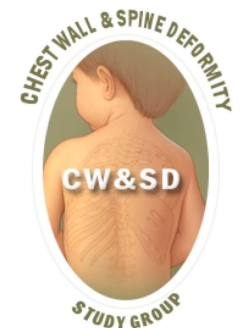


4th Annual ICEOS

To Operate or Not to Operate? Determining the Optimal Timing of Surgical Intervention for Patients with Early Onset Neuromuscular Scoliosis

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Chest Wall and Spinal Deformity Study Group***



Background

- Lack of evidence has led to variation in EOS management among providers
 - CWSDSG - Vitale et al, CORR 2010
 - GSSG - Sponseller et al, JPO 2010
- Clear need for *higher level of evidence studies*
 - Environment of uncertainty
 - Discrepancies in opinion and practice

Need for Higher Level of Evidence at all levels of Clinical Decision Making

1. Timing of intervention - “When”

- Conservative vs. Surgical

2. Treatment modality - “How” in a broad sense

- E.g. distraction based vs compression based vs. fusion vs. guided growth

3. Treatment-specific variables

- E.g. choice of distal / proximal fixation
- E.g. lengthening intervals
- E.g. pelvic fixation or not

Equipoise: Can We Agree to Disagree?

- ‘Clinical Equipoise’ is the condition when there is no preference between available treatment options - all treatments are deemed equal
- Understanding the extent of equipoise between treatments, helps drive and focus research efforts
- Ethical foundation for randomized clinical trials



Purpose

- **To assess the consensus of experienced orthopaedic surgeons in choosing a conservative or surgical treatment for case scenarios of neuromuscular scoliosis**

Methods

- **Semi-structured phone interviews identified variables that surgeons consider important in EOS management decisions**
 - Age
 - Diagnosis / Co-morbidities
 - Cobb Size and Progression of Curve
 - Sagittal Alignment
 - Curve Flexibility
 - Nutritional Status / Fragility
 - Pulmonary Function
 - Chest Wall Involvement

EOS Treatment Preference Survey

- **Problem:** permutation of all these variables leads to an impractical number of different case scenarios (10,000+)
- **Solution:**
 - eliminated combinations of variables that were impossible or impractical, with random selection of the remaining permutation
 - Focus on “when” issue and high level “how,” leaving decisions regarding technical details for future work
 - E.g. S hooks vs. iliac screws

Methods

- **226 theoretical case scenarios**
 - 114 high tone
 - 102 low tone
- **11 pediatric orthopaedic spine surgeons recorded their treatment choice for each case scenario**
 - responses were grouped into non-operative management vs. operative

Methods

- Cases systematically varied by:
 - Age (3, 6, 9 years)
 - Cobb angle (30, 60, 90°)
 - Rate of progression (0, 15, 30°)
 - +/- Hyperkyphosis (>55°)
 - +/- impaired lung function
 - +/- chest wall involvement
 - +/- osteopenia / low BMI
 - +/- spinal rigidity

EOS Treatment Preference Survey

[Exit this survey](#)



1%

What would be your choice of management for this patient if they had shown

	Observation	Casting	Bracing	Rib based Distraction	Spine Based Distraction	Growth Guidance (e.g. Shilla)	Growth Modulation (e.g. VBS)	Spinal Fusion	Other-surgical
0° progression in the past 6 months	☐	☐	☐	☐	☐	☐	☐	☐	☐
15° progression in the past 6 months	☐	☐	☐	☐	☐	☐	☐	☐	☐
30° progression in the past 6 months	☐	☐	☐	☐	☐	☐	☐	☐	☐

Hypertonic Neuromuscular Scoliosis

(E.g. Spastic CP)

- 3 years old
- No supplemental respiratory support needed
- Osteopenic, low BMI
- Cobb: 30°
- Normokyphotic
- Flexible
- Chest wall involvement



