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Coronal Plane Displacement Gradient Precedes Vertebral Growth Modification Using Hemiepiphyseal Staples

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Acknowledgments

- **Grant funding**
 - SRS Grant
 - NIH CTSA via UC Clinical and Translational Science Award
 - UC Women In Science & Engineering Program
- **Equipment granted**
 - SpineForm LLC
 - Custom implants and surgical instruments
 - Ethicon EndoSurgery
 - Materials test system
- **Regulatory status**
 - FDA IDE approved for prospective clinical safety study

Background

- Approved by US FDA for IDE safety study
- Simple Staple-Screw device made of Titanium
- Applied antero-laterally to the spine



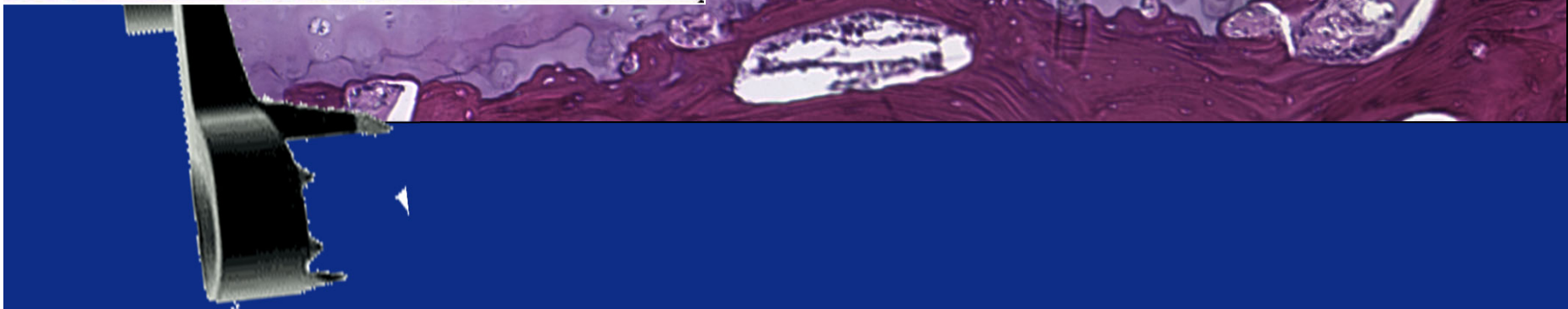
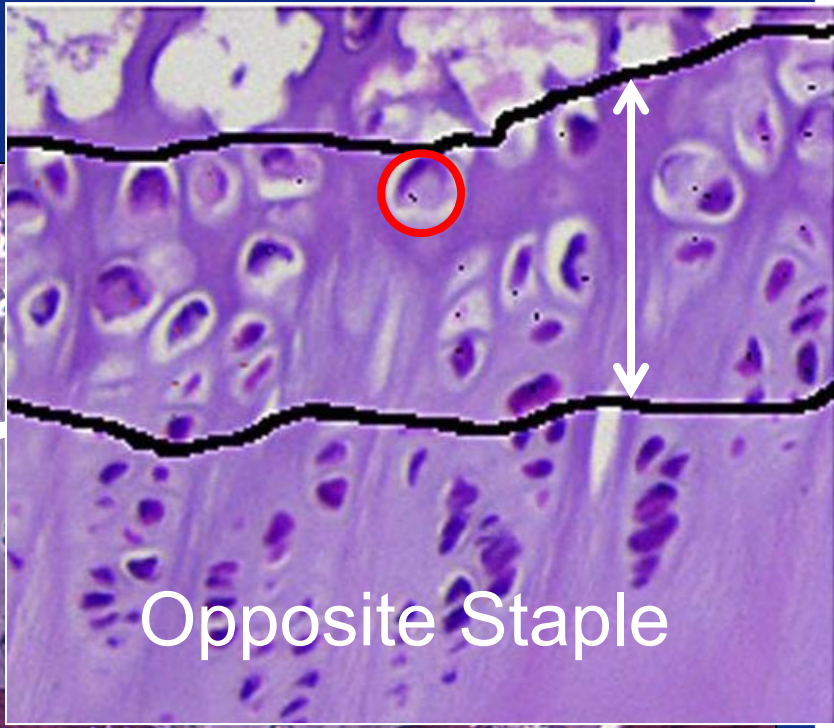
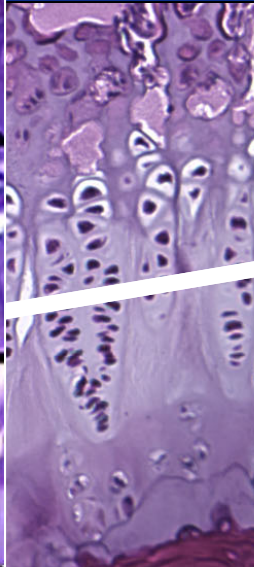
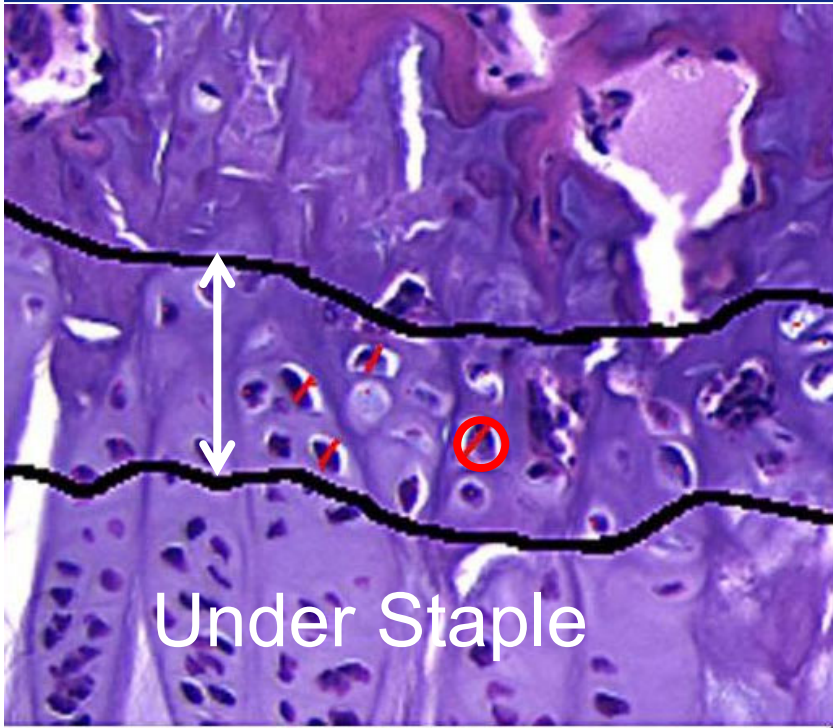
Background

