Inflatabal Vertebral Distractor

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Abstract

When discs in the vertebrae degenerate, it is necessary to remove them in a minimally invasive surgery. A current issue with this surgery is the tools used to perform it. Bulky tools and minimal surface area contact with the body can cause both tissue damage as well as a need for larger incisions in the spine. Our client, Dr. Nathaniel Brooks, wants us to design a distractor that will reduce the risk of tissue damage as well as take up less of the surgeon's space throughout surgery. He proposes an inflatable distractor that will be inserted through a stilette, attached to a pressure system that will inflate the distractor once it has been inserted into the anterior disk space. 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.

Problem Statement

In spinal surgeries, there is difficulty in maneuvering the tools around while creating the smallest incision site possible. Our client, Dr. Brooks, a neurosurgeon, 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. An inflatable distractor will not have a high risk of damaging both bone and tissue in the disk cavity due to its flexibility. A pressure gage will be used to inflate the device along with a tactile feedback system to monitor and control how much pressure is being applied to the vertebrae at all times throughout surgery.

Background

A normal spinal segment contains two vertebral bodies with an intervertebral in the middle, as well as two nerve roots that split off of the spinal cord [1]. 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 [2]. These discs are prone to degeneration from the constant weight and movement that they support, a problem that becomes increasingly common as a person ages (Figure 1).

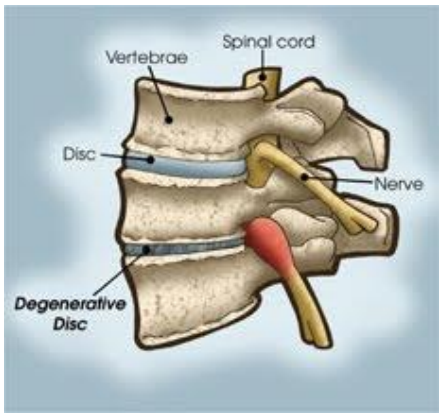

Figure 1 *A healthy intervertebral disc compared to one that has degenerated over time.*

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, which is a minimally invasive surgery (Figure 2) [3]. 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 vertebral 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.

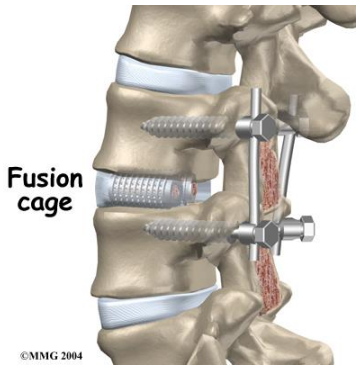

Figure 2 *Vertebral segment shown after intervertebral fusion was performed.*

When removing the degenerated disc, 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 as well as cause tissue damage. In order to prevent any damage, our client desires a distractor that is inflatable as well as that contains a tactile feedback system so the pressure exerted on the bone or tissue will not be allowed to exceed a specific amount.

Client Requirements

There are numerous requirements that this device must follow. After insertion, the device will need to withstand 421 N of compressive force that will be applied to it from the vertebrae. It will also need to deliver 1720 kPa (249 psi) of pressure to the vertebrae in order to distract them apart by the necessary amount of 4 mm. The 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 since it will be located in vivo during surgery. The safety specifications also include both 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 is also a central focus in the function of this device. The distractor will be inserted into the anterior third of the disk space, 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 16mm. The client has also specified that he wants three main design features. First, the device is to have a tactile feedback system in order for the user to manually apply and retract pressure delivered to the spine. Next, the client has requested a pressure gauge that will allow the user to visually monitor the amount of pressure delivered to the patient. Lastly, the client has specified that the device will need to be able to allow for minor manipulation while the device is inflated so that the user will be able to move surgical tools around the device.

Existing Products

There are currently many vertebral distraction tools on the market that perform their job sufficiently but are not ideal for multiple reasons. Current products are both too bulky,

restricting the area in which the surgeon may operate, as well as create too much pressure on the vertebrae, making them susceptible to damage.

Paddle Distractor

The simplest of these designs is the paddle distractor - a thin, oar-like device used by inserting the flat face perpendicular to the axis of the spine(Figure 3) [4.] The distractor is then rotated 90 degrees to distract the neighboring vertebrae from one another. Due to it's 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. The paddle distractor is also hard to work around for the surgeon, as the entire device must remain in the patient for the duration of its use.

Figure 3: *Paddle distractor*

Scizzor-Jack Distractor

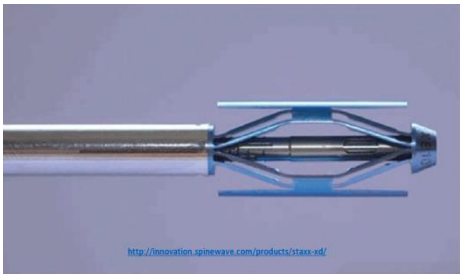

Figure 4: *Scissor jack distractor*

The scissor-jack system, a second design, is inserted parallel to the incision made by the surgeon(Figure 4) [5.] 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 relatively high. 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. The edges are also static making it difficult to move the device after initial insertion.

