Scoliosis Simulator

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Introduction

Background

- Scoliosis - spinal deformity with coronal plane curvature greater than 10°[2,12] (Figure 1)
- Degenerative scoliosis is painful and often requires surgery [1]
- 38,000 surgeries/year in the US[1]

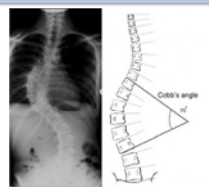

Figure 1: Example of Scoliotic Spine [12]

Problem

- No devices exist to realistically model deformed spine for surgical preparation

Needs Statement

- "A cost-effective, reusable, and portable way to give engineers and healthcare providers the ability to model varying Cobb angles in preparation for spinal surgery."

Testing Results

Ligament testing

- Native ligaments - 1.5MPa[6]
- Tensile testing performed on elastic bands; example trial in Figure 2 and results in Table 1

Disc testing

- Native discs - 5.8 -42.7MPa[5]
- Compression testing performed on rubber sheets; results in Table 1

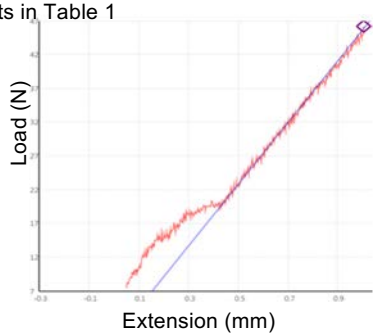

Figure 2: Load vs. extension curve in tensile testing

Elastic Moduli (MPa)	Average	SD
Yellow (Light)	0.675	0.109
Red (Medium)	1.246	0.180
Blue (Strong)	1.444	0.096
Compressive Moduli (MPa)	**Average**	**SD**
30 Duro	99.107	3.509
40 Duro	52.917	6.052

Table 1: Summary of disc and ligament testing with selected materials highlighted

Proposed Solution:
Mechanical & Anatomical Synthetic Scoliosis Simulator

Final model includes following elements

- User-friendly frame design (Figure 3)
- ABS 3D printed vertebrae w/ infill modeling cortical and cancellous bone (Figure 4)
- Snap-fit vertebrae (Figure 5)
- Torsional springs to model discs (Figure 6)
- Elastic bands as ligaments (Figure 7)

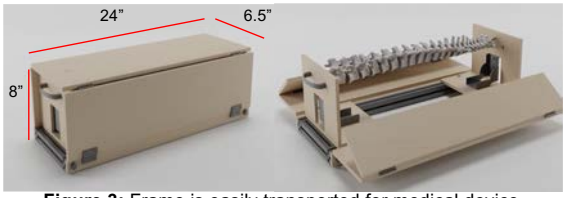

Figure 3: Frame is easily transported for medical device reviews; sliding frame is length adjustable to model different length and curvature of spines

Figure 4: Hard outer shell and less dense infill (See cross hatch pattern) mimic different bone types

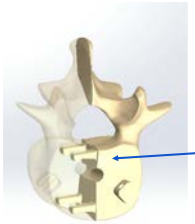

Figure 5: Snap fits allow easy individual replacement and adjustment

Figure 6: Ligaments add rigidity to spine

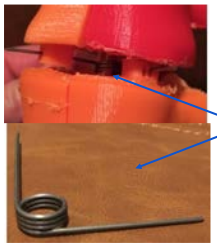

Figure 7: Torsional springs interconnect vertebrae and give appropriate relative rotation

Market Analysis and Patent Search

Market Analysis

- Medical simulation ~ $2.58 Billion industry in 2022[15]
- Table 2 and Figure 8 show market landscape for reusable spinal model

Sawbone Models (one-time use)	$500+[10]
Cadavers (one-time use)	$3000-$5000[11]
Proposed Solution (reusable)	$275

Table 2: Cost of existing & proposed models

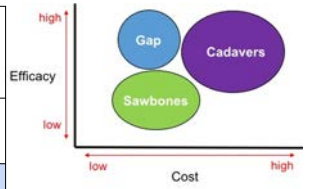

Figure 8: Efficacy vs. Cost of Existing Models

Results of Patent Search

- Patent search yielded two spinal models (Figure 9), 3D printing infill method, disc prosthesis with springs, & artificial ligaments[13,14]
- Risk of infringement is low

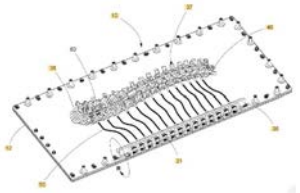

Figure 9: Growing spine model[14]

Future Work

- Quantitative testing on drillability of 3D printed vertebrae
- Verification of robustness of snap fit
- Quantitative testing on mechanical properties of the model to match forces used in correction surgeries

Acknowledgements

The Scoliosis Simulator Team would like to thank Dr. Zapanta and Erica Comber for their support over the course of the semester. Additionally, we want to thank Medtronic for their financial support and Medtronic engineers, Mark Grizzard and Jerald Redmond, for their mentorship. Finally, we would like to acknowledge the other Medtronic engineers and the the surgeons from AGH, particularly Dr. Boyle Cheng, for their support and guidance.

References

1. "Spinal Deformities: Scoliosis, Kyphosis, Lordosis: Spinehealthlife." *Spine*, 1 June 2018, www.spinehealthlife.com/symptoms/spinal-deformity/
2. "Scoliosis." *AANS*, www.aans.org/patients/neurosurgical-conditions-and-treatments/scoliosis.
3. Craig, C., Karabin, M. (2019, November 8). Phone interview with Dr. Vijay Yanamadala: Neurosurgeon and Spinal Deformities Specialist, Albert Einstein College of Medicine
4. Craig, C., Karabin, M., Solomon, T. (2019, November 6). Interview with Dr. Alexander Yu: Neurosurgeon, Allegheny General Hospital
5. J Biomech. 2016 May 3; 49(7): 1134–1140. doi:10.1016/j.jbiomech.2016.02.045.
6. Kirby, M., Sikoryn, T., Hukins, D., & Aspden, R. (1989). Structure and mechanical properties of the longitudinal ligaments and ligamentum flavum of the spine. *Journal of Biomedical Engineering*, *11*(3), 192–196. doi: 10.1016/0141-5425(89)90139-8
7. "CFR - Code of Federal Regulations Title 21." *Accessdata.fda.gov*, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=888.3070.
8. Correa, A. I., & Watkins-Castillo, S. I. (n.d.). Prevalence of Adult Scoliosis. Retrieved November 17, 2019, from https://www.boneandjointburden.org/2014-report/iii21/prevalence-adult-scoliosis.
9. Scoliosis Statistics. (n.d.). Retrieved from https://clear-institute.org/learning-about-scoliosis/scoliosis-statistics/.
10. "Spine." *Orthopaedic Models - Catalog*, www.sawbones.com/catalog/orthopaedic-models/spine.html?character11=68&p=2.
11. Reports, Special. "In the U.S. Market for Human Bodies, Anyone Can Sell the Donated Dead." *Reuters*, Thomson Reuters, 24 Oct. 2017, www.reuters.com/investigates/special-report/usa-bodies-brokers/.
12. Horne, John P., et al. "Adolescent Idiopathic Scoliosis: Diagnosis and Management." *American Family Physician*, 1 Feb. 2014, www.aafp.org/afp/2014/0201/p193.html.
13. Murdach, Charles. *Human Spine Model*. 25 Dec. 2008.
14. McClintock, Larry, et al. *Growing Spine Model*. 18 June 2015.
15. "Healthcare / Medical Simulation Market." *Market Research Firm*, www.marketsandmarkets.com/Market-Reports/healthcare-medical-simulation-market-1156.html.