Update on magnetically Controlled Growing Rod (MCGR)- MAGEC

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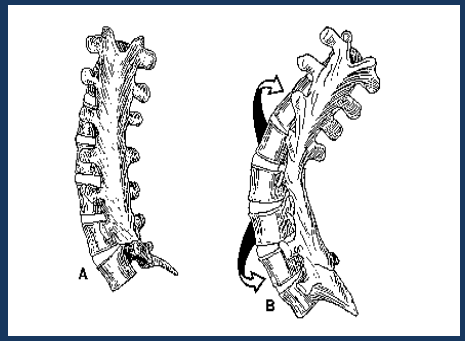
Disclosures

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

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

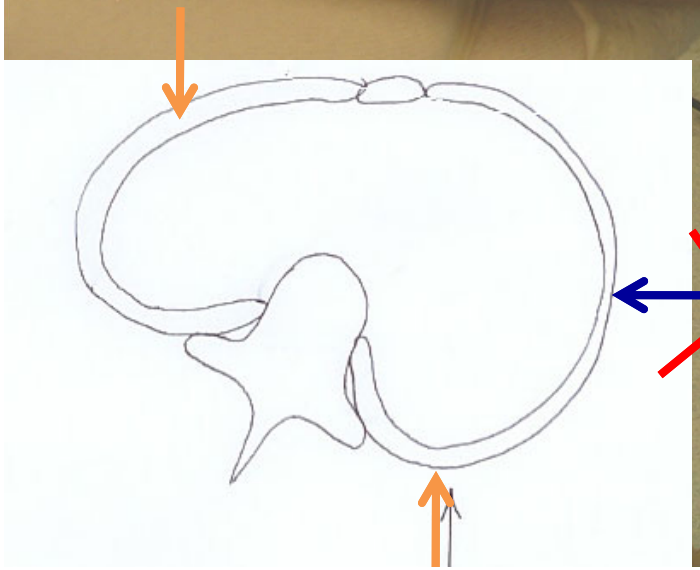
Progressive EOS
Treatment Options

- Non-operative (orthosis, casting and Traction)
  - *Mostly buying time for progressive curves*
- Fusion Surgery
  - *- PSF or PSF/ASF*
  - *- Resection*



- Growth Friendly Surgery:
  - *Distraction Based (GR, VEPTR, Remote)*
  - *Tension Based (staple, tethered)*
  - *Growth guided (Hemiepiphysiodesis, Shilla)*

Rotational correction cast



Growth Friendly Implant Classification

1. Distraction based
   - Growing Rods
   - VEPTR
   - MCGR (Phenix/ MAGEC)

2. Guided Growth
   - Luque-Trolley
   - Shilla

3. Tension Based
   - Tether
   - Staple

< age 8 ?

