Inflatable Vertebral Distractor

BME 300/200

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Department of Biomedical Engineering

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Table of Contents

Abstract

When discs in the vertebrae degenerate and cause the patient pain, it is necessary to surgically remove these discs in order to alleviate the pain. This is done by neurosurgeons via spinal fusion surgery. In order to perform this surgery the vertebrae must be distracted to allow bone graft material to be inserted between these adjacent vertebrae. Surgeons have reported it can be difficult, cumbersome and risky to perform this distraction because of the current distractors available for use. These devices are invasive, bulky tools and/or come into minimal contact with the body. These characteristics have been shown to cause tissue damage, a need for a large incision site, and risk of fracturing the vertebrae. Our client, Dr. Nathaniel Brooks, desires a distractor that will eradicate these current issues. Addressing these issues, we have designed an inflatable distractor that will be inserted into the vertebral area through a surgical stylet. This is specifically designed in order to minimize the incision site as well as provide a larger, yielding contact surface. Once inserted, pressure will be applied via an air intake tube initially threaded through the stylet. A tactile feedback system will be incorporated into the device to allow for a constant reading of the pressure that can be altered at any time throughout surgery. A fabrication plan to build this device using 3D machining and injection molding techniques has been proposed.

Introduction

Problem Statement

There are over 200,000 spinal fusion surgeries performed in the United States each year [1]. During these procedures, surgeons attempt to make the smallest incisions as possible without compromising their ability to maneuver tools during the surgical process. Our client, Dr. Nathaniel Brooks, a neurosurgeon at the University of Wisconsin Hospital and Clinics, wishes to create a device that can be used to distract the vertebrae during lumbar intervertebral fusion. This device will expand the cavity in between the vertebrae allowing for a greater opening for surgeons to maneuver throughout. He requires a device that is inflatable, which will allow for much greater safety than current products. Due to its elasticity, inflatable distractor will not pose the risk of damaging bone or tissue in the disk cavity due to its flexibility. A pressure gauge will be used to inflate the device, and a tactile feedback system will be implemented to monitor and control how much pressure is being applied to the vertebrae at all times throughout the surgery.

Background

A normal spinal segment contains two vertebral bodies with an intervertebral disc in the middle, as well as two nerve roots that split off of the spinal cord [2]. Often times when lower back pain is an issue for a patient, it is because a problem persists with the intervertebral disc. "Intervertebral discs are pads of fibrocartilage that resist spinal compression while permitting limited movements" that also help evenly spread the load of the vertebral bodies [3]. These discs are prone to degeneration from the constant weight and movement that they support. This is a problem that becomes increasingly common as a person ages (Figure 1).

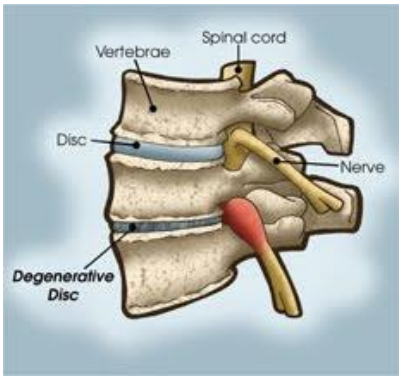

Figure 1 *A healthy intervertebral disc compared to one that has degenerated over time.*

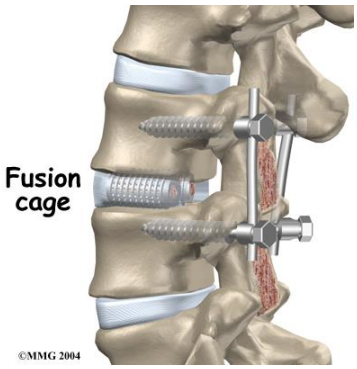

Figure 2 *Vertebral segment shown after intervertebral fusion was performed.*

Surgery is the preferred option to fix a degenerated disc. The surgery that Dr. Brooks and many other neurological surgeons perform to correct this ailment is called lumbar intervertebral fusion (Figure 2) [4]. The removal of bone and soft tissue is necessary at the beginning of this procedure in order to decompress the spinal cord and nerve roots near the degenerated disc. Screws are then placed into the vertebrae that are above and below the disc space. The disc space is entered through a trajectory below the nerve root, lateral to the spinal canal. Next the disc space is distracted to a maximum height of 16mm so that the degenerated disc material can be removed. A cage is then placed in this disc space and filled with bone graft, which allows fusion to take place with 6 to 12 weeks.

When removing the degenerated disc with current devices there is a high possibility of damaging surrounding tissues. The current products used by neurosurgeons are composed of stiff metals, which can fracture both the bone and cause tissue damage. In order to prevent any damage, our client desires a distractor that is inflatable and features a tactile feedback system so the pressure exerted on the bone or tissue will not be allowed to exceed a specific amount.

Existing Products

The two main products currently used are bulky, unyielding devices. This design characteristic necessitates a large incision site and restricts the area in which the surgeon may operate. These products also both apply axial forces via minimal contact surface areas, which makes vertebrae susceptible to fracture.