Non-operative treatment

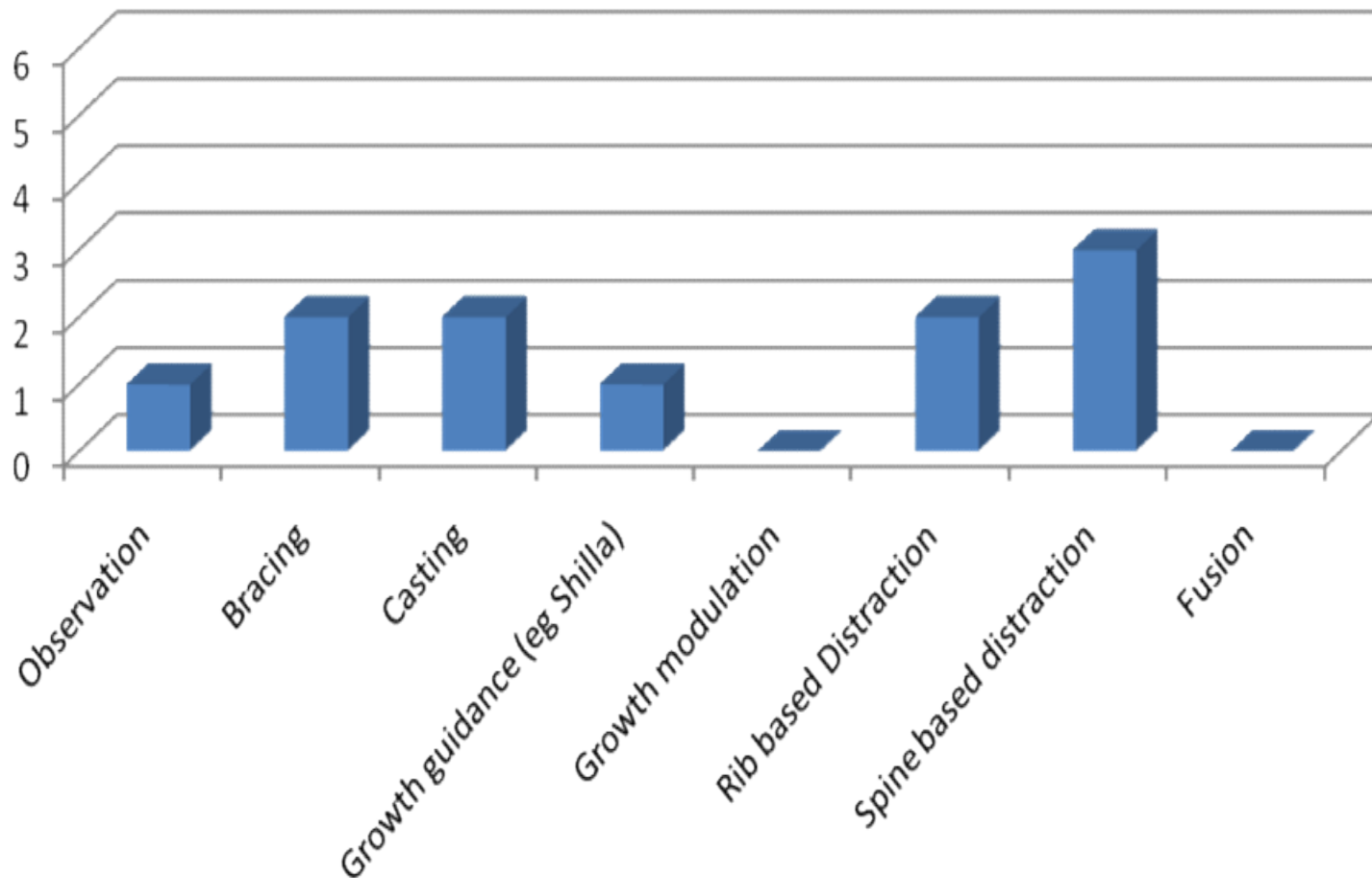
Operative treatment

[Next](#)

