Original Article

Global Spine Journal
2020, Vol. 10(4) 419-424
© The Author(s) 2019
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/2192568219858981
journals.sagepub.com/home/gsj

Range of Motion Testing of a Novel 3D-Printed Synthetic Spine Model

Michael A. Bohl, MD[1], Sarah McBryan, MS[1], Anna G. U. S. Newcomb, MS[1], Jennifer N. Lehrman, MS[1], Brian P. Kelly, PhD[1], Peter Nakaji, MD[1], Steve W. Chang, MD[1], Juan S. Uribe, MD[1], Jay D. Turner, MD, PhD[1], and U. Kumar Kakarla, MD[1]

Abstract

Study Design: Biomechanical model study.

Objective: The Barrow Biomimetic Spine (BBS) project is a resident-driven effort to manufacture a synthetic spine model with high biomechanical fidelity to human tissue. The purpose of this study was to investigate the performance of the current generation of BBS models on biomechanical testing of range of motion (ROM) and axial compression and to compare the performance of these models to historical cadaveric data acquired using the same testing protocol.

Methods: Six synthetic spine models comprising L3-5 segments were manufactured with variable soft-tissue densities and print orientations. Models underwent torque loading to a maximum of 7.5 N m. Torques were applied to the models in flexion-extension, lateral bending, axial rotation, and axial compression. Results were compared with historic cadaveric control data.

Results: Each model demonstrated steadily decreasing ROM on flexion-extension testing with increasing density of the intervertebral discs and surrounding ligamentous structures. Vertically printed models demonstrated markedly less ROM than equivalent models printed horizontally at both L3-4 (5.0° vs 14.0°) and L4-5 (3.9° vs 15.2°). Models D and E demonstrated ROM values that bracketed the cadaveric controls at equivalent torque loads (7.5 N m).

Conclusions: This study identified relevant variables that affect synthetic spine model ROM and compressibility, confirmed that the models perform predictably with changes in these print variables, and identified a set of model parameters that result in a synthetic model with overall ROM that approximates that of a cadaveric model. Future studies can be undertaken to refine model performance and determine intermodel variability.

Keywords

spine biomechanics, spine deformity, surgical planning, surgical training, synthetic spine model

Introduction

The Barrow Biomimetic Spine (BBS) project is an ongoing resident-driven effort to manufacture a synthetic spine model with high biomechanical fidelity to human tissue.[1-4] Various 3D printing technologies are employed in this effort because these technologies enable the creation of models that can replicate any variation of normal or pathological anatomy. The validation of a customizable synthetic spine model as a reliable substitute for human cadavers could have an enormous effect on the field of spine surgery, especially with respect to spine biomechanical research, surgical education, surgical planning, and medical device development and testing. Previous studies from this ongoing effort have demonstrated that BBS models can be reliably produced to mimic, with high fidelity, human gross anatomy; radiographic anatomy; the corticocancellous architecture of human bone; the biomechanical performance of pedicle screws in the synthetic bone; and certain physiological functions, such as bleeding, spinal fluid leaking from a

[1] Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, Phoenix, AZ, USA

Corresponding Author:
U. Kumar Kakarla, c/o Neuroscience Publications, Barrow Neurological Institute, St. Joseph's Hospital and Medical Center, 350 W Thomas Road, Phoenix, AZ 85013, USA.
Email: Neuropub@barrowneuro.org

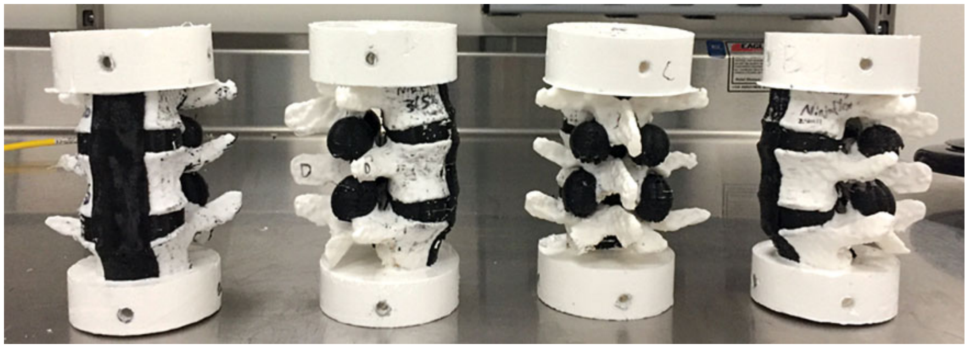

Figure 1. Four different synthetic spine models shown (left to right) in anterior, right lateral, posterior, and left lateral views. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

synthetic thecal sac, and electrical conduction in synthetic nerve roots.[2-4]

