Inflatable Vertebral Distractor

Mid Semester Report

December 9, 2015

Team:

Joshua Plantz - Team Leader

Joaquin Herrera - Communicator

Herman Feller IV - BSAC

Ellis Cohen - BPAG/BWIG

Client:

Dr. Nathaniel Brooks: UW Hospital

Advisor:

Professor Mitch Tyler

Table of Contents

Abstract

In 2006, The National Survey of Ambulatory Surgery recorded 102,173 surgical procedures performed for the treatment of intervertebral disorders [1]. 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. Current devices are large, requiring a large incision to be used creating a greater possibility of future pain, longer recovery time, and scarring for the patient. These devices are also commonly composed of metal and often will fracture and crack the vertebrae requiring additional surgery for the patient. The goal is to design a distraction device that is less invasive, is unobtrusive to the surgeon, and does not damage the vertebral bones or soft tissue. To solve this problem, a flexible, prism shaped device has been designed that will be inflated using an air hand pump to distract the vertebrae while protecting the various components within the spinal cavity. The design was tested under compressive forces of a MTS machine to determine the amount of force it could apply.

Problem Statement

One of the most common spinal procedures performed is disc removal surgery. This is a procedure in which a surgeon removes the disc space entirely. Reasons for this procedure include disc deterioration, collapsed discs, herniated discs, or other disc problems. With these spinal issues, the vertebral bodies experience bone-to-bone contact with one another and can pinch or squeeze the nerves, causing excruciating pain [2]. In order to perform disc removal, the surgeon must first gain access between the vertebral bodies to extract the remaining disc material, for which spinal distraction is required. Separation of the vertebrae alleviates pressure, helps with alignment, and provides surgeons with more room to work during surgery. The goal of this project is to design and fabricate a new inflatable vertebral body distraction device for the lumbar portion of the spine that can be easily manipulated and will not cause spinal fractures.

Background

Client Description

Our client is Dr. Nathaniel Brooks, of UW-Hospitals and Clinics. Dr. Brooks is a neurological surgeon who commonly performs minimally invasive spinal surgeries for a variety of spinal patients. Dr. Brooks has requested an expandable distraction device that would address the issues of current devices and provide optimal distraction.

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. [3]

When these problems occur, there are many treatment methods depending on the severity of degeneration. Typically the first step in 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 [4]. 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 the use of a 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.

Current Designs

Currently, there are several different types of vertebral distraction devices on the market. These devices are sufficient, but not ideal, for a variety of different reasons.

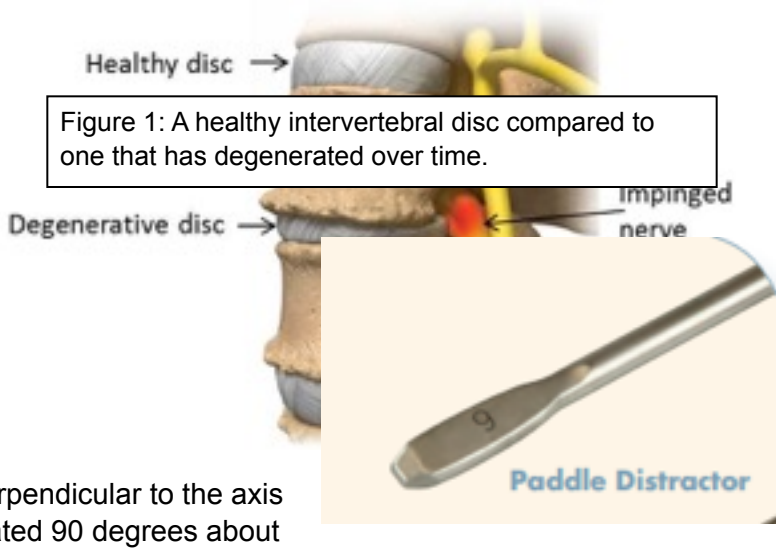


Figure 1: A healthy intervertebral disc compared to one that has degenerated over time.

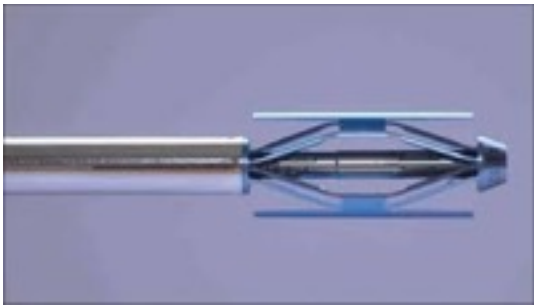
<u>Paddle Distractor</u>

A common distraction tool found in hospitals, the paddle distractor, is a simple, stainless steel, oar-shaped instrument. The head of the paddle is inserted into the vertebral disc space, with the plane of the flat-face perpendicular to the axis of the spine. The instrument is then rotated 90 degrees about the long axis to achieve distraction [5]. Given the stainless-steel material and small area of contact with the vertebral body, this mechanism occasionally causes non-trivial spinal bone fractures. Additionally, this device is bulky and obstructive for the surgeon as the entire device, including the handle, must be left inside the patient during surgery.

Figure 2: Image of a common hospital paddle distractor.

<u>Scissor Jack</u>

Another distraction device is the jack distractor, shown in figure 3 below [6]. The mechanism of operation is similar to that of a car jack. It is inserted into the vertebral disc space along the axis of the surgical opening. As a force is applied axially along the device, the jack platforms expand, and distraction is achieved.



The distraction and insertion mechanisms can be separated, allowing the surgeon more room to operate and for the insertion mechanism to be sterilized. These devices have a greater area of contact with the vertebral body than the paddle distractor; however, the rigid edges and force concentrations still induce bone fractures.

ck distractor.