< age 9 ?
All etiologies

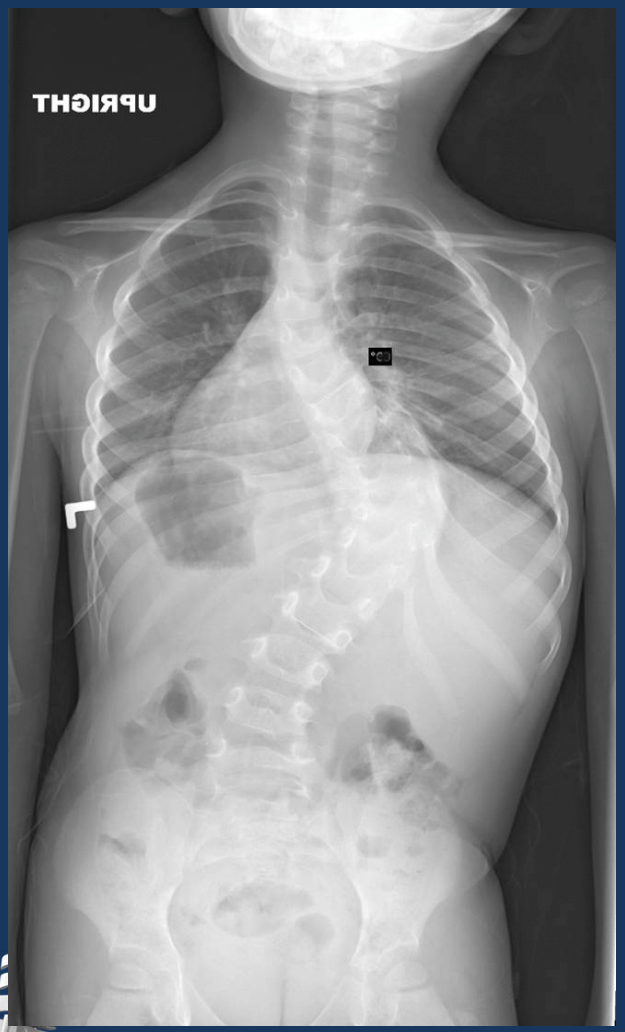
Only VEPTR FDA
Approved for Spine*

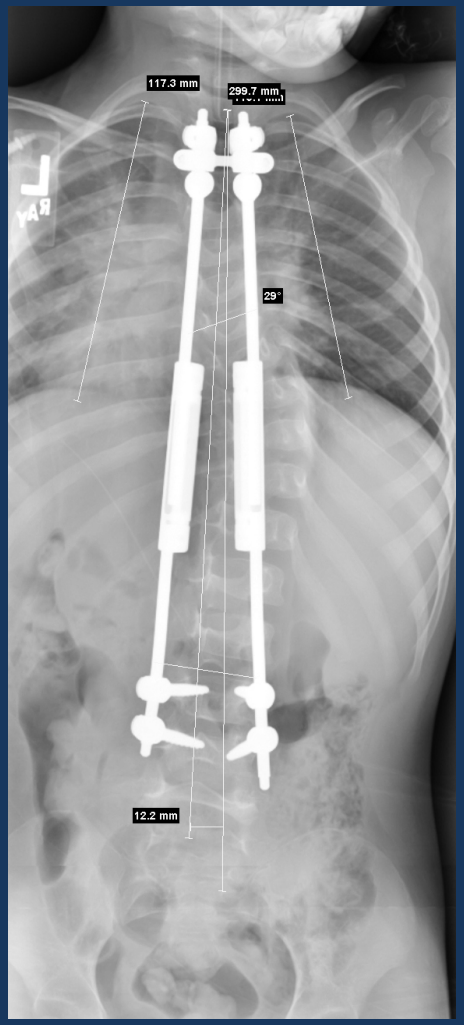
< age 9 ?
All etiologies

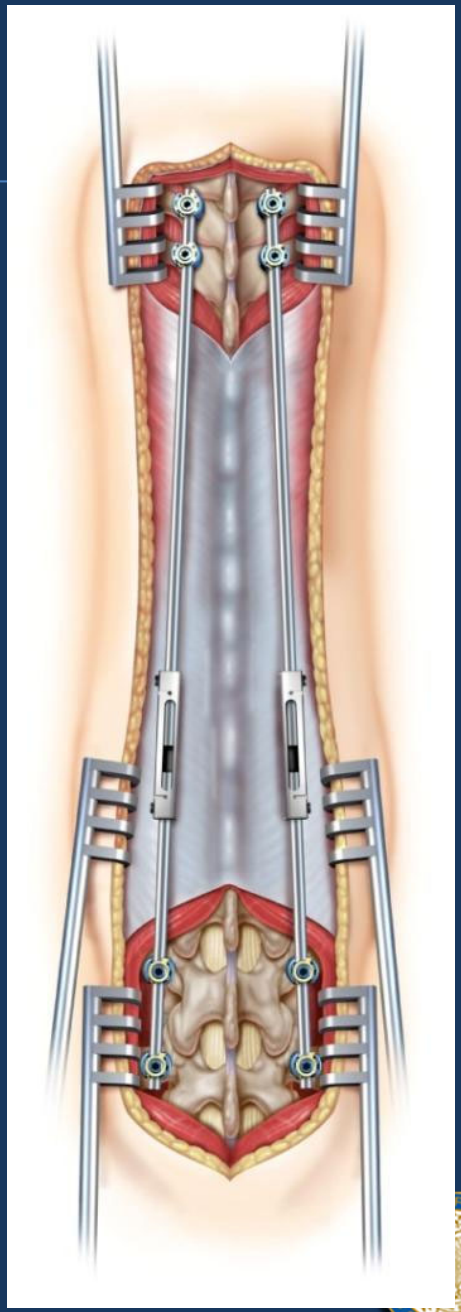
≥age 8
Non-congenital

Skaggs

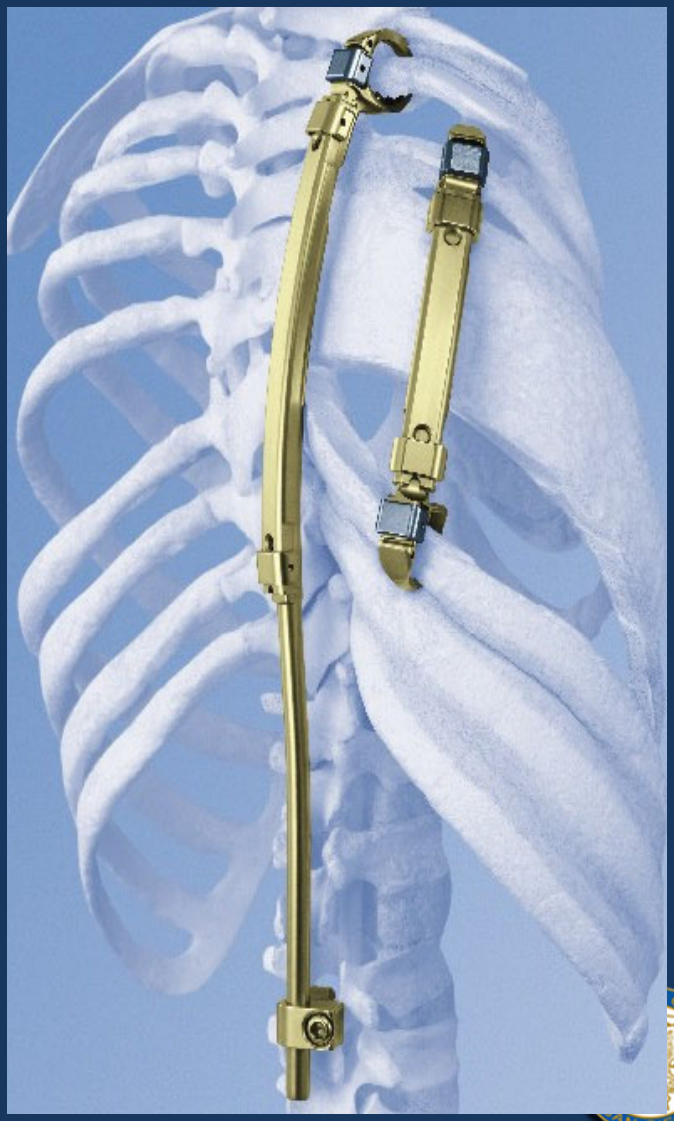
Growing Rods





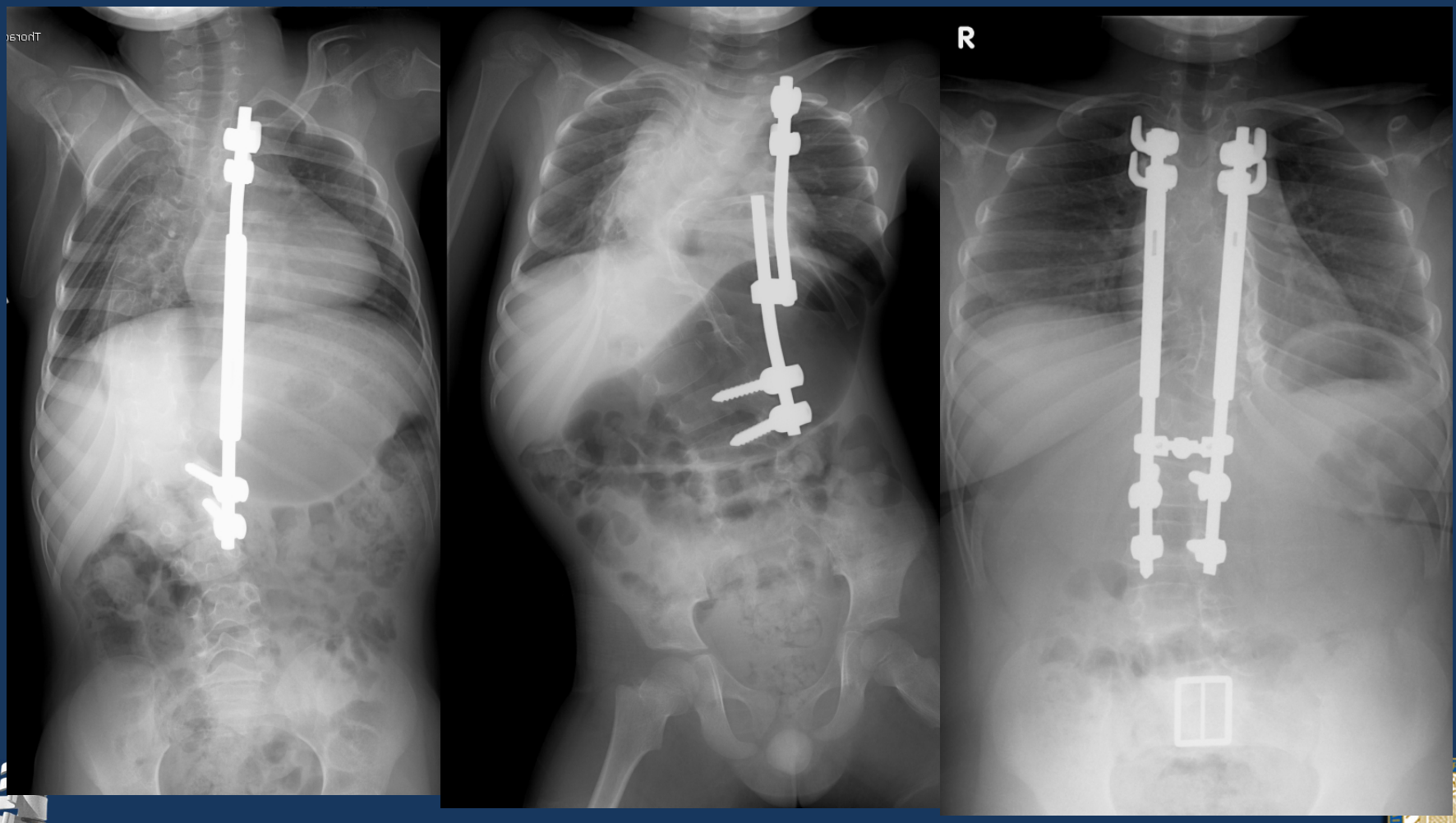


VEPTR (Synthes Spine)

