Risk of Implant Loosening after Cyclic Loading of Fusion-less Growth Modulation Techniques: Nitinol Staples vs Flexible Tether

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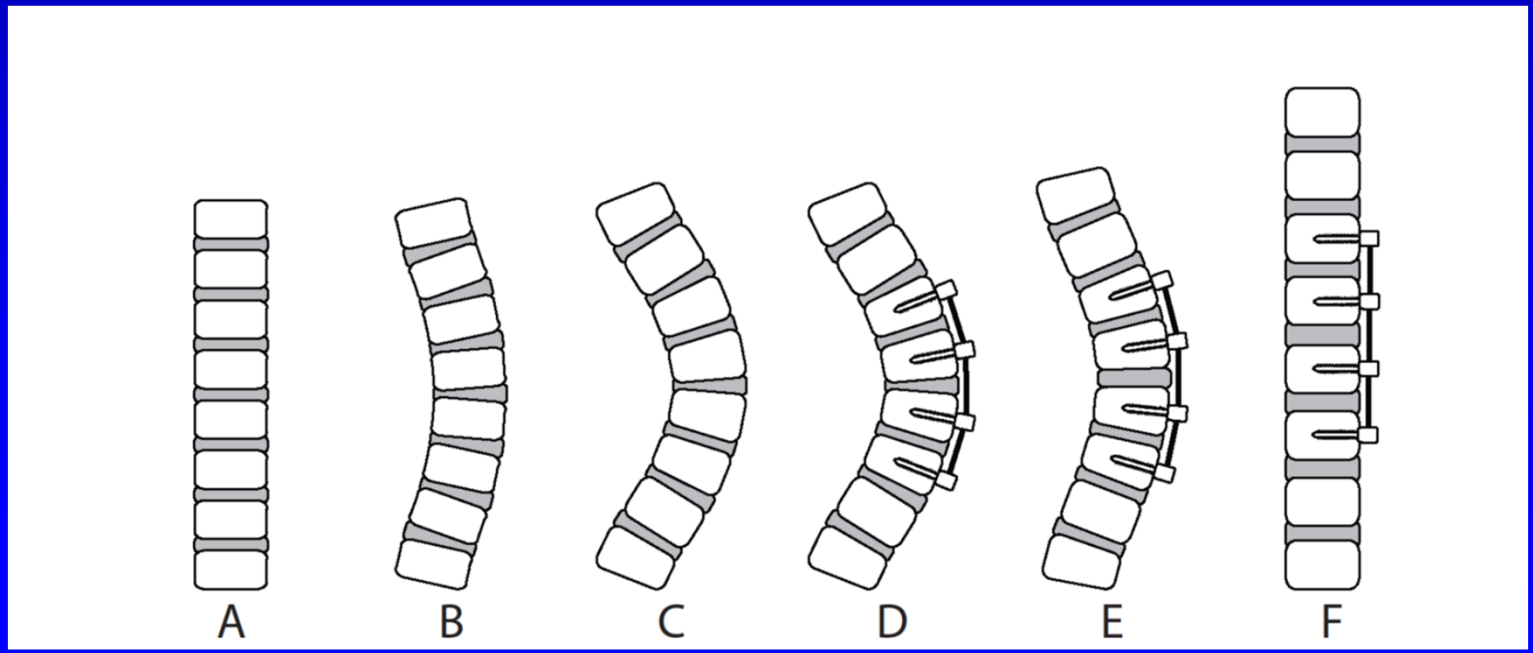
Introduction

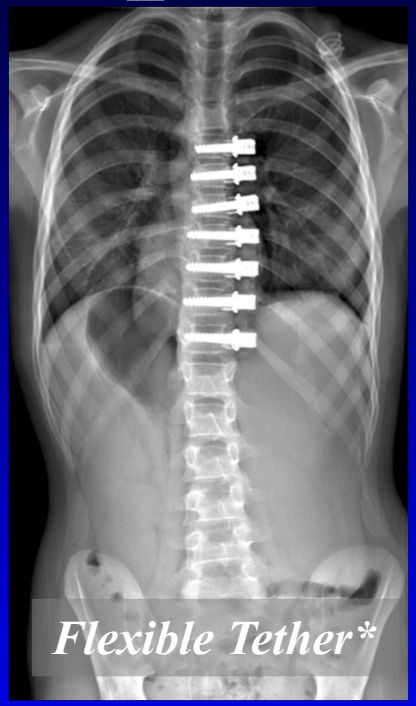
- Growth modulation implants are designed to stop and correct scoliosis without a fusion
- Current clinically relevant fusion-less spinal implants cross the disc and allowing motion

