Inflatable Vertebrae Body Distractor

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Abstract

- 102,173 spinal surgeries per year
- Need a device to safely and effectively distract the spine in the lumbar region
- Current devices are too invasive, and can damage the vertebrae during distraction
- Goal is to make a new distractor that is minimally invasive, unobtrusive, and does not damage the vertebrae or other softer tissue
- Compression and tensile testing were used to measure displacement and applicable force
- A working prototype was fabricated, but further testing is needed to verify the effectiveness

Background

- Discs resist spinal compression and help spread the load of vertebral bodies, are prone to degeneration, herniation, and other problems
- Approximately 60-80% of people will experience lower back pain in their lives due to some form of spinal disc degeneration
- Surgical process consists of either removing or replacing degenerated disc

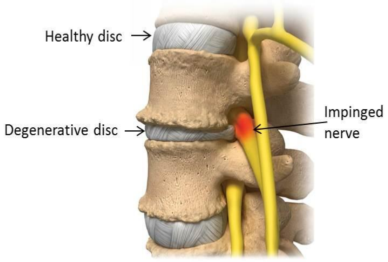

Figure 1: Vertebral column

- Distractor will be implemented in order to spread the disc area to create surgical work space
- Inserted through the use of a Jamshidi needle and then inflated, allowing surgeon to create space in between adjacent vertebrae
- Once the operation is finished, the distractor can be remove

Figure 2: Paddle Distractor

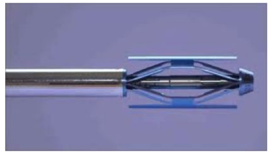

Figure 3: Scissor Jack Distractor

Figure 4: Spinal Wave Staxx

- These current designs are too bulky, hard to maneuver, can fracture bone, are made of hard material, and have poor load distribution

Design Requirements

- Design and fabricate a user-friendly, biocompatible, surgical tool to be used during spinal distraction surgery.
- The device should be able to distract the vertebrae 4-6 mm, applying a 430 N force, or 215 N force in both directions to successfully distract two vertebrae.
- Required pressure for distraction is calculated to be 537.5 kPa (78 psi)
- Insertion method must be minimally invasive
- Must fit in half of the vertebrae with dimension of 24 x32 mm
- Pressure feedback system

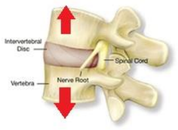

Figure 5: Line of distraction

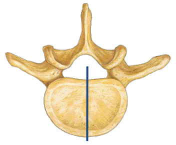

Figure 6: Cross sectional view of lumbar vertebra

Final Design

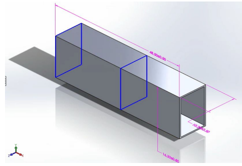

Figure 7: SolidWorks of final design

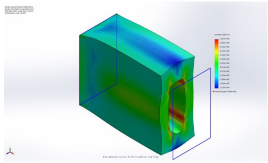

Figure 8: SolidWorks analysis of Von Mise stress distribution

Figures 9 (Left) and 10 (Right): Photo taken of prototype pre and post-inflation respectively

- Final design has dimension of 10x16x48.5mm and is composed of a two part system.
- SolidWorks analysis of Von Mise stresses showed factor of safety of 15.
- Max lateral displacement of 0.2mm.
- Prototype composed of Silastic(R) MDX4-4210 Biomedical Grade Elastomer Base because it's easy to hand mold

Testing

Figure 11: Compression testing

Figure 12: Tensile testing

- The device was loaded into a MTS machine and underwent compression testing but was limited due to pump failure
- Tensile testing was then used to find the yield stress to calculate how much compressive force the device could withstand
- Distraction distance was observed in both testing environments

Results

Figure 13: Stress-Strain graph of tensile testing

- The hand pump used can only withstand 5 psi
- Could only apply 11 N of force with limited pressure
- Using the yield stress of tensile testing gave the best insight of the force that can be applied
- The load reached 11 N and the device distracted 4.9 mm axially and 0 mm laterally when the pump began to fail
- The wall section had a tensile yield stress of 400 kPa, allowing a compression force of 153.6 N

Future Work

- Current testing indicates our device underperforms
- Need improved pump so we can more correctly assess performance
- Better made prototypes, different silicone, and thicker walls can also address problems
- Develop testing method to simulate vertebrae distraction
- Work on insertion method with Jamshidi canulla

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