Vertebral Body Distraction Device

Final Report
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Abstract

There are approximately 600,000 spinal surgeries performed each year in the United States for a variety of spinal issues. There is a need for a device to safely and effectively distract the lumbar portion of the spine during these spinal surgeries to enable the surgeon to complete the desired procedure with adequate room in the spinal cavity. The device should be unobtrusive to the surgeon and avoid damage to the fragile vertebral bones and surrounding soft tissue. Two hydraulically inflatable prototypes have been designed and fabricated to solve this problem: an inflating bladder encased in a padded rigid exterior and an unfolding bladder. Both will maintain vertebral separation while conforming to and protecting various components of the spinal cavity. The designs were tested against a 143 N (32.2 lb) compressive force to successfully achieve a 4 mm (0.157 in) distraction distance.

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Background

Client Description and Problem Motivation

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 patients with a variety of spinal ailments. One of the most common spinal procedures performed is disc removal surgery where a surgeon removes the disc entirely. Reasons for this procedure include disc deterioration, collapsed discs, herniated discs, or other disc problems [1] (See Figure 1). 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.

Figure 1: Healthy vs. Collapsed Disc. A healthy spine, pictured on the left has all discs intact. In comparison, disc generation on the right leads to vertebral bone-to-bone contact and nerve pinching [2].

In order to perform disc removal and alleviate this pain, the surgeon must first gain access between the vertebral bodies to extract the remaining disc material, for which spinal distraction is required. Distraction is defined as forced separation of two objects and is commonly used in collapsed joints [3]. This separation force alleviates pressure, helps with alignment, and provides surgeons with more room to work during surgery. One issue with current distraction methods is that the distractors are quite rigid and do not conform to the floor and ceiling of the vertebral disc space. This causes extreme point pressures on the fragile spine and ultimately leads to spinal fractures [4].

Dr. Brooks has requested an expandable distraction device that would address the issues of current devices and provide optimal distraction. The goal of this project is to design and fabricate a new vertebral body distraction device for the lumbar portion of the spine that can be easily manipulated and will not cause spinal fractures.

Current Devices

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

The paddle distractor, a common distraction tool found in hospitals, is a simple, oar-shaped instrument made of stainless-steel (See Figure 2). 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. The stainless-steel material and small area of contact with the vertebral body can cause non-trivial spinal

Figure 2: Paddle Distractor. The Paddle Distractor separates the vertebrae by parallel insertion and then forcing a 90 degree turn to push the bodies apart [5].

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.

Another distraction device is the jack distractor (See Figure 3). 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 components can be separated, allowing the surgeon more room to operate and the insertion portion to be sterilized post-surgery. 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.

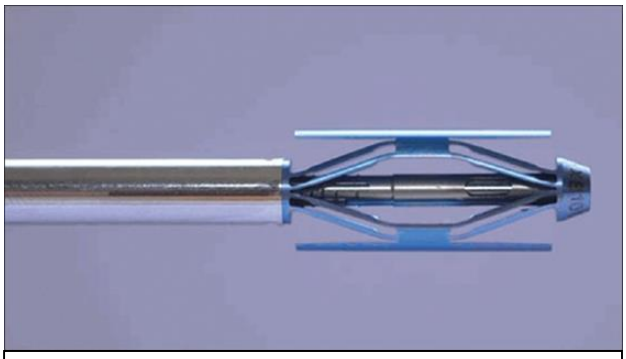


Figure 3: Jack Distractor. The Jack Distractor distracts the spine by mechanically expanding two parallel [6].

Figure 4: Spine Wave StaXx. The Spine Wabe StaXx uses 1 mm polymer sheets stacked in series to distract the spine [7].

A more recent device used in spinal distraction is the Spine Wave StaXx (See Figure 4). 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 [7]. It limits bone fracture more so than the paddle and jack distractors due to its increased surface area contact with the vertebral body and small (1 mm) increments of expansion. However, the insertion mechanism is bulky and its size limits the surgeon's ability to maneuver the device even though it is detachable from the insertion rod.

Patents

After an extensive search of existing patents, three are deemed most relevant to the desired device. The first patent, CA2583913, concerns the idea of a catheter with multiple balloons with one or many inflation lumens [8]. The idea of multiple balloons is one that could be implemented in a novel distraction device. The existing patent has not been prototyped, but consists of a blade and a predilation balloon as a method for vascular occlusion. This patent provides applicable information if the developing design requires multiple balloons for spinal distraction.

Another patent, EP0457456, is for a multiple layer high strength balloon for a dilatation catheter [9]. It includes a balloon with multiple layers to make the shape of thin-cone necks at both ends and a reinforced cylindrical portion in the middle. Since the design may include a balloon of a specific shape and strength

the method of fabrication as well as balloon reinforcement to create a stronger balloon described in this patent are relevant.

A final relevant patent is for a cervical distraction design, US9348979 [10]. This patented method is a procedure for treating cervical foraminal stenosis. The method consists of finding a nerve root, locating a facet joint, guiding an implant in a non-expanding state to location of interest, and then expanding the implant comprised of inelastic upper and lower walls to provide a distraction force. This patent essentially describes what the client is looking for, but lacks specific details needed for functionality. Therefore, this project aims to incorporate ideas from all of these patents to create a working prototype with functional distraction components.

