Spine growth modulation using titanium clip / screw device:

Vertebrae and disc heights at 1 year

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Disclosure: SpineForm LLC, consultant (uncompensated);
IP held under CCHMC standard policy

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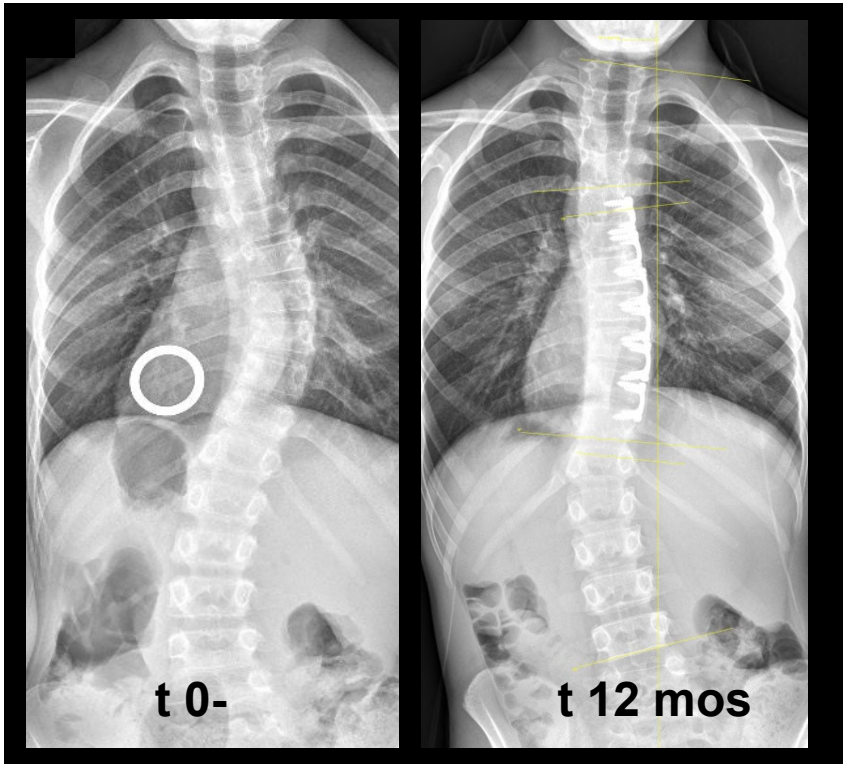
Spine growth modulation

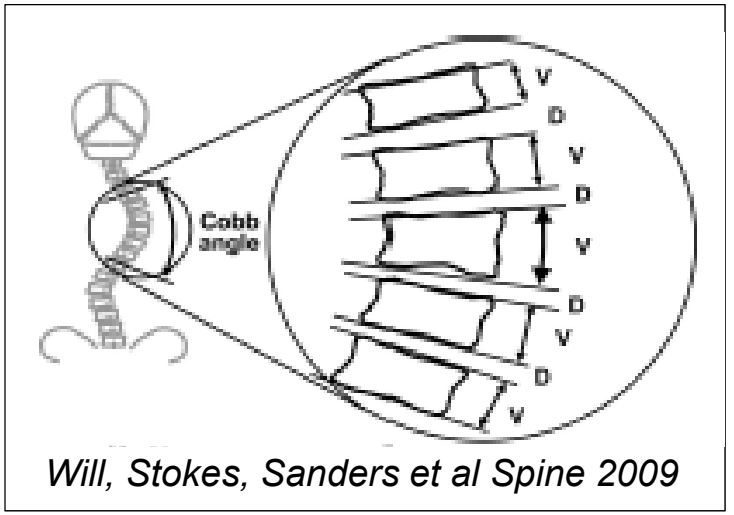
- **Prospective safety trial**
  - **First human use**
  - **IRB approved**
  - **USA FDA Investigational Device Exemption (IDE)**
    - **Clinicaltrials.gov**
- **Late juvenile or early AIS**
  - *Wall ICEOS '13, IMAST '14*



Best results at 1 year

Previous clinical studies

- **AIS curve progression**
  - **Disc wedging precedes vertebral body wedging**
    - *Grivas et al IRSSD 2006*
    - *Will et al Spine 2009*
    - *Schlosser, Castelein et al SRS 2014*



