Spinal Hemiepiphysiodesis Using Titanium Clinical Construct Series Retains Significant Spine Flexibility

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Spine Growth Modification

- Non-fusion growth modulation under clinical investigation for treatment of late juvenile and early AIS

- Titanium implant construct
  - Prospective clinical safety study completed under investigational device exemption
    - USA FDA IDE, clinicaltrials.gov NCT01465295
    - IRB approved
  - European CE Mark Certified
  - Expanded IDE clinical trial approved (USA FDA)
Previous Biomechanical Study
Single motion segment with one implant

- Lateral bending, flexion-extension, axial rotation
  - ROM decreased < 20%
  - Stiffness increased < 33%
  - Neutral zone decreased < 50%

Coombs et al AAOS 2013, SRS 2013
Spine - Accepted June 2013
Purpose

Determine changes in thoracic spine flexibility due to insertion of a typical series of titanium clip/screw implant constructs for spinal hemiepiphysiodesis

Hypothesis

Spine flexibility is reduced, yet mostly preserved, at instrumented levels
Methods: Specimens

- **6 porcine spines**
  - Skeletally immature
    - 2 – 3 months, ~40 kg

- **6 Ti clip-screw devices**
  - One non-interconnecting implant per motion segment
    - T5 –6 to T10 –11
  - 4 uninstrumented discs
    - 2 proximal and 2 distal
Experimental Design

- In vitro biomechanical tests
  - Clinical construct simulated

- Repeated measures
  - Before and after instrumentation

- Load directions
  - Lateral bending
  - Flexion extension

- Outcome measures
  - Flexibility
    - Instrumented region
    - Adjacent uninstrumented
Methods

• Moments applied
  – ± 5 Nm minimum peak-to-peak moment range (\(\Delta M\))

• Vertebral rotations measured
  – Video analysis of LED arrays at every level

• Flexibility calculated
  – ROM = Total rotation over entire moment range
  – Flexibility = ROM / \(\Delta M\)
  – Each level averaged to determine means for treated and adjacent untreated regions

• Statistics
  – Paired t-tests (\(\alpha=0.05\)), Bonferroni
Results: Flexibility

- In instrumented region overall, flexibility decreased
  - 35% in LB (p<0.001)
  - 17% in FE (p<0.001)
- At adjacent levels, flexibility increased ≤ 13%
Flexibility by Level
Lateral Bending

![Graph showing flexibility by level with T11-12, T10-11, T9-10, T8-9, T7-8, T6-7, T5-6, and T4-5 levels compared to control and instrumented groups with significance marks (*) and (**) indicating statistical differences.](image)
Flexibility by Motion Segment
Flexion - Extension

![Graph showing flexibility by motion segment with comparisons between control and instrumented groups.](image)
Discussion

• Limitations
  – In vitro tests on normal porcine spines simulates immediate post-op only
  – Species anatomic differences
    • Device placement more oblique in transverse plane than humans
    • Motion reductions in cardinal planes may be underestimated
  – Planar rotations
  – Loading method likely affects particular motion patterns

• Comparisons
  – Limited due to test method and control value differences
  – Motion reductions in LB and FE
    • Greater than Ni staple
    • Not greater than tether
      – Glaser et al ORS 2011; 827
Conclusions

• Titanium clip screw implants for non-fusion treatment of early AIS in a simulated clinical construct series preserved most intervertebral motion at instrumented levels
  – Largest decrease in flexibility at any level was 57%
  – Motion reductions greater than single motion segment tests
    • Likely due to adjacent implants

• Significance
  – Biomechanical changes necessary for treatment efficacy affect intervertebral motion