ICEOS 2013

Spinal Hemiepiphysiodesis Using Titanium Clinical Construct Series Retains Significant Spine Flexibility

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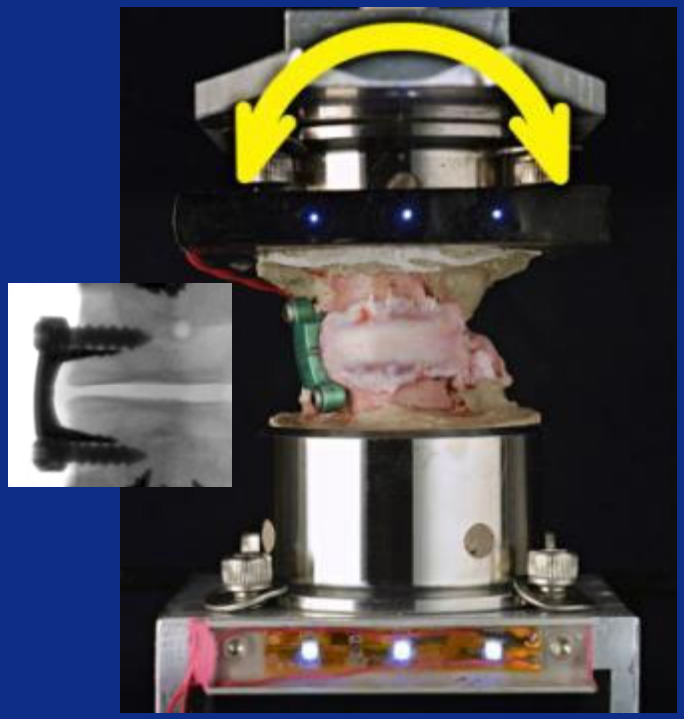
Spine Growth Modification

- 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)

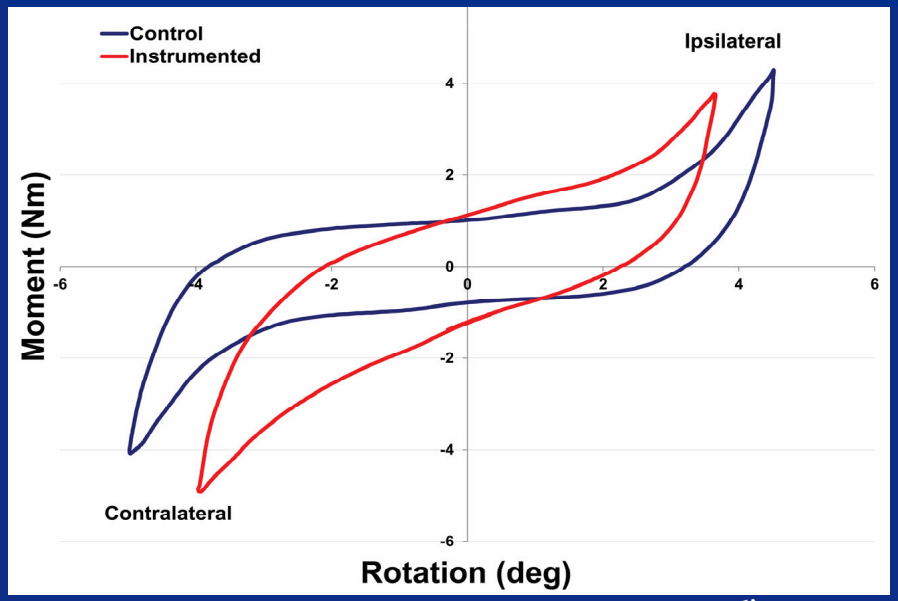
Previous Biomechanical Study

Single motion segment with one implant



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

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



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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

