Inflatable Vertebral Body Distractor

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Overview

- Introduction
- Project Summary
- Final Design
- Testing Protocols
- Future Work

Problem Statement

The goal of this project is to develop a minimally invasive inflatable vertebral body distractor for the lumbar region of the spine that can be easily manipulated and will not cause spinal fractures.

Background - The Spine

Anatomy

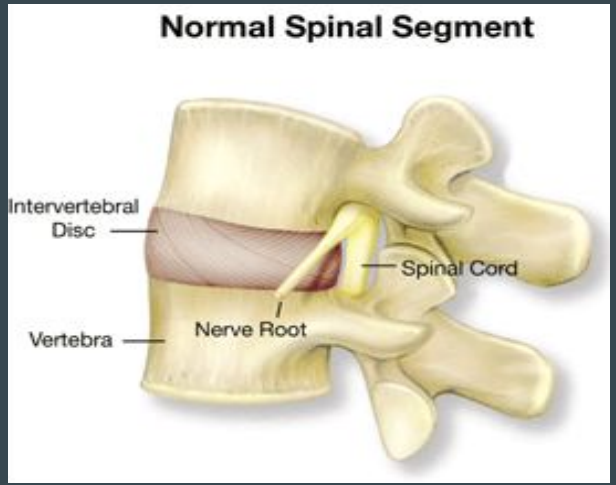
- Vertebral Body
- Intervertebral Disc
- Spinal Nerve
- Spinal Cord

Function

- Structural Support
- Protect Spinal Cord

Disc Degeneration

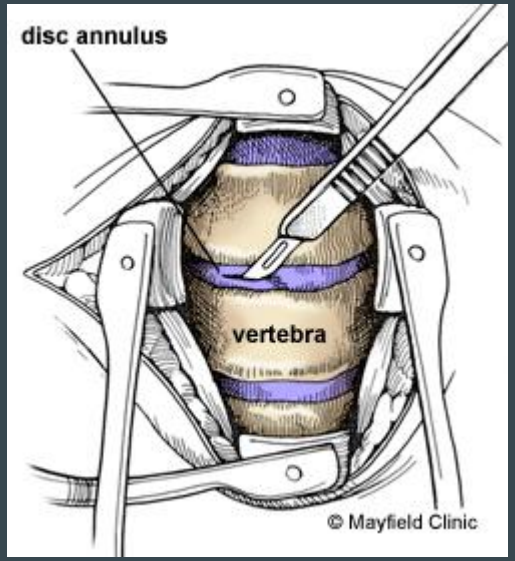
- Fluid content within disc decreases over time
- result in wear and tear
- causes tiny tears or cracks

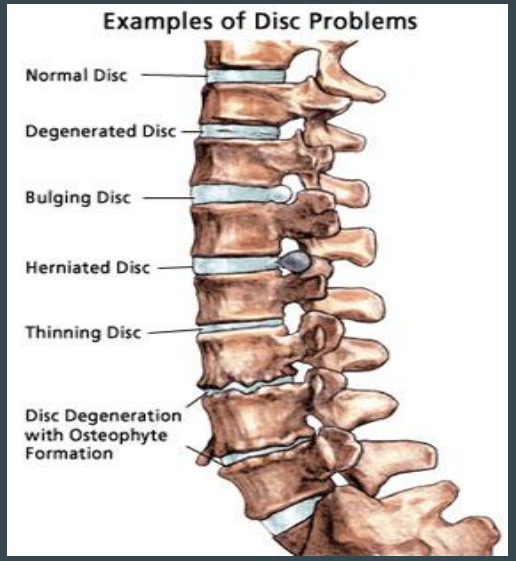


Background - Surgery

Surgical Procedure:

- Insertion of operating needle
- Insertion of distractor
- Disc space is distracted
- Desired procedure
- Deflation and removal of distractor



