Update on remotely controlled Growing Spinal Devices

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Disclosures

Author	Disclosure
Behrooz A. Akbarnia, MD	DePuy Spine (a,b); Ellipse (a,b,); K2M (a,b); K Spine (b); Nuvasive (a,b,c)

a. Grants/Research Support
b. Consultant
c. Stock/Shareholder
d. Speakers' Bureau
e. Other Financial Support

Background

- There is a significant increase in complication rate with repeated surgery in distraction based, growth friendly techniques.
- The idea of remote rod lengthening has been around but has further developed recently with the hope of minizing the overall burden of repeated surgeries.

Biomechanical concept

- The concept is basically about translating a magnetic field energy between two permanent powerful magnets, one internal (receiver) and one external (controller) to a mechanical power that drives the rod forward to gain length

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Two devices are available:

- Phenix
- MAGEC

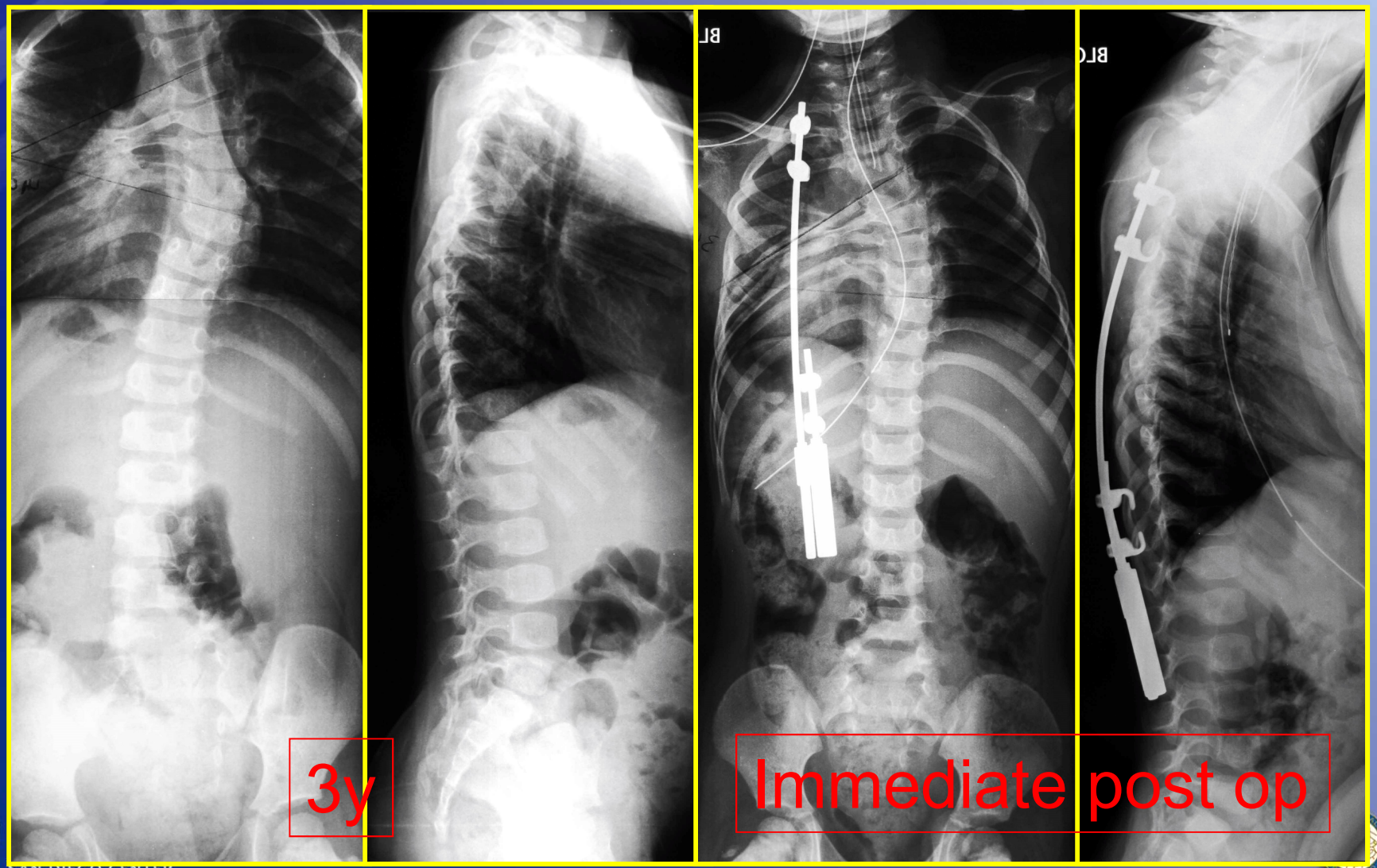
Phenix rod- Case 1

- A 2y10m boy with right thoracic scoliosis with multiple costovertebral malformations
- He underwent rib synostosis excision and Phenix rod application

Courtesy of Dr. Lotfi Miladi

The Phenix Rod- Case 1

Courtesy Dr. Miladi



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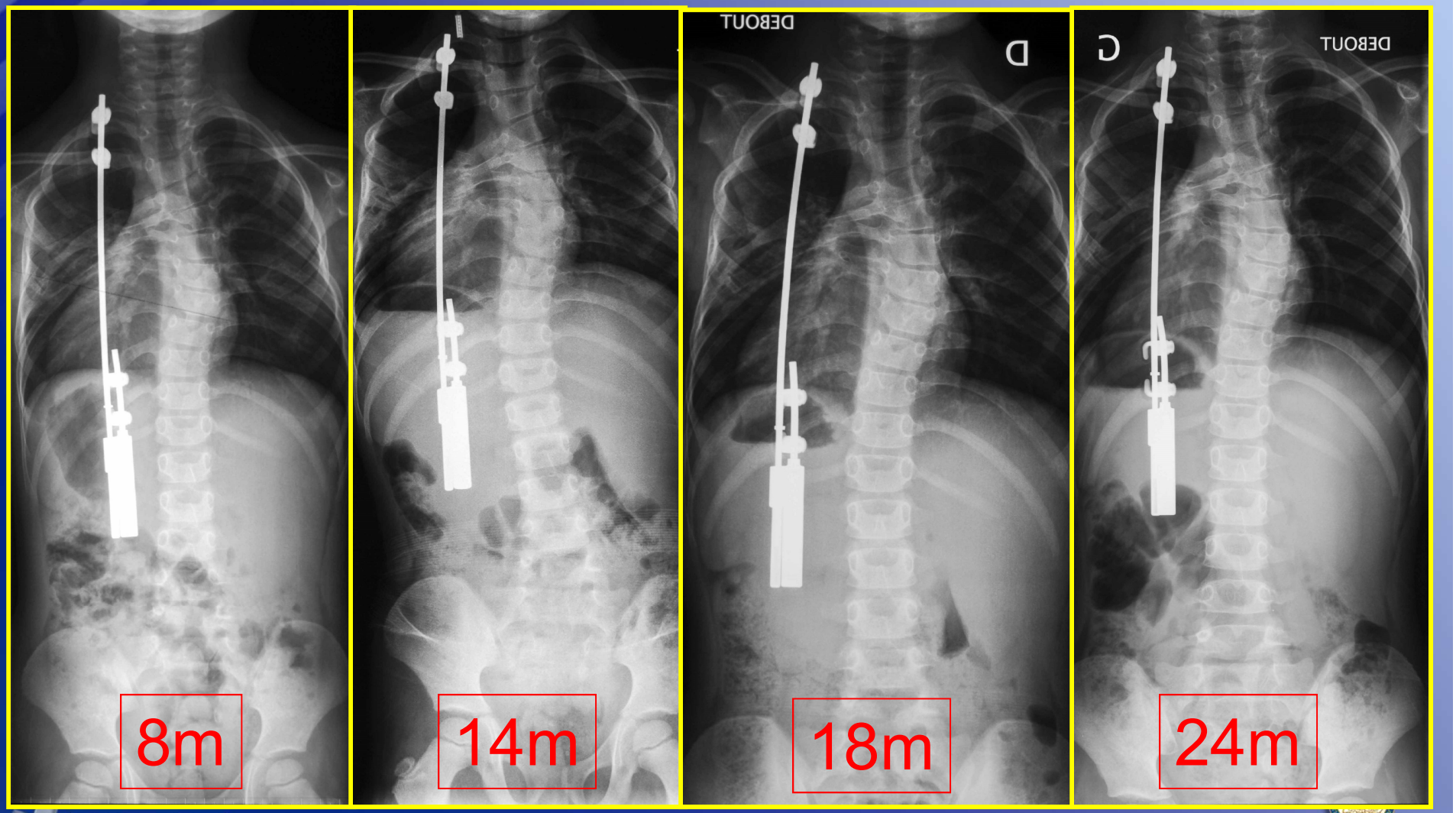
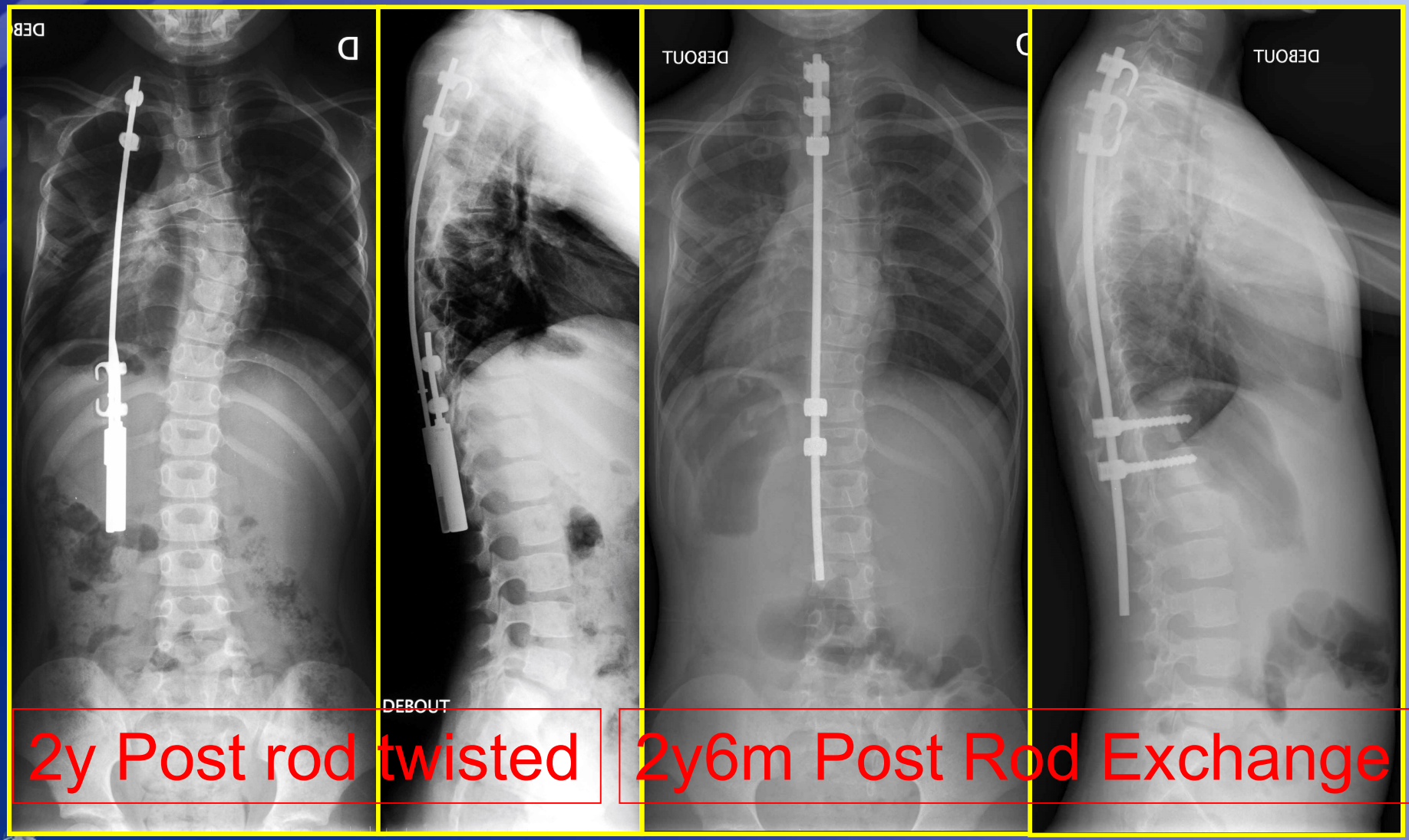
The Phenix Rod- Case 1



