Inflatable Vertebral Body Distractor

Final Manuscript

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Team:

Ellis Cohen - Team Leader

Joshua Plantz - Communicator

Herman Feller IV - BSAC

Joaquin Herrera - BPAG/BWIG

Client:

Dr. Nathaniel Brooks: UW Hospital

Advisor:

Professor Mitch Tyler

Table of Contents

Abstract

BACKGROUND: For the treatment of intervertebral disorders, a device is needed to safely distract two adjacent vertebra throughout the surgical process.
OBJECTIVE: To fabricate and test a distraction device that is minimally invasive, unobtrusive to the surgeon, and does not damage the surrounding vertebral bones or soft tissue.
METHODS: First, we identified variables to create a prototype for a proof of concept. Second, we evaluated our prototypes ability to apply a force in a uniaxial direction under an MTS machine. Third, we measured its ability to inflate to a distraction height that is suitable for exposing the intervertebral disc space. Lastly, we tested our insertion method in order to prove our minimally invasive concept using acrylic plates to simulate vertebral bodies.
RESULTS: Our device was capable of inflating to apply an average of 105.6±3.9 N (N=6) of force in the vertical direction without displacing horizontally. The maximum pressure before failure was 74±5 psi (N=6). Average displacement distance was 10±1.58 mm in the vertical direction. The device was successfully able to be inserted down a 5mm diameter cannula into the restricted area after a few attempts, and is a task a surgeon could perfect with practice.
CONCLUSION: Utilizing the necessary resources to fabricate a medical grade silicone into an inflatable vertebrae body distractor will allow our prototype to be successful within our design specifications.

Background

Current Methods

In 2006, The National Survey of Ambulatory Surgery recorded 102,173 surgical procedures performed for the treatment of intervertebral disorders [1]. Since then, this number has increased to over 500,000 surgeries annually. There is a need for a device to safely and effectively distract the human spine in the lumbar region during spinal surgery to enable the surgeon to complete the desired procedure with adequate room.

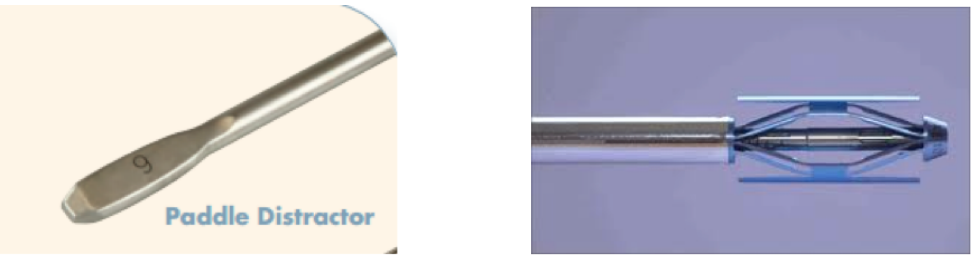


Figure 1: Current Designs – Paddle Distractor and Scissor Jack Distractor

Current devices are large, requiring a large incision which creates a greater possibility of future pain, longer recovery time, and scarring for the patient. These devices are also commonly composed of metal or other rigid materials which introduces the risk of fracturing the vertebrae during the distraction process, requiring additional surgery for the patient.

Spinal Column

A typical spinal segment consists of two vertebral bodies with an intervertebral disc in between them. At the ventral side of the vertebrae is the spinal cord and nerve roots that split off to the rest of the body. These discs resist spinal compression and help spread the load of vertebral bodies. Overtime, discs are prone to degeneration, herniation, and other problems. [2]

When these problems occur, there are many treatment methods depending on the severity of degeneration. Typically the first step on the road to recovery is exercise and physical therapy. A variety of medications including anti-inflammatories and epidural steroid injection may relieve pain as well. Additionally, some may proceed to seek out chiropractic manipulation which may increase range of motion and blood flow. Patients who are unable to function due to the severity of the pain, or are unhappy with their quality of life, may resort to surgery [3]. The surgical process includes removing or replacing the degenerated disk. The device will be implemented in order to spread the disc area to create surgical work space. It will be inserted through Jamshidi needle and then inflated. Once, the distractor is inflated the surgeon can perform the desired operation, such as the implantation of a fusion cage. Once the operation is finished, the distractor can be removed.

