Outcomes in Early Fusions

4th ICEOS

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Toronto, Canada

TWIN CITIES SPINE CENTER

John Lonstein MD

Clinical Professor
Dept Orthopedics Univ Minnesota

Twin Cities Spine Center
Minneapolis, MN

Gillette Specialty Healthcare
St. Paul, MN

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Disclaimers

- Consultant
  - Axial Biotec
  - Biomet Spine
  - K2M
- Royalties
  - Biomet Spine

Outcomes of Early Fusion for Congenital Scoliosis

- Initial search 110-120 possible pts
- Qualified 57
  - Congenital scoliosis
  - Fusion under age 8
  - 5+ levels fused in thoracic spine
  - Minimum age 20 now
- Follow-up
  - Radiographs, PFT, HRQOL

- Unable to trace parent or patient 29
- Completed 12

- In process 16

Challenges in Assessing Outcomes in EOS

EOS

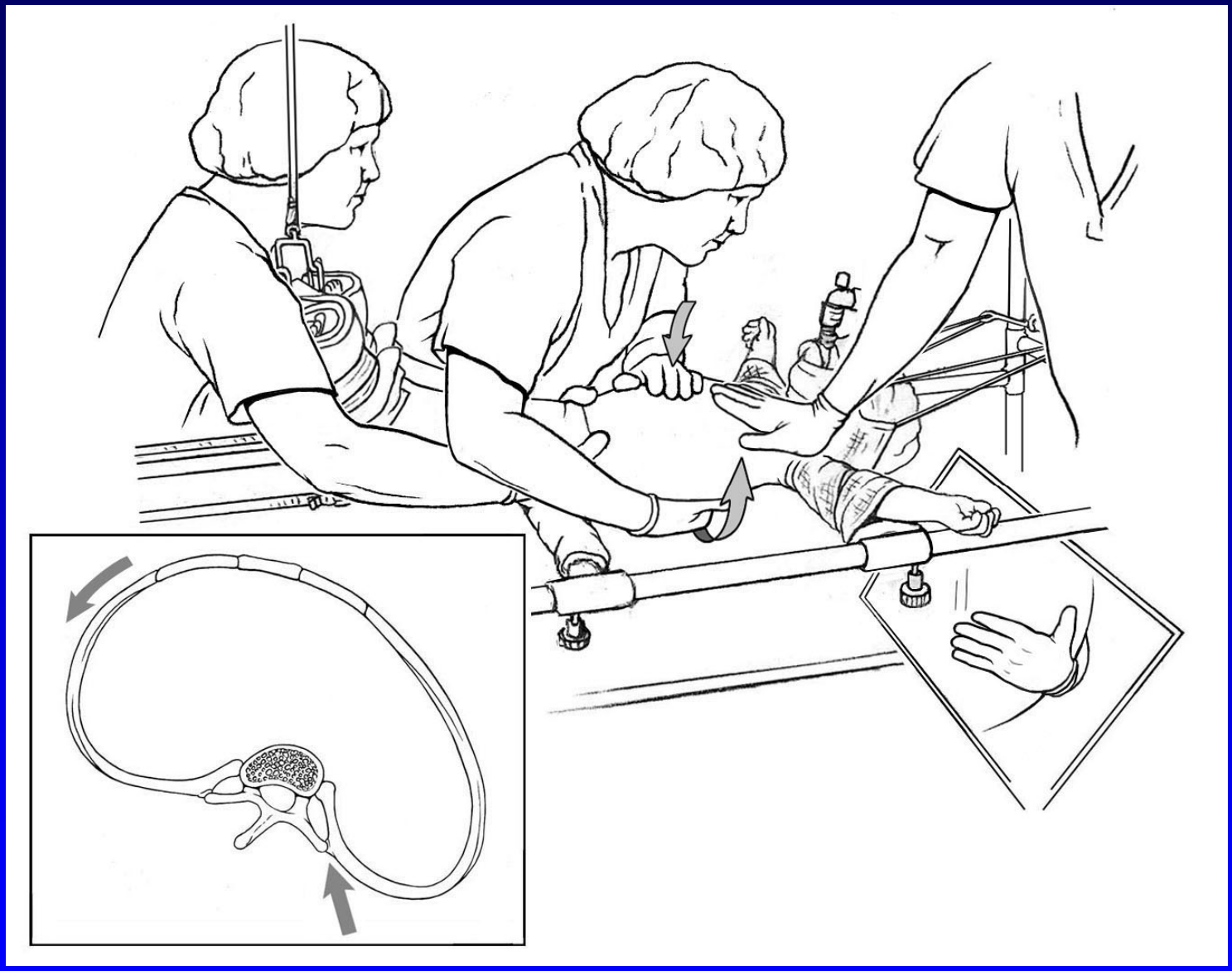
- Spine deformity <age 5
  - Infantile idiopathic scoliosis
  - Congenital scoliosis
  - Neuromuscular scoliosis
  - Syndromic scoliosis

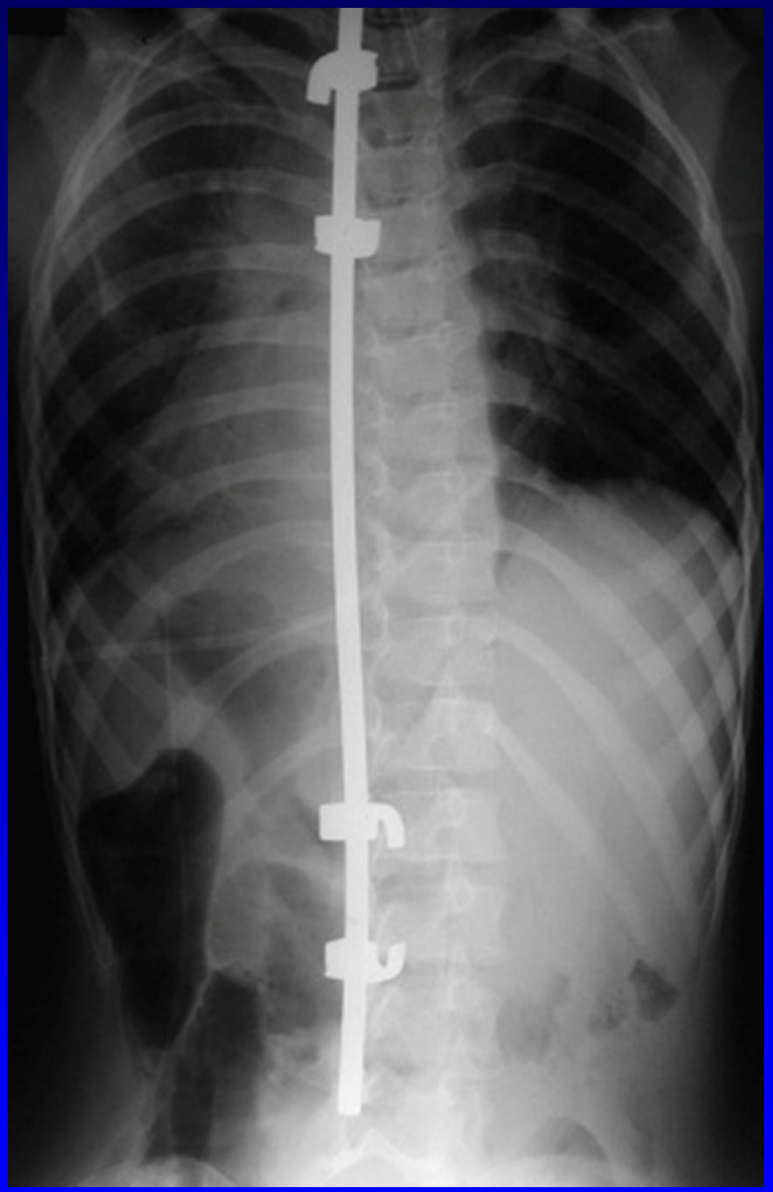
Aim of treatment of EOS

- Manage scoliosis delaying definitive fusion
- Allow spinal growth
- Maximize thoracic growth and lung function