Spine Staxx

A more recent device is the Spine Wave Staxx device. It is inserted into the vertebral disc space along the axis of the surgical opening. The device uses a PEEK Staxx housing at the end of the insertion rod that expands when thin polymer sheets are stacked in series. It limits bone fracture more so than the paddle and jack distractors due to its increased surface area within the vertebral body and small 1 millimeter increments of expansion [7]. However, the insertion mechanism is bulky and limits the surgeon's ability to maneuver the device even though it is detachable from the insertion rod.

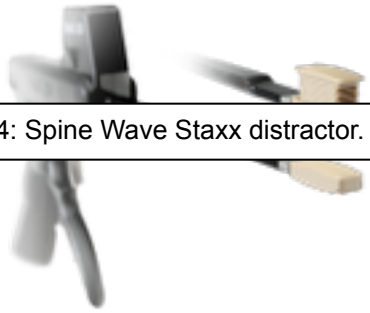


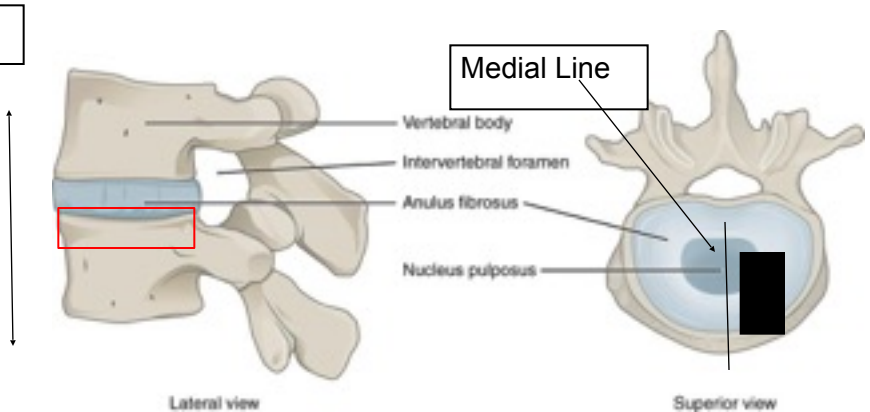
Figure 4: Spine Wave Staxx distractor.

Design Requirements

The goal is to design and fabricate a user-friendly surgical tool to be used during spinal distraction surgery. The device should be able to distract the vertebrae 4-6 mm. It will be located on one side of the medial line occupying half of the disc space by insertion from the dorsal side of the patient, seen in figure 5. Also depicted in figure 5 is the axial line of action for distraction. There are two main design criteria that the device should account for: effectiveness and patient safety.

First and foremost, the device must be effective and provide sufficient distraction force and size in order to keep two adjacent vertebrae in the lumbar region of the spine properly separated during surgery. In order for the spine to distract and maintain separation, the device should apply force in one axial direction along the spinal column to prevent unnecessary spatial occupation and damage to nerves. The force needed for a 4mm distraction is 430 N, or 215 N applied in both directions [8]. The allowed space for the device is 400 mm^2 with 10 mm of space in between the two vertebrae [9]. Therefore, with a total of 800 mm^2 of surface area, the required pressure for distraction is calculated to be 537.5 kPa (78 psi). Sufficient and reliable distraction of the spine is vital to a successful removal of the vertebral disc. The insertion method should be minimally invasive through the use of a Jamshidi cannula for implantation and removable after distraction.

Line of action



Another main concern of the client is patient safety. In order avoid bone fracture, which is a common occurrence using current methods, the distraction force should be applied over a large surface area of bone in one half of the disc space. The device will have a surface area of 16 mm x 25 mm in order to maximize the contact area. Dissipating the distraction force over a maximal surface area will reduce risk of soft bone fracture in the more delicate interior region of the spine. The device should not have sharp edges and should be made out of a malleable material that can conform to the shape of the vertebrae. Additionally, some sort of tactile feedback mechanism should be incorporated so the surgeon will be able to know and control exactly how much force he or she is applying to the bones by adjusting the pressure. This will also decrease risk of bone fracture. In regard to patient safety, the device must be biocompatible. All materials used should be hypoallergenic and able to withstand exposure to bodily fluids, high forces, and application of high pressure by the surgeon. Since the device will be used inside the body, it should either be able to be sterilized or be disposable [10]. With this in mind, the device should be cost effective and should be cheaper than, or comparable to, current surgical tools on the market.

Figure 5: Surgical Distraction Mechanism. The distractor is inserted posteriorly between the vertebral bodies and deposited on one half of the body for distraction.

The full design requirements are outlined and explained in further detail in the Product Design Specifications in the Appendix.

Proposed Designs

Design 1: Balloon

The first design's structure was based off of an angioplasty balloon [11]. The distractor is in the shape of an elliptical balloon, and is composed of one sheath of medical grade silicon in order to withstand the compressive forces of the vertebral column. The line of action for distraction is along the white arrow, where the balloon would come into contact with the lumbar vertebrae, seen in figure 6. The inflatable is connected to the air supply through a hose located at the distal end of the balloon. Once inserted into the vertebral column the balloon is inflated in order to distract the lumbar vertebrae. With such a simple shape it would fit easily into the Jamshidi biopsy needle, and also be easily manufacturable. However, the team's main concern for this design was the balloon's tendency to provide force not only in the axial direction along the vertebra, but also in the lateral direction due to bulging. If the device expanded laterally to the adjacent spinal nerve root with enough force it may damage the

Figure 6: Image of angioplasty balloon.

spinal cord and cause leg paralysis in our patient. With safety one of our top concerns it was decided to model our final two designs with more structure in order to prevent lateral bulging, and unwanted stress points along the spinal cord.

Design 2: Prism with Frame Meshwork

The second design is shaped as a prism composed of medical grade silicon. In order to give this design more structural stability, an inner framework made of denser ultra-high-molecular-weight polyethylene was added. The dimensions of this design are 16x10x26 mm, and the line of action of distraction is along the y-axis, seen in figure 7. This framework lines the y-axis faces of the prism to ensure the device keeps its rectangular prism shape without bulging laterally. In addition, the framework adds contact surface area with the bodies of the lumbar vertebra in order to prevent the distractor from slipping during surgery. A consequence of having a more rigid face is increasing the difficulty the surgeon has when inserting the device into the Jamshidi biopsy needle. Also, if the device were to fail during surgery the inner framework of the distractor may spill out of the device and into the spinal column of the patient. Overall, incorporating other pieces to the inflatable distractor lining proved too difficult to manufacture while also increasing the danger to the patient.

