Proximal Rib versus Proximal Spine Anchors In Growing Rods: Early Results of a Prospective Multicenter Study

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-Disclosures-

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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
Complications Classification	Standardize Way We Define and Report Complications
Clinical Trials	Proximal Anchors: Rib Vs Spine – Prospective

GSF
Growing Spine Foundation

CHILDREN'S SPINE FOUNDATION

Proximal Fixation is a Topic of Significant Equipoise

Corona et al. *Evaluating the Extent of Equipoise among Treatment Options for Patients with Early Onset Scoliosis. JBJS 2013*

1. In idiopathic 2-3yo with 90 degree curves, should we use **spine or rib** based distraction?
2. In 3-6yo with severe kyphosis, should we use **spine or rib** based distraction?
3. In children >12yo who have finished lengthenings, should we observe, remove growing constructs, or fuse?
4. In idiopathic children <9yo with curves >60 degrees, what should the lengthening intervals be?
5. In idiopathic 9yo with 30-40 degree curves who have progressed 30 degrees (last 6 months), should we treat conservatively, use growth modulation (VBS), or other?
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?

Correction and Complications in the Treatment of EOS: Is there a Difference between Spine vs. Rib-based Proximal Anchors?: a retrospective study

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Combined Project of GSSG and CSSG

NewYork-Presbyterian
Morgan Stanley Children's Hospital
Columbia Orthopaedics
Columbia University
Medical Center

