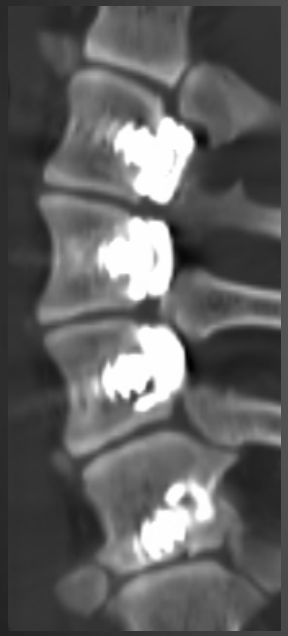
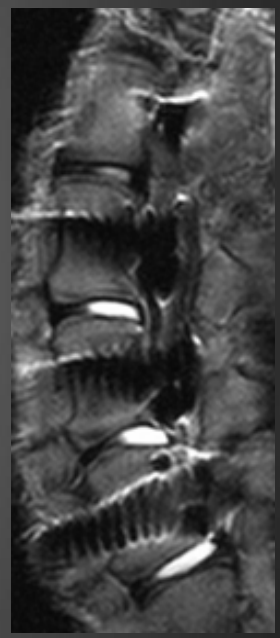
Maximizing Anterior Vertebral Screw Fixation for Spinal Growth Tethering





Eric S. Varley, DO[1]
Christine L. Farnsworth, MS[2]
Tucker Tomlinson, MS[2]
Claire Robertson, BS[2]
Thomas N. Nunn, BS[2]
Salil V. Upasani, MD[1]
Peter O. Newton, MD[1,2]

[1]University of California, San Diego, CA
[2]Rady Children's Hospital, San Diego, CA

UCSD

Rady Children's Hospital

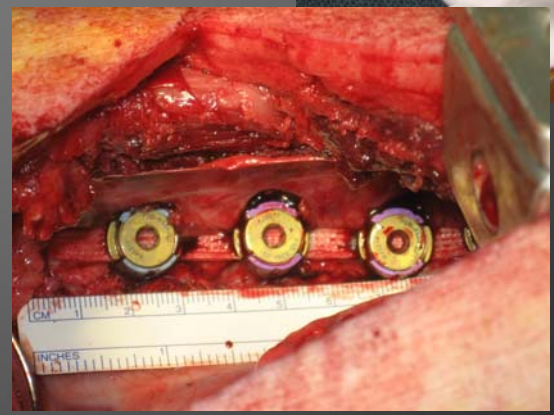
Potential Fusionless Scoliosis Correction

- Proposed Etiology Theory: Anterior spinal overgrowth[1]
- Propagated by: Heuter-Volkmann effect[2]
- Spinal buckling
- Fusionless treatments
  - Tension posterior spine
  - Compress anterior spine
    - ➡ Anterior Spinal Tethering

Anterior Spinal Growth Tethering

- Applies a compressive force to the physes on convexity of the curve

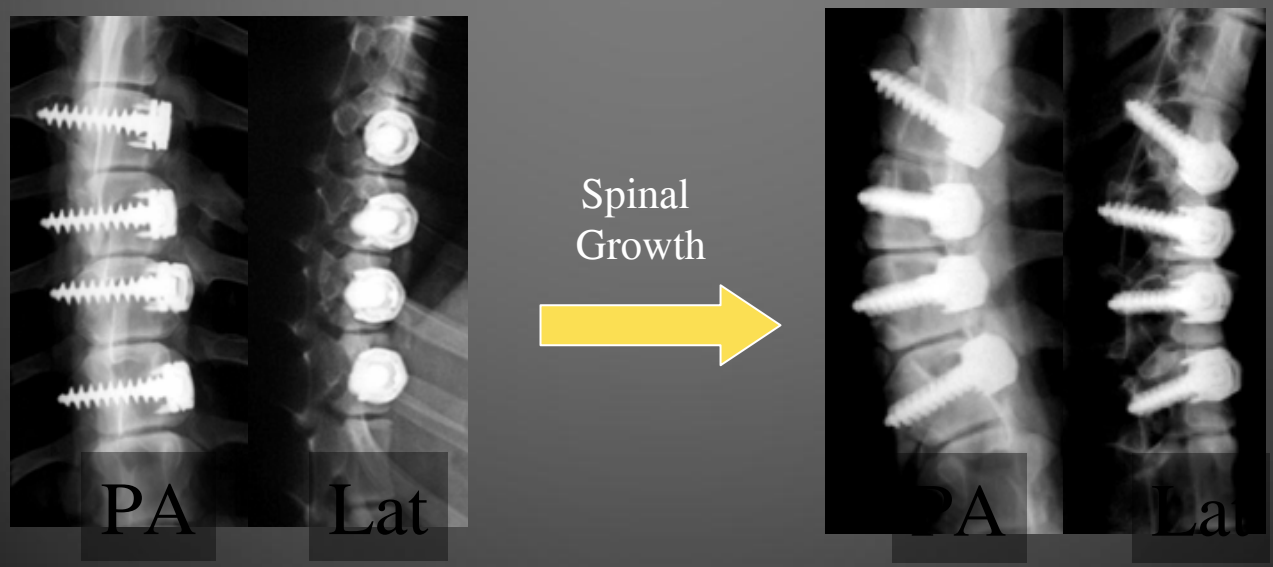
- Shown to create deformity in animal models[3,4]