Spinal Hemiepiphysiodesis Decreases the Size of Vertebral Growth Plate Hypertrophic Zone and Cells

By Donita I. Bylski-Austrow, PhD, Eric J. Wall, MD, David L. Glos, BSE, Edgar T. Ballard, MD,
Andrea Montgomery, BS, and Alvin H. Crawford, MD

Investigation performed at the Division of Pediatric Orthopaedic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio

- Staple device causes actual growth inhibition on ipsilateral side

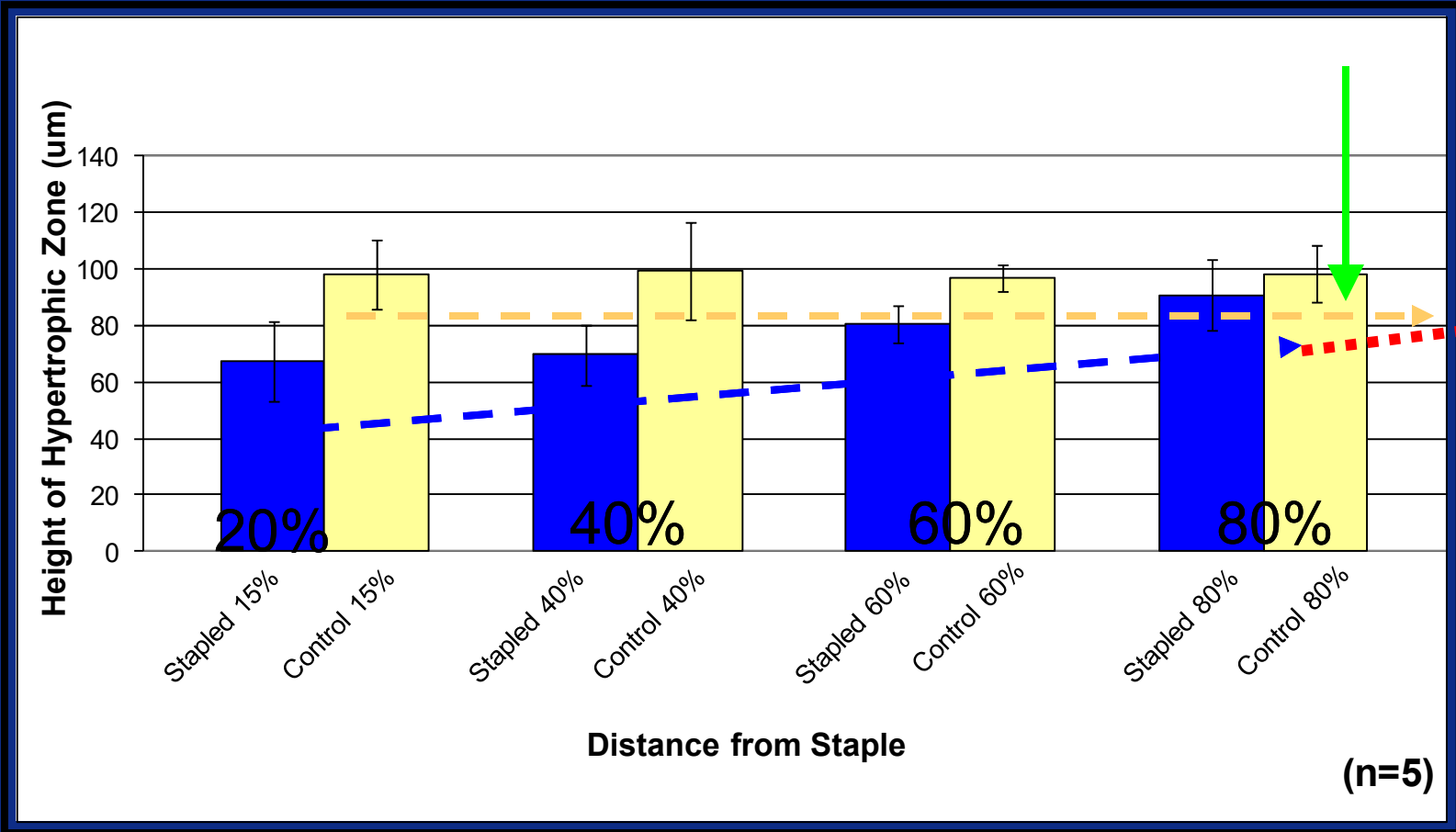


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Hypertrophic Zone Height Gradient

