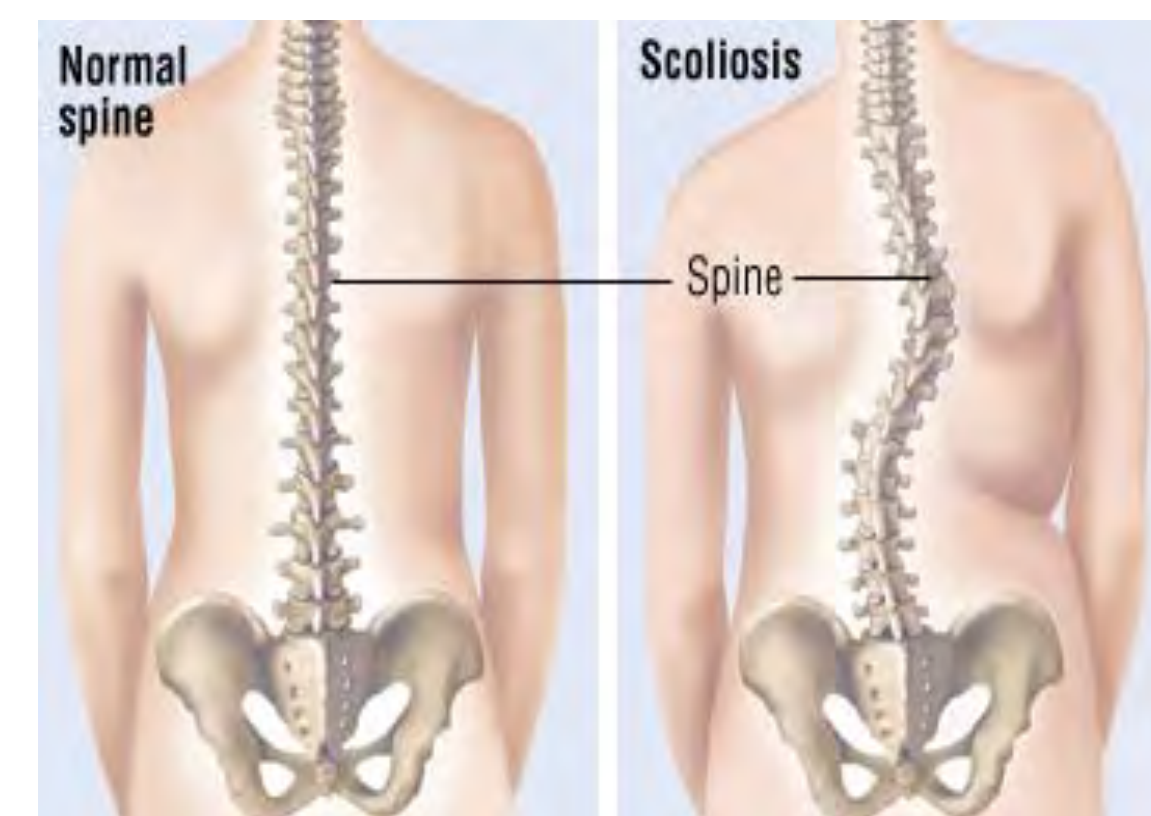


Problem

Background

- Scoliosis is a spinal deformity characterized by a 3D curvature of the coronal plane
- Affecting ~9 million people in the US¹
- ~400,000 doctors visits annually
 - ~29,000 of them require surgical intervention²



Normal Spine to Scoliotic Spine Comparison²

Current Spine Models

- Sawbone models
 - Anatomically realistic, but fail to represent the biomechanical properties of the spine
- Cadavers
 - Expensive, most do not have scoliosis, and mechanical properties of the body alter after death³

