

Intraoperative Measurement of Lumbar Spine Motion Segment Stiffness

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Study Design. Prospective trial.

Objectives. To test an intraoperative diagnostic tool to determine if it provided the surgeon with a safe, reproducible, accurate, quantitative measure of lumbar spine motion segment stability.

Summary of Background Data. Several devices have been developed to measure motion segment stiffness, however, few have been tested intraoperatively on humans, and none, to the best of the authors' knowledge have been tested as extensively as the device described in this study. Objective criteria, such as those provided by an intraoperative gauge, can be helpful in determining when and what type of fusion of a degenerated spinal motion segment unit should be performed following decompressive surgery.

Methods. The spinal stiffness gauge, placed between spinous processes of adjacent vertebrae, applies a controlled, constant loading rate along the spine's longitudinal axis, producing a load-displacement curve from which stiffness, range of motion, and hysteresis can be computed. Measurements from this tool were then used to investigate differences in stiffness of the motion segment before and after decompressive surgery, between spine levels, and between male and female subjects.

Results. The spinal stiffness gauge stiffness measurements correlated with the surgeon's subjective stiffness measurements on the same motion segments. The stiffness measurements had excellent repeatability. Stiffness was dependent on the spine level, gender, and degree of disc degeneration.

Conclusions. This study demonstrated the efficacy of the spinal stiffness gauge for providing an objective, quantitative, intraoperative stiffness (stability) measurement of the lumbar spine motion segment. [Key words: degenerative disc disease, joint instability, lumbar spine, motion segment, spinal diseases, surgical instruments] **Spine 2002;27:954-958**

To date, there are no objective criteria for determining when a fusion of a degenerated lumbar spine motion segment (MS) should be performed after decompressive surgery.^{1,14} An *in vivo* method for determining instability of an MS at the time of decompressive surgery was described by Dr. Albert Key in 1944; he stated, "... the spinous processes are grasped with a heavy toothed artery clamp and manipulated up and down in the hori-

zontal plane or are pushed on with an osteotome in order to demonstrate any abnormal mobility."¹² The traditional method for determining instability of an MS at the time of decompressive surgery is the type of manual test Key described. The surgeon places a clamp or towel clip on each of the adjacent spinous processes of the MS and then distracts and relaxes the spinous processes along the axis of the spine. From the tactile feedback felt by the resistance to distraction and the observed range of distraction, the surgeon assigns a relative stiffness grade to the MS, *i.e.*, loose, normal, or fused. The estimated MS stiffness and observed range of motion help the surgeon determine whether or not to fuse an affected lumbar level. Other devices have been developed to measure MS stiffness; however, few have been tested intraoperatively on humans, and none, to the best of the authors' knowledge, has been tested as extensively as the device described in this study.^{5,7,8,19}

The purpose of this study was to test an intraoperative diagnostic tool to determine if it provided the surgeon with a safe, reproducible, accurate, and quantitative measure of MS stability (stiffness). The MS stiffness measured by this tool was compared with the degree of disc degeneration, as determined by preoperative MRI scans. Measurements from this tool were also used to investigate differences in stiffness of the MS before and after decompressive surgery, between spine levels, and between male and female subjects.

Materials and Methods

The authors have developed and tested a two-dimensional hand-held stepper motor-driven vertebrae distractor called the *spinal stiffness gauge* (SSG).^{4,9} The SSG, placed between the spinous processes of two adjacent vertebrae, distracts the MS to a maximum load of 134 N and then relaxes the MS back to its starting position. The maximum load in the cadaver study of the SSG was 200 N^{4,9}; the maximum load in this study was decreased to 134 N because loads >134 N provided no additional information. Decreasing the maximum load also increased the safety of the measurement. The SSG operates at a controlled, constant loading rate, thus standardizing the viscoelastic response between MS units.