The Phenix Rod- Case 1



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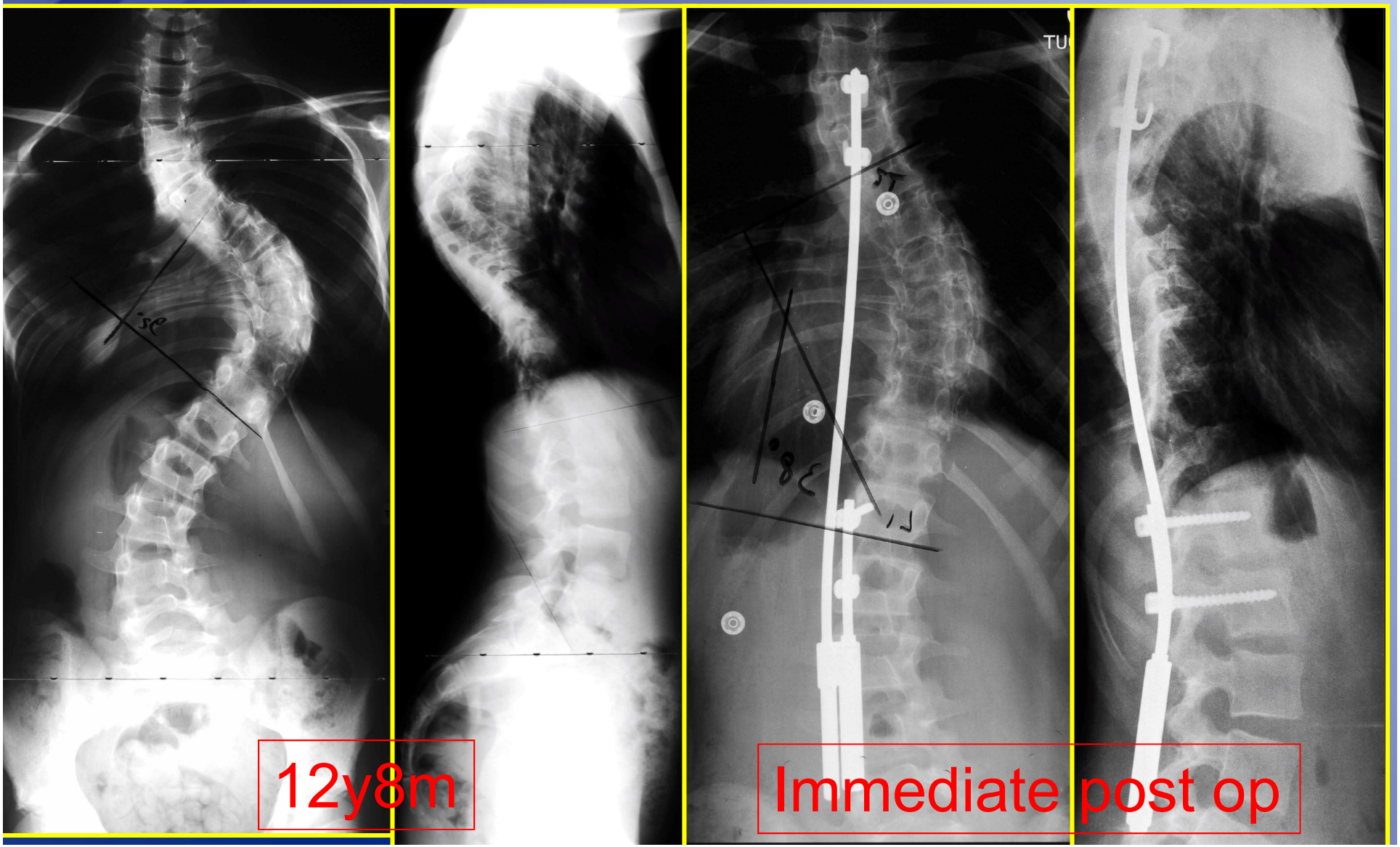
Courtesy of Lotfi Miladi, MD, France