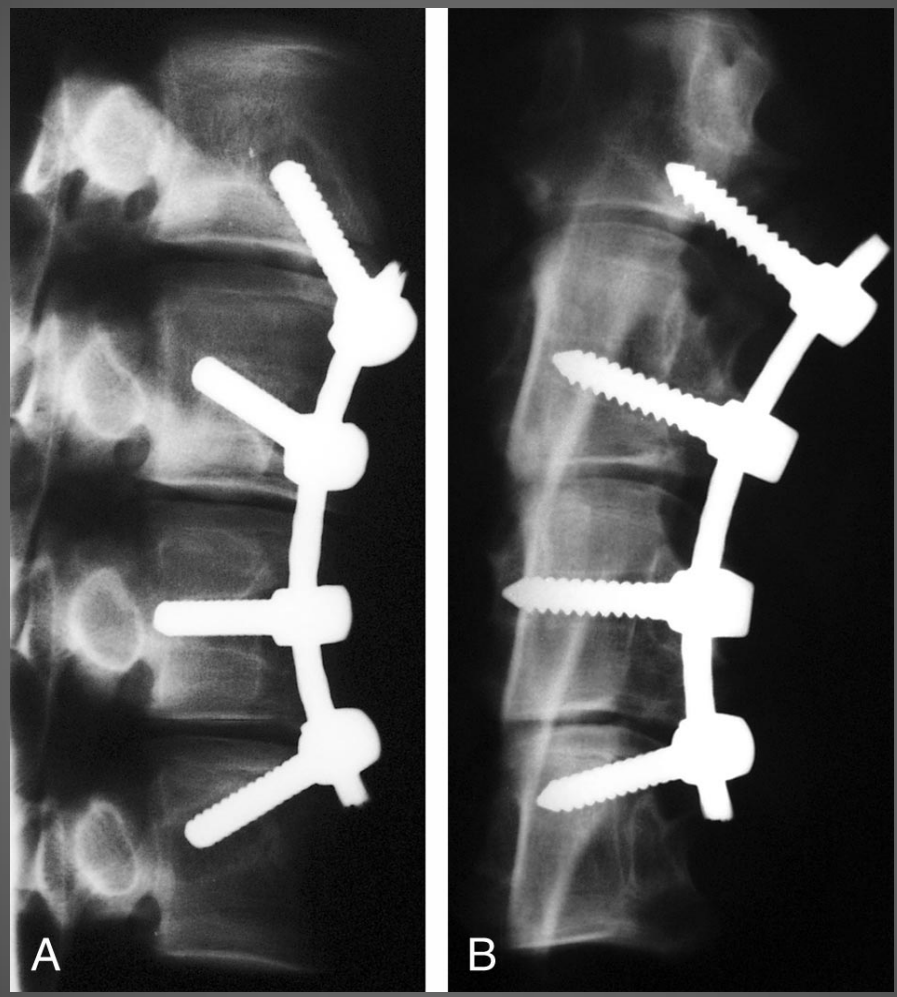
Pilot Study - Anterolateral Flexible Tether[4]

- 6 animals tethered over four levels
- Scoliosis creation: 12.4±8.3° at 6 month (n=12)
  26.8±14.4° at 12 month (n=6)
- Vertebral wedging: 4.4±1.3mm at 6 months*
  8.5±3.9mm at 12 months*

- **Conclusion: Tethering Alters Vertebral Growth**



Fixation Problems



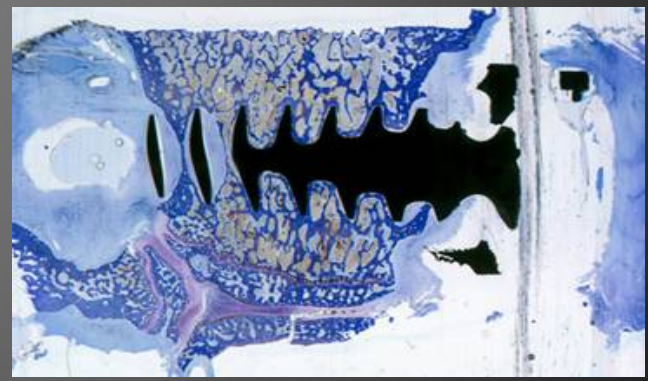
Previous Bovine Growth Study: 1st Generation Implant
Screws levered & plowed through the bone

Effect of Intra-Op Deformity Correction on Screw Fixation?

