Medtronic Scoliosis Simulator

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Clinical Need

Adolescent Idiopathic Scoliosis (AIS)

- Most common form of adolescent scoliosis[1]
- Affects children age 10-18 worldwide (4%)
- Cobb angles greater than 45° require surgery [2]

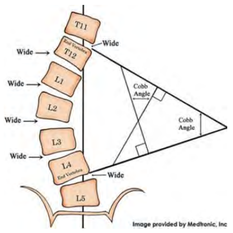

*Figure 1.*Cobb angle definition [3]

Risk of Scoliosis Progression			
Cobb Angle	Age 10-12	Age 13-15	Age over 16
<20°	25%	10%	0%
20°-30°	60%	40%	10%
30°-60°	90%	70%	30%
>60°	100%	90%	70%

*Figure 2.*AIS risk of progression data[10]

Available Treatment Plans

- Observation
- Bracing
- Spinal Fusion Surgery

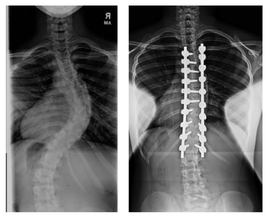

Figure 3. Realignment of a scoliotic spine through spinal fusion surgery [11]

Needs Statement

A mechanically and anatomically **accurate physical tool** that models **Adolescent Idiopathic Scoliosis** for Medtronic R&D engineers to **evaluate surgical instrumentation**

Market Analysis

- Spinal devices: 3rd most expensive medical field in U.S.
- U.S. spine device market is $9B (2019) and increases annually[4]

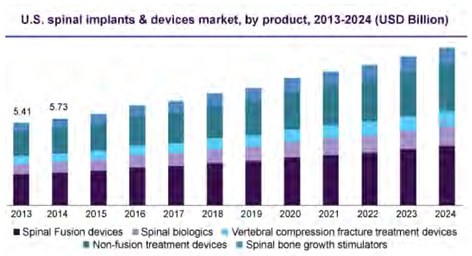

*Figure 4.*Market of spine devices[5]

Market Subgroups

- Medtronic Spine Engineers and Sales Representatives
  - R&D engineers: test and improve current AIS surgery tools with model
  - Sales representatives: use model to demonstrate how to use Medtronic's surgical tools
- Spinal Fusion Surgery Patients aged 10 to 18
  - Potential to impact 1.68 million adolescents [7] through improved surgical outcomes
- All Patients with AIS
  - Families and primary caregivers

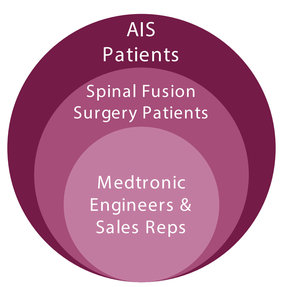

*Figure 5.*Market for Scoliosis Simulator

Our Solution

The design for our model includes the **thoracic and lumbar ranges** of a scoliotic spine. The Scoliosis Simulator has four main components:

Gooseneck Tubing

- Provides **internal resistance** similar to that of a spine
- Made of a metal gooseneck tubing used in adjustable lamps
- Silicone mat wrapped around gooseneck adds grip for vertebrae

3D-Printed Vertebrae

- Printed in two pieces using **ABS Plastic**
- Two pieces connected through dovetail rails for **reusable snap -fit**
- Accounts for **varying severity and types of AIS**
  - Multiple CAD models of scoliosis at Cobb Angles starting from 40° and increasing in increments of 15°

*Figure 6.*Vertebra with Dovetail Connection

Intervertebral Discs

- **Provide cushion** between the vertebrae
- Made of soft foam used in foam floor mats

Fluid Frame

- Two metal sheets held together by steel drawer slides
- Sliding mechanism **fits to desired curvature**
- Eye hooks secure elastics to frame
  - Elastics provide **tension similar to muscular forces**

Final Prototype

- Meets needs as mechanically and anatomically **accurate tool** for Medtronic engineers to use
- Compatible with Medtronic surgical instrumentation
- Can be reused for multiple tests

*Figure 7.*Final Prototype

Manufacturing

- Device will not be mass -produced as it will only be used internally at Medtronic
- Needs to rely on readily available components that are simple to make or purchase

Vertebrae

- 3D printed from ABS plastic
  - Fast, repeatable, and reliable manufacturing
- Selected after testing 3D-printed, custom molded, and store-bought models
- Can print sets of vertebrae with different curves and configurations

*Figure 8.*3D printed vertebra

Frame

- Needs to be inexpensive, easily manufactured, and easily replaceable
- Must withstand high forces of surgical spine correction
- Simple solution composed of sheet metal, steel drawer slides, and eye bolts
- Frame is simple to assemble on-site for Medtronic
- Easy to reconfigure and adjust

*Figure 9.*Fluid frame design

Testing and Validation

Instron Mechanical Testing

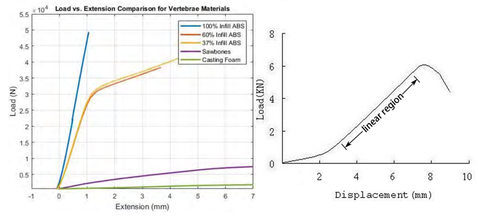

*Figure 10:*Load vs. Displacement Curves for Proposed Materials Compared to a Lumbar Vertebrae[8]

Compression tests for 3 vertebrae materials indicate 37% infill ABS best mimics properties of cadaver bone, given our manufacturing capabilities.

3-point bending test data for the gooseneck tubing was compared to the forces required to surgically realign a scoliotic spine (160.0 ± 81.1N on the concave side) [9]

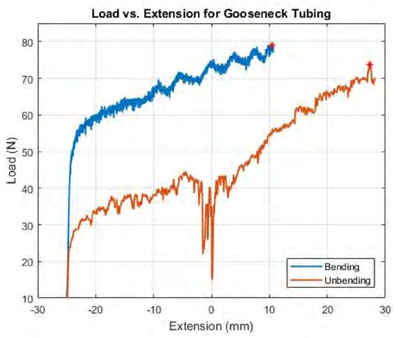

*Figure 11:*Load vs. Displacement Curves for Gooseneck Tube in 3-Point Bending

Future Validation

We have scheduled time for surgeons from AGH to give feedback on the looks-like and feels-like accuracy of our prototype in comparison to actual scoliosis surgeries that they have performed. We will use this data to determine use of elastics in our final prototype.

Future Work

The simulator could benefit from the following:

- Broader materials testing with more materials and better characterization
- Qualitative analysis regarding use of the device by Medtronic engineers

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