8 weeks

EJW1



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Slide 6

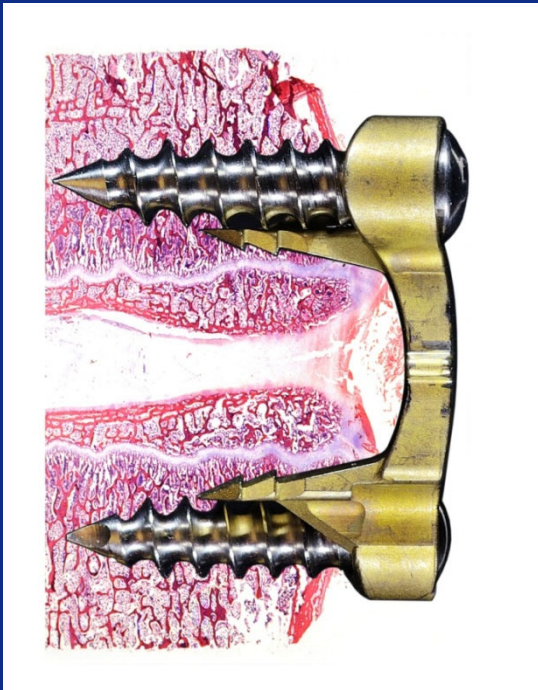
EJW1

WALG3F, 5/2/2006

Purpose and Hypothesis

- **Purpose:**

Determine if implantation of staple causes biomechanical gradients in coronal plane



- **Hypothesis:**

Coronal plane displacement and stress gradients occur at the time of initial implantation, preceding growth modification

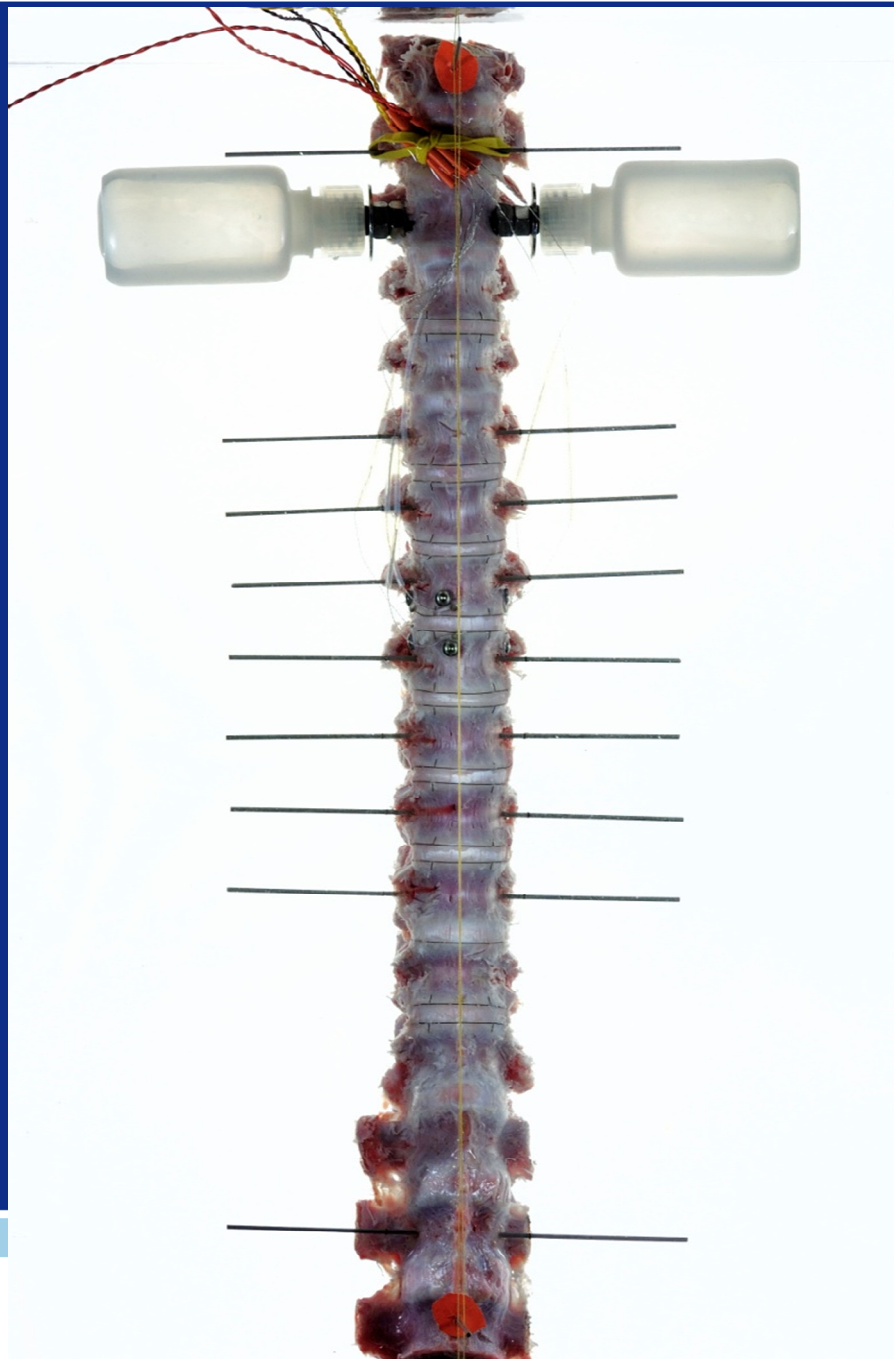
Methods: Experimental Design

Skeletally Immature Porcine thoracic spines

- Tested biomechanically
 - Before and after implant insertion
 - Paired t-tests

Two tests

- 1) Displacements (n=4)
 - Intact spines under “no-load” condition
 - Six staple-screw constructs
- 2) Load (n=5)
Compressive stresses bilaterally in annulus
 - During implantation
 - During cyclic compression

