Dynamic Biomechanical Examination of the Lumbar Spine with Implant Total Spinal Segment Replacement (TSSR) Utilizing a Pendulum System

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ABSTRACT INTRODUCTION:
Motion preserving spinal implants used as an alternative to spine fusion, such as Total Spinal Segment Replacement (TSSR) which combines total disc replacement and posterior flexible rods, represent an important technological development in spinal surgery.

The biomechanical properties of the cadaver lumbar spine with and without implanted motion-preserving devices have been studied utilizing a wide variety of experimental protocols. Limitations of these previously used protocols include high cost and complexity, and limited ability to apply physiologic compressive loads or dynamic bending moments while allowing unconstrained three-dimensional motion.

A novel pendulum system1 as a means to study the complex kinematics and dynamic nature of the lumbar spine addresses many of these limitations. It is capable of applying both physiologic compressive loads and a variety of dynamic bending moments without constraining the motion of the functional spinal unit (FSU), which are crucial requirements for testing FSUs in vitro. Previous testing with the pendulum apparatus revealed that after an initial rotation, FSUs behave as a dynamic, underdamped vibrating elastic system, and the bending stiffness and coefficient of damping increase significantly as the axial compressive load increases. Further study is needed to examine the applicability of this pendulum testing system for studying FSUs with implanted motion-preserving devices under physiologic axial loading conditions.

In this study, we hypothesized that the lumbar spine with implanted TSSR would have similar stiffness and motion patterns as the native lumbar FSU. We sought to determine the effects of various axial compressive loads on the dynamic biomechanical properties of native lumbar FSUs as compared to specimens with implanted TSSR devices.

METHODS:
Five unembalmed, frozen human lumbar FSUs were obtained then thawed and tested individually (1 from each level: L1/2, L2/3, L3/4, L4/5, L5/S1. Average age 68.8 years (range 59-91)). Biomechanical testing of the FSUs was performed on a pendulum apparatus as described previously1. The pendulum system consists of the lower lumbar vertebra mounted on a 6-DOF load cell fixed on a rigid platform via its potting cup and the pendulum arm (0.55m) mounted to the upper vertebral body via its potting cup. Dead weights are fixed directly to the lower end of the pendulum arm. The intervertebral disc or artificial disc serves as the unconstrained fulcrum of the pendulum.

Each intact FSU was tested on the pendulum system with an axial compressive load of 78N, 181N, 282N, 385N, and 488N, chosen to represent physiologic loading. Testing began by manually rotating the superior vertebra and pendulum to an initial angle of 5 degrees; resulting in unconstrained oscillatory motion of the superior vertebra. Testing was performed in flexion, extension, right lateral bending, and left lateral bending. The three-dimensional motion of the superior vertebra relative to the inferior vertebra was measured at 30 Hz using an Optotrak 3020 three-dimensional motion tracking system (accuracy to 0.1mm and three-dimensional resolution to 0.01 mm). Six infrared-emitting diode markers were attached to the upper potting cup, and six to the lower potting cup. Custom NDI First Principles software was used to track the marker position of the upper vertebral body with respect to the lower vertebral body.

After initial testing of the intact spines, the FSUs underwent Flexuspine FSU TSSR implantation per manufacturer protocol. The FSUs were then re-tested on the pendulum apparatus with the same loading protocol. Rotations from initial perturbation until the spine reached equilibrium were collected. The bending stiffness (N/m°), frequency (1/s), and average number of cycles to equilibrium were calculated from the time series and compared among the intact FSUs and TSSR groups. The significance of the differences for each load by outcome variable between the intact spine and TSSR groups was calculated using a paired t-test. A post hoc power analysis was performed to assess the number of paired comparisons needed for 1-β 0.8 for each analyzed variable. In all instances, statistical significance was set to 0.05 a priori.

RESULTS SECTION:
All 5 FSUs were tested on the pendulum apparatus without apparent mechanical failure. Data from 385N testing is presented.

The flexion stiffness for specimens with implanted Flexuspine device was 6.31 ± 1.52 N/m° versus 5.88 ± 2.02 N/m° for intact specimens (p=0.715). The extension stiffness for specimens with implanted Flexuspine device was 6.00 ± 1.32 N/m° versus 5.22 ± 1.25 N/m° for intact specimens (p=0.368). The right lateral bending stiffness for specimens with implanted Flexuspine device was 6.78 ± 2.38 N/m° versus 6.75 ± 2.35 N/m° for intact specimens (p=0.985). The left lateral bending stiffness for specimens with implanted Flexuspine device was 7.16 ± 1.05 N/m° versus 6.48 ± 2.13 N/m° for intact specimens (p=0.543). Power analysis for the stiffness calculations revealed that between 49 and 893 paired comparisons were needed for a power of 0.8.

The flexion frequency for specimens with implanted Flexuspine device was 6.93 ± 0.54 1/s versus 6.77 ± 0.71 1/s for intact specimens (p=0.694). The extension frequency for specimens with implanted Flexuspine device was 6.83 ± 0.48 1/s versus 6.54 ± 0.45 1/s for intact specimens (p=0.359). The right lateral bending frequency for specimens with implanted Flexuspine device was 7.07 ± 0.84 1/s versus 7.02 ± 0.83 1/s for intact specimens (p=0.992). The left lateral bending frequency for specimens with implanted Flexuspine device was 7.23 ± 0.35 1/s versus 6.97 ± 0.75 1/s for intact specimens (p=0.501). The power analysis for the frequency calculations revealed that between 49 and 893 paired comparisons were needed for a power of 0.8.

The average number of cycles to equilibrium was significantly less for the Flexuspine implanted specimens versus intact specimens: cycles to equilibrium in flexion/extension for specimens with implanted Flexuspine device was 8.3 ± 1.3 cycles versus 12.9 ± 3.0 cycles for intact specimens (p = 0.014). The cycles to equilibrium in lateral bending for specimens with implanted Flexuspine device was 6.1 ± 0.4 cycles, versus 18.0 ± 10.3 cycles for the intact specimens (p = 0.032).

DISCUSSION:
This study examined the dynamic biomechanical properties of the intact cadaver FSU and the implanted Flexuspine TSSR utilizing a pendulum testing apparatus. We found that the Flexuspine TSSR was not statistically different in stiffness or frequency than the intact FSU in flexion, extension, or lateral bending when loaded with 385N. We did find statistically significant differences in the number of cycles to equilibrium between the intact FSU and specimens with implanted Flexuspine device. These results provide insight into the biomechanical behavior of these devices under physiologic loading conditions.

The effects of the bending stiffness, frequency, and number of cycles to equilibrium of motion preserving devices on adjacent segments are not well understood. Further research is needed to assess the optimal performance of spinal motion preserving devices. Limitations of this study include the lack of assessment of disc degeneration of the intact FSUs, and that the computations of stiffness were based on a dynamic response, thus an average of the actual dynamic stiffness.

SIGNIFICANCE:
This study examined the biomechanical performance of an implanted TSSR in the cadaver lumbar spine on a pendulum testing system, providing additional insight into the behavior of motion preserving spinal implants in simulated physiologic loading situations. Studies such as this are important in the ongoing evaluation and development of spinal motion preserving implants.

REFERENCES: