

# **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

- Present the short-term results of ApiFix system
- Present the necessity of Schroth method exercises post-operation

PSSE



→  
 $\leq 25^\circ$

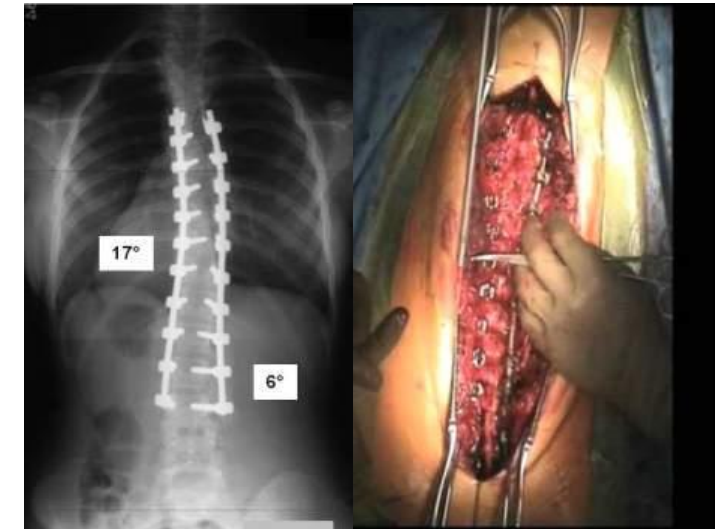
Brace



→  
 $25^\circ - 40^\circ$

Treatment Severity ↗  
**ApiFix®**

Spinal Fusion



$>45^\circ - 50^\circ$

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



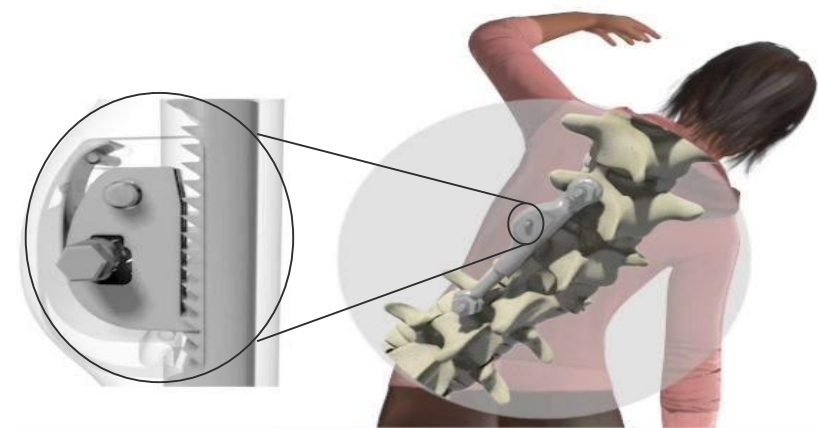
# Treatment process



Scoliotic deformity

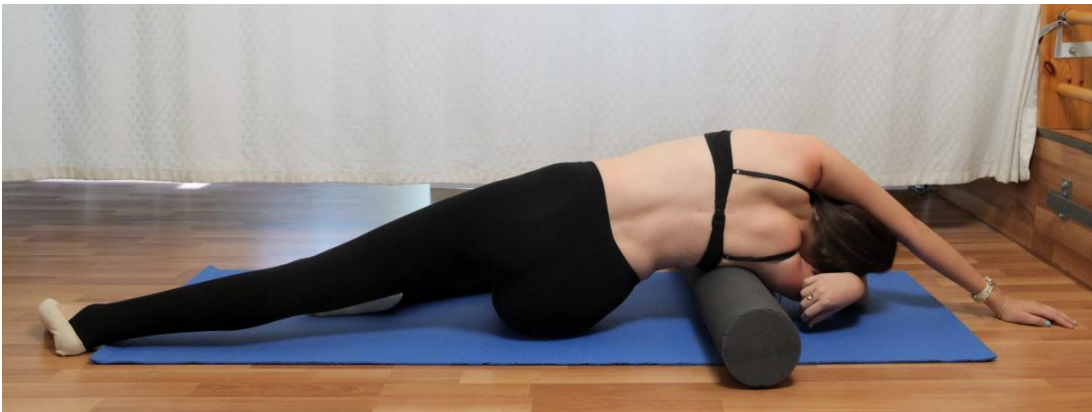


ApiFix Implant attaches to the pedicle with 2 screws – peri apical and a relative correction of the deformity is achieved



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

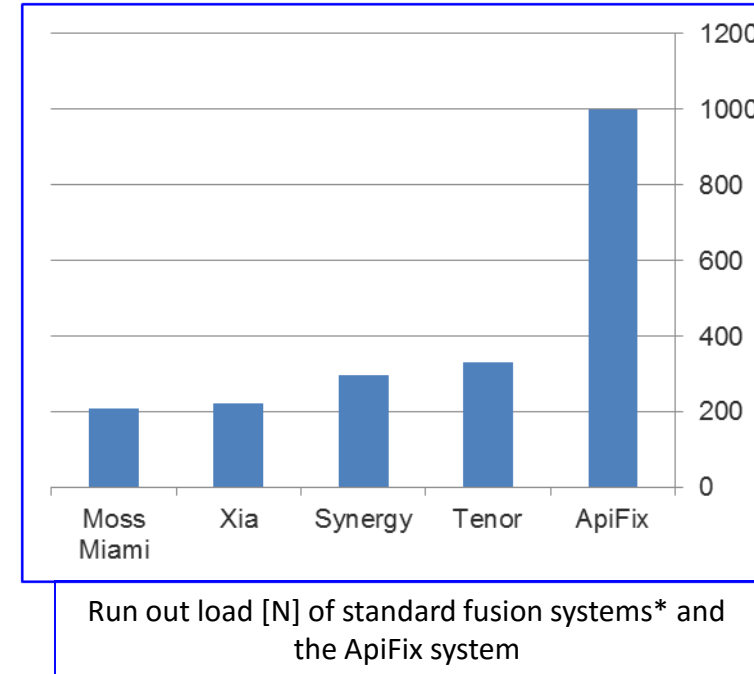
- Test performed by EndoLab GMBH (Germany)
- ApiFix Run-out load at 5,000,000 cycles was 1000N
- Standard fusion systems of good quality holds around **300N**\*