A critical component of the eventual creation of a comprehensively biofidelic model of the human spine is the biomechanical performance of the supportive ligamentous structures, specifically the intervertebral discs, the longitudinal ligaments, and the posterior column ligaments. Earlier studies that compared the performance of BBS models with that of human cadavers after undergoing Schwab grade 2 osteotomies demonstrated the ability to construct a model that closely mimics the human cadaver in terms of the degrees of lordosis achievable at a single disc space after removal of the posterior column supportive structures.[3] Further investigation was needed, however, to elucidate this finding and determine the optimal manufacturing method for creating a model with ligamentous structures that provide high biomechanical fidelity on range of motion (ROM) testing. The purpose of this study was to investigate the performance of the current generation of BBS models on traditional biomechanical testing of ROM and axial compression and to compare the performance of these models with historical cadaveric data acquired using the same testing protocol.[5,6]

Methods

Model Production

High-resolution computed tomography of a normal lumbar spine was imported into the Materialise Mimics software package (Materialise, Plymouth, MI), which was used to threshold the L3-5 vertebral levels. These structures were then exported into the Autodesk Meshmixer software package (Autodesk, Inc, San Rafael, CA), which was used to reconstruct the L3-5 spinal column with the exported vertebral bodies, intervertebral discs, anterior and posterior longitudinal ligaments, and facet capsules. The digitally reconstructed L3-5 spinal column was then imported into the Simplify3D printing platform (Simplify3D, LLC, Blue Ash, OH), where it was prepared for 3D printing.

Select printing variables were modified with the intention of creating a group of models with a wide range of biomechanical performance on ROM testing. These variables included shell thickness, infill percentage, and print orientation. A combination of these variables was chosen for each model and input into the Simplify3D printing platform. Each model was then printed on a FlashForge Creator Pro with dual extruders (FlashForge Corp, Zhejiang, China). Materials used for 3D printing were held constant across all models; polylactic acid was used for the vertebral bodies, and Ninja Flex (NinjaTek, Manheim, PA) was used for the ligamentous structures. These materials were chosen on the basis of previously published studies evaluating the performance of various materials in a synthetic spine model.[3,4] After printing, the models were embedded at the L3 and L5 vertebral levels in a fast-curing resin (Smooth-Cast 300Q; Smooth-On, Macungie, PA) in a cylindrical fixture for application of loads (Figure 1).

Flexibility and Axial Compression Testing of Models

Models underwent torque loading to a maximum of 7.5 N m using a servohydraulic test system (MTS, Minneapolis, MN). Torques were applied to the models to induce flexion-extension, lateral bending, and axial rotation (Figure 2). Torque loads were applied in 1.5-N m increments until reaching 7.5 N m. Testing was halted before reaching 7.5 N m if the model failed (experienced annulus or ligament rupture) or demonstrated steadily increasing ROM while being held at a constant load (termed "creep"). A final load of 7.5 N m was chosen because this was the standard load applied to cadaveric specimens used in the historical control.[5] Axial compressive stiffness (N/mm) was measured through the application of a uniaxial load of 300 N. This testing method is the same as that used to generate the cadaveric data that we used as the historical control, and the data were collected using the same hardware and software from the same laboratory.[6] Furthermore, a recent review of spine biomechanics literature has demonstrated that this testing method is the most common testing protocol used in spine biomechanical research and was originally chosen because it reliably reproduces changes in the intact cadaveric spine that closely match in vivo changes seen in living spines during the same flexibility maneuvers.[7]

