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Validation of a Custom Spine Biomechanics Simulator: A Case for Standardization

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Abstract

Mechanical testing machines used in cadaveric spine biomechanics research vary between labs. It is a necessary first step to understand the capabilities and limitations in any testing machine prior to publishing experimental data. In this study, a reproducible protocol that uses a synthetic spine was developed and used to quantify the inherent rotation error and the ability to apply loads in a single physiologic plane (pure-moment) of a custom spine biomechanics simulator. Rotation error was evaluated by comparing data collected by the test machine and the data collected by an optical motion capture system. Pure-moment loading was assessed by comparing the out-of-plane loads to the primary plane load. Using synthetic functional spine units previously shown to have mechanics similar to the cadaveric human spine, the simulator was evaluated using a dynamic test protocol reflective of its future use in the study of cadaveric spine specimens. Rotation errors inherent in the test machine were $<0.25^\circ$ compared to motion capture. Out of plane loads were $<4.0\%$ of the primary plane load, which confirmed pure-moment loading. The authors suggest that a standard validation protocol for biomechanical spine testing machines is needed for transparency and accurate field-wide data interpretation and comparison. We offer recommendations based on the reproducible use of a synthetic spinal specimen for consideration.

Keywords

Validation; Pure Moment; Spine Biomechanics; Test Machine; Synthetic

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⁷Data:

Data and code may be made available upon request.

1. Introduction:

Spine biomechanics are often studied with human cadaveric specimens manipulated by mechanical test machines with optical motion capture systems to measure the vertebral rotations (Goel et al., 1995; Kelly and Bennett, 2013; Malcolmson et al., 2007; Mannen et al., 2015; Panjabi et al., 1985; Tang et al., 2012; Wilke et al., 2001, 1998b). Some machines can apply a load in a single physiologic plane (pure moment) to better simulate *in vivo* biomechanics and facilitate comparison between laboratories (Wilke et al., 1994). With the increasing number of custom test systems, the validation of each machine is imperative for confidence in the data. Suggested standard design features were established by Wilke et al. (1994), yet no standard validation procedure exists. While testing parameters for each experiment are highly variable (Kelly and Bennett, 2013), establishing validation standards for spine simulators would increase confidence in results and facilitate comparison between laboratories.

The University of Arkansas for Medical Sciences' Spine Biomechanics Simulator (SBS, Figure 1) can apply and measure loads in real-time. While vertebral motion is typically measured with an external motion capture system, the SBS can also measure the global motion of a specimen, or the displacement (both rotations and translations) between the two potted ends (Eguizabal et al., 2010; Galvis et al., 2017; Mannen et al., 2015; Tang et al., 2012). Each of the commercially available components of the system have quantified rotation errors, however the custom setup does not. Quantification of the inherent angular displacement error of the entire system is necessary to assess the potential to use measurements from the SBS in place of external motion capture data for select experiments. Additionally, the quantification of the error in the primary-plane and two secondary-plane (out-of-plane) loads is necessary to ensure pure moment testing can be achieved. Finally, stiffness is calculated from the measurements of torque and rotation and should be compared between sources of rotation data (SBS versus motion capture).

In this study, we aim to validate the accuracy of the SBS and present a charge to the field to standardize spine biomechanical test machine validation procedures. We hypothesize that (1) the rotation maximum error will be 0.50° and rms error will be 0.20° , (2) the out-of-plane load maximum error will be 5.0% of the primary plane load, and (3) the primary plane overshoot of the intended load limit will be 5.0%.

2. Materials & Methods:

2.1 Experimental Components:

The SBS is a programmable, servohydraulic, six degrees-of-freedom (6-DOF) test machine (Table 1). The rotations in flexion-extension (FE) and lateral bending (LB) are achieved by both the superior and inferior gimbals (used in slave configuration), while axial rotation (AR) is achieved by one superior actuator. The 6-DOF superior torque transducer allows users to control the loading such that torques applied continuously in only one anatomical plane. Prior to testing, the X/Y table was used to position the specimen to eliminate external loading then fixed throughout testing, while the specimen is actively rotated to eliminate off-axis loads. Optical motion capture (MoCap, Optotrak Certus, Table 2) was used to

measure motion (Ilharreborde et al., 2010; Maletsky et al., 2007; Schmidt et al., 2009). Three synthetic functional spine units (FSUs, Table 3) previously shown to replicate the biomechanics of the human cadaveric lumbar L3–L4 specimens were used as test specimens (Camisa et al., 2014; Domann et al., 2011; Wang et al., 2014).

2.2 Study Design:

Specimens were rigidly fixed in the pots attached to either gimbal with MoCap research pins rigidly attached to each pot. Pure moments were applied at 1°/s in FE, LB, and AR (Wilke et al., 1998a) to a limit of $\pm 7.5\text{Nm}$ (Wilke et al., 1994) with a 100N axial preload (Domann et al., 2011) for 1000 cycles (Wang et al., 2014). After a rest period of at least 12 hours, the same parameters were used to apply pure moments for 5 cycles and the 4th cycle was used for analysis (Wang et al., 2014).