Paddle Distractor

The more primitive of these devices is the paddle distractor, which is a thin, oar-like tool, used by inserting the flat face perpendicular to the axis of the spine (Figure 3) [5]. The distractor is then rotated 90 degrees to distract the neighboring vertebrae from one another. Due to its small surface area and stainless steel design, this method poses a large risk of vertebral fracture as it places a large amount of pressure on a very small area of the bone. Considering that this device has to continually distract the vertebrae throughout the entire surgery, its bulkiness is cumbersome to work around.

Figure 3: *Paddle distractor*

Scissor-Jack Distractor

A second current product, the scissor-jack distractor, is inserted parallel to the incision made by the surgeon (Figure 4) [6]. Once placed between the vertebrae, the platforms on either side of the device separate axially to cause distraction. While this design creates a slightly larger surface area contacting the bones, the risk of fracture remains due to a still relatively small contact area and unyielding materials. The insertion mechanism of this design can be detached to increase the working space for the user; however, there is no method of providing tactile feedback to the user. Also, the edges are static, which makes it difficult to move the device after initial insertion.

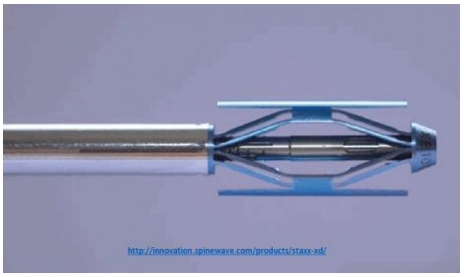

Figure 4: *Scissor-jack distractor*

Client Requirements

Device Requirements

There are numerous requirements that will help determine the success or failure of this product. After insertion, the device will need to withstand 431 N of compressive force in order

to distract the vertebrae the required amount [7]. This device will therefore need to deliver 1720 kPa (249 psi) of pressure on the vertebrae in order to distract them the necessary amount. This device will also have to meet specific safety requirements. This includes biocompatibility, which means the device will have to be passed by the FDA as a Class II Device [7] since it will be located *in vivo* during surgery. In order to make sure all components of the device are safe, it is recommended to fabricate with materials that have been used in implants and other surgical devices. The safety specifications also include yielding edges and optimal contact area in order to ensure that the pressure delivered to the bone does not cause fracturing of the vertebrae.

Size Requirements

Size is also a central focus in the function of this device. The distractor will be inserted into the anterior third of the disk space (Fig. 5), and therefore cannot exceed dimensions of 10 mm width, 25 mm depth, and 7 mm height upon insertion. When inflated, the depth and width must also not exceed these stated dimensions, and the height must not exceed 17 mm. The client has also specified that three main design features that we should consider. First, the device should have a tactile feedback system to allow the user to manually apply and retract pressure delivered to the spine as needed throughout surgery. Next, the client has requested a pressure gage that will allow the user to visually monitor the amount of pressure delivered to the patient. Lastly, it is important that the device allows for minor manipulation while inflated so that the user will be able to navigate surgical tools around the device.

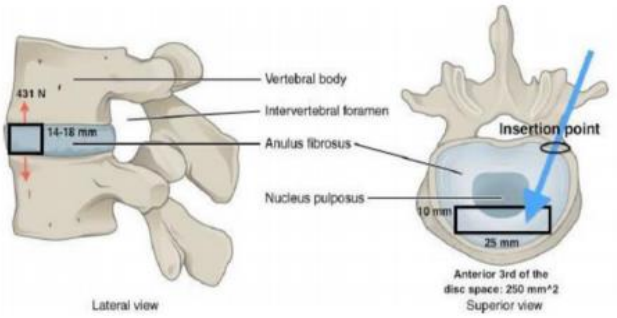

Figure 5*: Side and top view of device location in vivo and dimension requirements[2]*

Design Proposals

Design 1: Inflatable Reinforced Distractor

The first design features yielding caps on the top and bottom, where contact would be made with the vertebrae (Fig. 6). It also contains an inflatable cavity made up of an elastomeric lining and is reinforced with wire or fabric mesh at each rib junction.

Figure 6: *SolidWorks rendering of Inflatable Reinforced Distractor*

The mesh would span across the device to disallow equatorial inflation and would promote solely axial inflation. The outside of the device would be composed of polycarbonate material. The dimensions of this would be 24mm by 7 mm by 9.5mm in order to allow for optimal surface contact while not risking exceeding maximum dimensions. The maximum height of this device would not exceed 15.5 mm for the same reason.

