

# The 3 Studies that Should be Done over the Next Few Years to Help Us Improve the Care of Children with EOS

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# Evolving State of EOS

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- Expanding array of surgical techniques
- Growing research interest

## Variability of Expert Opinion in Treatment of Early-onset Scoliosis

Michael G. Vitale<sup>1</sup>✉, Jaime A. Gomez<sup>2</sup>, Hiroko Matsumoto<sup>1</sup>, David P. Roye Jr<sup>1</sup> and **members of Chest Wall and Spine Deformity Study Group**

*Vitale et al*, Clinical Orthopaedics and Related Research 2011

**Simultaneously emerging treatment options have led to significant variability in surgeon decision-making**

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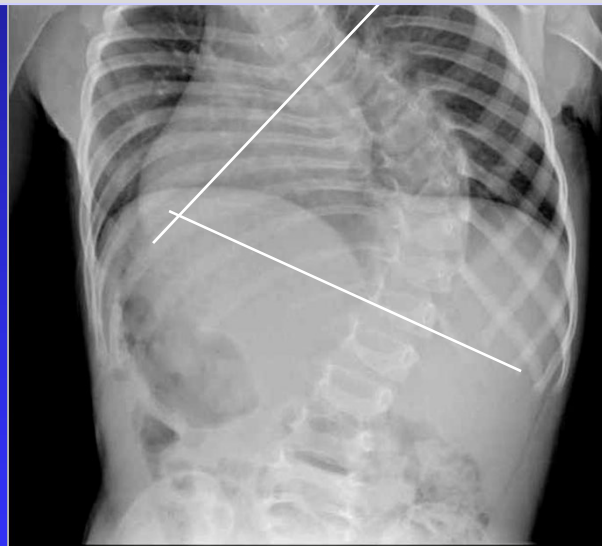
## Variability Study: Case 3 / 10:

18 mo Jehova's witness with undx "mild mitochondrial disorder"

77 deg bending to 56, progressed 60 deg/yr



*Unexplained variability reflects suboptimal care*



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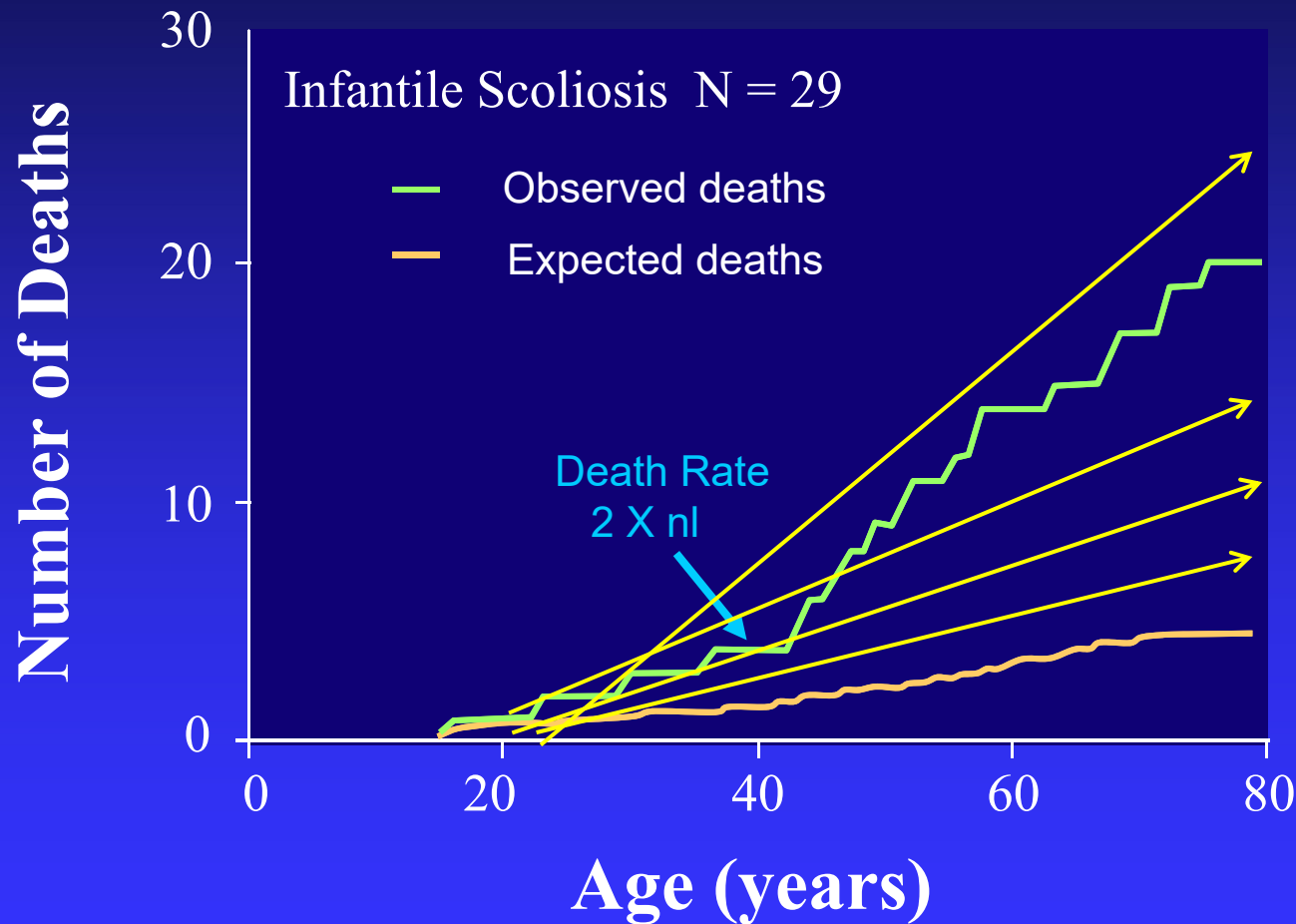
Interobserver: 8/13 surgery; 4/13 thoracostomy, 2VEPTR, 1GR, 1Fusion