The data from both the SBS and MoCap were collected for the quantification of rotation error. Standard spine biomechanical parameters of interest were calculated from the torque-rotation curve for both loading phases (flexion or extension, left/right LB, left/right AR; Figure 2a)(Wilke et al., 1998b).

2.3 Analysis:

MoCap data was filtered using a 4th-order Butterworth lowpass filter (4 Hz via residual analysis). Customized MATLAB (MathWorks, Natick, MA, USA) codes were used to synchronize the SBS and MoCap data and to calculate rotation and stiffness parameters using Euler decomposition techniques (Crawford et al., 1996). Primary-plane rotation, load, and stiffness parameters as well as out-of-plane ROM and load were computed for each mode of bending. The MoCap data was considered the actual rotation, and error was defined as the difference between the SBS and MoCap data. For rotation, error is reported as both average maximum error and root-mean-squared (RMS) error. Overshoot was any load beyond $\pm 7.5\text{Nm}$ in the primary plane. Out-of-plane torques were any torques measured in the secondary-planes.

3. Results:

The maximum and RMS errors of rotation fell below the hypothesized values of 0.50° and 0.20°, respectively, for each specimen (Table 4, Figure 2). The hypothesized overshoot of the target load limit in the primary mode of bending was <5.0% or 0.38Nm. The actual overshoot means (ranges) were: flexion: 2.4% (1.9–3.2%), extension: 4.7% (4.4–5.0%), left LB: 3.6% (2.6–4.7%), right LB: 2.9% (2.2–3.3%), left AR: 5.2% (4.6–6.0%), and right AR: 5.3% (4.6–6.4%) (Figure 3). The means of the out-of-plane loads as percentages of the primary mode of bending ($\pm 7.5\text{Nm}$) in FE, LB, and AR were <2.0%, 3.3%, <2.7%, respectively (Figure 3). The largest single out-of-plane load was 0.29Nm or 3.9% in AR. The differences between stiffness as calculated using SBS versus MoCap rotation data ranged from <0.01Nm/° to 2.93Nm/°. The mean error ranged from 0.08Nm/° to 1.44Nm/° (Table 5).

4. Discussion:

In this study, we sought to validate a custom spine biomechanics testing machine. Validation procedures for spine biomechanics simulators should be as similar as possible to actual experimental procedures yet should be simple enough to replicate in other laboratories. It is critical to quantify the error in rotation and loading to increase confidence in future experiments and allow for more accurate field-wide interpretation and comparison.

4.1 Rotation:

The hypothesized 0.5° maximum rotation error was chosen because of the planned use of the SBS. The SBS will be used in the study of both intact and surgically instrumented spine specimens where very limited ROM may indicate a clinically significant outcome. For instance, the diagnosis of pseudarthrosis is most often considered to be more than 2° ROM (range: 0° – 5°) at a vertebral junction (Oshina et al., 2018; Raizman et al., 2009). We chose 0.5° in order to be at the low end of the range. The rotation error was well within the accepted maximum error. The maximum errors were found to be near the extremes of the ROM, where the SBS changed direction from loading to unloading. This error could likely be limited by a stepwise or quasistatic testing protocol, though moving from continuous loading to more static loading may decrease the dynamic viscoelastic response of biological materials (Goertzen et al., 2004). The RMS error was 0.10° for each specimen, indicating that the rotation control of the SBS is accurate and can be used in place of MoCap data when an error of 0.25° is acceptable and the global rotation is of concern. However, when a high degree of accuracy is needed in dynamic testing, or in long spinal segments when more than the two potted vertebrae positions are desired, MoCap is required.

Wang et al. (2014) showed ROM increased significantly over 10,000 preconditioning cycles using the same synthetic FSU. Angular rates outside of the recommended range (0.5 – $5.0^\circ/\text{s}$) could occur when using a constant cycle frequency, causing degradation of the FSUs instead of reflecting the actual viscoelastic properties (Wilke et al., 1998a). The current study controlled angular rate ($1^\circ/\text{s}$) rather than cycle frequency to stay within the recommended range and avoid damaging the specimens.

4.2 Load:

The average maximum overshoot was $<0.27 \pm 0.09 \text{ Nm}$ for all modes of bending, and the mean overshoot of the SBS was $<0.08 \pm 0.10 \text{ Nm}$ which compares favorably to Kelly & Bennett (2013) who found the mean average error of their spine test machine to be $<0.15 \pm 0.12 \text{ Nm}$ with a single FSU. AR overshoot is the only mode of bending that exceeded the 5.0% target. The mean overshoot in AR exceeded 5.0% due to FSU1's AR overshoot of 0.49 Nm or 6.3%. When the AR load limit is critical, the rotation rate should be decreased to limit the overshoot. Because all out-of-plane loads were less than 5.0% of the primary mode of bending, the SBS can be considered capable of applying pure moments.