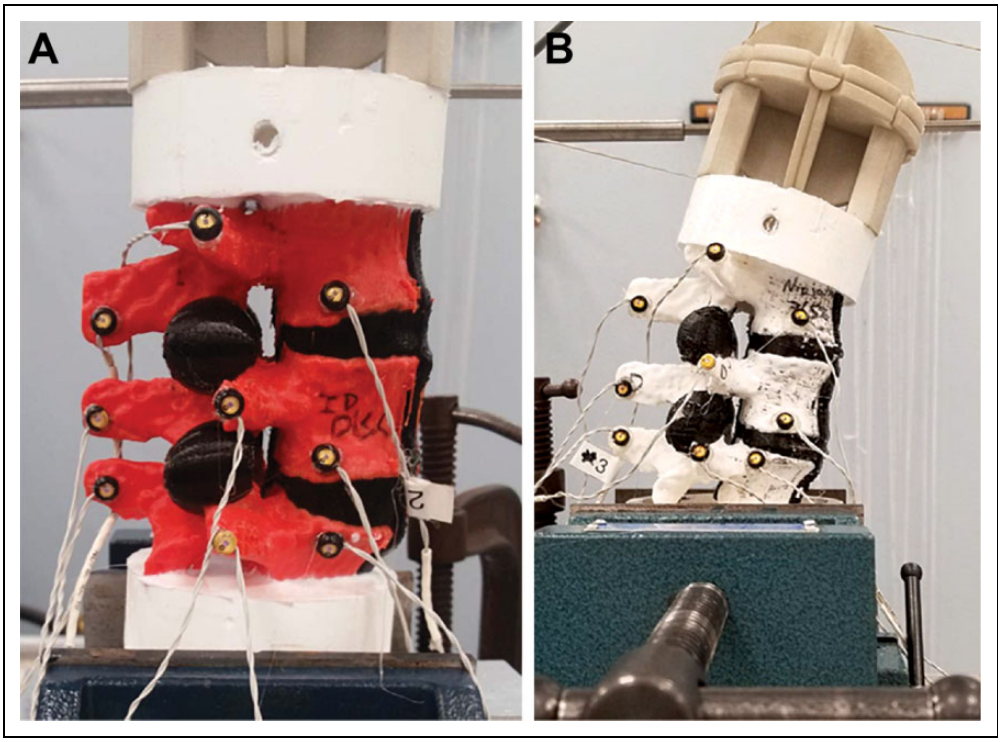

Figure 2. (A) Synthetic spine model undergoing range of motion testing. This model is shown in the resting state. (B) Synthetic spine model undergoing range of motion testing. This model is shown in the loaded flexion state. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

Table 1. Printing Variables for 6 Synthetic Spine Models and Flexion-Extension Range of Motion Test Results Compared With Historical Cadaver Data.

Model	Relative Density of Intervertebral Discs[a]	Print Orientation	Maximum Moment Achieved (N m)	Flexion-Extension Range of Motion (°)	
				L3-4	L4-5
A	1	Horizontal	1.5	22.2	12.6
B	5	Horizontal	6.0	17.3	12.7
C	10	Horizontal	6.0	14.0	15.2
D	17	Horizontal	7.5	14.7	12.9
E	27	Horizontal	7.5	3.7	3.5
F	10	Vertical	6.0	5.0	3.9
Cadaveric control group 1	NA	NA	6.0	5.5 ± 1.4[b]	7.6 ± 2.9[b]
Cadaveric control group 2	NA	NA	7.5	7.9 ± 2.6[b]	9.7 ± 3.5[b]

Abbreviation: NA, not applicable.
[a]Relative density is a unitless measure of the material density used to construct the intervertebral discs. The relative density of model A, the least dense model, was set at 1 to provide a reference for the density of the other models.
[b]Mean ± SD. Data adapted from Newcomb et al.[5]

Study Design

Informed consent for this study was not required and institutional review board approval was not sought due to the retrospective nature of the report. The study consisted of 2 phases: the first phase entailed testing 6 models in total flexion-extension ROM. See Table 1 for a summary of the print characteristics for each of the 6 models. The second phase entailed identification of those models from phase 1 with results closest to the cadaveric control data and then additional testing of those models in lateral bending, axial rotation, and axial compression. Results for each model were calculated and reported in comparison with other models that underwent the same testing protocol.