Intraobserver: 50% changed plan

Vitale, Smith, Emans et al, CORR 2010

## What We Have Learned

# Infantile Idiopathic Scoliosis Results in Shorter Life



Pehrsson, Larsson, Oden & Nachemson, Spine, 1992

# Standardizing EOS Management: Answering the Call for Higher Level of Evidence Studies

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- **Two Dedicated EOS Study Groups have emerged:**
  - **The Chest Wall and Spine Deformity Study Group**
  - **The Growing Spine Study Group**



- **Comprehensive research infrastructure via 5 parallel efforts:**
  - **Endpoints**
  - **Equipoise**
  - **Classification**
  - **Standardizing Complications**
  - **Clinical Trials**

# Improving the Evidence Base in EOS

## *Development of a Research Infrastructure Via Five Parallel Efforts*

Endpoints

Development/Validation of a Disease-Specific QoL Measure

Equipoise

Identifying Clinical Equipoise in the Field of EOS

Classification-EOS

Development / Validation of Classification for EOS

Standardizing  
Complications

Standardize Way We Define and Report Complications

Clinical Trials

Proximal Anchors: Rib Vs Spine – Retrospective  
(Prospective Underway)

# Top 10 Areas of Equipoise

*Vitale et al, JBJS 2013*

1	In idiopathic children <9yo, with curves >60 degrees, what should the lengthening intervals be?
2	In idiopathic 1-3yo children with 30 degree curves, should we observe or cast?
3	In children >12yo who have finished lengthenings of distraction based treatments, should we observe, remove growing constructs or fuse?
4	In 3-6yo children with severe kyphosis, should we use rib or spine based distraction?
5	In idiopathic 2-3yo children with 90 degree curves, should we use spine or rib based distraction?
6	In high tone neuromuscular children with 90 degree curves who are ambulatory but have pelvic obliquity, should we use pelvic or non-pelvic fixation?
7	In idiopathic 9yo children with 30-40 degree curves who have progressed 30 degrees (last 6 months), should we treat conservatively, use growth modulation or other?
8	In an idiopathic 1-2yo child with a 60 degree curve, should we be bracing or casting?
9	In 9yo children with 90 degree curves, should we distract (rib or spine-based) or fuse?
10	In idiopathic 3-9yo children with 60 degree curves, should we be conservative or employ distraction based techniques?