1. Immediate deformity correction

Intra-Operative Tether Tensioning

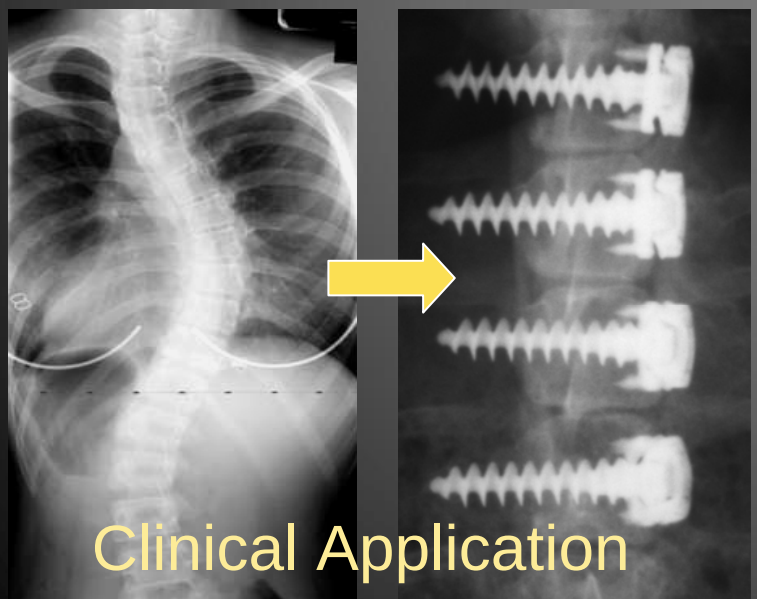
2. Improve Screw Fixation[5]



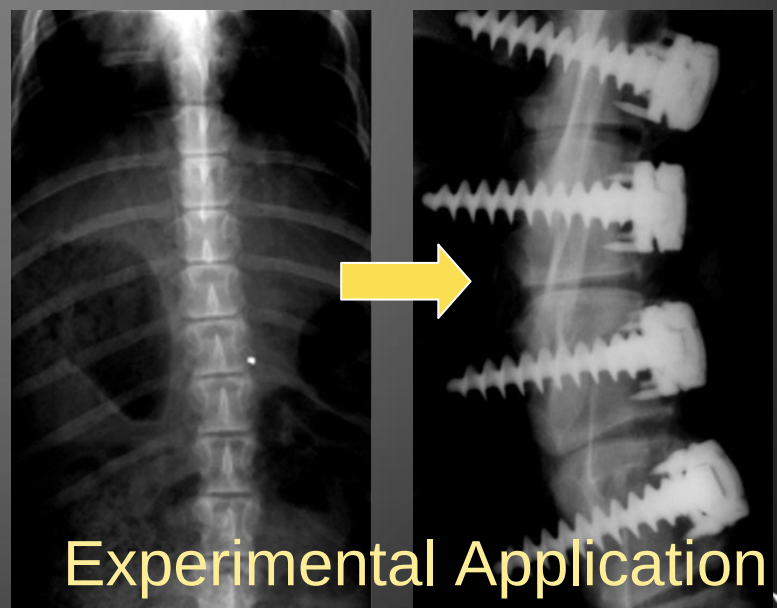
Hydroxyapatite Coating

Purpose

To evaluate the effect of hydroxyapatite (HA) coating of the vertebral body screws and intra-operative tensioning of the tether on screw integration as measured by the screw extraction torque.

