraoperatively with a portable x-ray apparatus (Fig. 2B). Nine degrees of rotation is usually within a normal ROM in L3–4 or L4–5. In our previous experiment, in which we used porcine spines,\(^9\) we performed the lumbar motion measurement by using the system with the same length of translation; 15 mm flexion and extension. Although the dimensions of the porcine spine, especially the disk height, are smaller than those of the human spine, a 15-mm translation of the spinous process holder demonstrated stable load–deformation data with no injury to the spinal elements. In a subsequent clinical study of 20 lumbar segments in 19 patients (10 men and 9 women, mean age 59.3 years, range 21–83 years) with degenerative lumbar disease,\(^9\) stable load–deformation data with high repeatability were obtained without any adverse effects such as fracture or ligamentous injury. The symptoms of all the patients, even those with severe nerve compression due to stenosis or disc hernia, did not worsen and other lesions such as herniated discs did not newly occur. Based on these preliminary results, we considered a 15-mm translation with this measurement system to be safe and launched its routine clinical use.

**Measurement Protocol**

Patients were placed in the prone position on a Hall frame and the paraspinal muscles were detached from the spinous processes by using standard procedures. Two spinous process holders were attached to the adjacent spinous processes. All ligamentous structures of the functional spinal unit, including the supra- and interspinous ligaments and facet joints, were preserved intact. The motion generator attached to the tips of the holders loaded the segment, producing 5 flexion–extension segmental motion cycles, and real-time load–displacement data were obtained with a sampling rate of 5 Hz. Data obtained during the third cycle were used for biomechanical analysis. We defined 3 motion parameters by using the load–displacement data; these were stiffness, NZ, and AE. Stiffness (in Newtons/millimeter) was defined as the slope of the line fitting the load–displacement curve from \(-15\) to \(-10\) mm on flexion motion. The NZ (in millimeters/Newton) was defined as the slope of the line fitting the load–displacement curve from \(-15\) to \(-5\) mm (flexion) to \(+5\) mm (extension) (Fig. 3). All the lines used for measuring stiffness and NZ were calculated using the least-squares method. The AE (in joules) was defined as the area of a hysteresis loop. Preliminary examination of a porcine lumbar spine revealed that the coefficient of variations (standard deviation/mean \(\times 100\)) of each parameter in the present measurement system were as follows: stiffness 8%, NZ 8%, and AE 11%.

**Patient Population**

Twenty-two patients (12 men and 10 women) were included in this study. The mean age was 66.2 years (range 27–80 years). The clinical diagnosis was degenerative spondylolisthesis in 10 cases, canal stenosis in 10, disc hernia in 1, and degenerative scoliosis in 1. The diagnosis was determined by a meticulous neurological evaluation with concomitant radiographic examinations (MR imaging, myelography, computed tomography scanning). These examinations were performed in all patients. The numbers of patients with degenerative spondylolisthesis in L3–4 and L4–5 were 4 and 6, respectively. The levels of the measurement, 11 segments each of L3–4 and L4–5, were all symptomatic and identical to the treated level. No patient had a history of L5–S1 fusion or a sacralized L-5 vertebra. Decompression surgery with or without Graf ligamentoplasty was performed in 13 patients and transforaminal interbody fusion was performed in 9 patients for the diseased levels. Informed consent was obtained from all patients following the approval of the Committee of Medical Ethics of Niigata University (approval No. 182, 2003).
Lateral x-ray films were obtained under the following conditions: lines between bilateral acromion processes and iliac crests were perpendicular to x-ray films, with a distance from the x-ray generator to the film of 2.5 m; the voltage of the x-ray generator was 110 kV; and the electric current was 140 mA. The ROM was determined using the procedure developed by Dupuis et al. Disc height was calculated as the mean value of anterior and posterior disc height divided by the anteroposterior width of upper vertebrae. Magnetic resonance images acquired with a 1.5-T MR imager were obtained in all patients. Grading of disc degeneration was performed on T2-weighted midsagittal fast spin echo MR images (TR 5000 msec, TE 130 msec) based on the systems of Pfirrmann et al. and Thompson et al. Twenty-two discs were divided into: Grade III (inhomogeneous gray nucleus with unclear distinction of nucleus and anulus), 7 discs; Grade IV (inhomogeneous gray to black nucleus without distinction of nucleus and anulus), 9 discs; and Grade V (black nucleus with collapsed disc space), 6 discs. If the disc height was \( \leq 50\% \) of the height of the adjacent upper disc, the disc was defined as "collapsed" (Grade V). All discs were further divided into 2 groups, as follows: 1) degeneration without collapse, including Grades III and IV (Collapse(−), 16 discs); and 2) degeneration with collapse, identical to Grade V (Collapse(+), 6 discs). For comparison, 4 segments with Grade I and 2 segments with Grade II from another series of patients (mean age 35 ± 10.2 years, range 21–48 years; 3 men and 3 women; L3–4 in 3 cases and L4–5 in 3 cases) were used as a Normal control group. These segments were adjacent to the treated symptomatic segments and were verified as asymptomatic by postoperative follow-up examination.