Phenix rod- Case 2

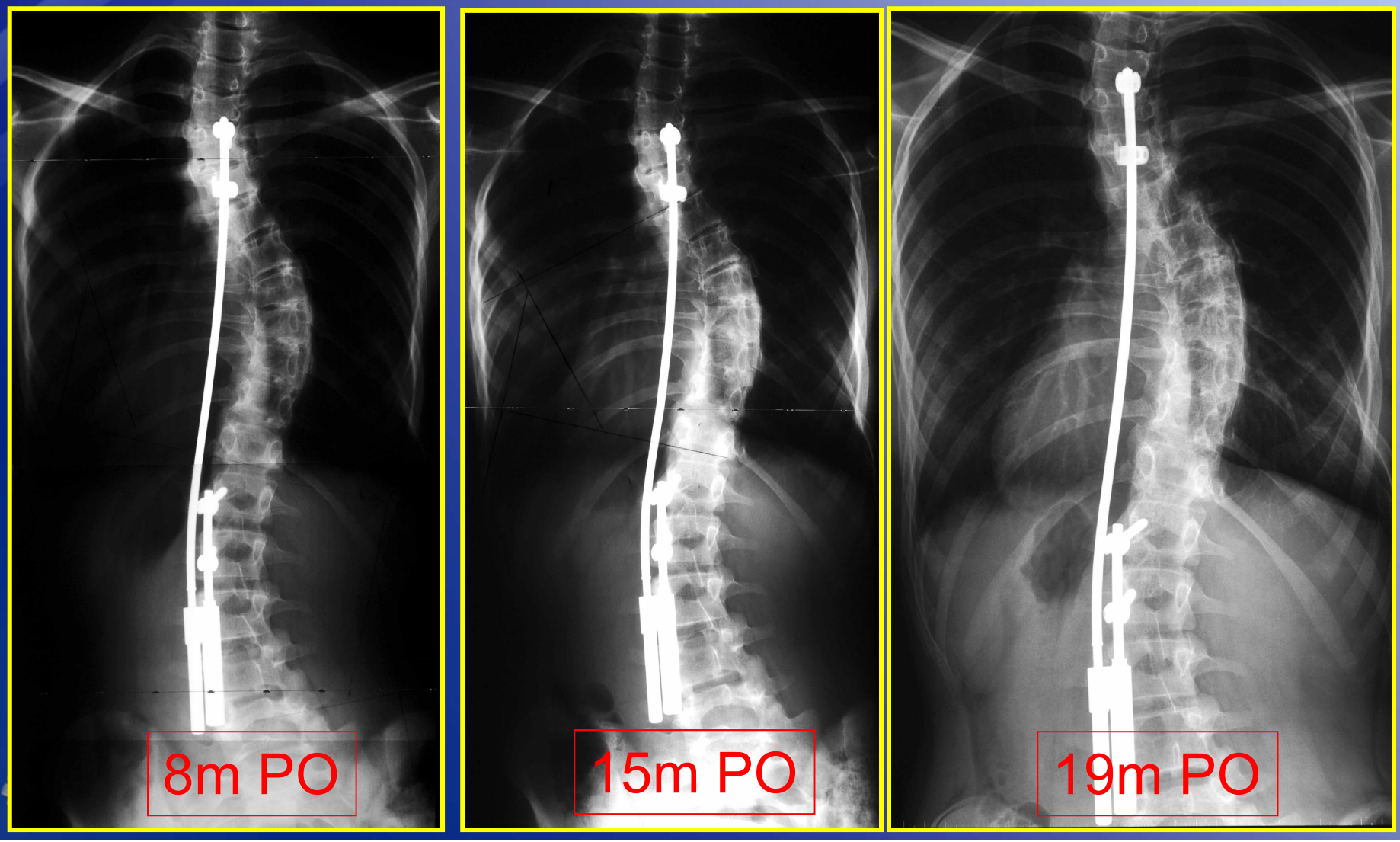
- A 12 yrs girl, neglected advanced juvenile idiopathic scoliosis with Scoliosis of 95°.
- She underwent anterior convex hemiepiphysiodesis and Phenix rod application

Lotfi Miladi, M.D.

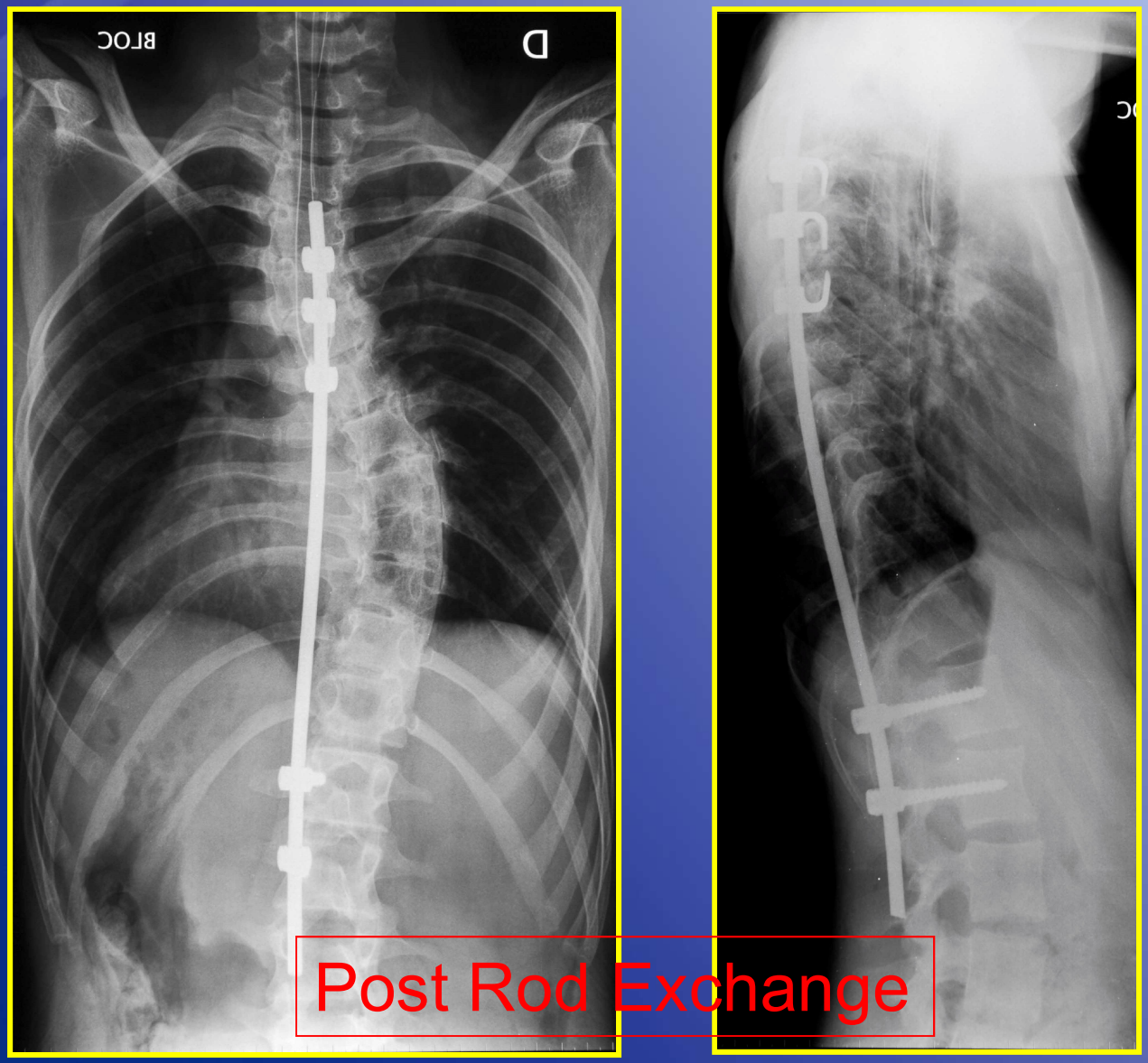
The Phenix Rod- Case 2



The Phenix Rod- Case 2



The Phenix Rod- Case 2



Post Rod Exchange

Courtesy of Lotfi Miladi, MD, France

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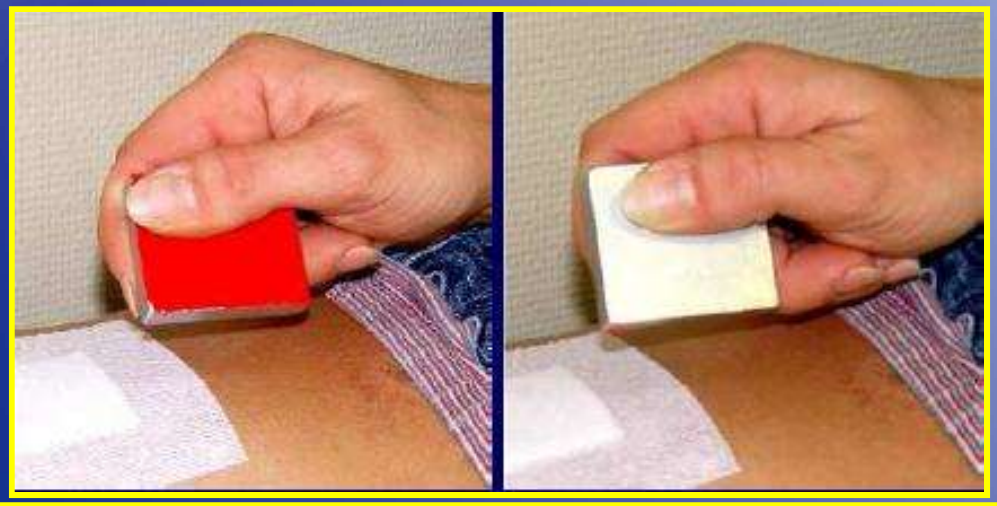
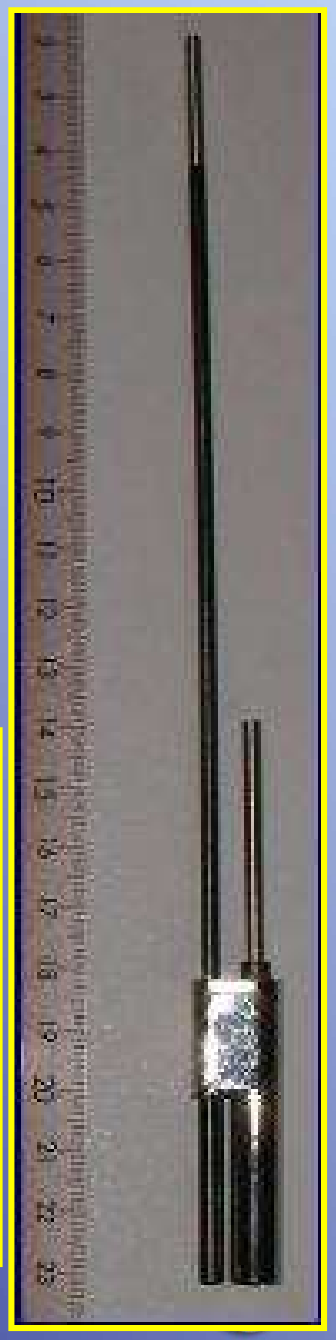
Phenix Rod Lengthening





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Phenix rod experience

- From Feb 2006 to June 2008, 26 patients (16 F, 10 M) were reviewed. The age at the time of surgery was from 22m to 13y 9m.
- There were 11 idiopathic, 7 congenital and 8 syndromic patients.
- Mean preop Cobb was 63° (25° -130°) and corrected to 33° (4° -92°) postoperatively.
- Before surgery, 3 patients underwent Stagnara casting, one halo pelvic Illizarov traction.