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Methods: Specimens

Coronal

Sagittal

- 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

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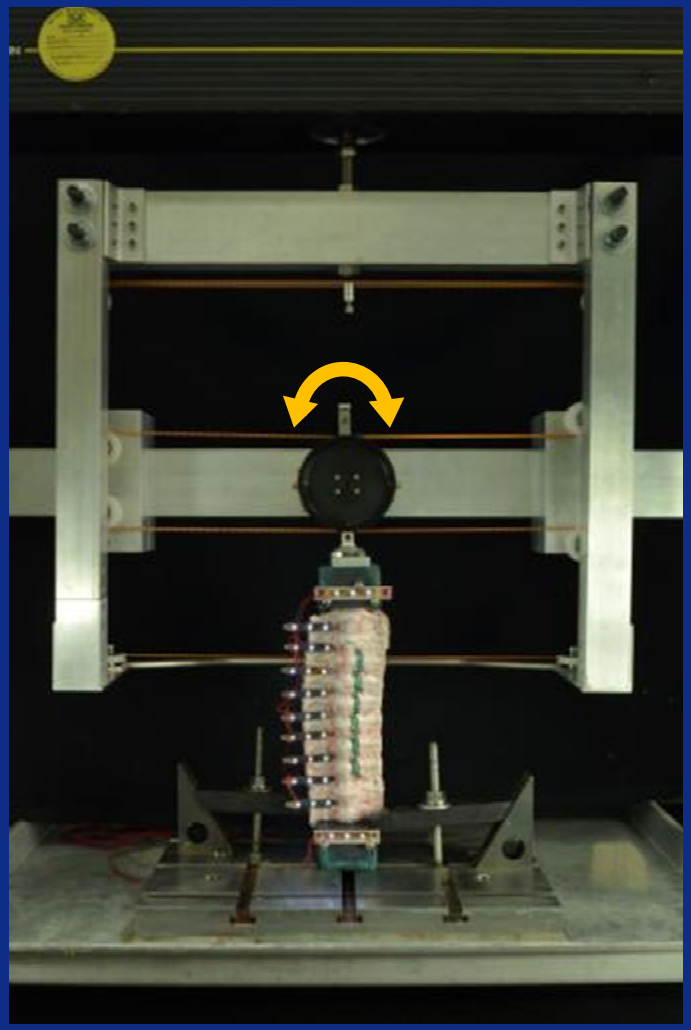
Experimental Design



- 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

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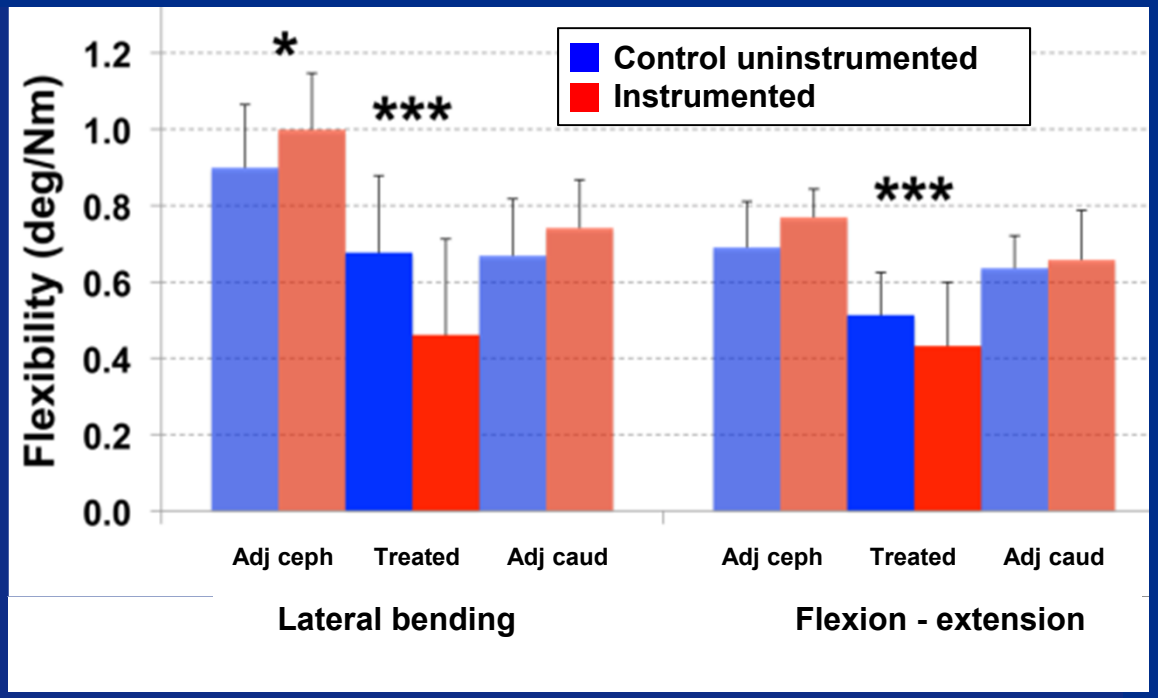
Methods