Results

Phase 1 Results

Six models were printed and tested according to the protocol described. Historical cadaveric data for mean (±SD) flexion-

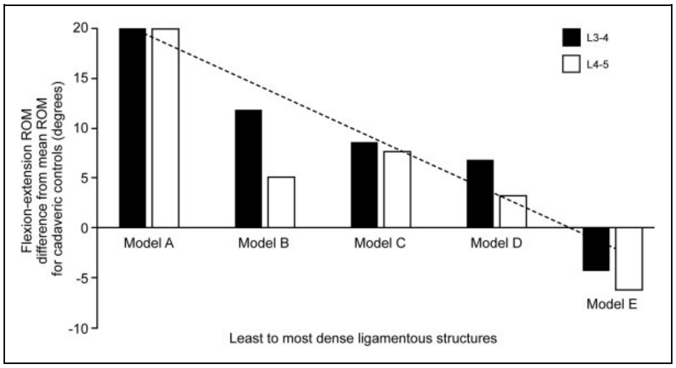

Figure 3. Flexion-extension range of motion (ROM) of synthetic spine models A to E relative to mean ROM for the cadaveric controls for L3-4 (black bars) and L4-5 (white bars). A value of 0 represents no difference in range of motion between the model and the mean range of motion for the cadaveric controls. A positive value indicates increased ROM compared with the mean ROM for the cadaveric controls, and a negative value indicates decreased ROM compared with the mean ROM for the cadaveric controls. Dashed line is a linear trend line demonstrating the inverse relationship between the density of ligamentous structures and model ROM on flexion-extension. Cadaveric control data adapted from Newcomb et al.[5] Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

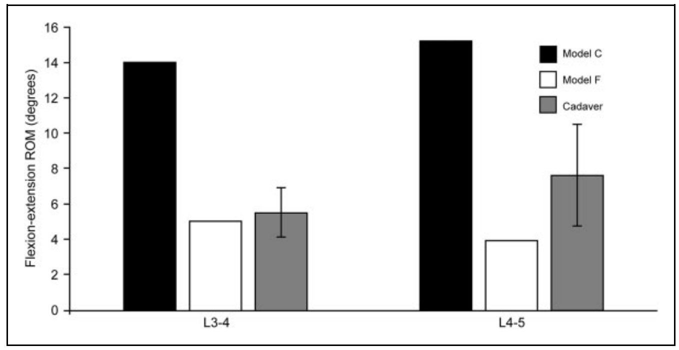

Figure 4. Flexion-extension range of motion (ROM) at 6.0 N m for a synthetic spine model with horizontal print orientation (model C) and a synthetic spine model with vertical print orientation (model F), compared with mean ROM data for cadaveric controls. Model F was the only model printed with a vertical rather than horizontal print orientation and was equivalent to model C in all other variables. Error bars indicate standard deviation. Cadaveric control data adapted from Newcomb et al.[5] Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

extension ROM of L3-4 and L4-5 disc levels was 5.5 ± 1.5° and 7.6 ± 2.7°, respectively, at 6.0 N m of torque and 7.9 ± 2.6° and 9.7 ± 3.5°, respectively, at 7.5 N m of torque. Each model demonstrated steadily decreasing ROM on flexion-extension testing with increasing density of the intervertebral discs and surrounding ligamentous structures (Figure 3). Of note, model A was printed with the least dense disc and ligamentous structures and demonstrated complete failure, including rupture of the annulus and the supportive ligaments, at a torque of 1.5 N m. Total flexion-extension ROM of model A at 1.5 N m was 22.2° at L3-4 and 12.6° at L4-5. Model B was printed with 5% greater disc density than model A and demonstrated creep at 6.0 N m of torque. Flexion-extension ROM prior to onset of creep for model B was 17.3° at L3-4 and 12.7° at L4-5. Model E was printed with the densest intervertebral discs and ligamentous structures, and this model withstood a torque of 7.5 N m without creep (similar to cadaveric specimens) with a total ROM on flexion-extension of 3.7° at L3-4 and 3.5° at L4-5. Model F was the only model printed with a vertical rather than horizontal print orientation and was equivalent to model C in all other variables. Model F demonstrated markedly less ROM than model C at the same torque (6.0 N m) at both L3-4 (5.0° vs 14.0°) and L4-5 (3.9° vs 15.2°) (Figure 4). See Table 1 for a complete report of all phase 1 test results.

