

Vertebral Body Distraction Device

Mid-Semester Report

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Client

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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. 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. It was determined that in the design criteria categories of functionality, safety, and size and shape, a multiple-balloon design is the most viable option because it will provide the proper distraction while still being flexible and versatile.

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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.

Problem Motivation

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 [1] (See Figure 1). With these spinal issues, the



Figure 1: Visual Comparison of healthy and unhealthy discs.

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. Distraction is defined as forced separation, and is commonly used in joints [2]. This separation force 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 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 different types of vertebral distraction devices on the market. These devices are sufficient, but not ideal, for a variety of different reasons.

A common distraction tool found in hospitals, the paddle distractor, is a simple, stainless steel, oar-shaped instrument (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. Given the stainless-steel material and small area of contact with the vertebral body, this mechanism occasionally causes non-trivial spinal bone fractures. Additionally, this device is bulky and obstructive for the surgeon as the entire device, including the handle, must be left inside the patient during surgery.



Figure 2: Paddle distractor

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 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.

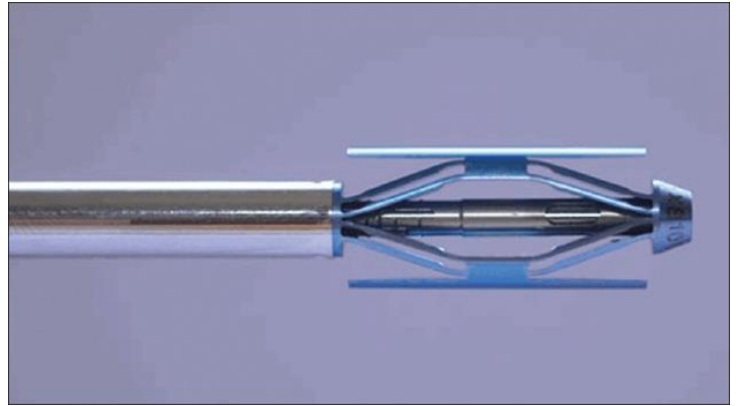


Figure 3: Scissor Jack system.

A more recent device is the Spine Wave StaXx device (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 [3]. 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.



Figure 4: Spine Wave StaXx system.

Design Requirements

Dr. Nathaniel Brooks has requested that we design and fabricate 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. 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. 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 to 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. All materials used should be hypoallergenic and be able to withstand exposure to bodily fluids, high forces, and high pressure applications 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

Our group has designed several devices that fit these specific criteria. 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

Our first design uses a mechanical method of expansion. As you can see in Figure 5, 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. You can also see in the figure that ridges in the bottom track hold the distractor in place. 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.

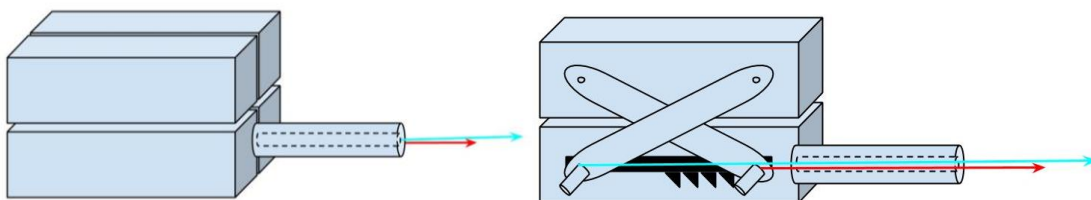


Figure 5: Schematic of the mechanical distraction system. External view on the left, and internal view on the right.

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 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.

