

# INFLATABLE VERTEBRAL DISTRACTION DEVICE

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## ABSTRACT

The majority of spinal procedures require spinal distraction, or separation of the vertebral bodies, to aid the surgeon throughout the operation [1]. Current methods can result in vertebral fractures and an inflatable device is, therefore, needed to safely distract the lumbar portion of the spine. The device should be non-obtrusive to the surgeon, avoid damage to the vertebrae and surrounding soft tissue, and distract axially to separate adjacent vertebrae while occupying minimal cavity space. We designed and fabricated an inflatable device that uses two vertically-stacked balloon catheters to conform to and distract the vertebrae. The device was tested and the spine was distracted 6 mm under representative anatomical loading.

## INTRODUCTION

Client: Dr. Nathaniel Brooks, UW Hospitals and Clinics

- ❖ Neurological surgeon
- ❖ Performs minimally invasive spinal surgeries

Background:

- ❖ Approx. 200,000 spinal surgeries per year in U.S. [2]
- ❖ Distraction allows surgeon better access during procedures [3]
- ❖ Current methods can result in spinal fractures



Figure 1: Lower Back Pain from Collapsed Vertebral Discs [1]



Figure 2: Vertebral Distraction [3]

Dr. Brooks has requested an inflatable 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 **on the market**, but none use an inflatable distraction method.

**Problems:**

- ❖ Requires large space for insertion
- ❖ Small contact surface area applies large point pressure to vertebral body [4]
- ❖ Not conforming



Figure 3: Paddle distractor [5]

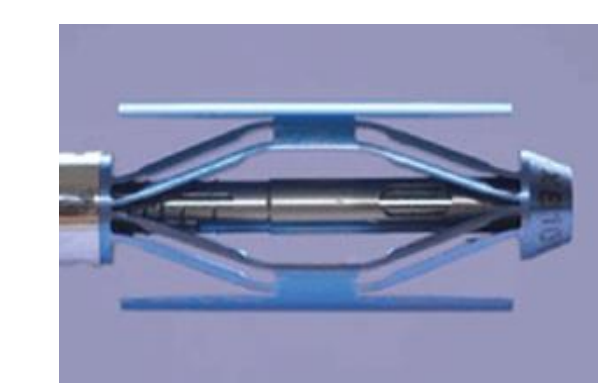


Figure 4: Scissor jack distractor [6]

Patents:

- ❖ EP0457456: Reinforced balloon [7]
- ❖ US9348979: Cervical distraction [8]
- ❖ CA2583913: Multiple Balloon Catheter [9]

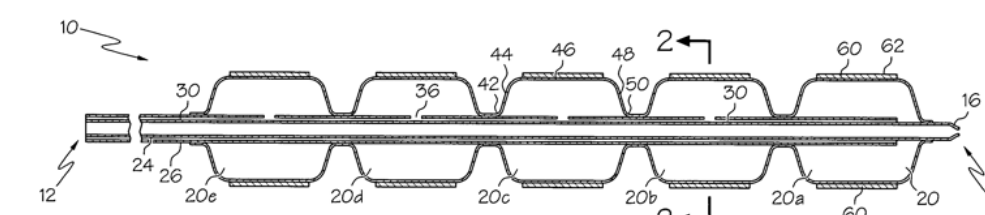


Figure 5: Multiple balloon patent [9]