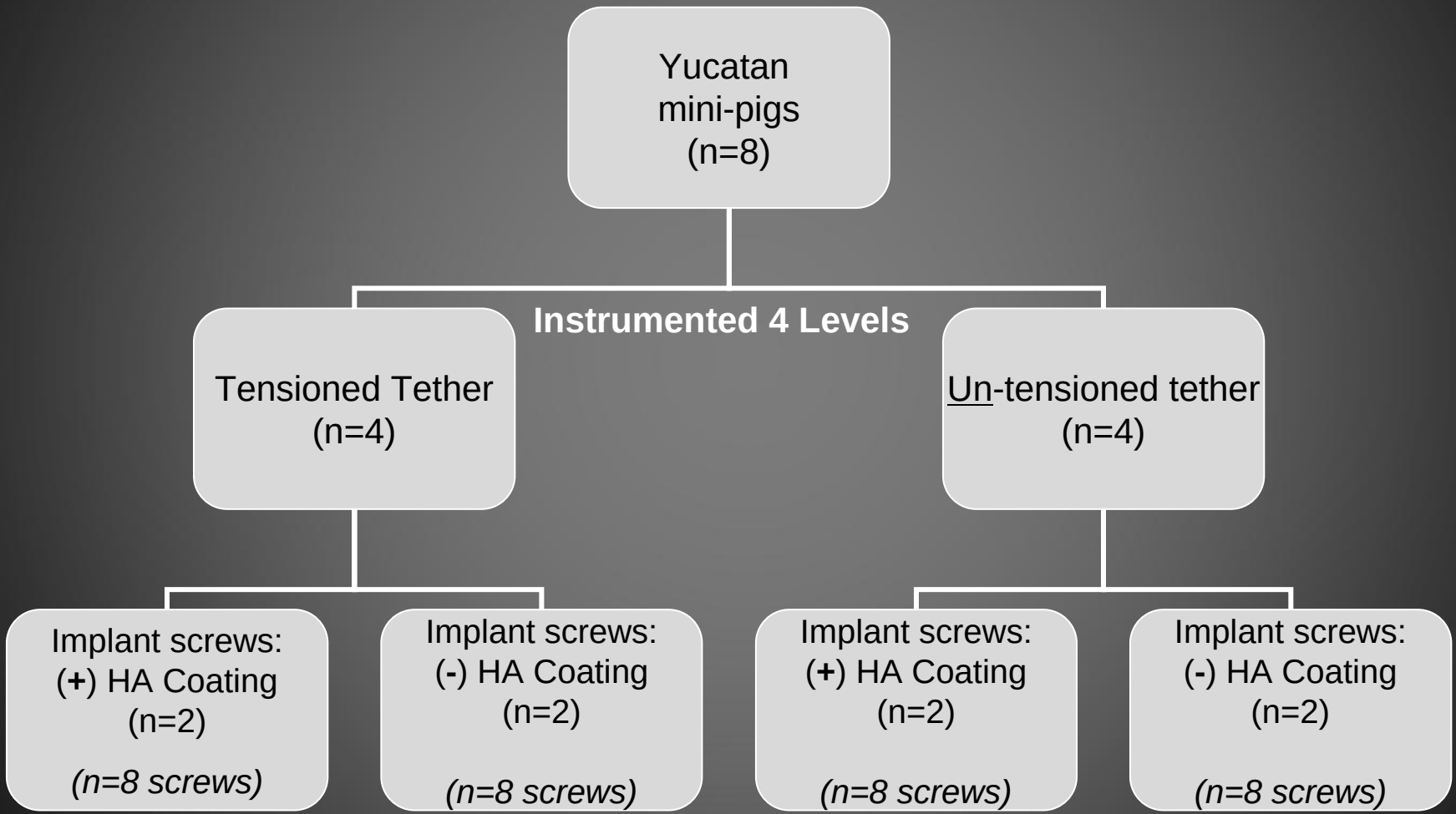


Clinical Application



Experimental Application

Study Design



Methods

- **T8-T11 – UHMWPE Tether/Screw Construct**
  - ***Non-Tensioned group*** **(n=4): Slack taken out**
  - ***Tensioned group*** **(n=4): Intra-op tensioning (250N)**

- **Animals grow for 12 months**
  - **Monthly Biplanar X-rays**
  - **Post Harvest 12 month 3T MRI**