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Phenix rod experience

Complications were:

- Hook Dislodgement 11
- Loss of evoked potential 2
- Deep infection 2
- Rod Fx 2
- Secondary loss of scoliosis correction 10
- Rod stopped to grow 4

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MAGEC Technology (Magnetic expansion control)

Innovation in Growing Rod Technique: A Study of Safety and Efficacy of Remotely Expandable Device in Animal Model

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Gregory M. Mundis, Jr., MD
Pooria Salari, MD
Jeff B. Pawelek, BS
Burt Yaszay, MD

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45th Annual Meeting of the Scoliosis Research Society
September 21-24, 2010 – Kyoto, Japan

METHODS

- MAGnetic Expansion Control (MAGEC™) is a newly developed spinal distraction system
- Using MAGEC, non-invasive lengthening/shortening of an implanted rod can be performed
- MAGEC comprises two major elements:
  - Implantable distraction rod
  - External adjustment device

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METHODS

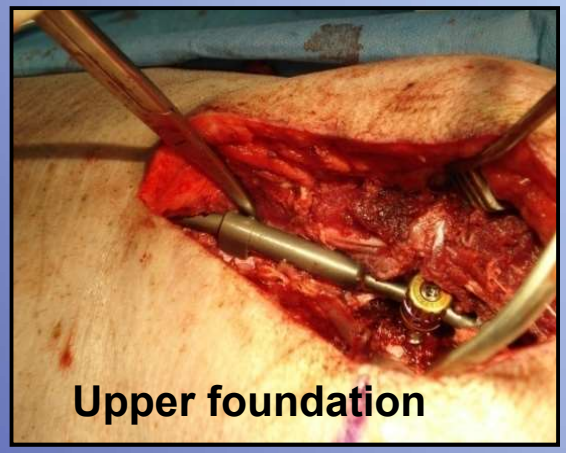
- The non-shapeable actuator is 9.0 mm diameter
- The shapeable rod comes in 4.5, 5.5 or 6.35 mm diameters
- A fully rigid construct may be chosen (a) or a freely-swiveling joint to lower stress on the construct and bones (b)
- Construct requires standard hooks and pedicle screws to be implanted

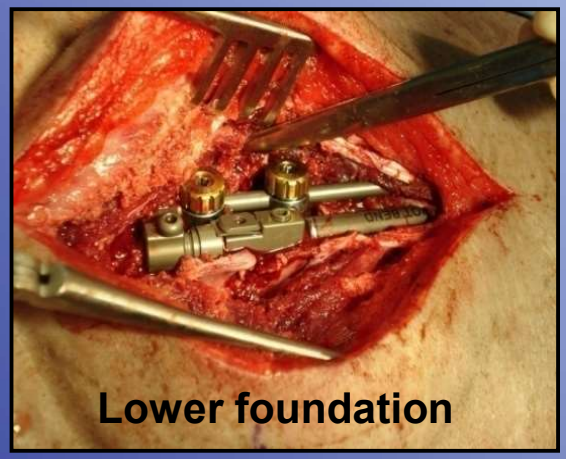
(a)

(b)

METHODS

- Nine (9) immature male Yucatan mini-pigs
  - Six (6) pigs in Experimental group (EG)
  - Three (3) pigs in Sham group (SG)
- Both groups had 3-level cephalad and 2-level caudal foundations
- EG instrumented with a unilateral rod





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METHODS

- 7-9 levels were un-instrumented between cephalad and caudal foundations
- 7 mm of remote distraction was performed weekly for 7 weeks in EG under sedation
- Implants were removed at week #7
- Animals were sacrificed 3 weeks after implant removal

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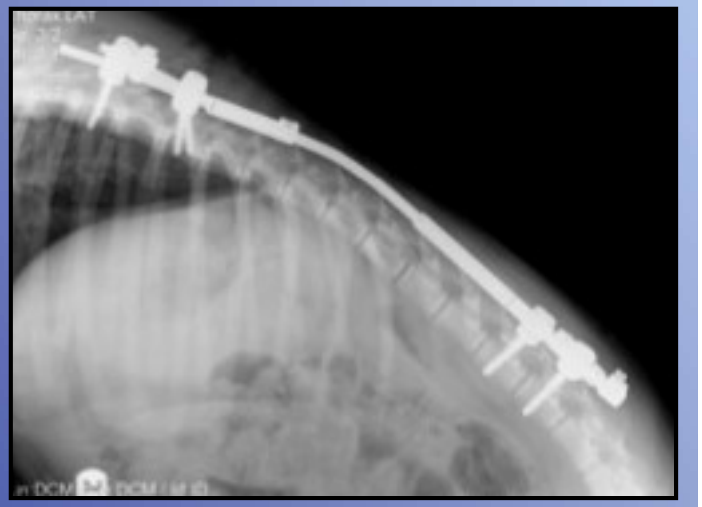
METHODS

- AP and Lateral Radiographs
  - Performed weekly for 10 weeks using fluoro
- CT Scans and Plain X-ray
  - Performed after initial surgery, before implant removal and prior to sacrifice
- Spinal growth recorded weekly on x-ray throughout the study
  - Vertebral body height including disc was measured
- Spines harvested for further study after sacrifice



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RESULTS

- Mean pre-operative age
  - EG = 7.1 months
  - SG = 7.3 months
- No difference in weight between EG and SG at initial surgery or throughout study
- 1 EG pig died after initial surgery due to neurologic complication caused by screw malposition
- Mean distraction achieved in EG was 39 mm (32-46 mm)
  - Planned distraction was 48 mm
  - We feel ↑ thickness of fatty tissue may effect distraction forces resulting in the difference between projected and actual distraction

