A New Posterior Dynamic Fusionless Device for Correction of Adolescent Idiopathic Scoliosis: Report on 27 Cases with 2-5 Years Follow-up


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The standard surgical management of AIS is spinal fusion. There is an increasing demand voiced by patients, parents and surgeons for non fusion solutions. Existing fusionless techniques such as VBT necessitate an anterior approach. A posterior dynamic fusionless deformity correction device was developed to address single, moderate Lenke type 1 or 5 curves. The objective of this study was to analyze the results of this new device in reducing and maintaining the correction of moderate curves in adolescents with IS.

Posterior dynamic fusionless deformity correction device
It is anchored to the spine with 2 pedicle screws
A ratchet mechanism provides unidirectional lengthening during and after surgery

Implant Design

The unique features of the implant are two poly-axial “eye” joints that connect to the screws and provide 50° freedom of motion
The poly-axial connectors dramatically reduce implant-screw & screw-bone stresses
Allow motion of the instrumented spine

Cadaveric thoracic spine testing
Only 40% reduction in flexion/extension
18% reduction in lateral bending
Axial rotation unaffected
A multicenter European pilot trial was conducted. The inclusion criteria for this study were:

- AIS (12-17 years)
- Lenke 1 (40°-60°)
- Lenke 5 (30°-60°)
- Curve reduction to ≤35° on side bending

Contraindications

- Kyphosis>55°
- Other Lenke types

Surgery

- Exposure of concave side only, 2 pedicle screws
- Implantation of 2 pedicle screws, device connected to screws
- Intraoperative distraction no fusion

Optional post-operative Schroth-like exercises for 3 months
40 consecutive AIS patients

Evaluated at minimum >2 years follow-up (average 2.8 years)

Met current indications - 27 patients with clinical & radiographic follow-up
  - Risser >4 at final F/U

Did not meet current indications - 12 patients
  - Curve > 60° - 5 patients
  - Stiff curve - 3 patients
  - Improper pedicle screw placement - 3 patients
  - Lost to follow-up - 1 patient

Deep wound infection - 1 patient
## Results - all patients
*(within & outside current indications)*

<table>
<thead>
<tr>
<th>Age 15 years (avg.)</th>
<th>Range 12-17 years</th>
<th>Final Cobb’s angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow up 2.8 years (avg.)</td>
<td>Range 2-5 years</td>
<td></td>
</tr>
<tr>
<td>Preop. Cobb angle <strong>49°</strong></td>
<td>Range 32°-74°</td>
<td>Postop. Cobb angle <strong>34°</strong> (P&lt;0.05)</td>
</tr>
<tr>
<td>% correction</td>
<td></td>
<td><strong>32%</strong></td>
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</tbody>
</table>
## Results - current indications

<table>
<thead>
<tr>
<th></th>
<th>Age 15 years (avg.)</th>
<th>Range 12-17 years</th>
<th>Risser 2.5 (avg.)</th>
<th>Range 0-5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lenke type</strong></td>
<td>Lenke 1</td>
<td>Lenke 5</td>
<td></td>
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<tr>
<td></td>
<td>22 patients</td>
<td>5 patients</td>
<td></td>
<td></td>
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<tr>
<td><strong>Follow up 2.8 years (avg.)</strong></td>
<td>Range 2-5 years</td>
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<tr>
<td><strong>Preop. Cobb angle  44°</strong></td>
<td>Range 32°-55°</td>
<td><strong>Post-op. Cobb angle 29°  (P&lt;0.05)</strong></td>
<td>Range 6°-45°</td>
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</tr>
<tr>
<td><strong>% correction</strong></td>
<td>38%</td>
<td></td>
<td>Range 15%-81%</td>
<td></td>
</tr>
<tr>
<td><strong>Preop. Trunk shift 14mm</strong></td>
<td>Range 10mm-19mm</td>
<td><strong>Post-op. 5mm</strong></td>
<td>Range 0mm-11mm</td>
<td></td>
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<tr>
<td><strong>SRS-22 Self image</strong></td>
<td>Pre-op. 3.1±0.5</td>
<td><strong>Post-op. 3.7±0.4</strong></td>
<td></td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td><strong>SRS-22 Pain</strong></td>
<td>Pre-op. 4.3±0.6</td>
<td><strong>Post-op. 4.4±0.5</strong></td>
<td></td>
<td>N.S.</td>
</tr>
</tbody>
</table>
Invasiveness of the fusionless dynamic procedure

<table>
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<th>N=18</th>
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<tbody>
<tr>
<td>Operative time</td>
<td>1.2 hours</td>
</tr>
<tr>
<td>Blood loss</td>
<td>37±43 cc</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>2.2 days</td>
</tr>
<tr>
<td>Postop. exercises</td>
<td>3 weeks post-op., no restrictions including sports</td>
</tr>
</tbody>
</table>

Motion preservation
15Y♀, Risser 2, 50° to 29° at 3 years post-op
The **sagittal profile** was minimally changed without clinical significance. There was no adding on, curve progression, or implant failures.

5/8 patients, with large (> 60°) or stiff curves, **underwent conversion to formal fusion**. No evidence of spontaneous fusion during the fusion procedure.
In summary:

- Major curve correction from 44° to 29° (p<0.05)
- Correction maintained over time
- Improvement in trunk shift
- Higher SRS-22 scores
- No implant failures
- Less invasive procedure

- Arnin U et al.: Pre-clinical bench testing.....- Spine Deformity-Accepted for publication
- Floman Y et al.: Surgical management of moderate AIS..... Scoliosis 10:4 2015
More than 245 cases were operated so far.

**Current Practice, Cobb to Cobb** (65% correction) (2 year F/U)

49°

17°
Disclosures

Y Floman co-founder ApiFix
R El-Hawary consultant ApiFix
RR Betz consultant ApiFix
BS Loner consultant ApiFix