- **Following Harvest: Uncoated screws placed**

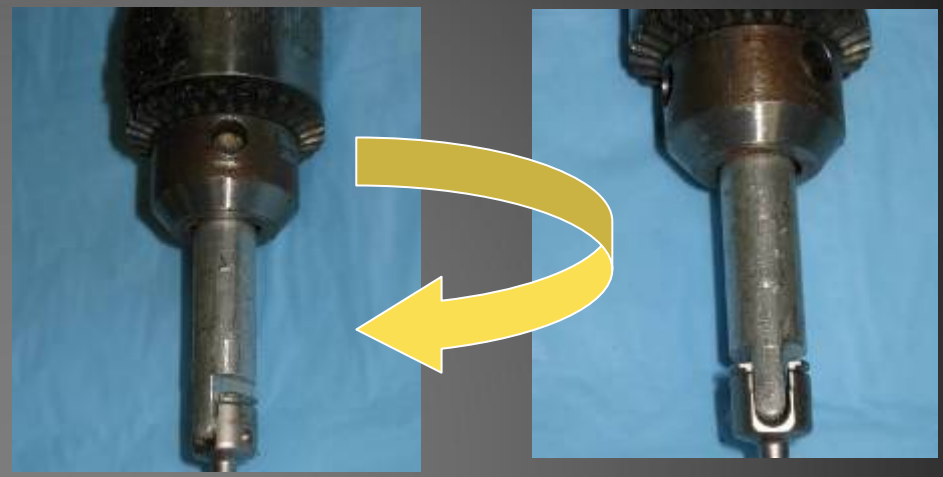
T7 & T8
T12 &T13

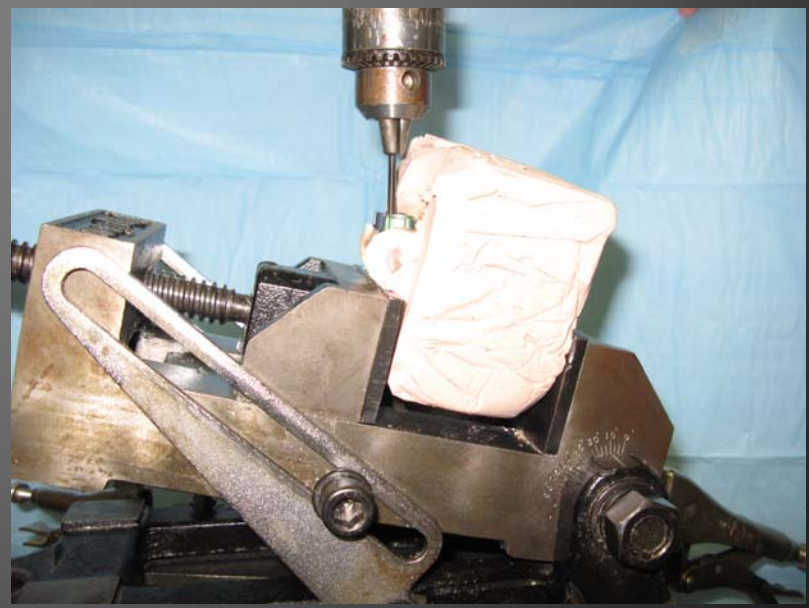
} **Time Zero (T0) Controls**

Screw Extraction Analysis

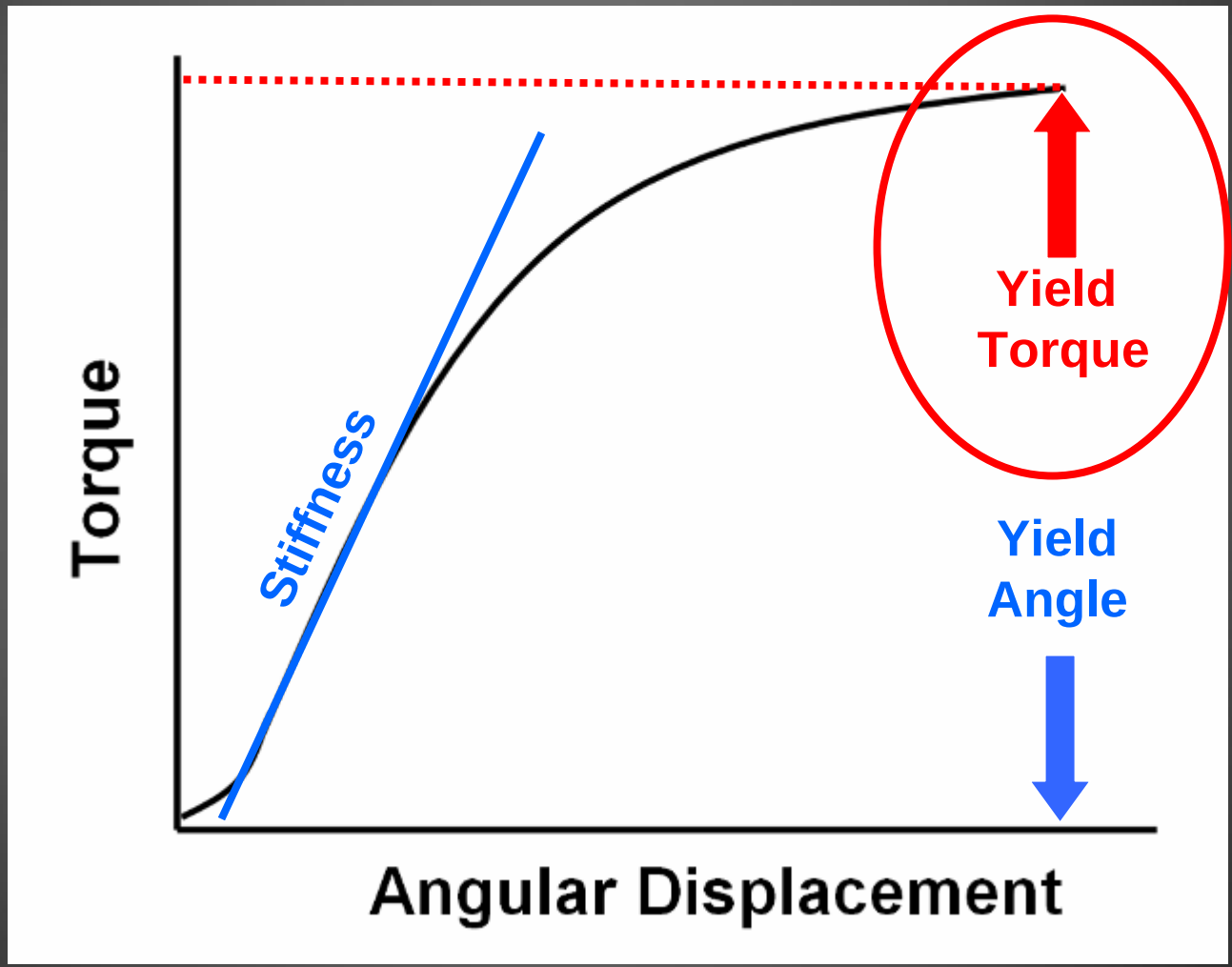
- Focus on the bone-screw interface[6]
- Screws rotated with custom jig
- No Axial load