Design 2: MatJack

This design alternative was inspired by the existing inflation technology used in a product called the MatJack. This product is used to jack loads of several tons using compressed air and a simple balloon and valve system (Fig. 7) [9]. The MatJack is composed of a polycarbonate material reinforced with steel. It shows significant inflation in the axial direction while maintaining its other dimensions. This design would incorporate similar systems found in the MatJack but on a smaller scale. The inflatable balloon component would be applying the distraction force and be comprised of a polycarbonate casing with aramid reinforcements to help maintain the shape. The dimensions upon insertion would be 7mm in width, 3mm in height, and 25mm in length (Fig. 8). After inflation inside of the disc space, the balloon would expand to maximum height of 16mm. An air valve will stem from one end of the balloon to act as an intake spot for air being administered by the surgeon through a pump. The hand pump administering the air must contain tactile feedback to let the surgeon know how much pressure is being applied. An insertion rod would be used to guide the balloon into the disc space but would be removed after suitable inflation is achieved with the tactile hand pump.

Figure 7: *Actual MatJack product in use*

Figure 8: *SolidWorks rendering of MatJack device*

Design 3: Accordion

This design alternative involves a system of balloons woven together in an accordion-like manner. The balloons would be made of a neoprene rubber material. Each balloon

component would be interconnected to allow air to flow throughout the system during inflation. They would be woven and stacked in an axial direction to ensure that there was preferential inflation in the desired direction in order to distract the disc (Fig. 9). The deflated dimensions would be 7mm in width, 7mm in height, and 25mm in length. The device would ultimately reach a maximum height of 16mm for full distraction. This design would also incorporate the same type of air valve intake, tactile hand pump, and insertion rod mentioned in the previous design alternative.

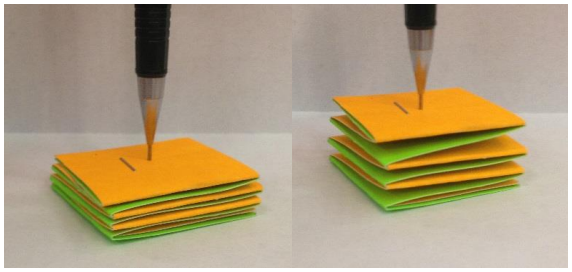

Figure 9: *Accordion device in various degrees of inflation*

Design Evaluation

After three preliminary designs were established, they were evaluated with a design matrix (Appendix B). The six factors considered were safety, axial inflation, ease of use, durability, feasibility, and size. These parameters were then weighted, with their total weights adding to 100.

Parameters

Because the device is to be used *In vivo* and can cause potential damage to the vertebrae and surrounding tissues, **safety** was of large importance. It was the most heavily weighted parameter in evaluating the design options, receiving a weight of 30. An excellent design would have a 100% probability of safety if used correctly.

Axial inflation was defined to be the amount that the device inflated in the vertical direction compared to how much it inflated equatorially. Due to the large emphasis the client placed on this design restriction, axial inflation was given a weight of 25. An excellent design would restrict all motion in the equatorial direction while still distracting to the maximum necessary height.

The only time the surgeon would come into direct contact with the device would be during insertion, so **ease of use** was defined as how simple the device would be to insert. Both size of the device and how often it could potentially tip over when inserted were taken into

consideration. This parameter was given a weight of 15, because if the device isn't used correctly it could affect the surgery and cause more damage to the vertebrae.

Durability, or how well the device could withstand the various pressures applied to it as well as the bodily fluids it would be exposed to, was also given a weight of 15. An excellent design would be able to withstand the pressures and environment for the maximum length of the surgery, which can reach 10 hours.

The ease of fabrication of the design, or **feasibility,** was defined as how simple it would be to manufacture given the client's budget and time constraints of the semester. While the definition of this constraint dealt with both cost and machining ability, the assumption was made that all three potential designs would be essentially the same cost, as they are manufactured from similar materials. This criterion was given a weight of 10, because all three designs would require difficult fabrication methods.

The final design constraint was **size,** which was only given a weight of 5. In order for a device to be deemed acceptable by the client, it would need to fit in the anterior third of the disk space, having dimensions of 10 mm width, 25 mm depth, and 7 mm height when deflated. All of the devices fit these restrictions, giving size the lowest ranking. An excellent device would compress to be significantly smaller than the given dimensions.

Design Critiques

After the establishment of the parameters, each design was evaluated on a scale of 1-5 for each of the parameters. Scores 1 through 5 corresponded to "poor", "fair", "good", "very good", and "excellent", respectively.

In the category of **safety**, the MatJack design received the highest score of a 5 because the design had no exterior reinforcement like the other two had. Therefore, the MatJack design would have the lowest probability of damaging the vertebrae. The Inflatable Reinforced Distractor, given a score of 3, has a wire/mesh material in the design, and if the device failed, these materials could cause damage. The Accordion was given a score of only 2 due to the material choice, neoprene rubber, which has a much lower compressive strength than polycarbonate, meaning it would be much more likely to fail than the other two designs.

The next category, **Axial Inflation,** was scored depending on the designs' ability to open up the disk cavity while reducing the space taken up by the distractor. The Inflatable Reinforced Distractor was given a perfect score of 5 because of the butyl rubber caps as well as the wire/mesh lining in this design. Both of these aspects would prevent the device from any

equatorial inflation. Both the MatJack and the Accordion were given scores of 4 because their designs risk slight equatorial expansion due to their more balloon-like materials.

