ELSEVIER

The Spine Journal 6 (2006) 55–60

THE SPINE JOURNAL

Inflatable vertebral body distractor for lumbar region of the spine.

Douglas J. Ciha, Taylor L. Lamberty, Catharine G. Moran, Myranda L. Schmitt

Sent 26 February 2014; Acceptance pending.

Abstract **BACKGROUND:** A common spinal procedure is disc removal surgery, which is used for collapsed, herniated, or deteriorated discs. With these spinal issues, the vertebral bodies can experience bone-to-bone contact with one another, causing pinching of the spinal nerves and excruciating pain. 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, a process in which spinal distraction is required. Joint distraction is defined as the forced separation of two joint surfaces, and is used to alleviate pressure, help with alignment, and provide 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 surfaces of the vertebrae. This causes extreme point pressures on the fragile vertebral bodies and ultimately leads to spinal fractures.
PURPOSE: There is a need for an expandable distraction device that addresses the issues of current devices while still providing optimal distraction. The goal of this project is to design and fabricate an inflatable vertebral body distraction device for the lumbar portion of the spine that can be easily manipulated and will not cause spinal fractures.
STUDY DESIGN/SETTING: A review of patents and relevant literature.
METHODS: The design process included an extensive literature search, analysis of current designs, determination of a set of design specifications, brainstorming of various design alternatives, methodical review of those alternatives, determination of a final design, fabrication of final design, and testing of a final prototype.
TESTING: Testing included mimicking the spinal compression force to test force of distraction and the insertion process.
RESULTS: The device was able to successfully distract the applied force to a distance of 6 mm, which is within the limits of the desired distraction. It was also able to be inserted into the dimensions of the disc space similar to a disc removal procedure.
CONCLUSIONS: As a proof of concept, this device is functional and provides a good baseline for future work of this project.

Keywords: Spine, Surgery, Distraction, Vertebral Body, Design, Prototype

Introduction

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, and 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 the 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 surfaces of the vertebrae. This causes extreme point pressures on the fragile spine and ultimately leads to spinal fractures [4.]

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 spine causes 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. The paddle distractor separates the vertebrae by parallel insertion and then forcing a 90 degree turn to push the bodies apart [5].*

Although spinal distraction is a common procedure, an inflatable method to achieve this distraction does not exist on the market yet. There are, however, patents concerning inflatable distraction. Listed are three existing patents most relevant to this desired device. The first patent, CA2583913, concerns the idea of a catheter with multiple balloons with one or many inflation lumens [6.] The existing patent has not been prototyped, but consists of a blade and a pre-dilation 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 dilation catheter [7.] 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 are relevant to the desired product. A final relevant patent is for a cervical distraction design, US9348979 [8.] 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-expanded state to the 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.

Purpose

There is a need for an inflatable distraction device that addresses the issues of current devices and provides optimal distraction. The goal of this project is to design and fabricate an inflatable vertebral body distraction device for the lumbar portion of the spine to be used during spinal surgery that can be easily manipulated and will not cause spinal fractures.

Methods

The design process included an extensive literature search, analysis of current designs, determination of a set of design specifications, brainstorming of various design alternatives, methodical review of those alternatives, determination of a final design, fabrication of final design, and testing of final prototype.

Testing

The device was tested in a spinal compressive loading simulation apparatus. Rectangular polymer blocks were used to mimic the vertebrae at dimensions of 13 mm in height, 45 mm in length, and 50 mm in width. The Anterior and Posterior Longitudinal Ligaments (ALL and PLL, respectively) of the spine were modeled using rubber specimens. Seven rubber samples were tested using a tensile testing machine to find their elastic moduli. The styrene-butadiene rubber (SBR) and Oil Resistant Vinyl were found to have the highest elastic moduli and therefore were used to most-closely simulate the ligaments of the spine. (See Appendix for graph)