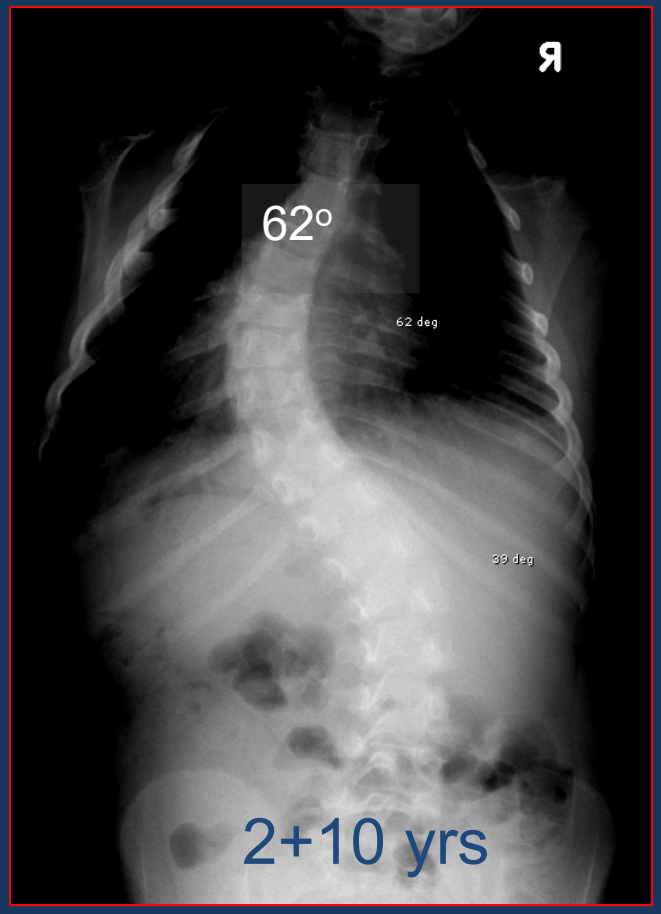


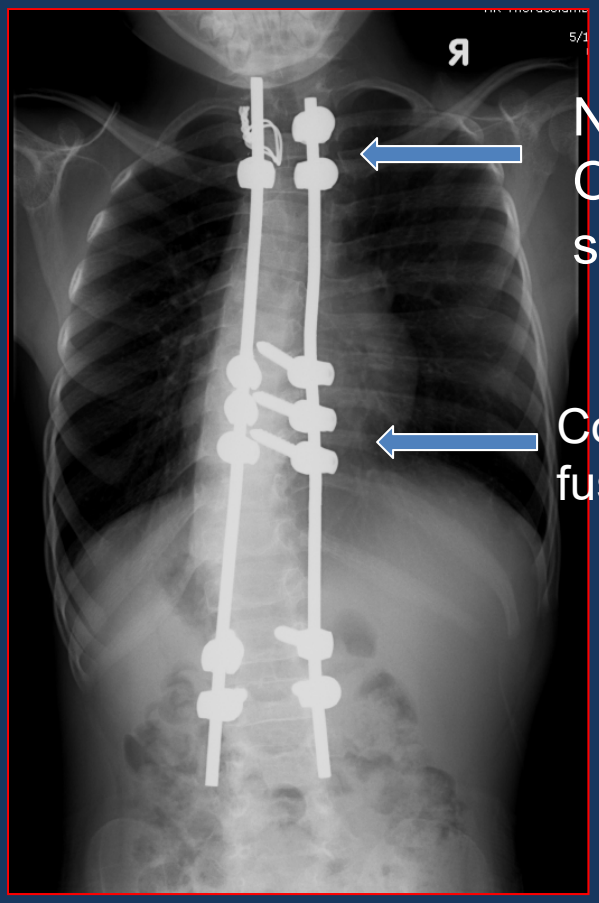
Photos curtsey of Synthes Spine

Hybrid Distraction Based Construct



Guided Growth





No fusion
Open
screws

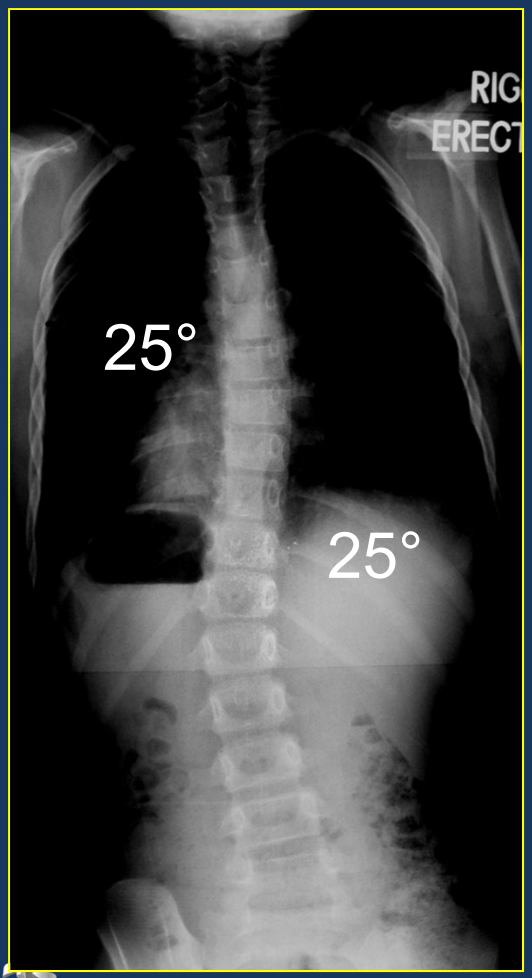
Correction and
fusion

Shilla

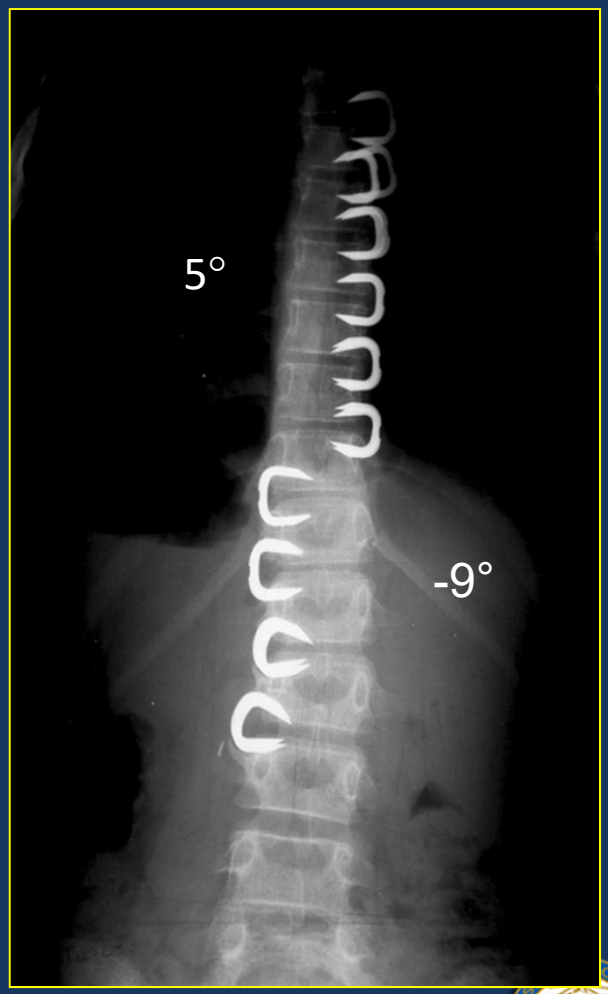
Developed by Rick McCarthy

8 yo female 3 year f/u
Courtesy Dr. Betz

Best for curves <25°
With growth remaining



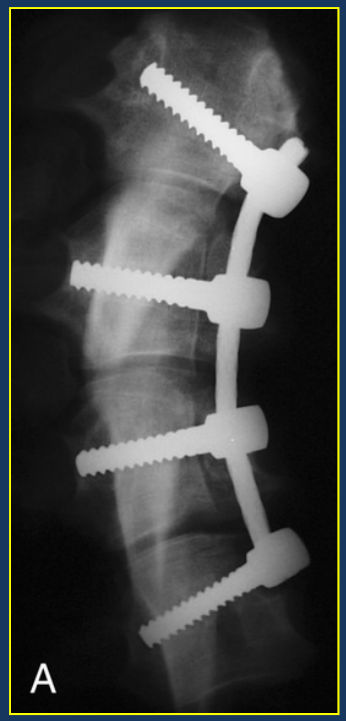
Nov. 2002



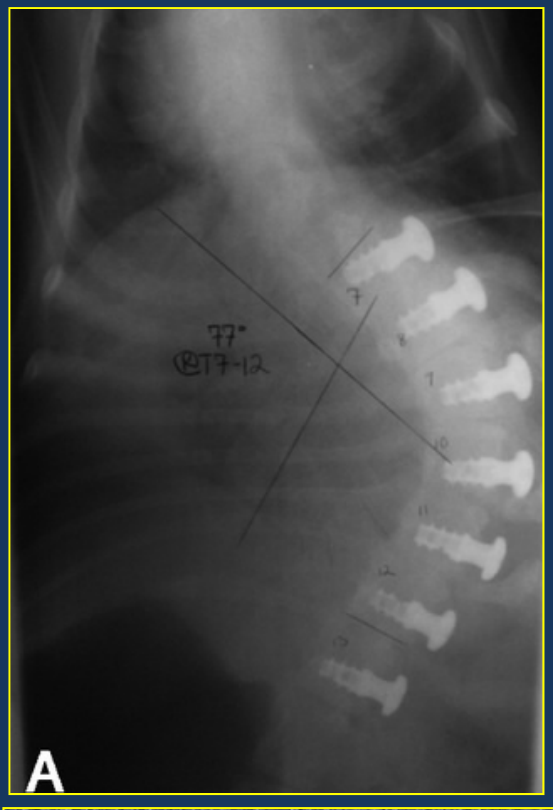
March 2005

Tethers

- Animal models
- Problematic
- Future ?



Newton, Spine, 2005



Braun, JBJS, 2006

Complications of Growing-Rod Treatment for Early-Onset Scoliosis

Analysis of One Hundred and Forty Patients

By Shay Bess, MD, Behrooz A. Akbarnia, MD, George H. Thompson, MD, Paul D. Sponseller, MD, Suken A. Shah, MD, Hazem El Sebaie, FRCS, MD, Oheneba Boachie-Adjei, MD, Lawrence I. Karlin, MD, Sarah Canale, BS, Connie Poe-Kochert, RN, CNP, and David L. Skaggs, MD

Investigation performed at San Diego Center for Spinal Disorders, La Jolla, California

Dec. 2010 JBJS

- 140 patients from GSSG database
- Risk of complications during treatment period decreased by 13% for each year of increased age at index surgery.
- The complication risk increased by 24% for each additional surgical procedure performed.
- Delaying index GR surgery, using submuscular dual rods, and limiting the number of lengthenings can reduces GR surgery complications

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

Two devices are available:

- **Phenix**
- **MAGEC**

MAGEC Technology (Magnetic expansion control)

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MAGEC™ Technology

- 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

MAGEC™ Technology

- 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)

MAGEC™ Technology

Implantable spinal rod with magnetic actuator

External remote controller

non-invasive adjustment

Example of current physician directed adjustable rod. Requires surgical intervention for adjustment

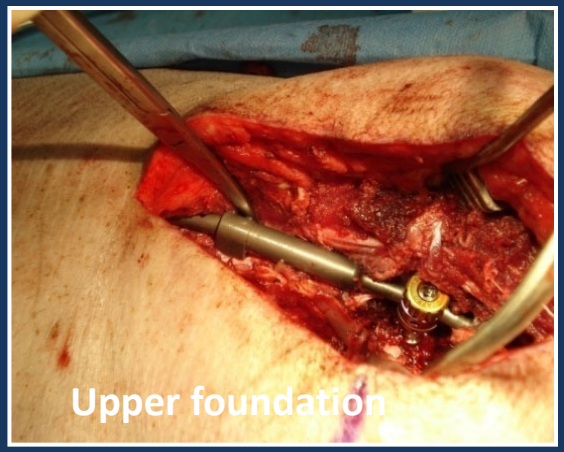
Innovation in Growing Rod Technique: A Study of Safety and Efficacy of Remotely Expandable Device in Animal Model