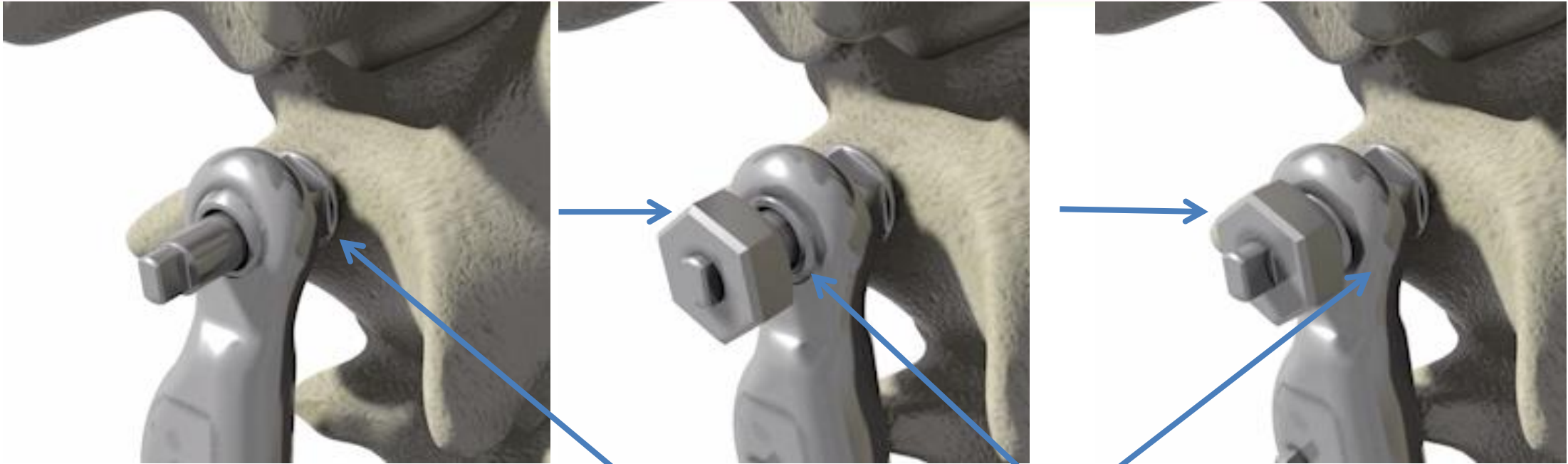
Testing Jig



Test Sample



\* Multiaxial Pedicle Screw Designs: Static and Dynamic Mechanical Testing. Ralph E. Stanford et al, Spine Vol. 29, No. 4 , 2004





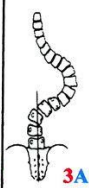
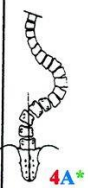


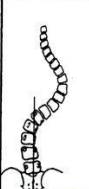






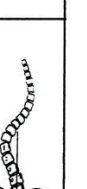
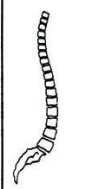

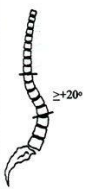

Spherical joint between the Implant and the Screw.  
No moments can be transferred, only pure axial loads.

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





- Apifix is not applied to every type of scoliosis
- Lenke type 1 (Main Thoracic), Lenke type 5 (Thoracolumbar)
- Cobb angle  $40^{\circ}$  –  $60^{\circ}$
- Moderate rotation
- Flexible curve  
(significant correction in side-bending x-rays)

Lumbar Spine Modifier	Curve Type (1 - 6)					
	Type 1 (Main Thoracic)	Type 2 (Double Thoracic)	Type 3 (Double Major)	Type 4 (Triple Major)	Type 5 (TL/L)	Type 6 (TL/L - MT)
<b>A</b> (No to Minimal Curve)	 1A*	 2A*	 3A*	 4A*		
<b>B</b> (Moderate Curve)	 1B*	 2B*	 3B*	 4B*		
<b>C</b> (Large Curve)	 1C*	 2C*	 3C*	 4C*	 5C*	 6C*
Possible Sagittal structural criteria (To determine specific curve type)	 Normal	 PT Kyphosis	 TL Kyphosis	 PT + TL Kyphosis		

\* T5-12 sagittal alignment modifier: -, N, or +  
 - :  $<10^{\circ}$   
 N :  $10-40^{\circ}$   
 + :  $>40^{\circ}$

## Pre-operation

- Curvature classification
- X-ray evaluation and estimation of Cobb angle
- Evaluation of flexibility by lateral bending x-rays
- Start of PSSE approx. 1 month pre-op
- Improve body awareness, flexibility and mobility
- Detailed information to the patient and their family, expectation management

## Post-operation

- Exit of the hospital 1-2 days after the operation
- Commencement of PSSE 2 weeks post-op
- Radiological assessment at 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> month
- Continuation of the exercises for at least 6 months
- Long follow-up

## 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**

- 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

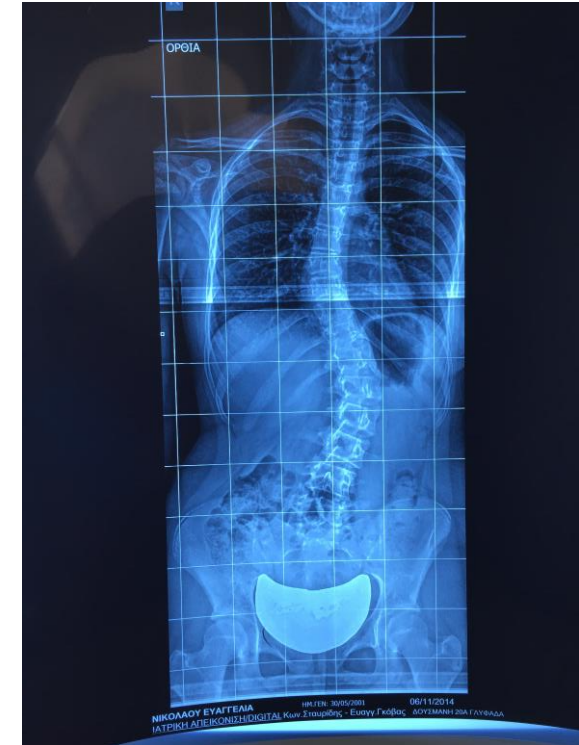
Age	Risser	Cobb pre-op	Cobb post-op	Cobb change	% correction
19	5	37	23	14	37,8%
15.5	4	30	6	24	80,0%
14	0	54	35	19	35,2%
17	5	59	39	20	33,9%
14	4	40	23	17	42,5%
14	4	37	28	9	24,3%
15,6	3,7	42,8	25,7	17,2	40,08%