Phase 2 Results

Models D and E withstood flexion-extension loads of 7.5 N m and demonstrated total ROM bracketing the historic cadaveric values. These models were therefore included in phase 2 testing. Model F demonstrated ROM on flexion-extension that was very close to that of the cadaveric control at 6.0 N m. Further testing of model F was not pursued because this model did not withstand testing at 7.5 N m, and previous studies have demonstrated a significantly detrimental effect of a vertical print orientation on pedicle screw performance in the 3D-printed synthetic bone.[3,4]

Phase 2 testing for models D and E included additional ROM testing of lateral bending and axial rotation at a torque load of 7.5 N m as well as axial compressive stiffness testing to a maximum load of 300 N m. These test loads were equivalent to the loads applied to the cadaveric controls. The cadaveric controls had a mean (± SD) ROM on lateral bending of 5.1 ± 1.5° at L3-4 and 4.9 ± 1.7° at L4-5. Axial rotation values for the controls were a mean (± SD) of 2.2 ± 1.2° and 2.5 ± 1.4° at L3-4 and L4-5, respectively. Finally, axial compressive stiffness testing of the control cadaveric specimens resulted in mean (± SD) values of 457.1 ± 143.7 N/mm at L3-4 and 438.5 ± 206.0 N/mm at L4-5. On flexion-extension, results for model D were approximately 1 SD greater than results for the cadaveric controls, whereas results for model E were approximately 2 SD less than results for the controls (Figures 3 and 5). On lateral bending, ROM for model D was within 1 SD of ROM for the control, whereas on axial rotation, ROM for model E was nearly identical to ROM for the control (Figure 5). On axial compressive stiffness testing, model D was 2 SD less stiff and model E was 2 SD stiffer than the controls at L3-4. At L4-5, model D was within 1 SD of the cadaveric controls (Figure 5). See Table 2 for complete reporting of phase 2 results.

Discussion

Several important findings are distinguishable in the ROM testing results. First, the models predictably perform with an inverse relationship between disc and ligamentous density and overall ROM at torque loads equivalent to those used for the historical cadaveric controls. This is an important finding

