

Inflatable Vertebral Distractor

Team Members:

Taylor Lamberty – Team Leader

Catharine Moran – Communicator

Myranda Schmitt – BWIG & BPAG

Douglas Ciha – BSAC

Client: Dr. Nathaniel Brooks, MD

Advisor: Dr. Willis Tompkins, PhD

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Outline

- ▶ Background
- ▶ Last semester
- ▶ This semester
- ▶ Timeline
- ▶ Budget

Client Description

- ▶ Dr. Nathaniel Brooks
- ▶ Spinal surgeon in Madison
- ▶ Disc removal surgery for collapsed discs



<http://www.sandiego-spine.com/subject.php?pn=xlif-conditions>

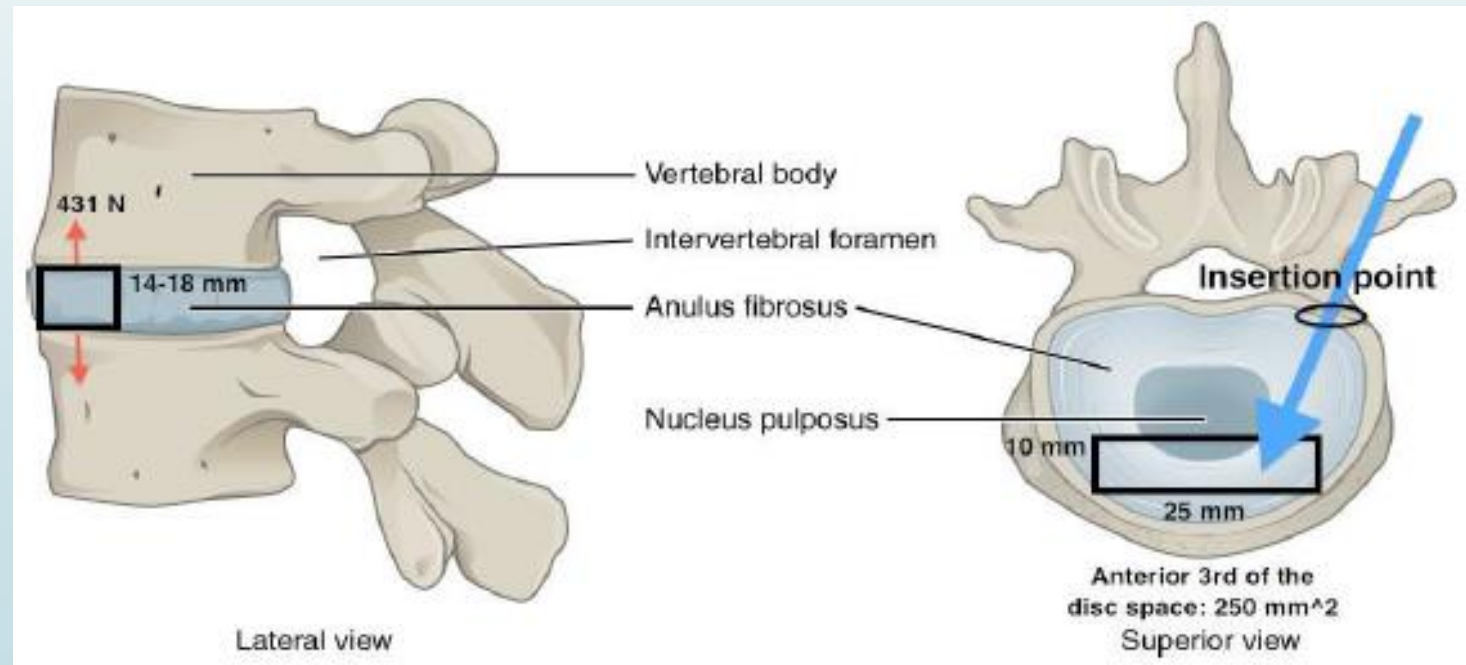
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Problem Statement

- The goal of this project is to design and fabricate an inflatable vertebral body distractor device for the lumbar portion of the spine that can be properly placed, easily maneuvered, and will not cause spinal fractures.