Problem

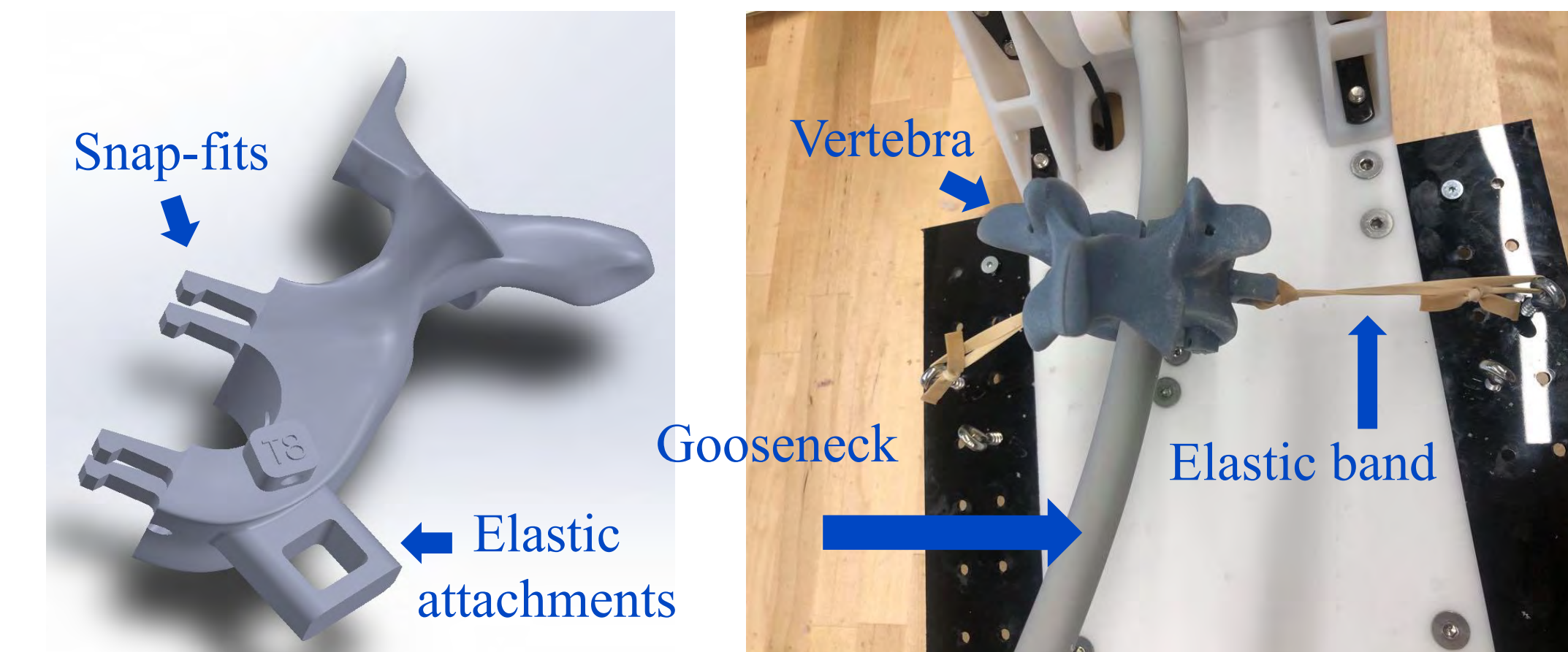
- Currently, there are no existing models that accurately replicate the anatomy and biomechanical properties of a spine during scoliosis surgery for adolescent patients.

Proposed Solution

A portable, reusable, cost-effective spinal model that accurately replicates the anatomy and biomechanics of the scoliotic adolescent spine

Anatomy

- 3D printed spinal vertebrae with snap fit features for easy assembly replacement
- Hook for attaching elastic bands
- Elastic bands connecting frame to vertebrae to simulate ligaments/tendons