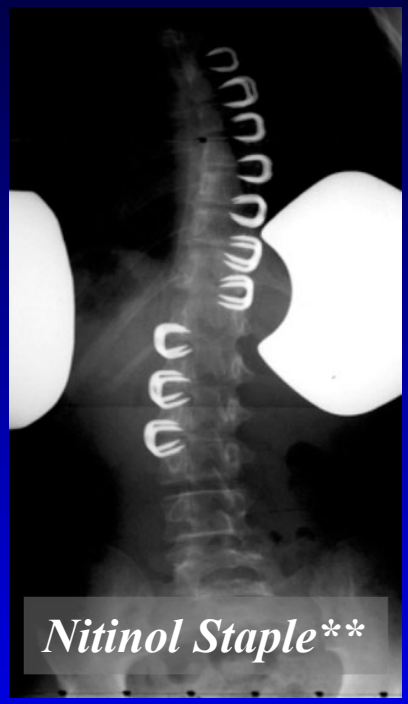


Introduction

- **Goal → preserve motion**
- **Implants must maintain spinal fixation to be safe and effective**
- **Motion over time may result in loosening or weakening of implants**

Purpose

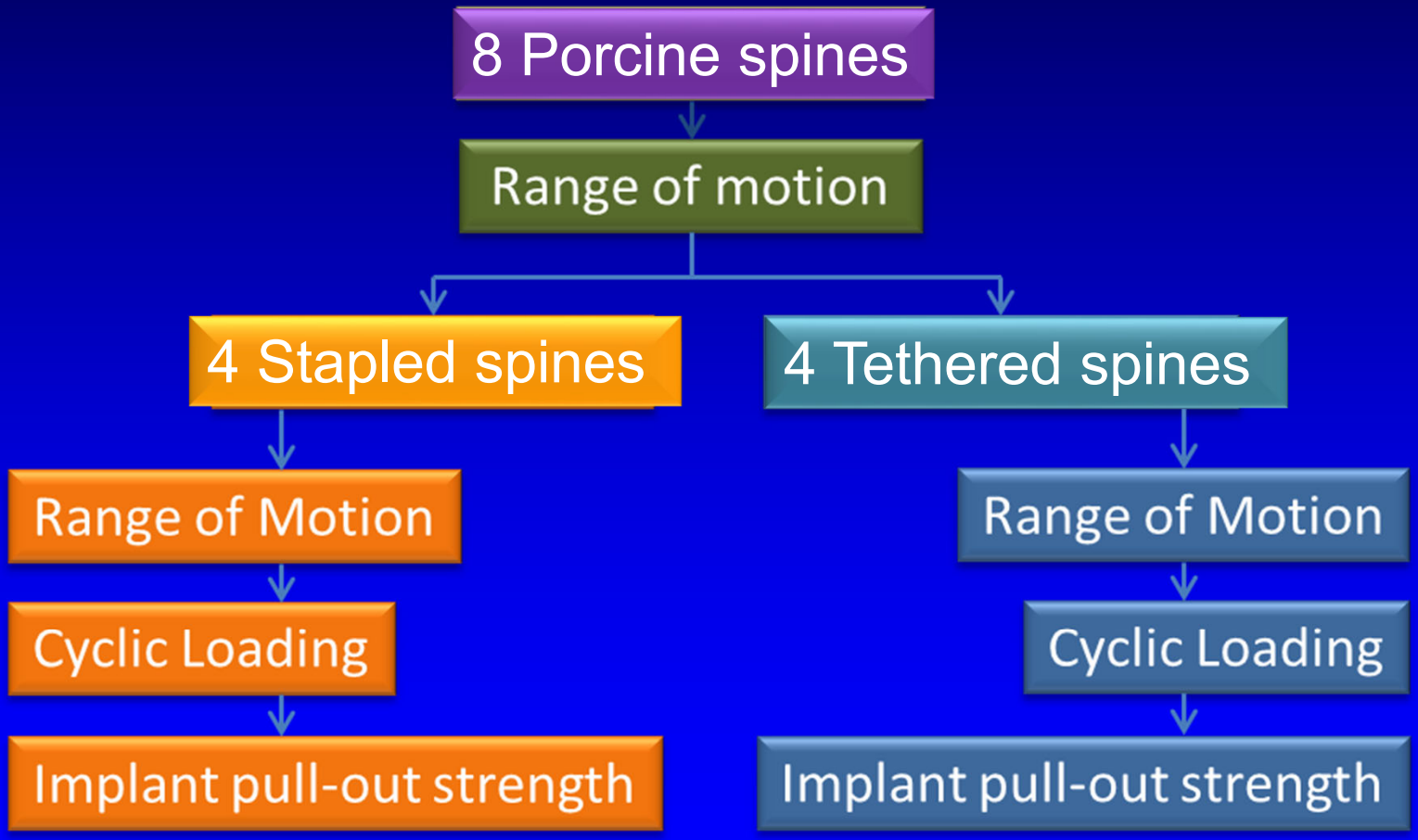




Compare fixation strength of two current clinically relevant anterior fusion-less scoliosis correction techniques prior to and following cyclic loading.

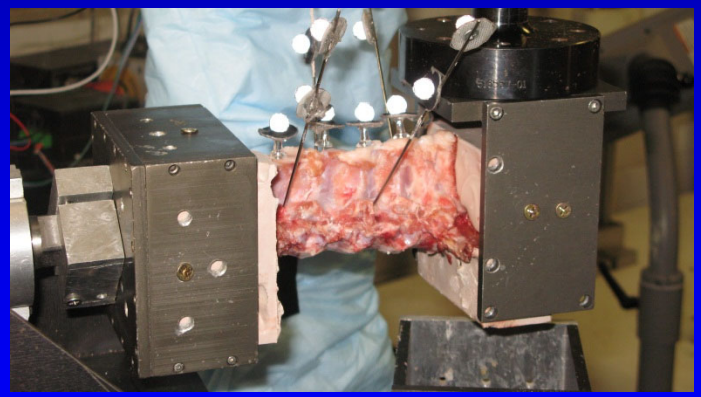
Images courtesy of P.Newton, R.Betz***

Methods


8 Porcine spines
Range of motion
4 Stapled spines
4 Tethered spines
Range of Motion
Cyclic Loading
Implant pull-out strength
Range of Motion
Cyclic Loading
Implant pull-out strength

Methods

- **Eight pig spines were divided:**
  - *cycled segments* = T10-T13
  - *un-cycled segments* = T7-T8, L2-L3
- **Initial range of motion (ROM) of *cycled segments*:**
  - Torsion
  - Flexion-extension
  - Lateral bending
  - 0.5˚ /sec to 1.75Nm



Methods

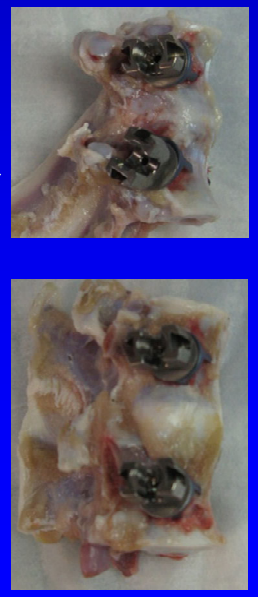
Staple Group (n=4)

- **Two 6mm parallel staples were inserted on the right side across the disc**
- **Cycled segments**
  - 6 staples across 3 adjacent discs
- **un-cycled segments**
  - 4 staples across 2 discs