- <u>Data processed for</u>
  1. Yield Torque
  2. Yield Angle

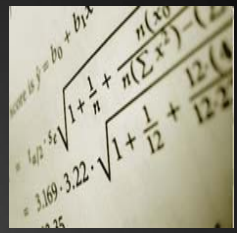




Biomechanical Data Collection



Statistical Analysis



ONE-WAY ANOVA

Changes with time

- **Each Group vs. Controls**

TWO-WAY ANOVA

Effects of HA & Tensioning

(1) Coating the screws

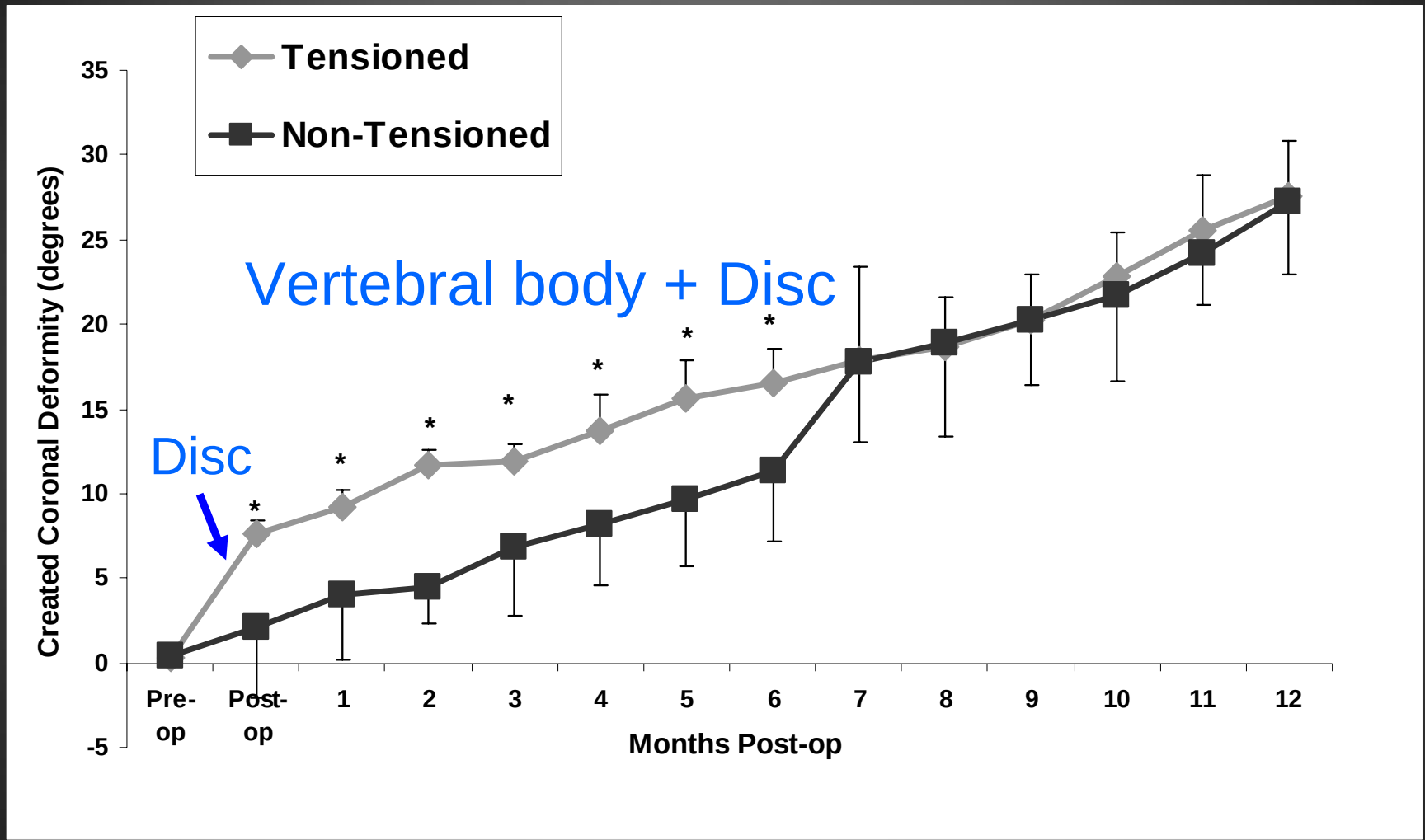
(2) tensioning the tether

(3) Interaction

4 experimental groups:

1. **Tensioned & HA Coating**
2. **Tensioned & No Coating**
3. **Un-tensioned & HA Coating**
4. **Un-tensioned & No Coating**

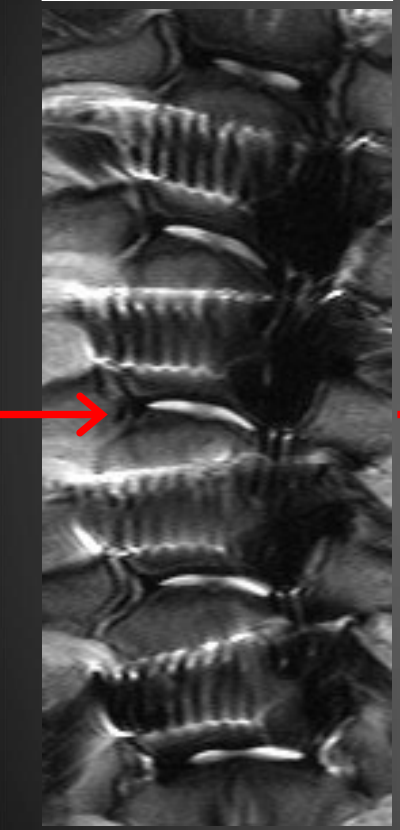
Deformity Creation



- Tensioned Group: Greater initial deformity
- Equal total growth modulation to non-tensioned group