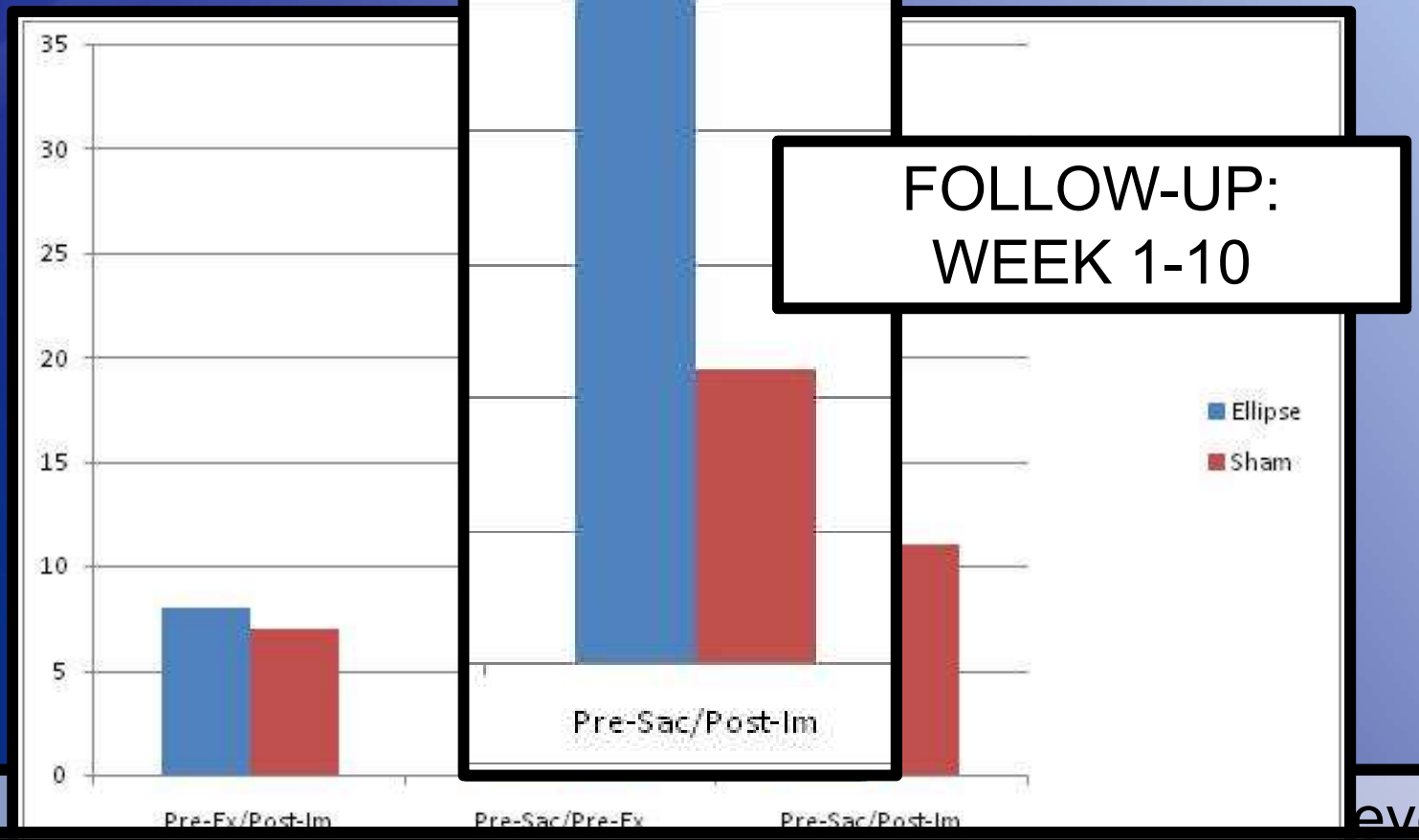
RESULTS

- No complications resulted from distraction
- No implant failure
- Histopathology
  - Internal organs – no significant changes in EG
  - Para-aortic lymph nodes – no significant changes in EG
- Magnetic field from the magnets (implant and external device) fell within international non-ionic radiation guidelines for patient and user exposure

RESULTS

- 1 pig had a sterile fluid collection at the lower foundation. Treated with drainage and prophylactic antibiotics. A retained sponge was found after sacrifice

RESULTS



FOLLOW-UP:
WEEK 1-10

- After implant removal, spine growth increased significantly in both EG and SG
- At sacrifice total growth(12-14 levels) was greater in EG vs. SG

CONCLUSIONS

- MAGEC was shown to be safe and effective in this study
- No complication resulted directly from distraction
- MAGEC distinguishes itself by:
  - Distraction accuracy / prediction
  - Ability to shorten

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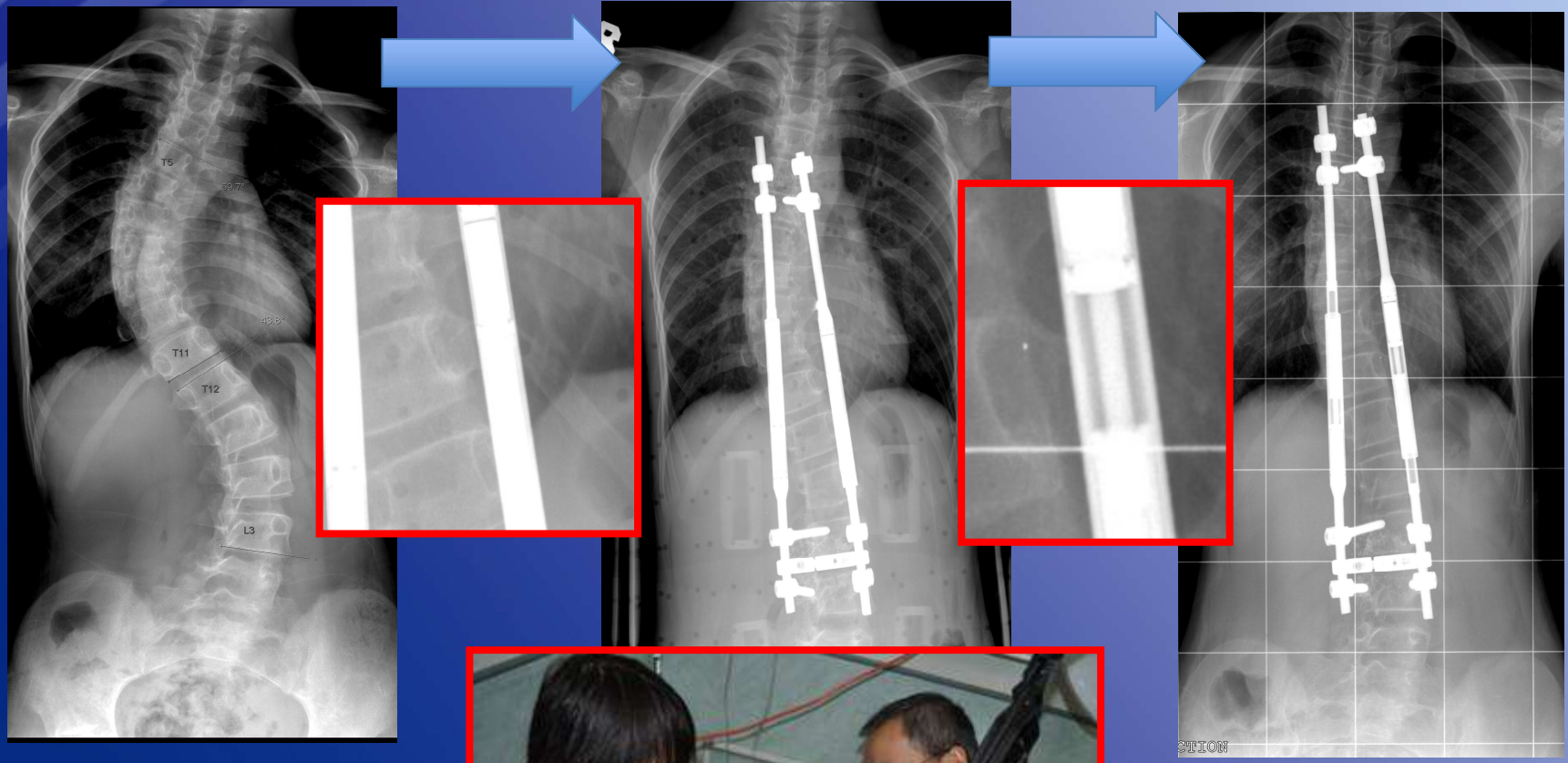
- **MAGEC shows promise as the next generation of distraction-based treatment for early onset scoliosis**



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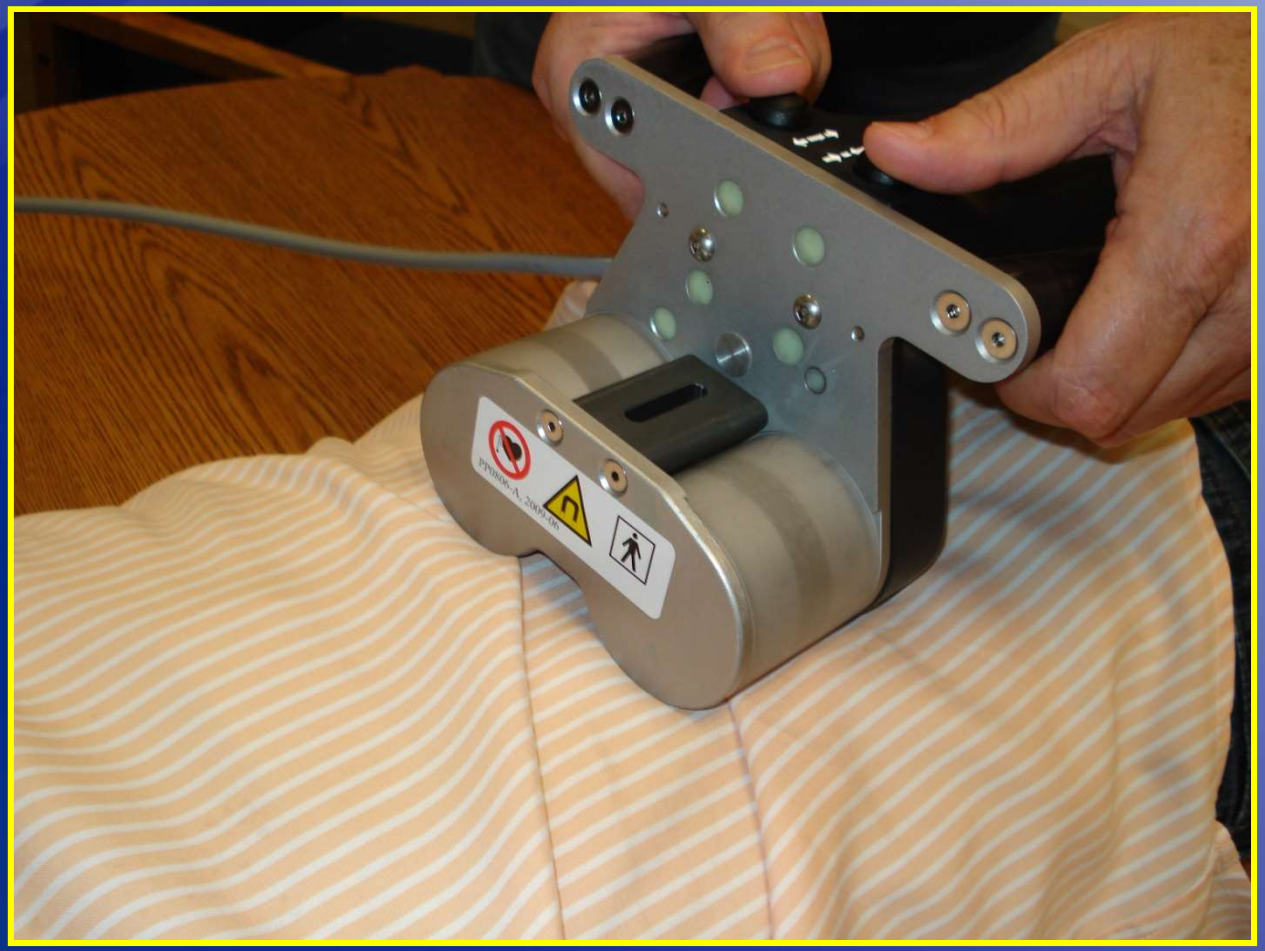
The MAGEC Technology



