Clinical Need

Adolescent Idiopathic Scoliosis (AIS)
- Most common form of adolescent scoliosis
- Affects children age 10-18 worldwide (4%)
- Cobb angles greater than 45° require surgery

Available Treatment Plans
- Observation
- Bracing
- Spinal Fusion Surgery

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 metal gooseneck tubing used in adjustable lamps
- Silicone mat wrapped around gooseneck adds grip for vertebrae

3D-PrintedVertebrae
- 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°

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

Testing and Validation

Intron Mechanical Testing
- Compression tests for 3 vertebrae materials indicate 37% in fall ABS best mimics properties of cadaver bone, given our manufacturing capabilities

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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Factors

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

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 through improved surgical outcomes
- All Patients with AIS
- Families and primary caregivers

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

References