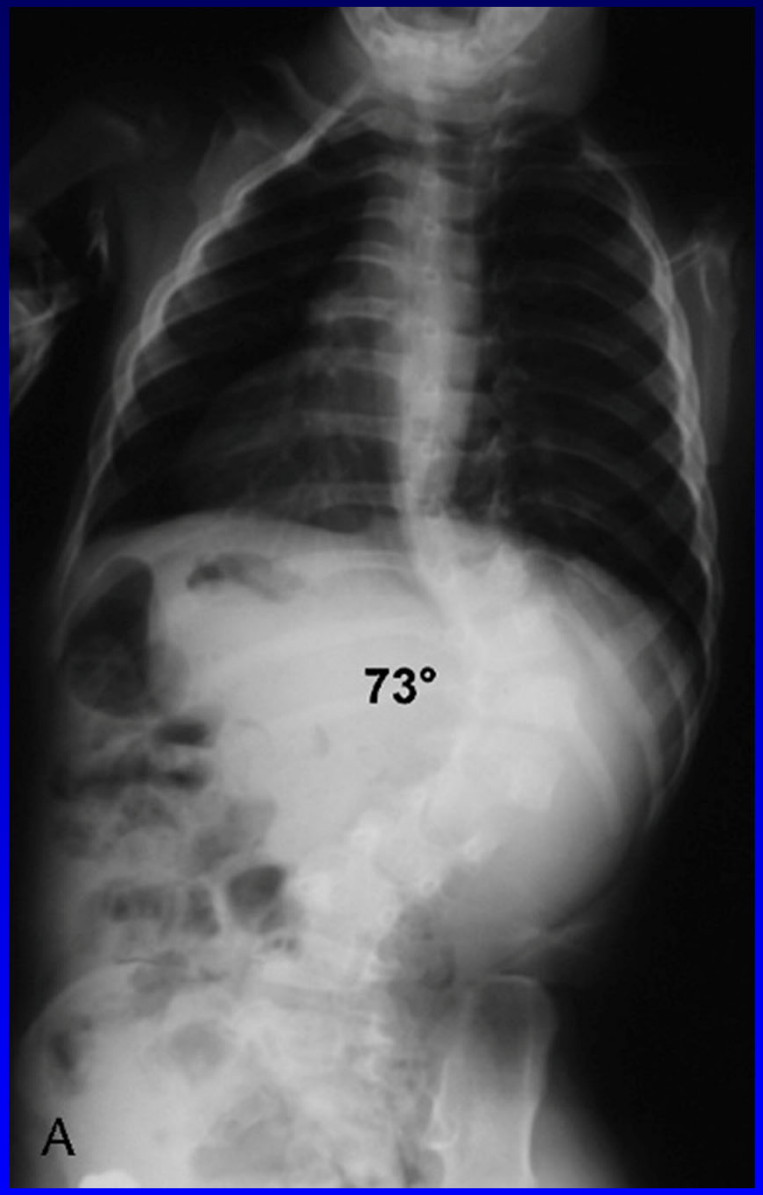
Treatment with:-

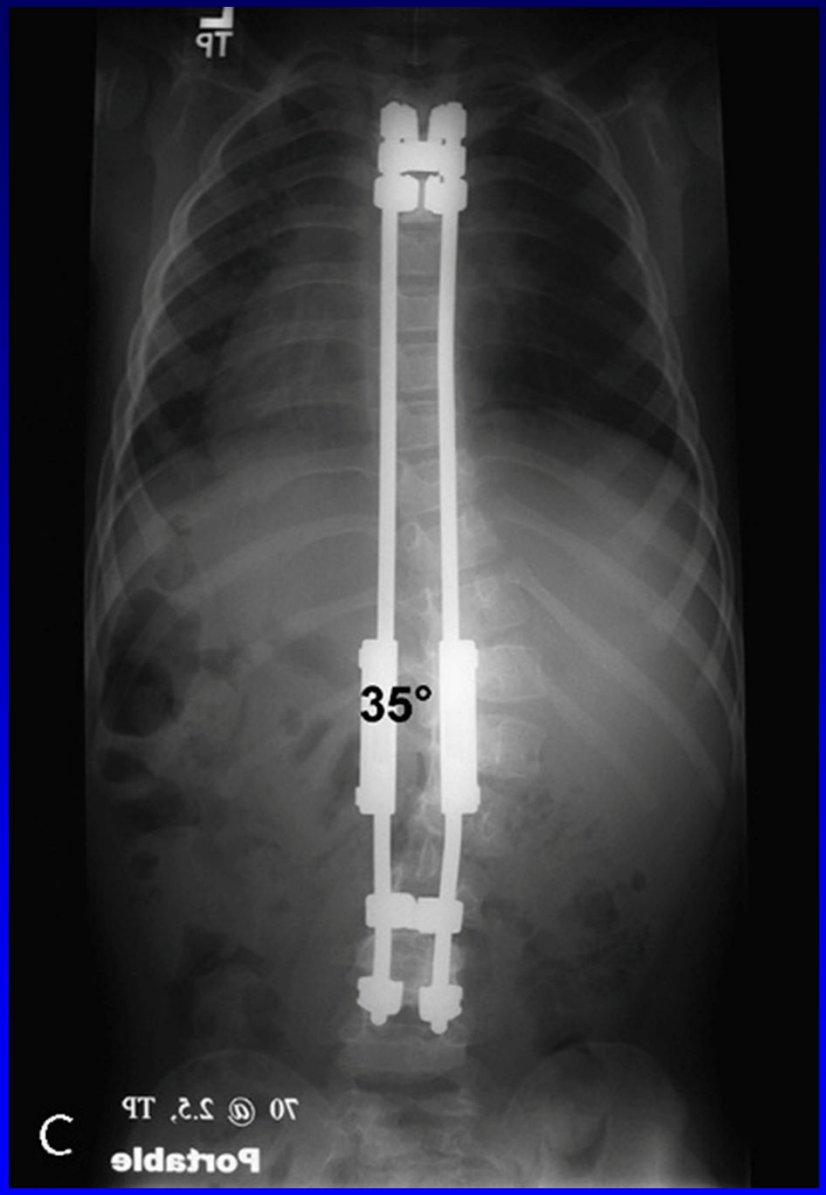
- Casting/bracing
- Growth rods
  - Single or dual
  - Submuscular or subcutaneous
- VEPTR
  - 1st surgery Campbell / Smith 1989
  - FDA approved 2004





Thompson GH et al. JPO: 27, 354, 2007





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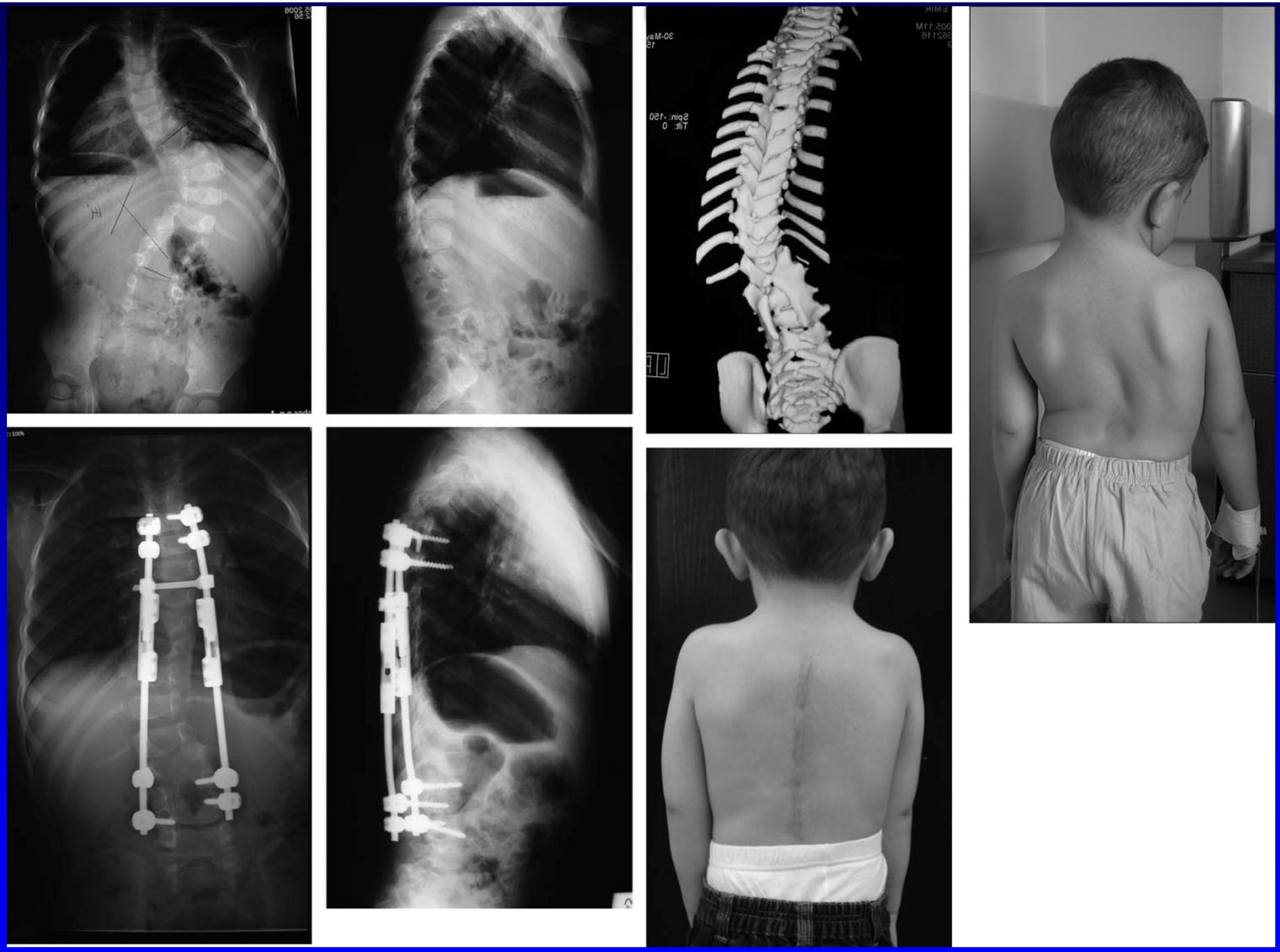

Yazici et al. Spin:, 34, 1800, 2009

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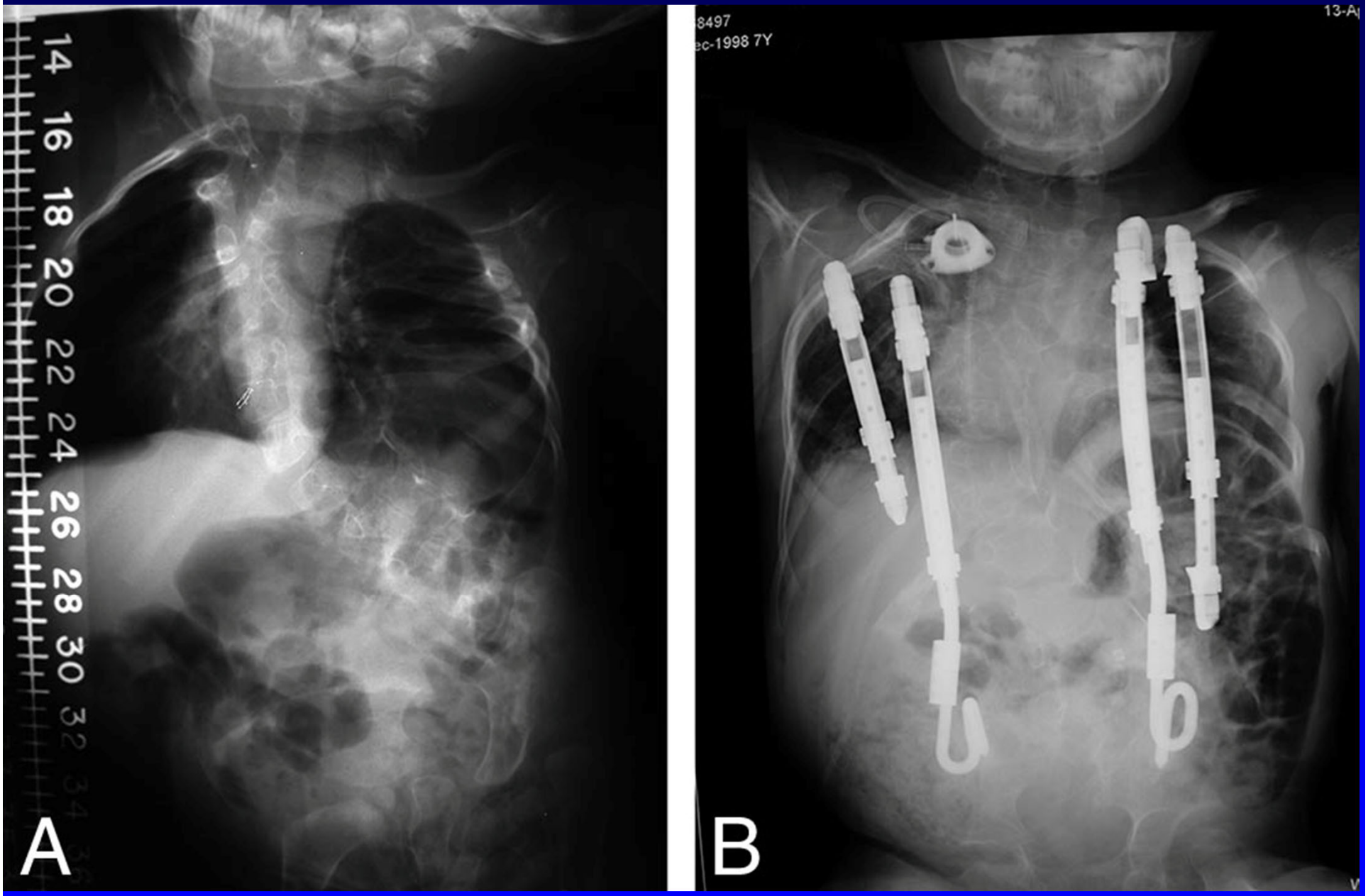
VEPTR

- Approved by FDA for:-
  - Flail chest
  - Congenital constrictive chest wall syndrome
  - Hypoplastic thorax
  - Progressive scoliosis
    - Neuromuscular
    - Congenital
- Choices
    - Rib to rib
    - Rib to spine
    - Rib to pelvis



