

INFLATABLE VERTEBRAL DISTRACTION DEVICE

Douglas Ciha, Taylor Lamberty, Catharine Moran, Myranda Schmitt, Spencer Strand

Client: Dr. Nathaniel Brooks, MD

Advisor: Dr. Willis Tompkins

ABSTRACT

There is a need for a device to safely distract the lumbar portion of the spine during spinal surgeries. The device should be unobtrusive to the surgeon and avoid damage to the vertebrae or surrounding soft tissue. We have designed and fabricated two devices that fit this criteria. One, a hydraulically inflatable bladder encased in a padded rigid exterior, and the other, an unfolding bladder. Both will maintain vertebral separation while conforming to and protecting the various components in the spinal cavity. Our designs were tested against a 32 lb. compressive force and were both able to achieve the desired 4 mm of distraction.

INTRODUCTION

Client: Dr. Nathaniel Brooks, UW Hospitals and Clinics

- ❖ Neurological surgeon at UW Hospital
- ❖ Performs minimally invasive spinal surgeries

Background:

- ❖ Approx. 600,000 spinal surgeries per year
- ❖ Collapsed discs
- ❖ Procedure



Figure 1: Visual Comparison of healthy and unhealthy vertebral discs.

- ❖ **Dr. Brooks has requested an expandable distraction device for the lumbar portion of the spine that addresses issues with current devices and still supplies adequate force to distract the vertebrae**

CURRENT DEVICES

There are a few current devices, but none are inflatable.



Figure 2: Paddle distractor

Patents:

- ❖ EP0457456: Reinforced balloon
- ❖ US9348979: Cervical distraction

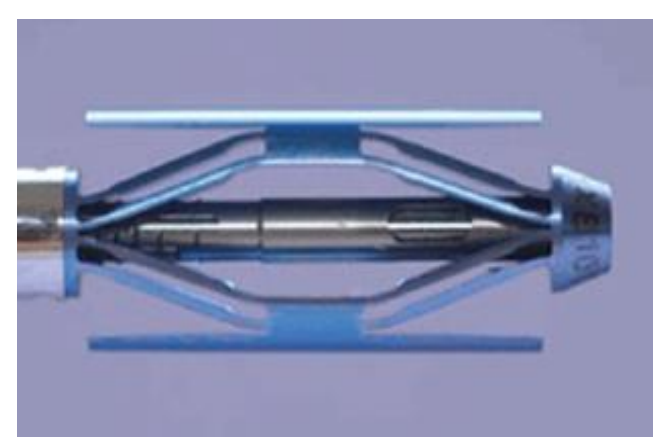


Figure 3: Scissor jack distractor

- Problems:
- ❖ Not conforming
 - ❖ Bulky

DESIGN CRITERIA



Figure 4: Vertebral body space

$$P = F / A$$

$$\text{Area} = 10\text{mm} \times 25 \text{ mm} = 250 \text{ mm}^2$$

$$F/A = 431 \text{ N} / 250 \text{ mm}^2 = 1.724 \text{ MPa}$$

$$1.724 \text{ MPa} = 17 \text{ atm}$$

- ❖ Provides sufficient distraction
Force = 431 N
Distance = 4-6 mm
- ❖ Remains minimally-invasive
Insertion height = 10 mm
Expanded height = 14-16 mm
- ❖ Avoids bone fractures
Conforming to vertebral space
- ❖ Costs less than \$500

FINAL DESIGNS

Box Design:

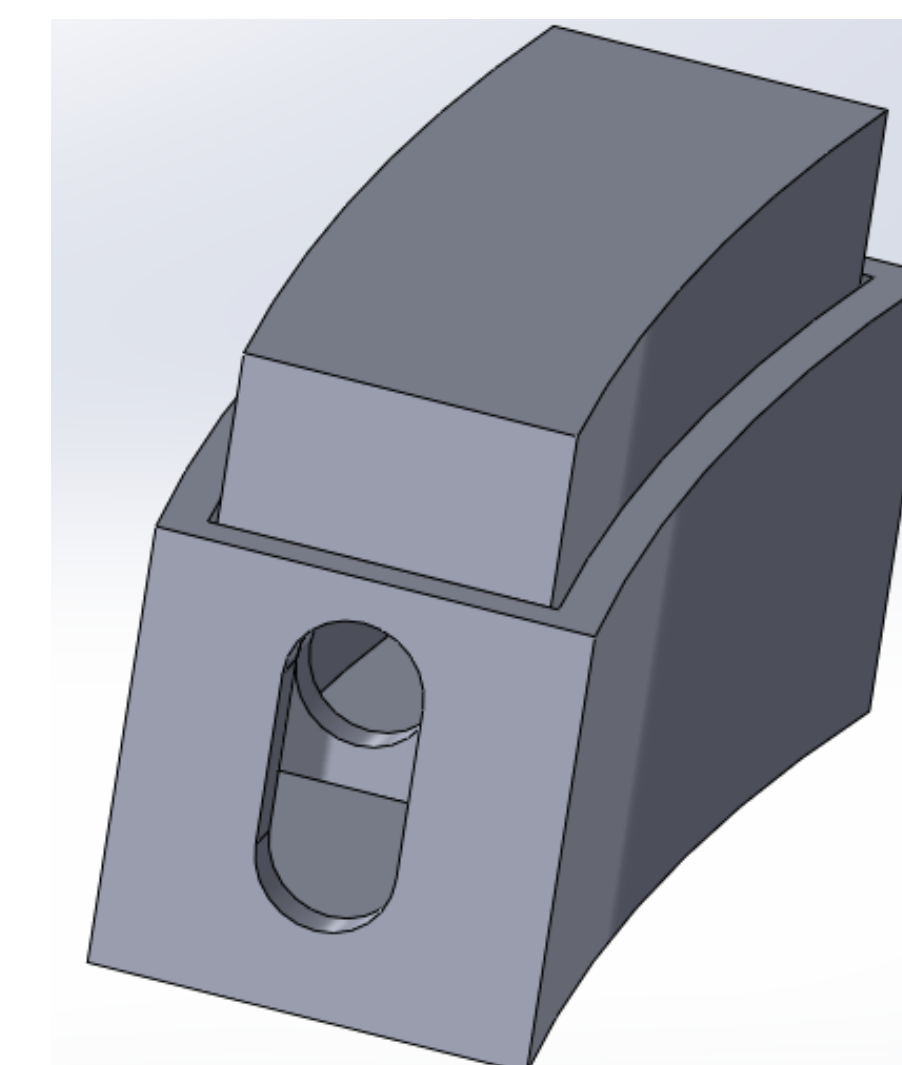
- ❖ Encased bladder
- ❖ 10 x 24 x 10 mm³
- ❖ Gel cushioning

Mechanism:

- ❖ Vertical Expansion
- ❖ Hydraulically inflated
- ❖ Limited expansion

Delivery System:

- ❖ Manual hand pump
- ❖ Inflation/Deflation



Catheter Design:

- ❖ Unfolding catheter
- ❖ 100 mm long
- ❖ 15 mm diameter
- ❖ Encased in box for stability