Will, Stokes, Sanders et al Spine 2009

- **30 year follow-up of AIS**
  - **Vertebral body height ratios (VBHR) increased ~ 5% during curve progression of 18°**
    - *Volz, Dolan et al Scoliosis 2012*

- **Not yet reported for any growth modulation**

Purpose

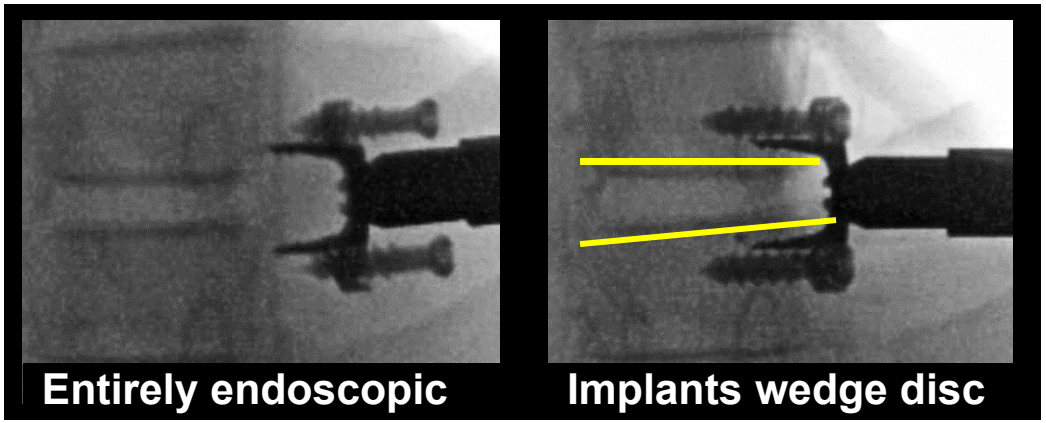
Determine heights, side-to-side, of discs and vertebrae at treated levels in coronal plane immediately pre-op and at 1 year post-op