Spinal vertebrae with snap fit and elastic attachments

Spinal vertebrae attached to peg board and gooseneck

Frame

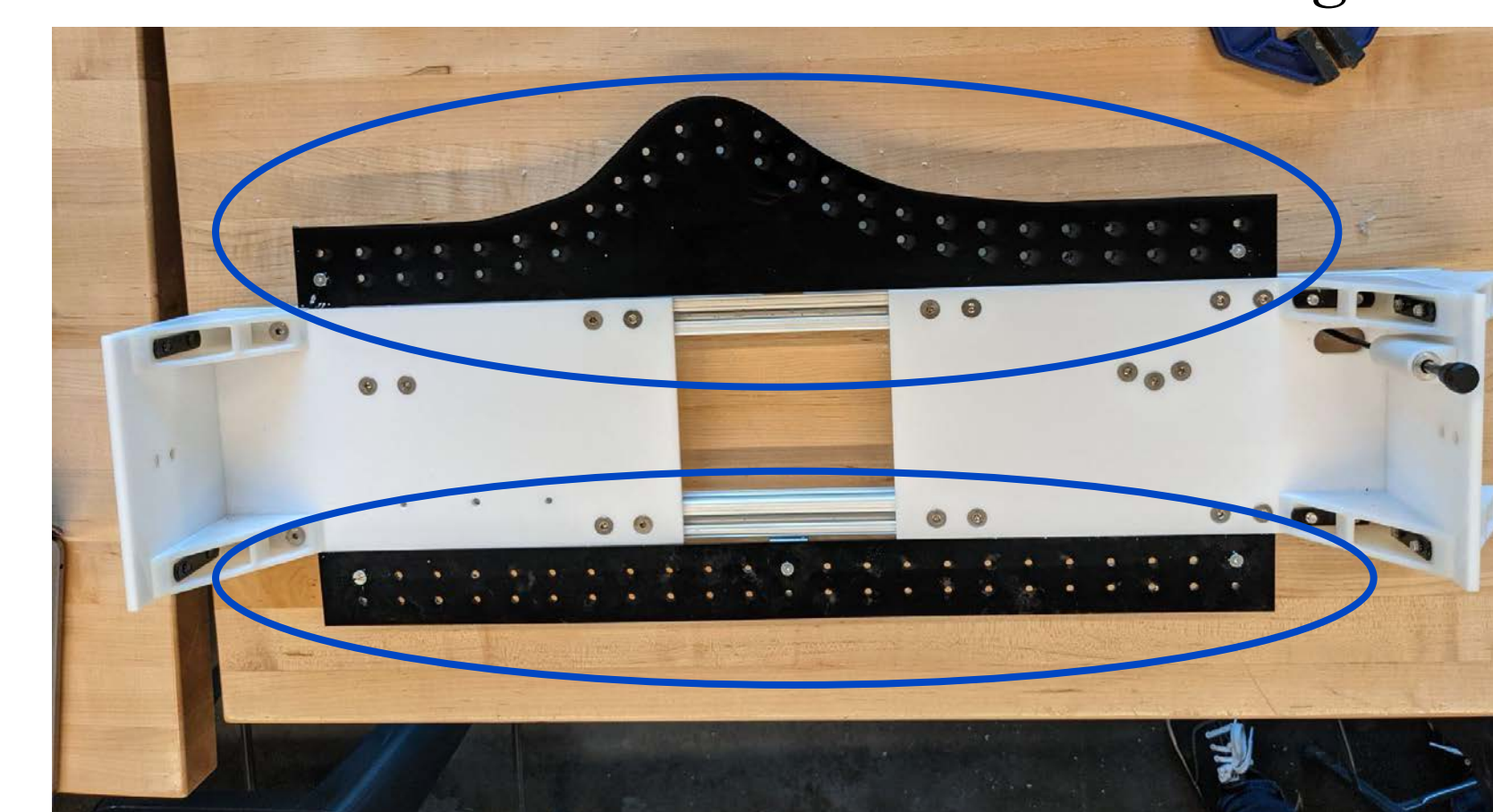
- Rail frame with acrylic plates to account for varying patient anatomy
- Spring loaded walls to allow for length variation during procedures