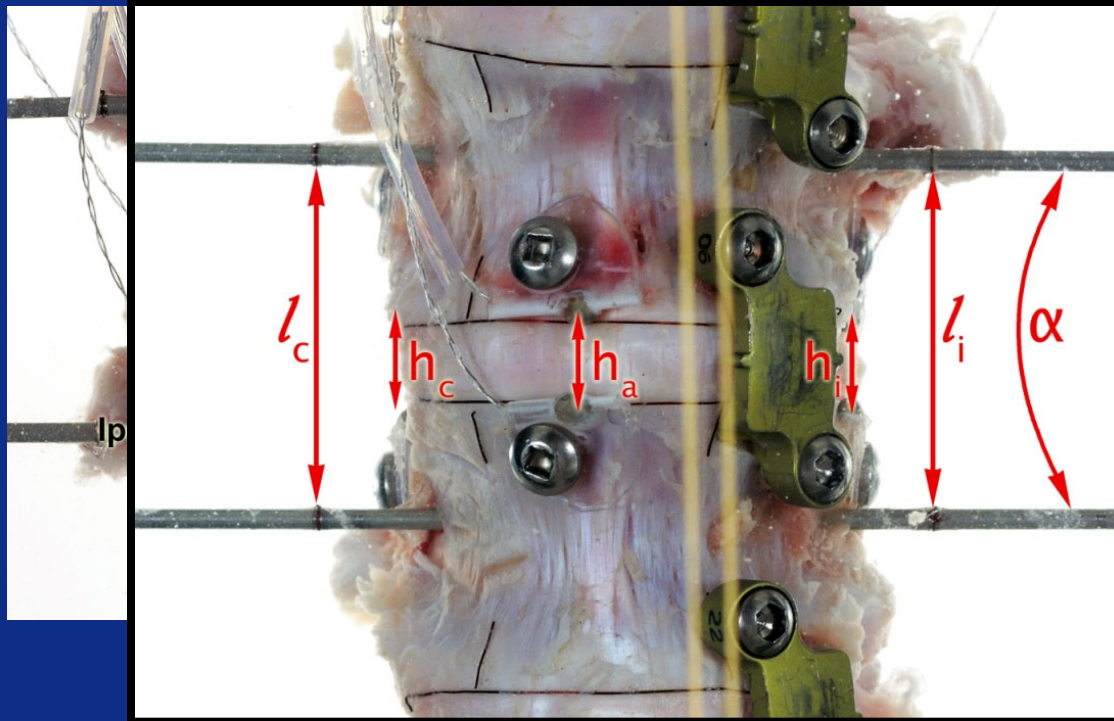


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Methods

Displacement



Methods

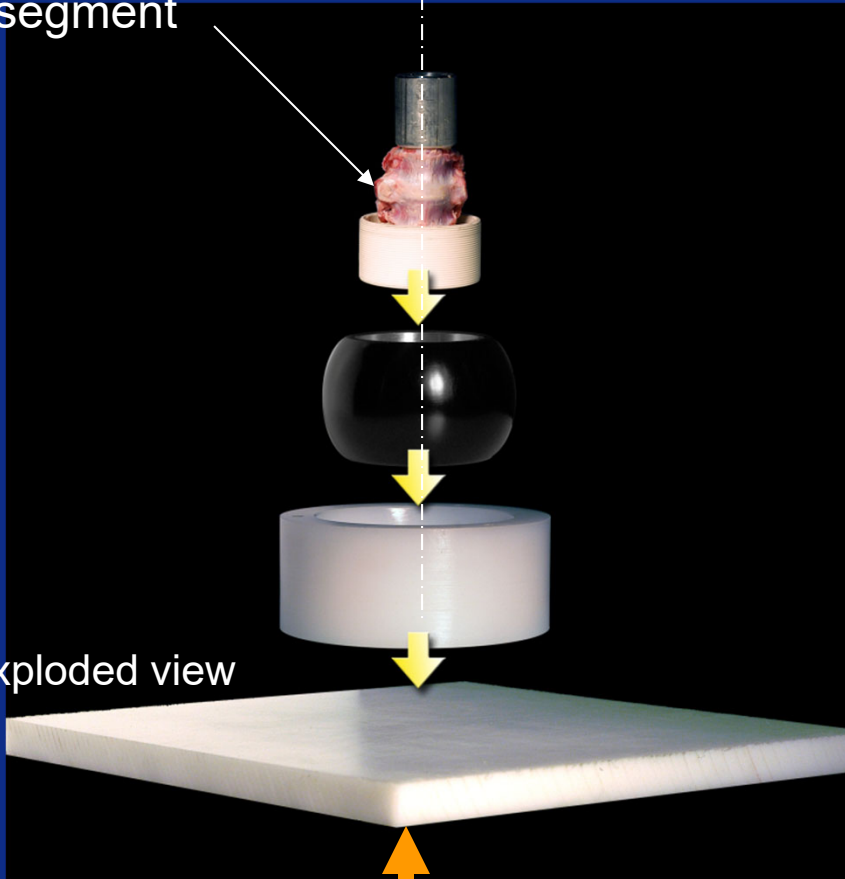
Stress gradient

Compression

- Custom fixtures
 - 5 degrees of freedom
 - Allowed realignment

Motion segment

Exploded view