Design Constraints

- **SIZE:** should fit into the anterior 1/3 of the disc space (250 mm².)
- **FORCE:** should apply 431 N of force for 4 mm distraction.
- **MATERIAL:** the material should be biocompatible and able to withstand the said pressure in the body.



Why is this important?

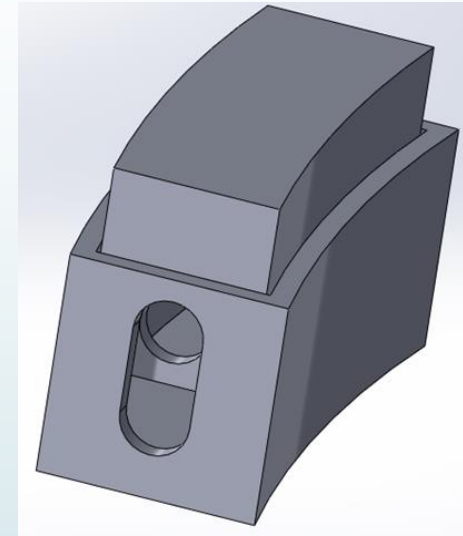
- ▶ Decrease risk of bone fracture.
- ▶ Streamline procedure for surgeons.
- ▶ Potential to affect other procedures that involve distraction.



<http://biscupspine.com/back-treatments/surgical/>

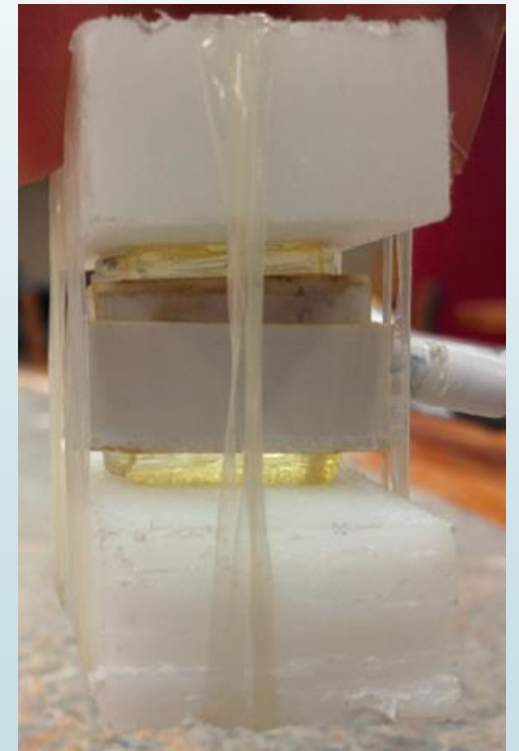
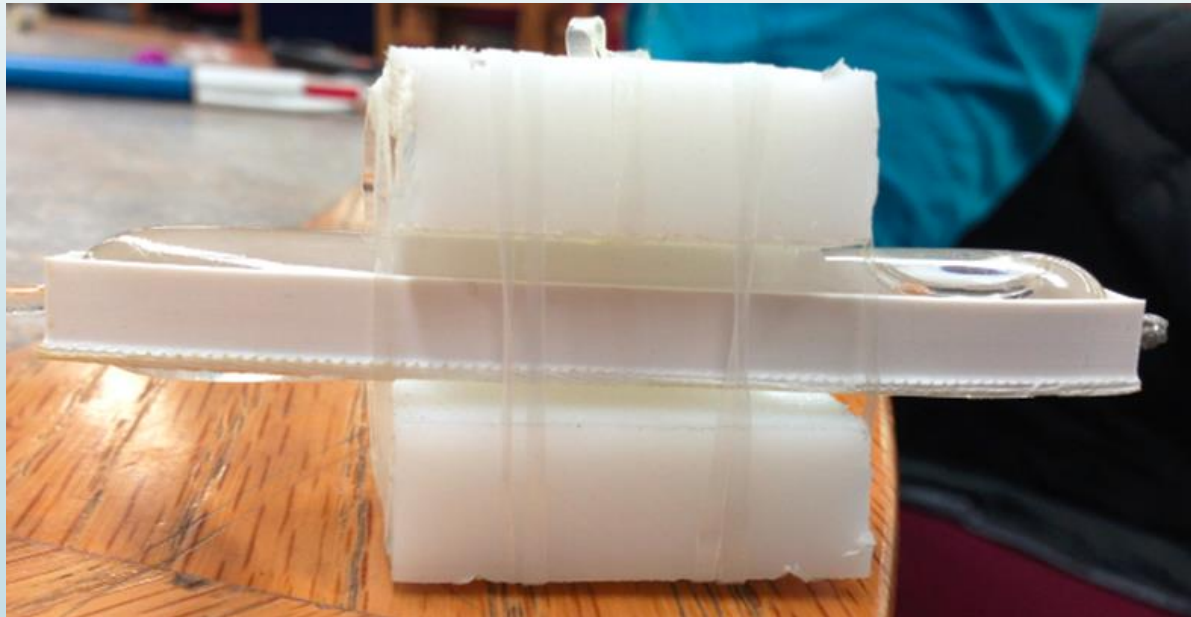
Final Design Prototypes