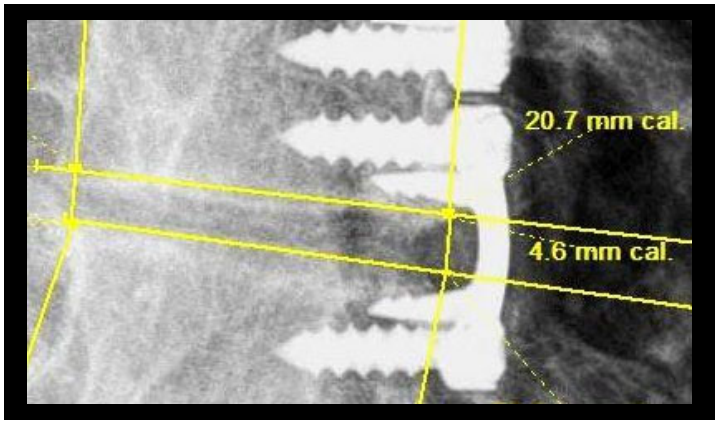
Hypothesis

Symmetry will increase with time

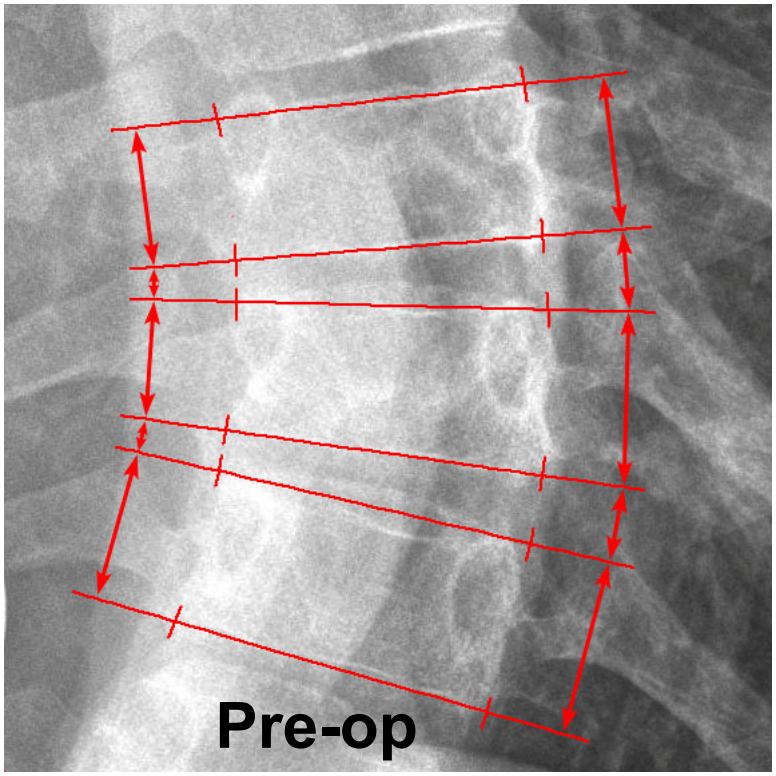
Methods

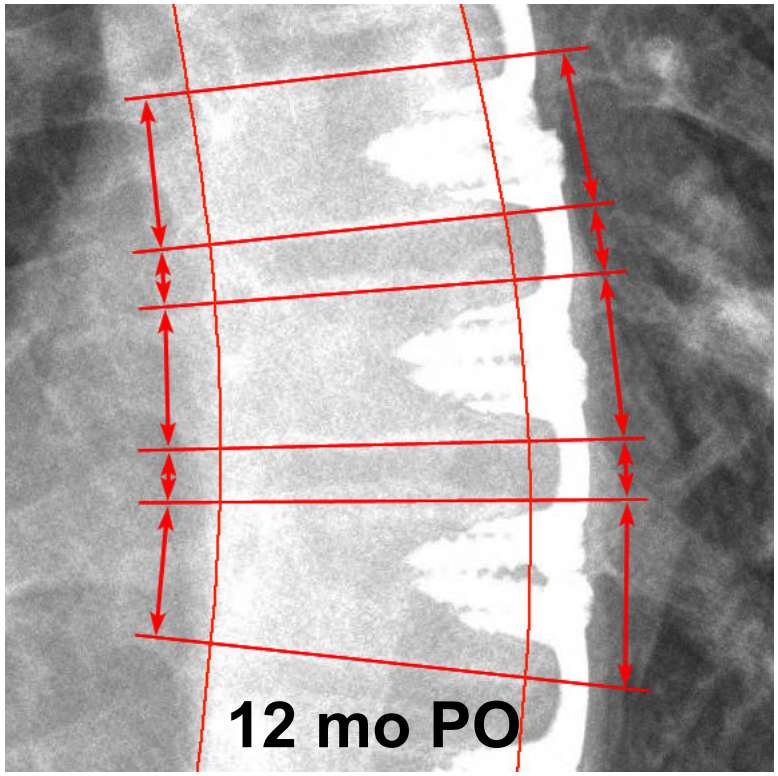
- All subjects (n = 6)
- High progression risk
  - Skeletally immature, age ≥ 10 yrs
  - Single thoracic curve, Lenke 1A/B
  - 25° to 40° Cobb angle
  - Risser 0 + Open triradiates
- Disc & vertebral heights
- Concave and convex
  - Every instrumented level with ~ clear boundaries
  - Digital radiography
  - Clinical PACS at 100% mag