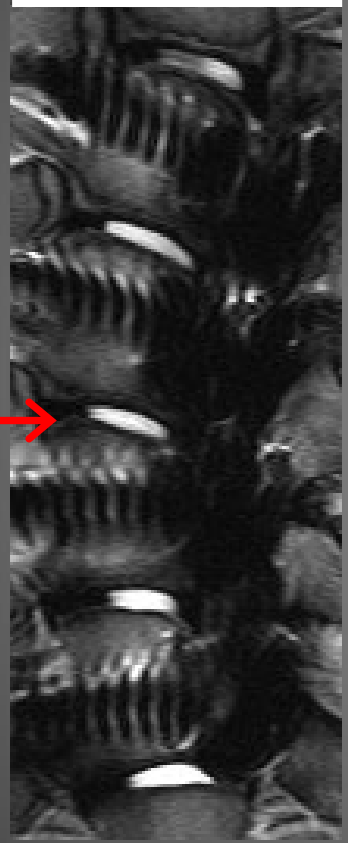
Post-harvest MR Analysis (3T)

Non-Tensioned



12-mo post-op T2

Tensioned



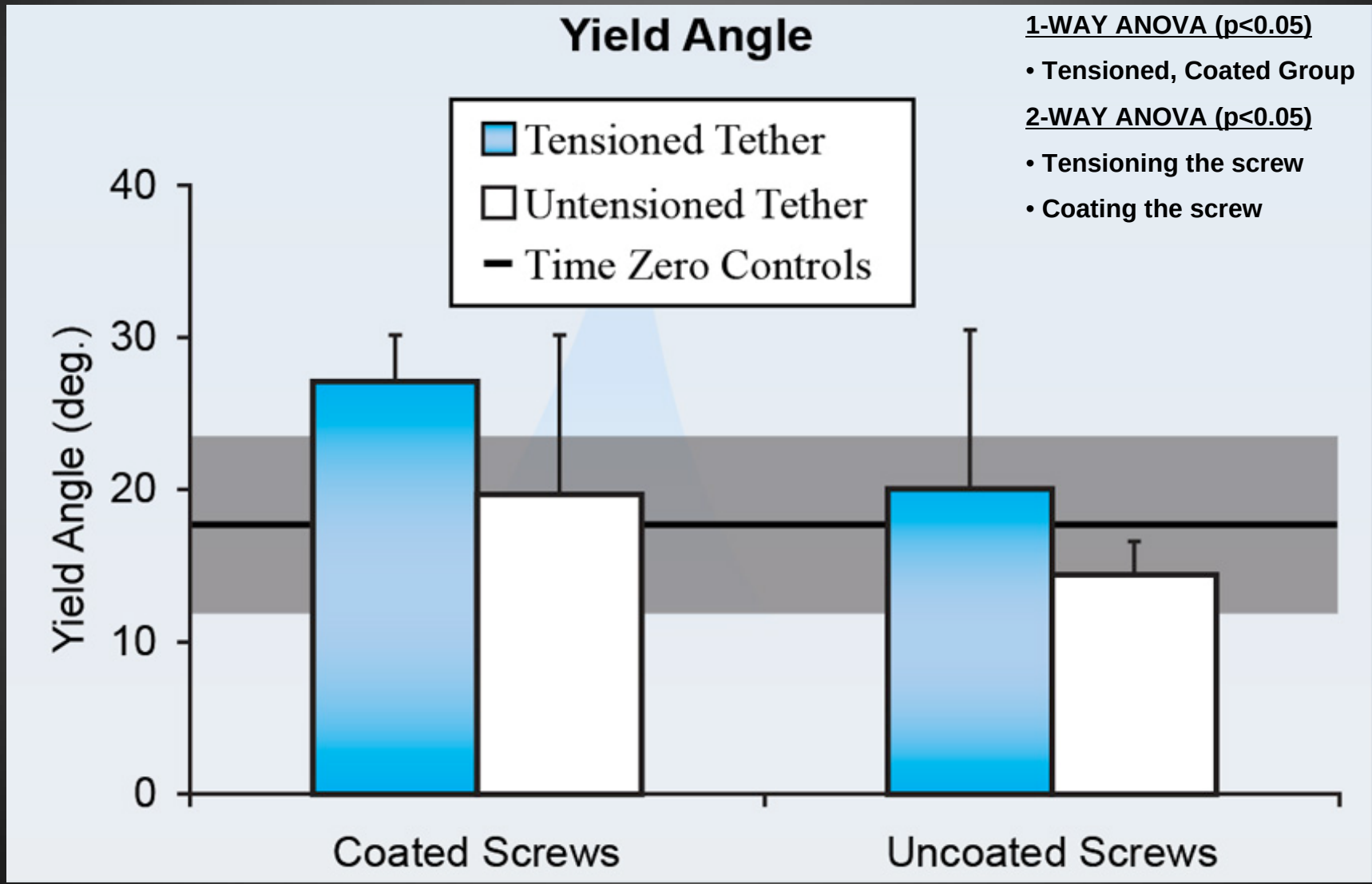
12-mo post-op T2

- Nucleus Pulposus migrated toward tether in both surgical groups

tensioned >> non-tensioned (p=0.02)

12 months post-op, all discs “healthy” except one tensioned and one non-tensioned motion segment with no T2 bright signal: *2/36 = 6% of all discs*