Design Requirements

Dr. Nathaniel Brooks requests the design and fabrication of a user-friendly surgical tool to be used during spinal distraction surgery. The design requirements outlined in the Product Design Specifications in the Appendix are explained in detail here. 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. The force needed for a 4 mm (0.157 in) distraction distance during surgery is 431 N (96.9 lb) over an area of 250 mm (9.48 in) [11] (See Figure 5). Using this data, the required pressure for distraction is calculated to be 1720 kPa (249 psi). In order for the spine to distract, the device should apply force in one axial direction. The uninflated device should have a height no larger than 10 mm (0.394 in) for insertion. The device should be able to expand to a total height of 18-20 mm (0.709-0.787 in), but only needs to distract 4-6 mm (0.157-0.236 in). 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 disc.

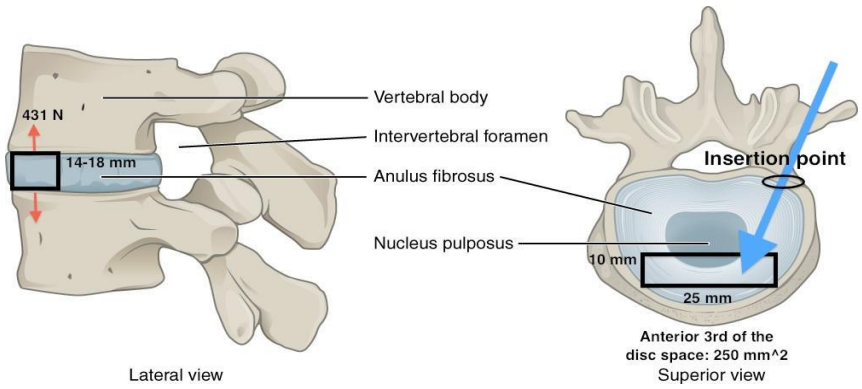


Figure 5: Surgical Distraction Mechanism. The distractor is inserted posteriorly between the vertebral bodies and deposited on the anterior third of the body for distraction [12, 13].

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. Because spinal distraction is only a temporary measure before a permanent cage is placed within the disc space, the distractor itself needs to be removable after cage implantation.

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. The device will preferably be inserted into the anterior third region, and should contact each adjacent vertebrate on a surface area of 10 mm by 25 mm (0.394 in by 0.984 in), or 250 mm^2 (0.388 in^2) [12]. 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 also 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 gauge and control exactly how much force is being applied to the bones. This system will also decrease risk of bone fracture.

Regarding 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. With this in mind, the device should be cost effective and should be cheaper than, or comparable to, current surgical tools on the market.

The design requirements are outlined and explained in further detail in the Product Design Specifications in the Appendix. Keeping these design requirements in mind while designing and fabricating the final device will be crucial to ensure effectiveness and client satisfaction.

Design Alternatives

Several devices that fit these specific criteria have been designed. One uses a mechanical mechanism of expansion, similar to current devices on the market but with several improvements. The other two use an inflatable system of expansion, one with a single balloon and the other with multiple balloons.

Mechanical System

The first design uses a mechanical method of expansion. As portrayed in Figure 6, the distraction force is applied to the spine via two expanding platforms. These platforms expand as two support rods slide along a track on the bottom platform. The device is inserted by a hollow rod containing two wires, one attached to the far support, and one attached to the near. As the blue wire is reeled in by the surgeon the supports slide past each other and the top platform rises. It is also depicted in Figure 6 that ridges in the bottom track keep the platforms separated. The incremented ridges and reeling technique would let the surgeon know the exact size of distraction. The insertion rod would be removed after implantation by unscrewing it from the distractor to give the surgeon more room to work. When the surgeon is finished removing the disc, the red wire can be pulled to unlatch the support and compress the device for removal.

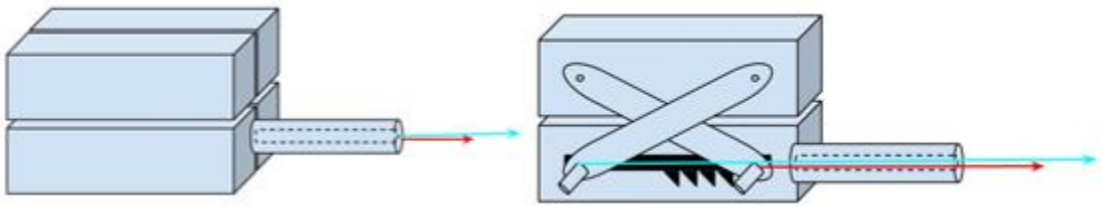


Figure 6: Mechanical Distraction Device. Schematic of the mechanical distraction system. External view on the left and internal view on the right.

Inflatable System

Two of the designs incorporate inflatable balloons for vertebral distraction. These methods include a deflated balloon being inserted between the vertebrae via an insertion rod controlled by the surgeon. This rod will initially be firm, allowing the surgeon to direct the balloon to the correct position. Once the balloon is in place, the surgeon will manually inflate it using a hand pump mechanism displayed in Figure 7 connected to the balloon via a thin tube. Once the balloon is inflated to the proper dimensions to supply the required distraction, a toggle valve between the hand pump and the balloon will be closed. This will allow for the hand pump to be detached from the inflation tube to reduce the bulk of the device during the rest of the surgery. In addition, since the balloon will no longer require the insertion rod, it will also be removed or become flexible to further reduce space occupancy during surgery. When the balloon is to be removed, the toggle valve will be opened to release the fluid within the balloon, causing the balloon to deflate and allow for easy removal.