- ▶ Box
 - ▶ Encased bladder
 - ▶ 10 x 24 x 10 mm²
 - ▶ Gel cushioning
- ▶ Catheter
 - ▶ Unfolding
 - ▶ 100 mm long x 15 mm diameter
 - ▶ Encased in box for stability



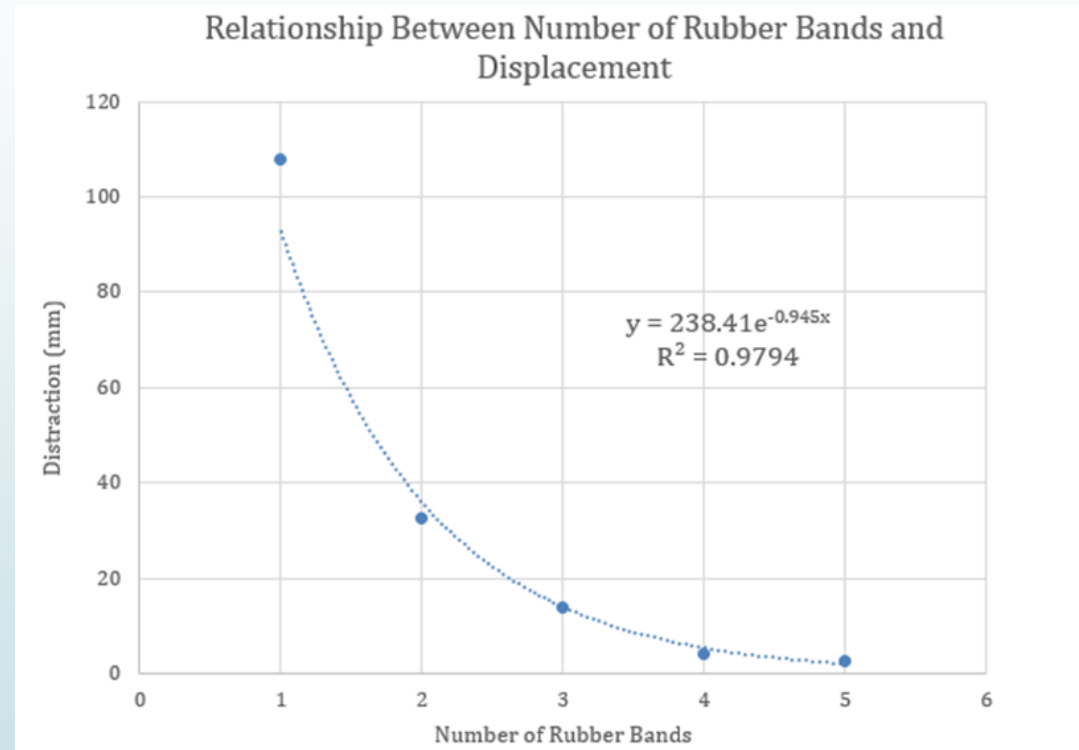
Testing

- ▶ Mechanism mimicked spinal compressive loading
 - ▶ Rubber bands provide resistance
- ▶ Devices inflated to 4 mm distraction



