SPINE SYSTEM EQUIVALENCE: A NEW PROTOCOL FOR STANDARDIZED MULTI-AXIS COMPARISON TESTS

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Accurately replicating the in-vivo loads of the spine is a critical aspect of in-vitro spine testing, but the complexity of this structure renders this challenging. The design and control capabilities of multi-axis spine systems vary considerably, and though recommendations have been made [1, 2], standardized in-vitro methods have not yet been established. As such, it is often difficult to compare different biomechanical studies [3]. The aim of this study was to use international standards [4, 5], and spine testing recommendations [1-3] to develop a standardized protocol for the evaluation of different multi-axis spinal test systems. The protocol was implemented on three six-axis spine systems, and the data used to establish stiffness and phase angle limits.

Synthetic lumbar motion segments (n=5) were produced, each comprising three heavy-duty, die-cast springs embedded in polymer [4, 5]. Specimens were tested on each system using pure moments of ±8 Nm at 0.1 Hz in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). Tests were completed using sine and triangle waves, and with axial preloads of 0 and 500 N. Five cycles were applied for each test, with the last three used to calculate the stiffness, phase angle, and R^2 value at the geometric center of each specimen. Stiffness and phase angle limits were calculated based on the 95% confidence intervals of the data from all three systems for each test (Table 1).

All test systems demonstrated similar stiffness across all tests, though there were small (<10%) but significant differences in FE ($p<0.002$) and LB ($p<0.003$) with a 500 N preload, and in AR ($p<0.046$) without a preload. There were significant differences ($p<0.032$) in 15 of 36 comparisons of phase angle, though the mean angle was <4° in all tests.

This test protocol can be adopted to evaluate and ensure equivalence of different multi-axis spine systems, providing a better way to compare in-vitro spine studies.

Table 1. Stiffness and phase angle limits for pure moment tests with synthetic specimens.

Parameter	0 N preload					
	FE		LB		AR	
	Sin	Tri	Sin	Tri	Sin	Tri
Stiffness upper limit (Nm/°)	3.50	3.48	4.12	4.11	7.73	7.82
Stiffness lower limit (Nm/°)	2.72	2.73	2.98	2.96	5.29	5.23
Phase angle limit (°)	6.12	6.43	3.03	3.63	3.17	4.19
	500 N axial preload					
	FE		LB		AR	
	Sin	Tri	Sin	Tri	Sin	Tri
Stiffness upper limit (Nm/°)	4.07	4.08	5.05	5.07	10.27	10.41
Stiffness lower limit (Nm/°)	3.23	3.24	4.01	4.01	6.79	6.74
Phase angle limit (°)	5.90	6.51	2.18	2.64	3.10	4.33

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[1] Goel et al, 2006. J Bone Joint Surg Am, 88 Suppl 2, 103-109. [2] Wilke et al, 1998. Eur Spine J, 7(2), 148-154. [3] Holsgrove et al, 2015. Int J Spine Surg, 9, 34. [4] BS ISO 12189:2008. [5] BS ISO 10243:2010+A1:2011.