# Lengthening Interval in Growing Rods



**Cast Vs brace in 2-4 year old with IIS**

# **Spine Vs Rib Based Proximal Anchors**

# **Role of Growth Modulation in JIS**

# Handling the VEPTR Graduate

**But what we need to know first is...**

*Is any of this better than Natural History?*

# Natural History of Untreated Scoliosis

## Weinstein et al 1981:

- No increase in mortality in idiopathic scoliosis with onset after age 8

## Branthwaite et al 1986:

- Respiratory failure in idiopathic scoliosis with onset before age 5

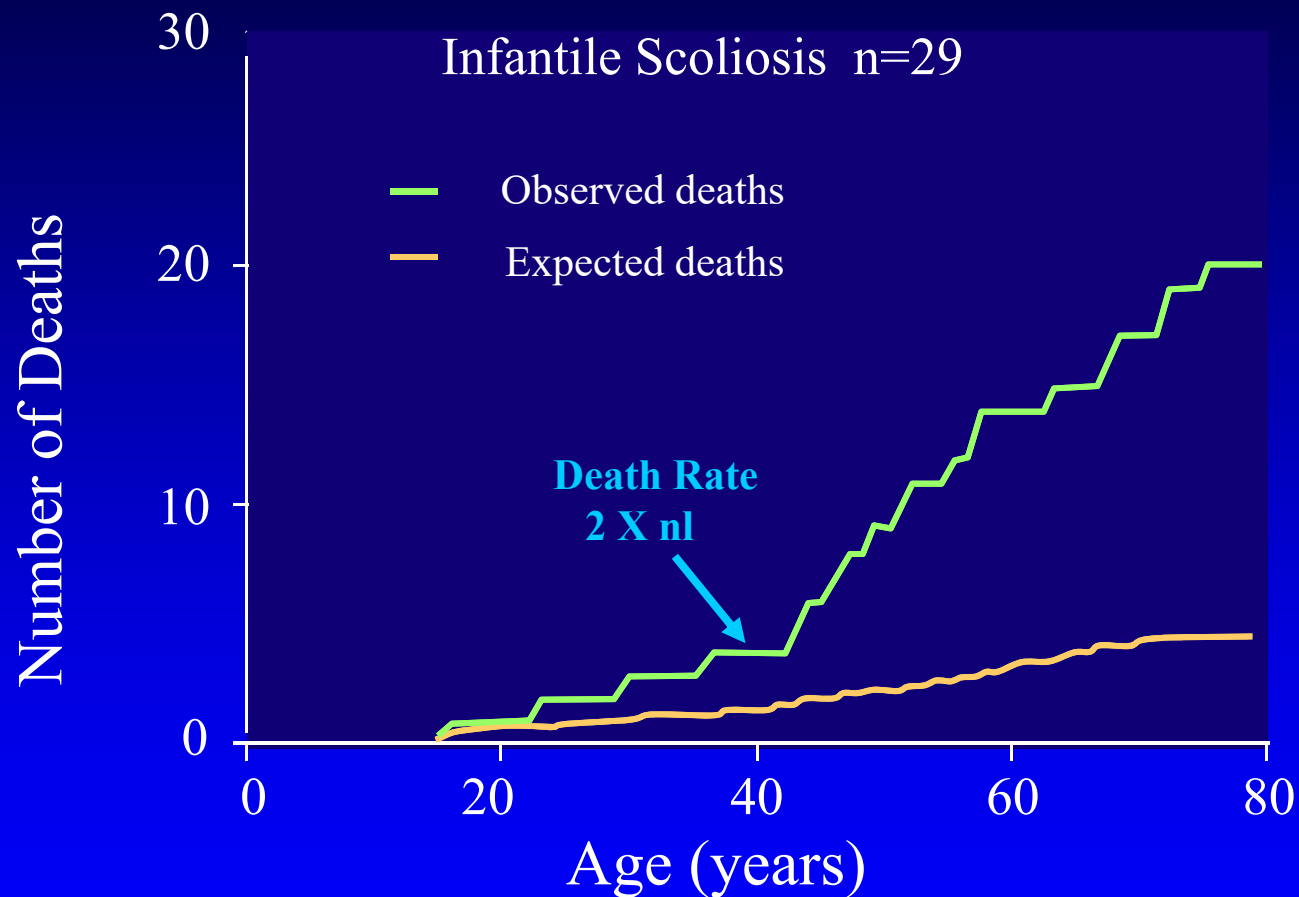
# Natural History of EOS

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**We need more studies that investigate the  
Natural history of EOS**