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

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

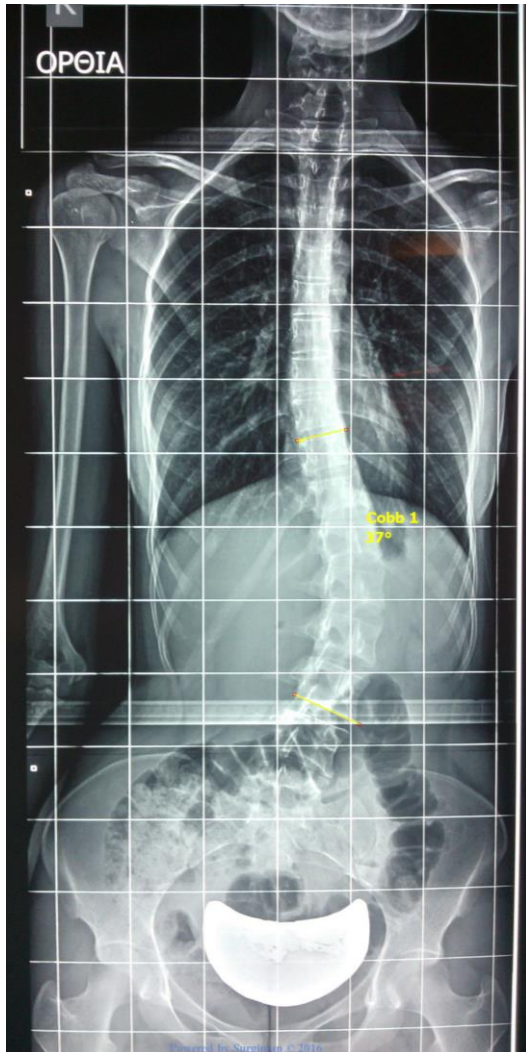


- Better results compared with previous research from Israel (avg Correction 32%)
- Not clear indication for ApiFix in some patients, might restricted the percentage of correction
- Complications: (1/6 patients)  
Revision surgery, due to a backup of the ratchet that was corrected by locking the mechanism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



- 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)

