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SSG Abstract

INTRAOPERATIVE MEASUREMENT OF FUNCTIONAL SPINE UNIT STIFFNESS

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OBJECTIVES

An objective measurement of intraoperative stiffness of the functional spinal unit (FSU) is relevant in understanding the pathogenesis of spinal instability secondary to intervertebral disc degeneration. To date, there are no objective criteria for determining when a fusion of a degenerated FSU should be performed following decompressive surgery.

An in-vivo method for determining instability of an FSU 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 horizontal plane or are pushed up with an osteotome in order to demonstrate any abnormal mobility."

The purpose of this study was to test an intraoperative instrument to determine if it provided the surgeon with a safe, reproducible, accurate, and quantitative measure of FSU stiffness. These objective measurements were then correlated with the patients disc morphology/degeneration as determined by preoperative MRI scans. Measurements from this instrument were also used to investigate differences in stiffness of the FSU before and after decompressive surgery, between spine levels, and between male and female FSUs.

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] (Figure 1). A total of 298 patients with 655 lumbar FSUs were tested. The patient population consisted of 162 females and 136 males, and ranged between 17 and 87 years of age, average age 59 years. The surgeon first subjectively measured the FSU stiffness by manually distracting and relaxing the adjacent spinous processes with two clamps and assigned a subjective stiffness grade between 1 (loose) and 10 (very stiff or fused). The surgeon then obtained a quantitative stiffness measurement of the FSU using the Spinal Stiffness Gauge (SSG). The SSG, placed between the spinous processes of adjacent vertebrae, applies a controlled, constant loading rate along the spine's longitudinal axis, producing a force-displacement slope, from which stiffness (N/mm), range of motion (mm) and hysteresis (N-mm) were recorded. The constant loading rate normalizes the viscoelastic response between motion segment units. At least two SSG measurements were done per FSU in order to evaluate reproducibility of the objective stiffness measurement. The SSG distracts the

FSU to a maximum load of 134 Newtons, and then relaxes the FSU back to the resting position of zero load. SSG measurements were recorded both before and after decompression in FSUs where there was sufficient spinous processes remaining after the decompressive procedure to allow for placement of the distractor legs.

Preoperative disc morphology was determined by midsagittal T2-weighted MRI scans, and graded between I (normal) and V (severely degenerated) as follows: Grade I - Normal high signal intensity in nucleus pulposus with a distinct border between the nucleus pulposus and annulus fibrosus; Grade II - Mild loss of signal intensity in the nucleus pulposus; Grade III - Loss of signal intensity in the nucleus, disc displacement but no disc narrowing, and loss of distinction between the nucleus and annulus; Grade IV - Severe loss of signal intensity in the nucleus pulposus, with less than 50% disc narrowing, as compared to adjacent discs; and Grade V - Severe loss of signal intensity throughout the disc, with greater than 50% disc narrowing. The MRI rating system was empirically developed to simulate grading systems for degrees of disc degeneration utilized in cadaver studies of the SSG.

The study was performed following the approval of an Institutional Review Board, and all patients signed an investigational informed consent. Of the 298 patients, 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 because of (i) the surgeon decided that testing should not be done, for reasons such as the spinous processes were too osteopenic; floating, loose, or absent spinous processes; spina bifida, interspace too narrow, or inaccessible spinous processes, (ii) operator error, or (iii) equipment failures. These exclusions did not cause any adverse effects to the patients.

RESULTS

The average values and ranges of the measurements made with the SSG instrument in 655 FSUs were calculated as follows:

	<u>Average</u>	<u>Range</u>
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

There was a normal distribution of stiffness measurements (Figure 2). Repeated SSG stiffness measurements at the same FSU had an average error of less than 1.6%. The intraclass correlation coefficient, which indicates the reproducibility of the measurement, was R = 0.954.

In the early stages of disc degeneration FSU stiffness decreased; in later stages of disc degeneration, FSU stiffness increased (Figure 3). However, only the stiffness for the most severely degenerated discs, morphology grade V, was significantly different from the stiffnesses for the less degenerated disc morphology grades (p < 0.01).

The surgeon's subjective manual FSU stiffness measurement was compared to the objective Spinal Stiffness Gauge measurement. The linear correlation between the manually obtained clamp test measurement and the SSG measurement was R = 0.67 (Figure 4). There was a statistically significant dependence between the manually obtained value and the SSG measurement (p < 0.000001, chi-square test).

FSU stiffness decreased by an average of 20% from pre to post decompression. This decrease was statistically significant (p < 0.0005, 1-tailed paired-comparison t-test). The maximum decrease was 60%. The range of motion increased significantly (p < 0.0005) from pre to post decompression.