Force and displacement measurements were recorded simultaneously and plotted on a computer screen, producing a curve representative of the stiffness of that MS. The instrument computes the slope of the stiffness curve between the 22 N and 67 N force levels and the hysteresis contained in the distraction-relaxation curve between the 22 N and 90 N force levels. This range of force levels provides the most interesting data for analysis. Displacement at 90 N (range of motion) and patient information are also displayed.

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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The study was performed following the approval of an Institutional Review Board, and all patients signed an investigational informed consent. A total of 298 patients participated in this study over a 6-year period. There were five patients for whom data from two operations at different spine levels were included. An additional 17 patients were intended to be included in this study but were excluded in the operating room for one of the following reasons: 1) the surgeon decided that testing should not be done, for reasons such as osteopenic spinous processes, floating, loose, or absent spinous processes, spina bifida, a narrow interspace, or inaccessible spinous processes; 2) technician errors; or 3) equipment failures. These exclusions did not result in any adverse effects to the patients. A total number of 655 MSs were tested. The patient population consisted of 162 female and 136 male patients, ranging between 17 and 87 years of age (mean 59 years).

Preoperative disc morphology was determined by midsagittal T2-weighted MRI scans and graded between 1 (normal) and 5 (severely degenerated) as follows: Grade 1 = normal high signal intensity in nucleus pulposus; Grade 2 = mild loss of signal intensity in the nucleus pulposus; Grade 3 = loss of signal intensity in the nucleus, disc displacement but no disc narrowing, and loss of distinction between the nucleus and anulus; Grade 4 = severe loss of signal intensity in the nucleus pulposus, with <50% disc narrowing *versus* adjacent discs; and Grade 5 = severe loss of signal intensity throughout the disc, with >50% disc narrowing. The MRI rating system was empirically developed to simulate grading systems for degrees of disc degeneration used in cadaver studies of the SSG.^{4,9,14}

Patients were positioned prone on a Relton-Hall laminectomy frame under epidural or general endotracheal anesthesia for surgery.¹⁶ Muscle paralysis was not induced in either type of anesthesia. The surgeon (M.D.B.) subjectively measured the MS stiffness by manually distracting and relaxing the adjacent spinous processes with two clamps and assigning a stiffness grade between 1 (loose) and 10 (fused). The surgeon then obtained a quantitative stiffness measurement of the MS using the SSG; the resulting force-displacement slope (N/mm), range of motion (mm), and hysteresis (N-mm) were recorded.⁴ Through a toggle switch on the top of the hand-held gauge, the surgeon controlled the distraction until the maximum force of 134 N was achieved and a servo feedback mechanism stopped the stepper motor automatically. The surgeon then toggled the switch in the opposite direction for reversal of the stepper motor, relaxing the spinous processes to the starting point, which was determined by watching the closing of the distractor legs. Built-in mechanical and software safeguards protected the patient's MS from excessive force or joint displacement. The surgeon also had the ability to abort the test at any time. In the event of software failure the motor electronic circuit design limits the power supplied to the motor, which in turn allows for the motor clutch to slip at 155 N, thereby preventing additional distraction and loading of the joint.

The surgeon and the technician running the SSG remained blinded to the other's measurements. The surgeon graded and recorded the degrees of disc degeneration from the MRI scans before surgery. During surgery the surgeon recorded the subjective stiffness measurement for each MS without revealing the results to the technician running the SSG. The technician running the SSG, in turn, did not inform the surgeon of the instrument readings.

At least two SSG measurements were performed for each

Table 1. Parameters Measured by the Spinal Stiffness Gauge in 655 Motion Segments

Parameter (units)	Average	Range
Stiffness (N/mm)	31.3	7.8 -65.0
Range of motion (mm)	4.1	0.3 -14.5
Hysteresis (N-mm)	20.8	0.0-214.7

MS to evaluate repeatability of the stiffness measure. SSG measurements were recorded both before and after decompression in MSs where there were sufficient spinous processes and lamina remaining after the decompression procedure to allow for placement of the SSG distractor legs. The spine level measured by the SSG was also recorded.