For the category of **Ease of Use,** the MatJack received a score of 4 because of its size when inserted. It can be deflated to a height of only 3 mm, which could be inserted through the smallest incision compared to the other two devices. The Accordion received an average score of 3. While it would need to be inserted at its height of 7 mm, there would be no complications with insertion. A lower score of 2 was given to the Inflatable Reinforced Distractor. Due to the stiffness of the materials, it was deemed that this device would be prone to rotating 90^{o}(tipping over) if inserted incorrectly.

Durability was the devices' ability to withstand the *in vivo* environment during surgery. Both the MatJack and the Inflatable Reinforced Distractor are made of polycarbonate material, which has a high compressive strength of between 55-75 MPa [4.] The MatJack is also reinforced with a steel material. This gave the MatJack the highest ranking of 5 due to its great compressive strength and resistance to collapsing due to high pressures. The Inflatable Reinforced Distractor has a high compressive strength but does not have the steel reinforcement, so it was given a ranking of 3. The Accordion, made of neoprene rubber, only has a compressive strength of 10.3 MPa, which could easily fail under the high pressures. This caused this design to receive a lower score of 2.

Finally, the lowest weighted criterion was the **Size**. All of the designs fit the necessary dimensions for insertion into the anterior third of the disk space and therefore received a score of at least 3. The MatJack received a higher score due to its ability to deflate to an insertion height of only 3 mm. Both the Inflatable Reinforced Distractor and the Accordion do not have this range of deflation, and therefore received lower scores of 3.

The final scores for the inflatable reinforced distractor, the MatJack, and the accordion were 67, 90, and 57, respectively. The MatJack scored relatively high in all areas, making it the best possible design (Appendix).

Final Design

Although the MatJack design was ultimately chosen, it was determined to be unsatisfactory after further research and discussion with experts. The fabrication of a device that could remain air tight at such high pressures would be nearly impossible, and the stretching of a polycarbonate material around a steel material wasn't feasible for this class. A new design

and fabrication route were developed with the help of Professor Lih-Sheng Turng and his graduate students Jason McNulty and Tom Ellingham.

Design

The final design (Figure 10) consists of a hollow cylinder that will be inserted perpendicular to the vertebrae and inflated during surgery. An inner inflatable balloon will be reinforced equatorially with another material, restricting the device to only inflate out of the top and bottom of the cylinder (in the axial direction.) The cylinder will have an insertion height of 7 mm, and will be circular in shape with a diameter of 7 mm.

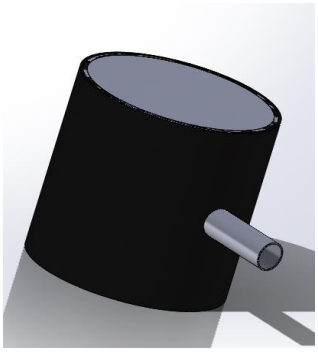

Figure 10*: SolidWorks image of final two-part design. TPU is grey (on top) and PEEK is black*

Materials

The inflatable inner portion of the device will be formed by Thermoplastic Polyurethane (TPU) Desmopan 9370 A, and is represented by the grey inner portion on the SolidWorks image (Figure 10). This specific TPU has an Ultimate Tensile Strength (UTS) of 25 MPa, suggesting that the material can withstand a force greater than 96 MN, which is significantly larger than the force caused by the vertebrae. While forces may vary in each patient, this UTS is more than sufficient to work in every patient. The TPU has an elongation of >300%, which is more than enough to inflate the device to the necessary distraction height of 14 – 17 mm. While the elastic modulus of TPU depends on the strain rate, its value is typically around 5 MPa [10.]

The equatorial reinforcement of the cylinder will be made of Polyether Ether Ketone (PEEK), and is seen in the black portion of the SolidWorks drawing. The PEEK to be used has a UTS of 100 MPa but an elongation at break of <30%. It has an elastic modulus of 3.76 GPa [11].

A third material, Polyvinyl Alcohol, which is a thermoplastic water-soluble, will be used in fabrication of the device but will not remain in the final device.

Fabrication

In order to construct the composite device that was designed, the only feasible option of fabrication is injection molding. Machine access was only available with the help of graduate students in the WID, but fabrication was unfortunately delayed past the deadline for this class. In place of a working prototype will be this outline of our work done to date as well as our fabrication plan moving forward will be presented.