Testing

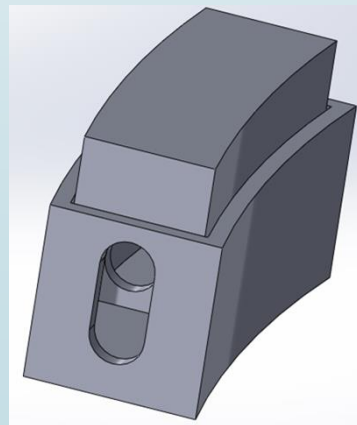
- ▶ Find force rubber bands apply
 - ▶ Determine displacement at known lb.
 - ▶ Extrapolate to 8 rubber bands
- ▶ $D = 238.41e^{-0.945*(8)} = 0.124 \text{ mm/lb}$
- ▶ $4 \text{ mm}/0.124 \text{ mm/lb} = 32.21 \text{ lb}$



Prototype Issues

Box

- Bulky in insertion
- Not as conforming as desired
- Limited expansion
- Bladder leaking

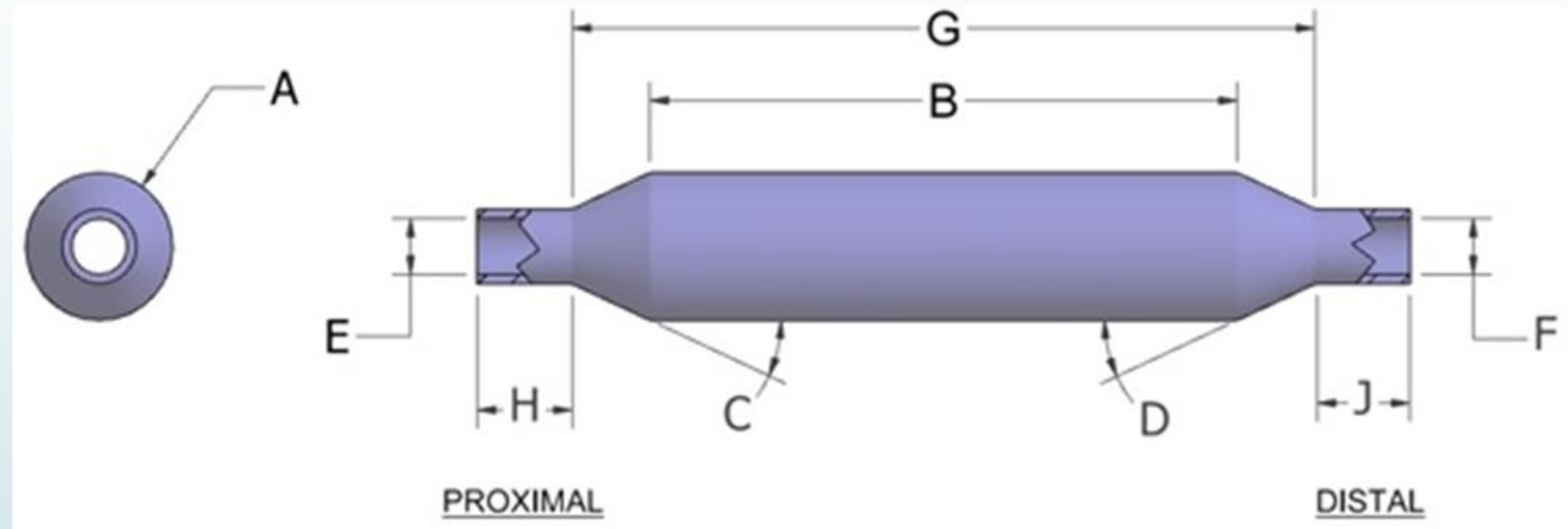


Catheter

- Radial expansion, rather than vertical
- Not shape fitting to the vertebral cavity