■ Results

Less than 2 minutes of operating time per level was required to test each lumbar MS unit with the SSG. There was no neurologic or soft tissue damage in any patient as a result of this testing. There were seven cases of spinous process fracture by the SSG, all of which occurred in female patients ≥ 67 years of age, and these were not clinically significant.

The average values and ranges of the parameters measured by the SSG were calculated (Table 1). There was an approximately normal distribution of stiffness measurements (Figure 1). Repeated SSG stiffness measurements at the same MS had an average error of <1.6%. The intraclass correlation coefficient, which indicates the repeatability of the measurement,⁶ was $R = 0.954$.

In the early stages of disc degeneration, MS stiffness decreased; in the later stages of disc degeneration, MS stiffness increased (Figure 2). However, only the stiffness for the most severely degenerated discs, morphology Grade 5, was significantly different from the stiffness measurements for the other, less degenerated disc morphology grades ($P < 0.01$), using the analysis of variance *post hoc* Tukey and Duncan tests for multiple comparisons.

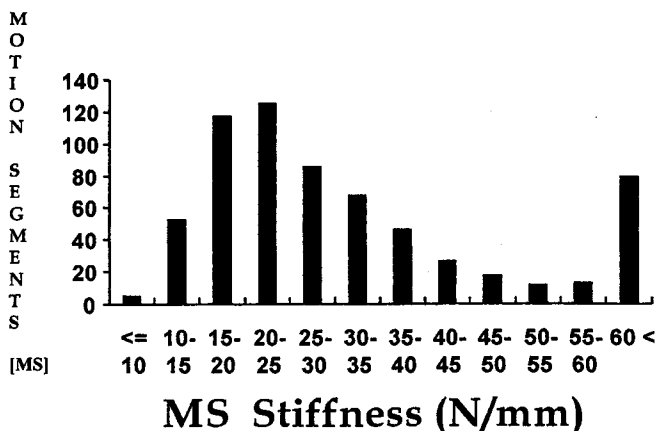


Figure 1. MS stiffness distribution as recorded by the SSG. Average stiffness was 31.3 N/mm. For stiffness values >65 N/mm, the MS is functionally fused and does not move.

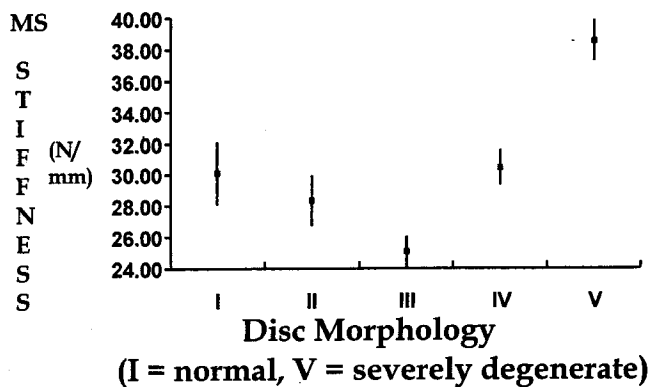


Figure 2. Association between mean MS stiffness and disc morphology. Lines indicate \pm standard deviation. As the degree of disc degeneration increased, MS stiffness first decreased and then increased.

The surgeon's subjective manual MS stiffness measurement was compared with the objective SSG measurement. The linear correlation between the manually obtained clamp test measurement and the SSG measurement was $R = 0.67$ (Figure 3). There was a statistically significant dependence between the manually obtained value and the SSG measurement ($P < 0.000001$, χ^2 test).

There was an inverse, nonlinear association between SSG stiffness and range of motion (Figure 4). The association between stiffness (y) and range of motion (x) was represented by the following equation: $y = -0.07x^3 + 2.37x^2 - 23.62x + 88.35$ ($R = 0.87$).