- **Moments applied**
  - ± 5 Nm minimum peak-to-peak moment range (∆M)
- **Vertebral rotations measured**
  - Video analysis of LED arrays at every level
- **Flexibility calculated**
  - ROM = Total rotation over entire moment range
  - Flexibility = ROM / ∆M
  - Each level averaged to determine means for treated and adjacent untreated regions
- **Statistics**
  - Paired t-tests (α=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 $\leq$ 13%

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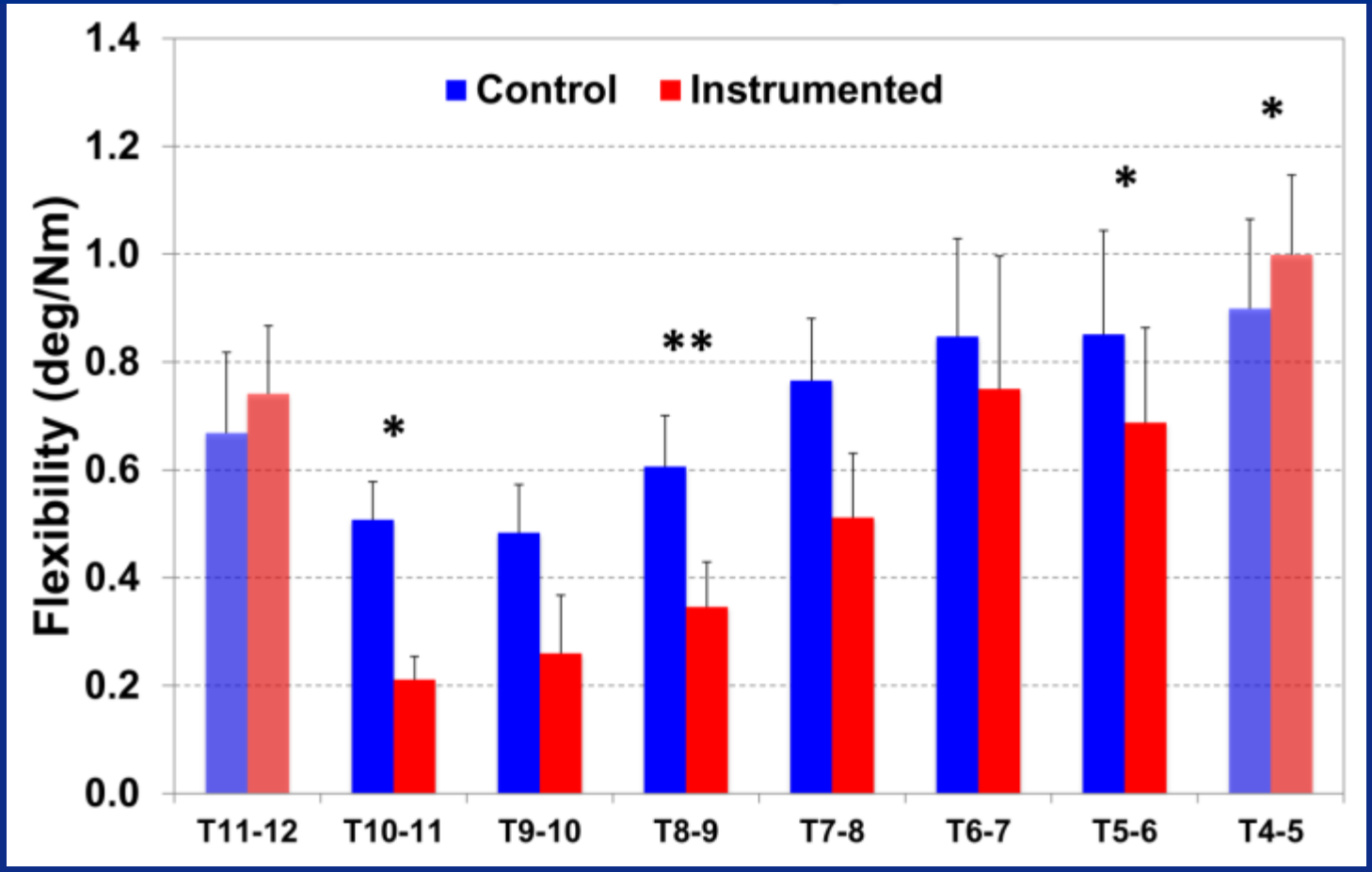
Flexibility by Level
Lateral Bending