Retrospective Study

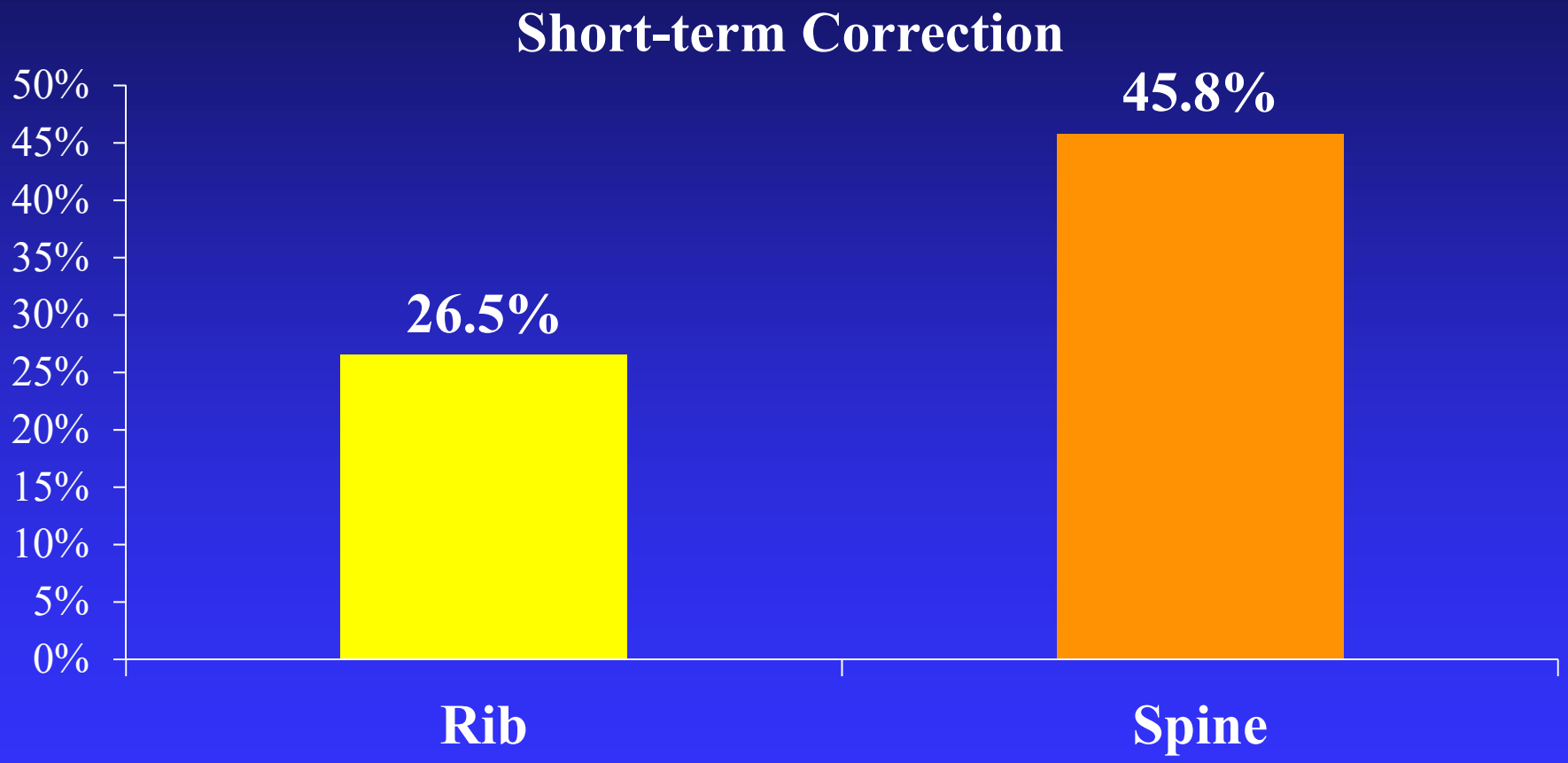
No Difference in Age or F/U

	Rib	Spine
GSSG	29	155
CWSDSG	153	0

	Rib	Spine
N	182	155
Age at Index Surgery	5.1	5.9
Mean F/U from Index	5.4	5.2

337 patients at 5 years after surgery

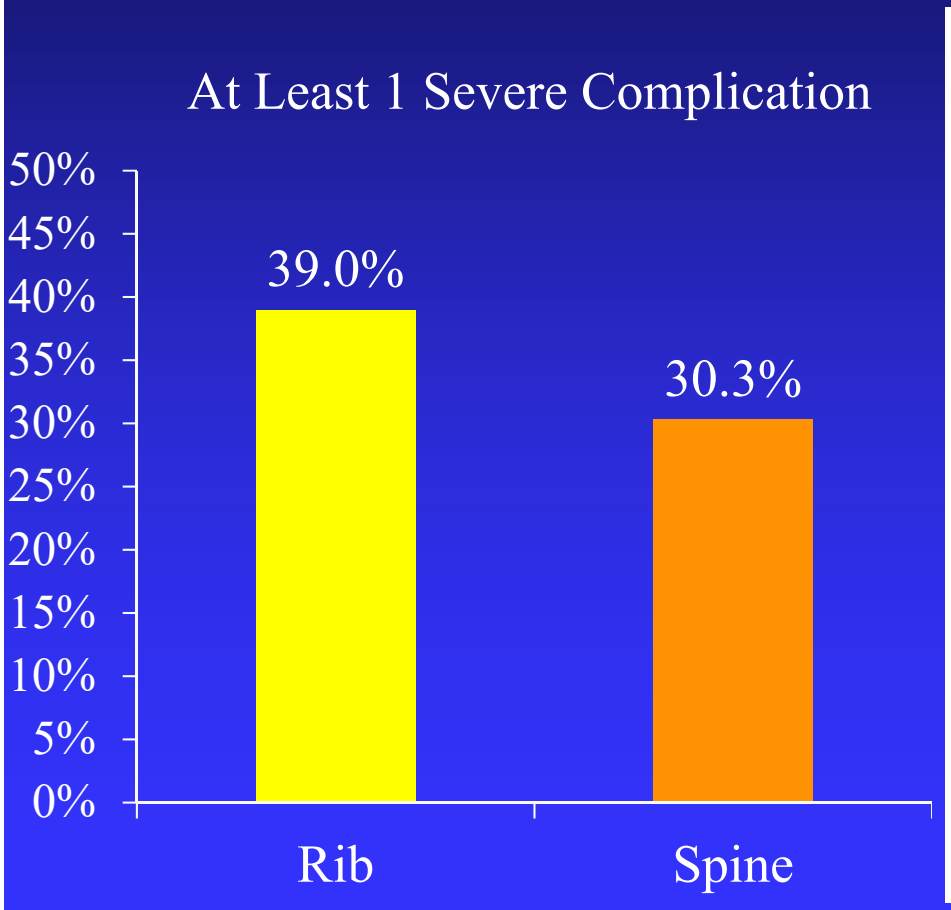
Spine-based proximal anchors achieve greater short-term (<1yr) Cobb correction