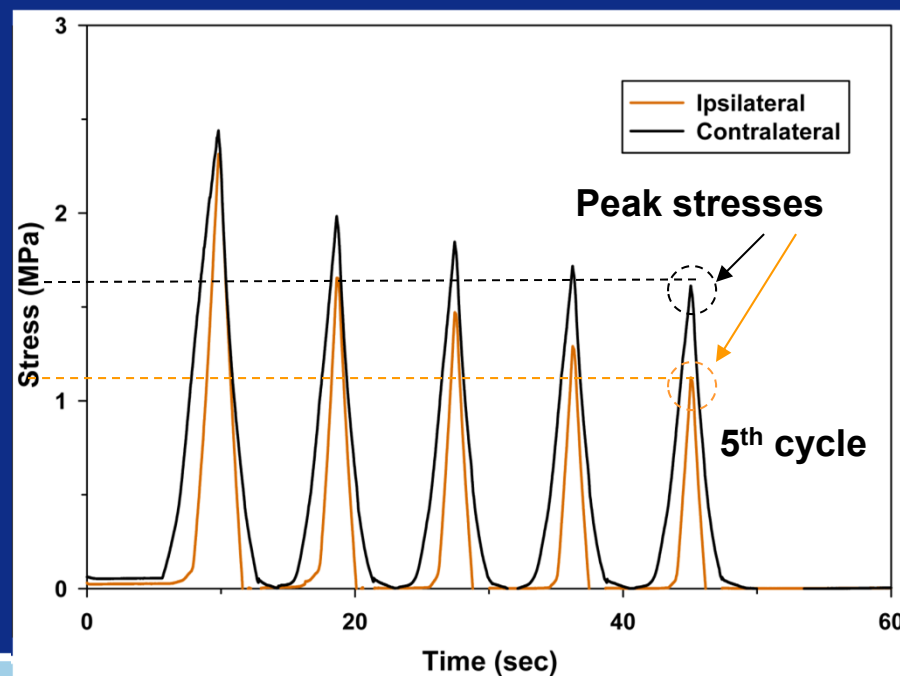


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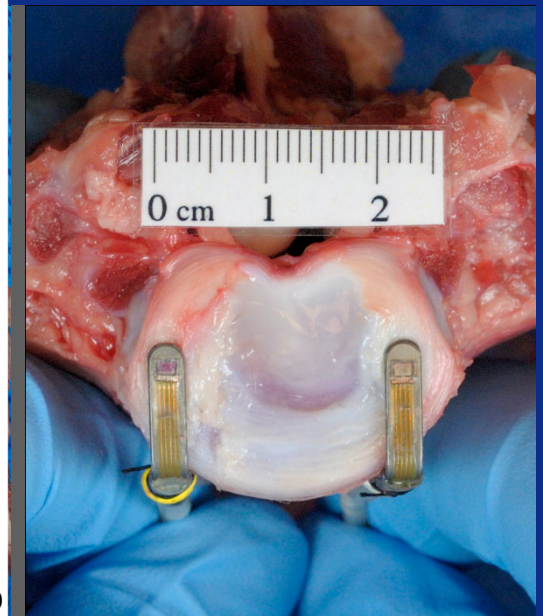
Methods

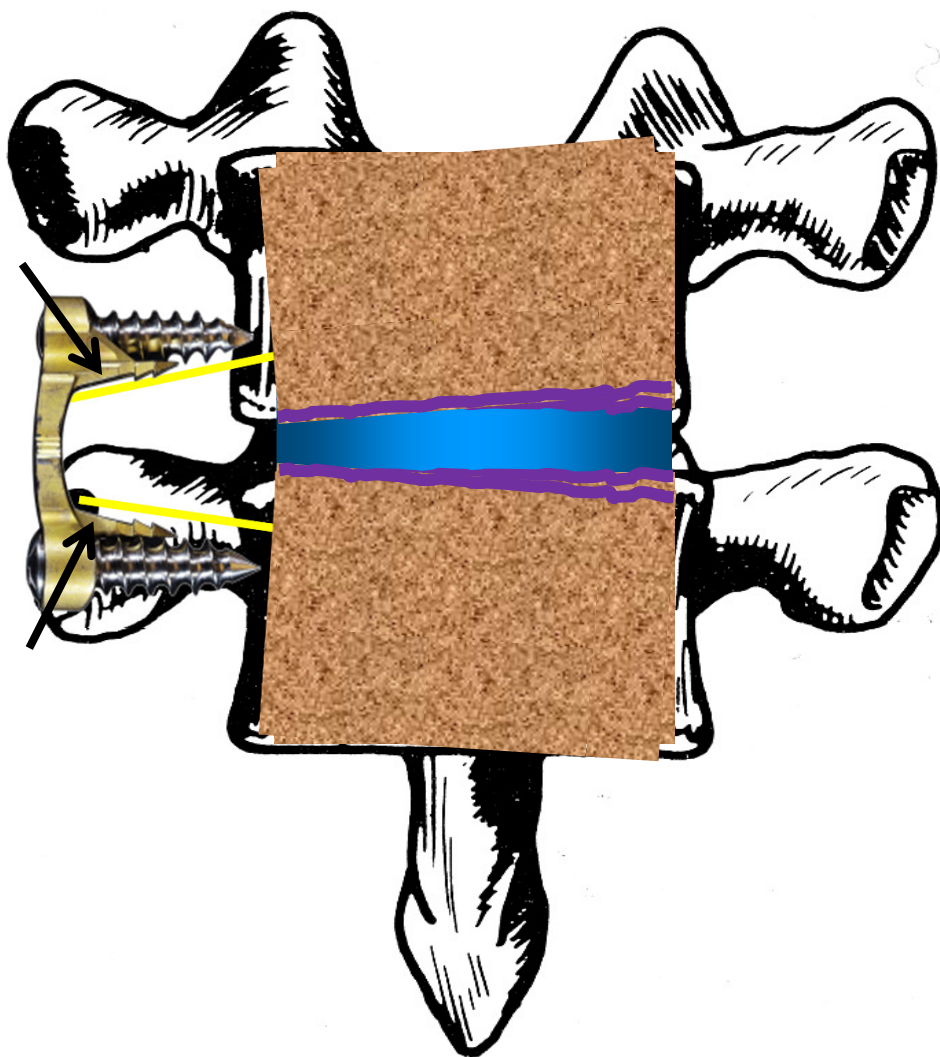
Stress gradient

- Cyclic compression
- Stresses measured bilaterally in annulus
 - Custom sensors (*J Biomech* 2010)