Campbell RM et al. Spine 32: 2171, 2007

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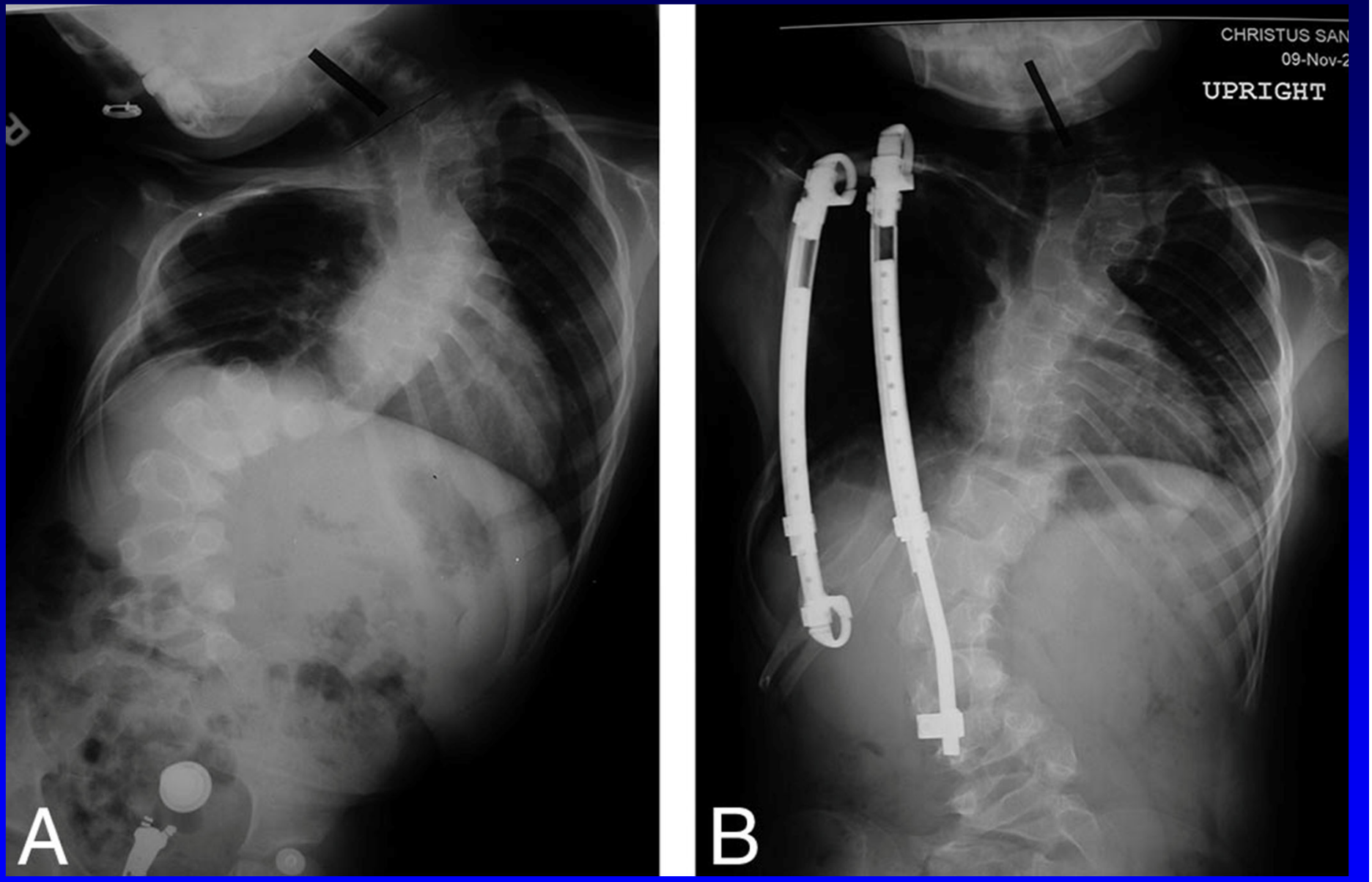


Campbell RM et al. Spine 32: 2171, 2007

EOS Studies

- Single center
  - Fewer patients
  - Single treatment principle
  - Single or multiple diagnoses
- Data base – Growing Spine Study Group
  - Larger patient numbers
  - Multiple treating surgeons
  - Single or multiple diagnoses

Challenges

- Mixed diagnoses
- Mixed ages
- Variable amount of TIS

- Because of rarity of these cases
  - Series tend to be small
- Many series have short F/U

Presentations

- Technique
- Complications
- Results

In EOS Treatment

- Improve Spinal Deformity
- Maximize Spinal Growth
- Improve Pulmonary Function – TIS

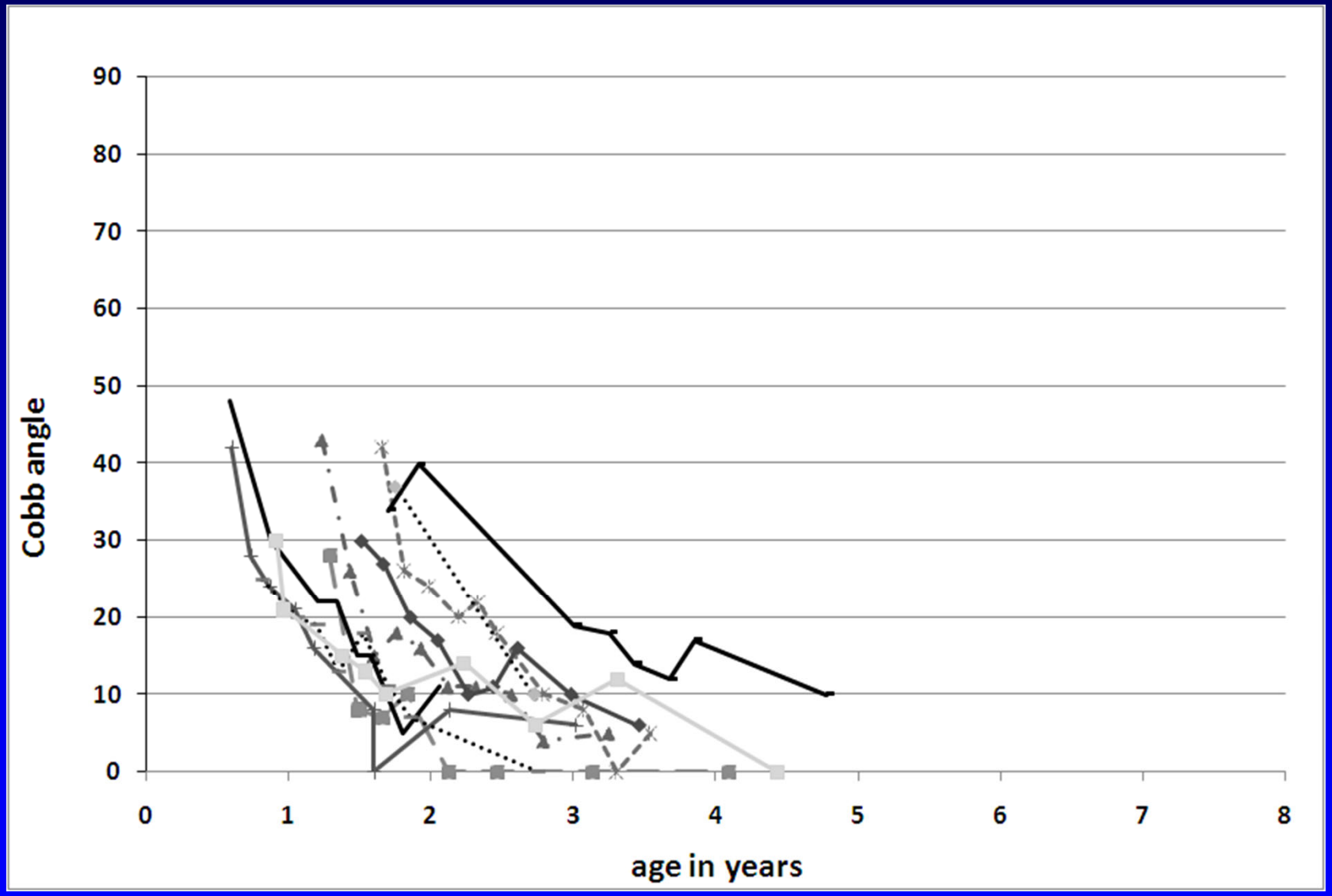
- Measure
  - Deformity correction
  - Spinal growth
  - Pulmonary function
  - HRQOL

Deformity Evaluation

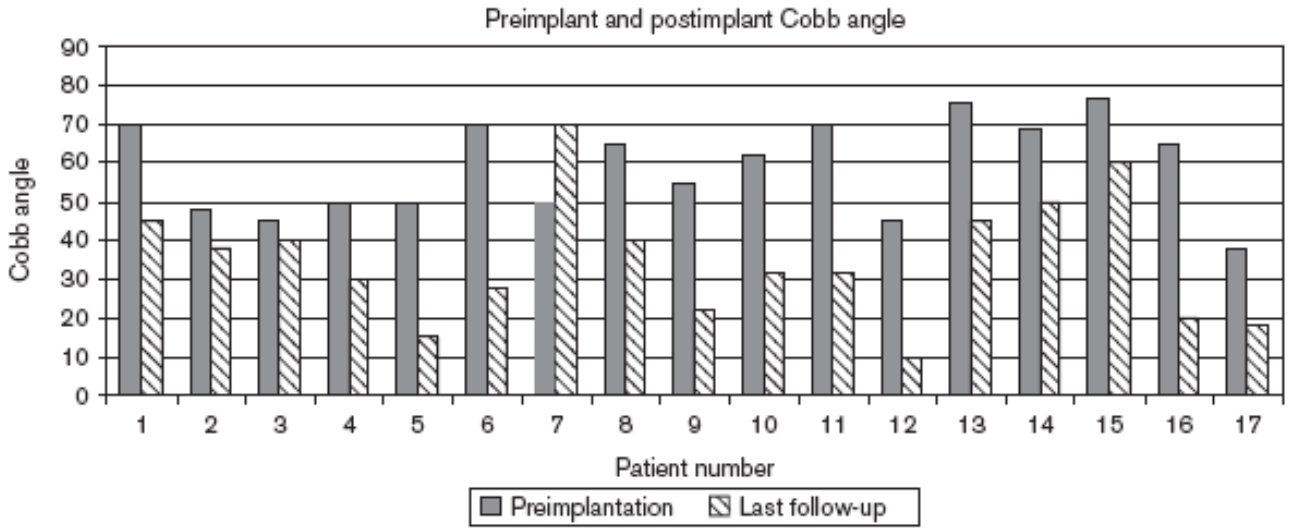
- Easiest to measure
- Measure
  - Scoliosis
  - Kyphosis
  - Decompensation / balance
- Cobb method
- Computer based measuring tools on digital radiographs

- **Advantages**
  - Assess multiple time points
  - Easy storage / retrieval of images

- **Accuracy is essential**
  - Same vertebrae
  - Same anatomical landmarks
  - One measurer


90
80
70
60
50
40
30
20
10
0
Cobb angle
0
1
2
3
4
5
6
7
8
age in years

Coronal Cobb

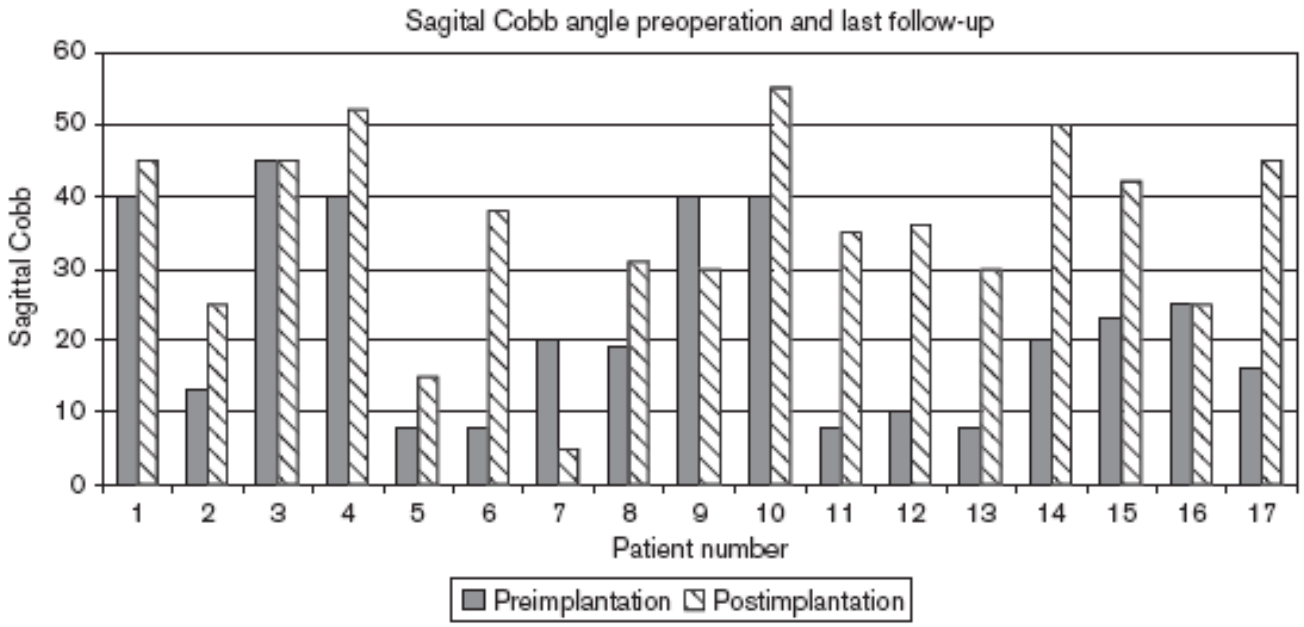


Preoperative Cobb angle of 59 ±12 (mean±SD) degrees (range 38–77), postoperative 35° ±16 (range 10–70) resulting in an average decrease of 59% in Cobb angle ($P<0.001$).