**How?**

# Can we revisit Pehrsson data?



Pehrsson K, Larsson S, Oden A, Nachemson A, Spine, 1992



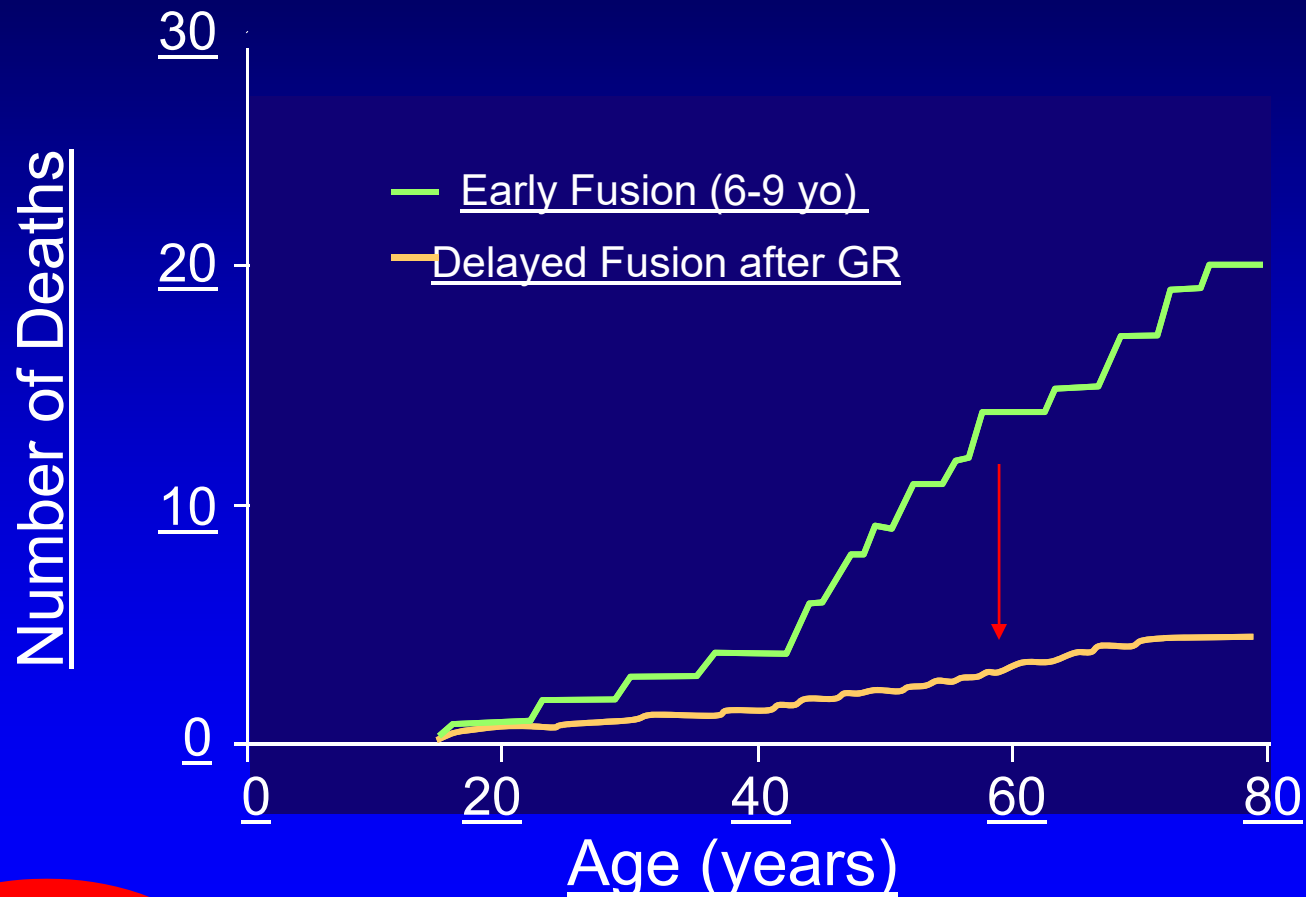
## **What about early fusion vs delayed fusion with growth strategy?**

- **Inclusion; Children 7-9 year old with curves >60 degrees**
- **Height > ?; Weight > ?**
- **Randomize to Growth Rods vs Fusion**

# RCT: 30 year f/u of EOS VS NonFusion

## Early Fusion (6-9 Year old)

### Growth Strategies/ Delayed Fusion



Vital et al., NEJM, 2014

What We Need to Know

# Why has it been so difficult to understand pulmonary outcomes and effect of intervention on pulmonary function?

- Do we need a national study of pulmonary norms in the developing child?
- What endpoints would be of value?