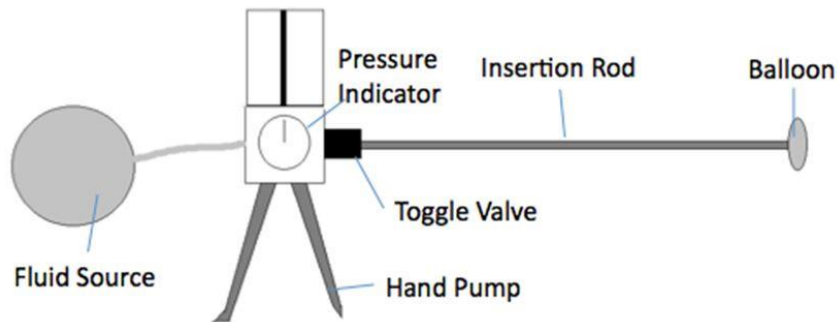


Figure 6: Inflatable system schematic of

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 (See Figure 7). The guide wires will provide the stiffness and rigidity needed for insertion of the balloon, 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.

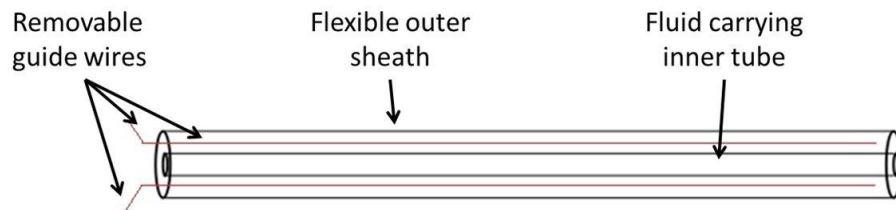


Figure 7: Insertion tubing with removable guide wires, flexible sheath and fluid carrying inner tube.

Single Balloon

The single balloon design uses an accordion-shaped balloon. 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.

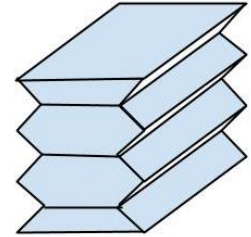


Figure 8: Accordion-shaped balloon design.

Multiple Balloons

Our 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.

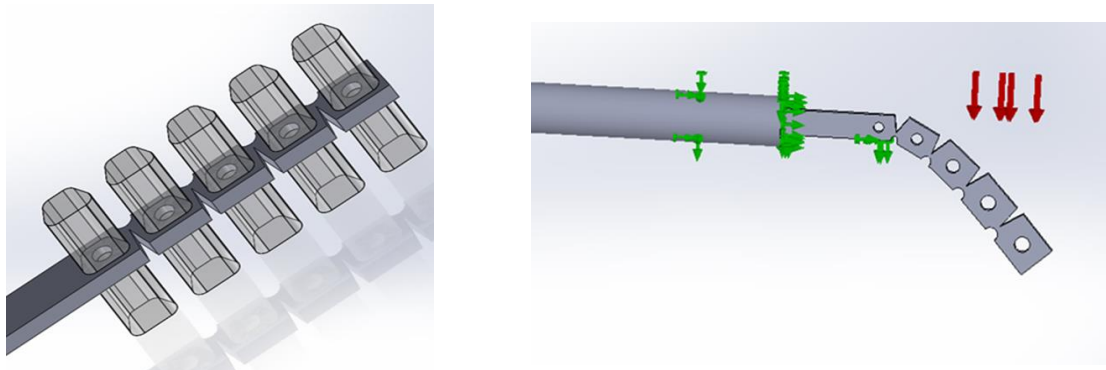


Figure 9: Multiple balloon design with close up of balloons (left) and depiction of flexible bending (right).

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 each category, and then these scores were 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.

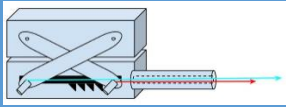
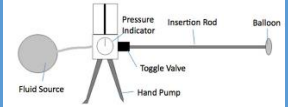

	Mechanical		Inflatable			
						
	Expanding Platforms		One Balloon		Multiple Balloons	
Functionality (25)	4	20	4	20	5	25
Safety (25)	3	15	4	20	4	20
Size / Shape (15)	2	6	4	12	5	15
Feedback supplied (15)	3	9	3	9	3	9
Ease of use / Bulkiness (15)	3	9	4	12	3	9
Cost effectiveness (5)	2	2	3	3	3	3
TOTAL (100)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

Table 1: Design matrix. Scores are out of 5. Displayed as: score | weighted score. The multiple-balloon design received the highest allotment of points (81) and will be the design that we will pursue.