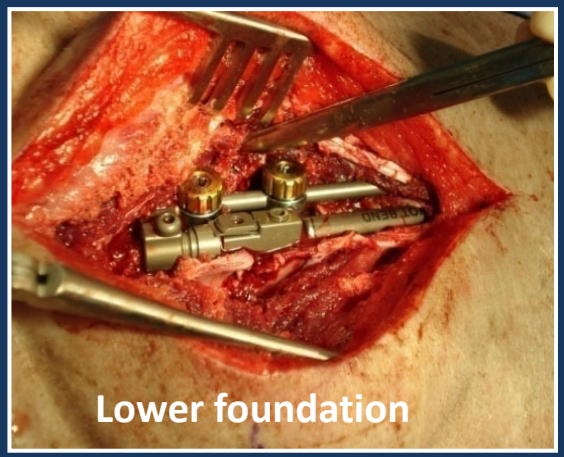
Behrooz A. Akbarnia MD
Gregory M. Mundis, Jr., MD
Pooria Salari, MD
Jeff B. Pawelek, BS
Burt Yaszay, MD

Spine, Accepted for publication, 2011

METHODS

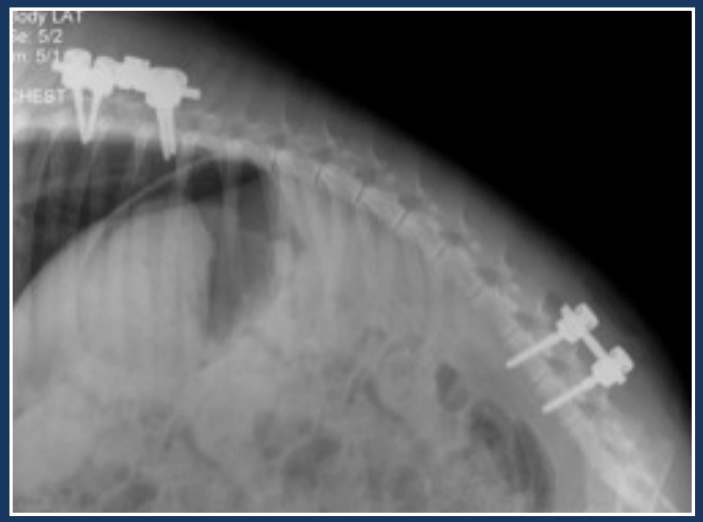
- Nine (9) immature male Yucatan mini-pigs
  - Six (6) pigs in Experimental group (EG)
  - Three (3) pigs in Sham group (SG)
- Both groups had 3-level cephalad and 2-level caudal foundations
- EG instrumented with a unilateral rod