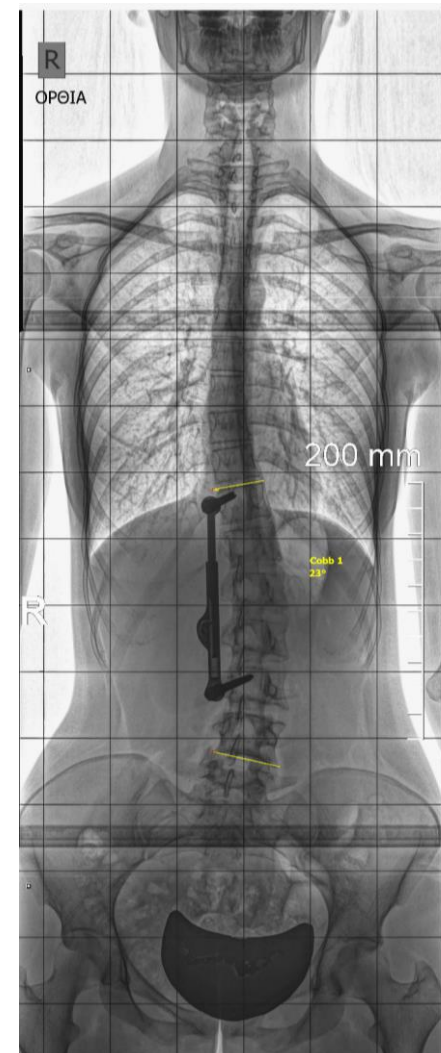
# Case study 1



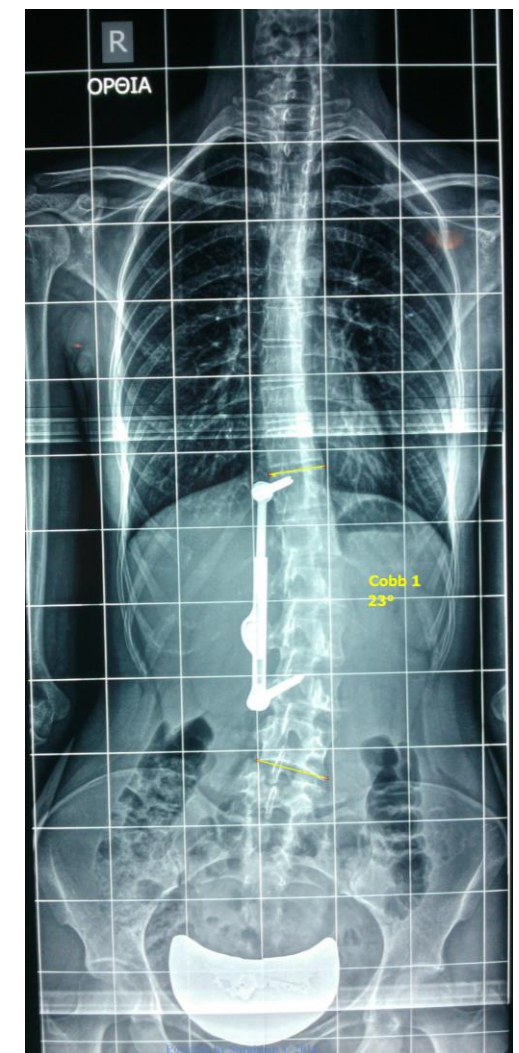
pre-op  
Lu (L) 37°



2w post-op (no exerc.)  
Lu (L) 26°



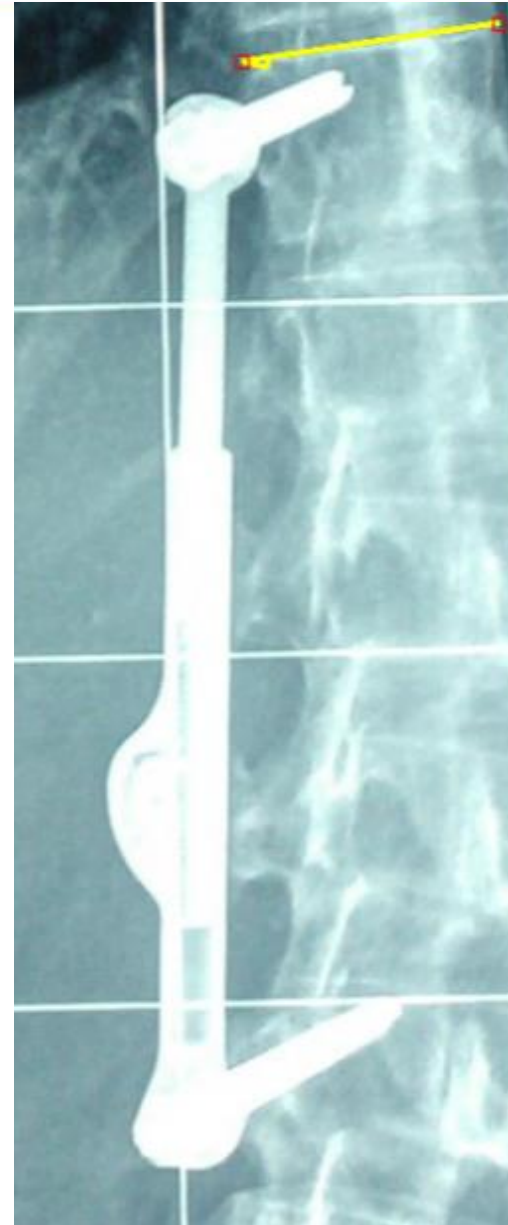
6m post-op  
Lu (L) 23°



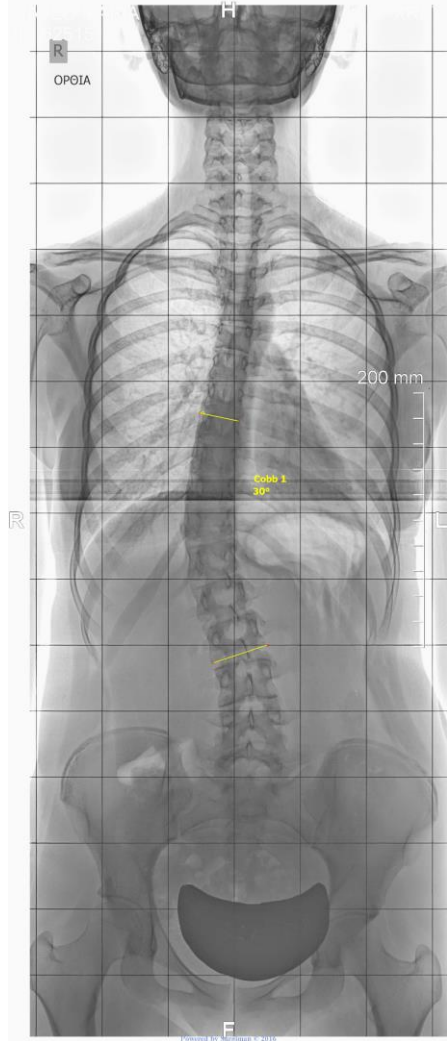
2y post-op  
Lu (L) 23°



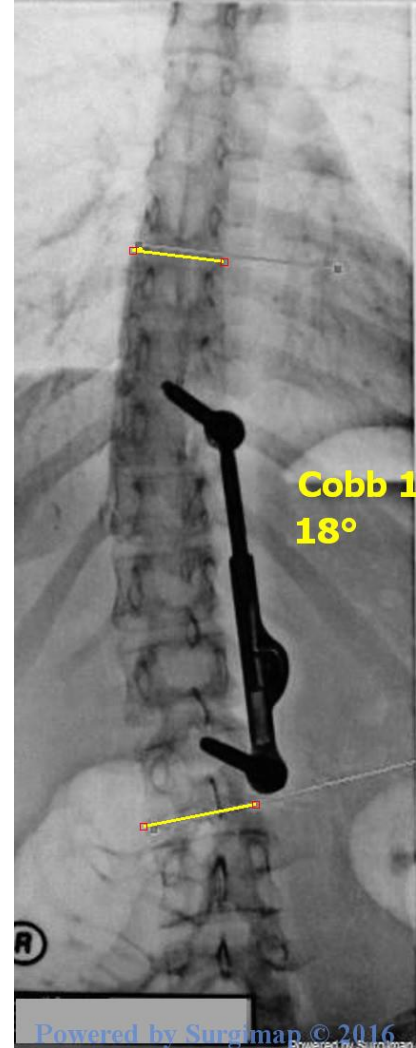
# Case study 1



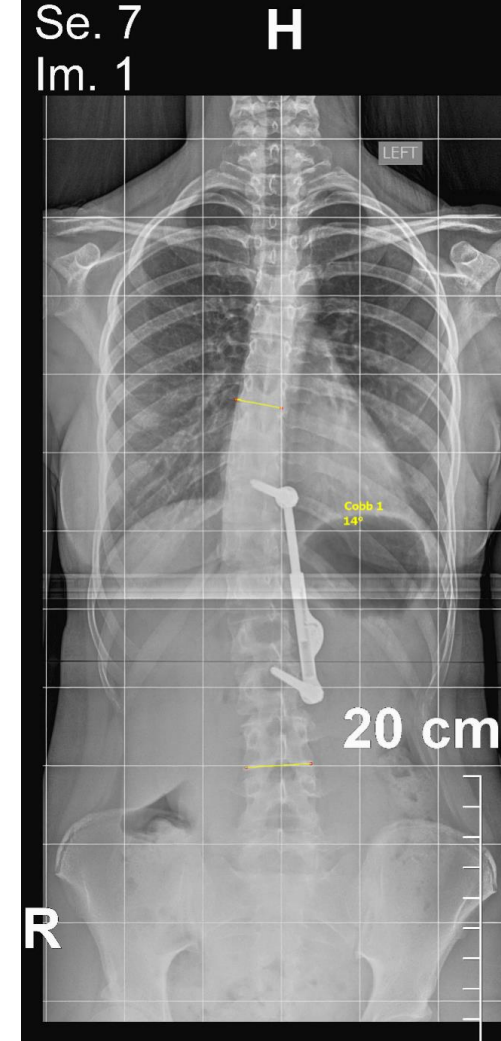
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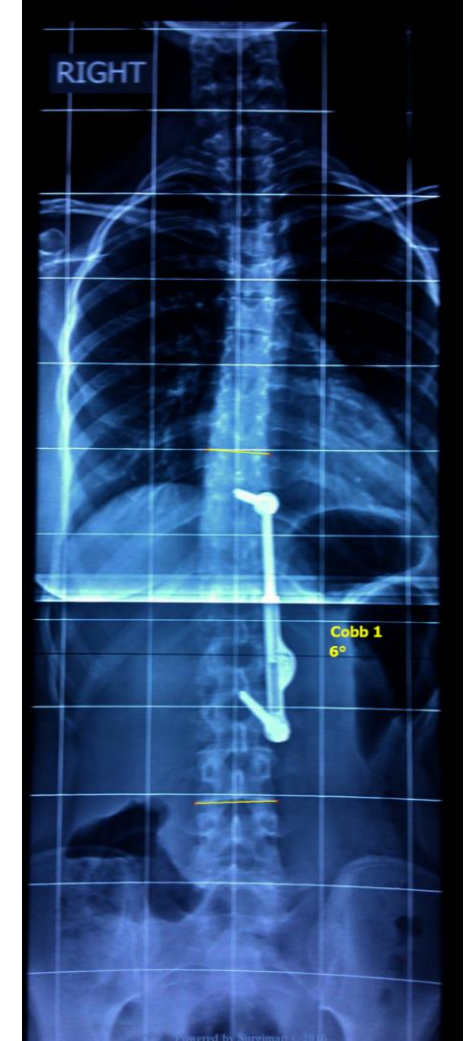
pre-op  
Th-Lu (R) 30°