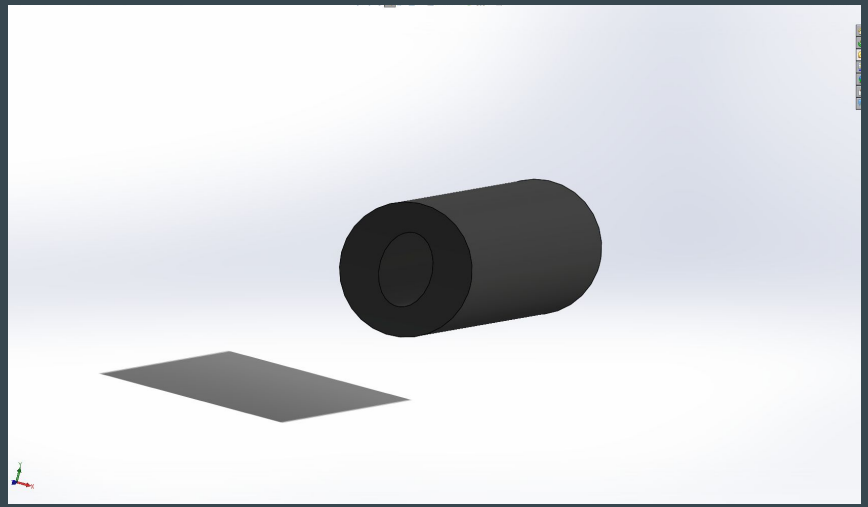


Project Summary

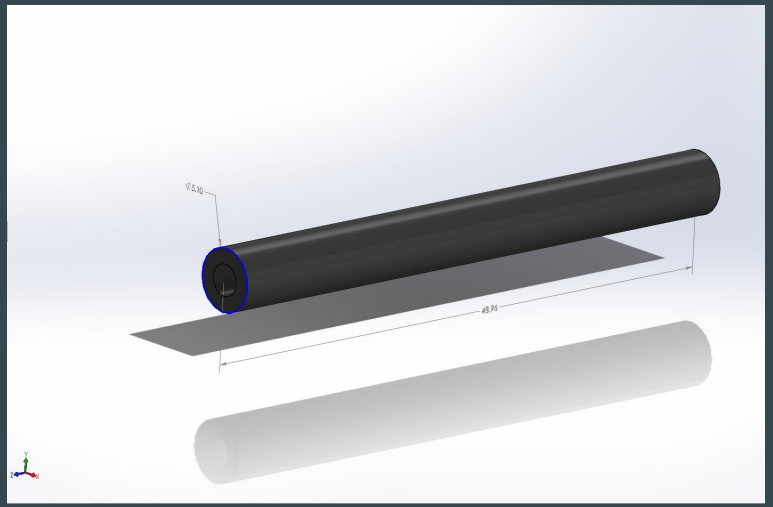
- Last semester developed enlarged prototype for proof of concept
- Concept showed success
- Client has now given insertion size constraints
  - Required a major decrease in size for the inserting process
- Developed testing methods
  - Insertion
  - MTS machine

Final Design: Inflatable Vertebral Distractor

- 49 mm long, 5.1 mm diameter
- Split into two parts: sheath and load bearing
- Three device system, composed of silicone based elastomer



