Composite Lumbar Spine Surrogate Biomechanical Variability During Multi-Laboratory Collaborative Testing

Emma C. Coltoff[1], Jeremy G. Loss, MS[2], Siril Teja Dukkipati[3], Jenna M. Wahbeh, MS[4], Kalle L Chastain, MS[5], Matthew H. Pelletier, PhD[6], Tian Wang, PhD[6], Philip J. Brown, PhD[1], Mark Driscoll, PhD[3], Sophia Sangiorgio, PhD[4], Edward Ebramzadeh, PhD[4], Kathleen Meyers, MS[5], William R. Walsh, PhD[6], G. Bryan Cornwall, PhD[6,7], Brian Kelly, PhD[8], Robb W. Colbrunn, PhD[2]

[1]Department of Biomedical Engineering, Wake Forest School of Medicine, Winston-Salem, North Carolina, [2]Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio, [3]Department of Mechanical Engineering, McGill University, Montreal, Quebec, [4]JVL Orthopaedic Research Center, University of California – Los Angeles, Los Angeles, California, [5]Hospital for Special Surgery, New York City, New York, [6]Surgical and Orthopaedic Research Laboratory, University of New South Wales, Sydney, New South Wales, Australia, [7]University of San Diego, San Diego, California, [8]Barrow Neurological Institute, Phoenix, Arizona

ecoltoff@wakehealth.edu

Disclosures: Emma C. Coltoff (N), Jeremy G. Loss (1; Cleveland Clinic, simVITRO), Siril Teja Dukkipati (N), Jenna M. Wahbeh (N), Kalle L Chastain(N), Matthew H. Pelletier (N), Tian Wang (N), William R. Walsh (N), G. Bryan Cornwall (N), Sophia Sangiorgio (N), Edward Ebramzadeh (N), Brian Kelly (N), Phillip J. Brown (N), Kathleen Meyers (N), Mark Driscoll (N), Robb W. Colbrunn (1; Cleveland Clinic, simVITRO)

ABSTRACT INTRODUCTION: Standardizing spine biomechanical testing is challenging due to a wide array of factors – from testing and measurement equipment variability to specifics of test protocol and specimen handling. In this study, seven international laboratories aimed to characterize the magnitude of variability in biomechanical testing outcomes when each laboratory used their "standard" equipment, experimental procedures, testing protocols, data collection, analysis tools, and data management systems. The objective of this study was to quantify the standard practices, and corresponding outcome variation, in order to standardize spinal biomechanical testing.

METHODS: A total of nine Sawbones synthetic lumbar spinal surrogates were obtained by the labs participating in this study. The group of nine were split into sub-groups of five and four spines, which travelled in opposing order through the seven participating labs. Each lab conducted pure moment testing on the surrogates in Flexion-Extension (FE), Lateral Bending (LB), and Axial Rotation (AR) following whatever protocol was deemed "standard" for the lab and reported the joint translations and rotations for the overall specimen in a joint coordinate system (JCS). This resulted in a mixture of trapezoidal and sinusoidal loading schemes, testing rigs, bending measurement methods, and fixturing choices, summarized in Table 1. The consortium met monthly to discuss findings as each group completed testing on the set of five spines.

RESULTS SECTION: The data in this study are only reported for the group of five spines. All labs reported, at a minimum, the rotation angles (in degrees) in FE, LB, and AR for the JCS kinematics of each of the L2-L5 lumbar spinal surrogates. This resulted in average rotation values in the six primary testing directions as follows: flexion (14.8±2.7°), extension (9.9±1.7°), left lateral bending (11.2±1.6°), right lateral bending (11.8±1.6°), left axial rotation (4.5±1.0°), and right axial rotation (3.8±0.8°). However, reporting these average values alone does not properly capture the variability in bending measures that the surrogates experienced throughout the testing sequence. For these specimens, full left to right lateral bending ranged from 17.1° to 24.1°, full left to right axial rotation ranged from 6.6° to 9.7°, and full flexion-extension ranged from 18.3° to 26.6°. This is shown in Figure 1.

DISCUSSION: There are significant differences between measured outcomes across the participating labs, suggesting there is a need and an opportunity to identify the root causes of the differences. Given that this study shared common composite specimens, this data set can be used to establish best practices with respect to equipment, procedures, loading protocols, and data analysis. Differences in measured range of motion in each of the testing directions may only be partially accounted for by variability in the specimens themselves. A mixture of testing equipment was used by the participating labs, which may account for differences in both measurement and reporting. Additionally, differences in loading profiles (trapezoidal vs sinusoidal), as well as choices made regarding which trials of testing are representative of true specimen bending, may also impact reported measures. The group of four spines will also be analyzed for variance in biomechanical behavior, and will facilitate removal of time as a variable in assessment for the full group of nine specimens due to their alternate path through the participating labs than the group of five spines. Future work will be conducted to characterize the effects of these factors in order to identify potential best practices for future spine biomechanical research.

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. The labs in this group are representative of global biomechanics labs and will be able to help make recommendations regarding how equipment and protocol execution may impact data accuracy for future spine biomechanics testing.

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Table 1. Inter-laboratory Equipment Summary

Summary Equipment Table					
Test Rigs	**Load Cell**	**Measurement Method**	**Software**	**Testing Approach**	**Specimen Removal**
Robotic Arm (4) -KUKA (3) -Denso (1)	ATI (4)	NDI (4)	simVITRO (4)	Primary: Trapezoidal Secondary: Sinusoidal (2)	No specimen removal/resetting during testing (5)
Universal Testing Systems (UTS) (2) -Instron (1) -MTS (1)	AMTI (1)	Motion Analysis Corp (2)	NDI (1)	Primary: Sinusoidal Secondary: Trapezoidal (3)	Specimen removal/resetting during testing (2)
Custom Gantry Robot (1)	JR3 (1)	From Testing Rig (1)	Omron (1)	Sinusoidal Only (2)	
	Instron (1)		Instron (1)		

Figure 1. AR, FE, LB Range Variation Across Testing