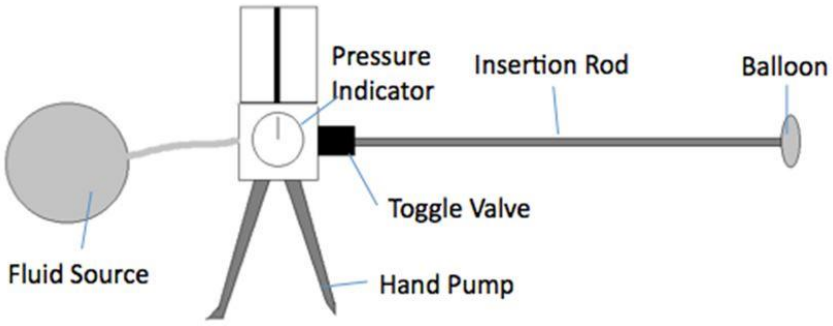


Figure 7: Hand Pump Inflation mechanism. The fluid source supplies water to inflate the balloon by activating the hand pump.

Varying flexibility of the insertion rod will be achieved using guide wires. A flexible sheath will surround the inflation tube, and the guide wires will be placed between this sheath and the tube. The guide wires will provide the stiffness and rigidity needed for insertion of the balloon as shown in Figure 8, but once the balloon has been properly placed and fully inflated, the guide wire will be removed. This will allow the remaining tube and sheath to become slack, so they may both to be pulled off to the side during surgery to limit space occupied outside the body.

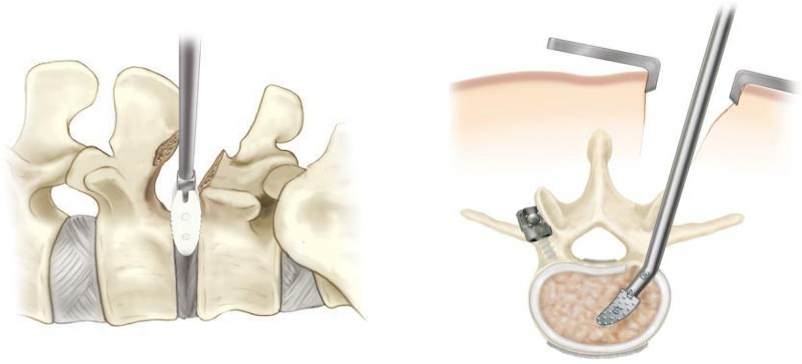


Figure 8: Inflatable Distractor Mechanism. The inflatable distractor is inserted posteriorly and activated in the anterior third portion of the vertebral bodies [14].

Single Balloon

The single balloon design uses an accordion-shaped balloon and is depicted in Figure 9. This shape will cause the balloon to primarily inflate along one axis without taking up excessive disc space. At full expansion, the balloon will be 10 mm wide, 30 mm long, and 18 mm tall. The simplicity of the balloon design will allow the surgeon to easily place the balloon in the correct position and orientation. Additionally, the use of only one balloon and the lack of mechanical parts inserted into the body result in few points of failure for the design, increasing reliability.

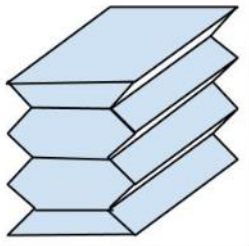


Figure 9: Single Balloon. A single accordion shaped balloon allows unidirectional inflation.

Multiple Balloons

The third design alternative also implements the inflatable mechanism of distraction but differs in its shape. The insertion shaft is segmented with multiple balloons placed periodically between segments in order to provide maximum flexibility and versatility in the device. Similar to the single balloon design, these balloons will also incorporate an accordion shape to provide vertical expansion along the spinal axis. With these additions, the device will be more conforming to the shape of the vertebrae and allow for alignment along the outer ridge of the bones where the vertebra is strongest to provide maximum support. This design is portrayed in Figure 10.

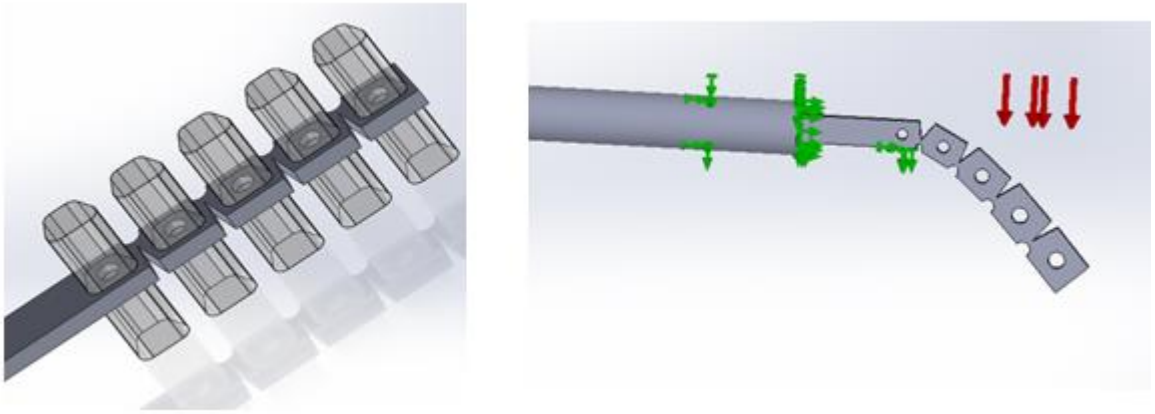
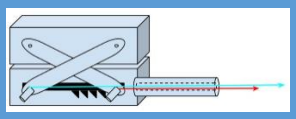
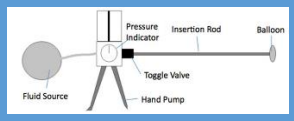
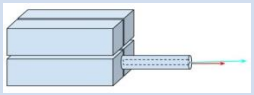
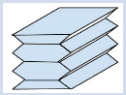


