INFLATABLE VERTEBRAL DISTRACTION DEVICE

Gabby Laures, Michael Lohr, Ryan Serbin, Christie Sorenson, Bridget Smith

Client: Dr. Nathaniel Brooks, MD *Advisor: Dr. Bill Murphy, PhD*

Abstract

When discs in the vertebrae degenerate, it is necessary to remove them with lumbar intervertebral fusion surgery. An issue with this procedure is the current devices available to distract the vertebrae. They necessitate large incisions, can risks tissue damage, and have been shown to fracture the vertebrae upon use. To eradicate these issues, we have designed an inflatable distractor that will be inserted into the anterior disc space through a stylet and attached to a pressure system to inflate the distractor. Biocompatible materials were selected and a report was written about fabricating the device via injection molding.

Background and Problem Definition

Client: Dr. Nathaniel Brooks, UW Hospitals and Clinics

- Neurological surgeon
- Performs lumbar intervertebral fusion surgeries

Background:

- About 200,000 spinal surgeries performed each year[1]
- Vertebral distractors are required for surgery to separate vertebrae and remove degenerated discs[2]

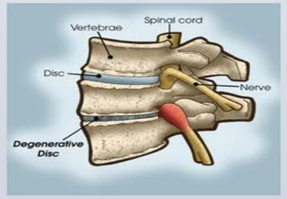

Figure 1: Degenerative vs. healthy disc

Dr. Brooks has requested an inflatable distraction device for use during lumbar intervertebral fusion surgery that still applies adequate force to distract the vertebrae.

Current Devices

- Paddle distractor(Fig. 2.)[3]
- Scissor jack distractor(Fig. 3)[4]

Figure 2: Paddle distractor

Problems:

- Require large space for insertion
- Non removable handles
- Non conforming

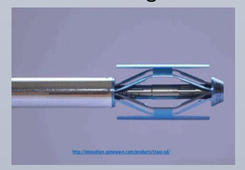

Figure 3: Mechanical jack

Design Criteria

Mechanics:

- 431 N compressive force from vertebrae
- >1720 kPa applied by device

Device Size Restrictions:

- Insertion Height: ≤7 mm
- Distracted height : 14-17 mm

Feedback Mechanism:

- Pressure Gage

Total Project Budget

- $1000

Safety:

- Biocompatible
- Inflatable
- Maximum contact surface

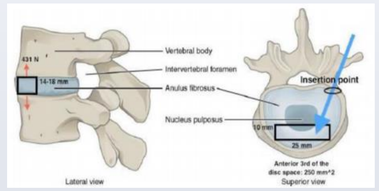

Figure 4: Side and top view of device location in vivo and dimension requirements

Final Design

The final device will be an inflatable cylinder composed of TPU reinforced equatorially with PEEK(Fig. 5)

Materials:

Polyvinyl Alcohol (PVOH):

- Dissolvable mold[5]
- Forms internal shape of balloon

Thermoplastic polyurethane (TPU)

- Distracts vertebrae by inflation
- TPU Desmopan DP 9370A
- UTS = 25 Mpa
- Elongation >300%[6]

Polyether Ether Ketone (PEEK)

- Equatorial reinforcement
- UTS = 100 Mpa
- Elongation 30-40% at break[7]

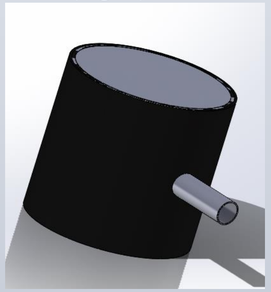

Figure 5: SolidWorks image of final two-part design. TPU is grey (on top) and PEEK is black

Fabrication Plan

Injection Molding[5]

- 3 sets of molds:
  - one for each material used
  - aluminum mold
  - symmetrical
  - sequentially and proportionally enlarged

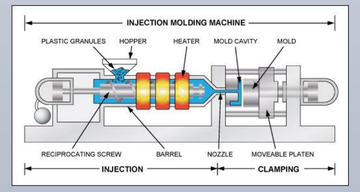

Figure 6: Diagram of injection molding that will be used in fabrication

Testing

- 431 N axially on TPU/PEEK = vertebral force
- 1720 kPa applied in axial and equatorial directions = air pressure applied
- PEEK restrictive forces modeled (equal and opposite to equatorial inflation forces)
- Preferential axial inflation was proven under assumed environmental and applied forces
- Materials subject to forces well below failure rate

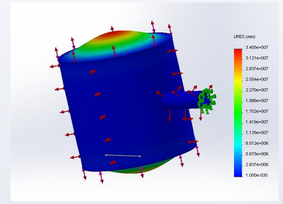

Figure 7: Displacement gradient after forces and pressures were applied.

Height (cm)	Axial (cm)	Equatorial Radius (cm)
7	0	0
8	1	.05
9	2	.07
10	3	.08
11	4	.11
12	5	.13
13	6	.16
14	7	.18

Figure 8: Axial vs Equatorial Displacement

Inflation Testing:

- Balloon reinforced with PET
- Tested equatorial expansion when distracted to necessary heights(Fig. 9)
- In working height range, increase in equatorial inflation found to be insignificant (Fig. 8)
- Max axial inflation ~39 times > corresponding equatorial inflation

Figure 9: Model of design using balloon and PET casing

Biocompatability:

- TPU used in catheters/tubing[6]
- PEEK used for spinal cages[7]

Future Work

- Fabrication of device
- Testing of device
- FDA approval
- Mass production protocol

Acknowledgements

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- Tom Ellingham
- Jason McNulty
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