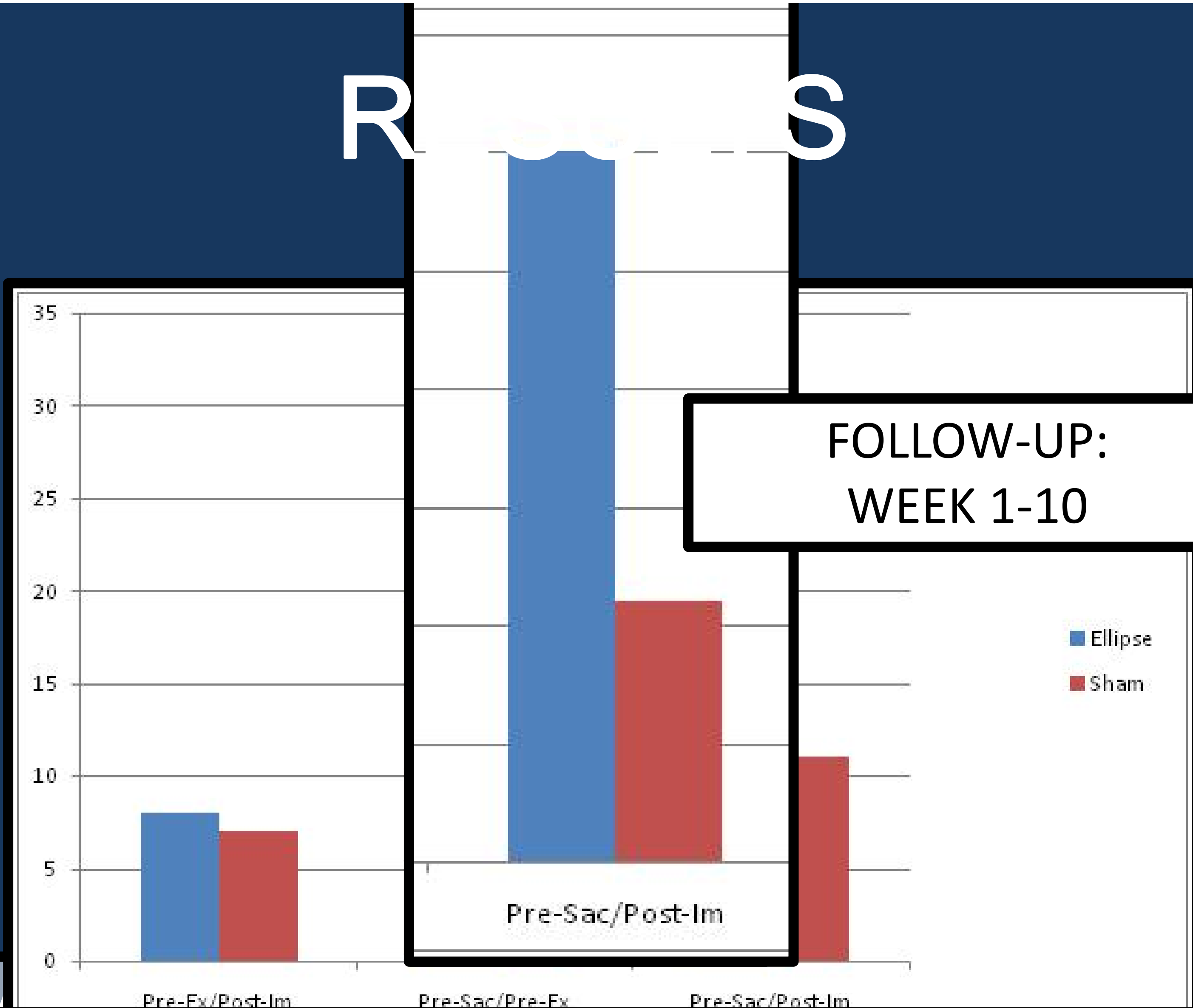
METHODS

- 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



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



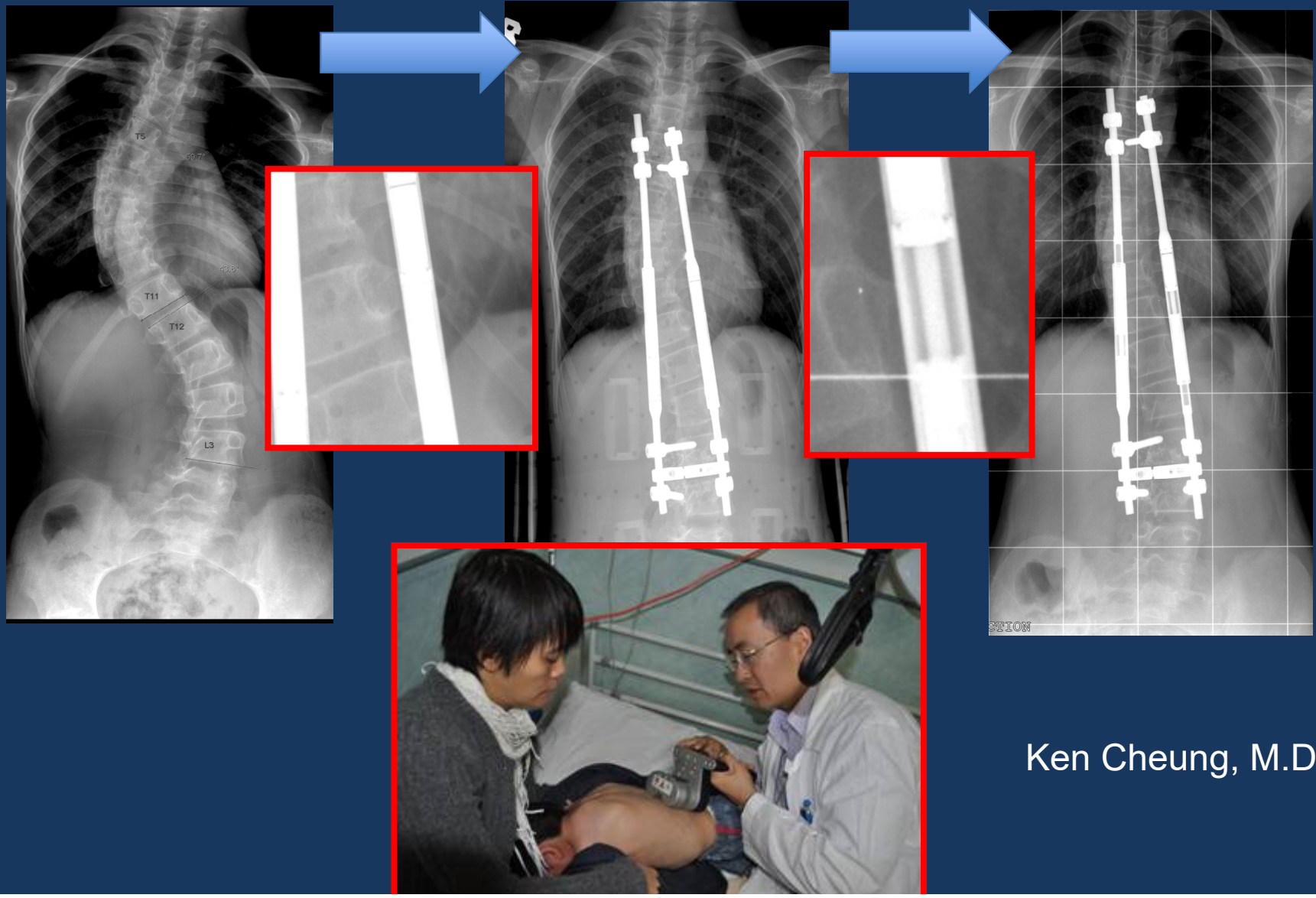
FOLLOW-UP:
WEEK 1-10

- After implant removal, spine growth increased significantly in EG

CONCLUSIONS

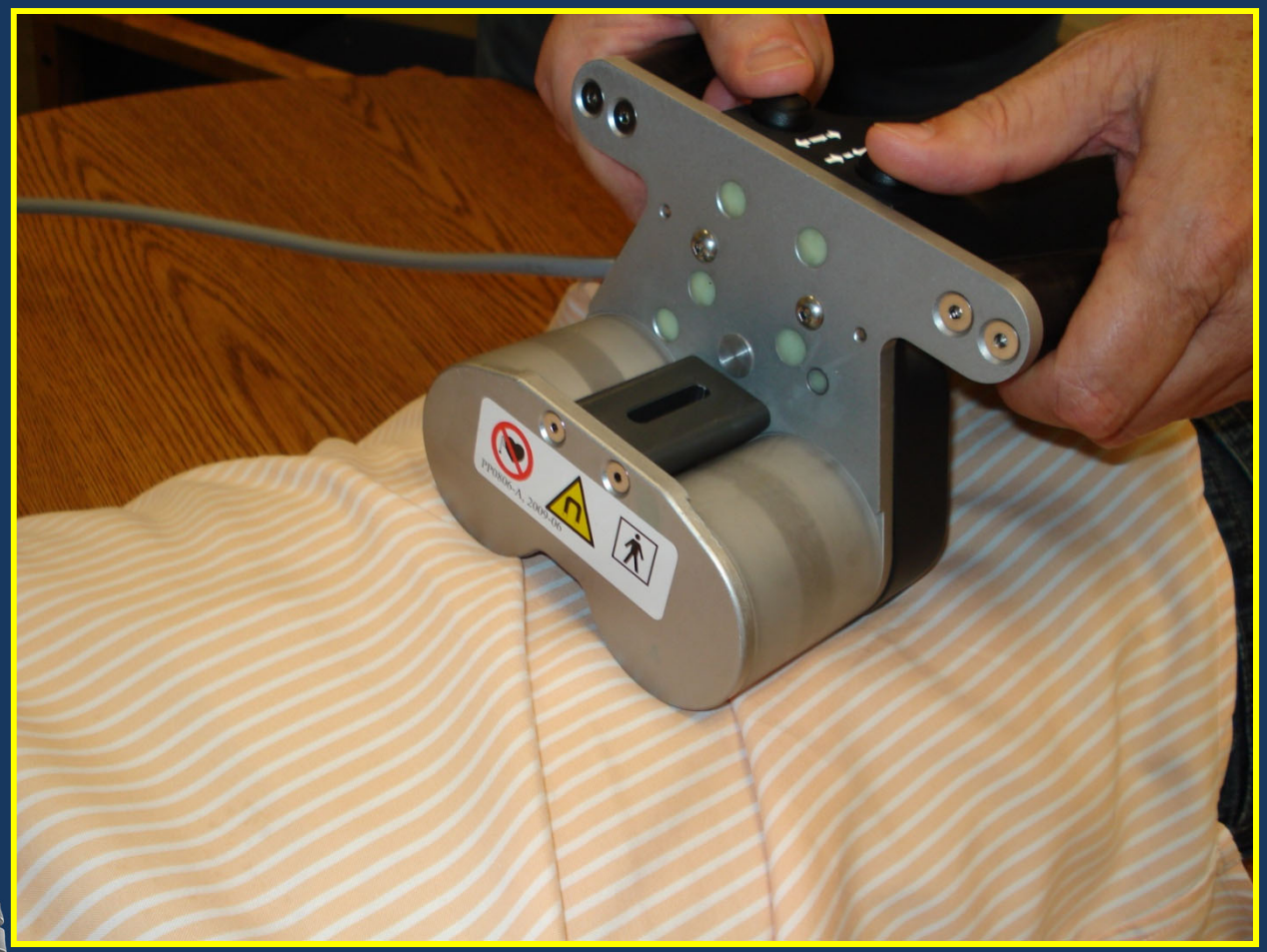
- MAGEC was shown to be safe and effective in this study
- No complication resulted directly from distraction
- MAGEC distinguishes itself by:
  - Distraction accuracy / prediction
  - Ability to shorten

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



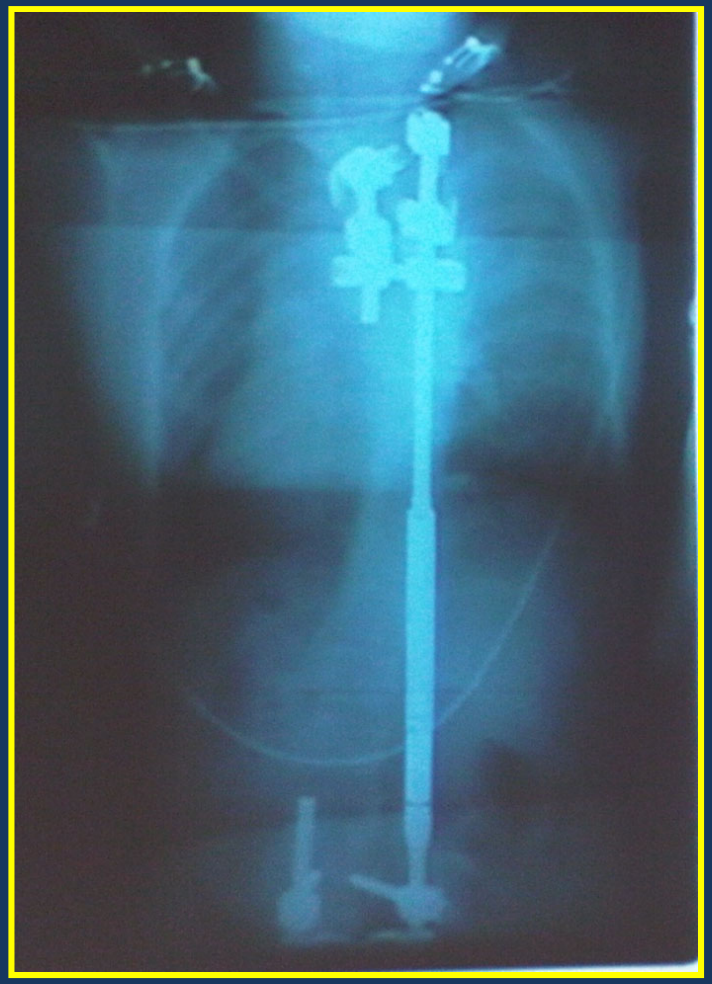
Ken Cheung, M.D.