Instrumented

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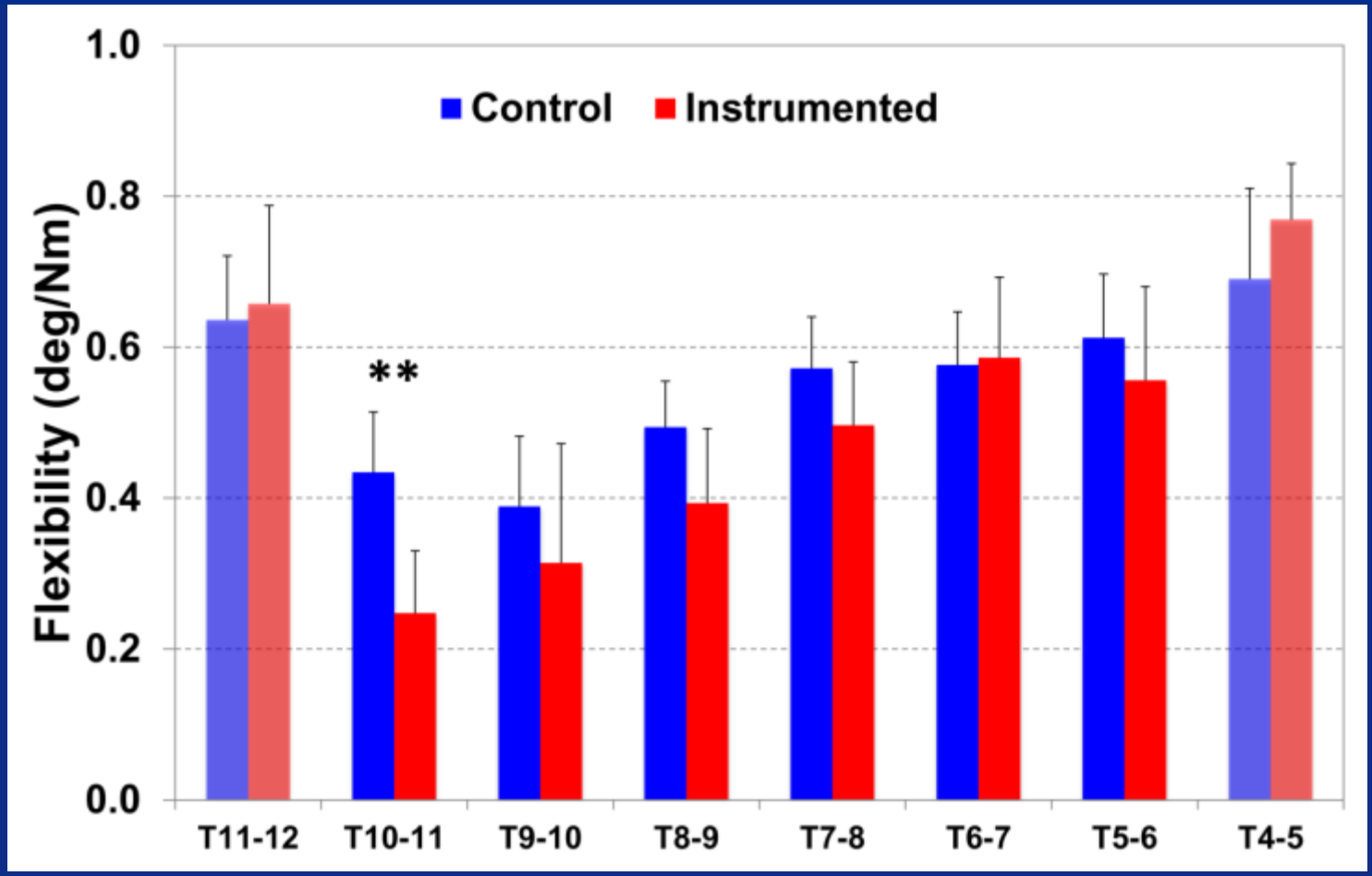
Flexibility by Motion Segment
Flexion - Extension



Instrumented

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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
      - Puttlitz et al Spine 2007; 32:766-771
    - 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