Figure 10. Multiple Balloons. The multiple balloon design allows for more flexibility to conform to the spinal cavity.

Design Matrix

Each preliminary design has its own strengths and weaknesses. To effectively evaluate the individual points of all three designs, a design matrix was used to analyze each design alternative. The two expansion methods and three specific designs were rated on a variety of design criteria. These aspects included functionality, safety, size and shape, feedback supplied, ease of use/ bulkiness, and cost effectiveness. It was determined that functionality and safety were the most significant criteria, and were therefore awarded the greatest weights of 25 each. Each design alternative was awarded a score for every category, and the scores were then added up to give a total score out of 100, as shown in Table 1. Based on the point distribution, the inflatable, multiple-balloon method received the largest allotment of points and is therefore the design we have chosen to pursue. It will be discussed later the feasibility of the fabrication of this design.

Table 1: Inflatable vs. Mechanical Design Matrix. Design matrix analyzing design components for feasibility.

	Mechanical 		**Inflatable** 			
	Expanding Platforms 		One Balloon 		Multiple Balloons 	
Functionality (25)	4	20	4	20	5	25
Safety (25)	3	15	4	20	4	20
Size / Shape (15)	2	6	4	12	5	15
Feedback supplied (15)	3	9	3	9	3	9
Ease of use / Bulkiness (15)	3	9	4	12	3	9
Cost effectiveness (5)	2	2	3	3	3	3
TOTAL (100)	61		76		**81**	

Design Matrix Criteria

Functionality

The category of functionality, or how effective the device distracts the spine, is tied for the highest weight because the ability to successfully distract the spine is the most important aspect the device needs to possess. The multiple balloon design is allocated the best score of 25 out of 25 as it is the most accommodating to the insertion as well as shape of the body while still providing the directional force necessary to provide distraction. The mechanical and one balloon inflatable design will both effectively distract the vertebrae but are slightly less conforming to the vertebrae disc shape, and therefore received a score of 20 out of 25.

Safety

Safety is the other category that is given the highest weight in order to ensure the patient-device interface will not be harmful to the patient in any way. Given the delicate nature of the bone in the patients undergoing these surgeries, the client requires that the device does not internally damage any components of the spine. For this reason, the mechanical device is considered the least viable option with 15/25 due to its rigid edges and collapsible components that have the ability to fracture the vertebrae or pinch the

spinal nerves. Since the single and multiple balloon designs both conform to the shape of the vertebrae and provide a large surface area for the force to dissipate across, they are considered less hazardous to the integrity of the anatomy.

Size and Shape

In the criteria of size and shape, we compared how efficiently the device uses the space within the spinal column, as it is very limited, and the client wants to ensure he will have room to move around the distractor. We also considered the conformability of the device to the vertebrae because there should not be any damage caused during distraction. The multiple balloon design is deemed the best option in that it is flexible and able to align with the curvature of the outer rim of the vertebrae. Additionally, the inflatable portion will allow for the device to conform to the bone and evenly disperse the distraction force over a larger surface area. The one balloon design was given a slightly lower score, as it does not possess this flexibility for maximum utility of the space. Mechanical was given the lowest score, as it is not at all conforming to the vertebrae or provided space.

Feedback supplied

Each of the three designs supply feedback to the surgeon as to how much pressure is being applied to the vertebrae. Both inflatable methods provide pressure feedback in the form of increased resistance felt from the pump with each successive pump. A value for the pressure is also supplied by the pressure gauge on the pump. The mechanical method also supplies feedback directly from the effort required to expand the jack. Since each method includes feedback in the form of a measured pressure quantity as well as the tactile feedback in resistance from the vertebrae, they were given equivalent scores. Due to the fact that the feedback provided is on par with current forms of distraction, all designs were given the score of a 9.

Ease of Use

The client desires a device that is also space efficient outside of the body and easily moved or removed so he or she has room to work. In this category, we compared the designs in aspects of insertion and operation. The one balloon inflatable design receives the highest score of 12/15 as it is smaller in insertion than the mechanical design and does not require the extra manual alignment after insertion that the multiple balloon design does. All designs will have detachable outer components and this therefore did not affect the overall matrix decision.

Cost Effectiveness

In the category of cost effectiveness, both of the inflatable designs are tied with a score of 3/5, while the mechanical design scored slightly lower with a value of 2/5. The difference is due to the increased number of components necessary for the mechanical device, which would result in a slightly higher cost.