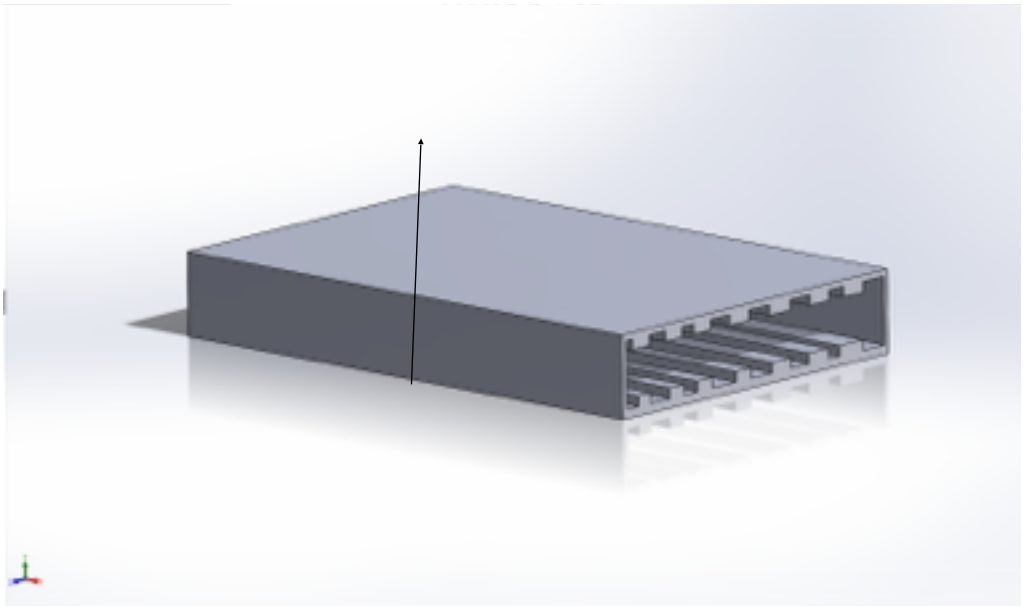


Figure 7: SolidWork model of design 2, prism with frame meshwork.

Design 3: Plated Prism

The third proposed design is composed of just one layer of medical grade silicone with thicker portions surrounding the vertical faces of the prism that come into contact with the vertebra. The device is 16x10x26 mm, and the line of distraction is shown in figure 8 along the arrow. Going into our final design it was known the device needed to have structure without adding extra danger to the patient. Therefore incorporated was the structural support of the device in its linings, so if the device ever failed during surgery the surgeon could just remove the casing and be sure the device did not leave foreign material in the wound. In addition, maximizing contact surface areas between the device and the vertebra makes the distractor less likely to slip during surgery.
The middle portion of the distractor would be composed of a thinner more flexible layer of silicone to prove space for the distractor to inflate only in the vertical direction. While providing the distractor with enough maneuverability to fit inside the Jamshidi needle.

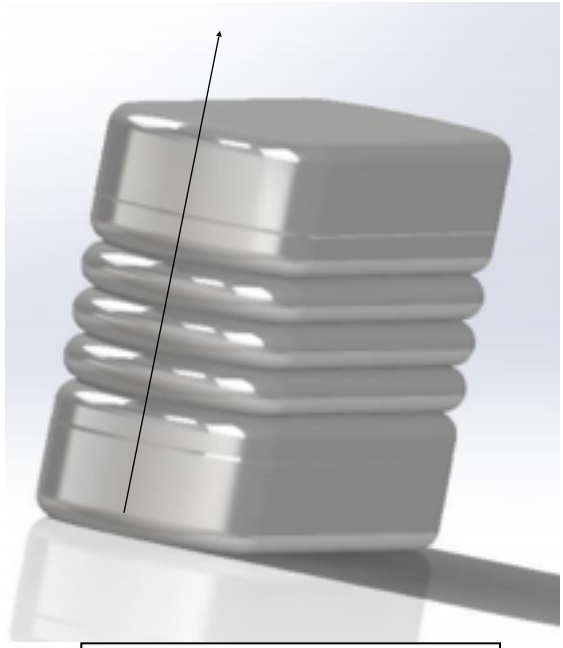


Figure 8: SolidWork model of design 3, Plated Prism.

Design Criteria

The criteria used to grade our three designs are safety, uniaxial inflation, ease of manufacturing, stability, size, and cost. Safety and uniaxial inflation are ranked the highest at 25 because our design will be used in spinal surgery where there is a great risk of paralyzing the patient so safety is of great importance. Moreover, uniaxial inflation is the requirement from our client that will make our device work and make it unique so it is also ranked the highest. Manufacturing is ranked second at 20 because manufacturing is the step that has stumped all previous groups working on this project. Stability is third at 15 because the design has to stay in place as it is applying force to the vertebra or the design won't work. In addition, stability has some safety implications because if the design breaks free and enters further into the spinal cord, damage could be done. Size is ranked next at 10 because our design has to fit in between individual lumbar vertebra before distraction can commence. Cost is ranked last at 5 because our device will be small and made mostly out of medical grade silicone, regardless of which design is chosen. Our budget of $500 should be more than enough to create a prototype.

For safety the plated prism design ranked the highest, followed by the mesh prism, and finally the balloon. This is because the mesh prism has additional material, either plastic or metal, as a frame that makes failure of the device much more dangerous. Also the balloon design is likely to expand like a sphere, possibly damaging the spinal cord. The plated prism, on the other hand, is made completely out of medical grade silicone and is designed to expand laterally with the vertebra.

