ApiFix Treatment For Adolescent Idiopathic Scoliosis (AIS): The importance of Schroth method exercises after the minimal invasive operation

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I am the Physiotherapist who treated all the ApiFix patients in Greece.

I received some financial support from the ApiFix Ltd company to attend the SOSORT – IRSSD 2016 Meeting.
Objectives

• Present the short-term results of ApiFix system

• Present the necessity of Schroth method exercises post-operation
Nowadays, there is a missing step between conservative treatment and spinal fusion. This gap can be covered (for some cases) by ApiFix, which offers the “internal brace” option.
Scoliotic deformity

ApiFix Implant attaches to the pedicle with 2 screws – peri apical and a relative correction of the deformity is achieved.

A miniature ratchet mechanism allows the elongation of an expandable rod.

The implant gradually elongates by Scoliosis Specific exercises, enlarging the distance between the two screws. This gradual correction targets to bring the curvature into the “safe zone”, below 30° - 35°.
Spinal fusion

- Surgical incision approx. 30-45 cm
- Duration of operation 6-8 hours
- Hospitalization 6-7 days
- Blood loss 800-1500cc

ApiFix

- Surgical incision approx. 10 cm
- Duration of operation 45-60 min
- Hospitalization 1-2 days
- Blood loss 50 cc
- No fusion, no effect on growth plates, does not affect growth
- Normal range of motion of spine after surgery
- Potential option to remove the device after maturity
- Option for spinal fusion in the future
- Lower rate of surgical complications
Fatigue Test per ASTM F 1717

- Test performed by EndoLab GMBH (Germany)
- **ApiFix** Run-out load at 5,000,000 cycles was **1000N**
- Standard **fusion** systems of good quality holds around **300N**

Risk reduction

Spherical joint between the Implant and the Screw. No moments can be transferred, only pure axial loads.

The Nut firmly holds the spherical ring but the joint is still free to move 3D.
Indications for ApiFix

- Apifix is not applied to every type of scoliosis
- Lenke type 1 (Main Thoracic), Lenke type 5 (Thoracolumbar)
- Cobb angle 40° – 60°
- Moderate rotation
- Flexible curve
  (significant correction in side-bending x-rays)
<table>
<thead>
<tr>
<th>Pre-operation</th>
<th>Post-operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Curvature classification</td>
<td>• Exit of the hospital 1-2 days after the operation</td>
</tr>
<tr>
<td>• X-ray evaluation and estimation of Cobb angle</td>
<td>• Commencement of PSSE 2 weeks post-op</td>
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<tr>
<td>• Evaluation of flexibility by lateral bending x-rays</td>
<td>• Radiological assessment at 1\textsuperscript{st}, 3\textsuperscript{rd} and 6\textsuperscript{th} month</td>
</tr>
<tr>
<td>• Start of PSSE approx. 1 month pre-op</td>
<td>• Continuation of the exercises for at least 6 months</td>
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<tr>
<td>• Improve body awareness, flexibility and mobility</td>
<td>• Long follow-up</td>
</tr>
<tr>
<td>• Detailed information to the patient and their family, expectation management</td>
<td></td>
</tr>
</tbody>
</table>
Goals of treatment:

- Personalized exercises based on the curvature type (Physiotherapeutic Scoliosis Specific Exercises-PSSE)
- 3D auto-correction of scoliosis and active self elongation
- Cobb angle and Angle Trunk Rotation (ATR) improvement
- Improvement of posture and clinical appearance
- Reduction or elimination of pain
- Improvement of spinal mobility and flexibility
- Improvement of Vital Capacity (VC) and breathing function
- Activities of Daily Living (ADL) training
- Reduction of mechanical forces that promote progression

The exercises must be prescribed only by Schroth Certified Therapists
Methods

• Prospective on-going case-series study

• 6 female patients
• Mean age 15.6 years, Risser sign 3.7, Cobb angle 41.8°

• Scoliosis Specific Exercises program for 6 months post-op (at least), Schroth method (Barcelona Scoliosis Physical Therapy School - BSPTS)

• Outcome parameters: Cobb angle, Angle Trunk Rotation (ATR), Aesthetics (TAPS – TRACE), Pain (VAS)

