Inflatable Vertebrae Body Distractor

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Abstract

- In the US, over 500,000 spinal surgeries per year
- Spinal surgery devices make up a $12 billion market
- Need a device to safely and effectively distract the spine in the lumbar region
- Current devices are too invasive, can damage the vertebrae during distraction
- Goal is to make a new distractor that is minimally invasive, unobtrusive, and does not damage the vertebrae or other softer tissue
- Compression and tensile testing were used to measure displacement and applicable force
- A working prototype was fabricated, but further testing is needed to verify the effectiveness

Background

- Discs resist spinal compression and help spread the load of vertebral bodies, are prone to degeneration, herniation, and other problems
- 60-80% of people's discs will degenerate and cause pain
- Surgical process consists of either removing or replacing discs
- Distractor separates the vertebrae to allow disc removal
- Once the operation is finished, the distractor can be remove

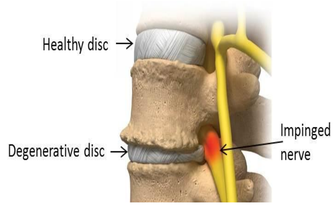


Figure 1: Vertebral column

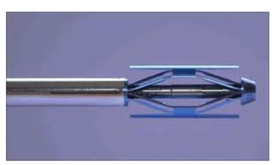


Figure 2: Scissor Jack Distractor

Design Requirements

- Design and fabricate a user-friendly, biocompatible, surgical tool to be used during spinal distraction surgery
- The device should be able to distract the vertebrae 4-6 mm, applying a total force of 430 N force to successfully distract two vertebrae
- Required pressure for distraction is calculated to be 827 kPa (120 psi)
- Insertion method must be minimally invasive
- Must fit in half of the vertebrae with dimension of 24 x32 mm
- Pressure feedback system

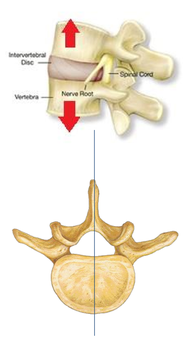
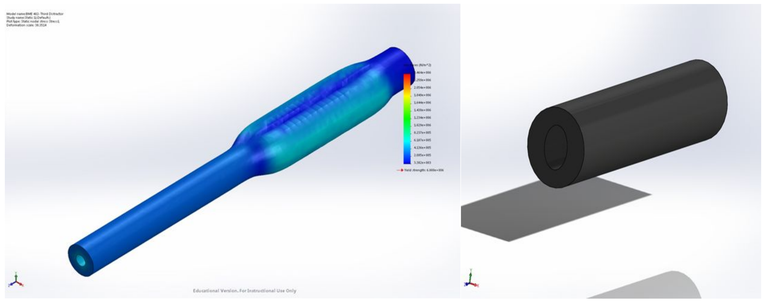


Figure 3: (Top) Axis of distraction and (bottom) cross sectional view of lumbar vertebra

Final Design



- Final design is 48.5mm long and is composed of a two part system.
- 3 device system
- SolidWorks analysis of Von Mise stresses showed factor of safety of 2.4.
- Max lateral displacement of 0.13mm.
- Prototype composed of Silastic(R) MDX4-4210 Biomedical Grade Elastomer Base because it's easy to hand mold

Testing

Force Generation

- The device was loaded into a MTS machine and inflated while measuring the applied force
- Both pressure and force were monitored throughout the testing

Distraction

- To measure if the device could distract far enough we inflated 5 samples and measured the distraction distance
- Samples were inflated until rupture or failure to return to size

Insertion

- We created a jamshidi cannula and inserted our device in between two acrylic plates representing two vertebrae

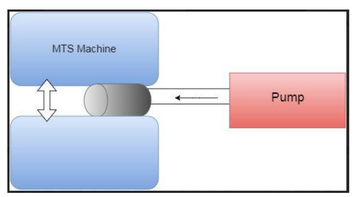
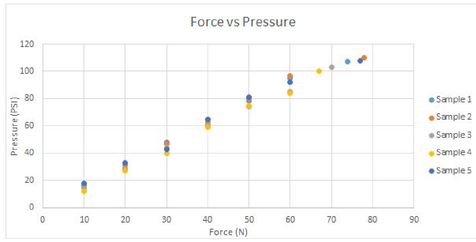


Figure 7: Schematic of MTS Testing

References

- 1. Best, M., Buller, L., & Eismont, F. (2015). National Trends in Ambulatory Surgery for Intervertebral Disc Disorders and Spinal Stenosis. *Spine, 40*, 1703-1711.
- Wood, Megan. *55 Statistics and Issues For Neurosurgeons and Orthopedic Spine Surgeons - Compensation, Global Device Market and More.* Becker Spine Review, 03 Aug. 2015. Web. 28 Apr. 2016.
- 2. "Anatomy and Back Pain." What Is Intervertebral Disc Degeneration, and What Causes It... : Spine. Zimmer, 3 June 2013. Web.

Results



Sample	Force Generated (N)
1	107.9
2	110.3
3	103.6
4	100.4
5	108.6
6	102.7

Sample	Distraction Distance (mm)
1	10
2	9
3	11
4	12
5	8

- The average force generated was 105.6±3.9 N with N= 6
- The max pressure was before failure was 74±5 psi with N=6
- The average distraction distance was 10±1.58 mm before damage was done
- The device was successfully able to be inserted into the restricted area after a few attempts. It is a task a surgeon could perfect with practice

Discussion

- With the size constraints of the insertion process, the design was developed for three devices to be used simultaneously
- Failed to reach the required force to properly distract the vertebrae
- Developed a design that is minimally invasive and safely distracts of vertebrae
- Small budget and limited resources
- With a proper budget, a better medical grade silicon could be used and the molds could be improved with a more sophisticated method such as injection molding
- Moving forward, a medical grade silicon inflation device can be designed to provide sufficient force for spinal distraction

Future Work

- Current testing indicates our device underperforms
- Obtain the resources for injection molding and curing methods
- Improve sealant/connection between pump and device
- Acrylic plate distraction testing
- Complete cadaver testing
- Clinical testing

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