The MAGEC Technology



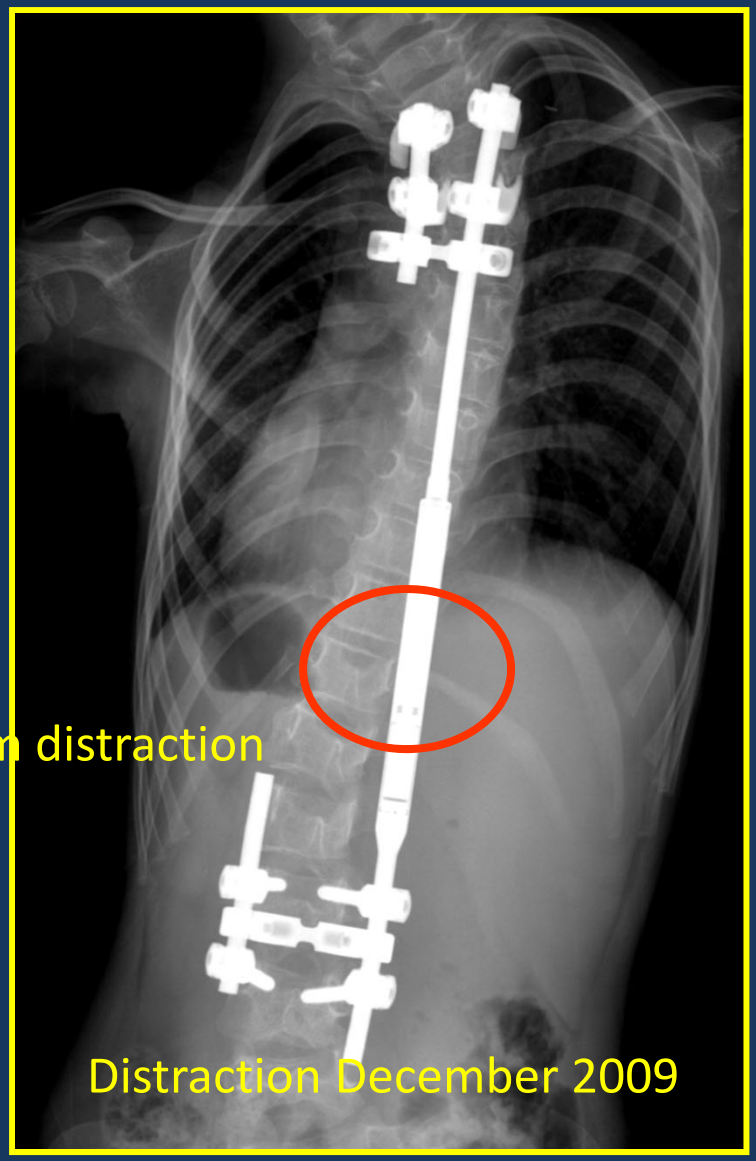
MAGEC- Case 1

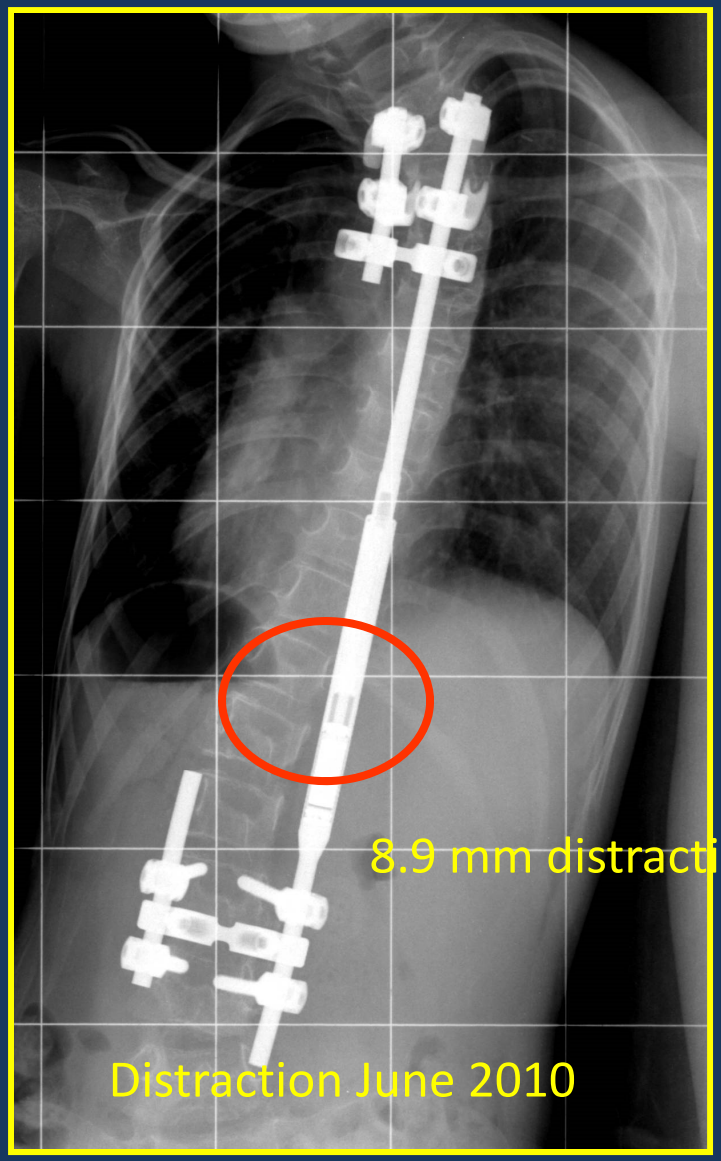
Pre Op AP



Pre Op AP

MAGEC- Case 1

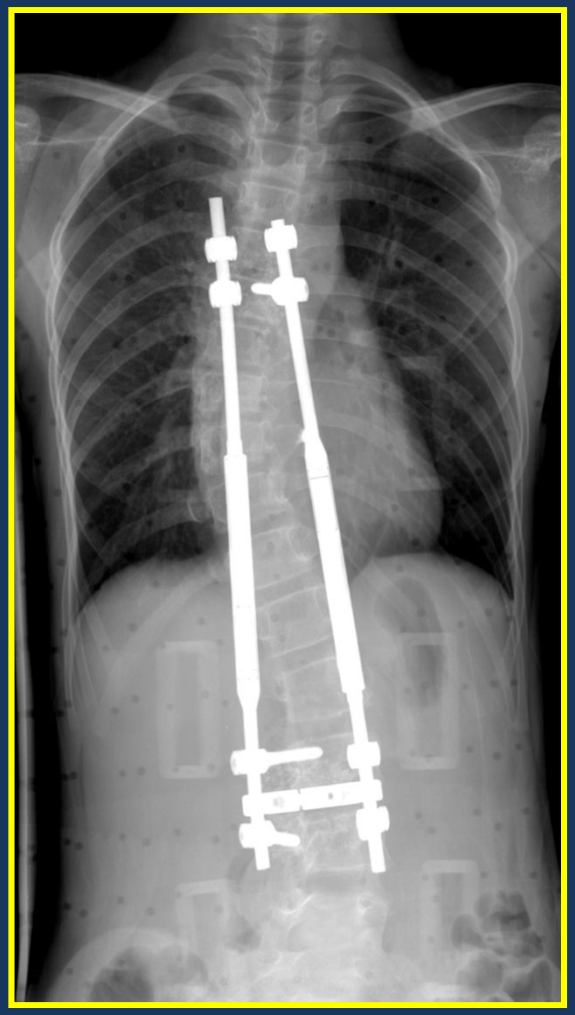




Courtesy of Ken Cheung, MD, University of Hong Kong, HK

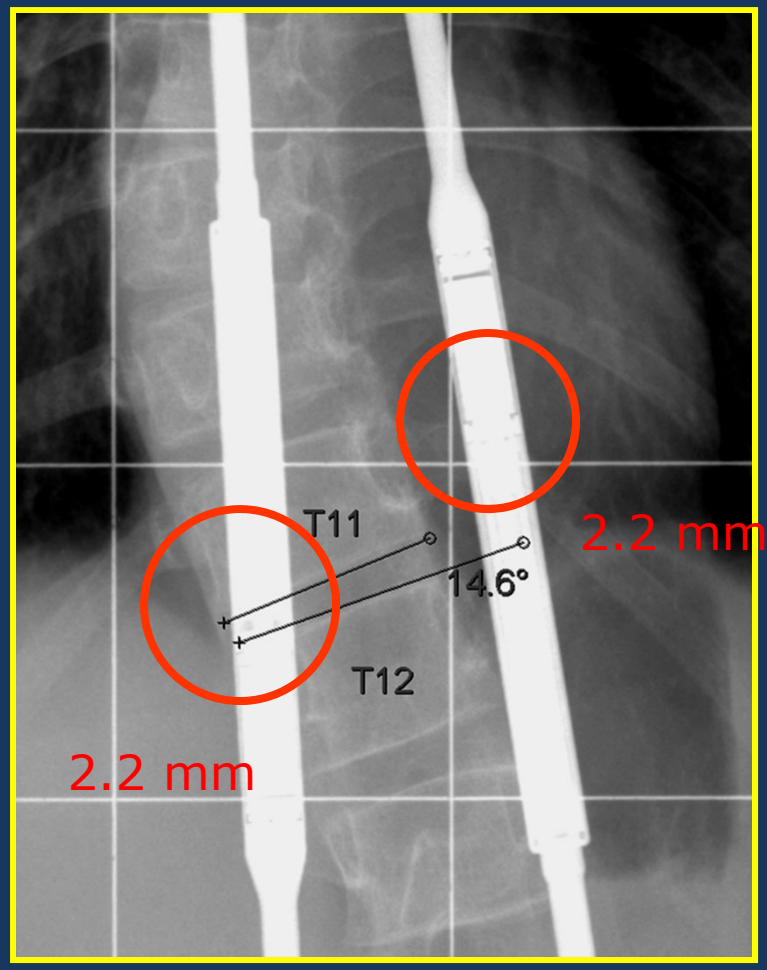
MAGEC- Case 2

Pre Op AP

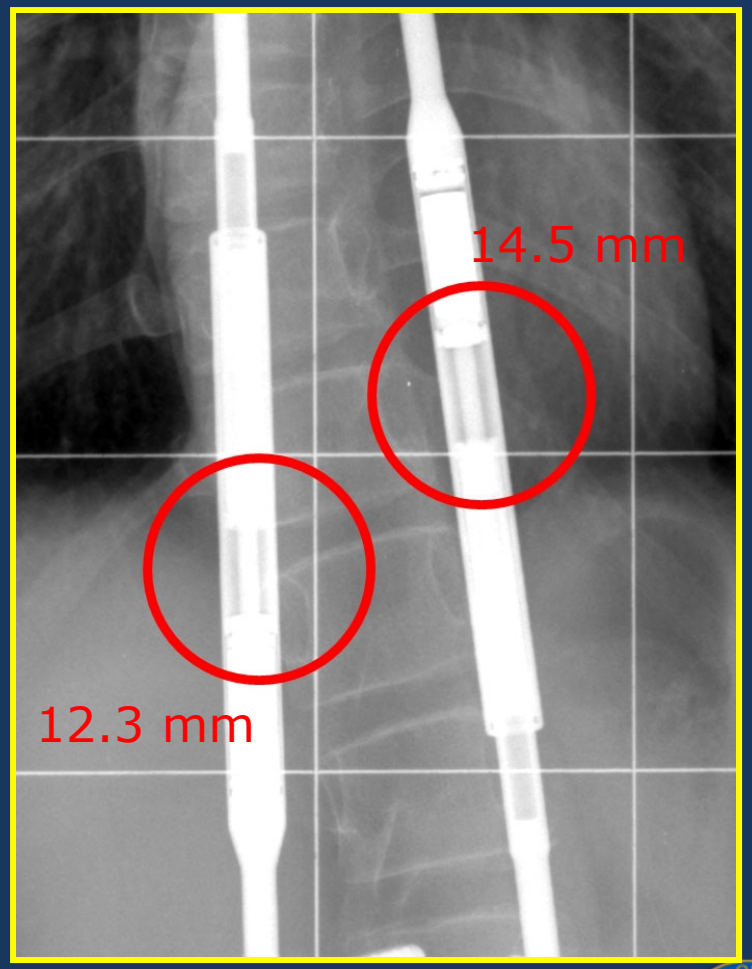


Post Op AP

MAGEC- Case 2

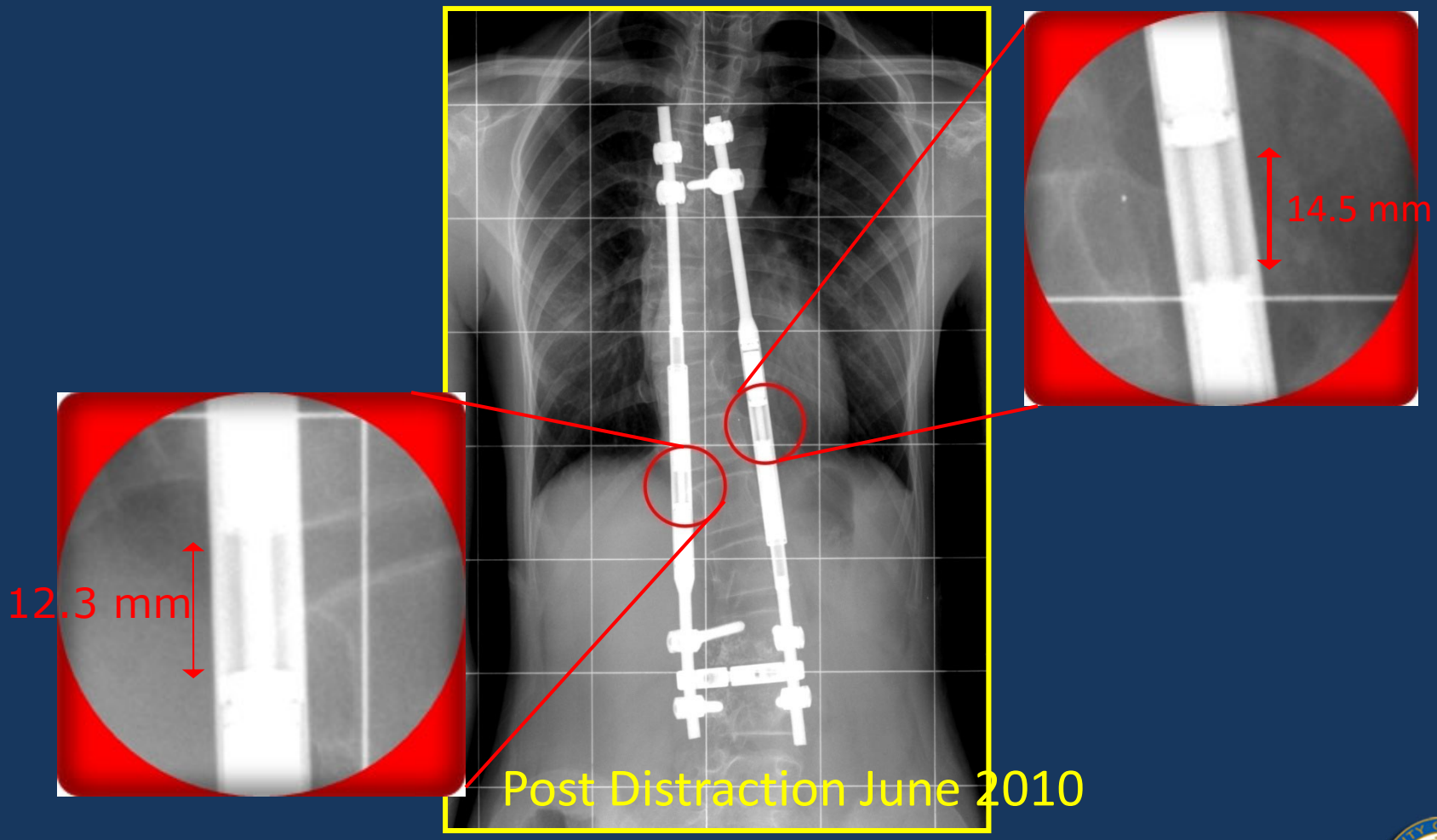


Distraction January 2010



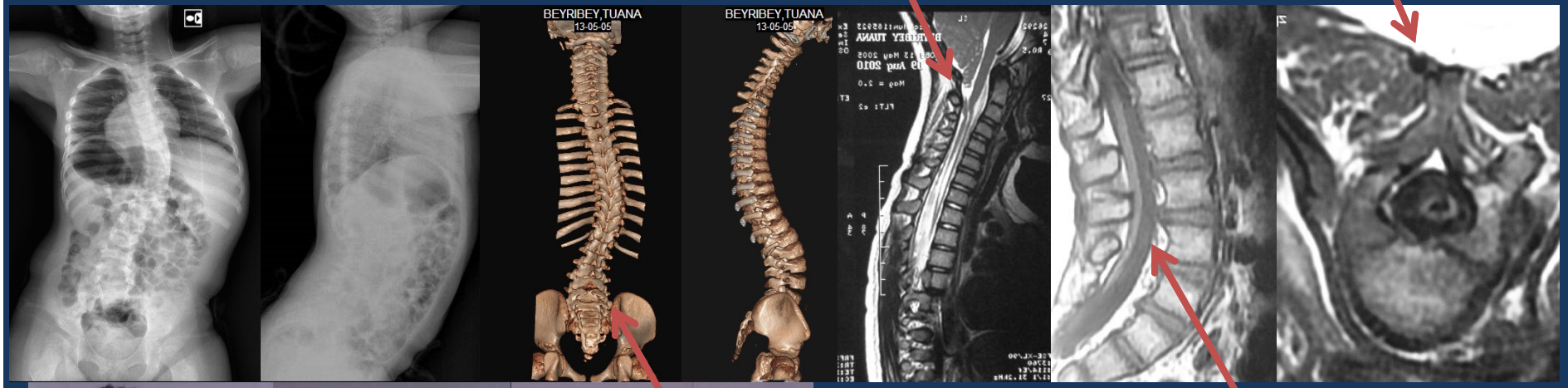
Distraction June 2010

MAGEC- Case 2



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

Case #3, spinal dysraphism



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

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Courtesy Dr. Yazici

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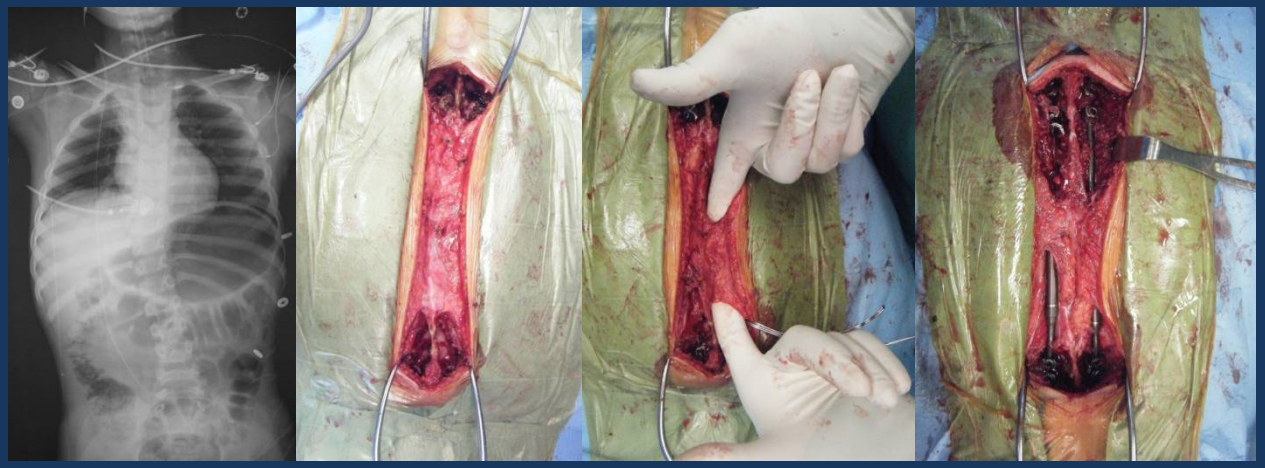
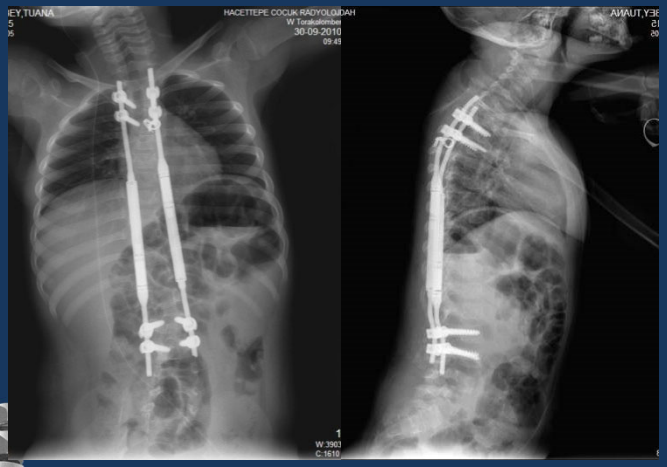
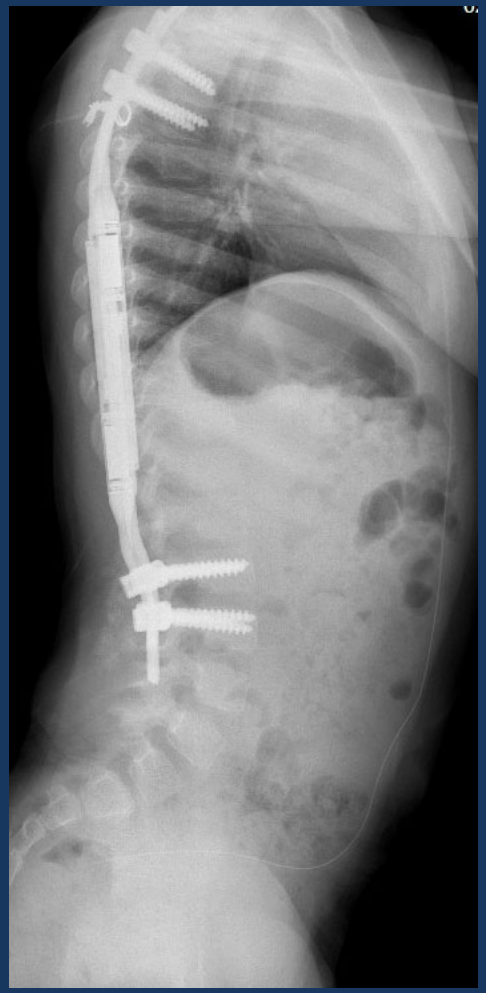
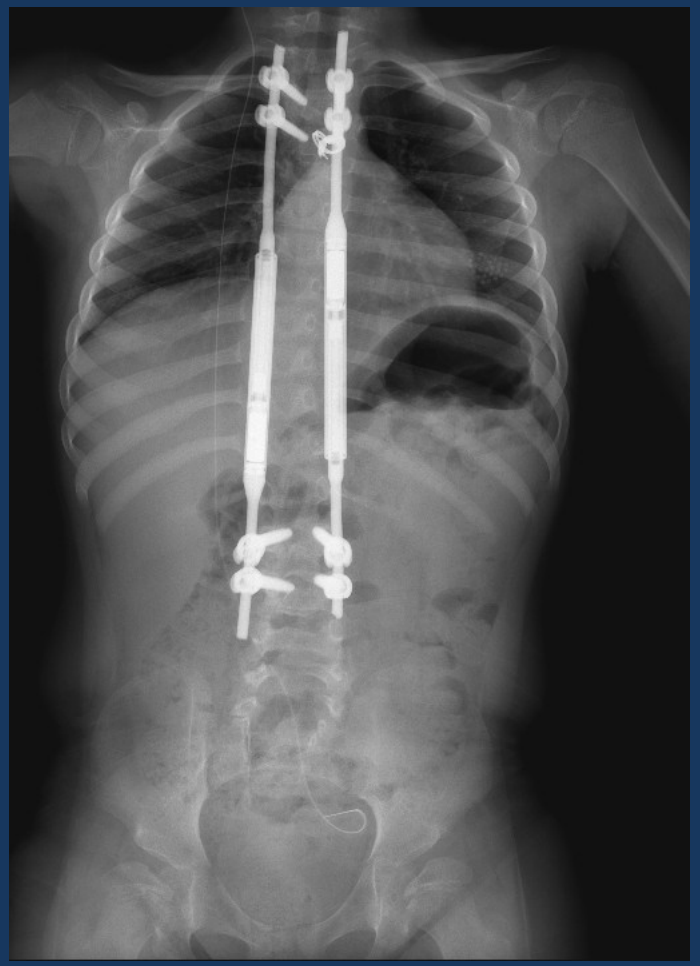
Spinal Dysraphism






Ellipse Tech
Cont. Mode
1.6 mm
Abs Length:17.6 mm





Post-op

MAGEC Data IMAST Abstract 2011