• Average follow-up 17.5 months
• Unpaired student t-test for statistical analysis
## Results

<table>
<thead>
<tr>
<th>Age</th>
<th>Risser</th>
<th>Cobb pre-op</th>
<th>Cobb post-op</th>
<th>Cobb change</th>
<th>% correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>5</td>
<td>37</td>
<td>23</td>
<td>14</td>
<td>37.8%</td>
</tr>
<tr>
<td>15.5</td>
<td>4</td>
<td>30</td>
<td>6</td>
<td>24</td>
<td>80.0%</td>
</tr>
<tr>
<td>14</td>
<td>0</td>
<td>54</td>
<td>35</td>
<td>19</td>
<td>35.2%</td>
</tr>
<tr>
<td>17</td>
<td>5</td>
<td>59</td>
<td>39</td>
<td>20</td>
<td>33.9%</td>
</tr>
<tr>
<td>14</td>
<td>4</td>
<td>40</td>
<td>23</td>
<td>17</td>
<td>42.5%</td>
</tr>
<tr>
<td>14</td>
<td>4</td>
<td>37</td>
<td>28</td>
<td>9</td>
<td>24.3%</td>
</tr>
<tr>
<td>15.6</td>
<td>3.7</td>
<td>42.8</td>
<td>25.7</td>
<td>17.2</td>
<td>40.08%</td>
</tr>
</tbody>
</table>

*Significant Cobb angle reduction (35.9%, p= 0.031)*

*Significant Cobb angle reduction (40.08%, p= 0.017)*
Results

• Better results compared with previous research from Israel (avg Correction 32%)
• Not clear indication for ApiFix in some patients, might restricted the percentage of correction
• Complications: (1/6 patients) Revision surgery, due to a backup of the ratchet that was corrected by locking the mechanism
• Another patient had no chance for elongation/further correction due to improper length of the mechanism
Pre/Post Schroth exercises Results

• 4 patients analyzed

• **Cobb angle** improvement by **3.3°** (from 26.3° to 23°, \( p=0.603 \))

  Cobb angle improvement by **4.6°** (from 26.3° to 21.7°, \( p= 0.53 \))

• **ATR** improvement by **2.3°** (from 10.5° to 8.2°, \( p=0.252 \))

• **TAPS** score improvement by **0.7** (from 3.2 to 3.9, \( p=0.113 \))

• **TRACE** score improvement by **2** (from 3.75 to 1.75, \( p=0.001 \))

• Pain score (**VAS**) improvement by **1.3** (from 2 to 0.7, \( p=0.11 \))
Case study 1

pre-op
Lu (L) 37°

2w post-op (no exerc.)
Lu (L) 26°

6m post-op
Lu (L) 23°

2y post-op
Lu (L) 23°
Case study 1
Case study 2

pre-op
Th-Lu (R) 30°

2w post-op (no exerc.)
Th-Lu (R) 18°

6m post-op
Th-Lu (R) 14°

18m post-op
Th-Lu (R) 6°
Case study 2
Case study 3

pre-op  
Th (R) 54° – Lu (L) 44°

1d post-op  
Th (R) 30° – Lu (L) 33°

1m post-op  
(before exercises)  
Th (R) 37° – Lu (L) 39°

6m after Schroth exercises  
Th (R) 35° – Lu (L) 39°
Case study 3

Clinical appearance improvement (shoulders, pelvic asymmetry, ATR) after Schroth exercises
Case study 4

pre-op
59°

3m post-op
35°

6 m post-op (before revision)
50°

after revision surgery
39°
Case study 4

pre-op

3m post-op

after revision surgery
Most recent ApiFix operation

Pre-op 59°

post-op 29°

Pre-op

3 months post-op
Most recent ApiFix operation

Pre-op 3 months post-op

Pre-op 3 months post-op
Conclusions - Discussion

- ApiFix system can offer an alternative treatment option for some scoliotic patients

- Proper patient selection and strict application of the ApiFix indications are very important and can potentially lead to even better results

- Schroth method exercises enhance the final treatment result and must always be applied

- Schroth method exercises achieved an improvement of Cobb angle, ATR, clinical appearance and pain

- Longer follow-up is needed to determine the long-term results, ADL training can play a key role
Thank you for your attention

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