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Inter-laboratory variability in in vitro spinal segment flexibility testing

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ABSTRACT

In vitro spine flexibility testing has been performed using a variety of laboratory-specific loading apparatuses and conditions, making test results across laboratories difficult to compare. The application of pure moments has been well established for spine flexibility testing, but to our knowledge there have been no attempts to quantify differences in range of motion (ROM) resulting from laboratory-specific loading apparatuses. Seven fresh-frozen lumbar cadaveric motion segments were tested intact at four independent laboratories. Unconstrained pure moments of 7.5 Nm were applied in each anatomic plane without an axial preload. At laboratories A and B, pure moments were applied using hydraulically actuated spinal loading fixtures with either a passive (A) or controlled (B) *XY* table. At laboratories C and D, pure moments were applied using a sliding (C) or fixed ring (D) cable–pulley system with a servohydraulic test frame. Three sinusoidal load-unload cycles were applied at laboratories A and B while a single quasistatic cycle was applied in 1.5 Nm increments at laboratories C and D. Non-contact motion measurement systems were used to quantify ROM. In all test directions, the ROM variability among donors was greater than single-donor ROM variability among laboratories. The maximum difference in average ROM between any two laboratories was 1.5° in flexion-extension, 1.3° in lateral bending and 1.1° in axial torsion. This was the first study to quantify ROM in a single group of spinal motion segments at four independent laboratories with varying pure moment systems. These data support our hypothesis that given a well-described test method, independent laboratories can produce similar biomechanical outcomes.

1. Introduction

Spinal implant devices must demonstrate safety and efficacy before being introduced into clinical use. Spinal construct efficacy is currently assessed with a battery of tests that includes material biocompatibility, basic bench top mechanical testing, wear testing, animal studies, full-construct kinematic evaluations and failure testing. While each test method is designed to evaluate a specific characteristic of the device, the overall goal of biomechanical testing is to prove device efficacy in a model that is most representative of the final clinical construct. A significant portion of testing is therefore focused on the use of cadaveric motion segments to evaluate spinal kinematics under controlled loading conditions. Variation in loading conditions, test apparatuses, motion measurement techniques and data reduction algorithms used between laboratories has made the findings of different research groups difficult to compare. This variability and the lack experimental standards make the demonstration of device efficacy difficult.

Over the past three decades, efforts have been made to standardize protocols for in vitro biomechanical testing of spinal implants, particularly in the quantification of specimen range of motion (i.e. flexibility testing). Non-constraining, pure moment loading in the three anatomic planes has been recommended, using either no preload or a compressive follower load system (Wilke et al., 1998b; Panjabi, 1988; Goel et al., 2006). It has been suggested that protocol standardization will enable new and existing devices to be compared in a laboratory-independent manner (Goel et al., 2006; Panjabi, 2007). For device comparison to be truly laboratory-independent, individual laboratories must adopt a common loading protocol and accurately apply and measure the agreed upon parameters. Given the high degree of specificity and variability in loading and motion measurement systems, consistency may not always be achieved. Conventional wisdom suggests that well-described in vitro test protocols (Wilke et al., 1998b; Goel et al., 2006; Panjabi, 2007) will mitigate any technical difference between

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