# Improving the Evidence Base in EOS

## *Development of a Research Infrastructure Via Five Parallel Efforts*

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Equipoise

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Classification-EOS

Development / Validation of Classification for EOS

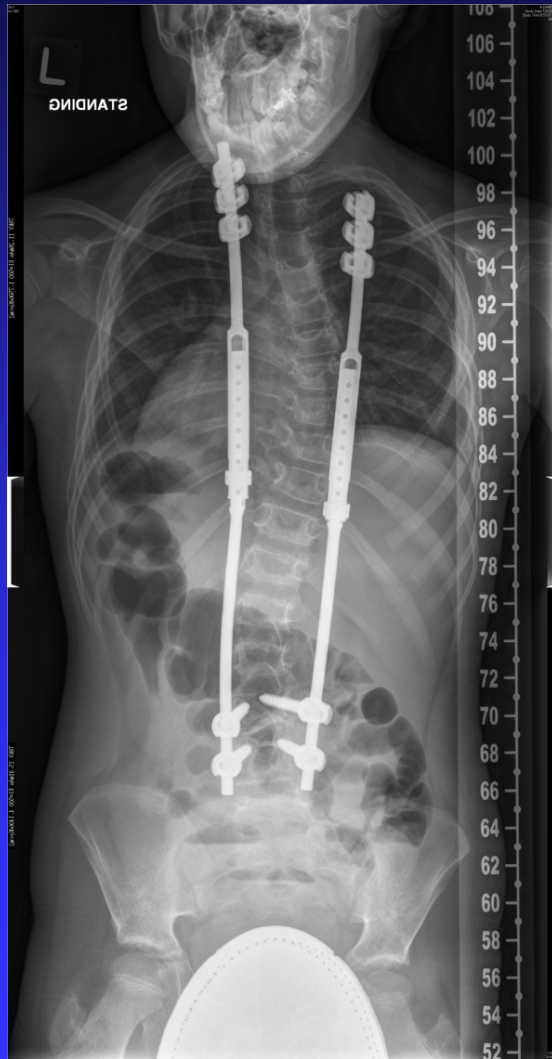
Standardizing  
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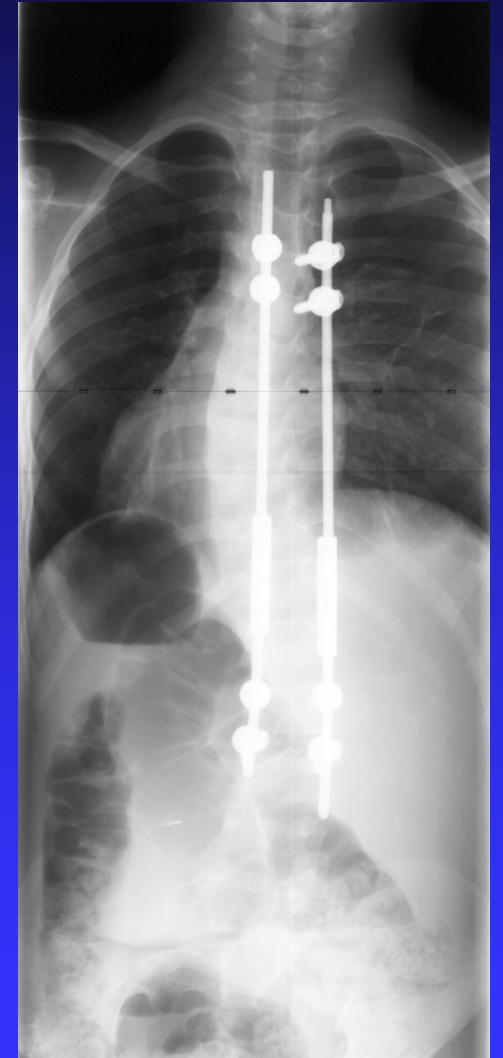
Clinical Trials

Proximal Anchors: Rib Vs Spine – Retrospective  
(Prospective Underway)

# Rib vs Spine Anchors



To examine the outcomes of **rib vs. spine based proximal anchors** in growing instrumentation surgery