Symmetry: Height ratios $H_{concave} / H_{convex}$





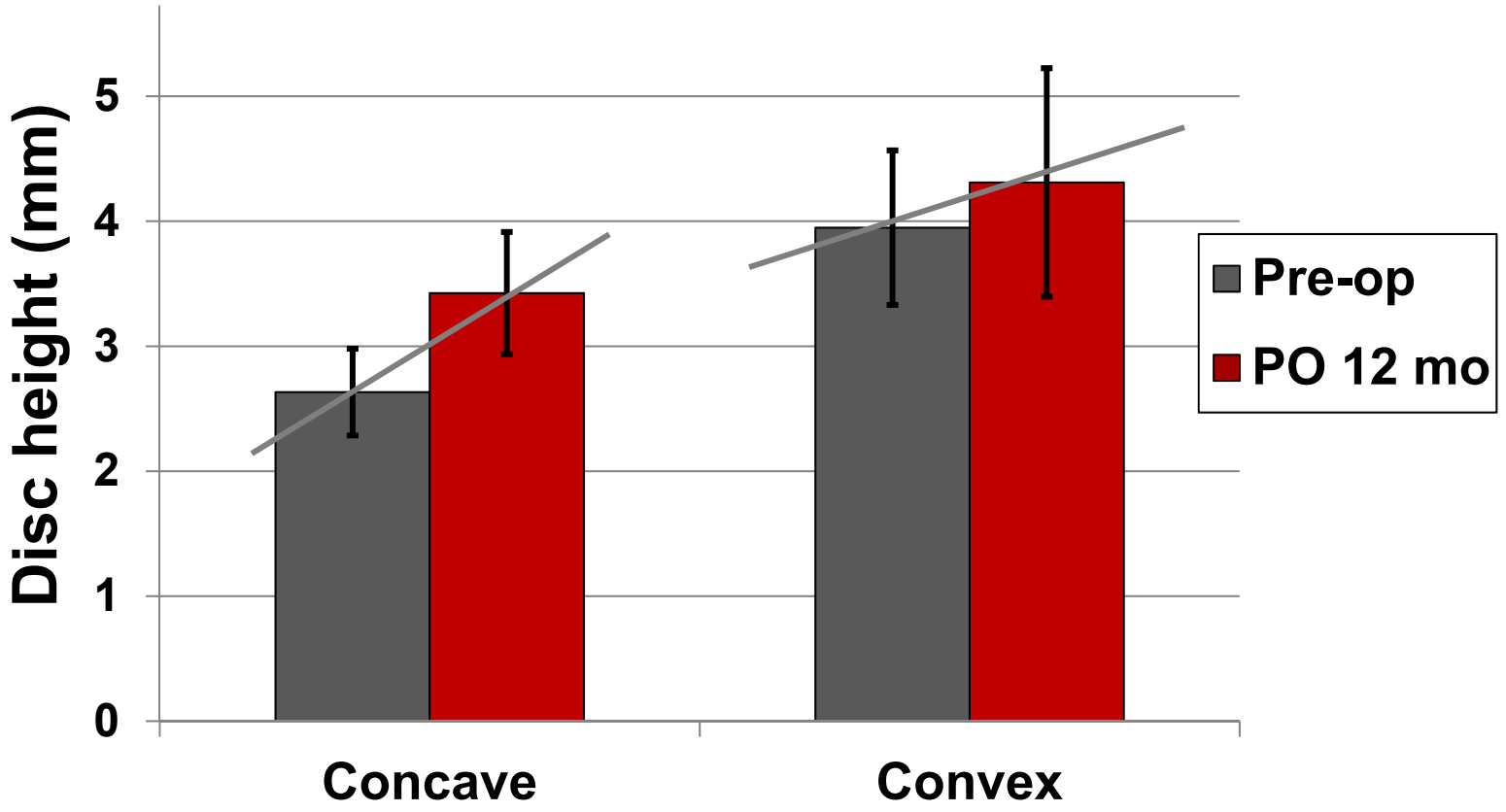
- **Statistics: Paired t-tests, one-tailed, Bonferroni**
  - **Two primary comparisons, α = 0.025**