Final Designs

The final design goal for this semester was to create a rough working prototype of the distracter as a proof of concept. This design would ideally be similar in size and functionality with the intended final prototype. After successfully constructing this prototype, the next step would be to continue with more complex fabrications. For simplicity, some aspects of the design were left out or altered at this point because fabrication proved to be difficult.

While the ideal design includes a delivery/removal system as well as a shaped, multi-chambered bladder (all of which would need to be biocompatible), fabrication proved to be too costly at this stage to implement all of these components. To manufacture a unique, high-quality bladder using a custom fabrication method would cost an excess of $3000, according to Kip Weller of Vention Medical. The rapid prototyping methods currently found on campus were also incapable of constructing the bladder. Since the construction of the bladder proved to be the most difficult part of the design, it became the primary focus this semester, leaving the delivery system to a very simple prototype and temporarily postponing the biocompatibility considerations.

The prototype of the delivery system is composed of 3.175 mm (1/8 in) nylon tubing and brass valves connected by compression seals. A check valve allows fluid to enter from a saline source, simultaneously preventing backflow. A T-valve forks the tubing from the bladder with one tube directed to the saline source and check valve and the other to a bleed valve that is used to deflate the bladder. To simulate the insertion rod, a hollow copper sheath surrounds the section of tube that is connected to the bladder. The copper rod provides support to make it easy to guide the end of the tube to a given position. Enough space is left between the end of the tubing and the T-valve so that after insertion, the copper rod can slide back out of the body and out of the user's way. While the delivery system is functional, it is unable to be tested. This is because the current fluid hand pump cannot connect to the rod properly and ordering another hand pump at this point is not financially feasible. All of the tubing and valves in the delivery system were ordered off of McMaster Carr [15] while the copper tube was purchased at local hardware store. With the completion of this simple delivery system, focus can shift entirely to bladder prototypes.

After consulting Professor Fronczak about methods to develop the desired bladder, he advised constructing a non-inflating bladder that unfolds as an actuator instead of an inflating balloon. This would allow the bladder to be properly shaped to provide expansion in only one direction, prevent energy lost from inflation, and allow for stronger materials to be used. As stated before, construction of such a bladder proved to be difficult, so a prototype was generated to mimic its features of directional expansion and strength using only a common water balloon. This led to the box design.

Box Design

The box design consists of a hollow base fit with a vertically sliding top. The 3-D printed box measures 25 mm (0.98 in) long, 10.2 mm (0.40 in) wide, and 10 mm (0.39 in) tall in a closed state with the top resting inside the box. A balloon is placed inside and inflated hydraulically. As the balloon expands, the box prevents any lateral expansion and maintains a vertical expansion as the top slides upwards until it reaches a maximum height of 14 mm (0.55 in), resulting in 4mm (0.16 in) of distraction. The desired directional expansion is achieved and the box prevents the balloon from inflating too far and rupturing. Additionally, gel is placed on the top and bottom surfaces of the box to better conform to the vertebrae and reduce bone fracture. The hydraulic pressure applied to the box is obtained through a fluid hand pump, as requested by the client, and it inflates as well as deflates the device so the surgeon can easily expand it to precisely the desired height and adjust it if need be. The slot on the side of the box, through which the fluid tube enters, catches on the tube after expansion, preventing the box from expanding beyond the desired 4mm for this prototype. This ensures a consistent distraction ceiling that prevents over-distraction that could result in damage to the patient or the distracter. The box design is pictured in Figure 10.

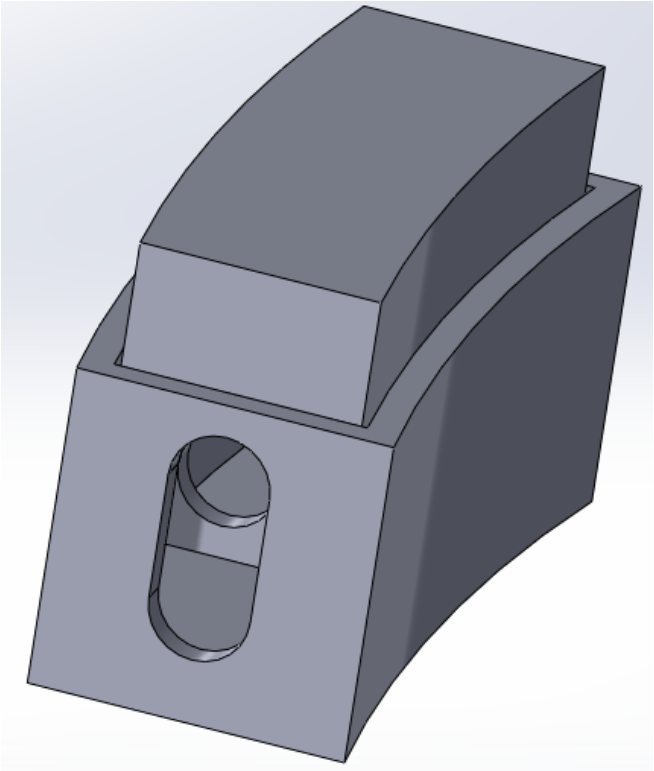


Figure 10: Box Design. Solidworks model of box design distractor prototype.

