Inflatable Vertebral Distractor

Project Design Specifications

12/8/2014

Group Members: Bridget Smith, Gabby Laures, Michael Lohr, Ryan Serbin, Christina Sorenson

Client: Dr. Nathaniel Brooks

Advisor: Bill Murphy

Function: During spinal surgery, the intervertebral disk may be removed. In order to do so, the adjacent vertebrae need to be distracted so that the spine can maintain its alignment. The current tools in use are difficult to maneuver and can cause damage to the vertebrae. The goal of this project is to design a device that will inflate and distract the vertebrae while also being minimally invasive and made of a material that will not fracture the vertebrae.

Client Requirements: *The client's specifications are as follows*:

- An inflatable device that can be inserted into the disk space and be used to distract vertebrae during collapsed disc spinal surgery
- A system that can apply and retract at least 1720 kPa of pressure during surgery as needed.
- A component that measures pressure inside the device applied to patient's vertebrae.
- A device with yielding edges that will not pose a risk of fracturing the vertebral body, which has a yield stress of 2.4 MPa.
- A device that is can be inserted through the main insertion site, requiring no extra incisions.
- A device that will obstruct the removal of the damaged disk.

1. ***Physical and Operational Characteristics***
2. ***Performance Requirements:*** The device is to be used during spinal surgery to separate the two vertebrae in the lumbar spine. It will be used once and then will be disposed of. It will be subjected to forces caused by the vertebrae of up to 431 N (96.9 lb.) In order to distract the vertebrae, the device will need to generate at least 1720 kPa (249 psi) of pressure.
3. ***Safety:*** The device is to be used inside the human body so it will need to be biocompatible. However, the will not permanently be left inside the body. It should not have any sharp edges that could damage the vertebrae or cause any other pain to the patient. The area of contact between bone and device should be as great as possible, which

will allow the vertebrae to dissipate the applied force and prevent bone damage. There is no target surface area as it is too difficult to provide a number due to the large variety between each patient.

4. ***Accuracy and Reliability:*** The device will be used once. However, it should include a tactile feedback system that will control the pressure that is applied to the patient. The device will need to open axially in one direction. It will need to fit in the 36 x 36 mm (1.42 x 1.42 in) cavity.
5. ***Life in Service:*** The product is to be used for one surgical spinal procedure, which may last up to ten hours.
6. ***Shelf Life:*** The inflatable component of the device will need to be replaced if there is a prolonged shelf time. However, the reusable components will need to have a shelf life of over one year.
7. ***Operating Environment*****:** The device will be exposed to various bodily fluids, forces applied by the user, and forces up to 431 N (96.9 lb) caused by the distraction.
8. ***Ergonomics*****:** The device should most importantly not cause any harm to the patient as well as be easy to maneuver into the small spinal cavities.
9. ***Size*****:** The project should have a size no greater than 10 x 25 mm (0.394 x 0.984 in) so that it may fit in ⅓ most anterior position in the vertebrae.
10. ***Weight:*** The weight of all the components of the device combined should not exceed five pounds as it is to be used during surgery and must not cause any ergonomic problems.
11. ***Materials*****:** This product will be temporarily inserted into the body during surgery. Biocompatibility is necessary for the parts that come into contact with the patient. Materials should be used that are commonly used in other implant and biomedical applications. The product should provide a smooth, non-slip grip that allows for precise control of the device. The materials also cannot chip or flake so that pieces are left behind inside the body.
12. ***Aesthetics, Appearance and Finish:*** The final product should be aesthetically pleasing in a way that it does not hinder functionality.
13. ***Production Characteristics***
    a. ***Quantity*****:** One unit will be constructed.
    b. ***Target Product Cost:*** The targeted cost for this product is <$1000

14. ***Miscellaneous***

a. Standards and Specifications: The device has to meet requirements to comply with the relevant FDA regulations. Specifically, the device is entering the body temporarily and therefore needs to be cleared by the FDA as a Class II device.

b. Patient-Related Concerns: Patient concerns include reliability of device function (accurate pressure gauge, sealed air intake, etc.), sterilization, allergies, severity and location of injury, and overall patient safety.

c. Competition*:* There are two popular devices that are on the market currently: a mechanical vertebrae distractor and a simple wedge. Both of these devices require force applied by the user to distract the vertebrae, and both devices contain hard edges that apply forces that could cause vertebrae to fracture or fail while in use.