Methods

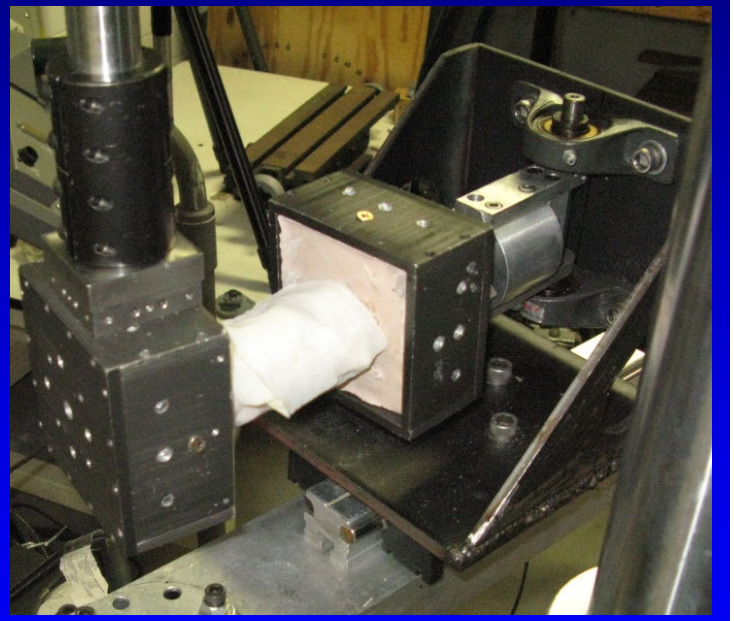
Tether Group (n=4)

- **5.35x35mm vertebral body screws into right side**
- **Cycled segments**
  - 4 screws connected with a flexible tether tensioned to straight alignment
- **Un-cycled segments**
  - 4 vertebrae, screws only



Methods

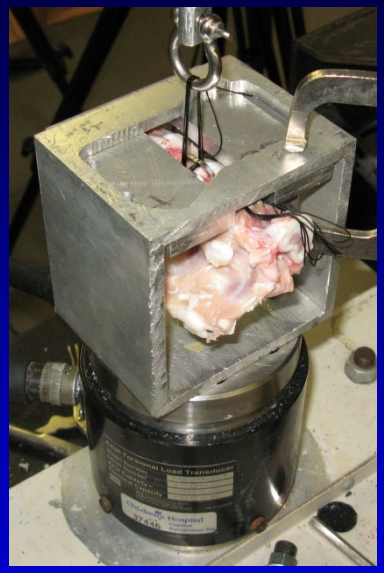
- **ROM of instrumented cycled segments was measured**



- **Segments were loaded to the measured ROM:**
  - flexion-extension (2000 X)
  - lateral bending (1000 X)
  - axial rotation (2000 X)