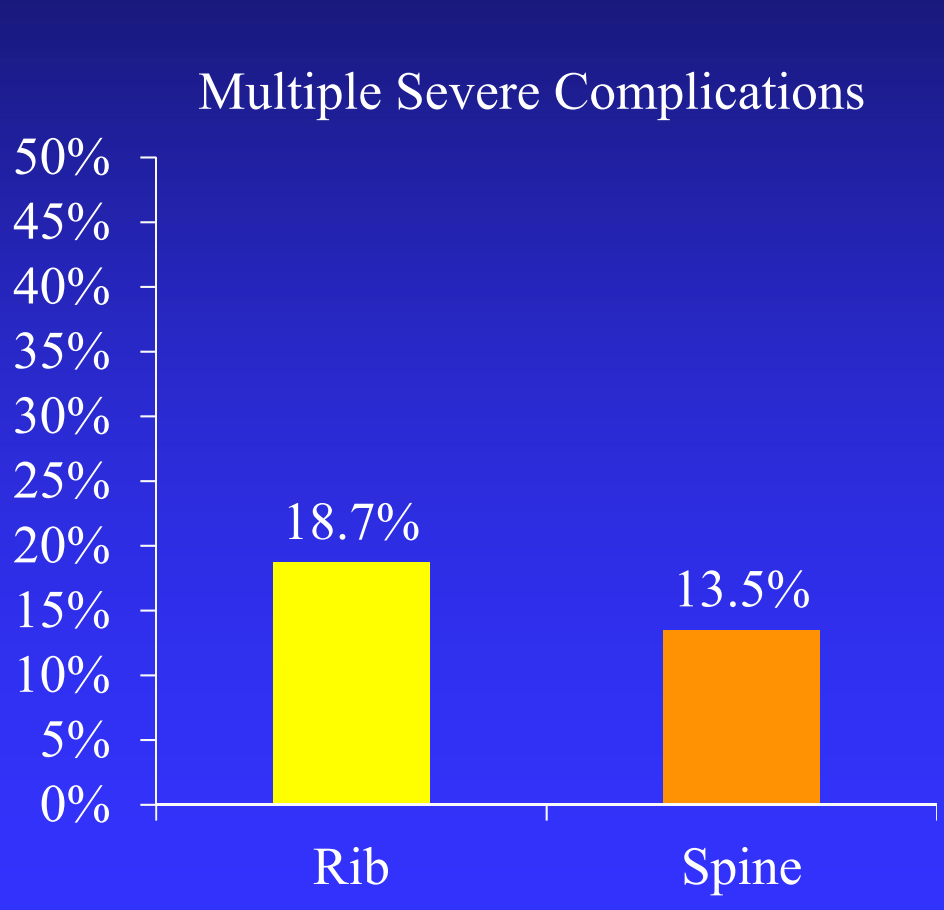


P < .001

More Grade I Complications in Rib Group but no difference in rates of Grade II or III

Severe (Class 2 or 3): Complications requiring unplanned trip to OR, hospitalization, or change in treatment plan





Conclusions- Retrospective

1. Spine-based proximal anchors superior with respect to acute and long-term Cobb correction

2. Rib-based proximal anchors associated with more complications, but no difference in complications which change treatment

Limitations- Retrospective Study

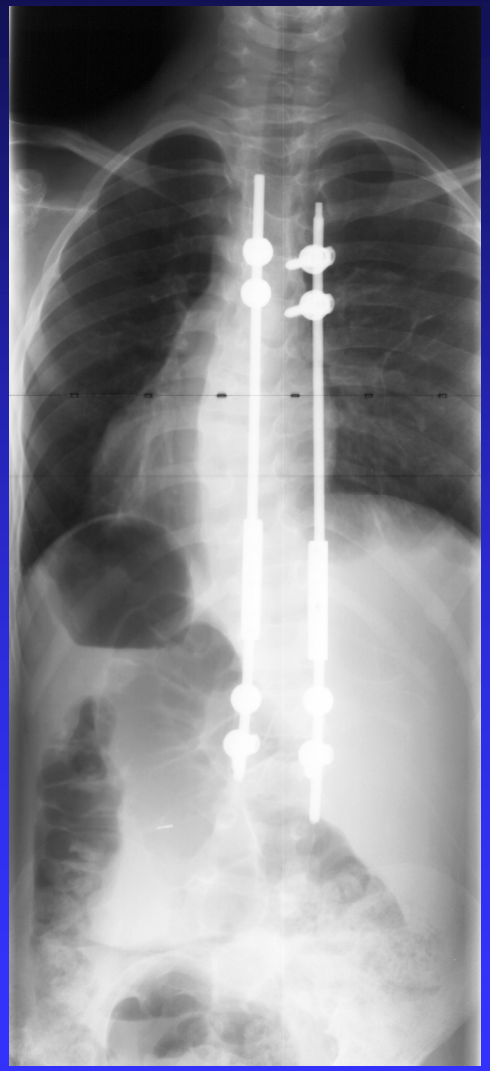
1. Complications defined differently between study groups