The cross-sectional areas of the rubber were altered until a stiffness similar to that of the ligaments was achieved. The exact mathematical methods of which can be found in the Appendix I. The ALL was estimated at a stiffness of approximately 46.1 N/mm and the PLL was estimated at 10.6 N/mm between the L3-L4 vertebrae. The starting length was considered 26 mm and the rubber specimens were cut to the proper cross sectional area. The device was then inserted between the polymer blocks and distracted. The device in the testing

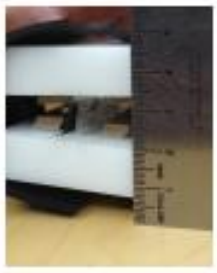


Figure 3: Physiological Loading Testing Apparatus. The device was tested in a vertebral simulation device using rubber specimens to mimic the physiological resistance of the ligaments.

apparatus is pictured in Figure 3.

The device was also tested in an anatomical model of the spine. A lumbar spine model was used and a portion of the disc was removed, similar to that in a surgical procedure. The device was then inserted posteriorly between the lamina of the L3-L4 vertebrae until submerged between the vertebrae. The device was then distracted, as shown in Figure 4.

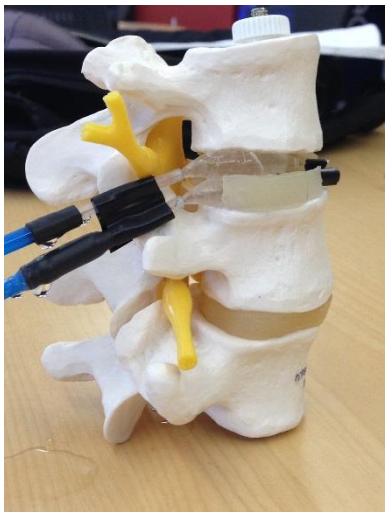


Figure 4: Anatomical testing apparatus that was used to test insertion method as well as distraction. The device is distracting the model in the image above.

Results & Discussion

In the physiological testing apparatus, the device was inflated to a height of 16 mm, while distracting the spinal model vertebral bodies a distance of 6 mm, which is well in the range of desired distraction distances.

In the anatomic model, the device could be inserted with ease and the model was distracted 6 mm as well.

There were a number of problems that were faced during testing of the device. Seals leaking was the most prominent issue during testing, as the system lost pressure as soon as a seal began to leak. To solve this issue in the future, the system should be streamlined and the seals should be welded together similar to that of catheter balloon delivery systems. This would not only provide better overall aesthetics to the device, but would also increase efficiency of the system.

Another problem encountered was the distal end of the device (balloons) tipping when pressure was applied to the vertebral bodies. This would cause the surgeon issues if the patient had little to no disc remaining between vertebral bodies. In order to address this issue in the future, the balloons would be shaped similar to a rectangle instead of circular. This would enable the balloons to lay on top of each other without wanting to roll off. This would also provide a flat base of the balloon to rest on the lower vertebral body.

Ideally, the inflatable device would be constructed out of a single, custom, catheter balloon, instead of two typical stock balloons. In order to do this, however, a custom balloon would need to be designed and manufactured, which would be rather expensive.

The designed device is functional and provides a visual example of a proof of concept, but future work is needed on the device in order for it to be put on the market and used in typical spinal surgeries.

Conclusions

Spinal surgery is in need of an inflatable device that conforms to the vertebral disc space and distributes the force of distraction evenly throughout the spinal cavity. The designed device proves to be a functional proof of concept and can be used as a model for future work for an inflatable spinal distraction device. The prototype addresses the issues of current devices on the market, as well as incorporates all of the design specifications given for a typical spinal procedure.

There is a significant amount of future work that could be done to this design if more money was available to design and manufacture a custom-made balloon. Streamlining the delivery system

to that similar to a catheter delivery system would offer better aesthetics as well as contribute to an increased efficiency in the system, and creating a custom-designed balloon would address the toppling issue and keep the balloons in the vertical position.

The prototype provides a good baseline for future work because it satisfies the majority of the product design specifications given by the client. It was able to be inserted within the given dimensions, inflate to the proper height, and provide adequate distraction of 6 mm for the compression forces felt by the spine.