Fabrication Proposal

Three sets of custom injection molds were designed with 3D modeling software (Solidworks 2014, Dassault Systemes)(Appendix C.) The first mold was designed in order to mold the internal cavity shape of our device. This mold will be used to fabricate a design-determined shape made out of PVOH, and thermoplastic, water-soluble material. It essentially will fabricate a solid 6 mm diameter x 6 mm height cylinder. The other two molds will fabricate the external shape of our device. The first set of these injection molds were designed to encompass the PVOH piece, proportionally enlarged from the first mold to allow for one mm of free space, symmetric in all dimensions, between each outer surface tangent plane of the PVOH piece and its parallel tangent plane on the second set of molds. This will allow us to inject the thermoplastic urethane into the mold so that when it cools the TPU will completely over mold the PVOH piece with one mm thickness in every dimension. The only place that this PVOH will be fixated in the machine is where the pressure intake comes in. There will be a one mm diameter needle that inserts into the center of the PVOH piece. This will allow for the TPU to over mold the entirety of the piece with the exception of where we have designed for air intake and will also give us an added dimension for the pressure spigot. This will allow for a 1 mm insertion for the pressure intake. On our pressure output system we will incorporate a 2 mm diameter ball pump needle (one mm thicker than the elastic TPU hole) to allow for a proper seal as air is pumped in. The last set of injection molds will then again be enlarged proportionately by the same process in order to allow the PEEK to be injected to over mold the TPU with a 1 mm thickness. The only difference in the way we fixate the now TPU/PVOH piece before injection molding is that our mold will also be in contact with the top and bottom circular surfaces of the TPU/PVOH piece to prohibit the mold from covering these top and bottom of our device. This will allow for TPU exposure in these areas. These two surfaces are the areas that will contact the vertebrae so it is necessary that they are exposed and able to inflate in the axial direction. The end result will then be that the PEEK solely restricts the TPU from inflating in the equatorial directions.

These SolidWorks designs will be used to fabricate the injection molds from 6061 aluminum with a computer numerical control (CNC) vertical machining center (MiniMill 2, Haas) programmed with computer-aided design/manufacturing (CAD/ CAM) software (MasterCAM X7, CNC Software, Inc.). All injection molding will then be performed on a 38 ton Arburg Allrounder 270A machine with an 18 mm injection unit. From the process described above, the result of injection molding will be the final shape of our device, but will be made up of the three

materials mentioned above as well. The innermost piece will be the solid PVOH from the first mold. The intermediate shape will be the TPU, which is one mm thick and will symmetrically encompass the PVOH piece. The outermost shape will be the solid PEEK that acts to encase the TPU in the equatorial direction. Once fabricated, water will be injected through the pressure intake hole in order to dissolve out the water-soluble PVOH. This will leave the final product of the elastic TPU encased by PEEK[12.]

Testing

Proof of Concept

As a proof of concept for the PEEK outer shell, a scale design was modeled for testing. It included a PET outer shell to represent the PEEK material in the original design and a standard silicon balloon to represent the TPU portion of our original design. PET was chosen because it has similar properties as PEEK and is readily available. The balloon is a rough model of the elasticity of the TPU portion of the actual design. The experiment consisted of inflating the inner balloon to different axial inflation heights while encased in the PET outer shell and measuring the equatorial inflation. After comparing the results of the measurements of the two types of inflations it was calculated that there was, on average, 39 times more axial inflation than equatorial inflation (Appendix C.) This provides some evidence for proof of our outer shell and inner bladder design, in that, the PEEK will provide preferential axial inflation when used in a practical application and restrict the TPU from inflating into the disc space. While this proof of concept was done on a 10x scale (cm compared to mm of actual design), it is believed that it can accurately reflect the degree of inflation in each direction.

Figure 11: *Model of design using balloon and PET casing*

SolidWorks Testing

A SolidWorks test was conducted to model the actual stresses and pressures the device would endure during a typical surgical procedure. 431 N compressive forces were imposed on the top and bottom of the device to model the distraction force needed to separate the discs themselves. Inter-vessel pressure was modeled by incorporating outwards pressure of 1720 kPa on all faces of the TPU inner-bladder. The results of this test showed that the device would inflate as expected with the incorporation of the PEEK outer shell. The test also showed the maximum displacement at the top and bottom of the TPU while there was insignificant

equatorial displacement. There was a 3.78mm displacement at both the top and bottom at these testing conditions allowing for a total distraction height of 7.56mm. It can be seen that greatest distraction occurred at the top and bottom of the device(shown in red) while the sides of the device, modeled to be reinforced with PEEK, didn't allow for any distraction(shown in blue.) It can be concluded that PEEK will be a sufficient material to restrict the equatorial inflation while still allowing the TPU to distract to necessary heights.

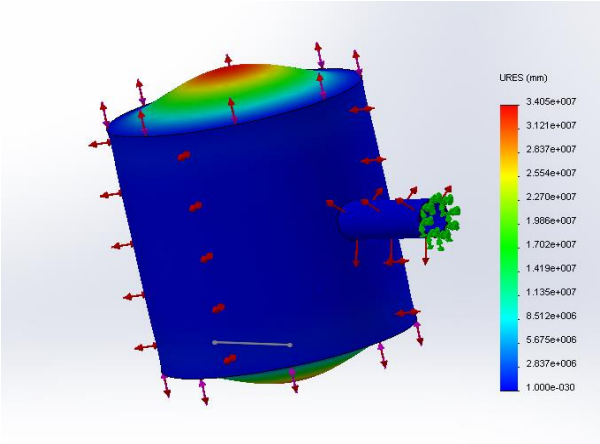

Figure 12: *Displacement gradient after forces and pressures were applied.*

Calculations

To determine if TPU and PEEK would be sufficient materials for the necessary distractions, a few calculations were run. The pressure required to distract the vertebrae and separate the device to its maximum height of 17 mm was given to be 1720 kPa. To determine what elastic modulus would be necessary to complete this distraction, the equation for hoop stress was implemented. Hoop stress, Θ_{hoop}, is the stress is equal to the force put on the device, P, times the radius r, divided by the thickness, t[Equation 1.]