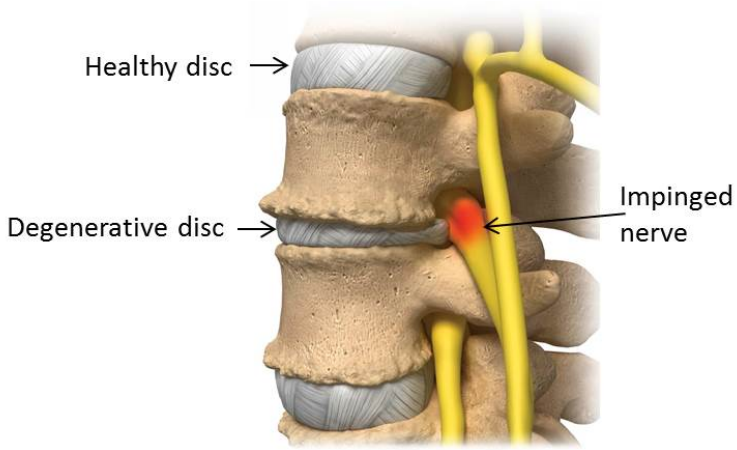


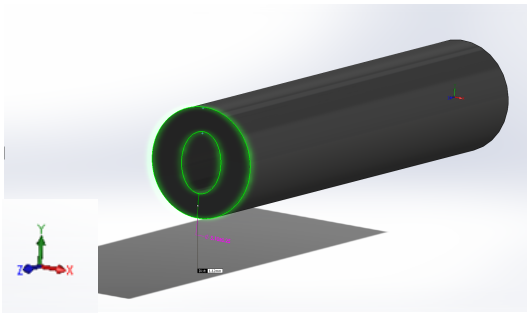
Figure 2: A vertebral Column comparing a healthy intervertebral disc compared to one that has degenerated over time.

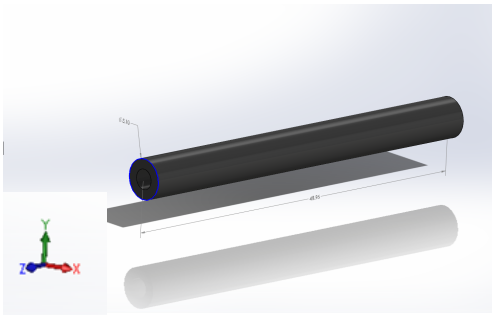
Final Design

Final Prototype

The final design was created using SolidWorks and consists of a cylinder with an open face that is used during inflation, seen in figure 3 below. The inflatable cylinder has an outer diameter of

5mm, and a total length of 49mm. During surgery the patient will be laying prone. The device will be inserted using a Jamshidi cannula into the spinal column along the x-axis shown in figure 2 below, closed face first, with the y-faces directed superiorly and inferiorly. The device is then inflated and will distract along the y-axis. This device is a two part system with a sheath and load bearing aspects. The sheath was incorporated to make sure there was no pressure leakage when the device is inflated. The load bearing portion is shaped like an ellipse so that when we do inflate the device the distractor will displace along the y-axis and not the x-axis, shown below in figure 2. The reason the load bearing part is an ellipse is because it will displace more along the y-axis than compared to the horizontal axis because the ellipse prevents horizontal bulging.





Figures 3 and 4: SolidWorks CAD of the load bearing aspect of the inflatable distractor (left), and the whole device (right) scale is in mm.

Testing Protocols

The device was tested for three areas of concern: how much force could be applied, how far can it expand, and can it be inserted through a Jamshidi cannula.

