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Basic Science

The development of a dynamic, six-axis spine simulator

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Abstract

BACKGROUND CONTEXT: Although a great deal of research has been completed to characterize the stiffness of spinal specimens, there remains a limited understanding of the spine in 6 df and there is a lack of data from dynamic testing in six axes.

PURPOSE: This study details the development and validation of a dynamic six-axis spine simulator.

STUDY DESIGN: Biomechanical study.

METHODS: A synthetic spinal specimen was used for the purpose of tuning the simulator, completing positional accuracy tests, and measuring frequency response under physiological conditions. The spine simulator was used to complete stiffness matrix tests of an L3–L4 lumbar porcine functional spinal unit. Five testing frequencies were used, ranging from quasistatic (0.00575 Hz) to dynamic (0.5 Hz). Tests were performed without an axial preload and with an axial preload of 500 N.

RESULTS: The validation tests demonstrated that the simulator is capable of producing accurate positioning under loading at frequencies up to 0.5 Hz using both sine and triangle waveforms. The porcine stiffness matrix tests demonstrated that the stiffness matrix is not symmetrical about the principal stiffness diagonal. It was also shown that while an increase in test frequency generally increased the principal stiffness terms, axial preload had a much greater effect.

CONCLUSIONS: The spine simulator is capable of characterizing the dynamic biomechanics of the spine in six axes and provides a means to better understand the complex behavior of the spine under physiological conditions.

Keywords: Spine biomechanics; Dynamic; Stiffness; Matrix; In vitro; Porcine

Introduction

In recent years, the spinal implant sector has maintained greater growth than any other orthopedic markets [1]. This growth is leading to an increase in the number of spinal devices becoming available. Preclinical testing is critical in determining the safety and suitability of any spinal device before clinical use [2]. Such a proliferation of devices makes it paramount that testing protocols are standardized [2,3] and assessment be ideally performed in comparison with an equivalent device with proven clinical outcomes [3]. Presently, wear and fatigue testing are the only requirements a device must meet before clinical trials [4–6]. For a fair assessment of the functional characteristics of all types of devices, these requirements should be extended to include studies aimed at assessing the efficacy of each device under physiological loading and ranges of motion (ROMs).

FDA device/drug status: Not applicable.

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Stiffness matrix testing can characterize the mechanical behavior of spinal specimens in 6 df using a position-based control system. There have been numerous studies, often using custom-developed testing machines, which have investigated both the spine and spinal implants in vitro [7–11]. However, there are few studies that have carried out such experiments in 6 df [12–16], few that have done so dynamically [17], and none that have characterized the full stiffness matrix dynamically. The aim of this study was to develop and validate a spine simulator that will provide a means of completing dynamic, six-axis stiffness matrix tests on spinal specimens.

Materials and methods

A custom spine simulator was developed that was capable of dynamically applying physiological movements in 6 df (Fig. 1). A Zwick testing machine (HBT 25-200; Zwick Testing Machines Ltd., Leominster, UK) provided axial compression-extension and rotation (TZ and RZ, respectively). An XY platform was mounted on the dual axis actuator of the Zwick machine, providing anteroposterior and medial-lateral shear (TX and TY, respectively). A gimbal head was mounted underneath the XY platform that provided rotations in lateral bending and flexion-extension (RX and RY, respectively). A cranial specimen holder was fixed to the gimbal head, and a caudal specimen holder was fixed to the base plate via a six-axis load cell (AMTI MC3-A-1000; Advanced Mechanical Technology, Inc., MA, USA).

The loading requirements for the spine simulator were based on the capability of a similar apparatus described in the literature [7,10,11,14]. The ROM of each axis was maximized within the geometrical constraints of the base platform.

The TX and TY axes each comprised a parallel arrangement of two linear guide rails, with two carriages (HSR25B2SS, THK UK, Milton Keynes, UK), driven with a zero-backlash ball screw assembly (BNK1202, THK UK) via a one-axis compression/tension load cell with a 500 N capacity (615; Proctor & Chester Measurements Ltd., Kenilworth, UK). The ball screws had a representative travel distance error of ±0.018 mm over the full scale and were driven by brushless motors (EC90; Maxon Motor UK Ltd., Finchampstead, UK) via zero-backlash couplings (GESM; Lenze Ltd., Bedford, UK).

The gimbal provided zero-backlash rotations in both the RX and RY axes through a Maxon EC90 motor and a Harmonic Drive gear (HFUC-17-80-2UH-SP+EC90+HEDL5540; Harmonic Drive UK Ltd., Stafford, UK). The transmission accuracy and repeatability of the Harmonic Drive gears were 0.0025° and 0.0017°, respectively. A torque transducer with a torque capacity of ±50 Nm (TRS; Proctor & Chester Measurements Ltd.) was mounted between each Harmonic Drive gear and the position of load application.

The existing Zwick hydraulic testing machine had a load capacity and ROM of ±25 kN and ±50 mm, respectively, in the TZ axes and ±200 Nm and ±45°, respectively, in the RZ axis. The TX and TY assemblies had a ROM of ±25 mm and a load capacity of ±500 N. The RX and RY axes could provide a ROM of ±22.5° and maximum continuous torque capacity of ±31 Nm.

Position and load control of the Z axes was achieved using Zwick Workshop 96 (Version 6.00; Zwick Testing

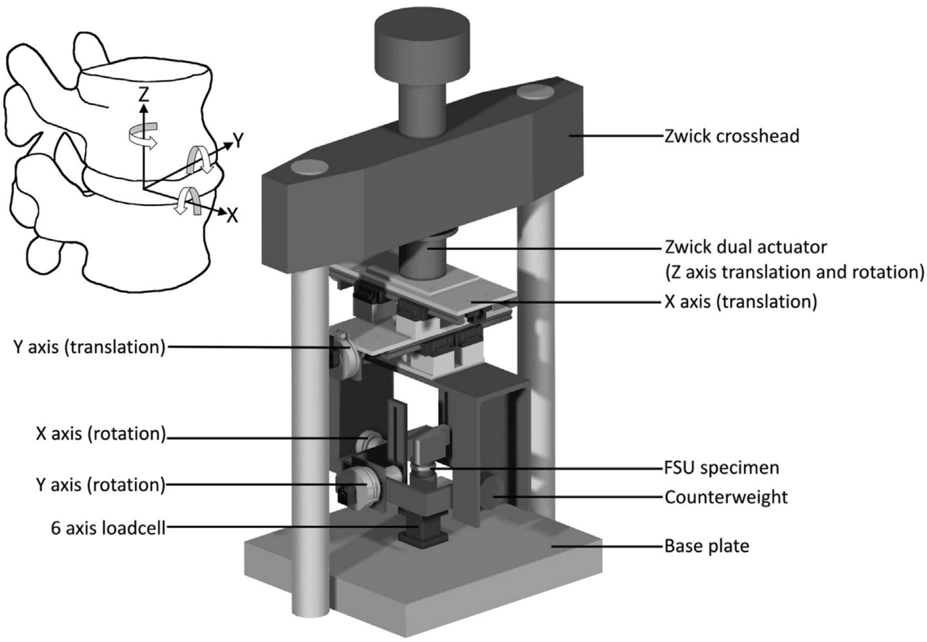

Fig. 1. The spine simulator design. FSU, functional spinal unit.