2w post-op (no exerc.)  
Th-Lu (R) 18°

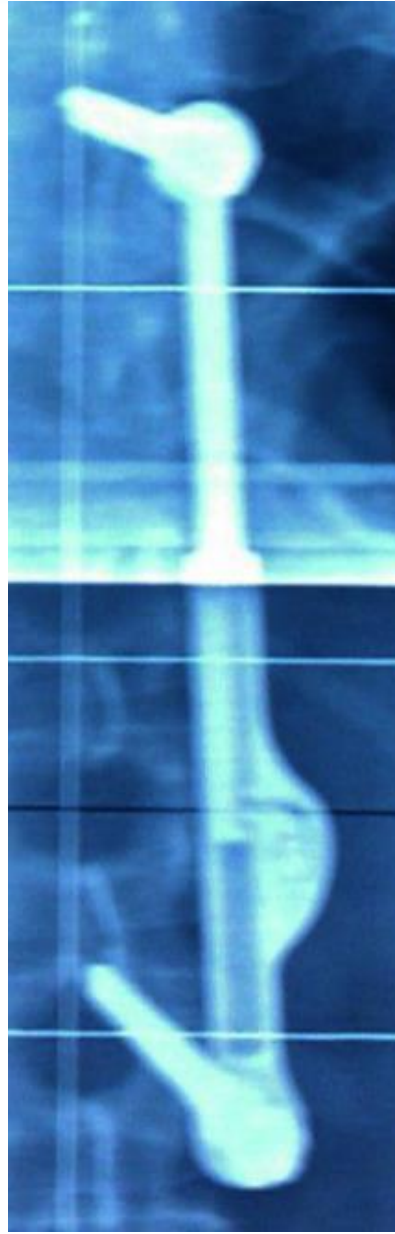
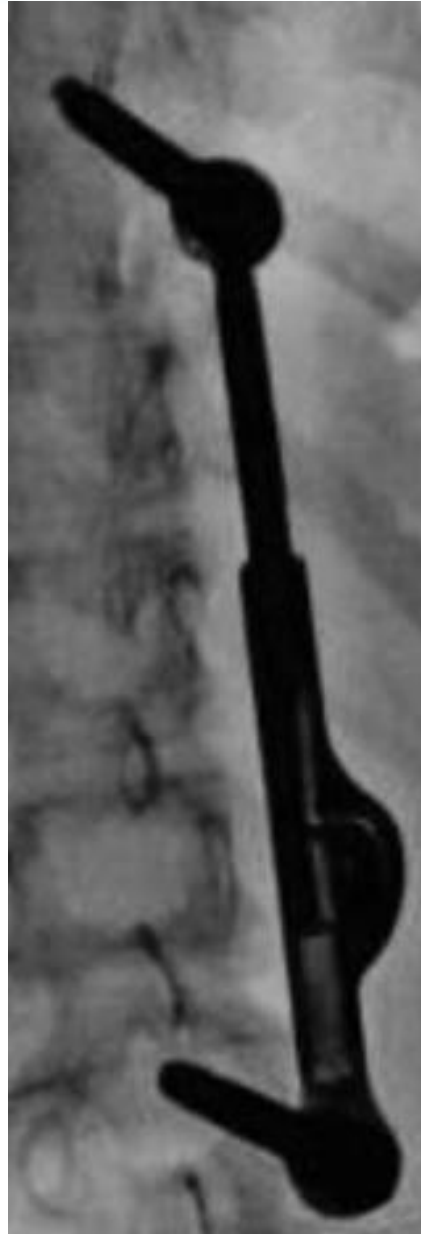