FEA Testing

After creating a CAD of the device with an ellipse as the load bearing shape, it was subjected to a static SolidWorks Simulation to determine the displacement and stresses of the load bearing part of our design. Since the sheath protrudes from the vertebral space and does not undergo stress a cross section of our device through the load bearing portion was analyzed and the sheath was excluded. Shown in figure 4 is the Von Mises Stress of our prototype when loads are applied. The simulation used the applied forces which are as followed; a total of 143 N was applied to the y-axis, 120 psi was applied inside of the inner chamber on the load bearing elliptical face, and the back z-axis face was changed into a non-moving face. The 430 N force is the total distraction force needed to separate the lumbar vertebrae, and was found in an article by

(Harvey, RM., 2012) However, since our new prototype is a three device system we can divide the total distraction force by 3 in order to determine the distraction force applied to one of our inflatable distractors (143N). In order to resist this force for full distraction, the inner pressure needed to fully inflate the device was calculated by using the equation Pressure = Force/Area. From our FEA testing we concluded the maximum stress applied to our device is 363 psi, the maximum horizontal displacement is 0.13 mm, maximum vertical displacement is 12 mm, and the factor of safety is 2.5.

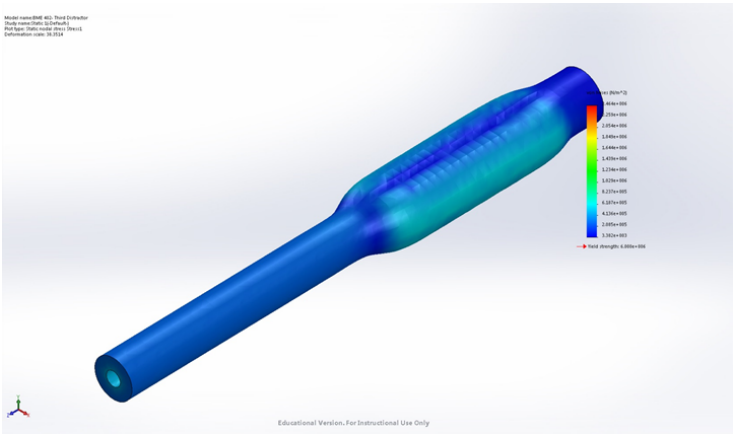


Figure 5: SolidWorks FEA of the final device.

Force Testing

In order to distract two vertebrae, one device is needed to be able to exert 140 N of force. To determine how much force the device could apply, tests were done using an electrodynamic compressive MTS machine. This initial testing was critical, as it is the foundation of how the device works and will allow it to move forward with more specific testing. The device was placed in between to load plates as can be seen in Figure 6 below. The load plates of the machine accurately measure how much force is being applied to them. For this testing procedure, a sample size of six devices was used. First, the deflated device was placed between two compressive load plates. The load plates were brought into contact with the deflated device, and the compressive load applied was set to zero. Then, using the pump, the device was slowly inflated. As the device inflates, the MTS machine displays and records exactly how much force the device is applying in a uniaxial direction. The data collected illustrates the forces the device is capable of applying at the initial vertebral displacement of 5mm.

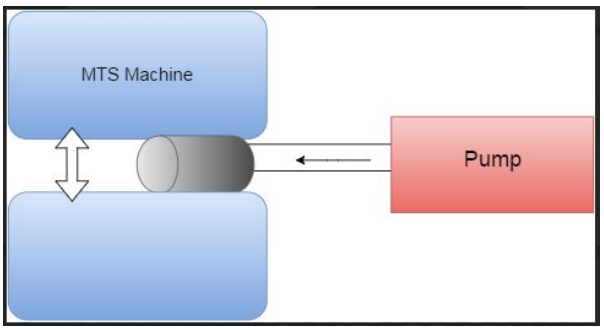


Figure 6: A schematic of force testing with a MTS machine. The device was inflated and the force was measured by the load plates.

While this test demonstrates initial force that can be applied, it fails to test whether it can withstand 140 N of force when fully inflated. A second test was designed to measure this but it proved to be too difficult to perform and the results were not trusted.

Distraction Testing

This device is required to be able to distract the spinal column 4-6 mm. A simple distraction test was developed to determine if the device could in fact inflate this distance without failing. The device was inflated until the device reached one of three failure points: 1) the device ruptured, 2) it began to bulge laterally or perpendicular to the spinal column, or 3) it could not be extracted through a 5 mm cannula. Using five samples, each device was measured vertically before and after the inflation process was performed. After 6 mm, the device would be deflated every 2 mm and tested to see if it could still fit through a 5 mm cannula. If it could not, it was considered as a failure point for the device.

