Inflatable Vertebral Distractor

Product Design Specifications
2/16/2013

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

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 to be temporarily placed in the body.

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 the use of 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.