While the box design closely mirrors the desired functionality of a non-inflating bladder, it is not able to conform to the vertebrae as well as a bladder and therefore, prevent bone fracture. The box design successfully proves the concept of a hydraulic actuator applying significant pressure to lift or distract a load, however, a design that more closely resembles the final goal of a non-inflating bladder is also quite valuable. This led to the development of an additional design: the catheter design

Catheter Design

The catheter design consists of a pre-inflated peripheral catheter from Boston Scientific with dimensions of 80 mm (3.1 in) in length and 18 mm (0.71 in) in diameter. Catheters are designed to be inflated during use, however they are unable to deflate back to their original state. Using a catheter that has already been inflated provides a bladder that can handle high pressures. Since a catheter is open at two ends, one end needs to be sealed to create a bladder. This seal is created by melting solder into one of the ends. A 3-D printed rectangular frame with length 80 mm (3.1 in), width 18 mm (0.71 in) and height 14 mm (0.55 in) is attached around the catheter. This frame is used to stabilize the cylindrical catheter and prevent it from rolling around during use and testing. The difference in the height of the frame and the full diameter of the catheter results in the targeted 4mm (0.16 in) of distraction when the catheter is unfolded hydraulically from a folded position. The catheter design is depicted in Figure 11.

Figure 11. Catheter Design. The catheter design involves an expanding balloon to provide distraction.

While the shape of the catheter is not perfect, it is a good representation and proof of concept of where the design is headed, towards a non-inflating bladder directly applying the required force to distract the spine. The catheter is able to slightly conform to the shape of what it is distracting so the risk of vertebral fracture is reduced. For this reason, the catheter design more closely models how the future prototype will function.

Discussion and Future Work

There are several key aspects of the design that will be altered next semester to accommodate the client's design requirements. The following components will need to be assessed on their functionality, *in vivo* biocompatibility, and factors of safety.

Tubing and Carrying Sheath

The current tubing is 3.175 mm (0.125 in) outer diameter high pressure nylon. The tubing can withstand pressures up to 5.515 MPa (800 psi), greater than the maximum required pressure of 1.722 MPa (249.8 psi). This calculates to a safety factor of 3.2. Nylon is biocompatible and will not degrade during the

typical time required for surgery. In addition, the tubing may be placed in a carrying sheath in the future to add navigation, so biocompatibility of this sheath will be necessary. This sheath will aid the user in navigation of the device *in vivo*, and once the device is placed and the required distraction is achieved, the user can detach the external sheath to allow for additional room to operate for the remaining duration of the procedure. Either nylon or PET could be used for this application.

Saline Pump

The pump and fluid flow system currently is a closed loop, meaning the saline is never ejected during operation. As the hydrostatic pressure is increased at the pump, the fluid flows into the inflatable bladder. When the pressure is released, the fluid simply flows back into the pump. Although this has not been thoroughly investigated, this is not ideal because it is suspected that a non-trivial hysteresis effect is present. An open-loop system where the saline is not recycled would limit this effect and result in a higher resolution feedback for the user. The current pump can be implemented into the open-loop system; however, an additional tubing line would need to be installed to flow the saline from the source to the inflatable bladder to outside of the system. Biocompatibility is disregarded because the pump does not interact with the patient in vivo. The pump and gauge have an upper pressure limit of 2.533 MPa (367.4 psi), which calculates to a safety factor of 1.5. Another medical-grade pump from Ralston Instruments could also be used in the future design [16].

Inflatable Bladder

An 18 mm (0.71 in) diameter, 80 mm (3.15 in) long catheter is used as the inflatable bladder currently. The catheter is rated to contain a maximum pressure of 1.519 MPa (220.4 psi) and provides a factor of safety of 0.88 at the desired pressure. This shows that the current catheter will not properly function given the requirements the design must meet. Custom molding a bladder with a desired geometry capable of expanding in primarily a uniaxial direction with nylon or PET is a solution. Molding techniques such as injection molding or blow-molding can be used for this component. In order to use either of these processes, a model of the molding tooling will need to be designed and fabricated. It is worth noting that the mold tooling will add the most additional cost to the future design. In line with the other components of our future design, a safety factor of 3.0 will be achieved for this component.

General Fittings and Connections

All of the current fittings can withstand pressures up to 5.515 MPa (800 psi), with the exception of the tubing-to-pump and tubing-to-bladder connections. An ad hoc seal made of tape is used now and can withstand 0.405 MPa (58.8 psi). These connections need to be altered for full functionality of the device. With this in mind, the new bladder will be designed to accommodate a high-pressure fitting which meets the pressure and biocompatibility requirements. A high density polymer such as HDPE could be used. Ideally, a safety factor of at least 3.0 will be achieved for all fittings.

Costs

The following tables outline the costs associated with the two final designs and the planned future design.

Current Design Costs

Table 2: Current Design Costs. The costs of the current designs are summarized in the table below for both the box and catheter design.

Box Design			**Catheter Design**		
Item	Cost [$US]	Reference	Item	Cost [$US]	Reference
Saline Pump	0.00	Donated by Boston Scientific	Saline Pump	0.00	Donated by Boston Scientific
Tubing	3.90	[15]	Tubing	3.90	[15]
Valves/Fittings	67.35	[15]	Valves/Fittings	67.32	[15]
Water Balloon	2.50		Catheter	18.00	[17]
Total	73.75		**Total**	89.25	

Future Design Costs

Table 2: Current Design Costs. The costs of the current designs are summarized in the table below for both the box and catheter design [17,18].