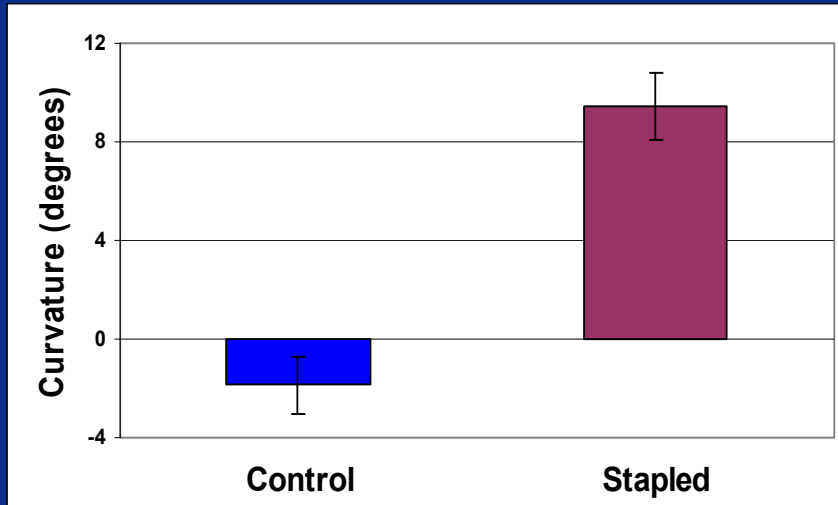
Cut-away to show sensor placement



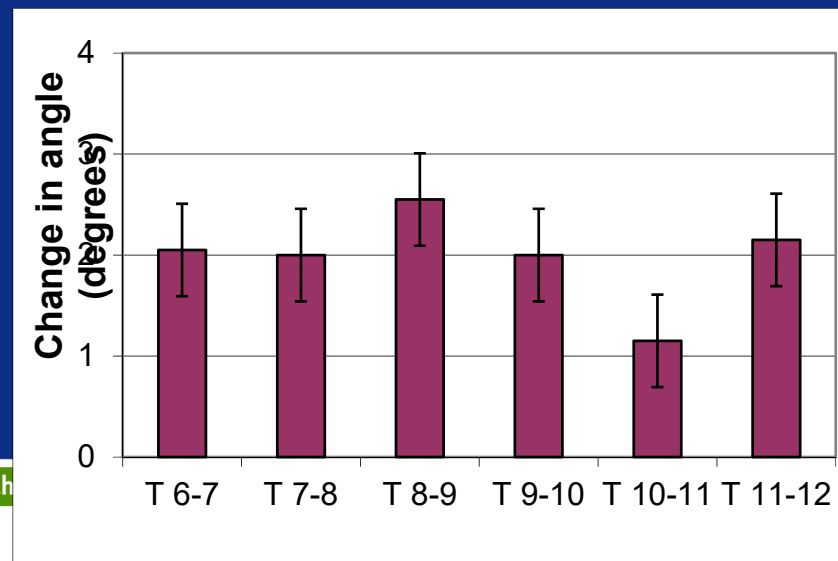


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Thoracic spine curvature



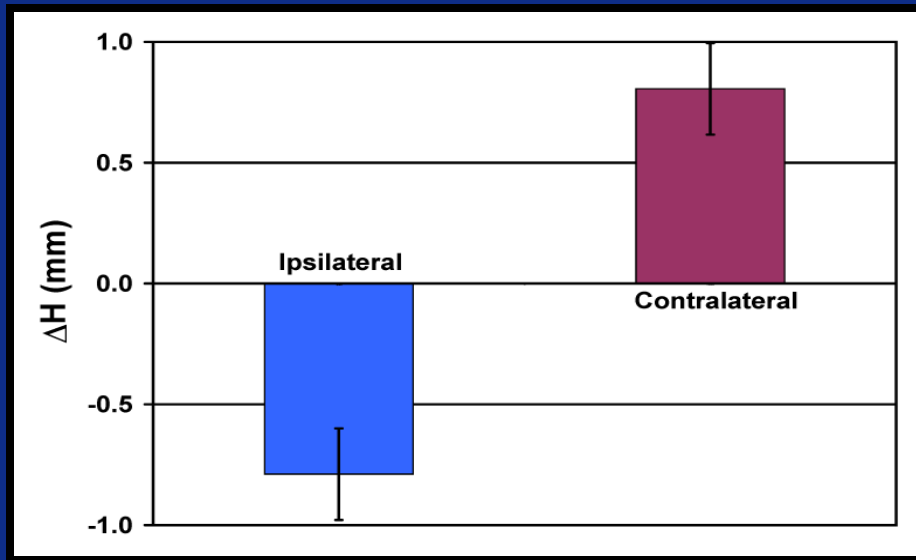
Increased 11.3° ($p < 0.005$)



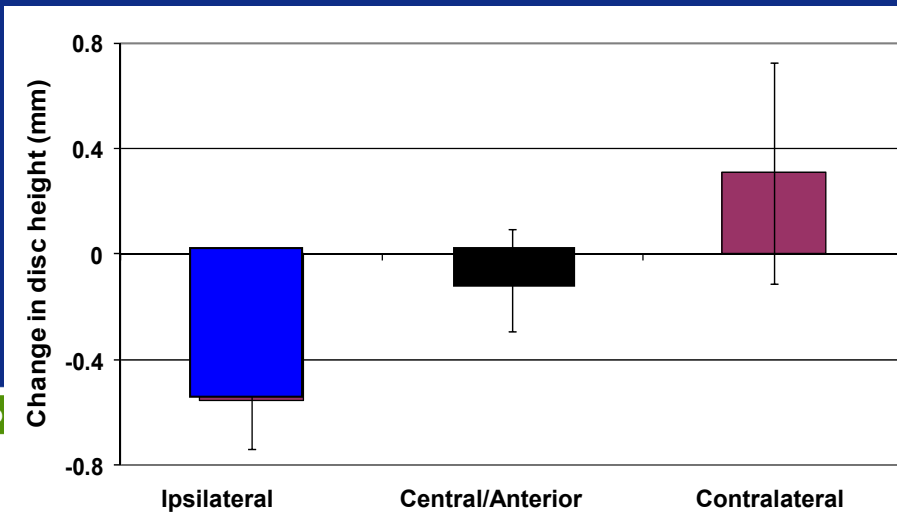
2° per level

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Side to side change in height