Yield Angle Comparison



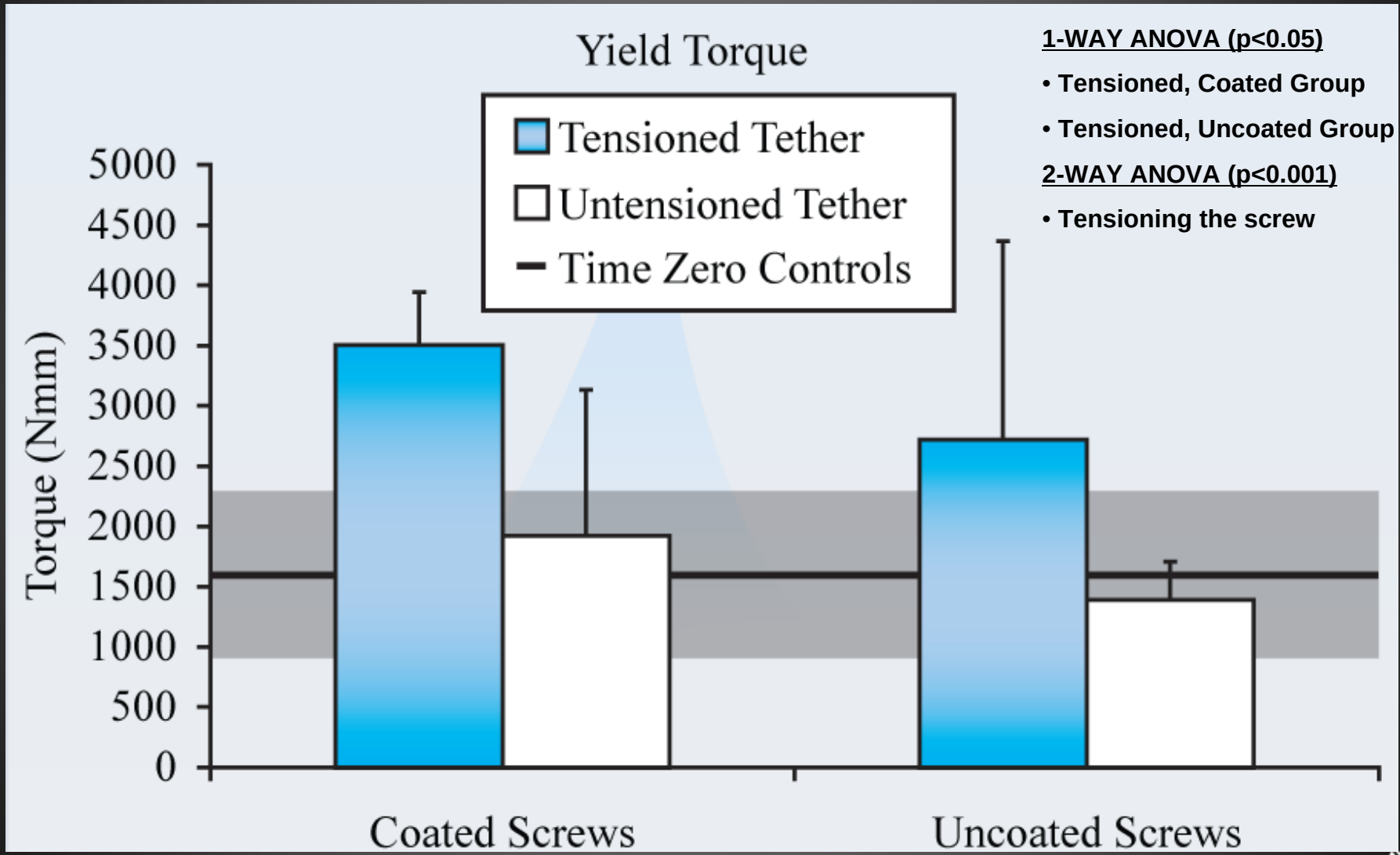
1-WAY ANOVA ($p<0.05$)

- **Tensioned, Coated Group**

2-WAY ANOVA ($p<0.05$)

- **Tensioning the screw**
- **Coating the screw**

Yield Torque Comparison



1-WAY ANOVA ($p<0.05$)

- **Tensioned, Coated Group**
- **Tensioned, Uncoated Group**

2-WAY ANOVA ($p<0.001$)

- **Tensioning the screw**

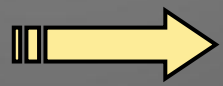
➢ **No screws had Torque < 500 Nmm**

Conclusions

Deformity Creation

1. Greater initial deformity, Same ultimate deformity
2. NP Migration: Tension>>Non-tensioned
3. Disc Health: No difference

Screw out testing: bone-implant interface integrity

1. Contrary to initial concerns 
   Tensioning appears to ***INCREASE*** fixation
   - More vigorous response to the greater biomechanical forces transmitted to the bone-screw interface
2. HA coating may moderately enhance osseous integration
   - Osteoconductive properties

References

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6. Sandén B et al., Improved extraction torque of hydroxyapatite-coated pedicle screws, *Eur Spine J* 2000