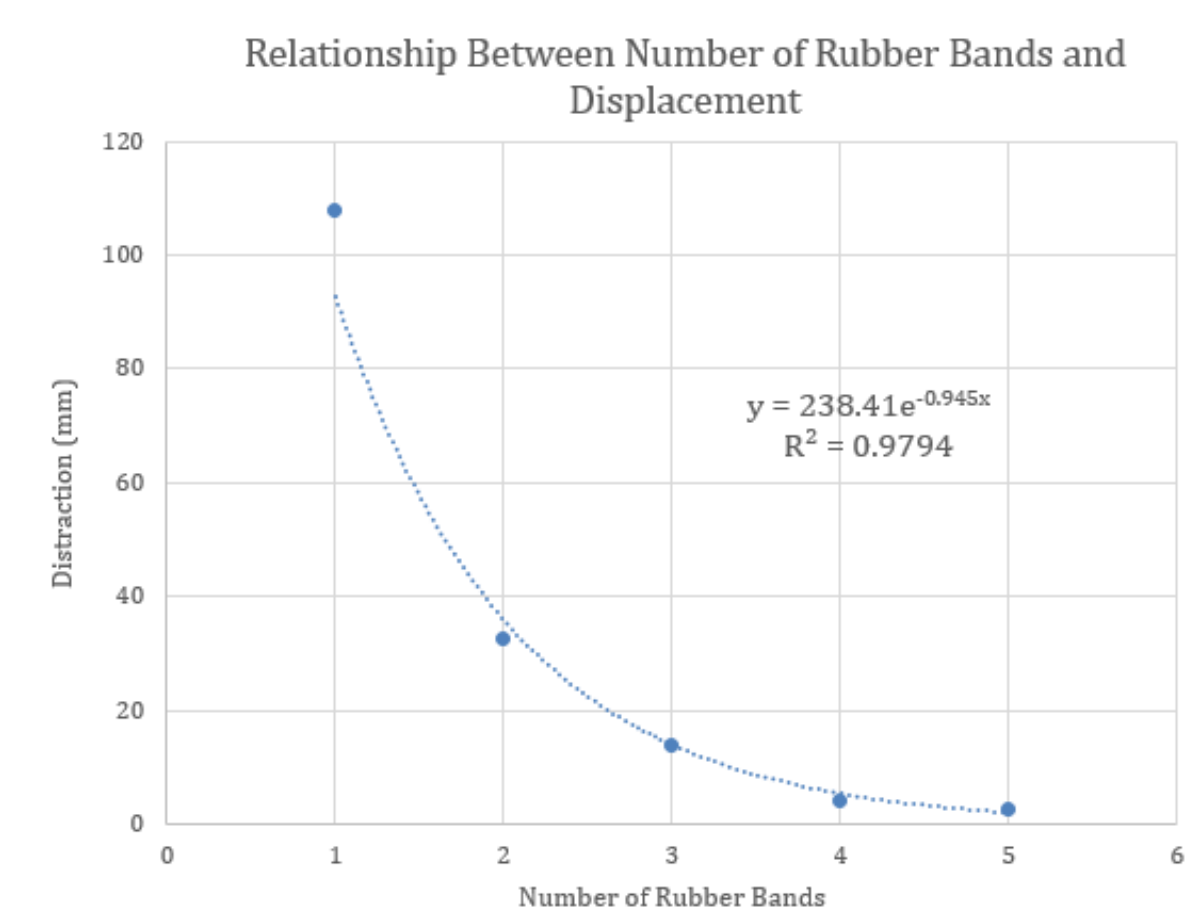
Mechanism:

- ❖ Hydraulically inflated
- ❖ Radial expansion
- ❖ Pressure applied



TESTING & RESULTS

- ❖ Proof of concept testing
- ❖ Determined compressive force:
 - Found displacement at known lb
 - Extrapolate to 8 rubber bands:
 $d = 238.41e^{-0.945 \cdot (8)} = 0.124 \text{ mm/lb}$
4 mm / 0.124 mm/lb = 32.21 lb