Average 59° to 35°

Ramirez N et al. JPOB: 18, 197 2009

Sagittal Cobb



Preoperative sagittal Cobb angle of 23 ± 13 (mean ± SD) degrees (range 8–45) to postoperative 36 ± 13 (range 15–55) ($P \leq 0.01$).

Average 23° to 36°

Ramirez N et al. JPOB: 18, 197 2009

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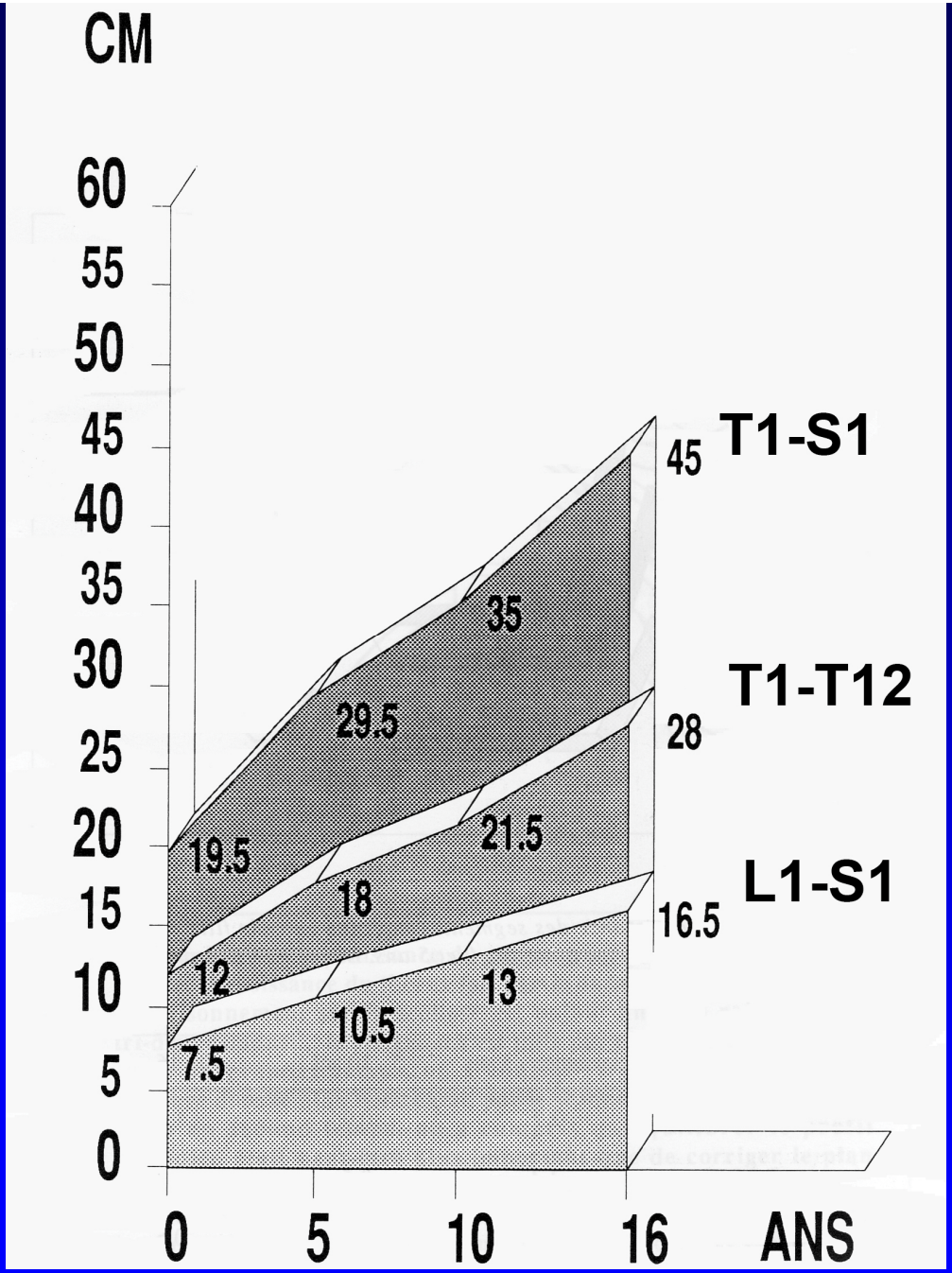
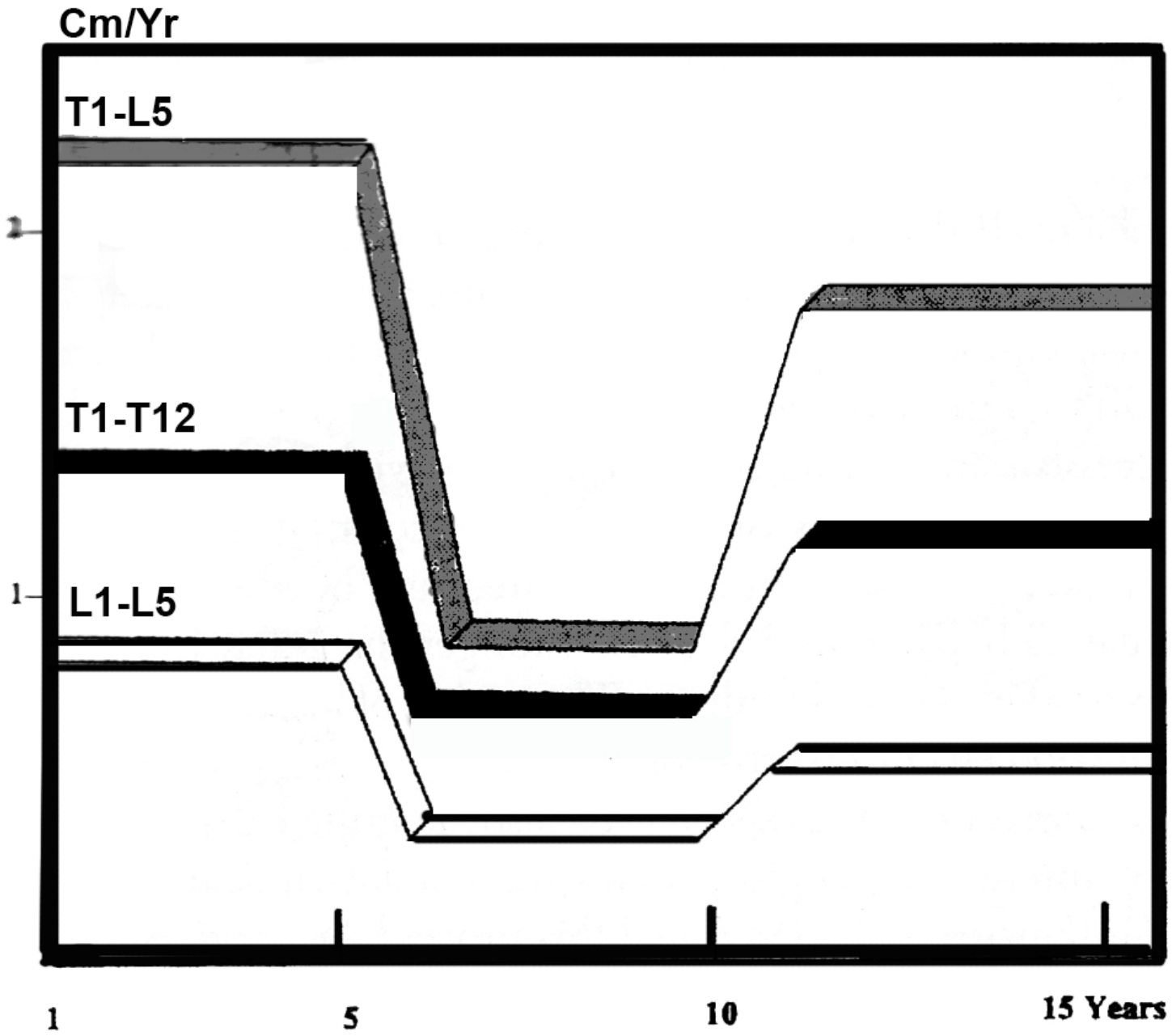
Three growth phases

- Birth to 5 years
- 5 to 10 years
- Puberty : 10 – 16

- T1S1
  - T1T12
  - L1S1



Dimeglio A, et al: La Rachis en Croissance. Springer 1990



Dimeglio A, et al: La Rachis en Croissance. Springer 1990

Thoracic Spine Growth
(Averages)

	Total	Rate
Birth to age 5	6cm	1.2cm/yr
Age 5-10	3.5cm	0.7cm/yr
Age 10-18	6.5cm	1.1cm/yr

Dimeglio A, et al: La Rachis en Croissance. Springer 1990

Challenges

- Rate varies by growth phase
  - Must adjust analysis for age of child
- Growth information on normal children
  - Averages
- No data for growth rates for EOS diagnoses
- Need longer F/U

