INTRODUCTION

In vitro biomechanical testing plays an integral role in the assessment of spinal implant efficacy. Previous studies have used different loading conditions and apparatuses, making test results across laboratories difficult to compare. Efforts have thus been made to standardize protocols for in vitro testing of spinal implants, particularly in the quantification of specimen range of motion (i.e. flexibility testing). Unconstrained, pure moment loading in the three main anatomic planes has been recommended, using either no preload or a compressive follower load system. It has been suggested that the standardization of test protocols will enable devices to be compared in a laboratory-independent manner. Well-described test methods may mitigate technical difference between laboratories, but to our knowledge there have been no attempts to confirm this assumption.

In the present study, we aimed to compare protocol execution between two independent laboratories capable of pure moment controlled loading by measuring functional spinal unit (L1-L2) biomechanical outcomes. Similar to the body of literature on spinal implant biomechanical testing, the following outcome measures were assessed: 1) range of motion (ROM), 2) neutral zone (NZ), 3) neutral zone stiffness (NZS) and 4) elastic zone stiffness (EZS). We hypothesized that the results of a well-described in vitro test method without axial preload would be reproducible across the two laboratories.

METHODS

Five fresh-frozen human cadaveric L1-L2 motion segments with a mean age of 68 years (range, 59 – 79 years; n=3 male, n=2 female) were dissected, leaving all ligamentous and bony structures intact. All specimens were screened radiographically for major anatomic abnormalities. Specimens were embedded in a urethane resin (Smooth-On 300, Smooth-On Inc., Easton, PA) such that the mid-disc plane was aligned horizontally.

Specimens were tested intact at two independent laboratories using well-described loading criteria without specific protocol instructions. Each group applied nondestructive, unconstrained pure moments of ±7.5 Nm in flexion/extension, lateral bending, and axial torsion without an axial preload. Three load-unload cycles were performed at a rate of 0.45 Nm/s, with data from the third cycle used for analysis. In each laboratory, all testing was conducted by individuals having at least one year of experience with their respective operating systems and each specimen was tested at both locations on a single day.

At Lab A, pure moments were applied to the superior vertebral body by a hydraulically-actuated gimbals mounted to a standard servohydraulic test frame (MTS 858, MTS Systems, Minnetonka, MN). A 6 DOF load cell, located immediately above the spinal specimen, was used to measure the applied loads and moments (Figure 1A). The inferior vertebral body was allowed unconstrained movement on an X-Y table (resistance < 0.1 N), and the test frame was allowed to float in the vertical direction.

At Lab B, pure moments were applied using three superior angular actuators on the crosshead of a servohydraulic load frame (8821 Biopuls, Instron, Norwood, MA). Moment application was controlled by a 6 DOF load cell (AMTI M4380, Watertown, MA) superior to the specimen and axial preload was controlled (to 0 N) by a second 6 DOF load cell fixed inferiorly. Specimen transverse plane shear was minimized using load feedback and a controlled X-Y slide table inferior to the specimen (Figure 1B).

Both laboratories utilized similar non-contact motion measurement systems (Vicon, Oxford Metrics, UK) to quantify angular intersegmental rotation. At Lab A, three reflective markers (6.5 mm diameter) were attached laterally to each vertebral body, whereas at Lab B, markers (9 mm diameter) were secured posteriorly via K-wires. The three-dimensional position of the markers was measured using five infrared digital cameras. The angular motion of the superior vertebra (L1) was computed with respect to the inferior vertebra (L2) using Euler angle calculations.

All outcome measures (NZ, ROM, NZS, EZS) were calculated according to the methods specified by Wilke et al (1998). NZ was defined as the range of motion between -0.25 Nm to 0.25 Nm. Each biomechanical outcome measure was compared statistically between laboratories using a paired student t-test.

RESULTS

Complete results for ROM are presented in Figure 2. There was a significant difference in ROM during flexion-extension between laboratories (6.5 ± 1.4° at Lab A vs. 5.8 ± 1.0° at Lab B; p = 0.03). Results between labs for all other metrics were not significantly different (p > 0.05). In all three anatomic planes, the ROM variability between specimens [maximum ROM – minimum ROM] was greater than same-specified ROM variability between laboratories (FE: 3.5° vs. 1.3°; LB: 3.3° vs. 1.2°; AT 1.4° vs. 0.6°). There was no significant difference in NZ between laboratories during flexion-extension (1.0 ± 0.3° vs. 1.5 ± 0.9°), lateral bending (0.9 ± 0.3° vs. 0.8 ± 0.5°), or axial torsion (0.3 ± 0.1° vs. 0.2 ± 0.1°). Similarly, there were no significant differences between labs in EZS and NZS (Table 1).

![Figure 1. Spinal testing apparatus for Labs A (left) and B (right)](image)

Table 1. Mean (± 1 SD) NZS and EZS results from Labs A and B

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Neutral Zone Stiffness (Nm/deg)</th>
<th>Elastic Zone Stiffness (Nm/deg)</th>
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<tbody>
<tr>
<td>A</td>
<td>4.9 ± 1.3</td>
<td>12.4 ± 3.6</td>
</tr>
<tr>
<td>B</td>
<td>3.2 ± 0.9</td>
<td>10.5 ± 2.8</td>
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</tbody>
</table>

DISCUSSION

This study subjected a single group of specimens to a standardized flexibility testing protocol at two independent laboratories. Our results demonstrate that the differences in biomechanical outcome measures (ROM, stiffness, etc.) between laboratories are less than the differences observed between specimens. There was a significant difference in ROM between labs during flexion-extension; protocol execution at Lab A produced 6.5 ± 1.4° and at Lab B generated 5.8 ± 1.0°. The difference between labs was significant due to a consistent decrease in flexion-extension ROM at Lab B with each specimen. However, the absolute difference in average ROM between labs during flexion-extension was only 0.7°. These data support our hypothesis that, given a well-described test method, independent laboratories can produce similar biomechanical outcomes.