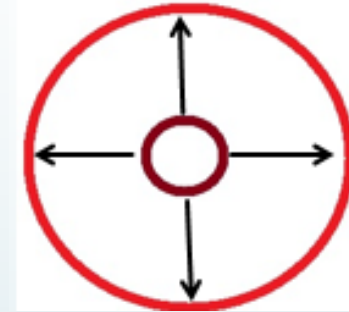
New Prototype



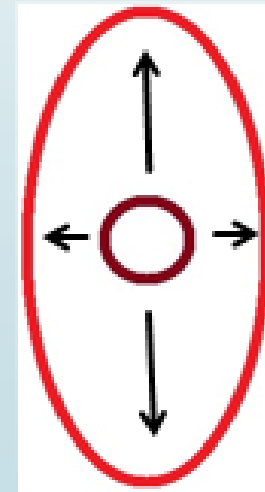
- Catheters
 - Already made from our ideal materials
 - Can maintain high pressures

Custom Development

► Typical radial expansion:



► Required axial expansion:
Ideally unidirectional expansion.



Cost of Development

- ▶ Custom catheters proved too pricy
 - ▶ Semester budget: \$820
 - ▶ Custom: \$3,000 - \$5,000

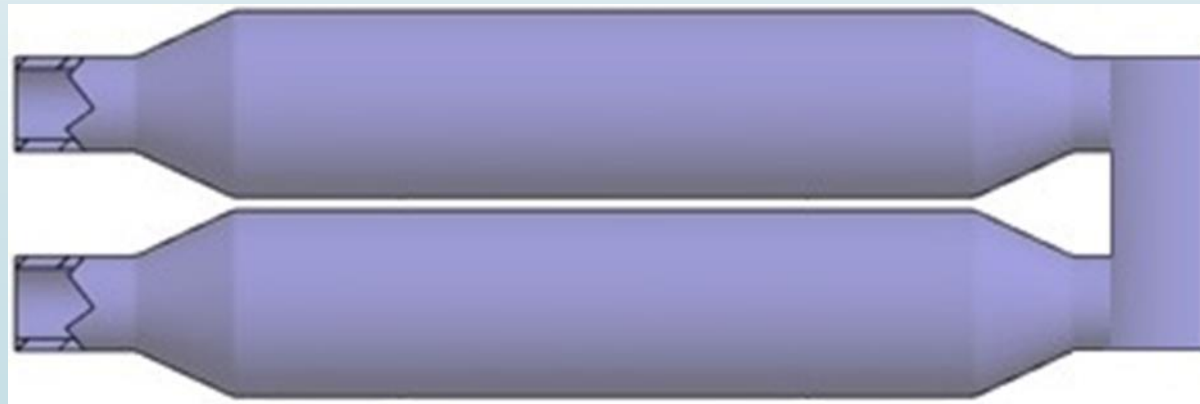
- ▶ Stock balloon catheters
 - ▶ Cheaper: \$108
 - ▶ Easily available



<http://test.adobepremiumfirearms.com/wp-content/uploads/2012/08/Payment-icon.jpg>

Solution

- ▶ Two stacked catheters
 - ▶ Connected to create one balloon
 - ▶ Expands primarily in one direction



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Testing

- ▶ Ideally cadaver/animal testing
 - ▶ Difficult to accomplish
 - ▶ Not required by our client
- ▶ Test Model
 - ▶ Ultimate strength of balloon tested by compressive tests
 - ▶ 3D print vertebrae to test insertion
 - ▶ Designed to simulate surgical conditions

Timeline

Tasks	January		February				March				April				May
	24	31	7	14	21	28	7	14	21	28	4	11	18	25	2
Brainstorming	X	X													
Product Development		X	X												
Design Prototype			X	X											
Order Materials				X											
Fabricate Prototype															
Testing															
Modifications															

Table 1: Timeline of this semester's progress. Boxes with "X" have been accomplished, while the green boxes indicate when we would like to accomplish tasks in the future.