6m post-op  
Th-Lu (R) 14°

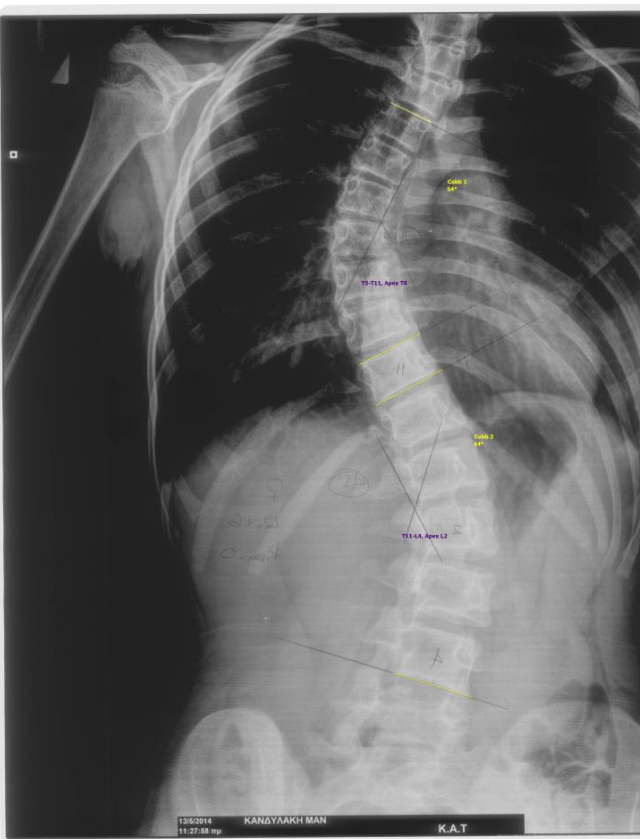


18m post-op  
Th-Lu (R) 6°

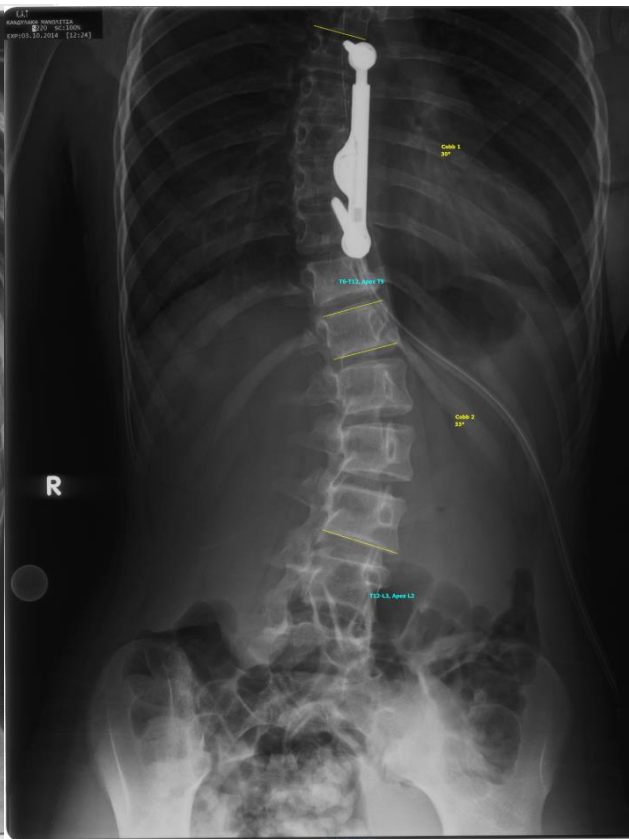




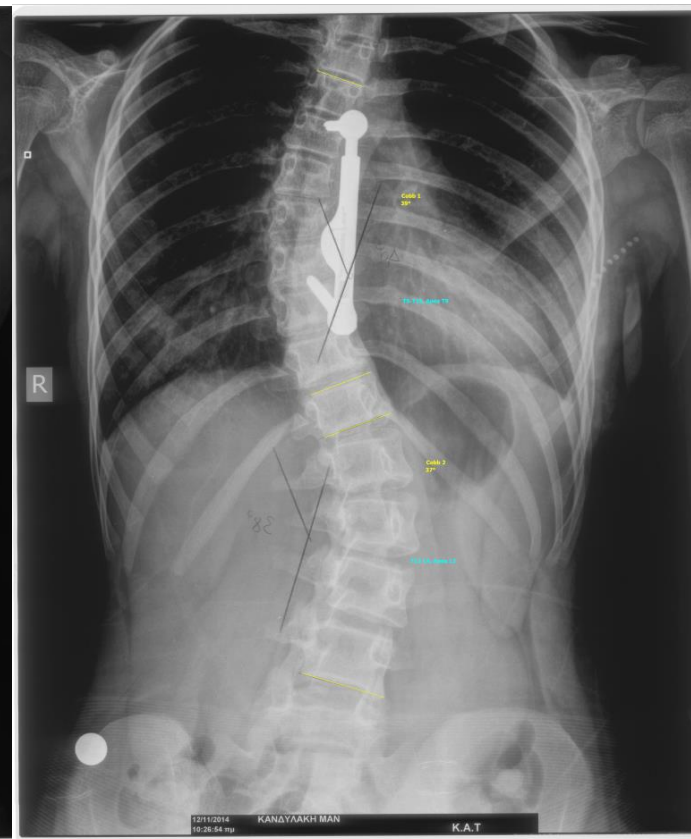
# Case study 3



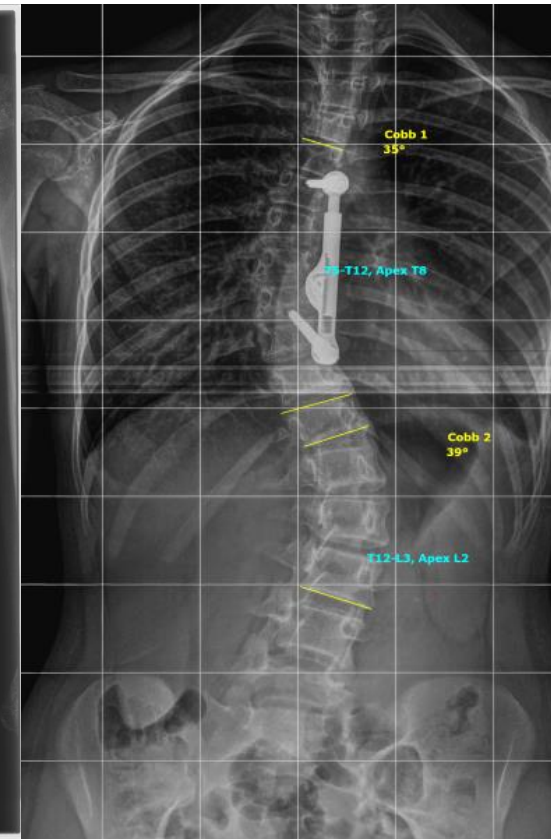
**pre-op**  
Th (R) 54° – Lu (L) 44°



**1d post-op**  
Th (R) 30° – Lu (L) 33°

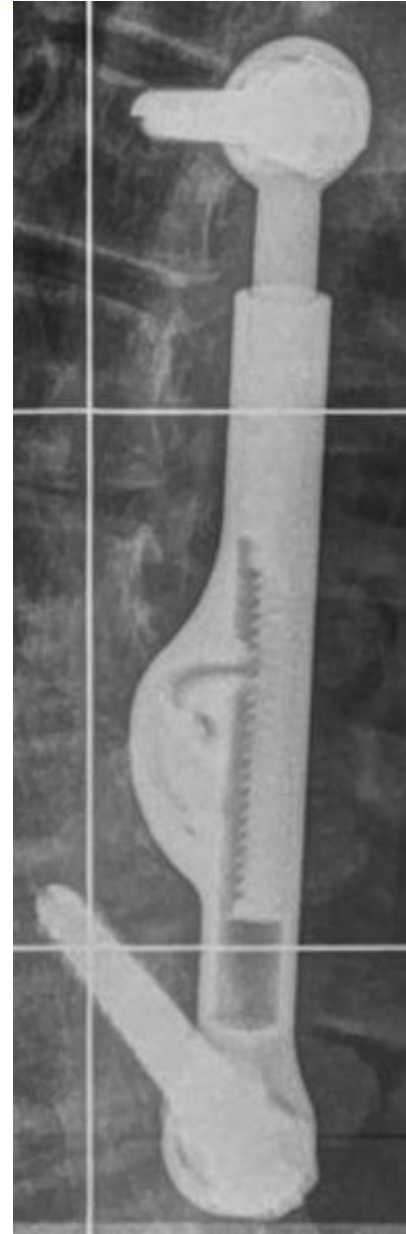


**1m post-op**  
(before exercises)  
Th (R) 37° – Lu (L) 39°



**6m after**  
Schroth exercises  
Th (R) 35° – Lu (L) 39°

## Case study 3





# Case study 3

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



Before Schroth ex.



6 months after Schroth ex.



Before Schroth ex.



6 months after Schroth ex.