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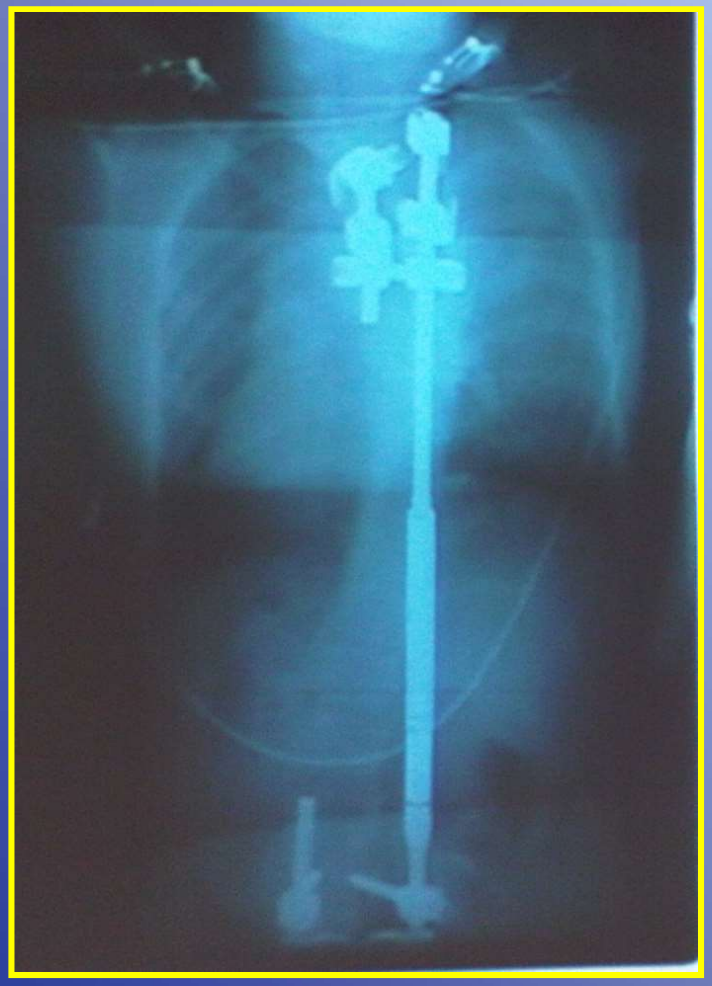
MAGEC- Case 1

Pre Op AP



Pre Op AP

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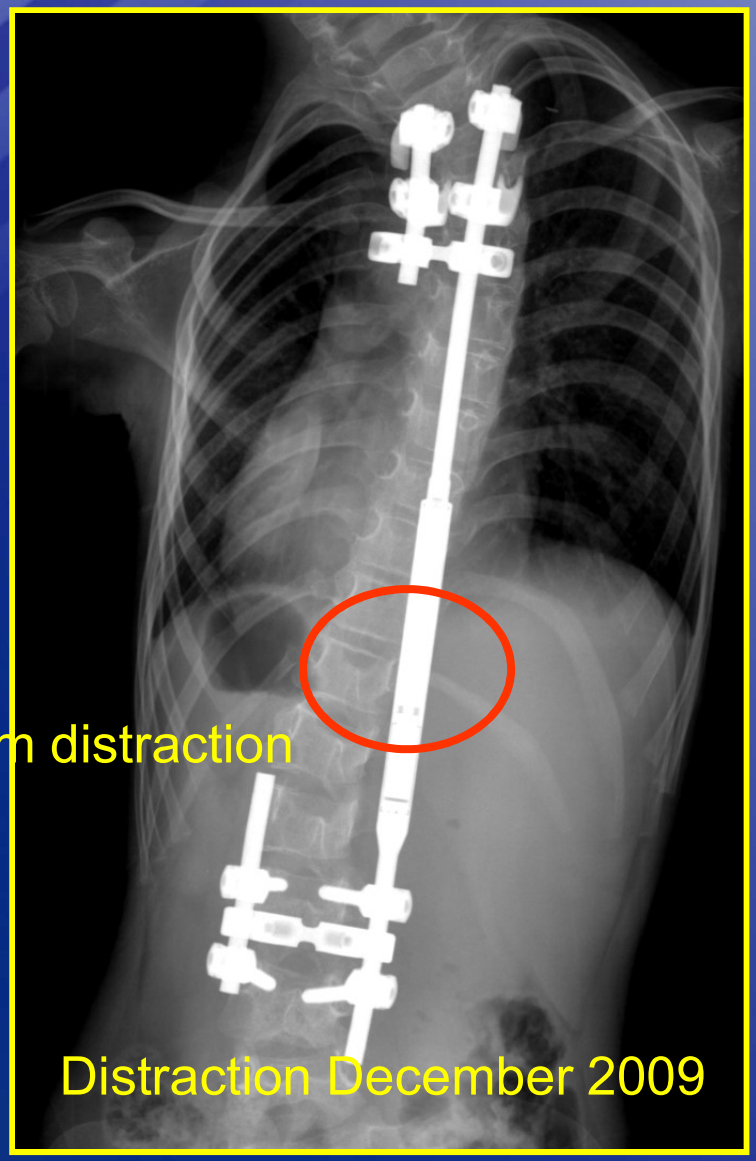
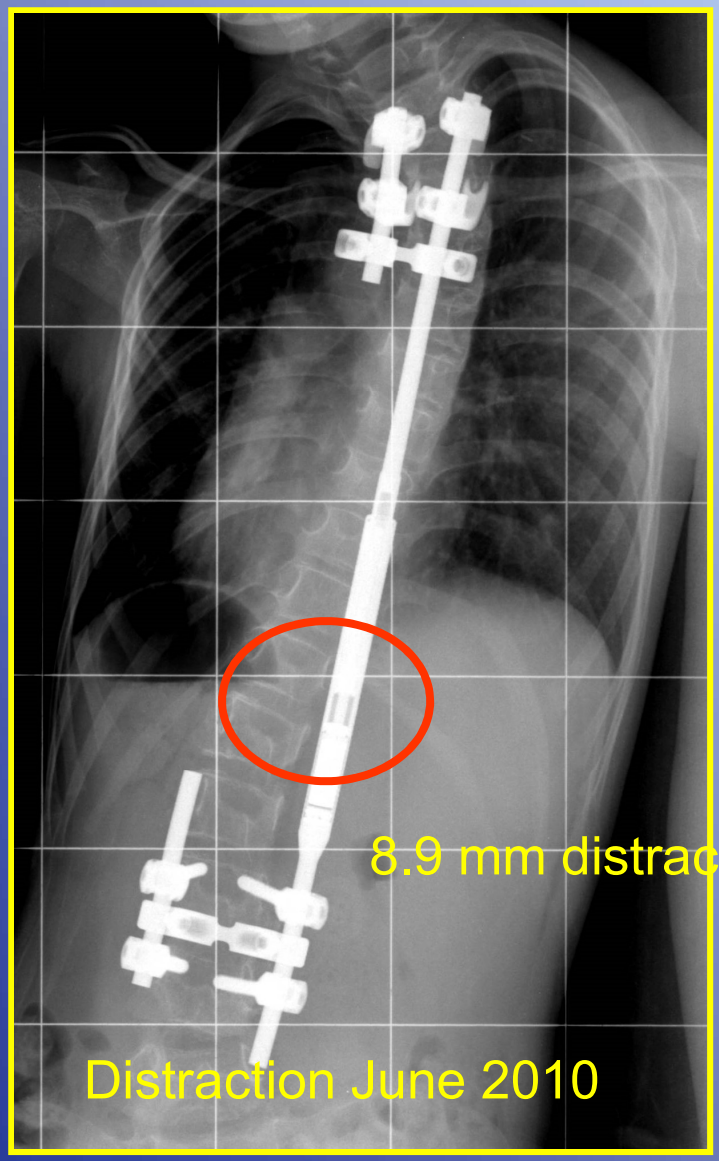
MAGEC- Case 1