# Retrospective Rib vs Spine

## Design:

*Retrospective review of CSSG & GSSG databases*

## Participants:

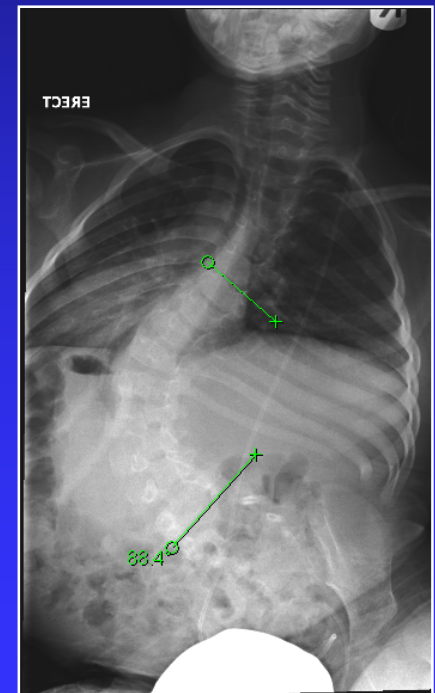
- Average Follow up - 5 yrs post op
- Age 2-10, Any Cobb Angle
- Underwent growing instrumentation surgery

## Outcomes:

- Cobb correction:
  - Short-term = <1yr, prior to 1<sup>st</sup> lengthening
  - Long-term = >2yrs, Cobb at last recorded f/u
- Complications

## Analysis

- Stratify by C-EOS



# Study Limitations

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1. Retrospective study design
2. Complications defined differently between study groups
3. Hard to stratify – apples vs apples?
4. Lung function and quality of life ?

**Impetus for prospective trial of Rib vs. Spine-based proximal anchors**

# Prospective Rib vs Spine

## Design:

*Prospective, multi-center study of growing instrumentation surgery*

## Participants:

### • Inclusion:

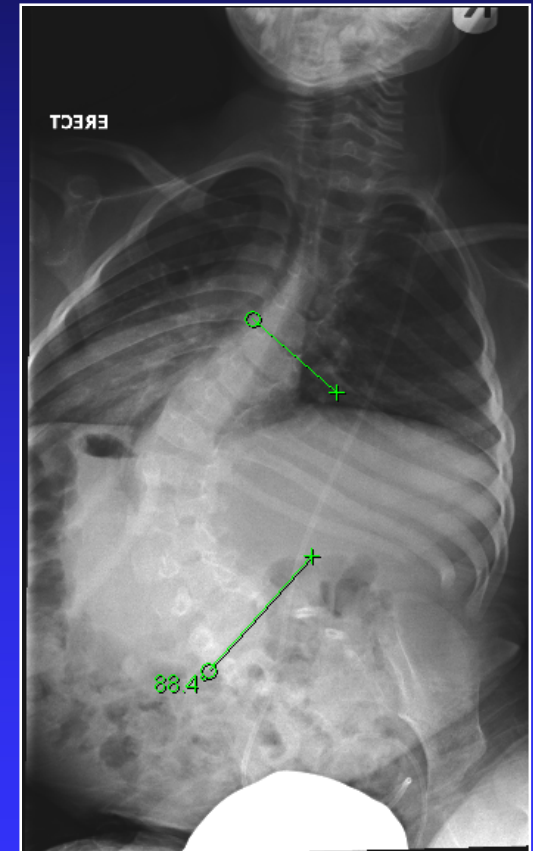
- EOS
- 3.0 – 9.9 years of age
- Cobb  $> 40^\circ$
- Undergoing rib or spine based proximal anchor growing instrumentation
- Able to Complete EOSQ (English or Spanish)

### • Exclusion:

- Prior spine surgery
- Guided-growth constructs, MCGR

## Outcomes:

- Cobb correction (6 mo post-op):
- Complications
- HRQoL (EOSQ-24 6 mo post-op)





# Study Limitations

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Although Prospective design is superior to retrospective, study design still has limitations

1. Complications defined differently between study groups
2. The pre-op and post-op evaluations (Cobb, pt characteristics, and EOSQ) are not consistent between the registries, making comparisons difficult

Impetus for Randomized Clinical Trial of Rib vs. Spine-based proximal anchors

# What We Need To Do

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***Randomized Control Trial*** comparing Rib vs  
Spine proximal anchors

**Consistent Outcomes measured at consistent intervals are key to determining clear results and conclusions:**

- Cobb correction
- Complications
- HRQoL (EOSQ-24)

# Conclusions

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## What Needs to be Done

1. **Natural History**
2. **Early Fusion vs Growth Rods**
3. **Rib vs Spine Fixation**



# THANK YOU

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