TIS

- Pulmonary consequences
  - Underlying disease
  - Treatment effects
- VEPTR

Thoracic growth

- 4th Dimension of the spine
- Same growth phases
  - 0-5
  - 5-10
  - 10-18

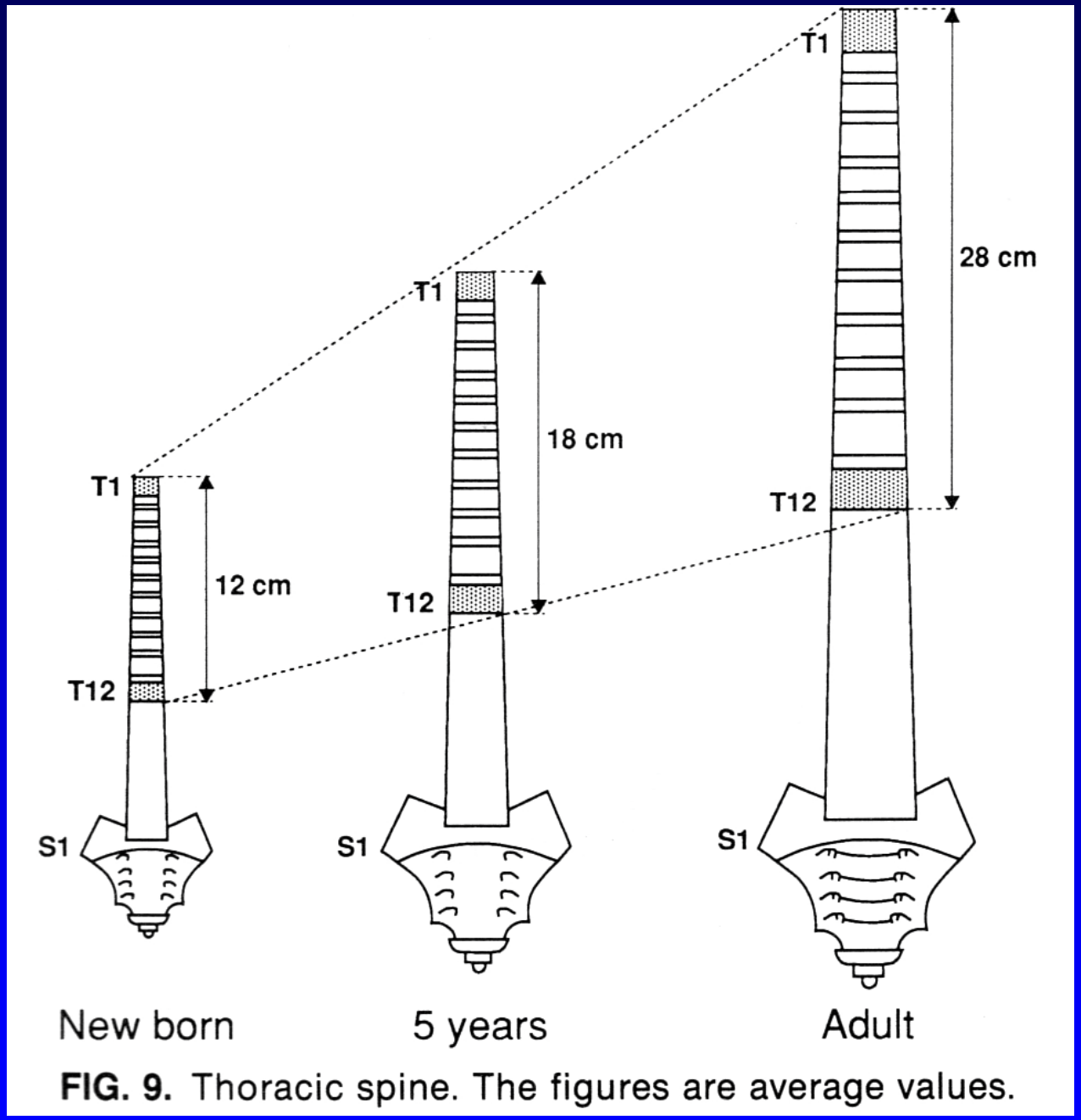
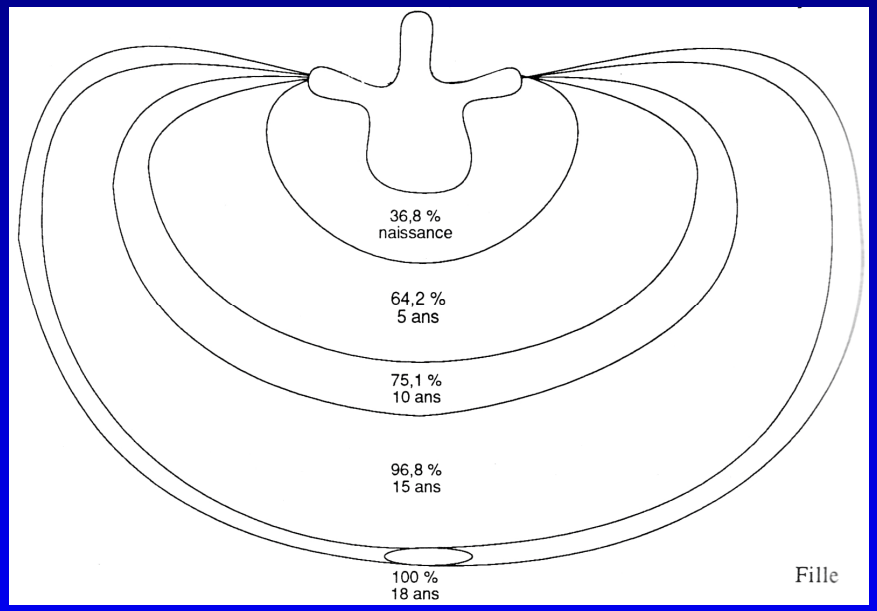
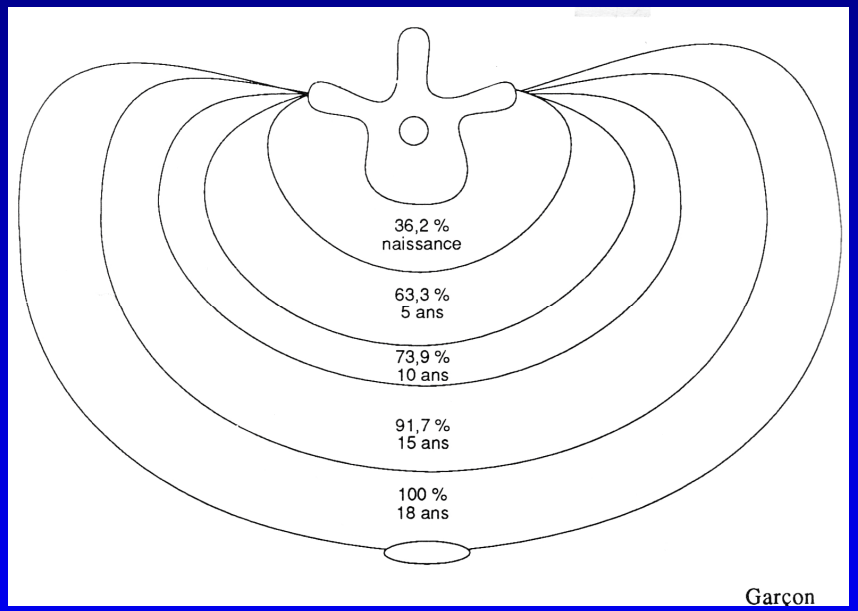


FIG. 9. Thoracic spine. The figures are average values.

Dimeglio A, et al: La Rachis en Croissance. Springer 1990

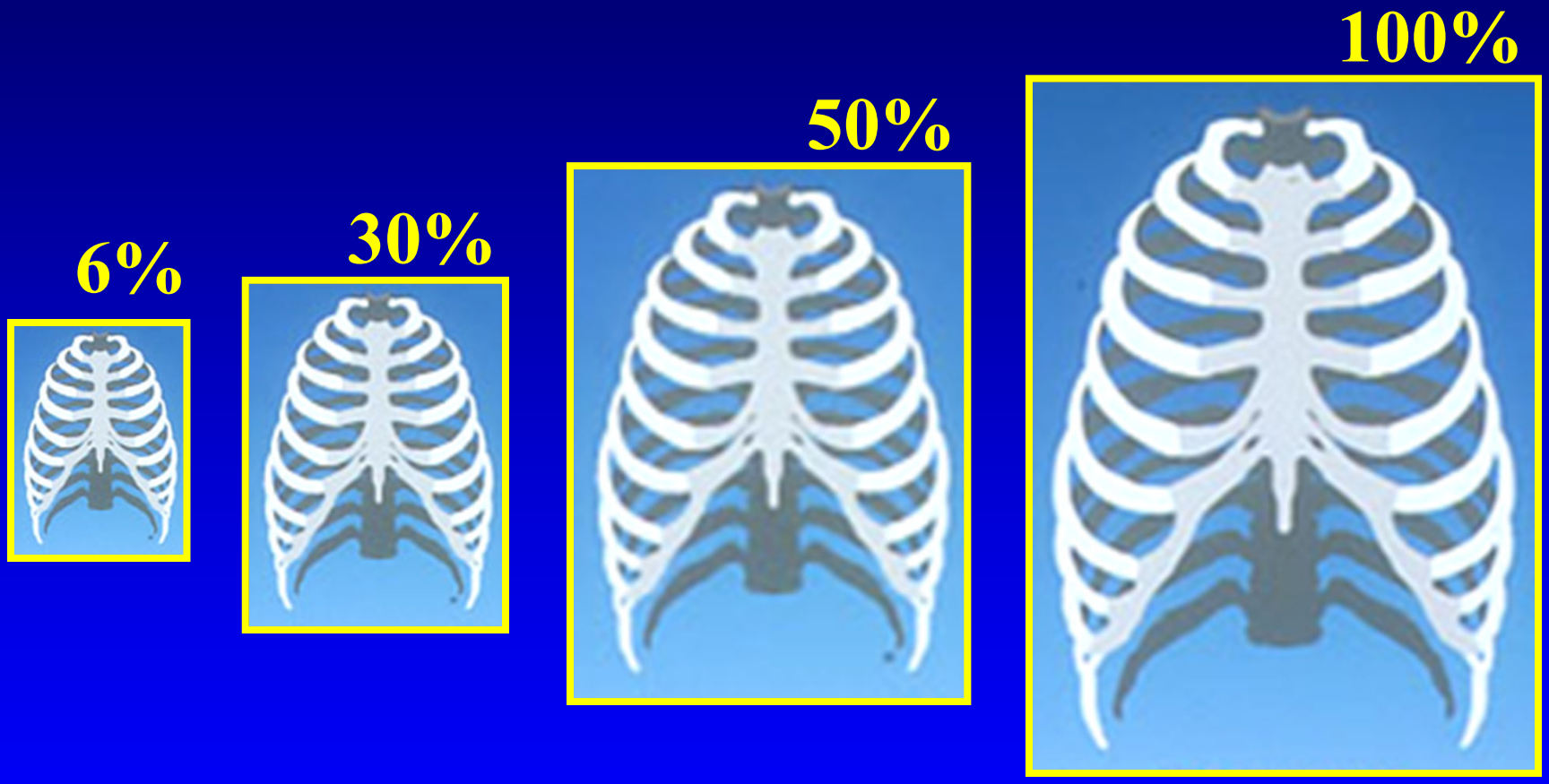
Thoracic Circumference





Dimeglio A, et al: La Rachis en Croissance. Springer 1990

VOLUMETRIC GROWTH



Dimeglio A, et al: La Rachis en Croissance. Springer 1990

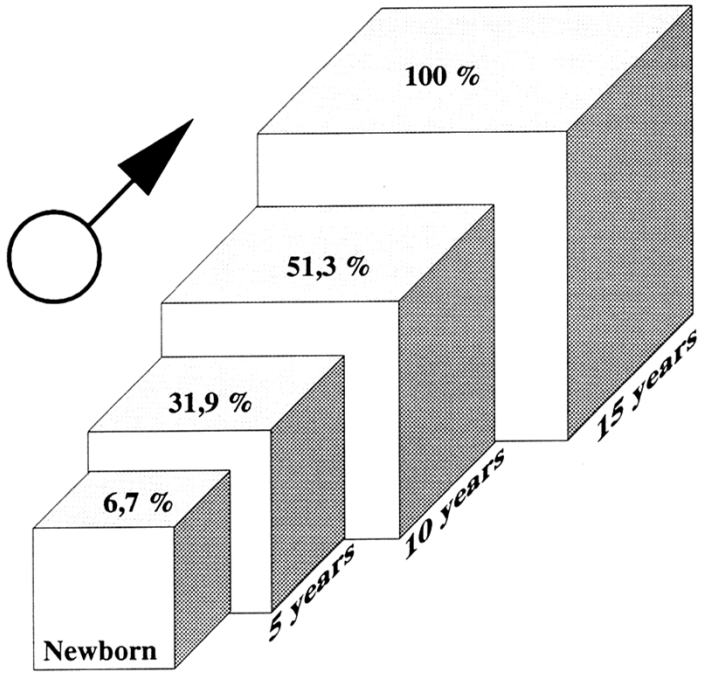


FIG. 15. Boys: Diagram of thoracic volume and its evolution expressed as a percentage.

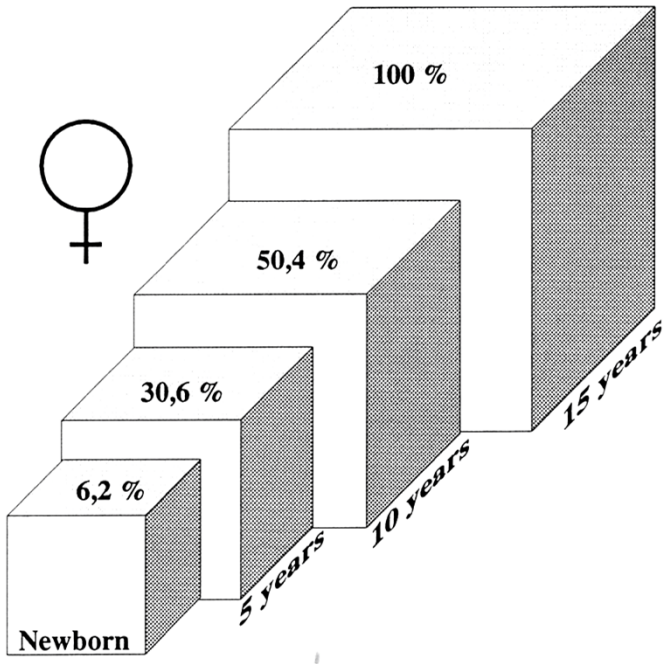


FIG. 16. Girls: Diagram of thoracic volume and its evolution expressed as a percentage.