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.

Future Work

Future work for our device will consist of finalizing different aspects of the design, as well as implementing proper testing. In our first task, we will calculate the required force necessary for distraction of the vertebral discs. Our client suggested looking at cadaver studies, which should be available online. We also need to determine our exact balloon shape for our design. We will decide if we want to incorporate an accordion-style balloon into our multiple-balloon design or if there is a better option for balloon shape. Finally, we will need to finalize the delivery method.

Testing

Testing for design development as well as verification and validation will be performed in the future. We will need to test the strength of the balloons and the pressure supplied by either pneumatic or hydraulic means. A potential problem in our future could be finding a facility to test these balloons adequately.

Projected cost

Our client has given us a budget of \$1,000 for the year; therefore, our device should not cost more than that. The insertion and fluid supply method components will cost approximately \$500 with some of these parts being custom fabricated while others will be implemented from concepts in existing devices. When considering the one balloon design, Vention Medical shows PET balloons 80mm in length and 18mm in diameter after inflation costs \$108.00 per 6 balloons [4]. For the multiple balloon design, PET balloons 20mm in length and 8mm in diameter after inflation cost \$144.00 per eight balloons [5]. Therefore, the total projected cost is between \$600 and \$650.

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.

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

Table 2: Timeline of the semester. X's indicate a completed task.

References

- 1) <http://www.surgery.com/procedure/disk-removal/purpose>
- 2) <http://dictionary.reference.com/browse/distract>
- 3) http://www.spinewave.com/products/xd_us.html
- 4) <http://www.ventionmedical.com/products-and-services/advanced-polymers/medical-balloons/catalog/ItemDetails.aspx?ItemNumber=16004012AA>
- 5) <http://www.ventionmedical.com/products-and-services/advanced-polymers/medical-balloons/catalog/ItemDetails.aspx?ItemNumber=08002020KA>
- 6) <http://www.ralstoninst.com/hydraulic-hand-pumps/gauge-connection/XHGV-0000>
- 7) <http://www.ptsinstruments.com/proddetail.php?prod=APGVgauge>
- 8) <http://www.ventionmedical.com/products-and-services/advanced-polymers/medical-balloons/technical-info/>
- 9) <http://www.madehow.com/Volume-6/Angioplasty-Balloon.html>
- 10) http://www.harleystreeturology.com/the_bladder/treatments/artificial_urinary_sphincter.php
- 11) <http://www.buxtonbio.com/images/78-3465.jpg>
- 12) http://www.Jcvjs.com/articles/2012/3/2/images/JCraniovertJunSpine_2012_3_2_47_116537_ul.jpg
- 13) http://innovation.spinewave.com/_assets/library/2013/04/Spine_Wave_DC_Microsite_Product_Hero_Slides_XD2.png

Appendix

Inflatable Vertebral Distractor

Product Design Specifications

10/06/2013

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 inserted and extracted manually for collapsed disc spinal surgery.
- A feedback system so that he can tell how much pressure he is applying to the distractor.
- Malleable edges (unlike the rigid edges that are currently used in the scissor jack) that do not risk fracturing vertebral bones.
- A distractor that can be inserted through the main insertion site.
- 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 said vertebrae during the expansion. It will need to be durable enough to generate enough 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 parts that may 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 so as to know 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.
- D. Life in Service:** The product will be in use for the hours of operation necessary to complete the particular surgical spinal procedure.

- E. **Shelf life:** Shelf life should be long for reusable components. Possible inflatable parts would need to be replaced after prolonged shelf-time.
- F. **Operating Environment:** The device should withstand exposure to bodily fluids, high forces during distraction, and applied forces by the user.
- G. **Ergonomics:** The device should be comfortable to use for the user, and it should not cause harm to either the patient or the user.
- H. **Size:** The product should have both the length and depth needed to perform spinal surgery, but 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 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.