This is also why the plated prism design is ranked highest in the uniaxial inflation category. The force is designed to go in the direction of extraction and the surface area of distraction is slightly higher with a solid slab of silicone than it is with a metal or plastic mesh frame as in the mesh prism design. The balloon design does not have this control over inflation and distraction force and is ranked last.

For manufacturing, hand pouring silicone in a mold will be used. Under that assumption the balloon design is the simplest and easiest to make. The plated prism design has the added difficulty of having various thickness of silicone. The mesh prism design adds the complication of having to add a plastic or metal insert into the mold so it is ranked last.

As far as stability is concerned, the balloon design has the least anchoring of the three designs and is therefore ranked last. The more controlled inflation of the mesh prism design gives it more stability. This is also true for the plated prism design, but the plated prism design also has the possibility of adding edges to the thick silicone top and bottom to help keep the device in place. That is why the plated prism is ranked highest in this category.

As for size, all the designs are fairly small, with the simpler designs with less hard components getting a better score. This is why the balloon design is ranked highest in this category. This is similar for cost effectiveness, where the simpler balloon design is ranked slightly above the other two.

Overall, the best design is by far the platted prism. For the two most important categories, safety and uniaxial inflation it is ranked the highest. For manufacturing it is second and for stability it once again is ranked first. In total the plated prism design is over 10 points better than the next design, the mesh prism. Therefore the plated prism design is our final design.

Final Design

The final design consists of a rectangular prism with one open face that is used during inflation, seen in figure 9. The inflatable prism has dimensions of 10x16x48.5 mm. During surgery the patient will be laying down with his/her face pointing inferiorly. The device will be inserted using a Jamshidi cannula into the spinal column along the x-axis in figure 9, closed face first, with the z-faces directed superiorly and inferiorly. The device is then inflated and will distract along the z-axis shown in the figure (which is the axial direction).

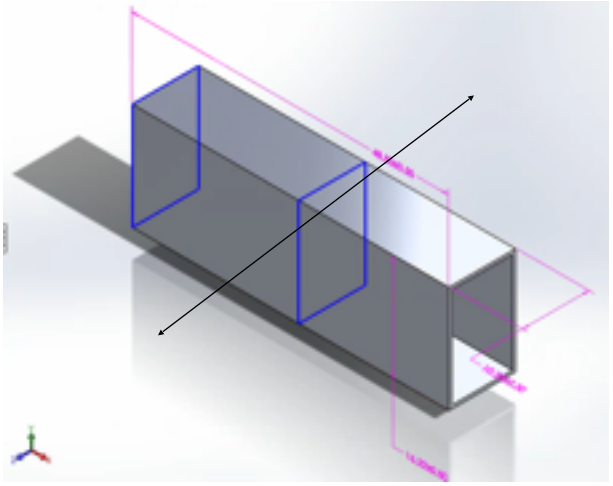
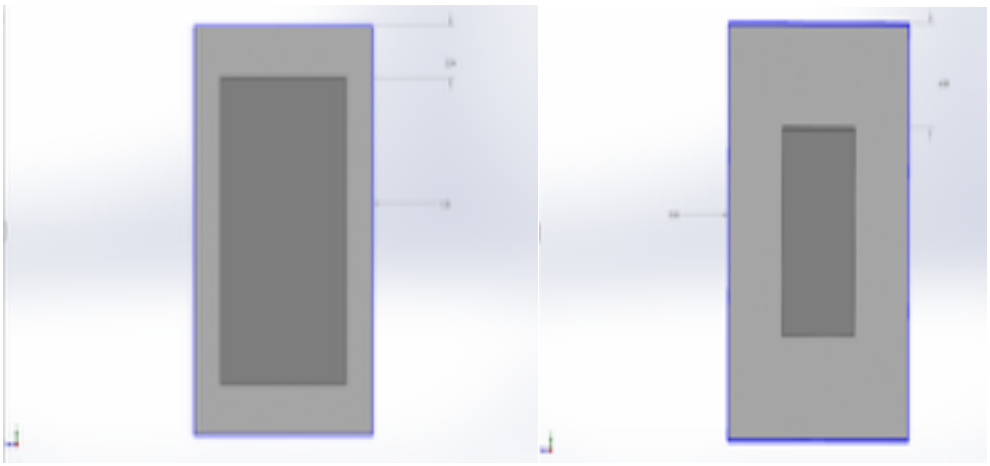


Figure 9: Isometric view of SolidWorks rendering of plated prism distractor final design.

There are two sections of the prism that serve distinct functions, and can be seen in figure x, separated by the blue line in the x-axis. The back half of the prototype is load bearing and this is where the lumbar vertebrae will come into direct contact with our device. Currently two different prototypes have been created with different thickness measurements (figure 10 and 11) in order to test the optimal wall thickness that will provide enough structural stability to prevent lateral bulging while also providing enough flexibility to fit in the Jamshidi cannula. The walls of load bearing parts for both prototypes are 1.5 and 3 mm in the z-faces, and 2 and 4 mm in the y-faces, respectively. In order to prevent bulging in the transverse plane these faces (y-face) were made thicker to create a stiffer more resilient wall. The front half of the prism is composed of a thin, 0.5 mm thick, sheath that is used to wrap around the intake hose. Permatex High-Temp RTV Silicone Gasket, a silicone adhesive, will be applied between this thin sheath and the intake hose to create a proper seal to prevent any air leakage.



Figures 10 and 11: SolidWorks of a cross section inside the load bearing part of our design. Picture on the left has wall thicknesses of 2 and 1.5 mm, and picture on the right has wall thicknesses of 3 and 4 mm.