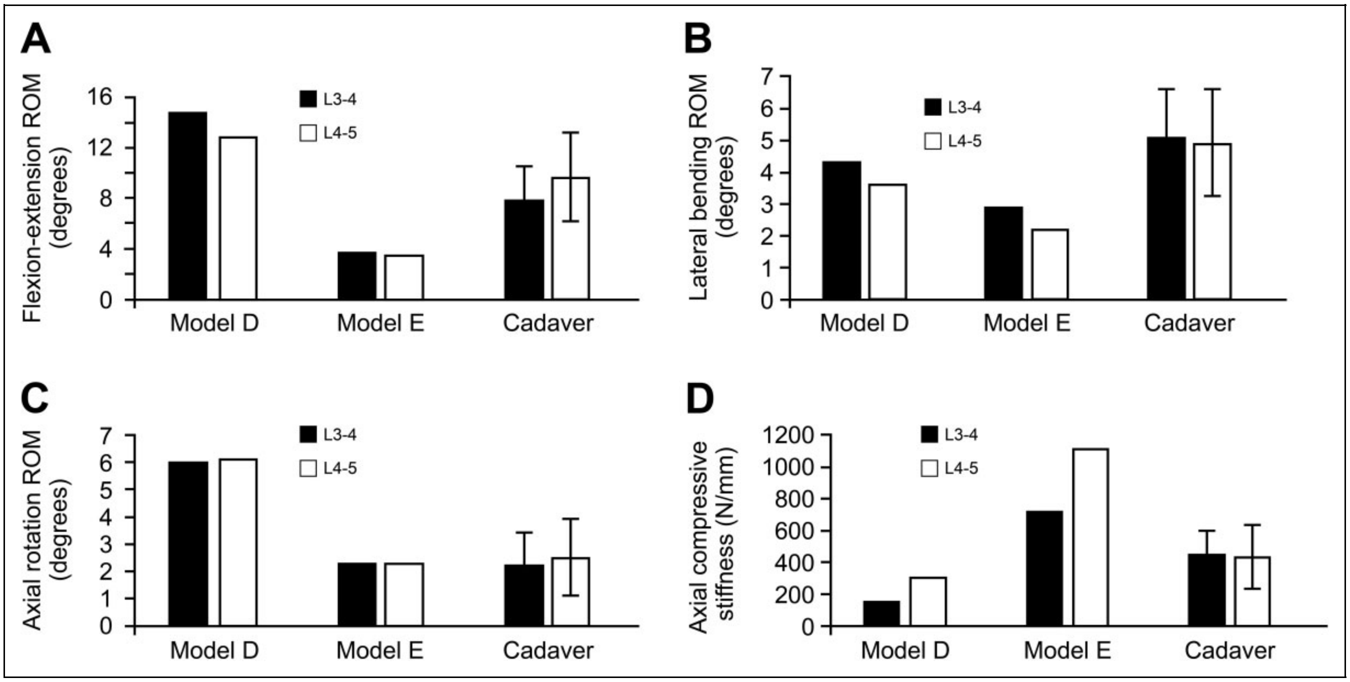

Figure 5. Synthetic spine models D and E compared with mean data for cadaveric controls with respect to (A) flexion-extension, (B) lateral bending, and (C) axial rotation range of motion (ROM) at 7.5 N m and (D) axial compression. Error bars indicate standard deviation. Cadaveric control data adapted from Newcomb et al.[5] Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

Table 2. Range of Motion (ROM) and Axial Compressive Stiffness Test Results for 2 Synthetic Spine Models Compared With Historical Cadaver Data.

	ROM (°)						Axial Compressive Stiffness (N/mm)	
	Flexion-Extension		Lateral Bending		Axial Rotation			
Model	L3-4	L4-5	L3-4	L4-5	L3-4	L4-5	L3-4	L4-5
D	14.7	12.9	4.3	3.6	6.0	6.1	152.1	302.9
E	3.7	3.5	2.9	2.2	2.3	2.3	715.6	1110.3
Cadaveric controls,[a] mean ± SD	7.9 ± 2.6	9.7 ± 3.5	5.1 ± 1.5	4.9 ± 1.7	2.2 ± 1.2	2.5 ± 1.4	457.1 ± 143.7	438.5 ± 206.0

[a]Data adapted from Newcomb et al.[5]

because it demonstrates that synthetic spine models can be reliably produced with prespecified ligamentous laxity and overall ROM values. This is perhaps the most important finding, because it demonstrates how a synthetic spine model composed of multiple motion segments can be created in a manner that results in overall biomechanical similarity to cadaveric models in terms of flexibility and compressibility. Further testing will be required to fine-tune the printing parameters and determine the intermodel variability that can be expected, but this study provides a clear starting point, because the most promising models have overall ROM values that bracket those of the historical cadaveric controls.

It is also important to note that print orientation (vertical vs horizontal) has a significant effect on model ROM performance. This is consistent with previous studies on the biomechanical performance of pedicle screws in 3D-printed vertebral bodies as well as motion segment testing of synthetic spine models after Schwab grade 2 osteotomies.[3,4] Unlike these other studies, which primarily evaluated the performance of 3D-printed bone and demonstrated reduced strength with a vertical print orientation, these results demonstrate increased model strength with a vertical print orientation (Figure 4). This can be seen most clearly when directly comparing the flexion-extension performance of models C and F, which were printed with settings that were identical except for print orientation. This difference in the direction of change between these results and those of previous studies likely has to do with the force vectors being applied to the model and their relative relationship to the print orientation.[3,4] In this case, a vertical print orientation places the synthetic disc and ligament fibers parallel to compressive and torque forces, whereas in previous studies a vertical print placed the synthetic bone fibers perpendicular to the applied forces. This finding also likely explains the much larger differences in ROM and compressive stiffness seen in this study between L3-4 and L4-5 disc levels in the models as compared with the cadaveric controls. The L3-4 and L4-5 disc levels are tested at slightly different angles because of the lumbar lordosis printed into the model. This means the applied force vectors vary in their relative angle to the L3-4 versus the L4-5 disc spaces. In summary, the print orientation in relationship to the applied force vectors seems to have a large effect on model performance. Efforts are underway to minimize this variability using various processing techniques after printing.