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, 76-90), and ANOVA and Duncan's multiple range tests were run. Disc degeneration increased with age; the FSU disc morphologies of the two oldest age groups were significantly different from those of the lower age groups (p < 0.05). Stiffness also increased with age; the age group with the lowest stiffness (31-45) was significantly different from the age groups with the highest stiffnesses (61-75 and 76-90) (p < 0.05). Range of motion decreased with age, but there were no significant differences between the age groups.

Male and female FSUs were significantly different in stiffness (p < 0.01, two-tailed z-test), range of motion (p < 0.01), and hysteresis (p < 0.05). Male FSUs had a larger stiffness, a smaller range of motion, and a smaller hysteresis than female FSUs, as follows.

	Males	Females	<u>p</u>
Stiffness (N/mm)	35.6	28.3	< 0.01
Range of motion (mm)	3.6	4.4	< 0.01

Hysteresis (N-mm)

18.5

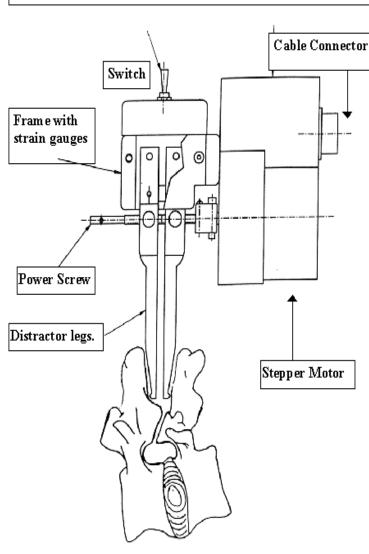
22.4

< 0.05

Differences in SSG parameters between spine levels, within the same spine, were studied using 2-tailed paired-comparison t-tests with Bonferroni's correction. Spine level L5-S1 had the highest stiffness; this level was significantly higher than L2-3, L3-4, and L4-5 (p < 0.01). Spine level L4-5 was significantly stiffer than L3-4 (p < 0.01). Spine level L5-S1 had a significantly lower range of motion than L3-4 and L4-5 (p < 0.01). Hysteresis was not significantly different between the spine levels.

CONCLUSIONS

FIGURE 1. SSG at the Base of the Spinous Processes.



The Spinal Stiffness Gauge (SSG) is an accurate, safe, and clinically useful tool for measuring intraoperative functional spine unit (FSU) stiffness. There is a need to record stability of the FSU at the time of surgery, to predict outcome and to document the need for arthrodesis. The SSG instrument can be used to indicate unstable FSUs. Clinical usefulness of the SSG was also considered in terms of measuring the change in FSU stiffness before and after decompression. The surgical procedures resulting in stiffness reduction included unilateral decompression and disc excision.

The SSG stiffness measurements can be recorded with excellent reproducibility. FSU stiffness, as measured by the SSG, was dependent on spine level, gender, and degree of disc degeneration.

FSU Stiffness Distribution

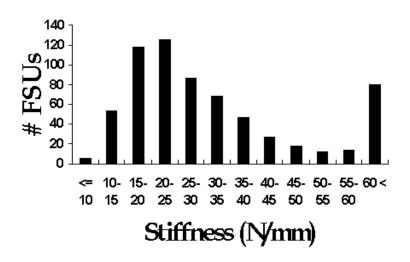


Figure 2

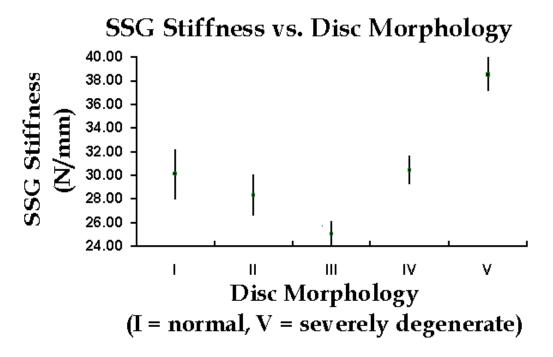


Figure 3

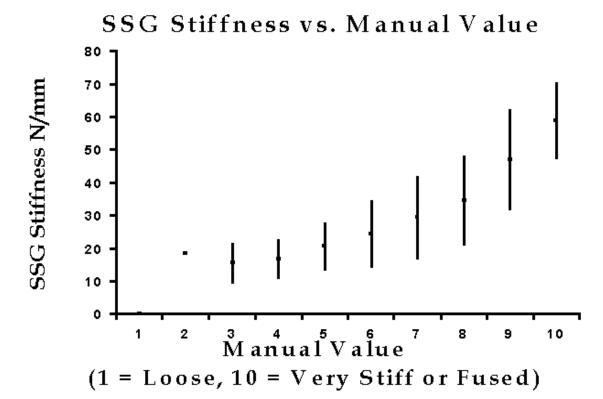


Figure 4