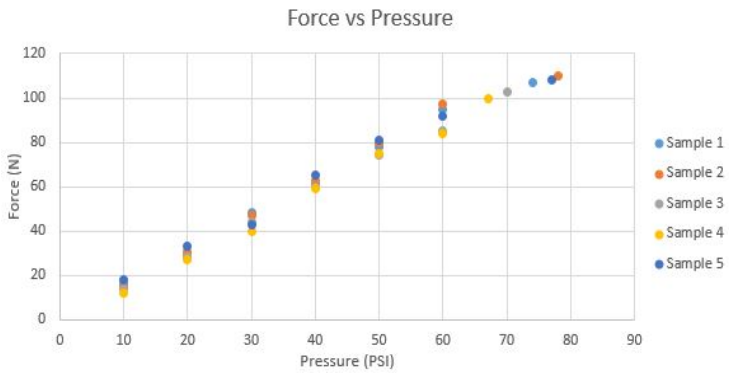
Insertion Method Testing Protocol

In order to test the insertion method of our distractor, a suitable lumbar vertebrae model must be created to mimic the dimensions of the lumbar region. Acrylic plate was used due to its similar mechanical properties to bone (tensile strength of 8,038 psi and young's modulus of 500,000 psi), with the dimensions of each being 10mm thickness, 16mm outer diameter, and 11mm inner diameter (10, 7). For the intervertebral disk polyurethane rubber will be used. The polyurethane rubber disk will be 5mm thick (height of lumbar intervertebral disk) and have a 15mm diameter (7). The polyurethane rubber disk was placed between two acrylic plates and a space was cut out for our device to be inserted into. To mimic the Jamshidi cannula a 5 mm hole was drilled

through an acrylic rod. The rod was held just above the created opening in the rubber and the device was slid through and placed in between the two plates or vertebrae.

Results

As the devices were inflated, the pressure was recorded and every 10 psi the force was measured. When the device would fail, the final force and pressure was obtained. Using six different devices it was found that the device could apply an average force of 105.6±3.9 N and withstand an internal pressure of 74±5 psi. The relation between pressure and applied force can be seen in Graph 1. The maximum applied force for each device can be found in Table 1.



Graph 1: During force testing, the amount of applied force was measured every 10 psi and at the failure point.

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

Table 1: Maximum applied force for six different device samples

Using a caliper, the height of the device was measured before and after inflation and the distraction distance was determined by subtracting the initial height from the final height. The results of the distraction testing show that the average maximum distraction distance before one of the three failure points were met was 10±1.58 mm. For five samples, the distances can be seen in Table 2.

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

Table 2: Maximum distraction distance before the device either ruptured, bulged laterally, or could not fit back through cannula. Five different device samples were used.

For the insertion testing, the results may be seen as subjective. Each team member took turns sliding the device through the cannula and into the space between the two plates. It was practiced by the team multiple times until every team member could successfully place the device on a single attempt. In only a couple hours, every team member could place the device accurately in one attempt. This leads us to believe that the technique is proven to work and a surgeon could perfect it with practice.

Discussion

Our device failed to reach the necessary force of 140 N to successfully distract two adjacent vertebrae. Our device was able to apply 75 percent of the required force. However, our device did serve as a proof of concept that an inflatable device can be inserted through a 5mm cannula, inflated, deflated, and removed from the vertebrae through the cannula.

For the purposes of this study, resources were limited to $500, so easily moldable hand molding silicone is used (Silastic(R) MDX4-4210 Biomedical Grade Elastomer Base). We are confident that with the correct resources, our design will be able to withstand well beyond the required pressure to create the needed distraction force. These resources include the use of an injection molding machine so we can utilize our mechanically stronger medical grade silicone and create better quality prototypes. Problems such as, lack of precision in mold center placement, adhesion between the mold and the device, and silicone not reaching certain areas of the mold altered the integrity of our prototypes. Table 3 compares properties of the silicone used in this design with a mechanically stronger injection molding silicone (HCRA 4130). An injection mold would cost $5000-$10000, was beyond the project's budget. With the accuracy and precision of injection molding our device would be perfectly aligned and molded.