Limitations and Future Directions

This study is limited by its small sample size and our subsequent inability to provide any data on intermodel variability. We also evaluated a single flexible material at variable print parameters, meaning it is possible that a different material may have performed better. This material was chosen on the basis of results of a previous study evaluating the performance of this material in a Schwab grade 2 osteotomy model.[3] These limitations were felt to be acceptable because the goals of this study were to identify the relevant variables that affect synthetic spine model ROM and compressibility, to confirm that the models perform predictably with changes in these print variables, and to identify a set of model parameters that results in a synthetic model with overall ROM that approximates that of a cadaveric model. We feel that the above-mentioned results demonstrate that these goals have been met. Future efforts will entail larger numbers of models and smaller variations in model variables to attempt to demonstrate that the synthetic spine models can be printed to closely approximate cadaveric models in terms of biomechanical performance and, furthermore, that intermodel variability will be reduced with the synthetic spine models as compared with cadaveric models. Future testing should also include measurements of material properties, including the modulus of elasticity of synthetic bony and ligamentous structures, for comparison against human tissue.

Conclusions

The BBS project is an ongoing effort to produce a synthetic spine model with high biomechanical fidelity to human tissue. Previous studies have demonstrated this model's ability to reliably mimic the synthetic bone of a cadaveric specimen on biomechanical measures of pedicle screw performance as well as ROM testing after posterior column osteotomies.[2-4] This study has demonstrated that these models can be produced to reliably mimic specific ranges of motion on standard ROM testing protocols as applied to cadavers. This finding is critical to the eventual development of a robust synthetic spine model because it demonstrates that a customizable, 3D-printed synthetic spine model can be produced with high biomechanical fidelity to cadaveric specimens. The validation of such a tool has the potential to transform the field of spine surgery.

Acknowledgments

The authors thank the staff of Neuroscience Publications at Barrow Neurological Institute for assistance with manuscript preparation.

Declaration of Conflicting Interests

Author MAB is the inventor on a patent filing describing the technology evaluated in this study. This patent filing was licensed to a new company during the late stages of the peer-review process. Authors MAB, SM, and UKK have financial interests in the new company that licensed the patent.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Barrow Neurological Foundation.

ORCID iD

Sarah McBryan, MS https://orcid.org/0000-0001-5918-1895
U. Kumar Kakarla, MD https://orcid.org/0000-0002-2051-5074

References

1. Bohl MA, Mooney MA, Sheehy JP, et al. The Barrow Innovation Center: a novel program in neurosurgery resident education and medical device innovation. *Cureus*. 2018;10:e2142.
2. Bohl MA, Mooney MA, Repp GJ, et al. The Barrow Biomimetic Spine: fluoroscopic analysis of a synthetic spine model made of variable 3D-printed materials and print parameters. *Spine (Phila Pa 1976)*. 2018;43:E1368-E1375.
3. Bohl MA, Mooney MA, Repp GJ, et al. The Barrow Biomimetic Spine: comparative testing of a 3D-printed L4-L5 Schwab grade 2 osteotomy model to a cadaveric model. *Cureus*. 2018;10:e2491.
4. Bohl MA, Morgan CD, Mooney MA, et al. Biomechanical testing of a 3D-printed L5 vertebral body model. *Cureus*. 2019;11:e3893.
5. Newcomb A.Variations among human spine segments and their relationships to in vitro kinematics: a retrospective analysis of 281 motion segments from 85 cadaveric spines [abstract 571]. Paper presented at: the International Society for the Advancement of Spine Surgery; April 13, 2017; Boca Raton, FL.
6. Crawford NR, Brantley AG, Dickman CA, Koeneman EJ. An apparatus for applying pure nonconstraining moments to spine segments in vitro. *Spine (Phila Pa 1976)*. 1995;20:2097-2100.
7. Gonzalez-Blohm SA, Doulgeris JJ, Lee WE 3rd, Shea TM, Aghayev K, Vrionis FD. The current testing protocols for biomechanical evaluation of lumbar spinal implants in laboratory setting: a review of the literature. *Biomed Res Int*. 2015;2015:506181.