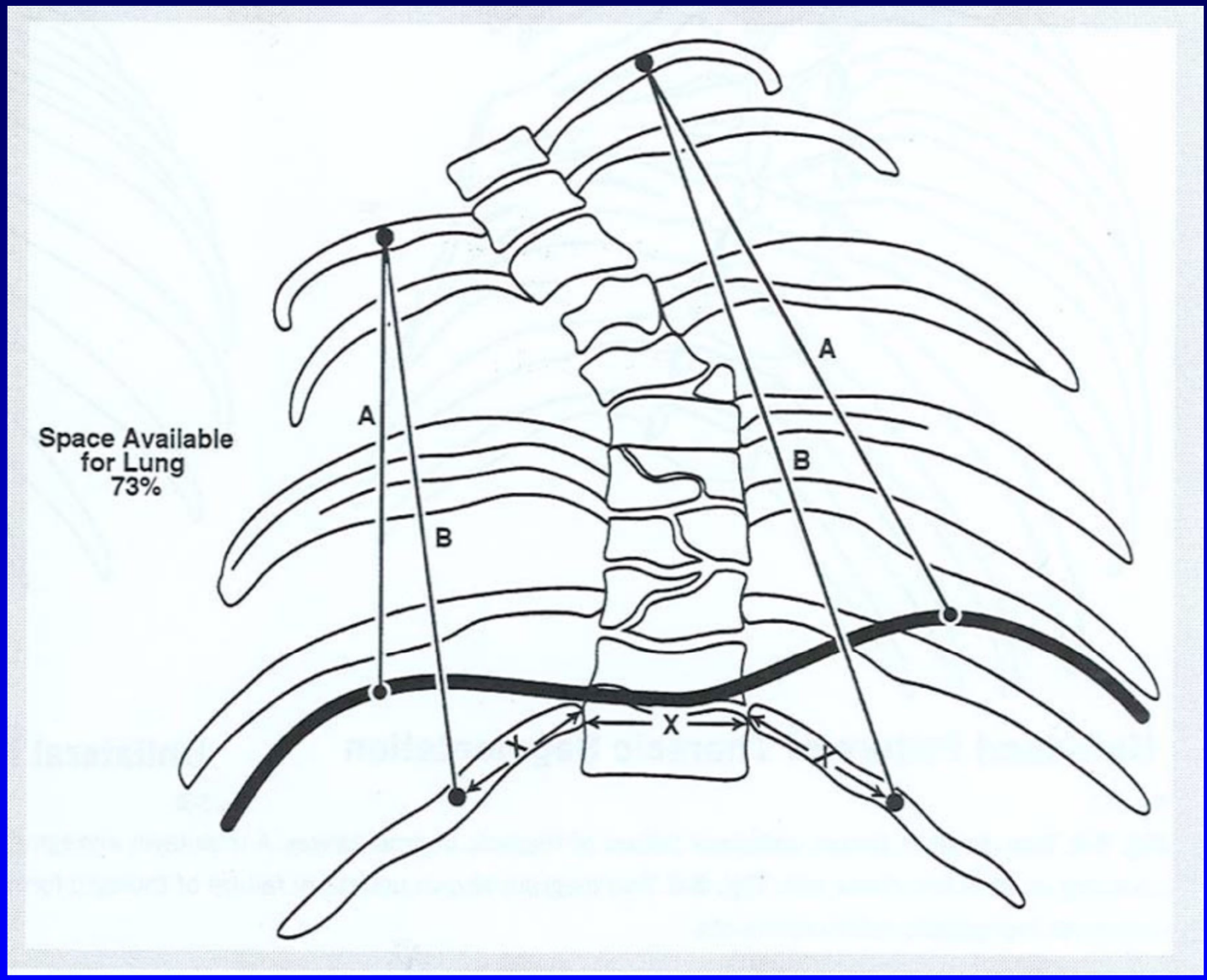
Dimeglio A, et al: La Rachis en Croissance. Springer 1990

Can Measure

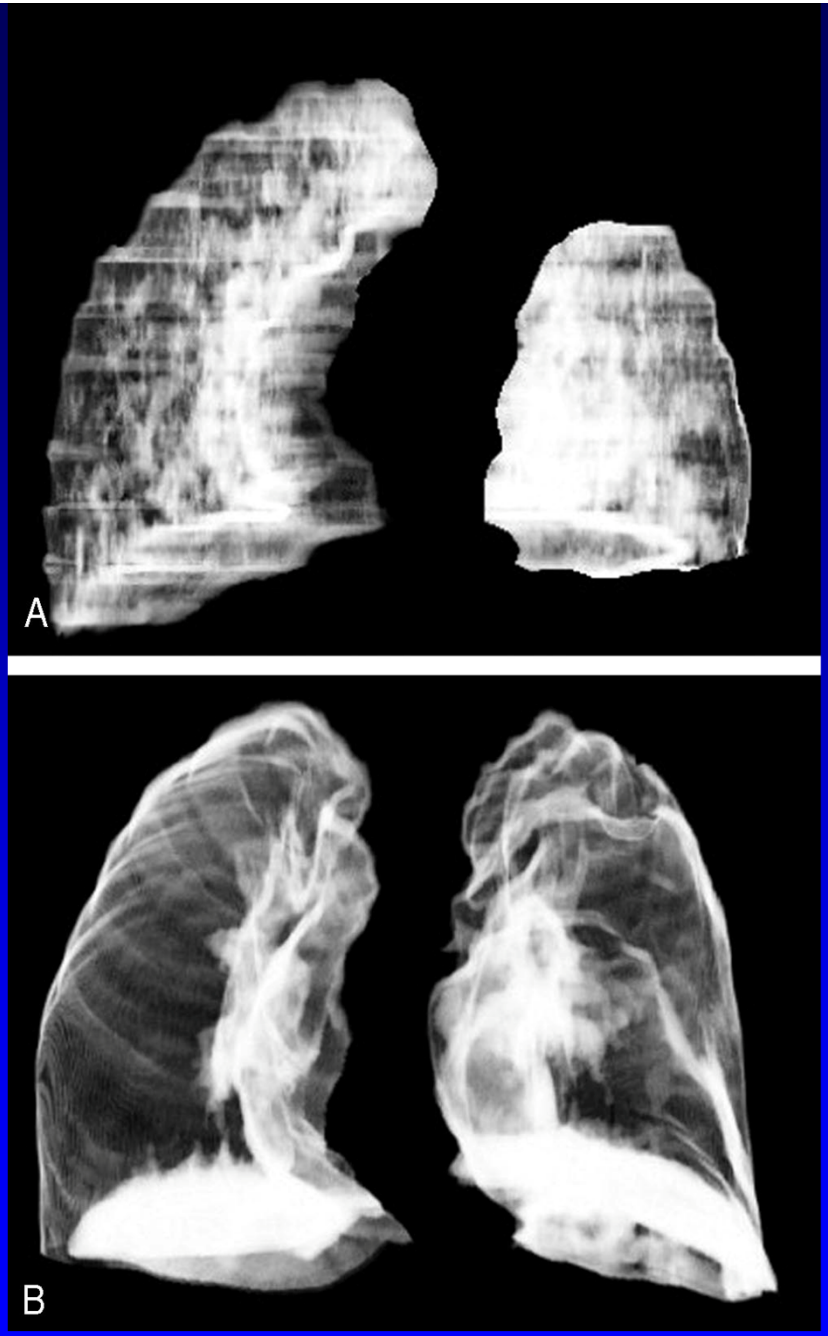
- Thoracic cage and Lung volume
- Spirometry
- Functional results

Challenges

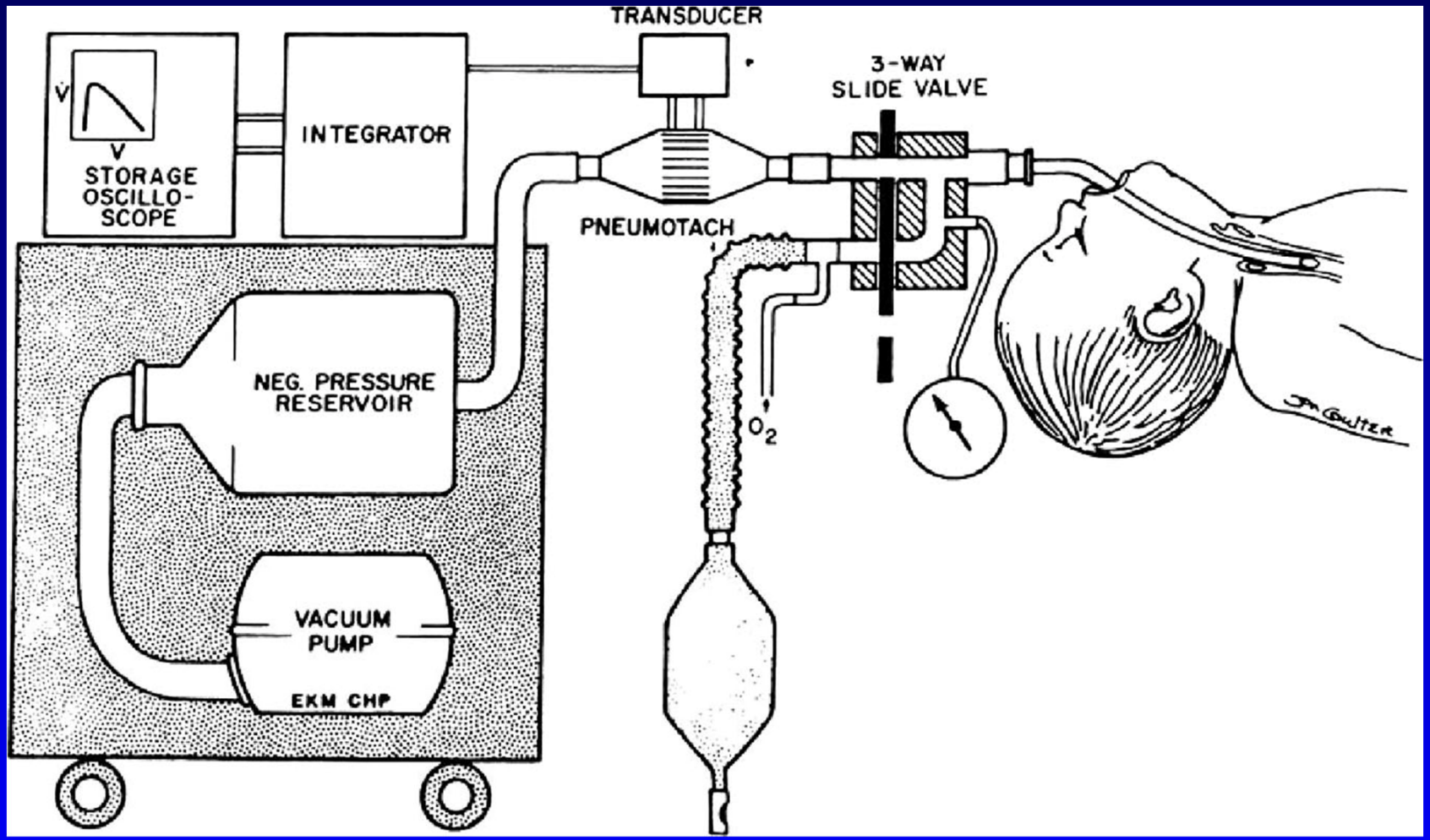
- Small children
- Cannot get Spirometry
  - X-rays / CT for thoracic / lung volumes
  - Spirometry under anesthesia
- Functional effects as a “proxy” for lung function



Campbell RM et al. JBJS: 85A, 2003



Emans JB et al. Spine 30: 558, 2005



Motoyama EK et al. Spine: 31, 284,2006

Thoracic cage and Lung Volumes

- ↑ Lung space (SAL)