Mold

- Foam mold to set spinal curvature and provide support



Foam mold of Lenke 1A curve



Frame with peg boards attached

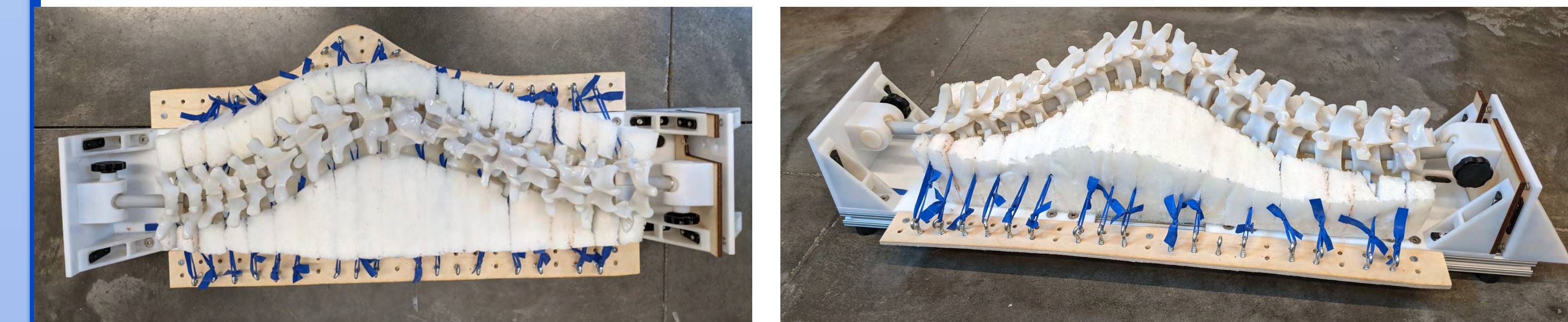
Final Prototype

Material Modifications

- Thicker gooseneck tubing with frictional rubber coating
- 25lb latex resistance bands
- 5lb density flexible polyurethane foam mold with defined Lenke 1A curvature
 - Represents soft tissue, muscle, and rib tension

Mechanical Modifications

- Vertebrae with predrilled holes, elastic attachment features, and snap-fit geometry
- Spring loaded walls to allow for 1/4" length variation during procedure
- Adjustable and lockable frame
- Wooden 1/4" peg boards for attaching elastic bands with eye hooks