The use of pure moments is the standard for in vitro spine biomechanics testing because it allows for physiologically-similar loading across many vertebral segments (Fuller et al., 2012; Tang et al., 2012; Wilke et al., 2001, 1994). Constraint of the specimen restricts the

coupled motion caused by the asymmetry of the spine and leads to out-of-plane loading. The use of pure moments allows the innate coupled motion to be observed and data to be compared across studies and laboratories (Eguizabal et al., 2010; Tang et al., 2012; Wilke et al., 2001).

4.3 Stiffness:

Stiffness of the human spine relates to fusion implant success and back pain (Sions and Hicks, 2016). The stiffness error in this validation study ranged from $<0.01\text{Nm}/^\circ$ to $2.93\text{Nm}/^\circ$. The magnitude of this error may be acceptable in some tests, but there is no standard for comparison. This indicates that when stiffness is a main concern of the study, MoCap is necessary to ensure accurate results.

4.4 Limitations and Future Work:

The small sample size ($n = 3$) may be seen as a limiting factor in the study. While the synthetic FSU has previously been shown to exhibit cadaveric biomechanics, the variability between specimens is less than cadavers allowing for a smaller sample size compared to a cadaveric study (Camisa et al., 2014, Wang et al., 2014). Cost is also a consideration when designing a validation experiment that may be replicated across laboratories.

The nature of coupled spinal motion limits the ability to achieve a truly pure moment where no out-of-plane loads occur. Programmable test machines must detect an off-axis load before it can correct itself. The SBS has been tuned to minimize the out-of-plane loads to fall within ranges of previous studies (Kelly and Bennett, 2013; Mannen et al., 2015) and is considered to apply pure moments.

The use of synthetic specimens in place of cadaveric specimens was necessary for this study. A synthetic specimen that closely replicates cadaveric biomechanics offers advantages for a validation study over cadaveric specimens or synthetic specimens that do not mimic coupled motion of the spine. When compared to cadaveric or animal specimens, synthetic specimens can be used beyond a single day, can withstand thousands of cycles, require less preparation, are not biohazardous, and require no refrigeration (Wang et al., 2014). Synthetic spines also replicate the coupled motion of a cadaveric specimen. The use of a symmetric specimen that does not behave like a human spine may result in the false validation of pure moment testing. However, ROM of this synthetic FSU is less and the stiffness is higher than most cadaveric specimens. The maximum errors in the SBS rotations occurred at the limits of the ROM. Therefore, it is possible that as ROM increases, the rotation error increases. Future studies will use longer specimens to quantify error with a greater ROM.

4.5 Challenge to the Field to Develop Standardized Validation Protocol:

This study confirms the accuracy of the SBS's measured rotation data as an acceptable approximation of the actual global rotation of a specimen by finding a maximum error of $<0.25^\circ$ under continuous loading conditions. The SBS was also confirmed to be capable of pure moment testing. However, it is impossible to compare the accuracy of the SBS to other machines since all validation protocols differ between labs.

There is a need for standard validation guidelines for the field. Rotation and loading are the fundamental tasks for each biomechanics simulator irrespective of build or software. It would benefit the field of spine biomechanics to have accepted, fundamental guidelines to validate these machines. The authors put forth these recommendations for a standard validation procedure:

1. Each new machine should be tested to validate functionality and accuracy for future studies.
2. A biomimetic synthetic spine specimen should be used to closely replicate future testing while minimizing the variability associated with human and animal specimens (Wang et al., 2014).
3. Rotation rate and load limits of the validation study should reflect spine testing recommendations (Wilke et al., 1998b, 1994).
4. When rotation data is available from the testing machine (without MoCap), the maximum error in global rotation should be $<0.5^{\circ}$.
5. Out-of-plane loading less than 5.0% of the primary-plane loading should be considered a pure moment.
6. The results of validation testing should be published prior to the first cadaveric study for which a new machine is used.

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Abbreviations:

SBS	Spine biomechanics simulator
FSUs	Functional spine units
MoCap	Optical Motion Capture
FE	Flexion/Extension
LB	Lateral Bending
AR	Axial Rotation
ROM	Range of Motion
NZ	Neutral Zone
EZ	Elastic Zone
6-DOF	Six Degrees of Freedom

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Figure 1:
Spine Biomechanics Simulator with a synthetic functional spine unit (FSU) and motion capture (MoCap) spine research pins in testing in testing conditions.