Motion segment unit stiffness decreased by an average of 20% from predecompression to postdecompression. This decrease was statistically significant ($P < 0.0005$, one-tailed paired-comparison t test). The maximum decrease was 60%. The range of MS motion increased significantly ($P < 0.0005$) from predecompression to postdecompression.

To investigate how disc degeneration and the SSG parameters varied with age, the patients' ages were separated into five 15-year intervals (16–30, 31–45, 46–60, 61–75, and 76–90 years), and analysis of variance and Duncan's multiple range tests were performed. Disc degeneration increased with age. The morphologies of the two oldest age groups were significantly different from those of the lower age groups ($P < 0.05$; Table 2). Stiffness also increased with age. The age group with the least stiffness (31–45 years) was significantly different from the age groups with the largest stiffness measurements (61–75 and 76–90 years; $P < 0.05$, Table 2). Range of motion decreased with age, but there were no significant differences between the age groups. Hysteresis showed no trend with age and no significant differences between the age groups.

Male and female MSs were significantly different in stiffness ($P < 0.01$, two-tailed z test), range of motion ($P < 0.01$), and hysteresis ($P < 0.05$). Male MSs had a larger

stiffness value, a smaller range of motion, and a smaller hysteresis measurement than female MSs (Table 3).

Differences in SSG parameters between spine levels, within the same spine, were studied using two-tailed paired-comparison t tests with Bonferroni's correction. L5–S1 had the greatest stiffness (mean 36.6), which was significantly higher than L2–L3 (mean 28.7), L3–L4 (mean 26.9), and L4–L5 (mean 28.8) ($P < 0.01$). L4–L5 was significantly stiffer than L3–L4 ($P < 0.01$). L5–S1 had a significantly lower range of motion than L3–L4 and L4–L5 ($P < 0.01$). Hysteresis was not significantly different between the spine levels.

Discussion

There are currently no accepted accurate intraoperative techniques for measuring spine joint instability. There is also a lack of a clinically useful definition for spine joint instability.¹⁷ Definitions of spinal instability may overlap symptomatic and asymptomatic patients.³ Lubin et al¹⁴ used a modified Cloward laminar spreader to measure the force required to distract adjacent lumbar vertebrae in cadavers. Differences in MS stiffness did not correlate with degrees of disc degeneration; the lack of correlation was attributed to using a manually operated distractor where rate of distraction and force applied could not be controlled. Ebara et al⁵ instrumented a manual lumbar spinal spreader to measure MS stiffness. They reported a correlation between MS stiffness and disc degeneration in patients but did not mention if the correlation was statistically significant. Other devices described in the literature have been tested only in cadavers and/or with very limited sample sizes.^{7,8,19} It was an objective of this study to investigate the usefulness of the SSG as a tool capable of objectively and quantitatively measuring the degree of stiffness (stability) of the human lumbar spine MS at the time of surgery. The repeatability of the SSG stiffness measurement was excellent,

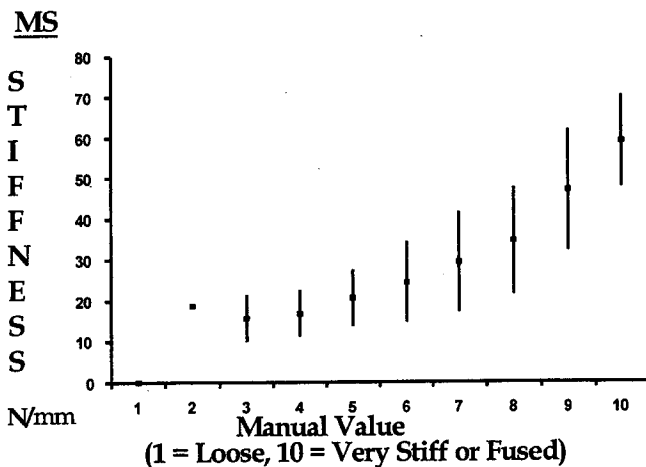


Figure 3. Objective SSG stiffness versus subjective manual clamp test value. Lines indicate \pm standard deviation. The correlation was $R = 0.67$.