Linear regression analyses were performed to identify relationships among age, ROM, disc height, and biomechanical parameters. The value of each biomechanical parameter was compared among the Normal, Collapse(−), and Collapse(+) groups by using the one-way analysis of variance followed by the Tukey–Kramer HSD analysis. The JMP software package (version 5.0.1a, SAS Institute) was used for all statistical analyses. A probability value \( p < 0.05 \) was considered statistically significant.

Results
There were no complications related to the measurement procedure. The spinous process holders were stable even after the 5 cycles of loading in all cases. In a previous report, we confirmed that the marks of the holder teeth on the bone are negligible (Fig. 4A). In all cases, the load–deformation curves after the second cycle were closely overlapped, demonstrating high stability and repeatability (Fig. 4B).

There was no apparent difference in the values of stiffness, AE, and NZ among clinical diagnoses in the patients with degenerated discs (Table 1). All values are expressed as the mean ± standard error of the mean. The mean stiffness value in the Normal group (1.47 ± 0.17 N/mm) was...
In addition, these values were as follows: stiffness, 0.24 N/mm; AE, 0.22 J; and NZ, 4.04 mm/N (Fig. 6A). On the other hand, in a case of Collapse(+)—a 71-year-old man with lumbar canal stenosis—the measurements were as follows: stiffness, 0.70 N/mm; AE, 0.24 J; and NZ, 1.09 mm/N (Fig. 6B). The NZ value in the case without disc collapse was higher than that of the case with disc collapse. These typical cases had notably different hysteresis loops.

Discussion

After a half century of controversy, a definition of clinical instability of the spine has yet to be clarified. One reason seems to be a gap between the facts elicited from ex vivo or animal studies and patients with mechanical low-back pain or motion-induced radiculopathy. Conventional radiographic measurements are still popular for the clinical diagnosis of instability. Radiographic examinations, however, are limited to still measurements with a large range of values so that normal angular motion cannot be precisely defined. In addition, these radiographic measures demonstrate some kinematics, but do not give biomechanical data in terms of a load–deformation relationship to determine the segmental instability. Thus, clinically convenient and biomechanically accurate tools whose results correlate with those of extensive basic studies have not been available. Our approach is an attempt to bridge the gap between the basic biomechanical data and the clinical symptoms arising from instability.

The present measurement system is an in vivo method with all ligamentous structures intact, providing multiple parameters based on continuous load–deformation data collected during surgery. All measurements in the present series were performed in a safe manner, and there were no injuries, such as fracture, ligament rupture, or nerve injury. Reliability of the measurement system was demonstrated by the high stability and repeatability (Fig. 4B). Although stiffness of the Normal group spines was higher than those in the Collapse(−) and Collapse(+) groups, no significant difference was found between Collapse(−) and Collapse(+). This suggests that the conventional parameter of stiffness alone cannot distinguish segmental instability in the patients with degenerative diseases. On the other hand, the NZ is thought to be affected by degeneration, leading to painful motion. In vitro study of fresh human cadav-

### Table 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal</th>
<th>DSp</th>
<th>LCS</th>
<th>DLS</th>
<th>LDH</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of segments</td>
<td>6</td>
<td>10</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>stiffness (N/mm)</td>
<td>1.47 ± 0.17</td>
<td>0.58 ± 0.20</td>
<td>0.72 ± 0.36</td>
<td>0.28 ± 0.05</td>
<td>0.65 ± 0.22</td>
</tr>
<tr>
<td>AE (J)</td>
<td>0.25 ± 0.03</td>
<td>0.26 ± 0.08</td>
<td>0.32 ± 0.16</td>
<td>0.25 ± 0.13</td>
<td>0.13 ± 0.05</td>
</tr>
<tr>
<td>NZ (mm/N)</td>
<td>1.12 ± 0.13</td>
<td>2.58 ± 1.06</td>
<td>1.96 ± 0.99</td>
<td>1.56 ± 1.59</td>
<td>1.59 ± 0.36</td>
</tr>
</tbody>
</table>