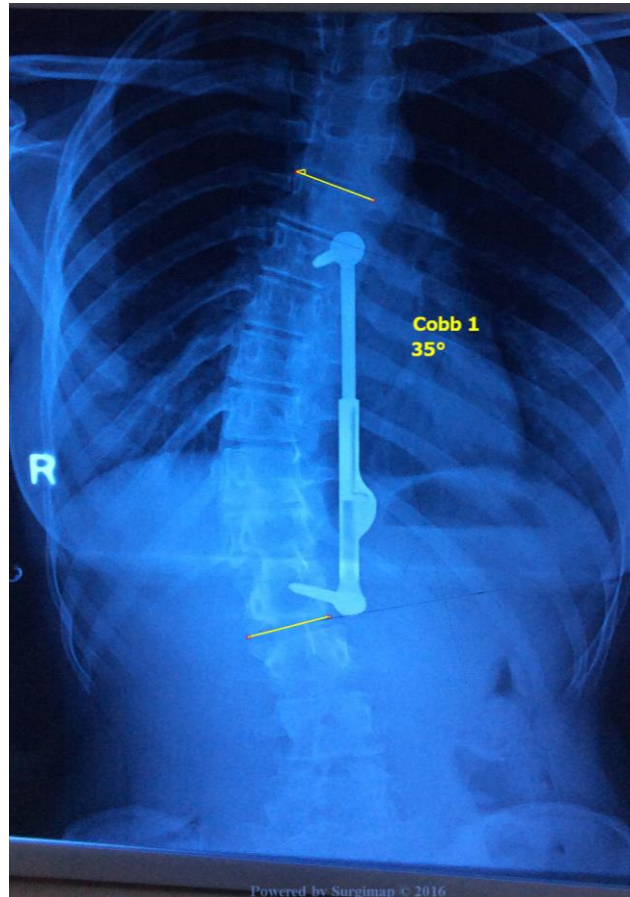


# Case study 4



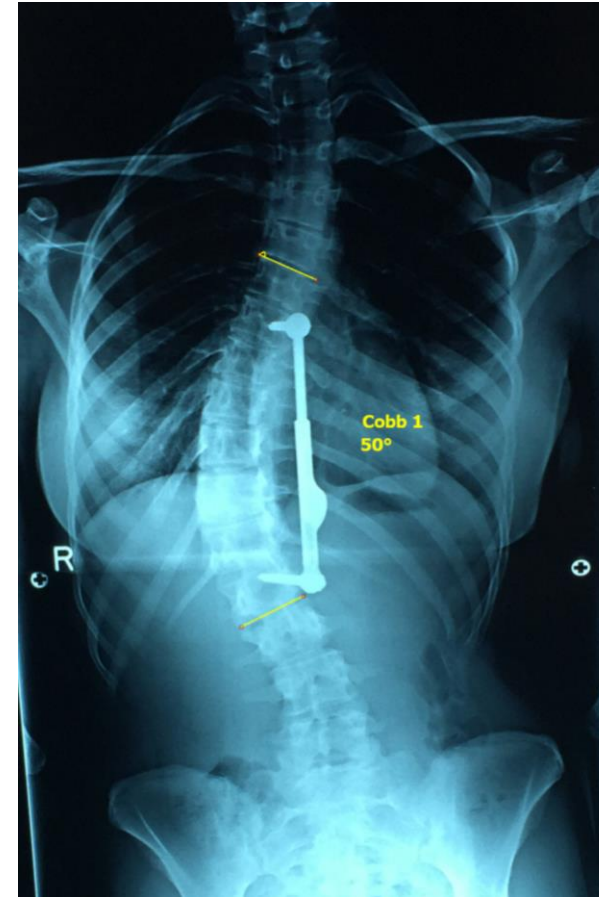
pre-op

59°



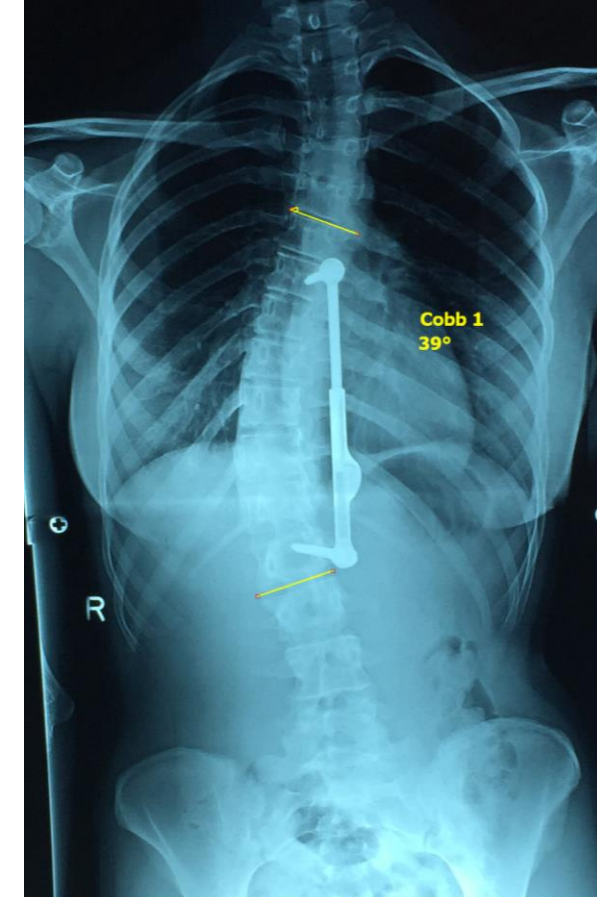
3m post-op

35°



6 m post-op (before revision)