Item	Cost [$US]	Reference
Medical Saline Pump	371.20	[18]
Tubing	3.90	[15]
Valves/Fittings	67.35	[15]
Balloon Mold Tooling	300.00	Estimate from polymer lab assistant at UW-Madison
Molded Balloon	25.00	Estimate from polymer lab assistant at UW-Madison
Custom Carrying Sheath	50.00	Estimate from polymer lab assistant at UW-Madison
Total	817.45	

The total cost this semester for the two prototypes was $163.00. After adding in the planned future design, the full-year total cost projects to $980.45. Considering the budget given by the client is $1000, the proposed future design cost is acceptable.

Testing

In order to test the prototypes and prove the inflatable distraction concept, a testing apparatus was designed to simulate the compressive loading the device would be subjected to in the spine. To do this, the apparatus was made of two plastic blocks and eight rubber bands to provide the compressive loading. The two blocks represented the two vertebral bodies and were stacked vertically on one another. The rubber bands were then wrapped around the blocks in both X and Y directions.

Because the force the rubber bands would apply to the blocks was unknown, it was necessary to manually test the bands to determine a quantitative value. A single rubber band was applied around the two vertically stacked blocks and a free weight of 4.45 N (1 lb) was hung from the base. The displacement distance between the interior faces of the blocks was measured to be 0.124 mm (0.00488 in). This process was continued, progressively adding additional rubber bands and measuring the achieved displacement until the best fit exponential curve in Figure 12 was created. By using this curve, the displacement of eight rubber bands was extrapolated to be 0.124 mm (0.00488 in). To find the force at our desired distraction of 4 mm (0.157 in), we found the conversion ratio between the 4 mm (0.157 in) displacement to the 0.124 mm (0.00488 in) testing displacement to be approximately 32.2. Multiplying this conversion ratio by the free weight used in the testing curve, we found a rubber band force of 143 N (32.2 lb).

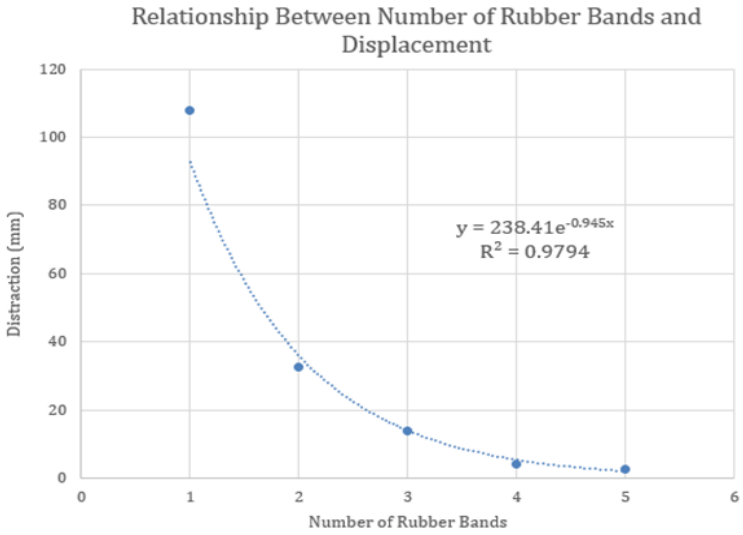


Figure 12: Rubber band force curve. Pictured is the best fit exponential curve function of the number of rubber bands and the distraction achieved between the testing blocks.

Pictured in Figure 13, the catheter and box design prototypes were both tested in the testing apparatus. In both cases the blocks were distracted to 4 mm of distraction and the pressure that each device supplied was measured on the hand pump. The catheter design provided a hydraulic pressure of approximately 405 kPa (0.0587 psi) while the box design supplied only 182 kPa (0.0264 psi). This decrease in pressure was presumably due to the extreme compliance of the balloon bladder inside the box that expended more energy in stretching the balloon material rather than separating the platforms with hydraulic pressure.

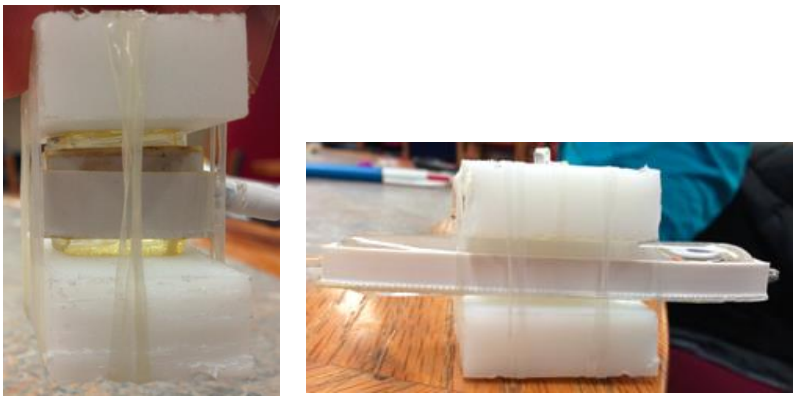


Figure 13: Prototype testing. Pictured left to right are the box prototype and the catheter prototype applying a 4 mm distraction distance to the blocks of the testing device.