Figure 2:

(a) Example load-displacement hysteresis with ROM, NZ, EZ, NZS, and EZS graphically defined. Representative load-displacement hysteresis curves for (b) FE, (c) LB, and (d) AR. SBS data appears in blue and motion capture in red. Mean max error (SD) and mean RMS error (SD) is displayed on each respective plot. ROM=Range of motion. NZ=Neutral Zone. EZ=Elastic Zone. NZS=NZ Stiffness. EZS=EZ Stiffness.

Figure 3:
Mean load maximums (SD) in each plane during loading of the primary mode of bending in
(a) Flexion/Extension, (b) Lateral Bending (LB), and (c) Axial Rotation (AR).

Table 1:

Custom Spine Biomechanics Simulator Specifications.

Spine Biomechanics Simulator	
Manufacturer	MTS Systems Corp. Eden Prairie, MN, USA
Model	Bionix Servohydraulic Test System
	370.02 Load Frame
Custom Configuration:	Gimbals (2),
	X/Y Slide Table,
	Load transducers (2)
Gimbals (2)	Superior & Inferior, X & Y Rotation
X/Y Slide table	Inferior, X & Y Translation
Superior Load transducer:	Sensing Ranges (Resolution)
ATI Force/Torque Mini 45	Fx, Fy: $\pm 580\text{N}$ (0.5N) Fz: $\pm 1160\text{N}$ (0.5N)
(ATI Industrial, Apex, NC, USA)	Tx, Ty: $\pm 201\text{Mm}$ (0.01Nm) Tz: $\pm 20\text{Nm}$
Inferior Load transducer:	Sensing Ranges (Resolution)
MTS Axial-Torsional Load Transducer Model: 662.20H-04	Fz: $15,000\text{N}$ (1.5N) Tz: 150Nm (0.015Nm)
Degrees of Freedom:	6
Methods of Rate Control:	Rotation/Displacement, Load, Frequency
Hydraulic Power:	MTS Silent6515
Controller:	MTS FlexTest60
Testing Software:	MTS Testsuite Multipurpose Elite v4.1.6.819
Data Collection:	Rotation, Displacement, Load (102.4Hz)

Table 2:

Optical Motion Tracking System Specifications.

Optical Motion Tracking	
Manufacturer	Northern Digital Inc. Waterloo, Ontario, Can
Model	Optotrak Certus
Cameras	3
Markers	Active
Spine Pin	3 non-colinear markers
Collection Rate	100.0 Hz
Calibration (factory)	>10,000 known positions
Accuracy within 1–4.5m	
Northern Digital Inc.:	±0.1mm
Maletsky et al. (2007):	±0.03mm or ±0.05°

Table 3:

Synthetic Functional Spine Unit Specifications.

Functional Spine Unit	
Manufacturer	Sawbones, Vashon, WA, USA
Model	Human L3–L4 FSU
SKU	3430-34-2
Cadaver-like	Camisa et al. (2014)
Biomechanics	Domann et al. (2011)
Validation	Wang et al. (2014)

Displacement maximum error and RMS error in each mode of bending for each functional spine unit (FSU).

Table 4:

	Flexion/Extension		Lateral Bending		Axial Rotation	
	Max Error	RMS Error	Max Error	RMS Error	Max Error	RMS Error
FSU 1	0.13°	0.05°	0.22°	0.07°	0.10°	0.04°
FSU 2	0.09°	0.04°	0.24°	0.10°	0.13°	0.07°
FSU 3	0.14°	0.07°	0.16°	0.06°	0.14°	0.07°
Mean (SD)	0.12 (0.02)°	0.05 (0.01)°	0.21 (0.03)°	0.08 (0.02)°	0.12 (0.02)°	0.06 (0.01)°

Table 5:

Differences in the calculated stiffness values between the Spine Biomechanics Simulator and motion capture data in flexion, extension, right and left lateral bending (LB), and right and left axial rotation (AR).

		Flexion	Extension	Left LB	Right LB	Left AR	Right AR
Neutral Zone	FSU 1	0.41	0.60	0.05	0.01	0.41	0.85
Stiffness	FSU 2	1.09	0.20	0.17	0.02	0.23	1.36
Differences	FSU 3	0.50	1.14	0.03	0.43	2.77	0.87
(Nm/°)	Mean (SD)	0.67 (0.30)	0.65 (0.38)	0.08 (0.06)	0.15 (0.20)	1.14 (1.16)	1.03 (0.23)
Elastic Zone	FSU 1	<0.01	1.58	0.77	0.24	1.02	0.24
Stiffness	FSU 2	0.26	1.52	1.04	0.43	0.09	2.93
Differences	FSU 3	0.20	1.21	0.78	0.70	0.96	0.98
(Nm/°)	Mean (SD)	0.15 (0.11)	1.44 (0.16)	0.86 (0.12)	0.46 (0.19)	0.69 (0.42)	1.38 (1.14)