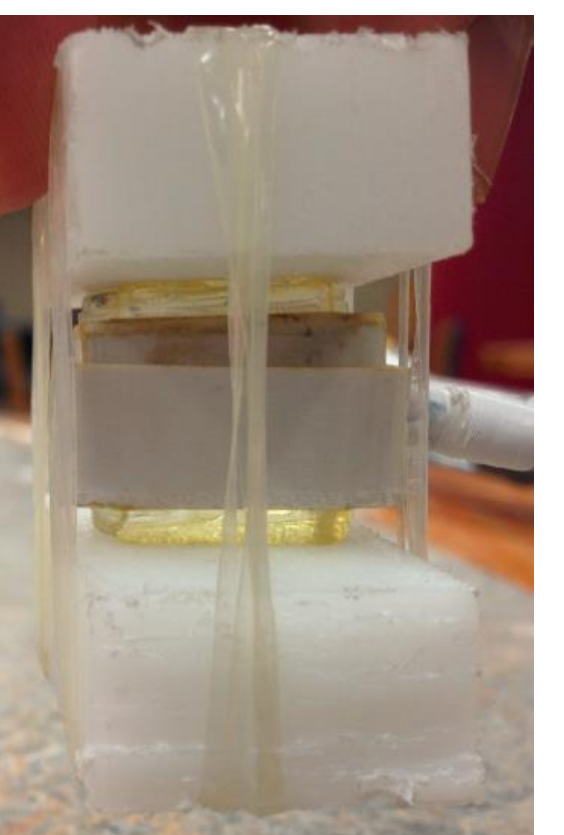
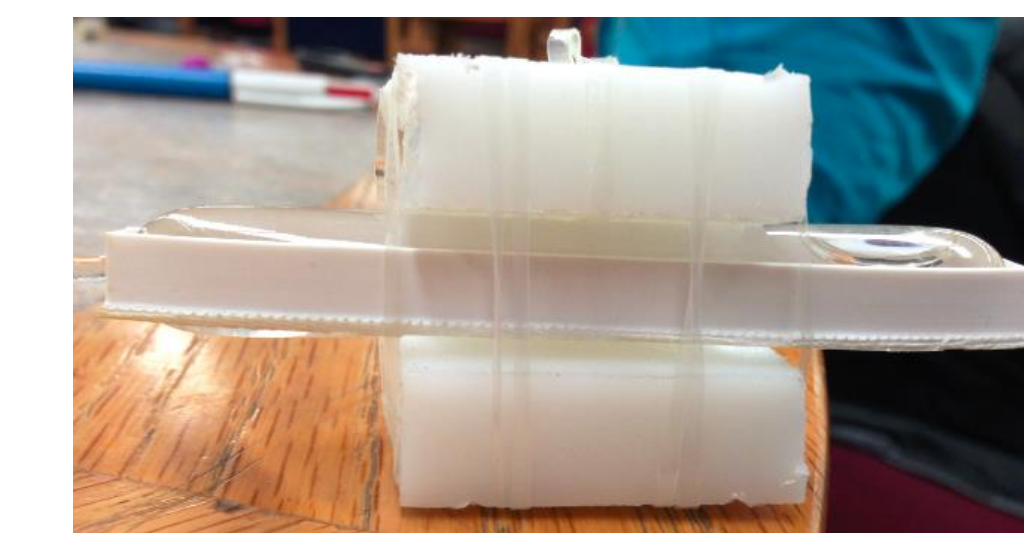


Catheter Design

- ❖ 4 atm
- ❖ 4 mm distraction

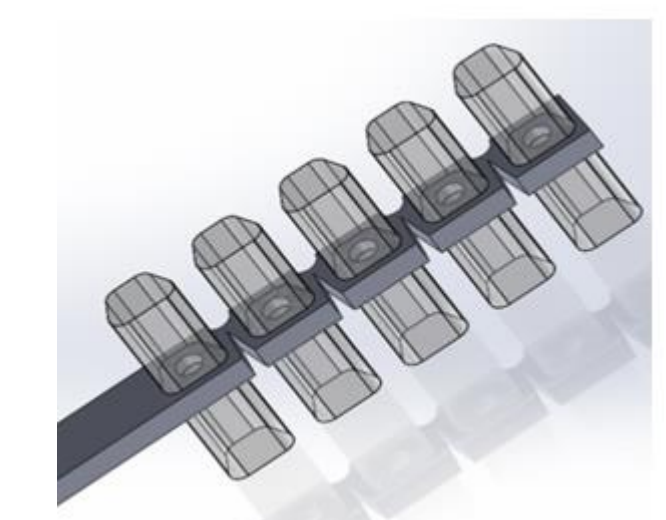
Box Design

- ❖ 4 mm distraction
- ❖ 1.8 atm



FUTURE WORK

- ❖ Dip-mold balloon or use existing balloon
- ❖ Balloon will unfold in one direction rather than expand
- ❖ Open-loop fluid system
- ❖ PET or Nylon
- ❖ Improve fittings



ACKNOWLEDGEMENTS

- Dr. Willis Tompkins
- Michael Zinn
- Bruce Lamberty
- Dr. Nathaniel Brooks
- Naomi Chesler
- Boston Scientific
- Frank Fronczak

References:

- ❖ <http://www.today.com/video/today/48985429#48985429>
- ❖ <http://www.buxtonbio.com/images/78-3465.jpg>
- ❖ <http://www.allaboutbackandneckpain.com/explore/minimally-invasive-lateral.asp>
- ❖ http://www.icvis.com/articles/2012/3/2/images/JCraniovertJunSpine_2012_3_2_47_116537_u1.jpg
- ❖ <http://www.cedars-sinai.edu/Patients/Programs-and-Services/Spine-Center/The-Patient-Guide/Anatomy-of-the-Spine/Vertebrae-of-the-Spine.aspx>