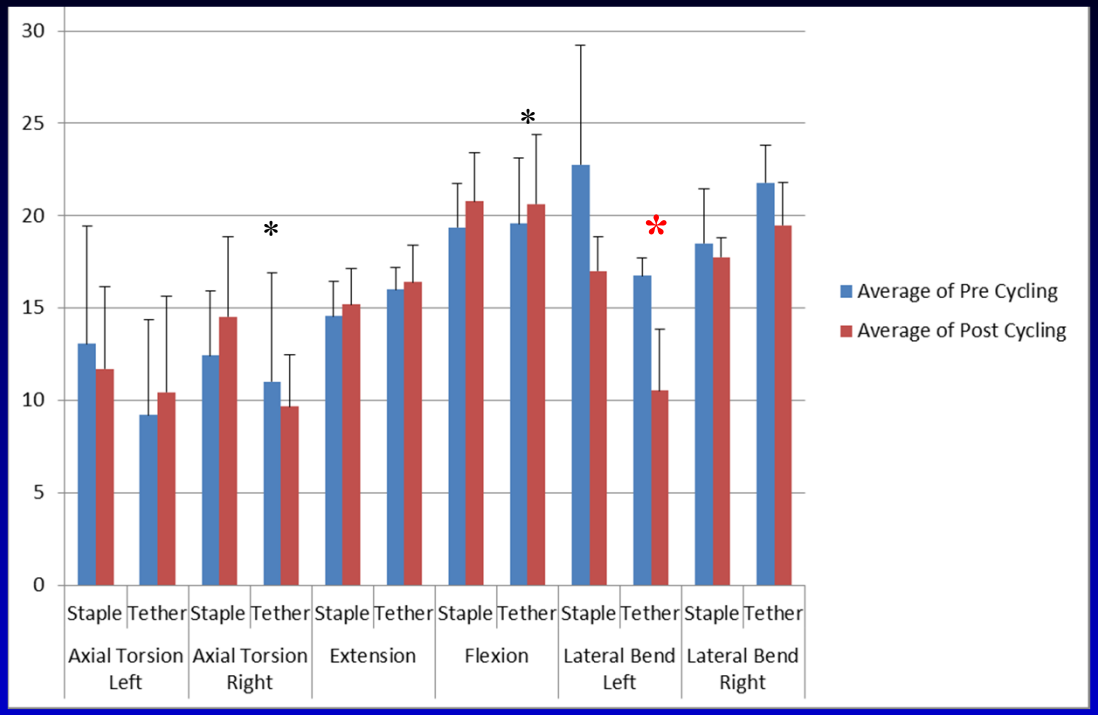
Methods

- Each staple and screw was then tested in axial pullout to failure
- Parametric tests compared pre to post implant ROM
- Non-parametric tests compared staple to screw pullout strength
- $p<0.05$ was significant



Results

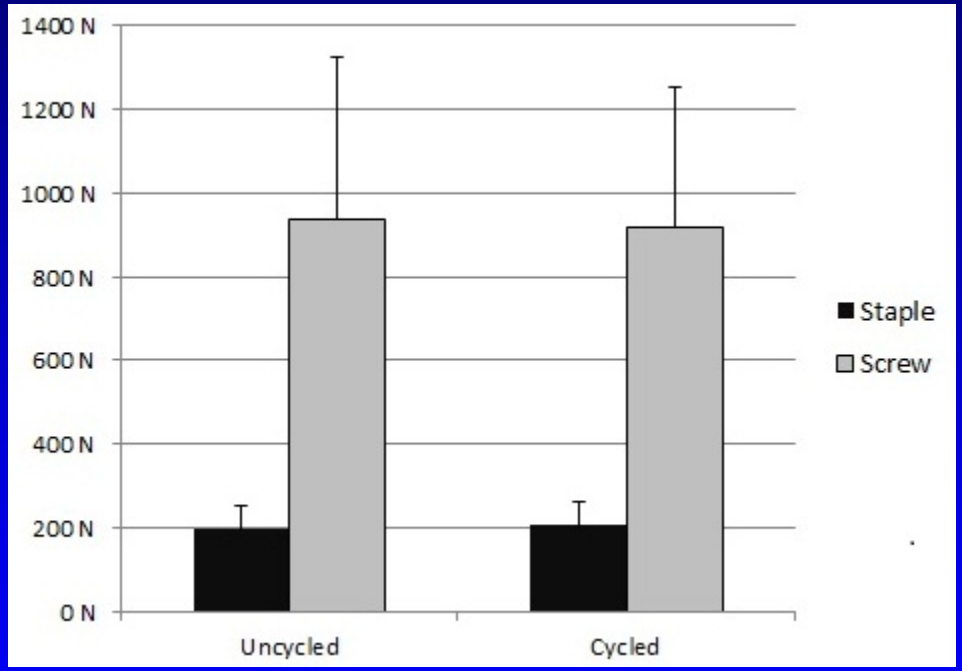
- **There were no differences between groups in the initial (un-instrumented) ROM**



- **ROM was not statistically different following placement of implants except:**
  - staples increased axial torsion to the right (2.0° = not clinically significant)
  - tethers increased flexion (1.1° = not clinically significant)
  - **tethers decreased lateral bending to the left by 6.2°**

Results

- Screw pullout required MORE FORCE than staple pullout ($p<0.05$)
- No DIFFERENCE in pullout between uncycled and cycled loading for screw or staple ($p=0.4$)



Study Limitations

- Very small numbers
- Porcine spine to model human condition
- Not in living subjects so effect of bone ingrowth into implant is not taken into account
- Spine is more stable in situ, so the effects of cycling in a harvested spine may be underestimated.

Conclusions

- **Tether decreased lateral bending away from side of tether**
- **The anterior tether screws required greater load to failure than the staples**
- **Cyclic loading did not significantly change pull out strength of either device**

Acknowledgements

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