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Inflatable vertebral body distractor for lumbar region of the spine.

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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 would address 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 included mimicking the spinal compression force to test force of distraction and the insertion process.
RESULTS: TBD
CONCLUSIONS: TBD

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 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 an inflatable vertebral body distraction device for the lumbar portion of the spine 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.

Results

Conclusions

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