$$\Theta = Pr/t \qquad \text{[Equation 1]}$$

Hoop stress relates to the equatorial expansion of the device. For the PEEK, we want this expansion to be as close to zero as possible. Using the pressure of 1720 kPa, radius of 3.5 mm, and thickness of 1 mm, it can be calculated that the hoop stress is 6.02 MPa. PEEK, as previously stated, has an elastic modulus, E , of 3.76 GPa. Knowing the hoop stress and elastic modulus, the equation for elastic modulus can be used to find strain, ε, of the PEEK.

$$\varepsilon = \Theta/E \qquad \text{[Equation 2]}$$

Using Equation 2, the strain of PEEK at maximum distraction is found to be .0016. Strain relates the change in length of the device to the initial device, and using the initial length to be 7 mm, the change in length of the PEEK is only .0112 mm when the maximum necessary pressure is applied. This shows the chosen material would be very good at restricting equatorial inflation, while still allowing the necessary pressures to inflate the TPU to the target distraction height.

Another calculation was run to determine the factor of safety at the failure of the device. The first part of the device to fail would be the TPU due to its lesser tensile strength

than PEEK. The TPU has ultimate tensile stress of 25 MPa, and using again the spherical stress equation (same equation for hoop stress), the TPU would fail at a pressure of 143 GPa. However, a pressure of only 1720 kPa is required for distraction, giving the device a factor of safety of 83 with respect to failure due to tensile stress.

Biocompatibility

There was no testing done to prove biocompatibility of the chosen materials. Both TPU and PEEK are already widely used in a variety of biomedical applications, and therefore require no testing to support their use *in vivo.* TPU is commonly used in many variants of medical tubing as well as common catheters [10.] PEEK is commonly used to build spinal cages that are permanently left in the body [11.]

Budget

Spent

The client set a budget of $1000 for the semesters work. Original fabrication plans required two materials, Kevlar and silicone rubber. A one-yard roll of Kevlar from FibreGlast was ordered, costing $54.95. The silicone was ordered from Grainger, product Rubber Sheet 50 A, .635 cm thick, and 30.48 cm in length, and cost $99.65. The silicone remains unaltered and is in the process of being returned. However, the Kevlar was manipulated to determine how well it could reinforce equatorial inflation, and therefore can't be returned. In total, only $154 was spent on this semester's work.

Future Budget

Future material costs for the proposed fabrication technique are comprised of the aluminum molds, the pressure system, and the material pellets for the thermoplastic polyurethane, polyether ether ketone, and the polyvinyl alcohol. Ideally, the pressure system will be a hand operated bike pump, which can produce pressures above 1720 kPa, which corresponds to around 300 PSI. While few bike pumps can provide this pressure range, there are some available which cost around $300-400. The rest of the materials are available for use at the Wisconsin Institute for Discovery and are owned by Professor Lih-Sheng Turng. While exact costs to purchase these materials from him would need to be determined, it is estimated that each aluminum mold would cost in the range of $50-100, totaling to be $150-300. Very little of the three materials used in the injection molding process would be needed, and could likely be

purchased for very little cost. It is estimated that fabrication of the complete device would cost between $700 and $900, which falls below the client's original budget of $1,000.

Future Work

Fabrication

The first step in continuing this project is to begin fabrication of the device. All necessary materials and resources are available at the Wisconsin Institute of Discovery. However, in order to use the injection molding machine and other necessary machinery, assistance would be required. The two graduate students of Professor Turng, Tom Ellingham and Jason McNulty, have previously stated that they would be willing to help with fabrication and use of the machine. SolidWorks renderings of each set of molds have been completed, and in order to fabricate would simply need to be run through the previously stated software.

Testing

After fabrication, the device would need to be thoroughly tested to determine if it was fit for use during surgery. Due to the fact that each patient provides such different conditions for the device, a variety of tests would need to be run. The first test would simulate insertion of the device in order to determine how often it would potentially tip over in the body. An unsafe device would fall over a significant number of times. A second test would be measuring equatorial versus axial inflation of the TPU at the top and bottom of the cylinder, just like was modeled with PET and a balloon.

Production

f the device passed all significant tests and met all of the requirements, the next step would be gaining FDA approval to use it as a Class II Device throughout intervertebral Lumbar Fusion Surgery. If approval is granted, a mass production protocol of the device would be put into action.