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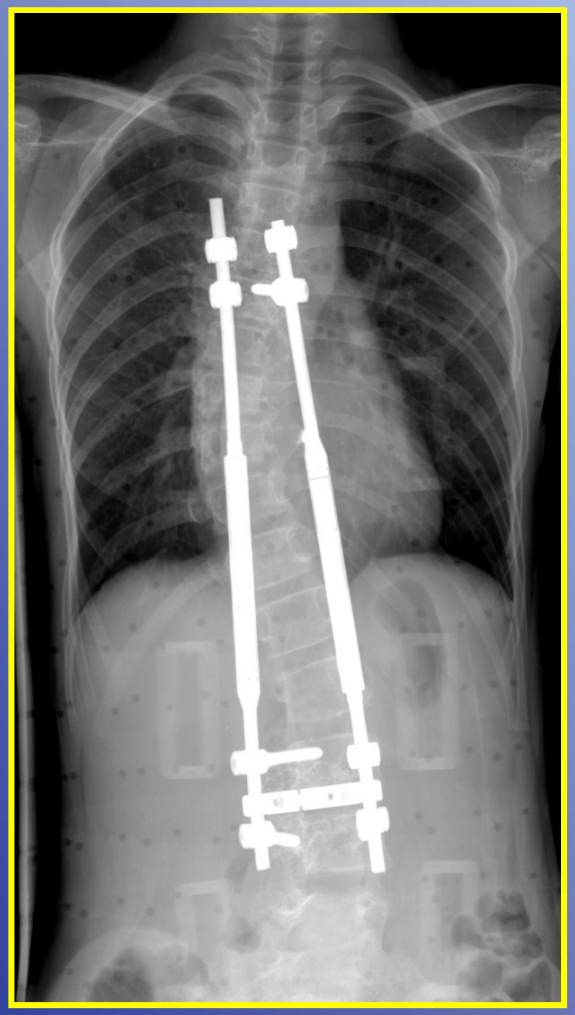
Courtesy of Ken Cheung, MD, University of Hong Kong, HK

MAGEC- Case 2

Pre Op AP



Post Op AP

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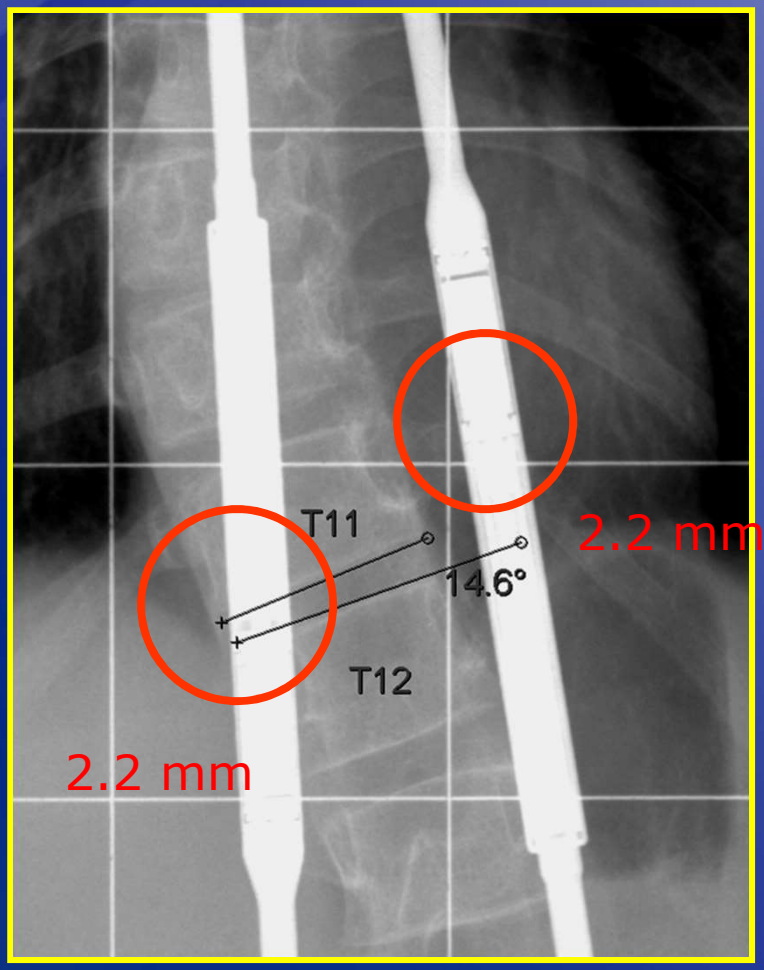
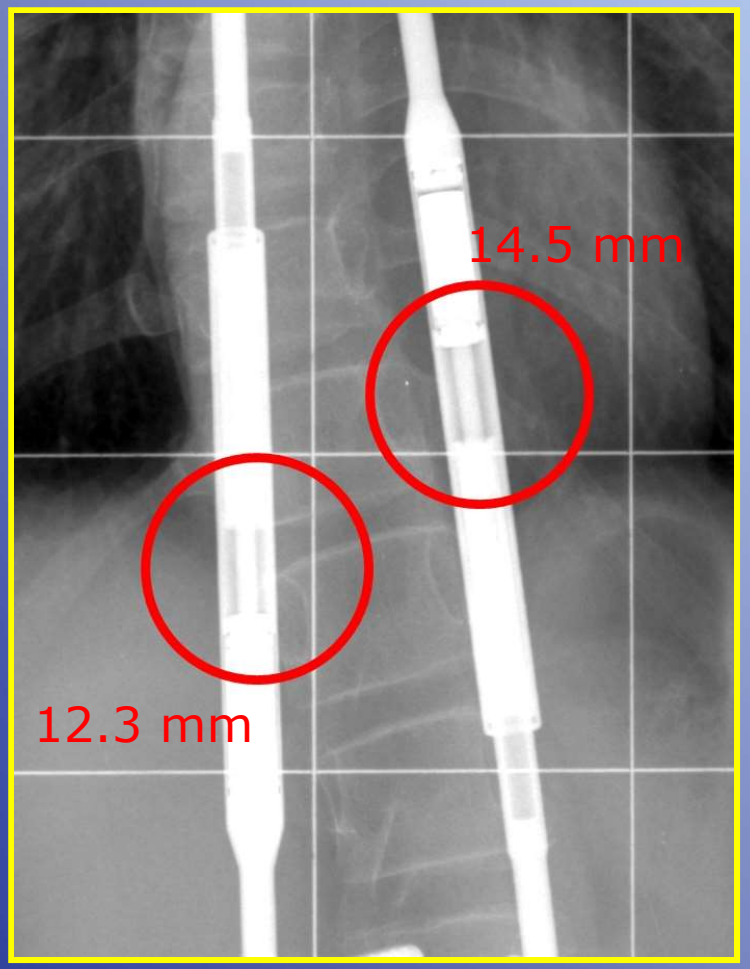
MAGEC- Case 2



Distraction January 2010



Distraction June 2010

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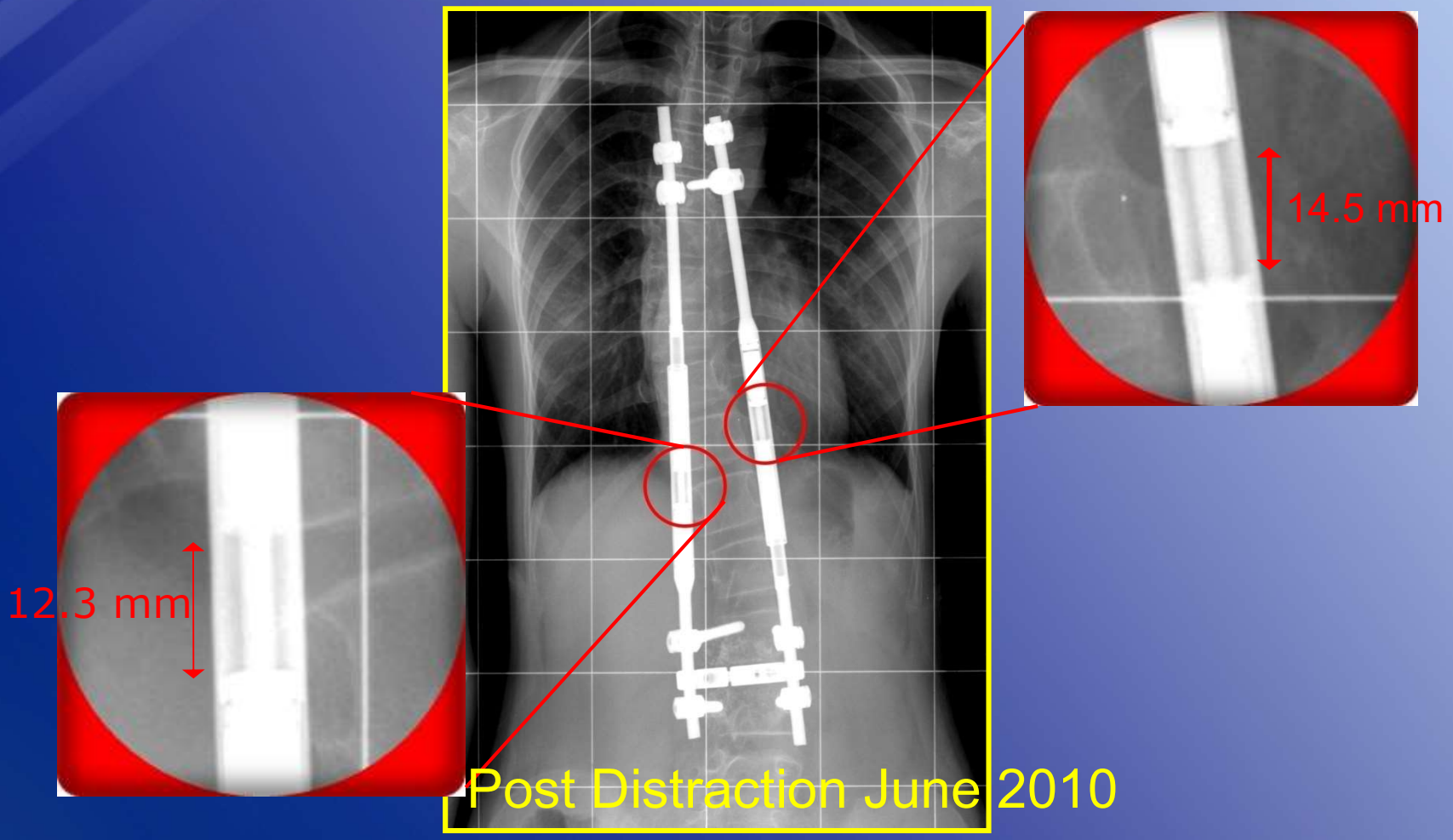
MAGEC- Case 2



