Maximizing Anterior Vertebral Screw Fixation for Spinal Growth Tethering

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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

- 6 animals tethered over four levels
- Scoliosis creation: $12.4\pm8.3^\circ$ at 6 month (n=12)
  $26.8\pm14.4^\circ$ at 12 month (n=6)
- Vertebral wedging: $4.4\pm1.3\text{mm at 6 months}^*$
  $8.5\pm3.9\text{mm at 12 months}^*$

- **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
   - 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

Yucatan mini-pigs (n=8)

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Instrumented 4 Levels

- Tensioned Tether (n=4)
  - Implant screws: (+) HA Coating (n=2) (n=8 screws)
  - Implant screws: (-) HA Coating (n=2) (n=8 screws)

- Un-tensioned tether (n=4)
  - Implant screws: (+) HA Coating (n=2) (n=8 screws)
  - Implant screws: (-) HA Coating (n=2) (n=8 screws)
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

- Data processed for
  1. Yield Torque
  2. Yield Angle
Biomechanical Data Collection

- Stiffness
- Yield
- Torque
- Degrees of Rotation (°)

Force x moment (N-mm)

Angular Displacement

Yield Torque

Yield Angle

Stiffness
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

Vertebral body + Disc

Disc

Created Coronal Deformity (degrees)

Months Post-op

Pre-op Post-op 1 2 3 4 5 6 7 8 9 10 11 12

Tensioned Non-Tensioned
Post-harvest MR Analysis (3T)

• Nucleus Pulposus migrated toward tether in both surgical groups

\[ \text{tensioned} \gg \text{non-tensioned} \quad (p=0.02) \]

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 Angle

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<tr>
<th>Tensioned Tether</th>
<th>Untensioned Tether</th>
<th>Time Zero Controls</th>
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Yield Angle (deg.)

Coated Screws

Uncoated Screws
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


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