Clinical application of a handy intraoperative measurement device for lumbar segmental instability

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Abstract We describe the development of a new device that permits handy intraoperative measurement of lumbar segmental instability. The subjects comprised 80 patients with lumbar degenerative disease. Relationships between preoperative radiological assessments and extended distance as measured using our new device were investigated. Mean extended distance measured using the device was 3.7 ± 1.9 mm. Correlation coefficients between angular motion and extended distance, and translational motion and extended distance were 0.76 and 0.66, respectively, revealing significant positive relationships between these values ($p < 0.01$ each). The correlation coefficient between the intervertebral endplate angle on the flexion film and extended distance was -0.78 , showing a significant negative relationship ($p < 0.01$). In conclusion, the device for intraoperative measurement of lumbar segmental instability that we have developed appears to permit simple measurement of intervertebral instability and provides operators with valuable information for selecting operative methods of spinal fusion or instrumentation.

Résumé Nous décrivons le développement d'un nouvel appareil permettant la mesure manuelle per-opératoire de l'instabilité lombaire segmentaire. Cette étude a été faite sur 80 patients présentant une pathologie lombaire dégénérative. La relation entre les mesures radiologiques préopératoires et

les résultats des mesures réalisées avec ce nouvel appareillage a été étudiée. La mesure moyenne de la plus grande distance en utilisant le nouvel appareil a été de $3,7 \pm 1,9$ mm. Les coefficients de corrélation entre la mobilité angulaire et cette mesure et la mobilité latérale en translation et cette mesure ont été respectivement de 0.76 et de 0.66, permettant de montrer une relation significativement positive entre ces valeurs ($p < 0.01$ chacun). Le coefficient de corrélation entre l'angle mesuré entre deux plateaux sur un film en flexion et la distance la plus grande a été de -0.78 , est significativement négatif ($p < 0.01$). En conclusion, ce nouveau matériel permet la mesure per-opératoire de l'instabilité lombaire et nous permet de faire une mesure simple de l'instabilité intervertébrale. Elle donne aux opérateurs une information valable de façon à sélectionner les techniques opératoires et le matériel d'instrumentation destiné à l'arthrodèse.

Introduction

Determining the degree of lumbar segmental instability is a key to the determination of therapeutic and operative strategies for degenerative lumbar diseases [1, 2]. Although lumbar segmental instability is generally assessed by functional flexion–extension radiography using plain lateral lumbar radiography, no standardised criteria for the diagnosis of this symptom have been determined [3, 4]. As a result, the proper degree of lumbar segmental instability may remain unknown preoperatively. Intraoperative measurement of instability is frequently performed using a manual test in which the operator grasps the spinous process to move it caudally. This test appears extremely subjective, depending on the experience of the surgeons. Some devices that allow intraoperative biomechanical measurement of the lumbar segmental instability have been

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Fig. 1 The new device consists of five elements: two pins, a main body, a spring, an upper cap, and a hammer for insertion of the pin

described [5–7], but all are time-consuming and not user-friendly. Such devices have thus not seen wide use in clinical settings.

In this study, we describe the development of a new device that permits handy intraoperative measurement of lumbar segmental instability. The device was applied to patients to evaluate the usefulness of this approach.

Outline of the device for intraoperative measurement of lumbar segmental instability

We invented a device that allows ready measurement of craniocaudal distraction instability, since angular motion on lumbar spine radiography for functional activity measurements and intervertebral endplate angle on flexion film are known to represent important parameters for assessing lumbar segmental instability on the basis of data from previous studies [8, 9].

The new device consists of five elements: two pins, a main body, a spring, an upper cap, and a hammer for insertion of the pin (Fig. 1). This device was used to preserve the supraspinal ligament after clearing the paravertebral muscles and hammering the two pins into the two spinous processes lying on either side of the lumbar vertebrae to be measured for instability (Fig. 2a). The distance between the two pins was set at 2.5 cm and stab depth of the pins was regulated to 1.0 cm by means of the hammer. To determine the initial distance between the two pins, we plotted the midpoints of the craniocaudal axes of L2, L3, L4, L5 and S1 spinous processes, and measured the distances L2–L3 (distance between the midpoints of L2 and L3 spinous processes), L3–L4, L4–L5 and L5–S1 by using the plain X-ray frontal views of 300 patients with lumbar diseases (168 men and 132 women, aged 14–92 years, mean age 67.8) who had been treated at our hospital. Based on the measurements, which were 2.9 ± 0.8 cm (mean $\pm$ SD), 2.7 ± 0.7 cm, 2.5 ± 0.7 cm and 2.1 ± 0.6 cm for L2–L3, L3–L4, L4–L5 and L5–S1, respectively, we considered that lumbar segmental instability could be measured if the distance between the two pins was set to 2.5 cm.