SolidWorks Analysis

After creating a CAD of both devices with varying wall thicknesses, they were run through a static SolidWorks Simulation to determine the displacement and stresses of the load bearing parts of our design. Since the sheath undergoes no stress a cross section of our device through the load bearing portion was analyzed and the sheath was excluded. Shown below are figures of the Von Mise Stresses, and total displacement of both prototypes. Both simulations used the same applied forces which are as followed; a total of 430 N were applied to the z-axis faces, 78 psi were applied inside of the inner chamber on each of the available five faces, and the back x-axis face was changed into a fixture. The 430 N force is the distraction force needed to separate the lumbar vertebrae, and was found in an article by Harvey, RM [8]**.** In order to resist this force for full distraction, the inner pressure needed to fully inflate the device was calculated by using the equation Stress = Force/Area.

The following images are a comparison of the stress applied to both devices, and which portions of the device that would fail under the applied forces were analyzed, figures 12 and 13. The z and y faces of the design were focused on because these are the faces with the highest possibilities of rupture. After running the simulation it was found that both devices would not fail under these applied forces and pressure. The thin walled prototype had a safety of factor of 15, and the thick walled prototype has a safety of factor of 30. However, at the corners of the thin walled prototype it was observed that this point stress could creep towards the outer wall and cause a tear along the x-axis. This was the main reasoning of making the second prototype thicker in order to prevent this creep stress and prevent a possible tear.

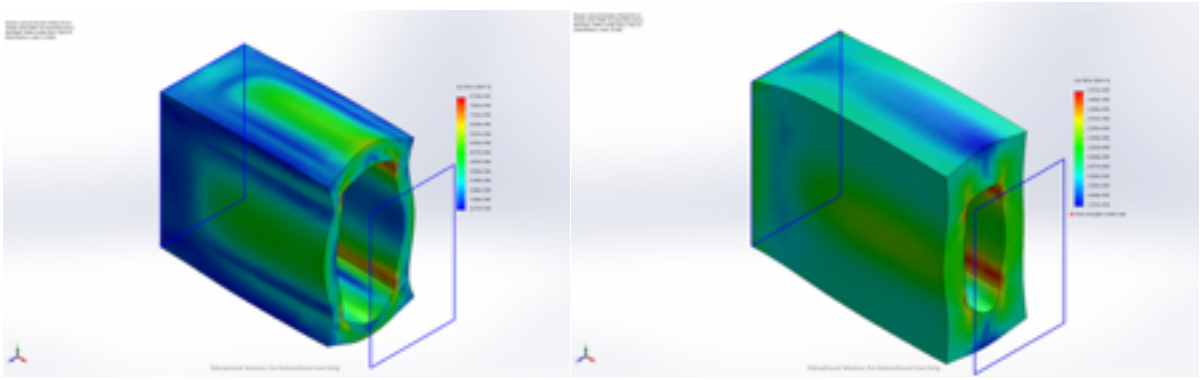


Figure 12 and 13: SolidWorks rendering of Von Mise stresses of both prototypes. Thin and thick walled devices are shown on the left and right, respectively.

The bottom images depict displacement of the devices after the loads were applied. The main points of unfavorable displacement was on the y-axis faces, which is partly due to the fact that a force of 430 N was placed on the z-axis faces and this added reinforcement to these faces and prevented bulging. In these images it is observed that the thin walled prototype has a max displacement of 1.2mm, and the thicker walled prototype has a max displacement of 0.199 mm, both along the transverse plane of the patient. These values are reasonable because there is an excess of 4 mm along the y-axis in either direction of where the device will be placed, as a result, it can be assumed that the device will not bulge outside of the vertebrae in the surrounding tissue.

Although the thicker walled prototype will not bulge out laterally as much as the thin walled device, we still have to account for the flexibility that will be needed in order to fit inside of the vertebrae before inflation. The thin walled device can support the applied loads however with such a thin wall there is a possibility for creep stresses that could compromise the edges of the device, and cause a tear along the x-axis between the y and z faces. By adding additional material to theses faces we increase the strength of the device, however we compromise the flexibility as well. Future work must be done in order to determine which wall thickness is optimal for insertion into the vertebral column while maintaining the structural stability of the device. By testing if the thicker walled device will fit in the vertebrae pre-inflation we can disregard the thin walled device and move forward with the thicker more robust model.

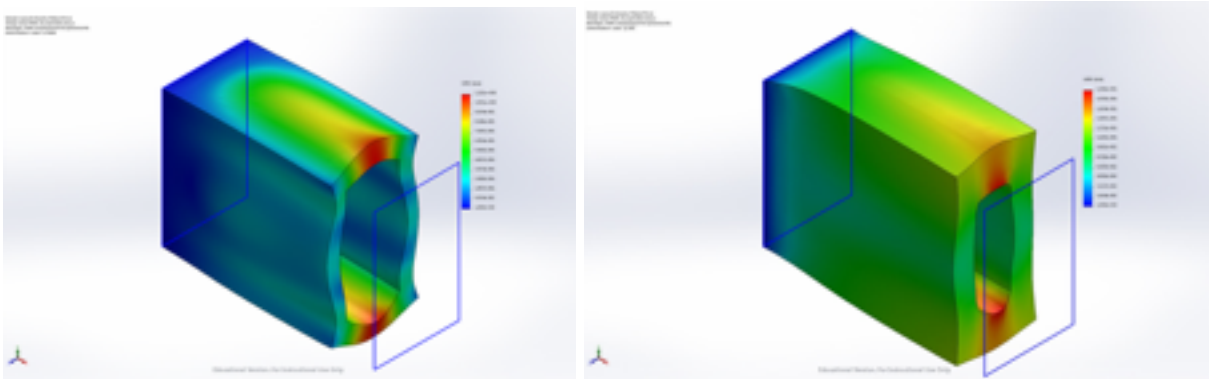


Figure 14 and 15: SolidWorks rendering of displacement measurements of both prototypes. Thin and thick walled devices are shown here on the left and right, respectively.

Manufacturing

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 an open face into our device. 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 figure 16 below.