2. Hard to stratify – apples vs apples?
   - Are patients equivalent;
   - Implant characteristics
   - Difference is Study Group Protocols

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

Purpose: Prospective Study

To compare outcomes of **RIB** versus **SPINE** based Proximal Anchors in growing instrumentation surgery.



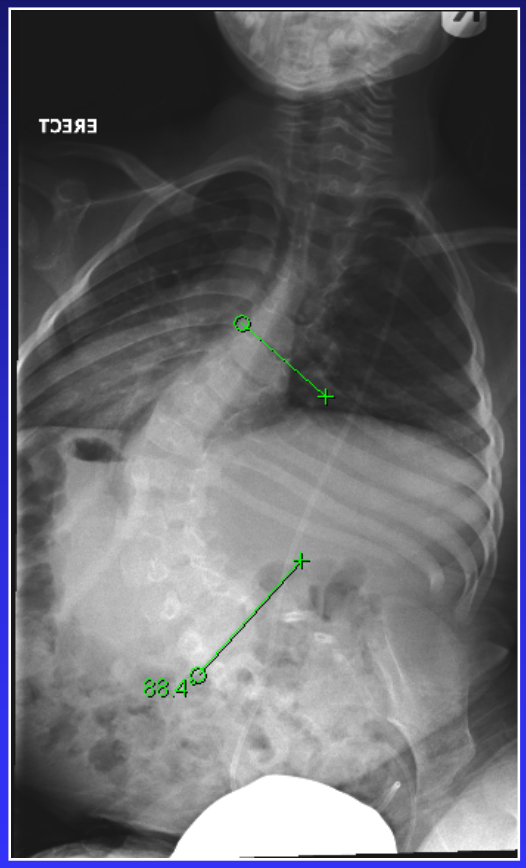
Methods

Design:

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

Participants:

- **Inclusion:**
  - **EOS**
  - **3.0 – 9.9 years of age**
  - **Cobb > 40˚**
  - **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 – over time
- HRQoL (EOSQ-24 6 mo post-op)

Patient Characteristics

Total (n) = 77	Rib Anchors	Spine Anchors	P-value
Subjects (n)	60	17	
Age (yo)	6.6 ± 2.0	6.7 ± 1.5	0.858
Gender	40.0% male	35.3% male	0.730
Weight (kg)	19.5 ± 6.8	20.4 ± 5.3	0.644
Height (cm)	108.0 ± 18.2	110.6 ± 12.1	0.652
Sitting Height (cm)	55.2 ± 7.9	63.8 ± 15.6	0.054
Arm Span (cm)	112.9 ± 17.4	114.4 ± 16.2	0.823
Kyphosis (deg)	47.6 ± 24.6	44.4 ± 15.3	0.709
Cobb (deg)	66.9 ± 15.1	73.6 ± 14.0	0.129
Follow up (years)	0.97 ± 0.55	1.09 ± 0.57	0.446

Analyzed Correction by The Classification for Early Onset Scoliosis

Etiology	Cobb Angle (Major Curve)	Maximum Total Kyphosis	Progression Modifier (optional)
Congenital/Structural	1: ≤20°	(-) ≤20°	P0: <10°/yr
Neuromuscular	2: 21-50°	N: 21-50°	P1:10-20°/ yr
Syndromic	3: 51-90°	(+): >50°	P2: >20°/yr
Idiopathic	4: >90°		