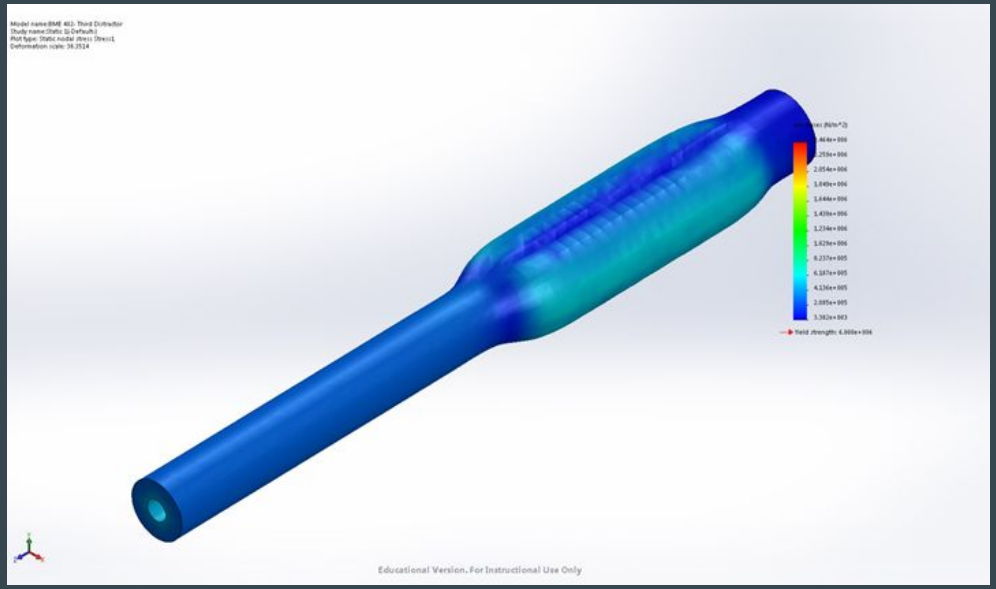
Sectioned view of inflatable distractor



Full view of inflatable distractor

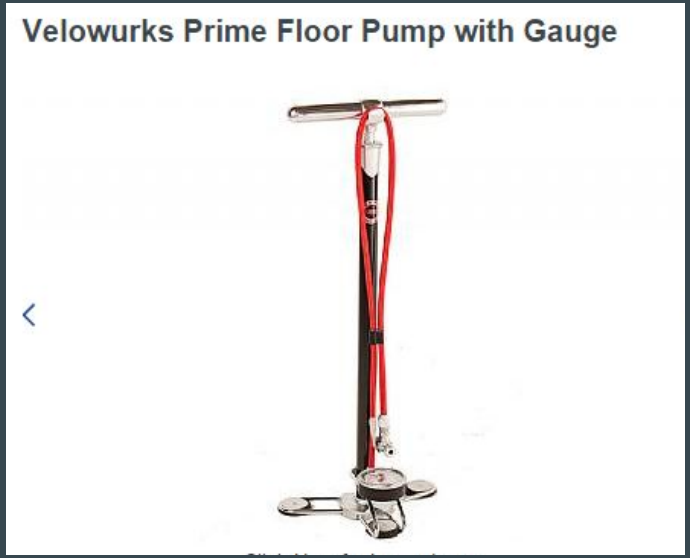
SolidWorks: FEA

- Applied Loads:
  - Internal pressure of 120 psi
  - Applied force of 143N
- Factor of Safety = 2.5
- Maximum Displacement of 0.13 mm
- Von Mises Stress Graph
  - Max stress of 363 psi



Final Design Continued

- Using Velowurks Floor Pump with gauge to pressurize distractor
  - Pumps up to 250 psi
  - Includes quick release valve



Testing Protocol-MTS Machine

- MTS testing to determine maximum compression load and sustainable pressure
- Loading the device in the MTS machine, a compressive load will be slowly applied as pressure is increased
- Once maximum load is determined, device will be left inflated with load to determine length of operation

Distractor Insertion Testing

- Model lumbar vertebrae with acrylic plates
- 2 acrylic plates- 10mm thick, 16mm outer diameter, 11mm inner diameter
- Model intervertebral disk with polyurethane rubber
- 1 polyurethane rubber disk- 5mm thick, 15mm diameter
- Glue acrylic plates to rubber disk
- A jamshidi needle and cannula with 5mm inner diameter will be used for insertion

Acrylic Plate Distraction Testing

- Once load and pressure testing is complete, test distraction capability
- Add constraints (i.e. rubber bands) to acrylic plates to create a vertebrae simulator
- Testing will be done to determine the strength and number of constraints needed to simulate force of vertebrae
- Once the simulator is developed, the device will be placed in between plates and inflated to test the distraction capability

Cadaver Testing

- Once the device has passed the MTS testing and the Acrylic Plate testing, it can be tested in a cadaver
- Using a human or an animal with similar spinal column forces
- Device can be inserted and inflated and tested in real environment
- This will give best indication of conflicts that are hard to visualize now

Future Work

- Complete testing protocols
- Create acrylic plate vertebrae simulator for testing
- Locate best angle and location for device implantation
- Determine best method of device removal

Acknowledgements

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Questions?