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Budget

- ▶ Given \$1000 for year
- ▶ Spent \$71.25 last semester
- ▶ Spent \$108.00 on catheter balloons
- ▶ **\$820.75 left to use this semester!**

Companies to consider

- ▶ Interface
- ▶ Vention medical
- ▶ Carefusion



ventionmedical.com



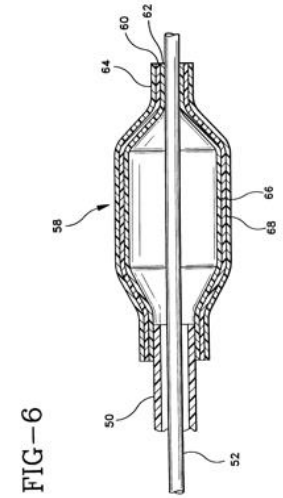
interfaceusa.com



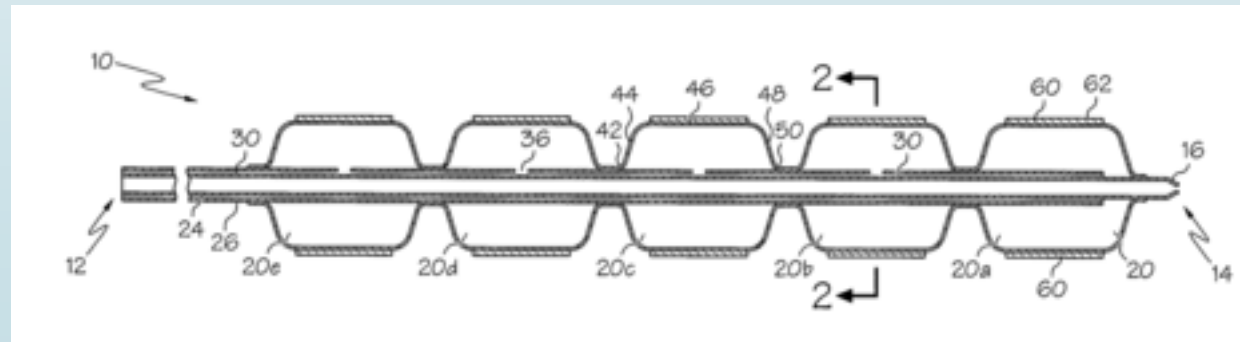
carefusion.com

Patents

- Multiple relevant patents
 - Multiple Layer Balloon (EP0457465)
 - Multiple Balloon Catheter (CA2583913)
 - Method for Cervical Distraction (US9348979)
- Once we fabricate our final design, we will file an IDR with WARF.



<http://www.google.com/patents/EP0457456B1?cl=en&dq=Multiple+layer+balloon&hl=en&sa=X&ei=17QGU7WSFdGKkAeEmiDIDg&ved=0CEEQ6AEwAg>



<http://www.google.com/patents/US7658744?dq=CA2583913&ei=MrQGU6D5M43ykQeY9YCYDQ&cl=en>

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Acknowledgements

- ▶ Dr. Nathaniel Brooks
- ▶ Dr. Willis Tompkins
- ▶ Spencer Strand
- ▶ Kenny Mazzaresse
- ▶ Boston Scientific

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- <http://www.google.com/patents/US8348979?dq=cervical+distraction+method+patent&hl=en&sa=X&ei=iLUGU4KxLlyFkQeVq4DgAw&ved=0CDMQ6AEwAA>
- <http://biscopspine.com/back-treatments/surgical/>



Questions???