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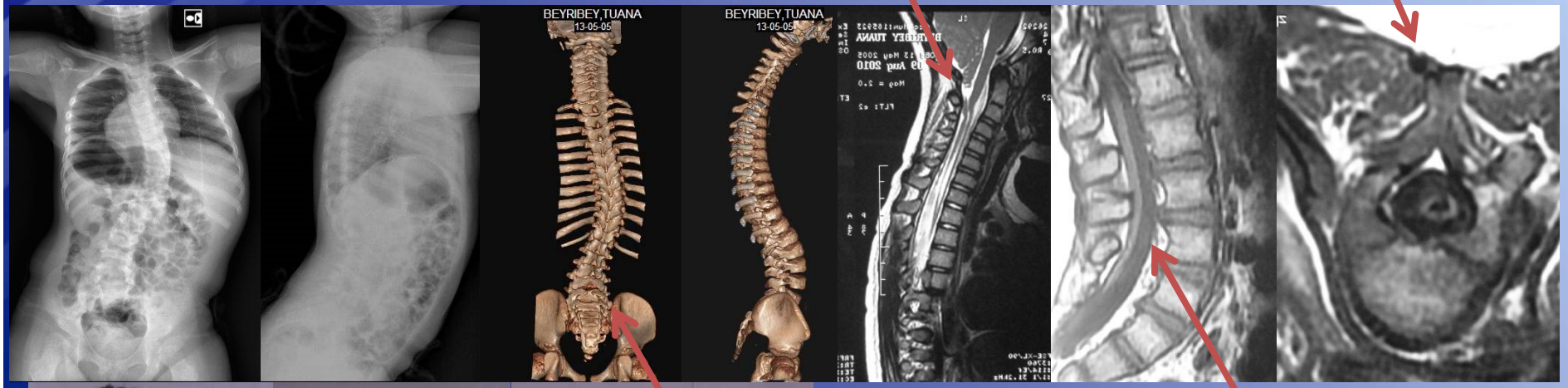
Courtesy of Ken Cheung, MD, University of Hong Kong, HK

Case #1, spinal dysraphism



- Arnold-Chiari
- Posterior elements deficiency
- Low conus and tight filum
- Syrinx

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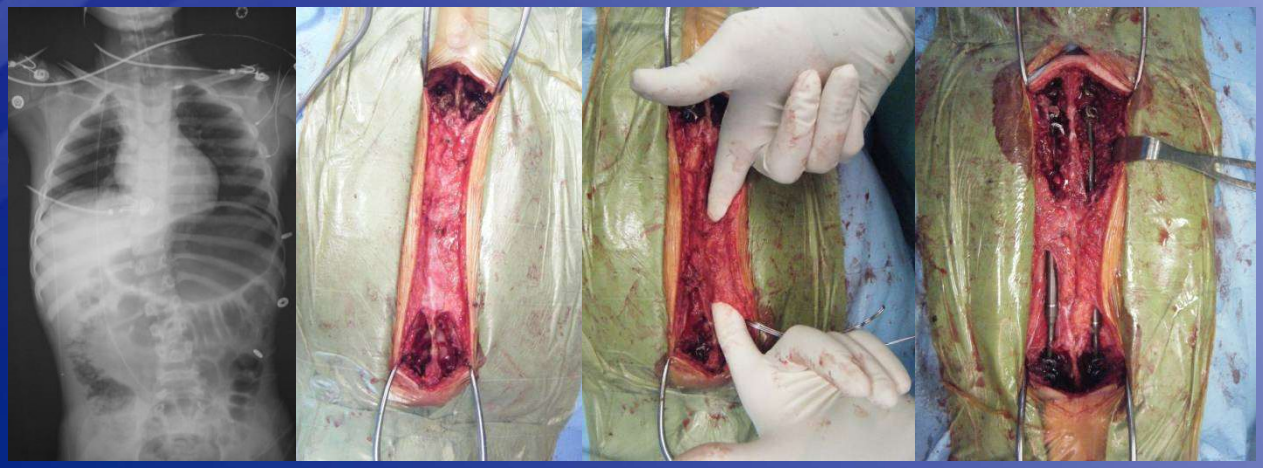
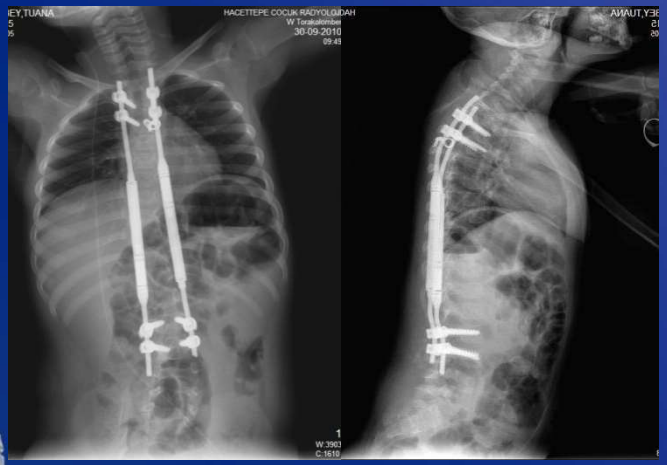
Courtesy Dr. Yazici

Case #1, spinal dysraphism





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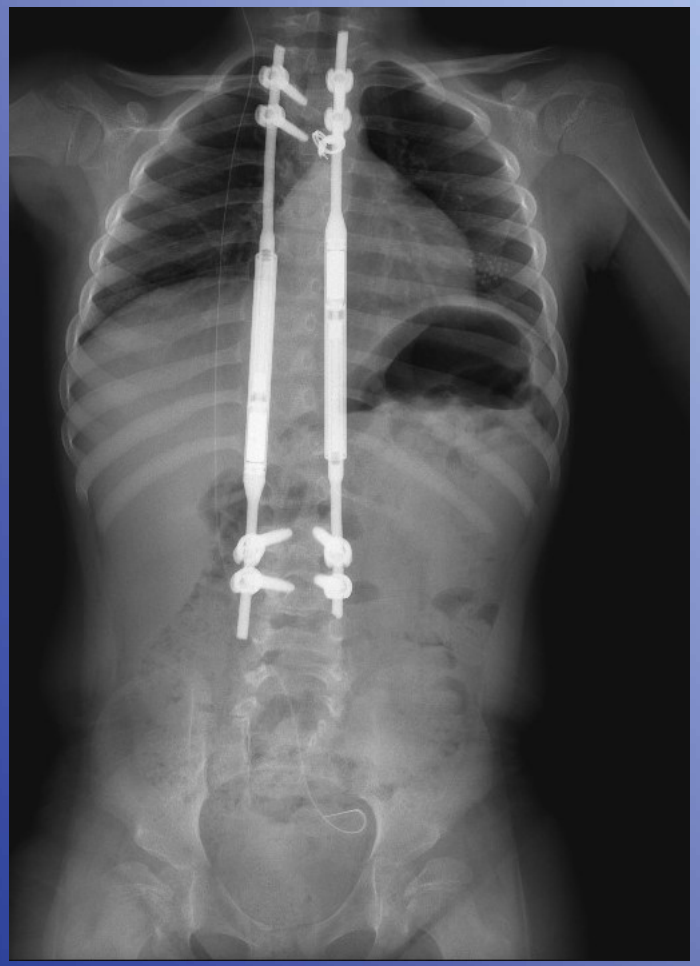

Post-op

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Summary

- Frequency of surgeries is an important factor for a high rate of complication in distraction based growing rod techniques
- Growth guided surgical techniques such as Shilla reduce the number of surgeries but do not take the advantage of distraction
- Remote control devices may decrease the number of surgeries and still keep the benefit of distraction and growth stimulation
- The devices are not approved for sale in the United States
- Clinical trials are pending

Thank You

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