The mold was oriented so that the load bearing part of our device is located near the open end, and the thin sheath is at the back end of the mold. A small ABS plastic cube was used to block this open face during curing to ensure none of the silicone leaked out. There was a concern that during casting the liquid silicone would not flow to the base of the mold where the sheath was, so a circular opening in the back end of the mold was added in order to pipette additional silicone during filling. The mold was then cut around the outer edge to facilitate simple separation between the silicone and mold which can be seen in the figure 17 below. This cut was added after the first cast was created, because there were difficulties with separating the device from the mold without pulling and ripping the load bearing base.

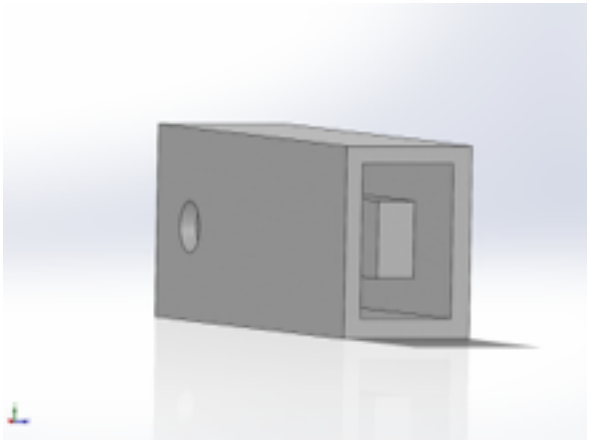


Figure 16: SolidWork image of mold in isometric view.

Figure 17: Picture of separated mold with cut.

Manufacturing: Casting Process

For the main silicone used so far we set a water bath to 75^{o}C. The silicone is carefully mixed in a 10:1 ratio with the catalyst to prevent bubbles. If a strong enough (710 mmHg) vacuum is available it can be used to de-gas the mixture, but if less it only makes it worse. Take the outer casing of the mold with the cap and pipette the silicone until it is full. Then carefully add the inner mold piece so that parallel sides are even. Silicone will ooze out, but just pipette this to add to the top of the mold. Add the cap and put the mold in the heated water for 30-35 minutes. Once done, allow the mold to cool off for a few minutes. Then carefully pull out the inner sheath and scrap the distractor from the walls of the outer sheath until it can be pulled out

Materials

The rectangular prism will be molded using one of three possible types of silicone. They include Silbione HCRA 4130-AB HC, an inflatable silicone elastomer that is often applied to medical stoppers, plungers, seals, needle entry ports, and tubing, Silastic(R) MDX4-4210 Biomedical Grade Elastomer Base, which is often used for tubing, and Silbione 4325 Soft Liquid SIlicone Rubbers (LSR) for Healthcare, which has a broad range of applications including balloons, insoles, and rollers. HCRA 4130 has a tensile strength of 1,500 (10.3) psi with an elongation percentage of 1,100%. The MDX4-4210 has a tensile strength of 730 psi with an elongation percentage of 470%. Lastly, the LSR 4325 has a tensile strength of 1198 (8.2) psi, with an elongation percentage of 950%. The prism will be sealed to the tubing of the inflation source with Permatex High-Temp Red RTV Silicone Gasket, a silicone adhesive. For the current prototype, the source of inflation is from a Lumiscope Deluxe Aneroid Blood Pressure Monitor. This pump does not exceed 5.8 psi. In order to create the inflating device, a mold was created out of acrylonitrile butadiene styrene (ABS), a thermoplastic polymer with a glass transition temperature of about 105˚C. After a few iterations during the manufacturing process, the final plated prism design was chosen.

Testing and Results

In order to see the effectiveness of the design, how much force and pressure the device could withstand before rupturing and how much it would inflate in the axial and lateral directions were tested. The total surface area used to created force for the distraction is 16 mm x 25 mm for the axial surfaces of the device. Therefore, the total surface area is 800mm^2 and the force needed to distract the vertebrae is 430 N. However, pumps are measured with pressure, which is force per unit area. Using the pressure needed is 537.5 kPa or 78 psi.

First, to be tested was how much compression load the device could withstand and distract. Using a MTS machine, the device was placed in between the load cells and slowly added an increasing compressive force while simultaneously inflating the device as seen in Figure 18. The client, Dr. Nathaniel Brooks, prefers the use of a manually controlled pump and does not want to spend a lot of the $500 budget before there is a proof of concept that the distractor can be sealed to a pump. Therefore, in order to save money a cheap hand pump was used to test the idea concept. When the applied load reached 11 N, the hand pump's valve (not the sealed distractor) began to leak. At this point the device had been distracted 4.9 mm in the axial direction and has yet to distract in the lateral (bad) direction. Although the test was limited by the effectiveness of the pump, the test did prove that the concept behind the design works. However, the true total force that the device could withstand was still unknown.

Figure 18: The device undergoing compression testing in the MTS machine.

To estimate the amount of force the device can withstand, a tensile test was used to find the yield stress. A sample equal and size and thickness of the surfaces to be used in the compression loading was clamped into the MTS machine. A tensile load was slowly applied until the specimen ruptured. Using the stresses and strains recorded, a graph was created (Figure 19) and the yield stress was found as 400 kPa using . Then, the yield stress was used to find the maximum applied load in compression by multiplying it with the area to be used in compression. This load was found to be 153.6 N. This value is below the desired 215 N, but future compression testing with an adequate pump will give us a more accurate value of the true maximal force. The tensile test also showed the elasticity of the silicone. The sample was stretched from 25 mm to 44mm, a 76% expansion. This shows the device will be able expand the required distance. Furthermore, better fabrication methods can reduce bubbles in the silicone that reduce mechanical properties.