Results

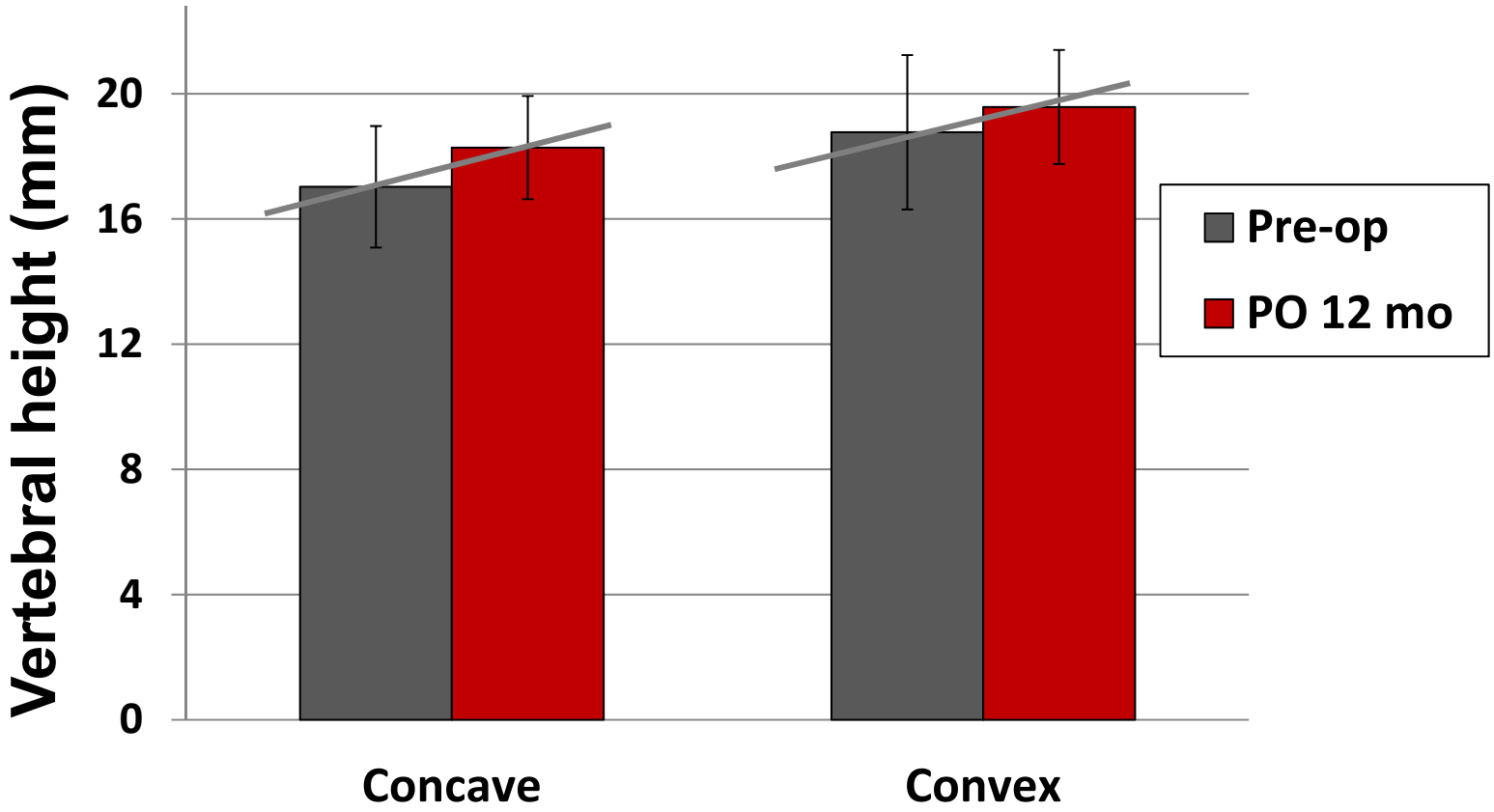
- 3 females, 3 males
  - 12.1 years (±1.7) at surgery
- Curvature
  - 34° Pre-op (± 3)
  - 30° PO 1 yr (± 13)

