Spine growth modulation using titanium clip / screw device:
Vertebralae and disc heights at 1 year

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

- **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

Entirely endoscopic  Implants wedge disc
Symmetry: Height ratios $H_{\text{concave}} / H_{\text{convex}}$

- Statistics: Paired t-tests, one-tailed, Bonferroni
  - Two primary comparisons, $\alpha = 0.025$
Results

- 3 females, 3 males
  - 12.1 years (±1.7) at surgery

- Curvature
  - 34° Pre-op (± 3)
  - 30° PO 1 yr (± 13)

<table>
<thead>
<tr>
<th># Implants</th>
<th>6</th>
<th>range 5 – 7</th>
</tr>
</thead>
<tbody>
<tr>
<td># Discs</td>
<td>5.2</td>
<td>range 4 – 7</td>
</tr>
<tr>
<td># Vertebrae</td>
<td>6.5</td>
<td>range 6 – 8</td>
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</tbody>
</table>
Disc heights

![Bar chart showing disc heights for concave and convex shapes. The chart compares pre-operative (Pre-op) and post-operative (PO 12 mo) data.](image)
Vertebral body heights

Vertebral height (mm)

Concave
- Pre-op
- PO 12 mo

Convex
- Pre-op
- PO 12 mo
Height ratios

Symmetric 1.0

H_{concave} / H_{convex}

Disc

Vertebra

Pre-op

PO 12 mo

* p < 0.025

* p < 0.02

0.67

0.82

0.91

0.94

Cincinnati Children's

UNIVERSITY OF Cincinnati
Height differences: Pre-op to 1 year

Vertebra

$\Delta 3\%$

Disc

$\Delta 15\%$

$
\Delta: $ Side-to-side difference in height from t 0- to t 1yr

Concave

Convex

Vertebra +7%

Disc +23%

+4%

+8%
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)

<table>
<thead>
<tr>
<th>Tolerance limits</th>
<th>Intra-rater</th>
<th>Inter-rater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertebral body height ratio</td>
<td>± 12%</td>
<td>± 23%</td>
</tr>
<tr>
<td>Disc wedge angle</td>
<td>± 7°</td>
<td>± 11°</td>
</tr>
</tbody>
</table>

- Volz, Dolan et al Scoliosis 2012
Comparisons

Cobb angle progression in AIS begins at disc

Will, Stokes, Qui, Walker, Sanders
Spine 34: 2009

Cobb angle =

Disc wedge angle +
Vertebral wedge angle

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
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Dziękuję Thank you