A few of the challenges faced during testing concern the box design prototype. First, the balloon inside the box was much larger in diameter than the tubing, so it was very difficult to seal the connection while maintaining the thin balloon material intact. We also encountered complications in constraining the balloon inside the box, rather than expanding out the tubing hole.

Timeline

The following table shows our timeline with goals outlined for this semester. As you can see, filled boxes are our projected timeline and the checks are the actual progression. So far this semester, our team has stayed on track.

Table 3: Timeline. The timeline outlines the progress over the course of the semester.

Tasks	September				October				November				Dec
	7	13	20	27	4	11	18	25	1	8	15	22	6
Meetings													
Advisor		X	X	X		X	X		X		X	X	
Client		X	X	X		X		X				X	
Team	X	X	X	X	X	X	X	X	X	X	X	X	
Product Development													
Research	X	X	X	X									
Brainstorming			X	X	X	X							
Design Matrix				X	X	X							
Design Prototype							X	X	X	X	X		
Order Materials									X	X	X		
Fabricate Prototype											X	X	
Testing												X	
Deliverables													
Progress Reports	X	X	X	X	X	X	X	X	X	X	X	X	X
PDS			XX										
Mid-Semester PPT					X								
Mid-Semester Report					X								
Final Report													X
Final Poster													X
Website Updates	X	X	X	X	X	X	X	X	X	X	X	X	X

Filled boxes = projected timeline

X= task was worked on or completed

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Appendix

Inflatable Vertebral Distractor

Product Design Specifications
12/11/2013

Group Members: Doug Ciha, Taylor Lamberty, Catharine Moran, Myranda Schmitt, Spencer Strand

Client: Dr. Nathaniel Brooks
Advisor: Dr. Willis Tompkins

Function: In some cases of spine surgery the intervertebral disc is removed and the vertebral bodies are distracted to help with alignment of the spine. The goal of this project is to develop an inflatable vertebral body distractor that can be easily manipulated and will not cause spinal fractures.

Client Requirements: The client has specified some things that he hopes can be incorporated into the design. They are as follows:

· A temporary distraction device that can be manually inserted and removed for collapsed disc spinal surgery.
· A feedback system to gauge how much pressure the distractor is applying.
· A device with malleable edges (unlike the rigid edges that are currently used in the scissor jack) that do not risk fracturing the vertebral bones.
· A distractor that can be inserted through the main insertion site or percutaneously.
· A device that is out of the way during surgery.

1. Physical and Operational Characteristics

A. **Performance Requirements:** The device will be used to separate two vertebrae in the lumbar spine during spinal surgery and will be subjected to the reaction forces of up to 431 N (96.9 lb) of said vertebrae during the expansion. It will need to be durable enough to generate at least 1720 kPa (249 psi) of pressure to distract the vertebrae. It will likely be used once and disposed of thereafter.

B. **Safety:** The device will be placed inside the human body, and therefore the materials will need to be biocompatible and completely sterilized before use. The device should not have any sharp edges or rigid components that could cause physical harm to the patient. There should also be a large surface area in contact with the vertebrae to dissipate the applied force in order to prevent any bone damage.

C. **Accuracy and Reliability:** The device will be used once, but the client would like to incorporate a tactile feedback system to gauge and control the amount of pressure being

applied to the patient. The device should apply force in one axial direction to prevent unnecessary spatial occupation in the 36 x 36 mm (1.42 x 1.42 in) cavity.

D. **Life in Service:** The product will be in use for anywhere between four and ten hours of operation to complete the particular surgical spinal procedure.

E. **Shelf life:** Shelf life should be long for reusable components. The inflatable components would need to be replaced after prolonged shelf-time to ensure they still function.

F. **Operating Environment:** The device should withstand exposure to bodily fluids, up to 431 N (96.9 lb) forces during distraction, and applied forces by the user.

G. **Ergonomics:** The device should be comfortable to use for the user, and should not cause harm to either the patient or the user.

H. **Size:** The product should be no more than 10 x 25 mm (0.394 x 0.984 in) in the ⅓ most anterior portion of the vertebra. The external components should not be clumsy or bulky for the user.

I. **Weight:** The device is intended to be used for surgery and must be light enough to not cause ergonomic problems. The total weight of all components should not exceed five pounds.

J. **Materials:** Product will be inserted into the body temporarily during surgery. Parts of the device that come into direct contact with the patient must be biocompatible. Placement is delicate so the device must have an ergonomic handle with a good grip position and a non-slick texture that allows precise control. Most of the component that is inserted must be smooth and not abrasive to the patient while the piece that is used to distract the vertebrae cannot slip after distraction has started.

K. **Aesthetics, Appearance and Finish:** The finished product should be aesthetically pleasing but also functional.

2. Production Characteristics

A. **Quantity:** We will be constructing one unit.

B. **Target Product Cost:** The target product cost will be below $500.

3. Miscellaneous

A. **Standards and Specifications:** The device should comply with applicable FDA regulations and will need Class II clearance since it will be placed in the body and then completely removed.

B. **Patient-Related Concerns:** Patient concerns include, but are not limited to, patient allergies, sterilization, severity of patient injury, location and type of spinal injury, and overall patient safety during surgery.

C. **Competition:** The current method is a scissor jack, which is a device that mechanically distracts the vertebrae. Another current method is physically wedging material into the disk space, thus causing distraction. The main issues with these designs are their bulkiness and rigid edges.