Design 1: Inflatable Reinforced Distractor

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

Figure 5: *Solidworks rendering of Inflatable Reinforced Distractor*

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[7.] 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. 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 as one of the design criteria. 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 6: *Actual MatJack product in use*

Figure 7: *SolidWorks rendering of MatJack device*

Design 3: Accordion

This design alternative involves a system of balloon woven together. 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. 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 8: *Accordion device in various degrees of inflation*

Design Evaluation

The final design was determined by evaluation using a design matrix. The criteria considered were, in order of importance, safety, axial inflation, ease of use, durability, feasibility, and size. Table 1 displays the matrix with criteria, the weight of each criterion, and the points scored by each design. The criterions were assigned a weight depending on how important it was deemed to the selection of the final design. Each design scored between one and five for each criterion, which was then scaled to the weight. The maximum possible score for any design was 100 points.

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	2	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 Evaluation Matrix. Displays the three designs and how they ranked in terms of the selected criteria. The MatJack design scored the highest and was selected as the final design.*

The design matrix was an essential part of the determination of the final design. The minimization of the device to cause any tissue or bone damage throughout surgery (safety) was the most important criteria for the client and was given a weight of 30. For this specific criterion, the MatJack design received the highest ranking. All of the devices would have equal surface area contact with the vertebrae due to their same size upon expansion. However, the inflatable reinforced distractor is compromised of a wire/mesh material. If the device were to fail, these materials could greatly damage the vertebrae. The accordion was given the lowest weight due to its material, neoprene rubber, having a much lower compressive strength than polycarbonate, meaning it would be much more likely to fail.

The second highest weighted criterion was the degree to which the device would only inflate axially compared to equatorially. The client's desires for this product are to open up the disk cavity while reducing the space taken up by the distractor. An ideal product would only inflate axially to separate the vertebrae while not interfering with the surgeon's maneuverability. The inflatable reinforced distractor received the highest score because of the butyl rubber caps as well as the wire/mesh lining would prevent the device from any equatorial inflation. Both the MatJack and accordion received lower scores, as they could allow for slight inflation equatorially. The MatJack is somewhat balloon-like, which will cause for slight inflation in all directions.

The next highest ranked criteria were ease of use as well as durability, both with the same weight of 15. Ease of use was deemed to be how simple the device would be to insert. The MatJack received the highest device 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. The inflatable reinforced distractor received the lowest scores. Due to the stiffness of the materials, it was

deemed that this device could be prone to rotating 90 degrees (tipping over) if inserted incorrectly.

The durability of the device was deemed to be how well the device could withstand the various pressures applied to it. Both the MatJack and the inflatable reinforced distractor are made of polycarbonate material, which has an incredibly 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, due to its great compressive strength and resistance to collapsing due to pressure. The accordion, made of a neoprene rubber only has a compressive strength of 10.3 mPa. This could easily fail under the great pressure caused by the vertebrae, which gave it its low ranking for durability.

Finally, the lowest weighted criterion was the size. In order for a device to be acceptable, 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 these devices do have these dimensions and therefore received a score of at least 3. The MatJack received a higher score due to its ability to deflate to a 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.

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.

Future Work

The remainder of the semester will be focused on refining the MatJack design. The first step would be to create the pressure system that the client desires, a pressure gage with a tactile feedback system. A pressure sensor would be needed to monitor pressure of the device, and a microcontroller may need to be programmed to automatically alter the pressure of the device. A proof of concept would be appropriate for this to make sure it is feasible. Next, material and fabrication costs would need to be researched. Due to the small dimensions of this device, it may be realistic to determine that such a device will not be produced this semester. Custom creation of a device like this can cost thousands of dollars. A proof of concept of a larger balloon, similar to the MatJack, would be a more realistic goal to create.

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Appendix A: Product Design Specifications

Inflatable Vertebral Distractor

Client: Dr. Nathaniel Brooks

Advisor: Professor Bill Murphy

Team: Bridget Smith – Leader
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Ryan Serbin – BWIG
Christina Sorenson - BPAG

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 used to distract vertebrae during collapsed disc spinal surgery, a process that can last between two and ten hours.
- A system that can apply and retract 1720 kPa pressure during surgery as needed.
- A component that measures pressure applied to patient's vertebrae
- A device with yielding edges that will not pose a risk of fracturing the vertebrae when in use.
- A device that can be inserted via the main incision site through an opening of 7 mm by 10 mm.
- A device that in unobtrusive throughout surgery, remaining in the anterior 1/3 of the disk space as to not restrict surgeons workspace.

1. **Physical and Operational Characteristics**
    a. **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.
    b. **Safety:** The device is to be used inside the human body so it will need to be biocompatible. However, the device is not meant to be left inside the body permanently. It should not have any sharp edges that could damage the vertebrae or cause any other pain to the patient. There should be a large

surface area, preferable that of the total anterior 1/3 of the disk space, that will make contact with the vertebrae to dissipate the applied force and prevent bone damage. The surface area should aim to target 70 mm^2.

c. **Accuracy and Reliability:** The device is meant to 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.
d. **Life in Service:** The product is to be used for one surgical spinal procedure which may last up to ten hours.
e. **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 long shelf life.
f. **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.
g. **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.
h. **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.
i. **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.
j. **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. It will have to be approved by the FDA as a Class II Device. 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.
k. **Aesthetics, Appearance and Finish:** The final product should be aesthetically pleasing in a way that it does not hinder functionality.

2. Production Characteristics

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

3. 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 risk fracturing the vertebrae while in use.