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Appendices

Appendix A: Product Design Specifications

Inflatable Vertebral Distractor

Project Design Specifications

12/8/2014

Group Members: Bridget Smith, Gabby Laures, Michael Lohr, Ryan Serbin, Christina Sorenson

Client: Dr. Nathaniel Brooks

Advisor: Bill Murphy

Function: During spinal surgery, the intervertebral disk may be removed. In order to do so, the adjacent vertebrae need to be distracted so that the spine can maintain its alignment. The current tools in use are difficult to maneuver and can cause damage to the vertebrae. The goal of this project is to design a device that will inflate and distract the vertebrae while also being minimally invasive and made of a material that will not fracture the vertebrae.

Client Requirements: *The client's specifications are as follows:*

- *An inflatable device that can be inserted into the disk space and be used to distract vertebrae during collapsed disc spinal surgery*
- *A system that can apply and retract at least 1720 kPa of pressure during surgery as needed.*
- *A component that measures pressure inside the device applied to patient's vertebrae.*
- *A device with yielding edges that will not pose a risk of fracturing the vertebral body, which has a yield stress of 2.4 MPa.*
- *A device that is can be inserted through the main insertion site, requiring no extra incisions.*
- *A device that will obstruct the removal of the damaged disk.*

1. ***Physical and Operational Characteristics***
2. ***Performance Requirements:*** *The device is to be used during spinal surgery to separate the two vertebrae in the lumbar spine. It will be used once and then will be disposed of. It will*

be subjected to forces caused by the vertebrae of up to 431 N (96.9 lb.) In order to distract the vertebrae, the device will need to generate at least 1720 kPa (249 psi) of pressure.

3. ***Safety:*** *The device is to be used inside the human body so it will need to be biocompatible. However, the will not permanently be left inside the body. It should not have any sharp edges that could damage the vertebrae or cause any other pain to the patient. The area of contact between bone and device should be as great as possible, which will allow the vertebrae to dissipate the applied force and prevent bone damage. There is no target surface area as it is too difficult to provide a number due to the large variety between each patient.*
4. ***Accuracy and Reliability:*** *The device will be used once. However, it should include a tactile feedback system that will control the pressure that is applied to the patient. The device will need to open axially in one direction. It will need to fit in the 36 x 36 mm (1.42 x 1.42 in) cavity.*
5. ***Life in Service:*** *The product is to be used for one surgical spinal procedure, which may last up to ten hours.*
6. ***Shelf Life:*** *The inflatable component of the device will need to be replaced if there is a prolonged shelf time. However, the reusable components will need to have a shelf life of over one year.*
7. ***Operating Environment:*** *The device will be exposed to various bodily fluids, forces applied by the user, and forces up to 431 N (96.9 lb) caused by the distraction.*
8. ***Ergonomics:*** *The device should most importantly not cause any harm to the patient as well as be easy to maneuver into the small spinal cavities.*
9. ***Size:*** *The project should have a size no greater than 10 x 25 mm (0.394 x 0.984 in) so that it may fit in ⅓ most anterior position in the vertebrae.*
10. ***Weight:*** *The weight of all the components of the device combined should not exceed five pounds as it is to be used during surgery and must not cause any ergonomic problems.*
11. ***Materials:*** *This product will be temporarily inserted into the body during surgery. Biocompatibility is necessary for the parts that come into contact with the patient. Materials should be used that are commonly used in other implant and biomedical applications. The product should provide a smooth, non-slip grip that allows for precise control of the device. The materials also cannot chip or flake so that pieces are left behind inside the body.*

12. ***Aesthetics, Appearance and Finish:*** *The final product should be aesthetically pleasing in a way that it does not hinder functionality.*

13. ***Production Characteristics***
    a. ***Quantity:*** *One unit will be constructed.*
    b. ***Target Product Cost:*** *The targeted cost for this product is <$1000*
14. ***Miscellaneous***

    a. Standards and Specifications: *The device has to meet requirements to comply with the relevant FDA regulations. Specifically, the device is entering the body temporarily and therefore needs to be cleared by the FDA as a Class II device.*

    b. Patient-Related Concerns: *Patient concerns include reliability of device function (accurate pressure gauge, sealed air intake, etc.), sterilization, allergies, severity and location of injury, and overall patient safety.*

    c. Competition*: There are two popular devices that are on the market currently: a mechanical vertebrae distractor and a simple wedge. Both of these devices require force applied by the user to distract the vertebrae, and both devices contain hard edges that apply forces that could cause vertebrae to fracture or fail while in use.*

Appendix B: Design Matrix

Criteria	Weight	Inflatable Reinforced Distractor		MatJack		Accordion	
Safety	30	3	18	5	30	2	12
Axial Inflation	25	5	25	4	20	4	20
Ease of Use	15	3	9	4	12	3	9
Durability	15	3	6	5	15	3	9
Feasibility	10	3	6	4	8	2	4
Size	5	3	3	5	5	3	3
Total	100	67		**90**		57	

