Inflatable Vertebral Distractor

Mid Semester Report

October 7, 2015

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Table of Contents

Abstract

Problem Statement

Background

Current Designs

Design Requirements

Proposed Designs

Design Matrix

Future Work

Abstract

Many spinal surgeries are performed each year for a variety of different spinal problems. There is a need for a device to safely and effectively distract the human spine during spinal surgery to enable the surgeon to complete the desired procedure. Current devices are too large and can cause harm to the patient. Our client, Dr. Nathaniel Brooks wants a distraction device that is less invasive and safer for the patient. The distraction device should not damage the soft tissue or bone of the spine, and should also not inhibit the surgeon in any way with size or space occupancy. To solve this problem, we have designed a flexible, inflatable distraction device that will distract the vertebrae while protecting the various components within the spinal cavity.

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. 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 back 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. [1]

When these problems occur, the best solution is surgery. Our device will be implemented in the beginning of surgeries. 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.

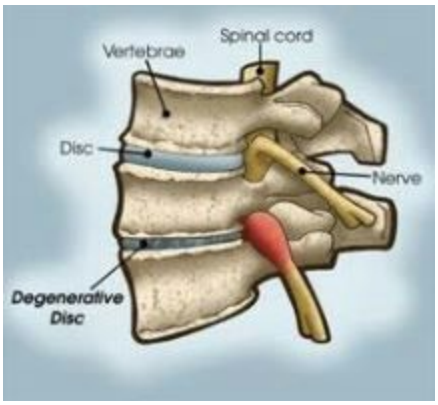


Figure: 1 A healthy intervertebral disc compared to one that has degenerated over time.

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.

Paddle Distractor

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. 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.

Scissor Jack

Another distraction device is the jack distractor. 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.

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. 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.

Design Requirements

Dr. Nathaniel Brooks has requested that we design and fabricate a user-friendly surgical tool to be used during spinal distraction surgery. There are three main design criteria that our device should account for: effectiveness, ease of use during surgery, 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, the device should apply force in one axial direction. Unidirectional expansion will also prevent unnecessary spatial occupation of the device. Sufficient and reliable distraction of the spine is vital to successful removal of the vertebral disc. Upon request, the insertion method should be minimally invasive and removable after distraction to allow the surgeon greater visibility and more room for disc removal.

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 the anterior region of disc space. 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. This will also decrease risk of bone fracture. In regard to patient safety, the device must be biocompatible.

Proposed Designs

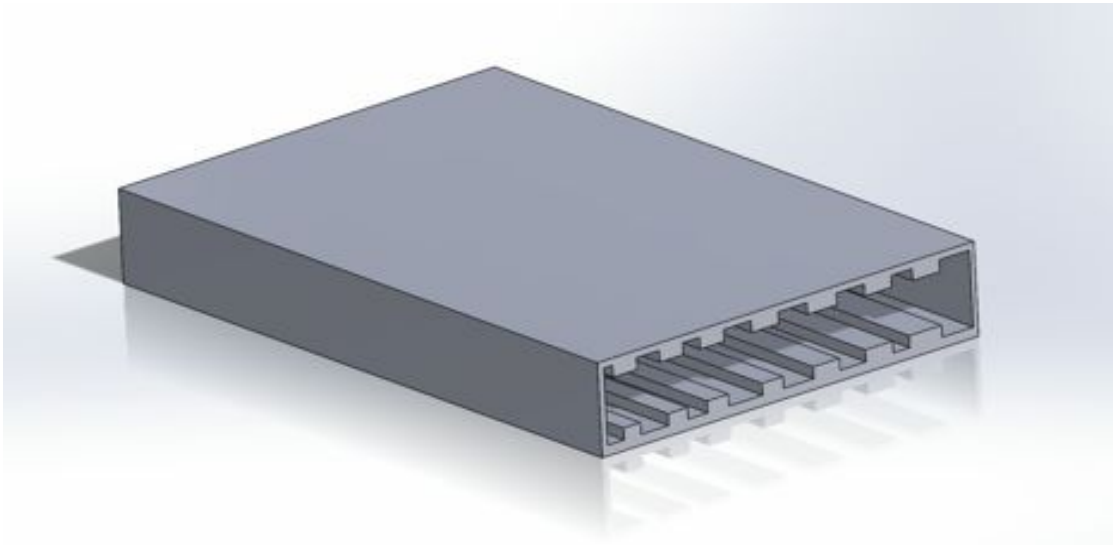
<u>Design 1: Balloon</u>

The first design’s structure was based off of an angioplasty balloon. 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 weight of the vertebral column. 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 vertical direction along the vertebra, but also in the horizontal direction due to bulging. If the device expanded laterally to the adjacent spinal nerve root with enough force it may damage the spinal cord and cause leg paralysis in our patient. With safety one of our top concerns we 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 UHMWPE was added. This framework lines the top and bottom faces of the prism to ensure the device keeps its prismal shape without bulging horizontally. 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 vertical 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 our 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 to difficult to manufacture while also increasing the danger to the patient.



Design 3: Plated Prism

Our final 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. Going into our final design we knew the device needed to have structure without adding extra danger to the patient. Therefore we incorporated 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.

Final Design

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

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 we choose. 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, we are planning on hand pouring silicone in a mold. 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.

Future Work

Now that we have chosen a final design we have a lot of work to do in the future. The first order of business in the future is to fabricate our design. This would require us making an exact solidworks of our idea and then creating the solidworks of a feasible mold that can be 3D printed in the student shop. In addition to making the mold we need to acquire the silicone we need. Once we have both the silicone and the mold we hand pour the silicone in the mold and cure it. Once curing is done we remove any excess material and then have a prototype. We can make as many prototypes as our silicone supply allows. Once we have the inflatable distractor prototype we then decide what method to inflate it with. Once we decide between a liquid or air inflation method we can test the device. For preliminary testing we can determine if the distractor inflates the needed amount and whether the necessary distraction force can be reached. Eventually we will need to create a testing method to simulate a lumbar distraction. In these later tests we should make sure that using a jamshidi needle as a delivery mechanism works and also ensure that once inflated the device can be deflated and removed safely. Throughout this entire process we will be adjusting our design as needed.

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