## DESIGN CRITERIA

**Optimal Distraction:**

- ❖ Force: 431 N
- ❖ Distance: 4 - 6 mm

**Device Size Restrictions:**

- ❖ Insertion height: < 10 mm
- ❖ Distracted height: 14 - 18 mm

**Insertion Method:**

- ❖ Minimally-invasive

**Balloon Material:**

- ❖ Conformable
- ❖ Biocompatible
- ❖ High strength

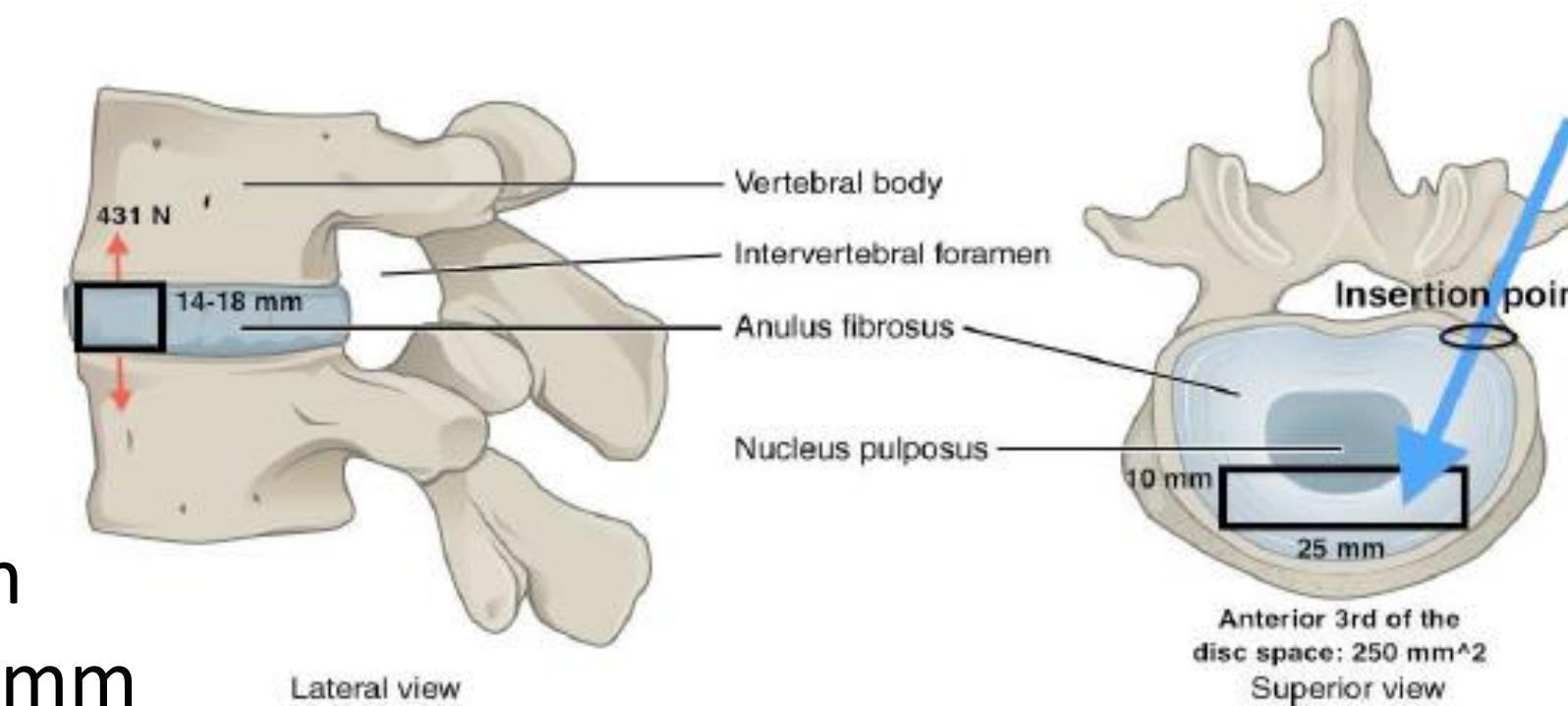


Figure 6: Diagram of optimal vertebral distraction [5]

**Required Balloon Pressure:**

- ❖ 17 ATM

**Feedback Mechanism:**

- ❖ Pressure Gage

**Total Project Budget:**

- ❖ \$1,000

## FINAL DESIGN

**1<sup>st</sup> Prototype: Box with inflatable bladder**

PROS:

- ❖ Directed expansion

CONS:

- ❖ Rigid
- ❖ Bulky exterior
- ❖ Limited distraction

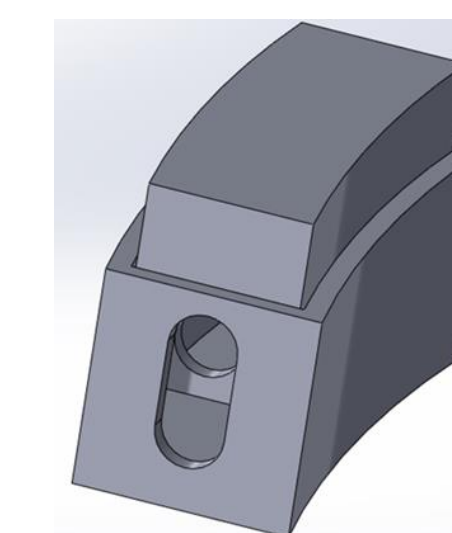


Figure 7: Boxed inflatable bladder

**2<sup>nd</sup> Prototype: Single balloon catheter with structural walls**

PROS:

- ❖ Conforming to vertebrae

CONS:

- ❖ Radial expansion



Figure 8: Structured wall single balloon catheter

**Final Prototype: Two stacked catheters**

PROS:

- ❖ Directed expansion
- ❖ Large range of distraction

CONS:

- ❖ Possibility of tumbling

- ❖ Budget friendly: \$36
- ❖ Individual OD: 8 mm
- ❖ Length: 20 mm



Figure 9: Vertically stacked catheter design

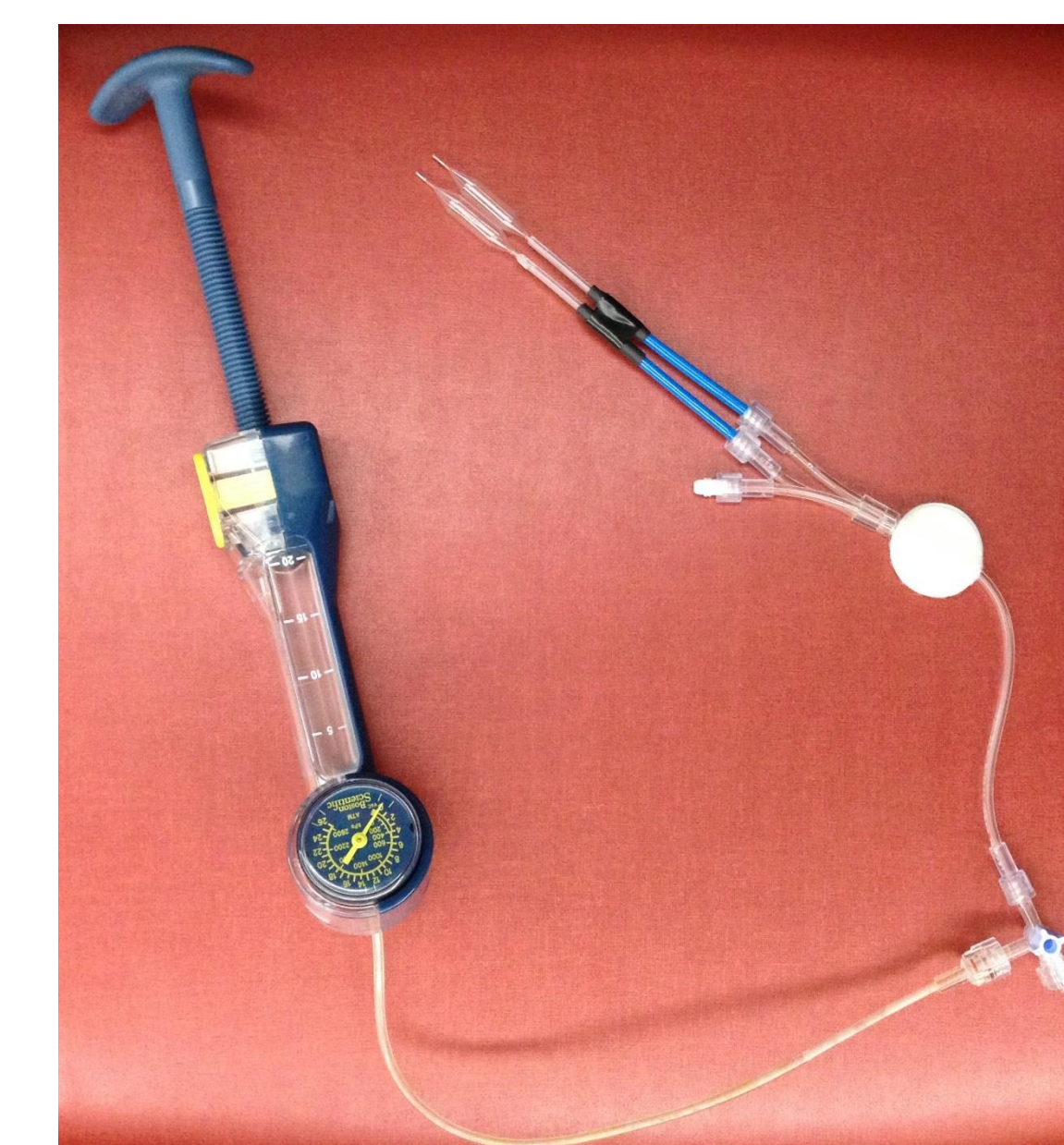


Figure 10: Inflatable distraction pump system

## TESTING & RESULTS

- ❖ Compressive simulation
- ❖ Polymer blocks = vertebral bodies
- ❖ Rubber strips = ligaments
- ❖  $A_R = \frac{K_f I_o}{E_R}$
- ❖ ALL and PLL modeled
- ❖ Distracted 6 mm
- ❖ Anatomical representation
- ❖ Spine model
- ❖ Disc removed similar to surgical removal
- ❖ Posterior insertion