* Values are expressed as the mean ± standard error of the mean. "Normal" designates an asymptomatic segment with MR imaging findings of Grade I or II (see Clinical Material and Methods). Abbreviations: DLS = degenerative lumbar scoliosis; DSp = degenerative spondylolisthesis; LCS = lumbar canal stenosis; LDH = lumbar disc hernia.
ers reported that the NZ increased slightly with greater disc degeneration in lumbar flexion–extension motion. In the present study, although there was no significant difference in stiffness and AE between the Collapse(-) and Collapse(+) groups, a more sensitive parameter, NZ, was higher in the Collapse(-) than in the Collapse(+) group (Fig. 5). Furthermore, because there was a significant positive relationship between NZ and disc height ($r^2 = 0.285$, $p < 0.005$), preserved disc height can be an indicator of instability in the segments with degenerative disease. Considering the significance of the NZ, the methods used in past studies that analyze stiffness alone from a single loading direction (flexion or extension), are far from sufficient to analyze segmental instability. There was no significant relationship between NZ and ROM (Table 2). This is compatible with the previous reports on flexion–extension x-ray films that showed a large range of normal motion with a significant overlap of underlying pathological conditions.

There are, however, several limitations to our system, because the measurement was performed after induction of general anesthesia for which a muscle relaxant was used, and because the posterior muscles of the segment were detached, the results mostly represent the effects of passive stabilizers. The musculature surrounding an injured motion segment has a stabilizing effect by reducing abrupt kinematic behavior, particularly in the neutral region where the muscles are under reduced tension. The second limitation is an alteration in a segmental alignment due to surgical positioning. We attempted to make the patient’s positioning as constant as possible by controlling hip and knee angles. Alignment of hip and knee were controlled 10–20° of flexion by placing pillows under the patient’s knees and ankles. Nevertheless, the prone position is considered to change the alignment into extension. This might affect the starting point of measurement from the neutral position. The shift to the extension side might explain why the load–deformation curve in extension is steeper than that in flexion (Figs. 4B and 6A and B). The third limitation is that the present measurement is performed in the sagittal plane alone. Instability of the segment can occur in any direction. Multidirectional measurement of the target segment is desirable. Although we are now developing an axial motion measurement system in our laboratory, such an additional measurement is time-consuming and increases the risk of surgical complications. Therefore, from a surgeon’s point of view, we consider that the measurement should, at present, be restricted to the sagittal plane.

Kirkaldy-Willis and Farfan proposed the concept of the progression of disc degeneration, which consists of dysfunction, unstable, and restabilization phases. In the patients with disc degeneration in the present study, the seg-
ments are considered to lie in the range of the dysfunction to restabilization phases (Fig. 6C). Although there was no significant relationship between AE and age or disc height, stiffness was negatively and NZ was positively correlated with age or disc height (Table 2). The degenerative segment with disc collapse showed lower stiffness than the Normal group, but it demonstrated comparable NZ to this group (Fig. 5C). These results suggest that degenerative discs with preserved disc height lie on an unstable phase and are prone to latent instability that resolves once the disc collapses. This assumption is compatible with the concept of unstable and restabilization phases in the Kirkaldy-Willis and Farfan hypothesis, and is a result of a human cadav-
er study in which the segmental motion increased with increasing severity of disc degeneration up to Grade IV, but decreased in both sexes when the disc degeneration advanced to Grade V. Segmental instability is thought to change continuously as a function of the progression of degeneration. If a patient has a certain instability level (asterisk in Fig. 6C) determined by the intraoperative measurement, the stage of degeneration might be different (points labeled #1 and #2 in Fig. 6C). Therefore, other clinical manifestations and the findings of x-ray films and MR images are necessary to determine real instability. Indications for fusion, the gold standard therapy, in the setting of instability are predicated on subjective symptomatology, objective neurological findings, and radiographic parameters. The final goal of this project is to establish a reliable system to obtain the biomechanical data that can be referred to for decision-making regarding lumbar fusion. The information derived from the present study is, however, still preliminary and must be reproduced and validated in future studies.

Conclusions

Although stiffness in the Normal group was higher than that in the Collapse(−) or Collapse(+) ones, there were no significant difference in stiffness between the Collapse(−) and Collapse(+) groups. The values of a more sensitive parameter, NZ, were higher in the Collapse(−) than in the Collapse(+) group, with a significant positive relationship to the disc height, demonstrating that degenerative segments with preserved disc height have a latent instability compared to segments with collapsed discs.

Disclosure

We have applied for patent rights for this intraoperative measurement system; we have not yet received approval. We have received no grants or any other funding.

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