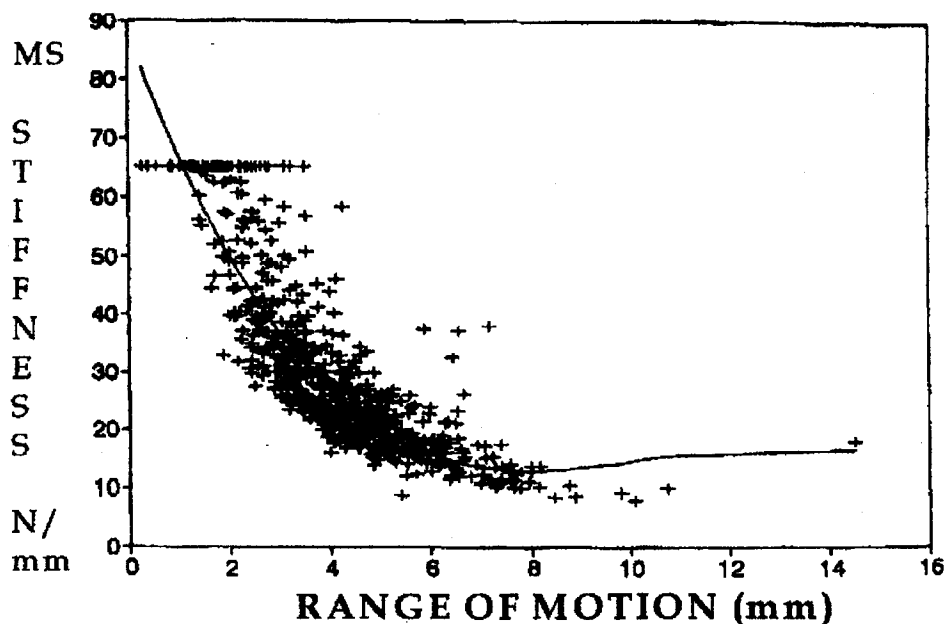


Figure 4. SSG stiffness versus range of motion. Cubic curve fitting gave a correlation of $R = 0.87$.

as indicated by the intraclass correlation coefficient of $R = 0.954$.

The seven cases of spinous process fracture by the SSG all occurred in female patients ≥ 67 years of age. None of these fractures was clinically significant; there was no damage to the lamina, ligamentum flavum, dura, nerve roots, or spinal cord, and the patients experienced no adverse effects. Spinous process fracture also occurs while performing the subjective manual stiffness measurement described earlier and has been of no consequence to the patient's safety.

There may be a need to record stability of the MS at the time of surgery, to predict outcome, and to document the need for arthrodesis and the technique of arthrodesis, *i.e.*, with or without rigid spinal fixation. Clinical usefulness of the SSG was also considered in terms of measuring the change in MS stiffness before and after decompression. The reduction in measured stiffness ranged from 0% to 60%, with a mean reduction of 20%. The surgical procedures resulting in stiffness reduction included unilateral decompression and disc excision.

As the degree of disc degeneration increased, MS stiffness at first decreased and then increased (Figure 2). The results of this study quantitatively substantiate Kirkaldy-Willis' hypothesis of MS degeneration,¹³ *i.e.*, destabilization of the MS in middle stages of disc degeneration,

followed by restabilization with advanced stages of degeneration. The age group with the least stiffness (31–45 years), *i.e.*, least stability, was also the age group with the highest percentage of Grade 3 disc morphology ratings (Table 2). These findings correlate well with those of Kirkaldy-Willis.¹³ The lack of statistically significant differences between SSG stiffness for disc morphology Grades 1–4 can be attributed to variables such as physical dimensions of the MS, age, level of hydration, loss of viscoelastic properties of the disc, and the diagnosis.

