

(1.) Every year, over 100,000 spinal surgeries are performed for the treatment of intervertebral disorders. (2.) Currently, surgeons need to make large incisions in the patient's back and use large paddle distractors to create the space needed for surgery. These distractors are commonly made of metal, and because of this, it is common for the vertebrae to experience small fractures during the distraction process.

(3)

Our client, Dr. Nathaniel Brooks of University Hospital, requested a distraction device that is minimally invasive, can be easily manipulated by the surgeon, and safer for patients undergoing spinal surgery.

(4) We made our product out of medical grade silicone by creating a mold in the shape of an ellipse. The elliptical shape allows for the maximum size of the device to fit the constraints of the cannula upon insertion. Also, by making the side walls thicker, the device only expands in one axial direction so upon inflation, the device expands to create separation of the vertebrae but does not bulge horizontally into the operation space or harming spinal nerves. The device is able to be inserted into the cannula and then using a hand pump, we can simply inflate the device to create the separation needed of 4-6 mm.

(5.) With this device, surgeons around the world will be able to perform spinal surgery with less invasive techniques. It will create a safer procedure for the patients by reducing the occurrence of spinal fractures during the distraction process. By taking up less space and not requiring a large incision, this device can help reduce operation time, patient recovery time, and also reduce the visual effects from the surgery. *Additionally, this type of distractor could influence the advancement of body distractors for all applications, maybe even spark the innovation of inflatable implants.*

(6) We tested our device by placing it in an MTS machine and inflating it to see how much force it could produce. From our research, we found for a 4-6 mm distraction, 215 N of force needed to be applied in both directions. With the size constraints of the insertion process, we divided this force between three devices so that each device only had to apply 140 N. After testing multiple samples, we had an average force generation of 105 N.

(7) Our device does not apply the amount of force needed for our problem. However, because we were on a very limited budget we were testing the design concept more than the effectiveness. With a larger budget we will not only be able to acquire the best possible silicone for this application, but also maximize our resources, making necessary advancements in the fabrication process. We have successfully proven that this method would work and simply need the appropriate materials and resources that are outside our budget.

(8) If this product were to be commercialized, it could be revolutionary for the distraction process and drastically improve the spinal surgery field. It is easier for surgeons to use, safer for patients, and reduces surgery time. Surgeons would be able to effectively and safely distract the

spinal column and perform their appropriate surgeries with plenty of room, without the risk of further harming the patient.