In measuring the degree of lumbar segmental instability, the upper cap placed on the main body was removed to create a spring force generated by the two pins (3.8 cm long, 1.0 cm diameter; spring constant 3.0 N/mm), resulting in the provision of a distraction force (Fig. 2b). As a result, the distance between the two pins was increased. As for the setting of the spring power, we performed a tensile test using fingers with the help of five orthopaedic surgeons, imagining an intraoperative manual test in which spinous processes were pinched and moved in the craniocaudal direction, and found that a tensile force of 15.1 ± 3.6 N was required to move a spinous process by 5 mm. Thus, the spring constant was set to 3.0 N/mm based on the following: 15.1 divided by 5 equals 3.02 N/mm. The distance extended from the original

Fig. 2 How to use the device. **a** Two pins were hammered into the two spinous processes lying between the lumbar intervertebrae to be measured for instability. **b** The upper cap placed on the main body was removed to create a spring force generated by the two pins, resulting

in the provision of distraction force. **c** The distance extended from the original 2.5 cm between the two pins was measured using a millimetre scale engraved on the back of the upper cap

Fig. 3 The endplate angle was defined as the angle generated by one line drawn from the inferior margin of the superior vertebral body and another from the superior margin of the inferior vertebral body

2.5 cm between the two pins could be measured using a millimeter scale engraved on the back of the upper cap (Fig. 2c). Approximately 1 min was required to measure the distance of a single intervertebral space, including the time required for inserting the two pins.

Materials and methods

Subjects in this study comprised 80 patients (46 men, 34 women; lumbar spinal canal stenosis, $n=45$; lumbar spondylolisthesis, $n=18$; herniated lumbar disk, $n=17$) who visited our department or affiliated hospitals between January 2005 and December 2005 and provided informed consent before use of this device. Mean age on the day of operation was 58 years (range 23–88 years). A total of 127 lumbar intervertebrae were measured intraoperatively using this device (L2/L3, $n=14$; L3/L4, $n=33$; L4/L5, $n=52$; L5/S1, $n=28$). Posterolateral fusion using spinal instrumentation was performed in 35 patients, posterolateral fusion alone in 19, and decompression alone without fusion in 26.

Using the lateral lumbar spine radiograph taken preoperatively for functional activity measurements, as well as the device for intraoperative measurement of lumbar segmental instability, instability was measured by two independent observers for 127 lumbar intervertebrae in terms of angular motion ($^{\circ}$), translational motion (mm) and intervertebral endplate angle ($^{\circ}$) on the flexion film. With regard to the measuring methods, the endplate angle (Fig. 3) was defined as the angle generated by one line drawn from the inferior margin of the superior vertebral body and another from the superior margin of the inferior vertebral body; angular motion was defined as the difference between the endplate

angle obtained from the extension film and that from the flexion film. Translation motion was calculated according to the method of Stokes and Frymoyer et al. [10]; the distance between the two arrows shown in Fig. 4 was measured; the endplate angle was obtained from two lines drawn from the posterior margin of the superior and inferior vertebral bodies and then the endplate angle bisector was drawn. Mean values of these radiological assessments obtained by the two observers were used for analyses. Relationships between these radiological assessments and extended distance as measured using the device and difficulties and complications associated with use of the device were investigated. Pearson's correlation test and Student's t -test were used for statistical analyses.

Results

Difficulties and complications associated with the device for intraoperative measurement of lumbar segmental instability were observed in five of the 127 intervertebrae. Instability in these five cases was not measurable due to incomplete fixation of the pins, probably due to thin spinous processes of the vertebrae. Complications, such as fracture of the spinous process, were not seen in any patients.

In 122 of 127 intervertebral spaces, excluding the five that were not measurable for instability, mean ($\pm$ standard deviation) angular motion, translational motion, and intervertebral endplate angle on the flexion film were $8.7 \pm 4.1^{\circ}$, 0.8 ± 0.5 mm, and $2.1 \pm 3.6^{\circ}$, respectively. Values measured by the two independent observers did not differ by $>5^{\circ}$ for angular motion and intervertebral endplate angle on the flexion film or by >3 mm for translational motion.