Table 1: *Design Matrix*

Appendix C: SolidWorks Molds

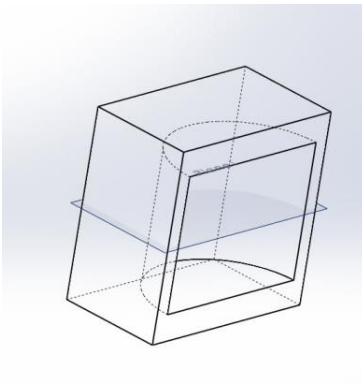

Figure 13: *Polyvinyl Alcohol left mold.*

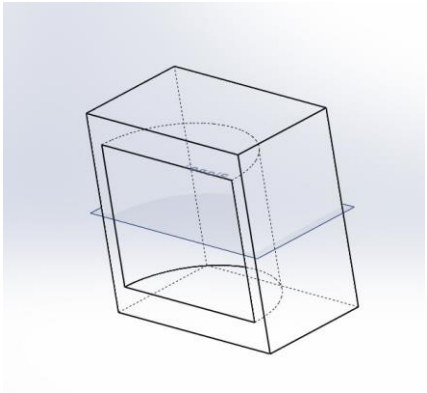

Figure 14: *Polyvinyl Alcohol right mold.*

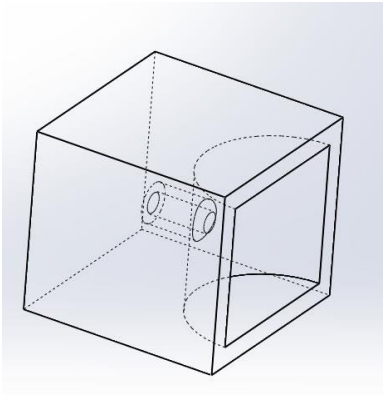

Figure 15: *TPU left mold.*

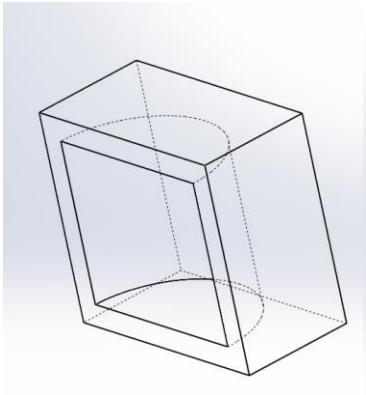

Figure 16: *TPU right mold.*

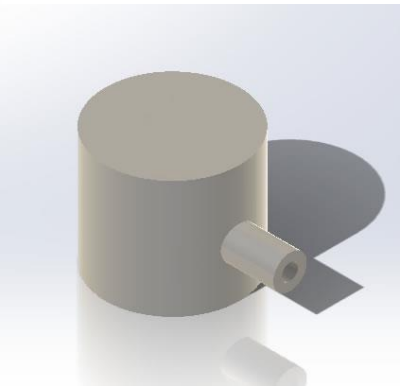

Figure 17: *TPU product formed from figure 15 and 16 molds.*

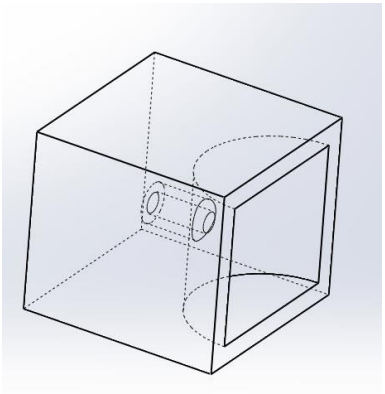

Figure 18: *PEEK left mold. Dimensions Of previous mold increased by 1mm.*

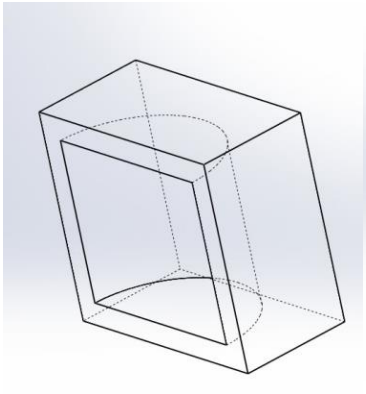

Figure 19: *PEEK right mold.*

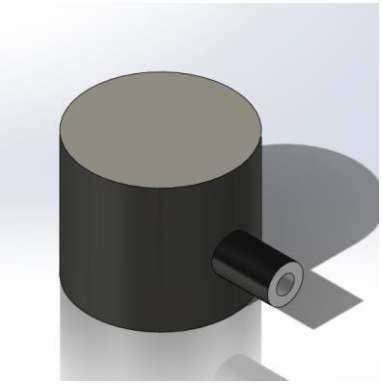

Figure 20: *PEEK formed from figure 19 and 20 molds. Shown in black.*

Appendix D: Testing

Height(cm)	Axial Distraction(cm)	Equatorial Radial Expansion(cm)
7	0	0
8	1	.04
9	2	.07
10	3	.08
11	4	.11
12	5	.13
13	6	.16
14	7	.18

Table 2: *Equatorial Radial Expansion due to Axial Distraction in balloon reinforced with PET*