50°

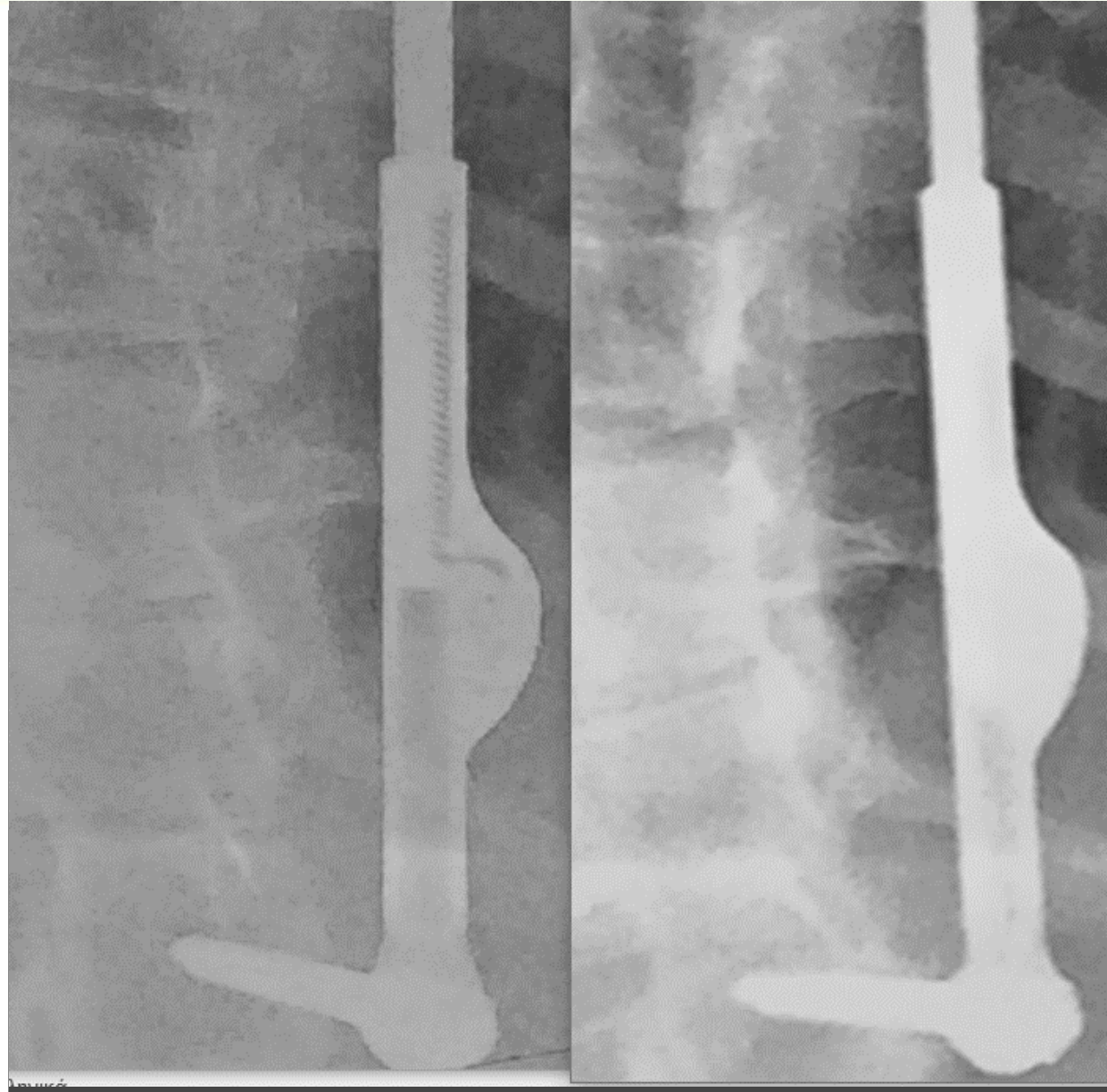


after revision surgery

39°



## Case study 4



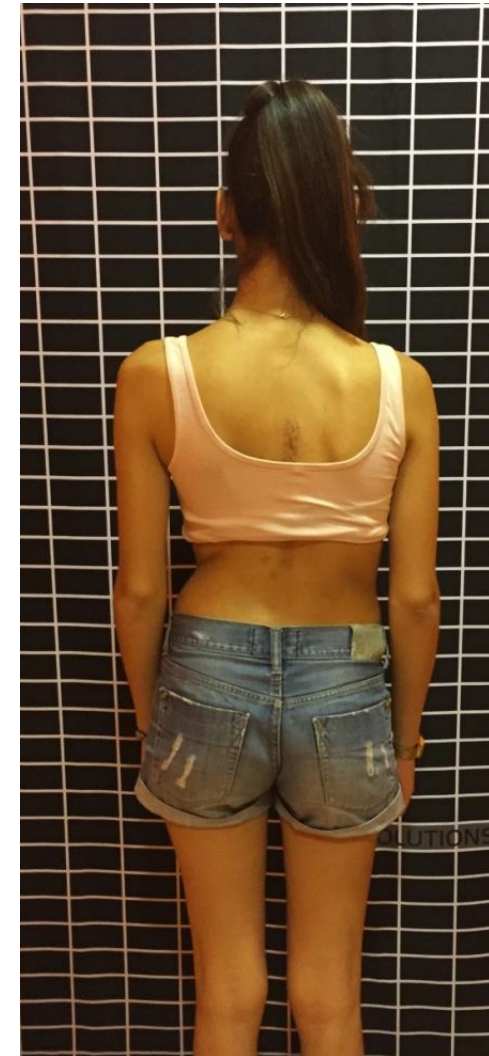
# Case study 4



pre-op

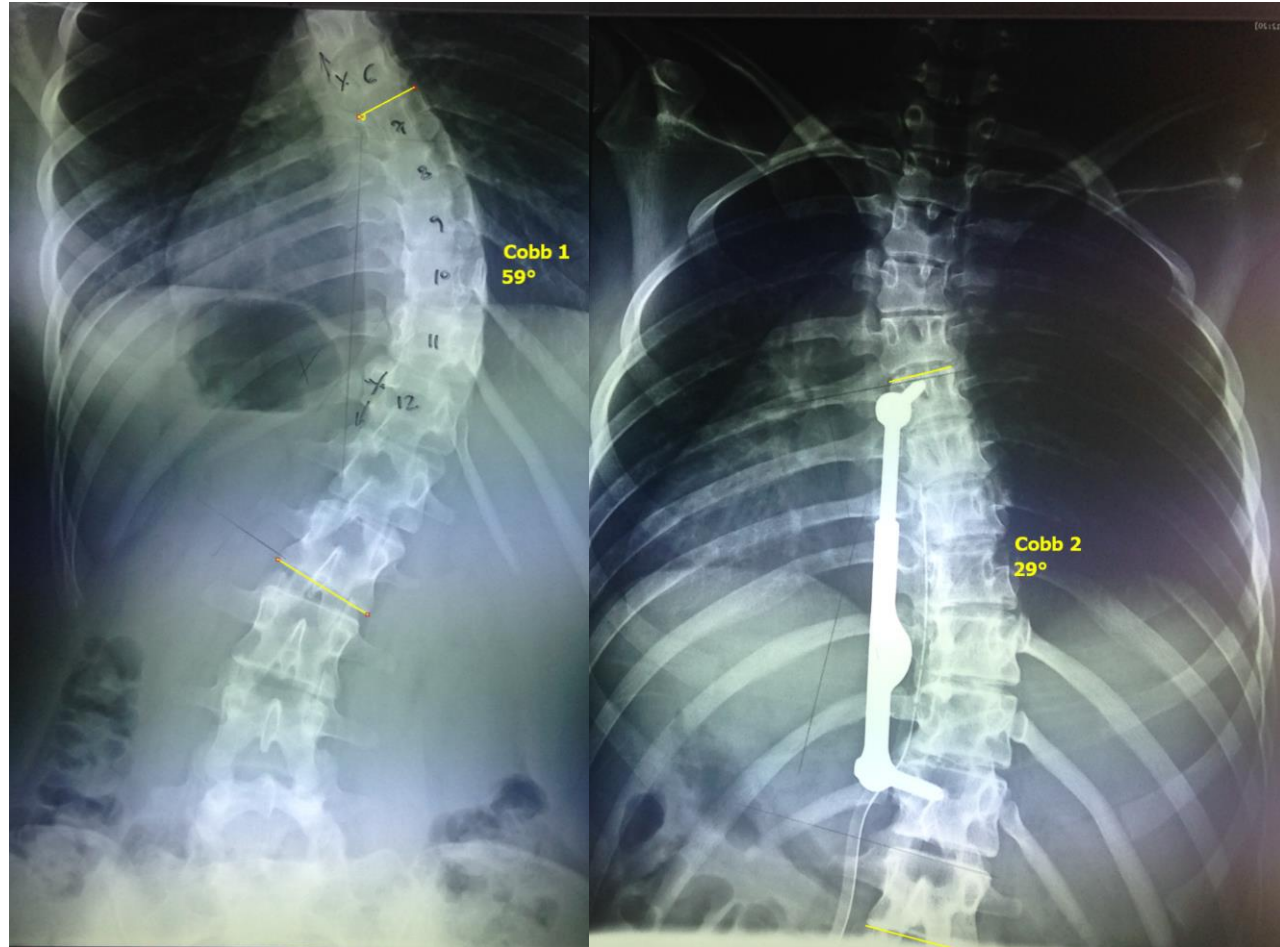


3m post-op



after revision surgery





**Pre-op**  
59°

**post-op**  
29°



**Pre-op**



**3 months post-op**



**Pre-op**



**3 months post-op**



**Pre-op**



**3 months post-op**

- 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

ApiFix



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