# Implants	6	range 5 – 7
# Discs	5.2	range 4 – 7
# Vertebrae	6.5	range 6 – 8

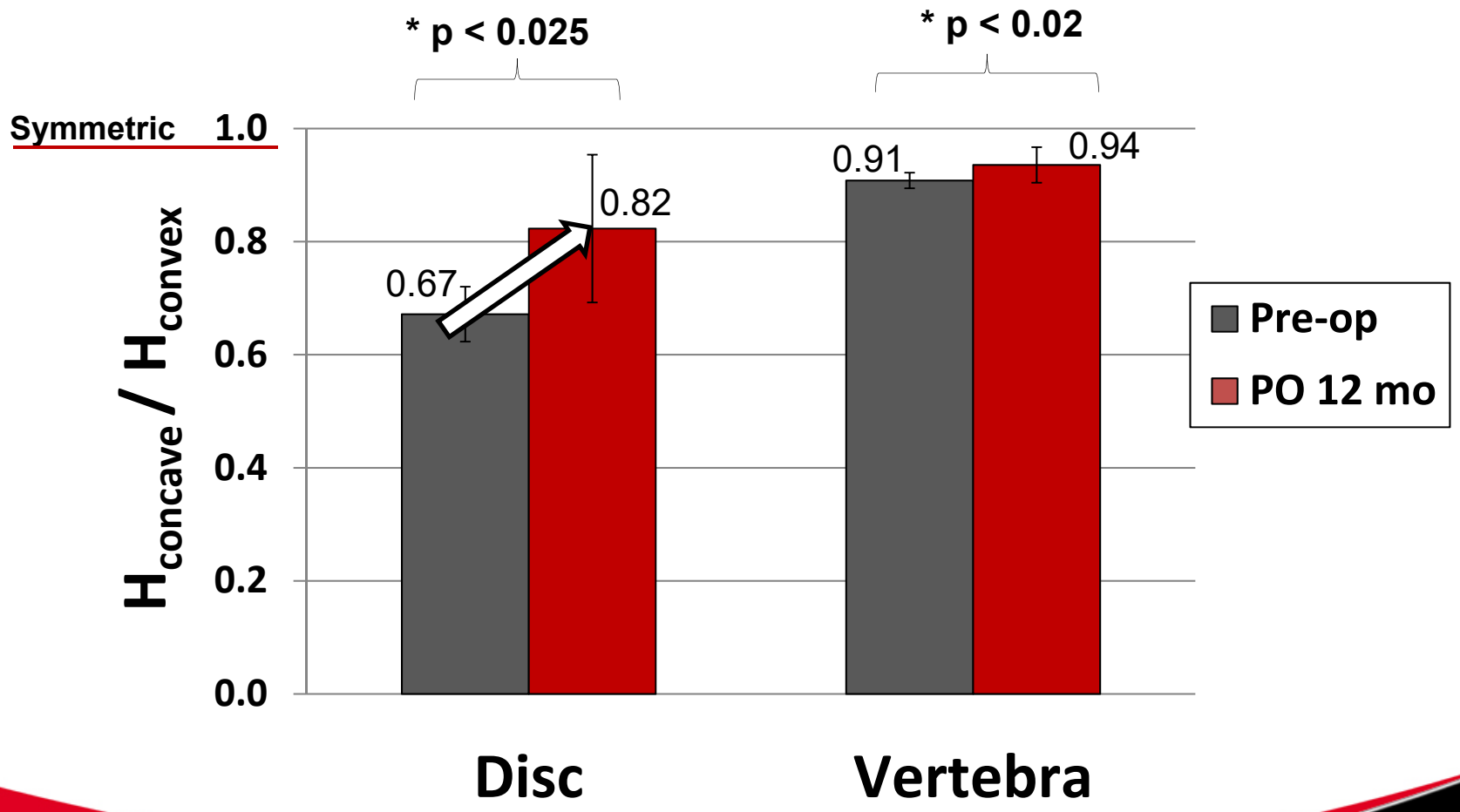
Disc heights



Vertebral body heights



Height ratios



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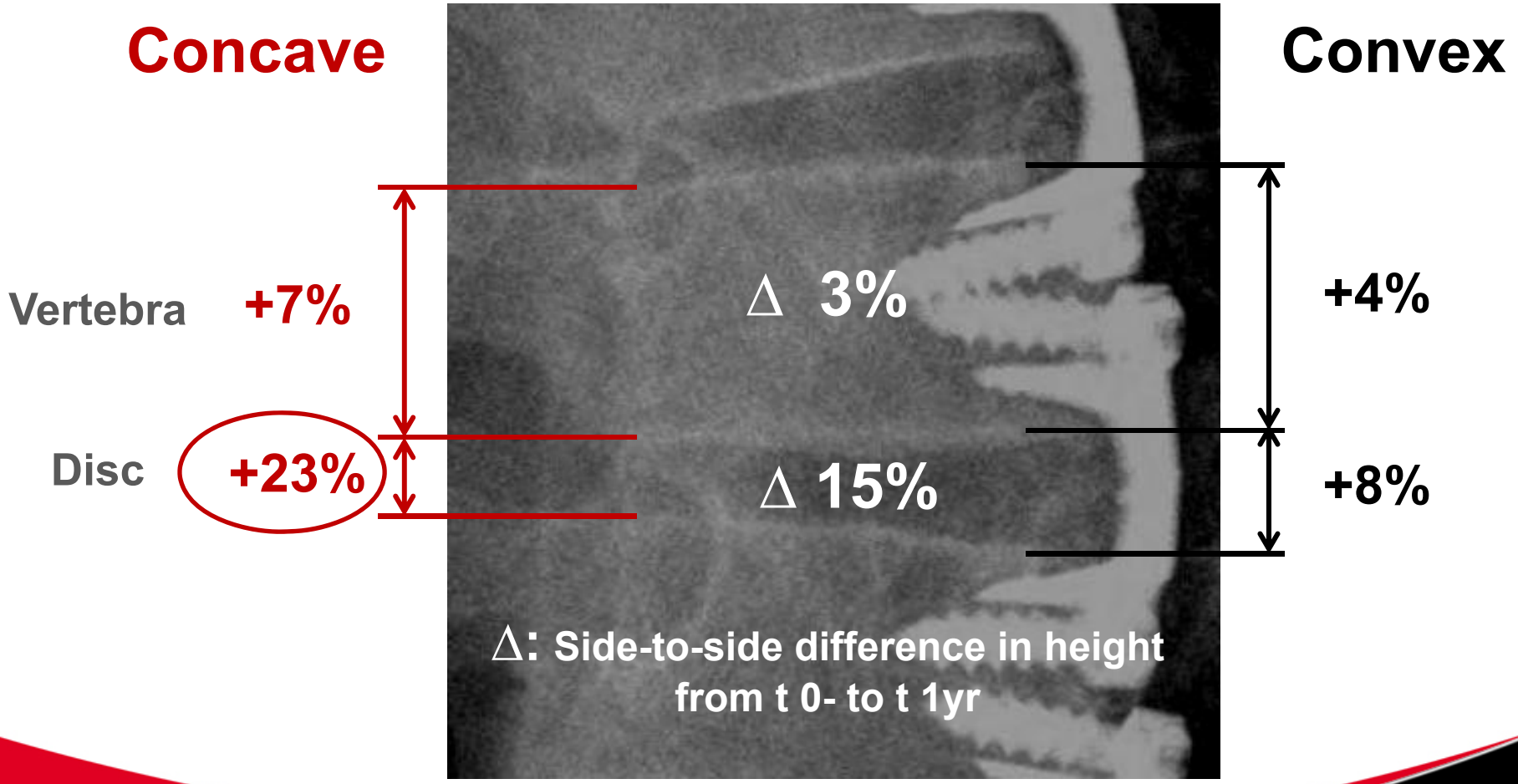
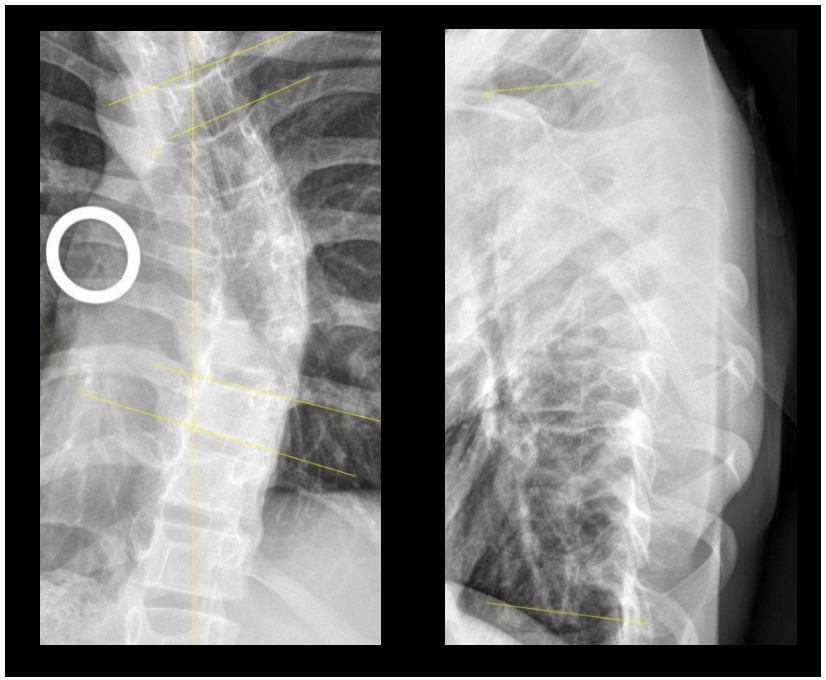
Height differences: Pre-op to 1 year



Discussion

- **Limitations**
  - **Small n**
  - **Short PO time**
  - **Resolution, 2D**
  - **Biased - curve with greatest axial rotation & progression**
    - **Apical discs not discernible**
  - **Longer-term & reliability**