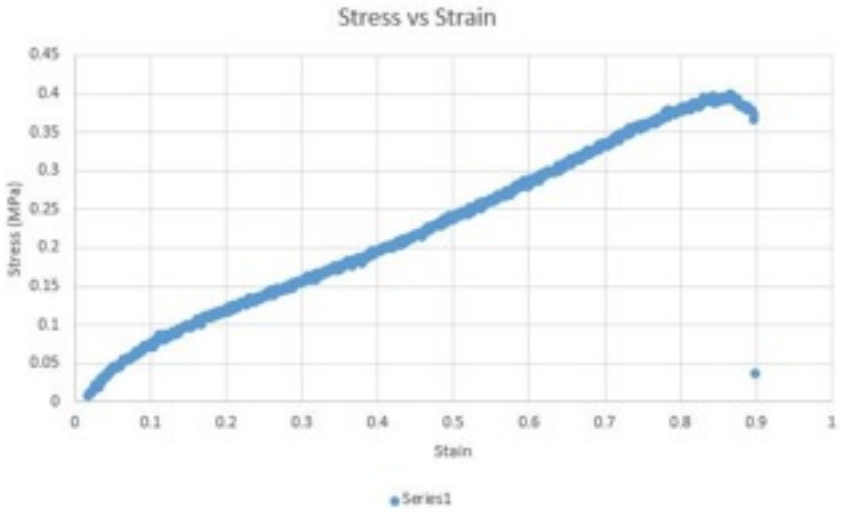


Figure 19: Stress vs Strain graph of a sample of the device from tensile testing.

Future Work

At this point a rudimentary distractor made out of Silastic(R) MDX4-4210 Biomedical Grade Elastomer Base has been created with a silicone adhesive connecting it to a blood pressure pump. We plan on making major advancements in our design and inflation mechanism. To start, we will be creating prototypes out of Silbione HCRA 4130 and test their mechanical properties. We may also attempt injection molding with Silbione 4325 Soft Liquid SIlicone Rubbers if it can be done economically. We then evaluate which material best serves our overall purpose. Additionally, we will be upgrading our pump to one that can attain 537.5 kPa of pressure and has a pressure gauge to allow feedback so the user can track exactly how much pressure is applied. The new pump can be used not only for distractor inflation, but also silicone de-gassing. We will continue MTS testing with our new prototypes and pump, adjusting our design and mold as needed. This testing is very important because at the moment we have only been able to do indirect testing through tensile strength testing of individual walls and the results have shown our imperfect prototype to be insufficient. Testing with different silicone, testing in a more representative condition, and fabricating a prototype with no bubbles are all ways we can better reach and evaluate our goal. Eventually we will need to create a testing method to further simulate a lumbar distraction, such as using an animal cadaver. Once a testing methods proves our distracting concept, the next order of business is to confirm the Jamshidi needle as being the least invasive insertion method. That includes being able to insert, inflate, deflate, and remove the device safely. Throughout this entire process we will be adjusting our design as needed.

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.

2. Cloward, R. “The treatment of ruptured lumbar intervertebral discs by vertebral body fusion. I. Indications, operative technique, after care.” Journal of neurosurgery 10.2 (1953): 154.

3. "Anatomy and Back Pain." What Is Intervertebral Disc Degeneration, and What Causes It... : Spine. Zimmer, 3 June 2013. Web.

4. Scoville, W., & Corkill, G. (1973). Lumbar disc surgery: Technique of radical removal and early mobilization. *Journal of Neurosurgery, 39*(2), 265-269.

5. http://www.amedicacorp.com/files/6414/0138/4045/400009_-_Valeo_TL_Surgical_Technique.pdf

6. http://www.arcos.com.uy/pdf/productos/65/563_capstone_peek_st.pdf

7. http://www.spinewave.com/products/xd_us.html

8. Havey, R., Voronov, L., Tsitsopoulos, P., Carandang, G., Ghanayem, A., Lorenz, M., Patwardhan, A. (2012). Relaxation Response of Lumbar Segments Undergoing Disc-Space Distraction. *Spine,* 733-740.

9. Mahato, N. (2011). Disc spaces, vertebral dimensions, and angle values at the lumbar region: A radioanatomical perspective in spines with L5–S1 transitions.*Neurosurgery Spine, 15*, 371-379.

10. "Polycarbonate Remains Proven and Preferred for Medical Applications." - Nasa Tech Briefs. N.p., n.d. Web. 25 Sept. 2014.

11. http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiovascular/catheters/balloon-dilatation-catheters/sprinter-legend-rx-semicompliant-balloon-dilatation-catheter/

Appendix:

PDS

Inflatable Vertebral Distractor
Client: Dr. Nathaniel Brooks
Advisor: Dr. Mitch Tyler

Team:
Josh Plantz, jplantz@wisc.edu - (Team Leader)
Joaquin Herrera, jaherrera@wisc.edu - (Communicator)
Hermann Feller,hjfeller@wisc.edu - (BSAC)
Ellis Cohen, eycohen2@wisc.edu - (BWIG/BPAG)

Date: September 20, 2015

Problem Statement:
In some cases of spine surgery the intervertebral disc is removed and the vertebral bodies are distracted to help with alignment of the spine and to create more operating space. The goal of this project is to develop an inflatable vertebral body distractor that can be easily used and will not cause spinal fractures. It must be less invasive than current distracting techniques and create a separation of 4-8mm. Currently, spatula-like distractors are used but are susceptible of chipping of pieces of the vertebra or causing fractures.
Client Requirements:

- Insertable using a needle with an inner diameter of 2-3mm, preferably jam sheedy needles
- Medical grade silicone recommended
- The inflatable portion will have one use
- Needs to work on lumbar region
- Consider use of pressure sensors, but not required

1. Physical and Operational Characteristics
    a. Performance requirements:

* This product must successfully distract vertebra 4-8 mm to allow disc removal and disc replacement. It is to be less invasive than current techniques, ideally to be inserted in the space created by the needle used in the operation. It will be inserted on the opposite side of the vertebrae of which the the procedure will take place. The product must maintain separation of

the vertebra for the duration of the operation which can be up to 8 hours. Inflatable distractor inside of cannula must be reversibly distractible.

b. Safety:

* It should not cause further harm to the patient or user while in use
* Should have a surface area enough to prevent cracking and chipping of the bone of the vertebra.
* Must be easily removable without damaging vertebrae

c. Accuracy and Reliability:

* The device should create enough force in a uniaxial direction to separate vertebrae a distance of 4-8 mm for the client to operate on the disc. It must last the duration of an operation (3-8 hours) and occupy only half of the space in between the vertebrae (approximately 13-15mm^2). This device should never fail under any circumstances.

d. Life in Service:

* The device needs to last the whole procedure, approximately a few hours up to 8 hours.

e. Shelf Life:

* The main component of the product which will be used outside of the human body must last up to 6 years. The inflatable component of the product used within the body to separate the vertebrae will only be used on time.

f. Operating Environment:

* There are two different operating environments. One part of the product will be used inside the human body, specifically in the spinal region in between the lumbar vertebrae. Therefore the material must be biocompatible and withstand body temperature of 37 degrees Celsius. The other part of the product will be used in the sterile operating room and does not need to be biocompatible.

g. Ergonomics:

* inflatable with one hand, implantable by a single person
* Must fit in the desired operating space in between two lumbar vertebrae (minimum 1.75mm high, 7.4mm wide) while being less invasive than current distracting techniques.

h. Size:

* The product must be easy to transport by hand by the users and compact enough as to not disrupts the surgical operations performed by the client. The client would prefer if it could be inserted through the space created by the needle already used by the client.

i. Weight:

* No more than 500 g

j. Materials:

* A portion of the product will be used within the human body, meaning it must be composed of a biocompatible material. The client wants it to be inflatable while being able to withstand enough force to create separation between the vertebrae. The portion outside the body must be durable and lightweight as it will be used multiple times, however it does not need to be biocompatible.

k. Aesthetics, Appearance, and Finish:

* Rust preventative and smooth outer surface surrounding the inflatable distractor .

2. Product Characteristics

a. Quantity:

* We must fabricate one working product and if time fabricate multiple attachments for use inside the body.

b. Target Product Cost:

* Less than $500.00

3. Miscellaneous

a. Standards and Specifications:

* Abide to FDA medical device regulations

b. Customer:

* Prototype refinement
* Requires testing in bone analog

c. Patient-related Concerns:

* Must not generate debris
* Must not damage bone or influence patient physiology after use

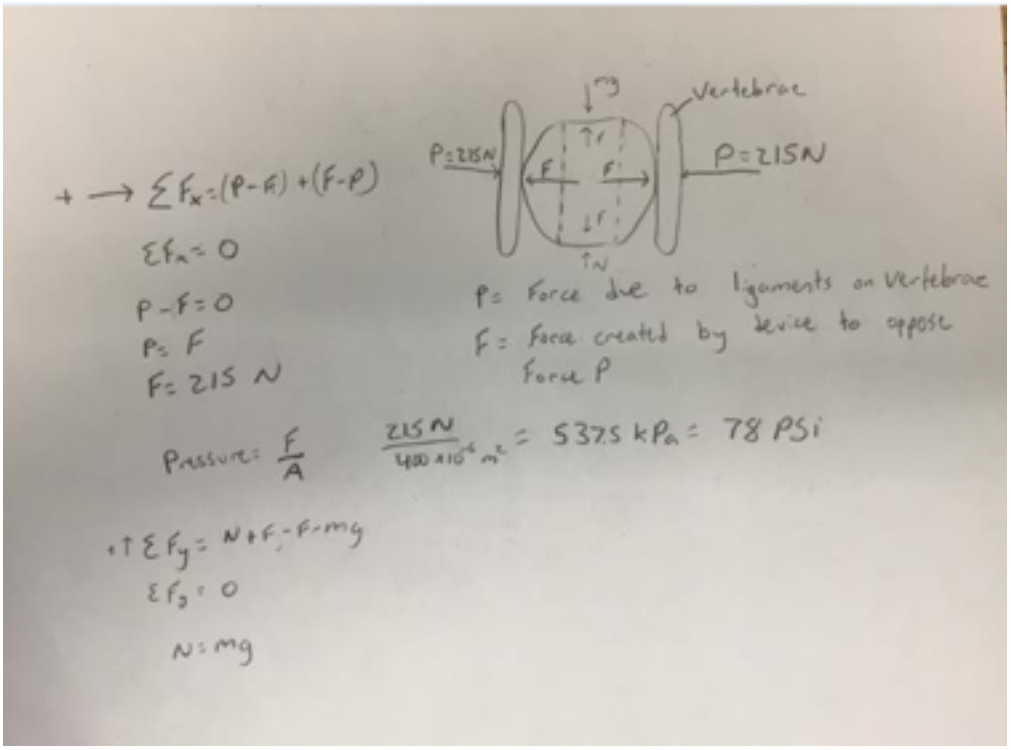
d. Competition:

* Synthes Vertebral Distractor: Uses metal rods and a pneumatic pump in order to create separation between vertebrae. However, does not incorporate a balloon or inflatable segment.

Design Matrix

Criteria	Balloon	Mesh Prism	Plated Prism
Safety (25)	2 (10)	3 (15)	4 (20)
Uniaxial Inflation (25)	2 (10)	4 (20)	5 (25)
Ease of Manufacturing (20)	5 (20)	2 (8)	3 (12)
Stability (15)	2 (6)	3 (9)	4 (12)
Size (10)	4 (8)	3 (6)	2 (4)
Cost Effectiveness (5)	5 (5)	4 (4)	4 (4)
Total (100)	59	62	77

FBD



$+\rightarrow \sum F_x = (P-F)+(F-P)$

$\sum F_x = 0$

$P - F = 0$

$P = F$

$F = 215\ N$

P = Force due to ligaments on vertebrae

F = Force created by device to oppose Force P

$\text{Pressure} = \frac{F}{A}$ $\quad \frac{215\ N}{400 \times 10^{-6}\ m^2} = 537.5\ kPa = 78\ PSi$

$+\uparrow \sum F_y = N + F - F - mg$

$\sum F_y = 0$

$N = mg$