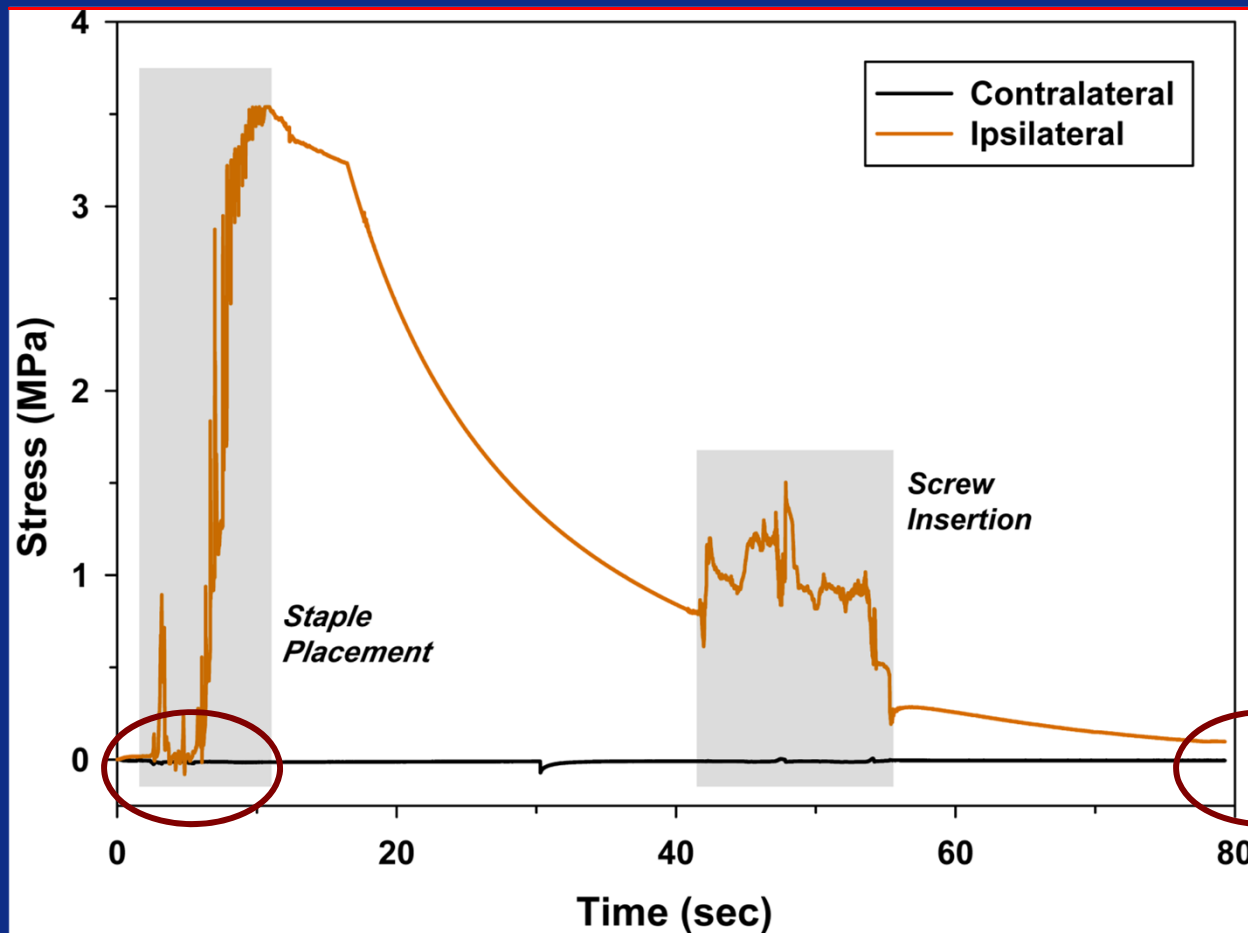
Motion segment height change



Disc height change

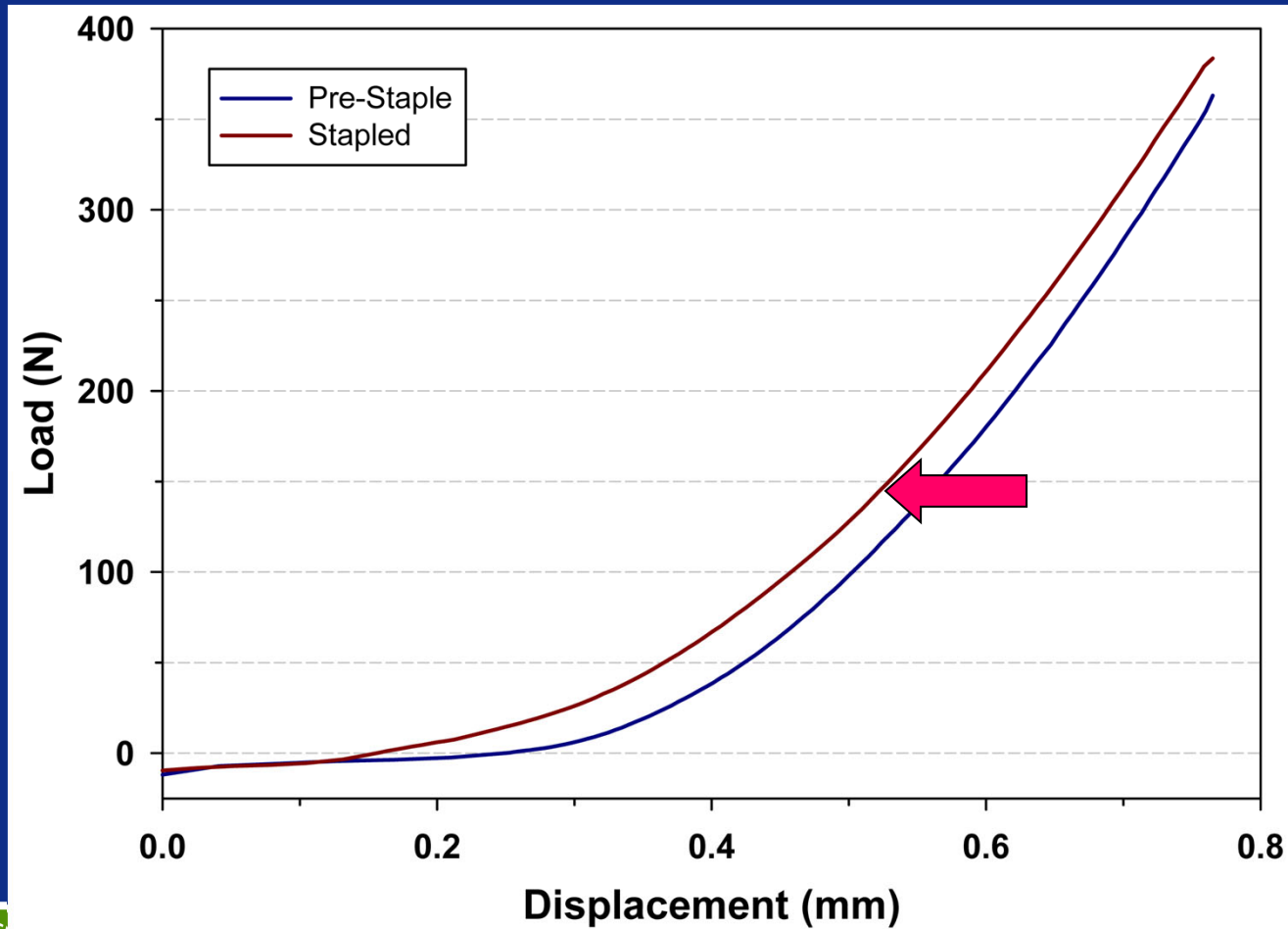
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Stresses during stapling *in vitro*



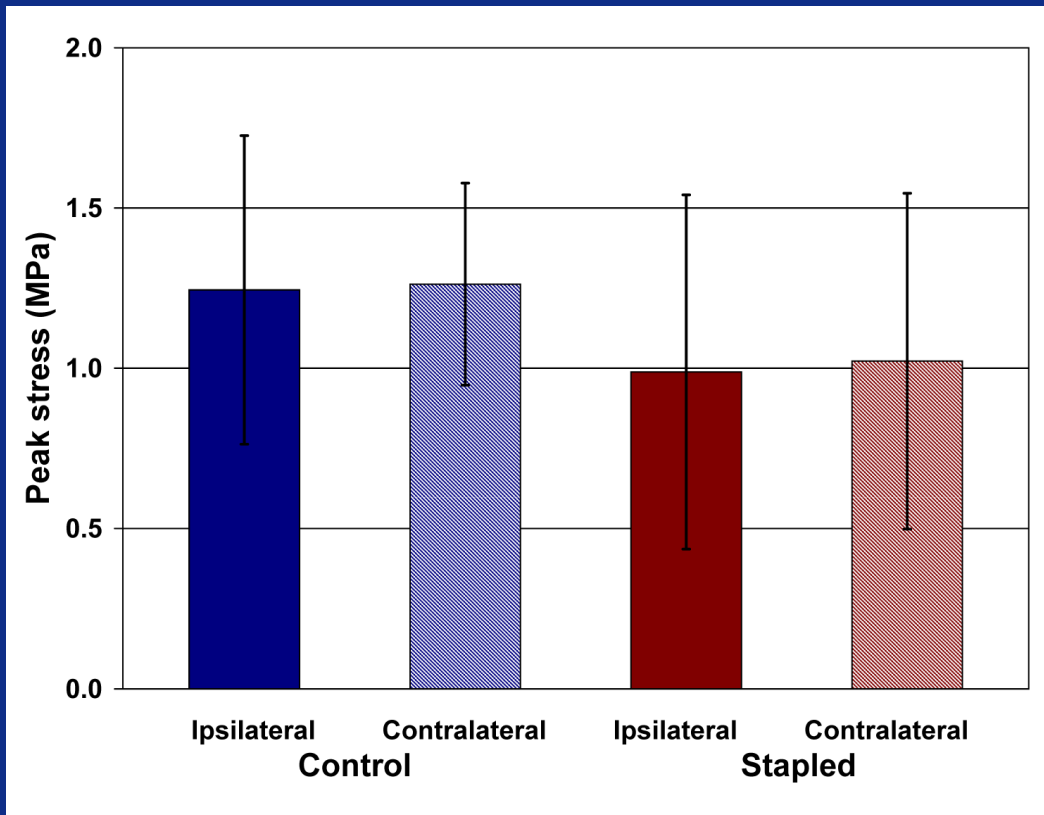
- Ipsilateral side stress
- Increased then relaxed

Load – displacement curves



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Peak compressive stresses decreased after stapling



- Stress shielding
- No peak stress gradient measurable

Conclusions & Significance

- **Staples caused displacement gradient**
 - Compressive to tensile
 - Blade angle
 - Likely to maintain growth on contralateral side
- **No compressive stress gradient either Static or Peak dynamic**
 - Mild stress shielding effect bilaterally