  Campbell RM, et al: Spine 2007
  Yazici M, et al: Spine 2009

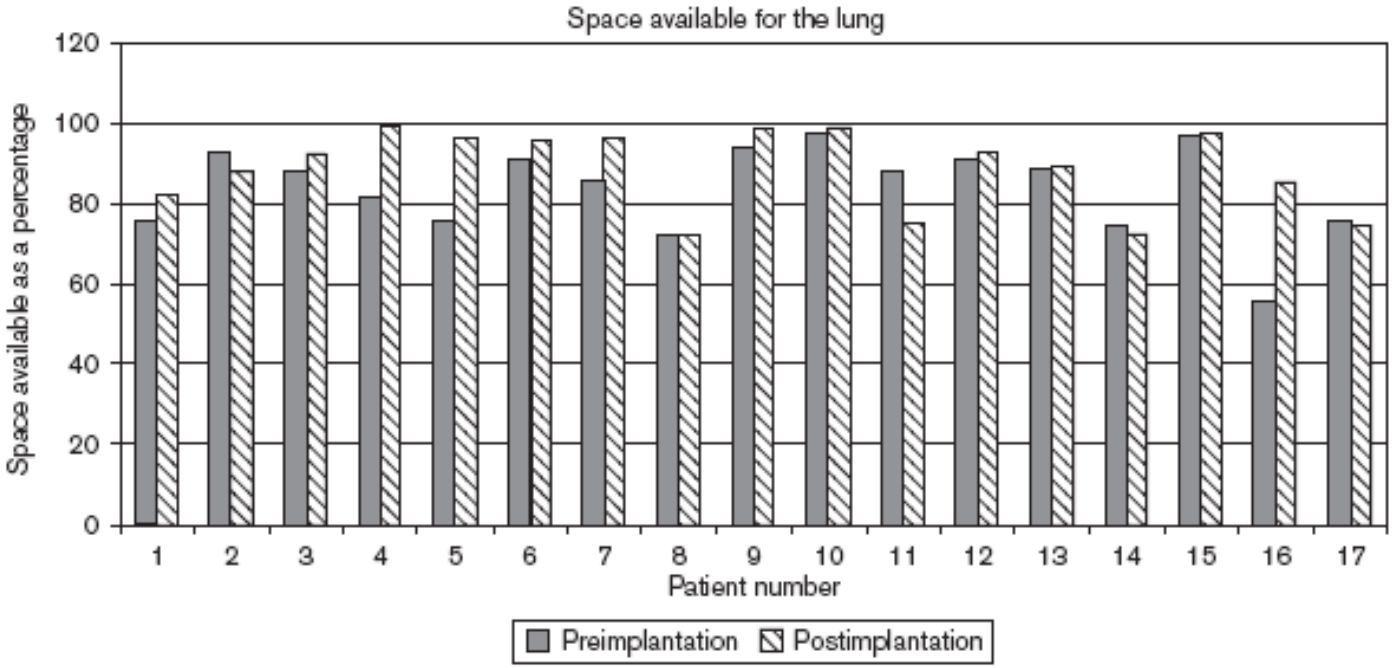
- ↑ Thoracic volume

  Campbell RM, et al: Spine 2007
  Yazici M, et al: Spine 2009
  Emans JB, et al: Spine 2005

- No Δ Lung volume

  Meyer OH, et al: JPO 2009

SAL



Preoperative ratio of 84% ±11 (range 56–97) and postoperative ratio of 89% ±10 (range 72–100) ($P \leq 0.01$).

Average 84% to 89%

Ramirez N et al. JPOB: 18, 197 2009

Spirometry

- ↓ FVC%

  Mayer OH, et al: JPO 2009
  Motoyama EK, et al: Ped Resp Rev 2009

- ↑ RV

  Mayer OH, et al: JPO 2009

- ↓ Compliance

  Motoyama EK, et al: Ped Resp Rev 2009

Blood Gases

- ↓ CO_2 Retention

  Waldhausen JH, et al: J Peds Surg 2007

- ↓ Elevated Hgb and Hct

  Caubet J-F, et al: Spine 2009

- No Δ
  - p_a0_2, p_aCO_2, HCO_3, Resp rate

    Ramirez N, et al: JPO 2009

Functional effects

The "So What" Question

- Weight Gain

  Skaggs DL, et al: Spine 2009

- ↑ Activity

  Waldhausen JH, et al: J Peds Surg 2007

- Improved Health

  Ramirez N, et al: JPO 2010

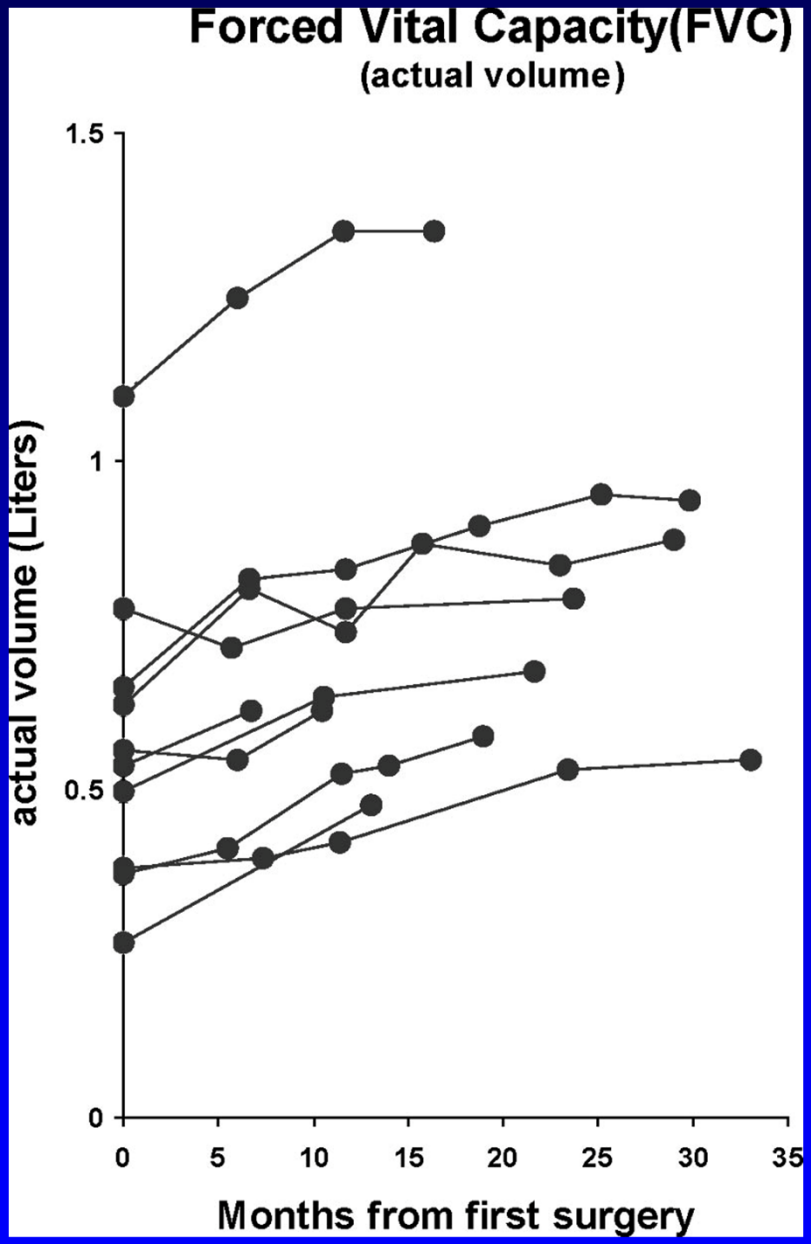
- ↓ Need for mechanical respiration

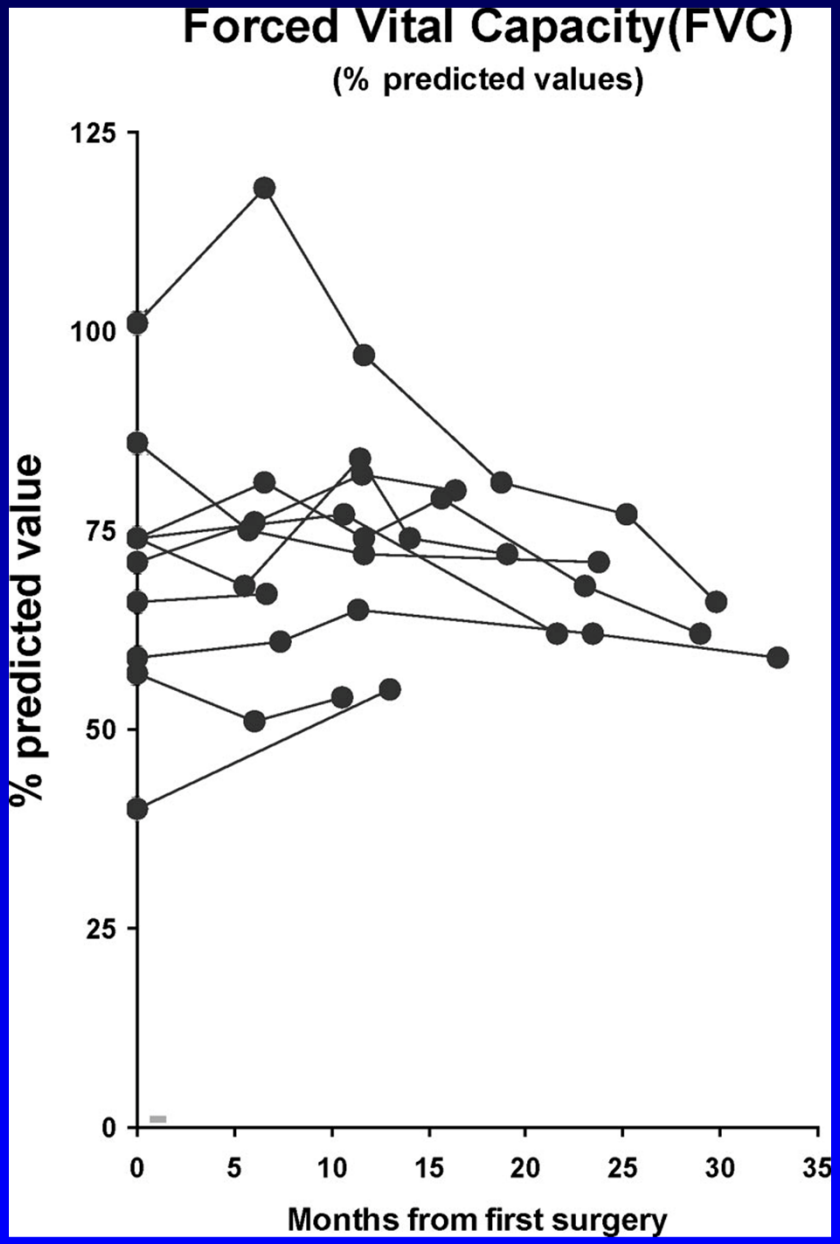
  Emans JB, et al: Spine2005
  Waldhausen JH, et al: J Peds Surg 2007
  Yazici M, et al: Spine 2009