Property	Current Silicon	Improved Silicon
Tensile Strength (MPa)	**5.1**	**10.3**
Elongation %	**1090**	**1100**
Tear Strength (N/mm)	**20**	**39**
Hardness	**10**	**28**

Table 3: This table compares certain properties of the current silicone used with our device compared to a silicon we would use with injection molding to better our results.

Conclusion

Our design of an inflatable vertebral distraction device will improve the science of neurosurgery and improve the safety and comfort of future patients. Using a variety of testing procedures, we analyzed the effectiveness of our device and have a proof of concept, but still have to create as prototype that can provide enough distraction force. With the proper resources a prototype that could apply the desired force can be created and the field of spinal surgery would be greatly improved. Large incisions would no longer be needed and spinal fractures from current distraction devices would be eliminated. All of this would lead to faster recovery time, less pain, and less scarring for patient.

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Appendix

Fabrication Methods

In order to create our inflatable device we first needed a CAD of the mold. The first few iterations of our design had to be changed in order to facilitate simple separation, and this is why we incorporated a two part mold cavity. The mold was created in SolidWorks using some commands in the mold toolbox. First the mold was scaled up by two percent in order to account for any shrinkage that may occur during casting. Then in order to create a pull direction, which is the plane at which we want to pull apart the solidified silicone from the mold, a pull plane was implemented along the y and z plane at the base of our device. A parting surface was created by referencing the pull plane, and this is required in order to create a tooling split which needs an additional surface to reference. Once the pulling surfaces have been created we can apply a tool

split, and this requires an outline of how large you want the mold (aka “tool”) to be. After defining all of these reference planes we launched the tool split and the mold was created, seen in the figures A and B below.

The mold was oriented so that the load bearing part of our device is located near the back end shown on the figure B below. The thin sheath is at the front end of the mold cavity shown in the figure below on the right. The mold cavity, shown in the figure below on the left, is what gives our device the internal ellipse in the load bearing part of our prototype. There was a concern that during casting the liquid silicone would not flow to the base of the mold where the sheath was, so the mold cavity was split into two pieces to facilitate easy separation from the mold. This cut was added after the first cast was created, and there were difficulties with separating the device from the mold without pulling and ripping the load bearing base.

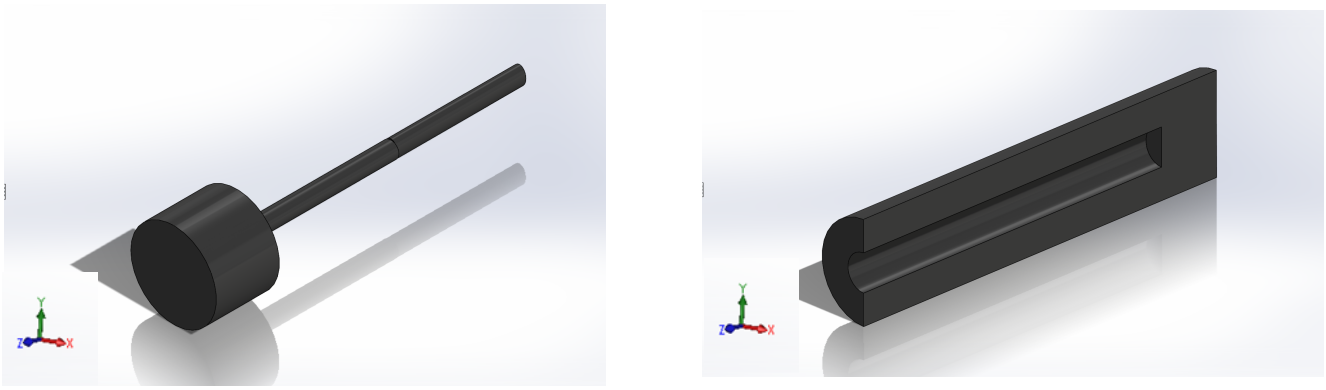

Figure 7 and 8: End mold for our final design. Mold core is shown on the left, and half of the mold cavity is shown on the right.