**Elastic Modulus of Rubber Samples**

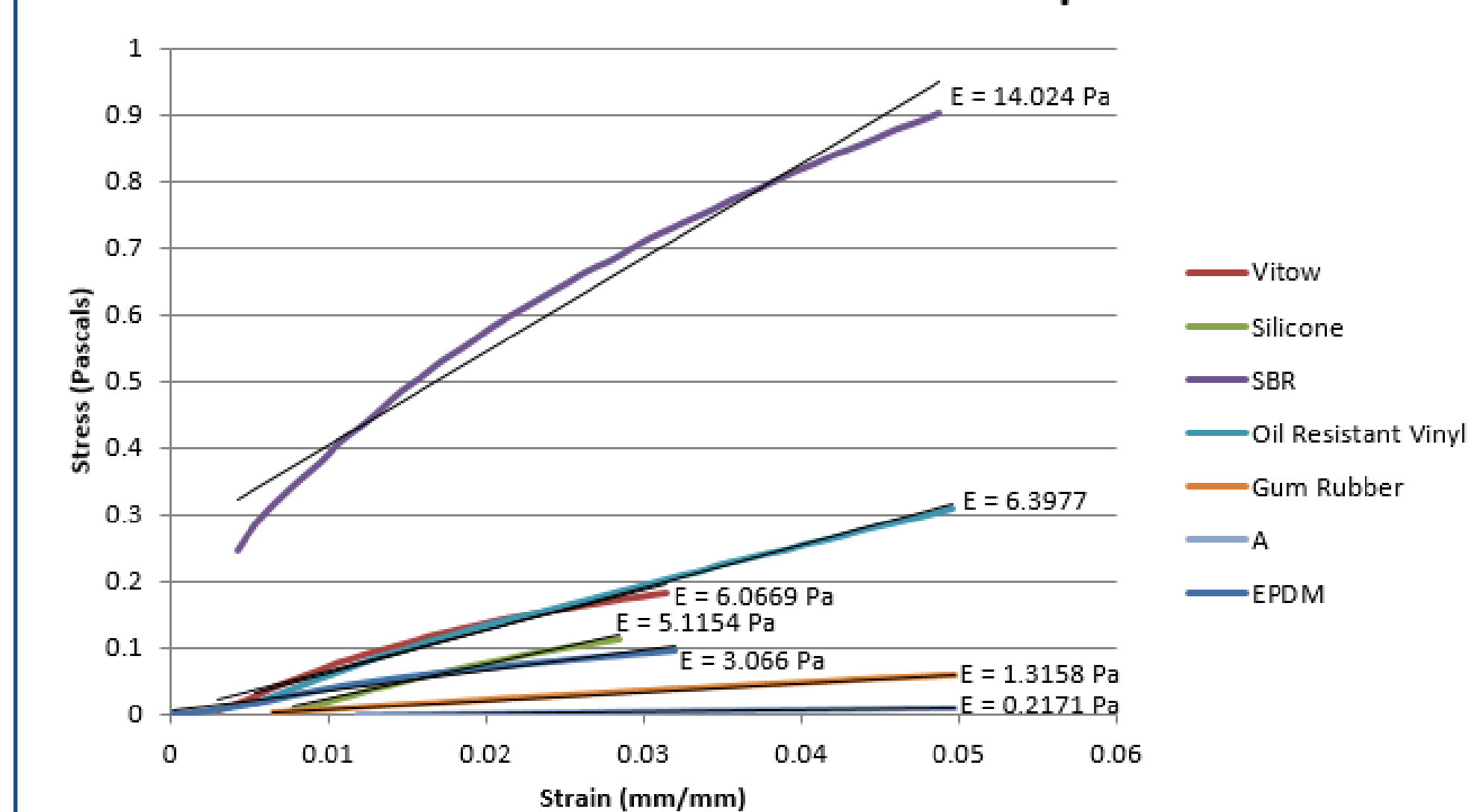


Figure 12: Elastic moduli of potential spine model rubber

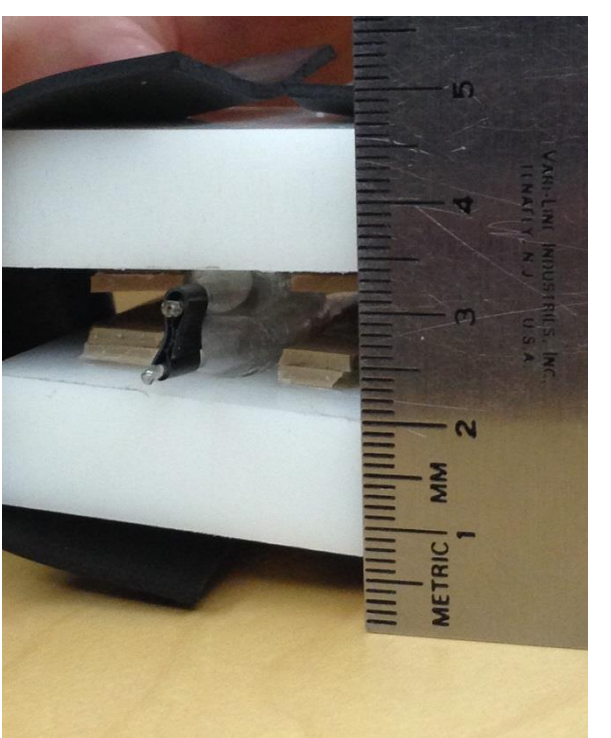


Figure 11: Distraction of compressive force spine model

## FUTURE WORK

- ❖ IDR submission pending acceptance
- ❖ Custom fabrication of an axial-inflated balloon
- ❖ Streamline system
- ❖ Bulk manufacturing of device
- ❖ Multi-chambered balloon