The objective SSG stiffness measurement and the surgeon's subjective value by manual testing had a positive linear correlation, both intraoperatively and in the cadaver study⁴; the correlation coefficient was identical in both studies ($R = 0.67$). Although these two methods of measuring MS stiffness were statistically dependent on one another, differences exist between the two techniques (Figure 3). For instance, during one operation a surgeon could assign the subjective stiffness value of 8 to an MS with a stiffness of 40 N/mm and during another operation assign the same stiffness value to an MS with a stiffness of 20 N/mm. These differences also exist between surgeons, strengthening the need for an objective measurement of spinal stiffness.

The negative correlation between SSG stiffness and range of motion indicates that a stiff MS will have a very

Table 2. Variation of Disc Morphology (Degeneration) and Stiffness With Age

Age Group (yr)	Mean Stiffness (N/mm)	% Grade 3 Disc Degeneration
16–30	28.6	18
31–45	26.6	40
46–60	30.1	26
61–75	31.6	15
76–90	35.0	17

Table 3. Differences in Spinal Stiffness Gauge Parameters Between Male and Female Motion Segments

Parameter (units)	Male	Female	P Value
Stiffness (N/mm)	35.6	28.3	<0.01
Range of motion (mm)	3.6	4.4	<0.01
Hysteresis (N-mm)	18.5	22.4	<0.05

limited range of motion, whereas a very loose MS will have a large range of motion (Figure 4). This association was also seen in the cadaver study.⁴ The viscoelastic response of a spine joint is related to joint degeneration, and hysteresis is one such measure of viscoelasticity. The SSG, which operates at a controlled, constant rate, allows for hysteresis to be measured and compared across MSs. There was no significant difference in hysteresis between different spine levels, degrees of disc degeneration, or age groups. However, the hysteresis between male and female MSs was significantly different. Virgin¹⁸ found a variation of hysteresis with age in cadaver intervertebral discs loaded under axial compression; hysteresis was largest in very young discs and smallest in middle-aged discs and in older discs that had no evident disc degeneration. Virgin¹⁸ also found a variation of hysteresis with spine level; hysteresis was smaller in the upper lumbar and lower thoracic discs and larger at L5-S1. The difference between the current results and Virgin's¹⁸ results may be explained by the differences in the samples and loads. This study measured MS stiffness *in vivo* under flexion-traction, whereas Virgin measured cadaver intervertebral discs under axial compression; Virgin did not report whether his results were statistically significant.¹⁸

Disc degeneration and SSG stiffness increased with age, and range of motion decreased with age. The cadaver study also showed an increase in stiffness with age. The trend of increased MS stiffness with increased age has been previously noted by other investigators!^{9,18}

Female MSs were less stiff and had a larger range of motion than male MSs. This was consistent with the results of Nachemson et al. who reported that individual lumbar cadaver female MSs were more flexible than male MSs.

Except for L5-S1, the spine level had no significant effect on SSG stiffness within the same spine. Nachemson et al. found little correlation between spine level and the mechanical properties of individual lumbar cadaver MSs.

The cadaver and clinical studies of the SSG showed many of the same trends of MS stiffness. The average SSG stiffness of the cadaver MSs, 21.1 N/mm, was less than the average stiffness of the intraoperatively measured MSs, 31.3 N/mm.

Conclusion

The spinal stiffness gauge is a clinically useful tool for measuring intraoperative lumbar motion segment stiffness. It can be used to indicate the mobility of motion segments and to make predecompression and postdecompression stiffness measurements. The spinal stiffness gauge stiffness measurements can be recorded with excellent repeatability. Motion segment stiffness, as mea-

sured by the spinal stiffness gauge, was dependent on spine level, gender, and degree of disc degeneration.

Key Points

- Intraoperative lumbar spine stiffness measurements can be recorded with excellent repeatability.
- Stiffness, as measured by the SSG, was dependent on spine level, gender, and degree of disc degeneration.
- The SSG is a clinically useful tool for measuring lumbar spine motion segments.

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