

Temporal Variation in Artificial Composite Spinal Surrogates through Inter-laboratory Spine Biomechanics Testing

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ABSTRACT INTRODUCTION: Biomechanical testing of the spine has evolved greatly over the past several decades with the development of new testing techniques, improved testing fixtures and software, novel methods of *in vivo* measurement, and determination of crucial anatomical structure-function relationships. However, despite previous efforts to capture best practices in spinal biomechanical testing¹, no consensus has been drawn. Artificial composite spine surrogates have been used to counteract some of the challenges with using cadaveric specimens for biomechanical testing standardization and comparison across labs such as degradation over time, inter-specimen variability, storage requirements, and transportation regulations². However, while these composite spines have been used for hundreds of orthopaedic studies, large scale evaluation of these surrogates' performance for use in spine biomechanical testing standardization has not been conducted. The objective of this study was to characterize the changes seen in these surrogates over a long-term, multi-laboratory study to understand time-based, repeated testing specimen variation as well as to inform future spinal surrogate development.

METHODS: Seven established biomechanical testing laboratories conducted the testing reported in this study over a total time of 26 months. Five Sawbones synthetic lumbar spinal surrogates were passed through the seven participating labs. Each lab conducted pure moment testing on each of the surrogates in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation (AR) through trapezoidal and/or sinusoidal loading schemes. All labs reported, at a minimum, the bending angles (in degrees) in FE, LB, and AR for the overall joint coordinate system (JCS) kinematics of each of the L2-L5 lumbar spinal surrogates. Most labs were able to report Anterior, Lateral, and Superior translations as well as individual functional spinal unit behavior for the L2-L3, L3-L4, and L4-L5 vertebral pairings. This report is centered on the behavior of the JCS kinematics and specifically the overall L2-L5 spine rotation in the primary direction of loading. The consortium met monthly to discuss findings as each group completed testing on the set of five spines, and to troubleshoot any issues or confusion that arose in testing.

RESULTS SECTION: This study resulted in ranges of reported rotation values in the six primary testing directions – flexion (8.8° to 16.1°), extension (6.7° to 11.1°), left LB (7.6° to 12.5°), right LB (9.6° to 13.7°), left AR (3.4° to 5.4°), and right AR (3.1° to 4.4°). The average rotation angle in the primary direction of the loading experienced non-significant increases ranging from 0.9° (right AR) to 3.1° (flexion) between the first and last test (same lab) for all testing directions. Despite an increase in average rotation angle across all testing directions, the standard deviations for each testing direction mostly decreased over time (0.7° to 0.6° for AR, 1.5° to 2.2° for Flexion, 1.4° to 1.3° for Extension, 1.0° to 0.8° for LB). These data are shown in Figure 1.

DISCUSSION: Some of the Sawbones surrogate spines experienced significant visible deterioration shown in Figure 2. However, despite this degradation, the surrogates did not experience significant time-based changes to their range of motion measures in any of the tests reported. Asymmetries in left and right bending (LB, AR) were visible. The highest variation between labs occurred in FE testing while the lowest variation occurred in AR. This both reflects the expected normal variation in these ranges of motion and is consistent with prior testing on these surrogate types². Inter-laboratory variation was larger than temporal variation. Future studies are required to investigate variations in reported rotation angles due to differences in test methods, equipment, etc.

SIGNIFICANCE/CLINICAL RELEVANCE: Inter-laboratory studies are a crucial part of the standardization of any test protocol and for the wider dissemination of best practices. This is the largest inter-laboratory study conducted on widely used synthetic spinal surrogates, to the knowledge of the authors. These results indicate that additional factors outside of specimen variability play a role in the measured range of motion across laboratories. This study is part of a greater effort to not only provide best practices for spinal biomechanics testing, but also how to manage specimen degradation over time and how to manage a comprehensive spine biomechanics dataset.

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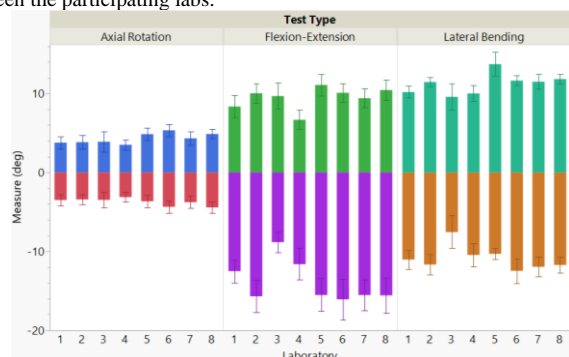


Figure 1. AR, FE, LB Bending Ranges by Lab – In Sequential Time Order

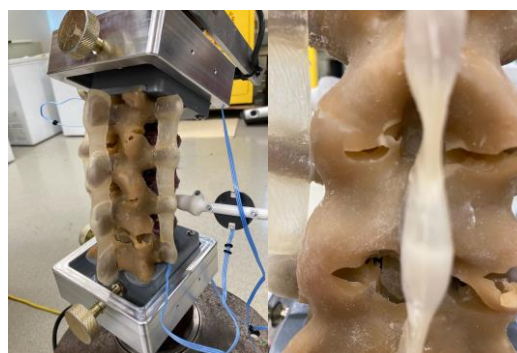


Figure 2. Specimen degradation.