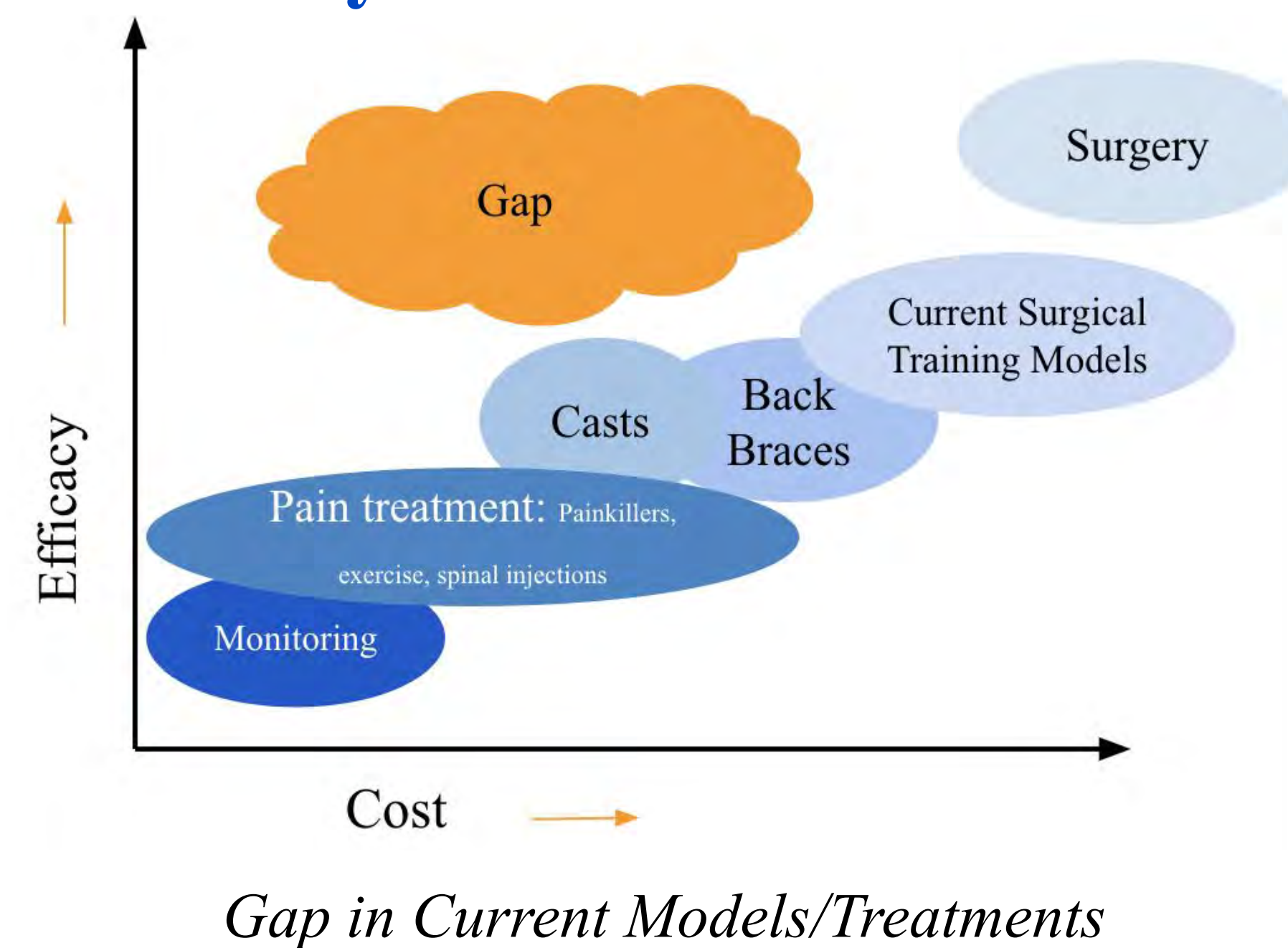


Final prototype with material and mechanical improvements

Market Analysis and Patents

Market Analysis

- Figure (right) identifies gap in current treatments/models
- Patients w/ adolescent scoliosis account for around 29,000 surgeries per year⁵
- Global medical simulation market size is projected to reach \$3.7 billion by 2025⁶
- This solution would be ~\$400, while current models are between \$500-5000



Patent Search

- Two possible conflicting patents were identified
 - Human spine model (US7942676B2), Growing spine model (US20150170548A1)
 - Risk of infringement is low since our model adds additional features⁷
 - E.g. biomechanical accuracy, elastic material to simulate ligaments, etc.

Testing

Elastic Tensile Testing

- Stiffness of spinal ligaments is roughly 1.5 MPa⁴
- Applied the best material from results of last years' tensile tests
- Chosen elastomer accurately represents the variable resistance behavior of spinal ligaments

Elastic Moduli	Run 1	Run 2	Run 3	Average	SD	
Yellow (Light)	0.600	0.800	0.625	0.675	0.109	Literature Values
Red (Medium)	1.059	1.263	1.417	1.246	0.180	1.5MPa
Blue (Strong)	1.333	1.500	1.500	1.444	0.096	

Elastic Moduli Results from Tensile Testing

Polyurethane Foam Compression Testing

- Tested compressive properties of 4 different density PU foams
- Estimates from surgeon interviews were used as a comparison

Surgeon Feedback

- Virtual demonstration of prototype with surgeons resulted in positive feedback regarding Elasticity of vertebral column, stiffness of spine, and compressibility of 'soft tissue' when compared to typical adolescent spine
- Results help quantify feels right criteria

Conclusions

Ongoing/Future Work

- Determining best elastic material attachment points on model
- Creating foam mold and molding the foam to sit underneath the vertebrae
- Retrofitting better snap-fit attachment for a more secure connection around tubing
- Hands-on testing and feedback with Medtronic consulting surgeons
- Analyze ways to accurately model the effects of intervertebral disks

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