- ❖ Animal testing & clinical trials
- ❖ Improved navigation/maneuverability

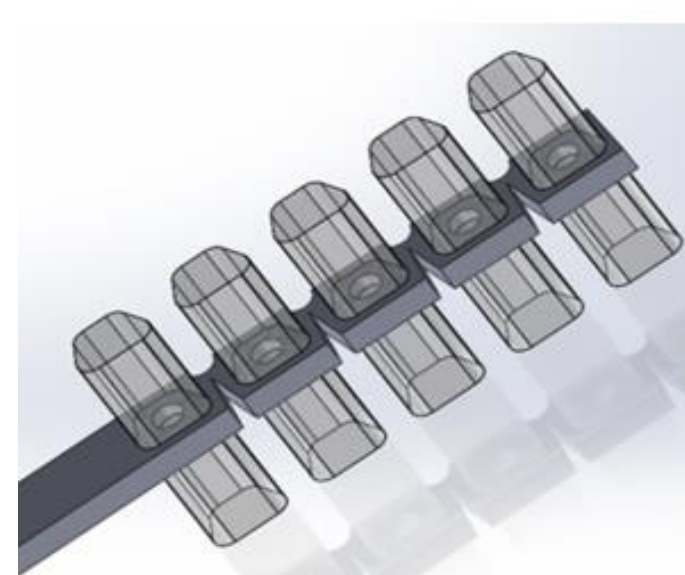


Figure 13: Multiple balloon design

## ACKNOWLEDGEMENTS

- Dr. Willis Tompkins
- Dr. Nathaniel Brooks
- Spencer Strand
- Frank Fronczak
- Naomi Chesler
- Heidi Ploeg
- Michael Zinn
- Kip Weller
- Bruce Lamberty
- Boston Scientific
- Sarah Duenwald-Kuehl

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