Fig. 4 Translation motion was measured as the distance between the two arrows

Mean extended distance measured using the device was 3.7 ± 1.9 mm. Correlation coefficients between angular motion and extended distance, and translational motion and extended distance were 0.76 and 0.66, respectively, revealing significant positive relationships between these values ($p < 0.01$ each). The correlation coefficient between intervertebral endplate angle on the flexion film and extended distance was -0.78 , showing a significant negative relationship ($p < 0.01$).

Discussion

Intervertebral instability was defined as a “symptomatic condition where a physiological load induces abnormally large deformations at the intervertebral unit” by Kirkaldy-Willis et al. [11] and “loss of spine’s ability under physical stress” by White and Panjabi et al. [12]. However, these are obviously conceptual definitions. Meanwhile, clinical signs caused by lumbar segmental instability include “giving way”, “slipping out”, “instability catch”, and “apprehension sign” [13, 14]. These signs are also abstract and vague [15]. Furthermore, although this instability is determined by functional flexion–extension radiography using plain lateral lumbar radiography, no standardised criteria exist for the diagnosis of this symptom [3, 4].

The assessment method and criteria for the diagnosis of the lumbar segmental instability have not been unified. In recent years, other imaging analyses and biomechanical measurements have been attempted for the diagnosis of lumbar segmental instability, including measurement of axial rotation using preoperative images on computer tomography or magnetic resonance imaging [16–19], motion analysis with electrogoniometry [20] or videofluoroscopy [21], and measurement of intraoperative spinal motion stiffness using a strain gauge [6] or transducer [22]. These methods, however, have not become widespread due to difficulties such as the time required to obtain results and the need for specialised instruments. The device that we invented in this study can measure instability in approximately 1 min and requires no connection to a computer. We thus expect that this device could gain acceptance as a useful tool.

The results obtained in this study revealed that the extended distance measured with the invented device showed relationships to angular motion, translational motion, and intervertebral endplate angle on the flexion film. Prior to this study, we expected that the extended distance would display a significant negative relationship with the intervertebral endplate angle on the flexion film. The results showed that our device also had a significant relationship with angular and translational motions, indicating that this device permits accurate measurement of lumbar intervertebral instability.

When measured using the device, an extended distance of ≥ 6 mm was seen in 23 patients, with an intervertebral endplate angle on the flexion film of $\geq 0^\circ$ and angular motion of $\leq 8^\circ$ in seven patients. In taking functional radiographs using plain lateral lumbar radiography, those patients probably hesitated to perform anteflexion and extension due to fear of the occurrence of lower back pain or lower leg pain, resulting in small values of angular and translational motions and large values of the intervertebral endplate angle on the flexion film. This indicates that the device is able to detect intervertebral instability that might be missed on preoperative functional radiography.

On the basis of the results of fundamental experiments using lumbar spines from human cadavers and this study, we propose classifying the stability of lumbar segments into three levels to simplify its assessment: “stable” if the extended distance is < 3 mm, “slightly unstable” if the extended distance is ≥ 3 mm and < 6 mm, and “unstable” if the extended distance is ≥ 6 mm. Ideally, operative methods can be chosen based on intervertebral instability. For example, spinal instrumentation or fusion is not required for a “stable” intervertebral space, fusion but not spinal instrumentation is required for “slightly unstable”, and spinal instrumentation is required for “unstable”.

The drawbacks of this study are that the number of cases assessed was insufficient, that five of the 127 intervertebral spaces were not measurable, and that instability after spinal decompression and stability after spinal instrumentation or fusion were not assessed. Clinical data after decompression is more important than that before decompression with regard to the instability. In this study, 25 of the 80 subjects had the two pins placed in the same spinal locations after decompression as those before decompression, and had their levels of lumbar segmental instability successfully measured. The results in these cases revealed that discectomy tended to increase the level of lumbar segmental instability, whereas decompression such as with laminectomy or partial excision of the facet joints was less likely to change the instability level. Therefore, we consider that the level of lumbar segmental instability after decompression such as laminectomy may be predictable based on data on the instability level before decompression if the decompression procedure is not accompanied by a discectomy. However, it is often impossible to measure the level of lumbar segmental instability after decompression such as laminectomy by placing the pins in the same spinal locations as those before decompression. In fact, data on the instability level after decompression could not be obtained in 55 of the 80 subjects in this study. Since this suggests certain structural limits of the device, we are developing a new device that allows measurement of the instability level even after decompression.

In conclusion, the device for intraoperative measurement of lumbar segmental instability that we have developed appears

to permit simple measurement of intervertebral instability and provides operators with valuable information for selecting operative methods of spinal fusion or instrumentation.

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