Challenges

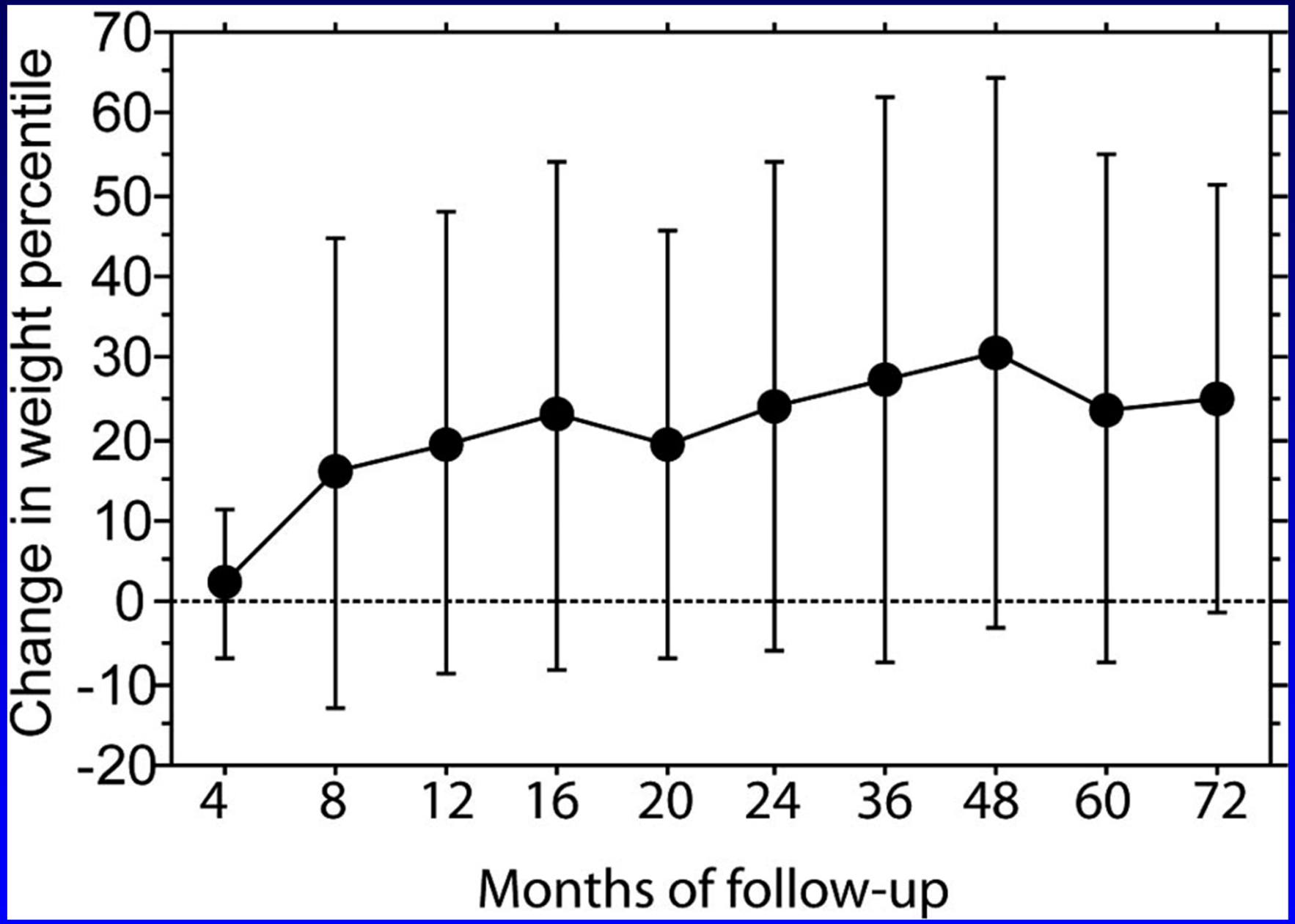
- All changes seen with treatment
- Seen in some patients, not all

- Immediate changes after insertion
  - FVC, Weight gain
  - Not sustained





Motoyama EK et al. Spine: 31, 284,2006



Skaggs DL et al. Spine: 34, 2530, 2009

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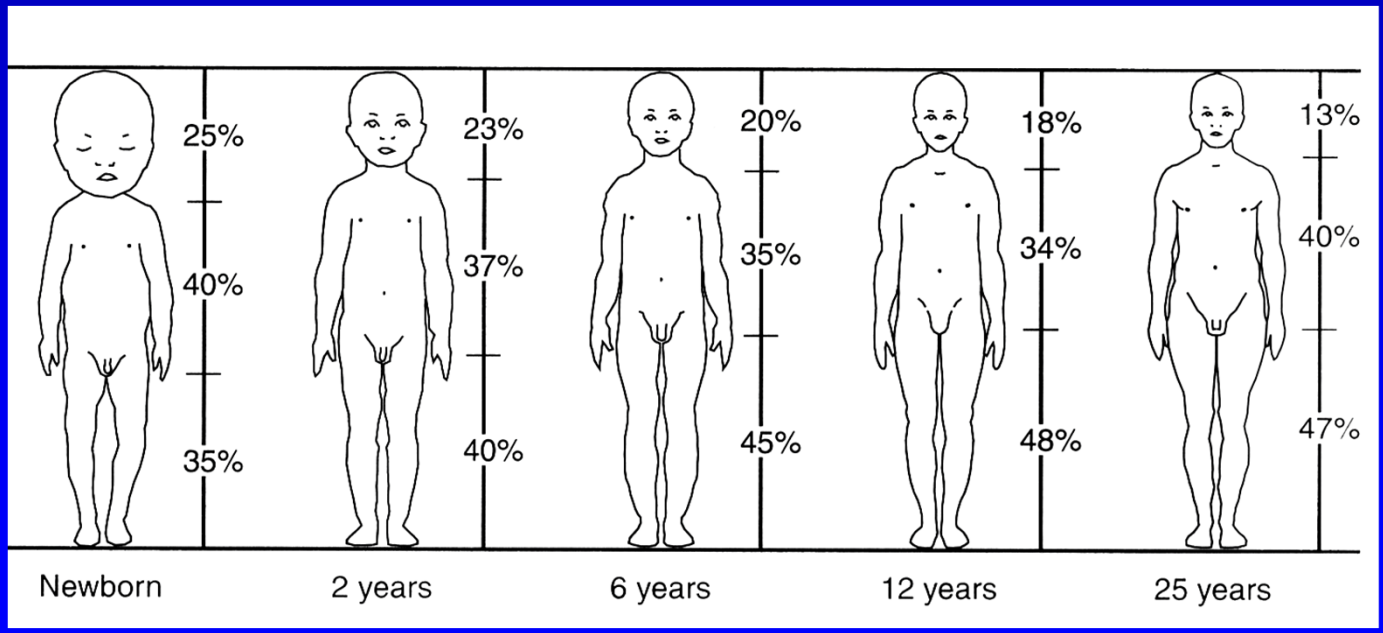
Challenge

- Treating children
- Children grow



- Are the changes seen
  - Result of the treatment?
  - Due to growth?

Series in Literature

- Single Center
- Database
  - Multicenter IDE Study
  - EOS database
- Mixed diagnoses
- Various ages

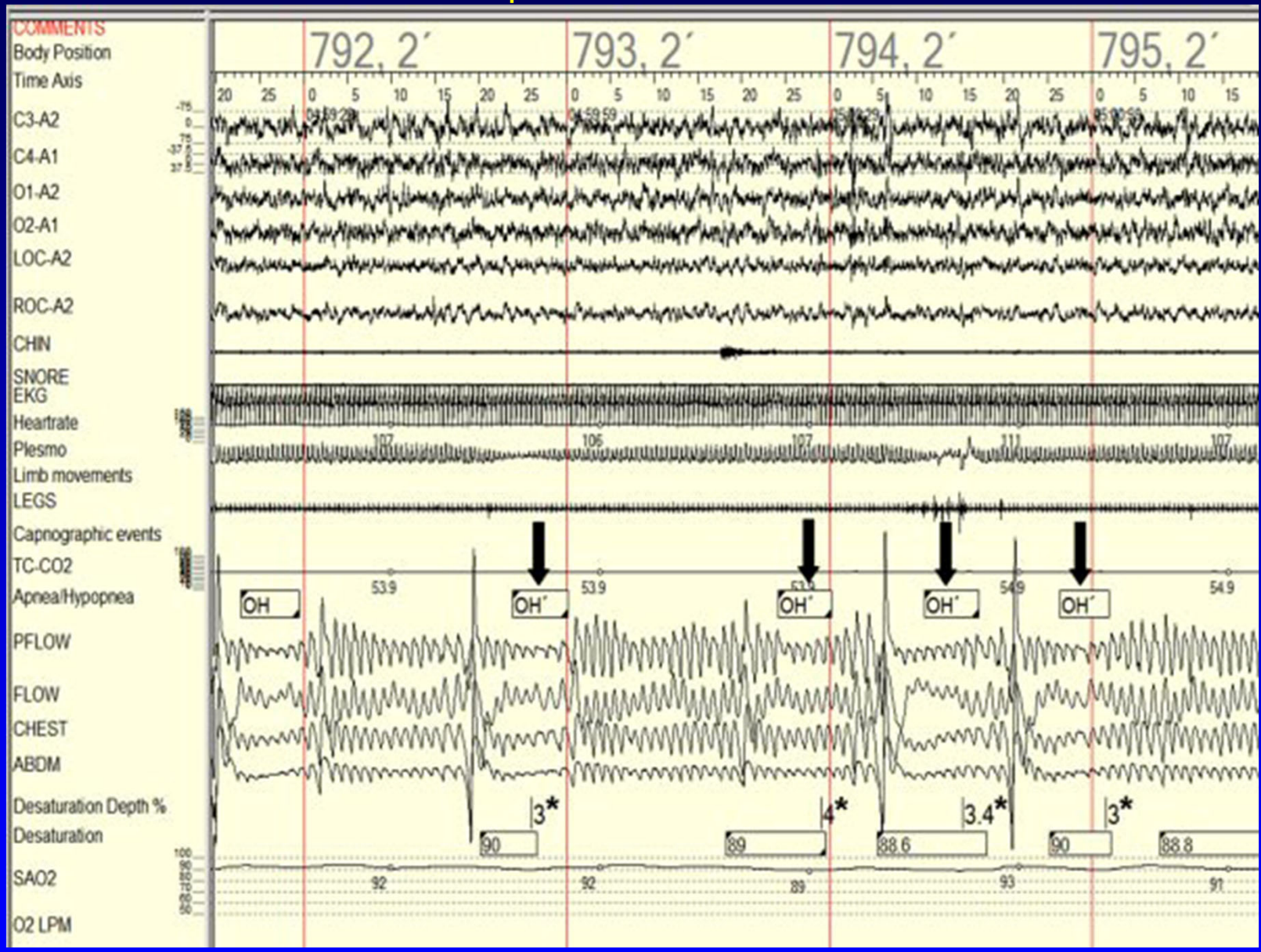
Challenges

- No untreated controls
  - Do not know the natural history of many diagnoses
  - Do not know the patient's natural history
- Need to compare
  - Casting/Bracing
  - VEPTR
  - Growth rods
  - Early fusion

Need to measure

- O_2 consumption, O_2 need
  - Differ
    - Active IIS
    - Wheelchair bound N/M
- Exercise Tolerance
- Thoracic cage excursion / compliance
  - During treatment
  - After treatment
- Sleep disturbance

Sleep Disorder in EOS



Streigl A et al. Ped Pulmonol: 45, 469, 2010

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Ultimate question

- What happens in adulthood?
  - Scoliosis
  - Pulmonary function
  - Quality of life
- Effect of disease
- Effect of treatment

There is nothing that destroys confinence…

Like follow-up!

Biggest Challenge

- Young field
- Small patient numbers
- In young children ultimate analysis of treatment only at end of growth

- Normal early enthusiasm

Challenge

- Assess and compare studies
- Varied
  - Diagnoses
  - Ages
  - Treatments
  - Varied follow-ups

Same problem in AIS Brace treatment

- Guidelines from a working group
  - Series make up
  - Assess results

Standardization for criteria for AIS bracing studies

- Inclusion criteria
  - Age 10+ at initiation of Rx
  - Initial curve 25° - 40°
  - Risser 0-2
  - Female
  - Pre menarchal or < 1 year post menarchal
- Results – minimal 2 yr F/U
  - 5° or less progression, 6° or more
  - % progressed to > 45°
  - % surgery undertaken or recommended

Richards B et al, Spine 30:2068, 2005

Should this occur in EOS studies

- Working group
  - Study guidelines
  - Outcome assessment
    - Curve assessment
    - Spine growth
    - TIS
    - Function

Early Enthusiasm

Diagnosis

Skin coverage

Age

Function

Respiratory Support

TIS

Pneumonia

Family support

Cast

Rods

Single

Double

VEPTR

Rib-rib

Rib-spine

Screws

Hooks

Rib-pelvis

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What Light?

I'm still looking for the Tunnel

A Triumph of Technology over Principles

A Triumph of Technology over Reason


Primum
non
nocere

First – Do no Harm

Thank You

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Minneapolis, Minnesota
USA