- 14 patients treated outside the US with MAGEC
- Minimum of 3 distractions for each patient

MAGEC Data

IMAST Abstract 2011

- 14 patients treated outside the US with MAGEC
- Minimum of 3 distractions for each patient
- Peri-operative data
  - After initial surgery

	Pre-operative	Post-operative	Result
Cobb Angle (°)	58.8 ± 12.3 (range 40.6 to 76)	33.7 ± 10.8 (range 14 to 51)	43% deformity correction
Thoracic Spine Height (mm)	186 ± 28 (range 129 to 234)	205 ± 27 (range 150 to 251)	10% Increased thoracic spine height

MAGEC Data

- Post distraction outcomes
  - After last non-invasive lengthening procedure
  - Average # of distractions: 4.9
  - Average follow up time: 7.6 ± 3.2 mos (range 3.1 to 13.4)

	Pre-operative	Most recent	Result
Cobb Angle (°)	58.8 ± 12.3 (range 40.6 to 76)	31.4 ± 9.3 (range 5 to 44)	47% deformity correction
Thoracic Spine Height (mm)	186 ± 28 (range 129 to 234)	212 ± 28 (range 161 to 262)	14% Increased thoracic spine height

Comparison Data

	Pre-operative	Most recent	Result
GSSG Data (average follow up 28 months)			
Cobb Angle (°)	77.6 ± 16.7	41.3 ± 16.6	47% deformity correction
Thoracic Spine Height (mm)	165.6 ± 22.1	203.5 ± 27.5	23% Increased thoracic spine height
MAGEC Data (average follow up 7.6 months)			
Cobb Angle (°)	58.8 ± 12.3	31.4 ± 9.3	47% deformity correction
Thoracic Spine Height (mm)	186 ± 28	212 ± 28	14% Increased thoracic spine height

MAGEC Update – Oct 2011

- OUS Activity – approximate numbers
  - Since late 2009 (CE Mark Approval)
    - Commercially available in 11 countries
    - With approximately 120 patients treated
      - Roughly 220 rods implanted
      - Approximately 75% dual rods

MAGEC Update – Oct 2011

- At more than 30 centers
- Over 250 “office visit” lengthening procedures
- reported rod fractures approx. 4%
- Maximum number of distractions in a single patient is 20
- Maximum distracted length in a single patient is approximately 40mm

Summary

- Multiple surgeries is related to 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 growth stimulation by distraction
- MCGR may decrease the number of surgeries and still keep the benefit of growth stimulation
- The devices are not approved for sale in the United States
- Clinical trials are ongoing outside the US

Thank You