References

1] "Surgery.com-Information on Disk Removal, with Instructions on Why to Have Surgery, Tips, and Recommendations." N.p., n.d. Web. 11 Dec. 2013.

2] DePuy Synthes Spine, Inc. "Minimally Invasive Lateral Spinal Fusion." AllAboutBackandNeckPain.com. DePuy Synthes Spine, Inc., 2012. Web. 11 Dec. 2013.

3] "Distract." Dictionary.com. Dictionary.com, n.d. Web. 11 Dec. 2013.

4] Gumley, G, TK Taylor, and MD Ryan. "Distraction fractures of the lumbar spine." Bone & Joint Journal. 64-B.5 (1982): 520-525. Print.

5] Buxton BioMedical. "Buxton Biomedical." Buxton BioMedical, 2011. Web. 11 Dec. 2013.

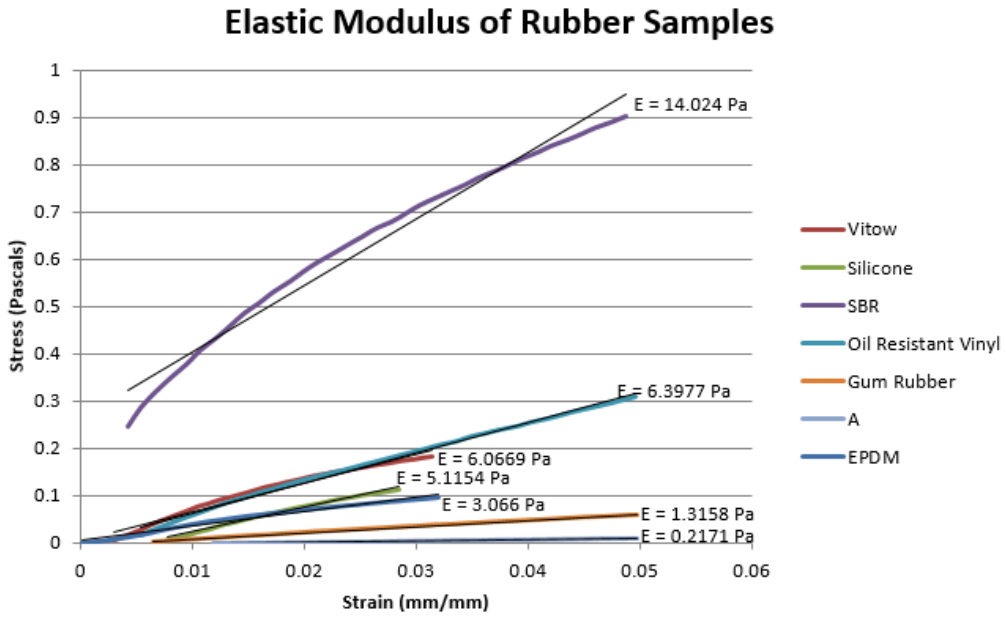
6] Jackson, Brad. Multiple Balloon Catheter. Boston Scientific, assignee. Patent CA2583913 A1. 15 June 2006. Print.

7] Saab, Mark A. Multiple Layer High Strength Strength Balloon for Dilatation Catheter. C.R. Bard, Inc., assignee. Patent EP0457456 B1. 27 Dec. 1996. Print.

8] McCormack, Bruce M. Cervical Distraction Method. Providence Medical Technology, assignee. Patent US20130123922 A1. 16 May 2013. Print.

Appendix

I. Finding the elastic moduli for all rubber samples.



II.

Mathematical computation to translate rubber elastic moduli to a stiffness similar to physiological ligament values:

$$E = \frac{\sigma}{\varepsilon} = \frac{\frac{F}{A}}{\frac{d}{l_o}}$$

$$K = \frac{F}{d}$$

Therefore:

$$A_R = \frac{K_l l_{o,R}}{E_R}$$

Where:

K_l = ligament stiffness;

$l_{o,l}$ = ligament original length;

E_R = rubber elastic modulus;

A_R = rubber cross-sectional area