No Differences in C-EOS

Total (n) = 77	Rib Anchors	Spine Anchors	P-value
Etiology (72)	60	17	0.433
Congenital (C)	16.7% (10)	5.9% (1)	
Neuromuscular (M)	50.0% (30)	41.2% (7)	
Syndromic (S)	16.7% (10)	23.5% (4)	
Idiopathic (I)	16.7% (10)	29.4% (5)	
C-EOS Cobb (56)	44	16	0.718
2: 20-50 (deg)	13.6% (6)	6.3% (1)	
3: >50 – 90 (deg)	81.8% (36)	87.5% (14)	
4: > 90 (deg)	4.5% (2)	6.3% (1)	
Kyphosis (21)	11	10	0.625
(-): < 20 deg	7.1% (1)	9.1% (1)	
N: 20 – 50 deg	57.1% (8)	72.7% (8)	
(+): > 50 deg	35.7% (5)	18.2% (2)	

Surgical Characteristics

Total (n) = 77	Rib Anchors	Spine Anchors	P-value
Subjects (n)	60	17	
Proximal Anchors	3.2 ± 1.6	4.9 ± 1.3	< 0.001
Instrumentation Type	57 VEPTR 3 GR	2 VEPTR 15 GR	

No significant difference in Cobb angle correction between patients who received rib vs spine anchors

	Rib	Spine	P-value
Subjects (29)	17	12	
Pre-Op Cobb	64.8 ± 20.0	75.3 ± 12.6	0.121
6 mo Cobb Correction (%)	32.5 ± 26.8	39.8 ± 19.2	0.426

No significant difference in the QoL EOSQ scores between patients who received rib or spine anchors

	Rib	Spine	P-value
Subjects (25)	20	5	
Pre-Op EOSQ QoL Domain	63.9 ± 22.9	74.7 ± 22.7	0.354
6 mo Score Change (%)	7.0 ± 26.5	-6.2 ± 31.1	0.349

Proximal Device Migration

23 Patients total had > 1.2 years follow up.
Of those patients 4 had a proximal device migration

	Rib Anchor	Spine Anchor
Subjects (23)	18	5
Device Migration Events	4 (22%)	0

Implant Density

Of 18 Patients with Rib Anchors with > 1.2 years follow up, no patient with 5 or more proximal anchors experienced migration

	≥ 5 Prox Anchors	3 – 4 Prox Anchors
Subjects (18)	4	14
Device Migration Events	0	4
	0%	29%

Complications: All Device Related

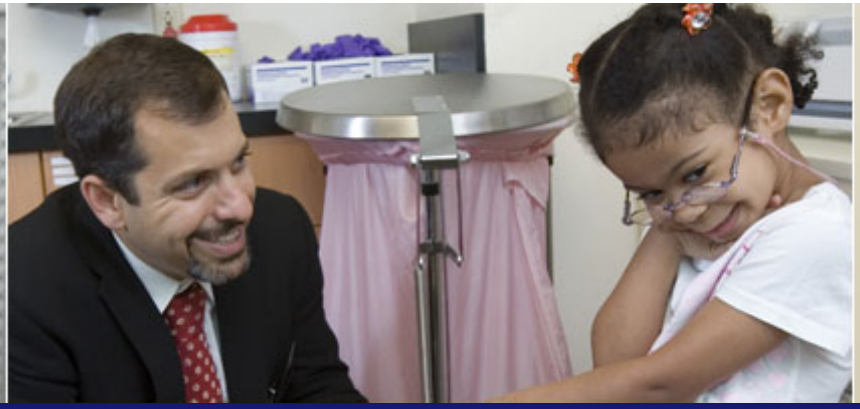
Subjects (12)	VEPTR/Rib (11)	TGR/Spine (1)
Total CCx	**14**	**1**
Grade I	**8**	**1**
Device Migration	4	1
Loss of IONM	1	
Spine Infection	1	
Rib Fracture	1	
Hardware Failure	1	
Grade II	**5**	
Device Migration	4	
Hardware Failure	1	
Grade III	**1**	
Spine Infection	1	

Conclusions: Rib Vs Spine Prospective

- No difference in Cobb angle Correction
- Only complication in Spine Anchor group consisted of distal rod loosing from pelvic anchor
- 5 or more rib anchors protective against proximal hardware migration

Limitations

- Early results with limited follow up
- Prospective but non randomized study may still reflect biases in patients and also in differences in study group reporting
- Do we need a RCT?


THANK YOU

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