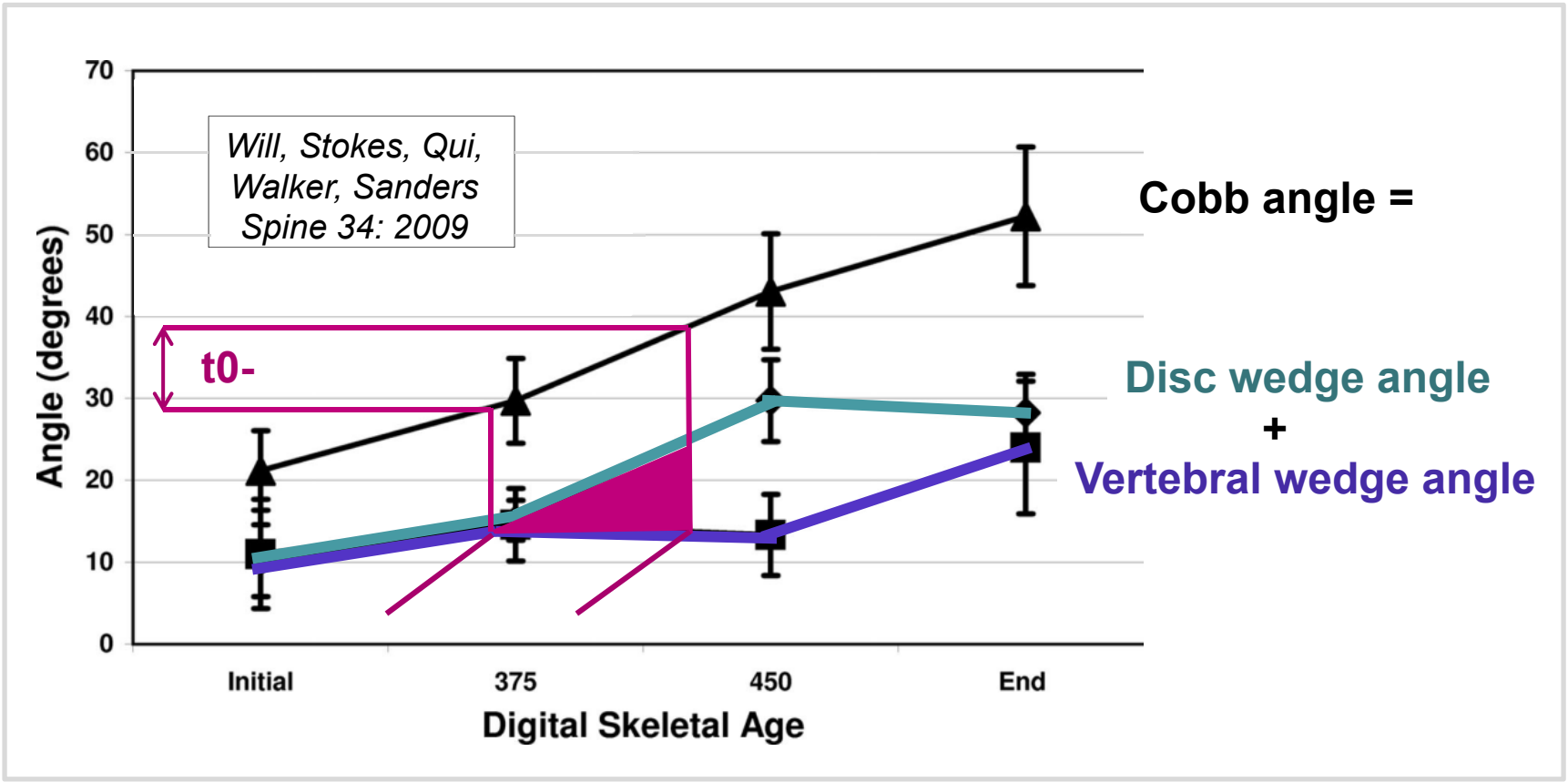
  - **In 30 year f/up of AIS (scanned plain films, not digital radiography)**

Tolerance limits	Intra-rater	Inter-rater
Vertebral body height ratio	± 12%	± 23%
Disc wedge angle	± 7°	± 11°

- *Volz, Dolan et al Scoliosis 2012*

Comparisons

Cobb angle progression in AIS begins at disc



Stop disc wedging early, prevent vertebral wedging?

Conclusions

- **Symmetry of discs and vertebrae increased in 1 year in trial of growth modification using titanium implant constructs**
- **Greatest increase was in disc height on concave side**
  - **Decompression of discs on side contralateral to implants**
- **Increases in heights and ratios suggest mechanisms of both curve correction, and of continued curve progression, after treatment, in small early stage cohort**

Acknowledgments & Disclosures

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Base study

- **Ohio Third Frontier**
  - TECH 11-042B
- **FDA R01 -** 04144-01

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