Methods: Statistical Analysis

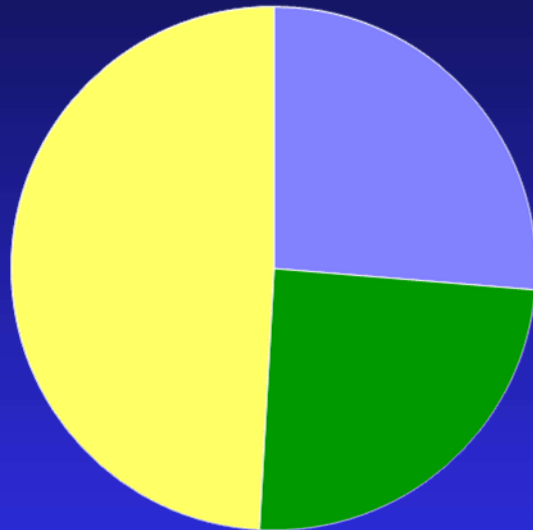
- Group consensus or uncertainty (equipoise) was identified with binomial distribution calculations
 - $p > 0.05 = 3:8$ ratio at least
- Associations between each case variable (i.e. age, Cobb, etc.) and the tendency towards group agreement/disagreement were assessed
 - Chi squared analysis – univariate relationships
 - Multinomial logistic regression – multivariate relationships
 - SPSS 17.0 was used for analysis

Example of Case with Complete Equipoise



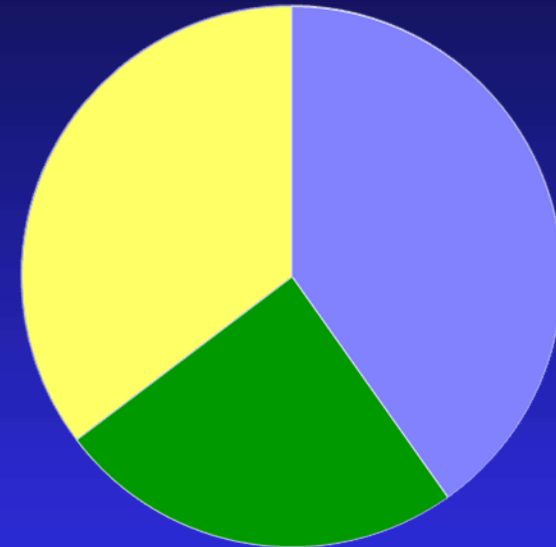
Results

HIGH TONE



- Operative Treatment in 56/114 (49.1%)
- Non-operative treatment in 30/114 (26.3%)
- **Group *equipoise* in 28/114 (24.6%)**

LOW TONE



- Operative Treatment in 36/102 (35.3%)
- Non-operative treatment in 41/102 (40.2%)
- **Group *equipoise* in 25/102 (24.5%)**

Results – Univariate Analysis

High tone

- Cobb $p < 0.001$
 - 100% of 30° curves managed conservatively
 - **75 % of 60° curves showed equipoise**
 - 97.9% of 90° curves were managed surgically
- Respiratory Involvement $p < 0.001$
- Flexibility $p = 0.003$
- Chest wall involvement $p = 0.051$
- All other factors were not significant

Results – Multivariate Analysis

High tone

- Relative to surgery as the baseline and looking at significant univariate predictors other than Cobb
 - Lack of respiratory involvement predicted conservative management ($p < 0.001$)
 - Lack of chest wall involvement predicted equipoise ($p = 0.049$)
 - Flexibility predicted equipoise ($p = 0.001$)

Results – Univariate Analysis

Low tone

- **Cobb $p < 0.001$**
 - 97.6% of 30° curves managed conservatively
 - 66.7% of 60° curves showed equipoise
 - 100% of 90° curves were managed surgically
- **Progression $p=0.009$**
- **Respiratory Involvement $p=0.012$**
- **All other factors were not significant**

Results – Multivariate Analysis

Low tone

- Relative to surgery as the baseline and looking at significant univariate predictors other than Cobb
 - Lack of respiratory involvement predicted equipoise management ($p=0.002$)
 - Progression 0 degrees predicted equipoise management ($p=0.001$)
 - Progression 15 degrees predicted equipoise management ($p=0.003$)

Summary

Areas of Equipoise

- **Equipoise in treatment of all 60 degree curves.**
- **75% of scenarios showed uncertainty and variability in treatment in a child with 60 degree**
 - **Especially in cases where chest wall involvement, respiratory issues, flexible curves and progression were present**
- **Tone, bone quality, BMI, and kyphosis, and age did not predict choice between conservative and surgical treatment in univariate analysis**

Limitations

- Any survey associated with some constraints
- Small group of clinicians
- Selected Cobb angle values
- Presence or absence of some co-morbidities
- BUT countered with
 - *Formal process of consensus building through a nominal group process effectively uncovers equipoise*

Discussion

Implications for Future Research

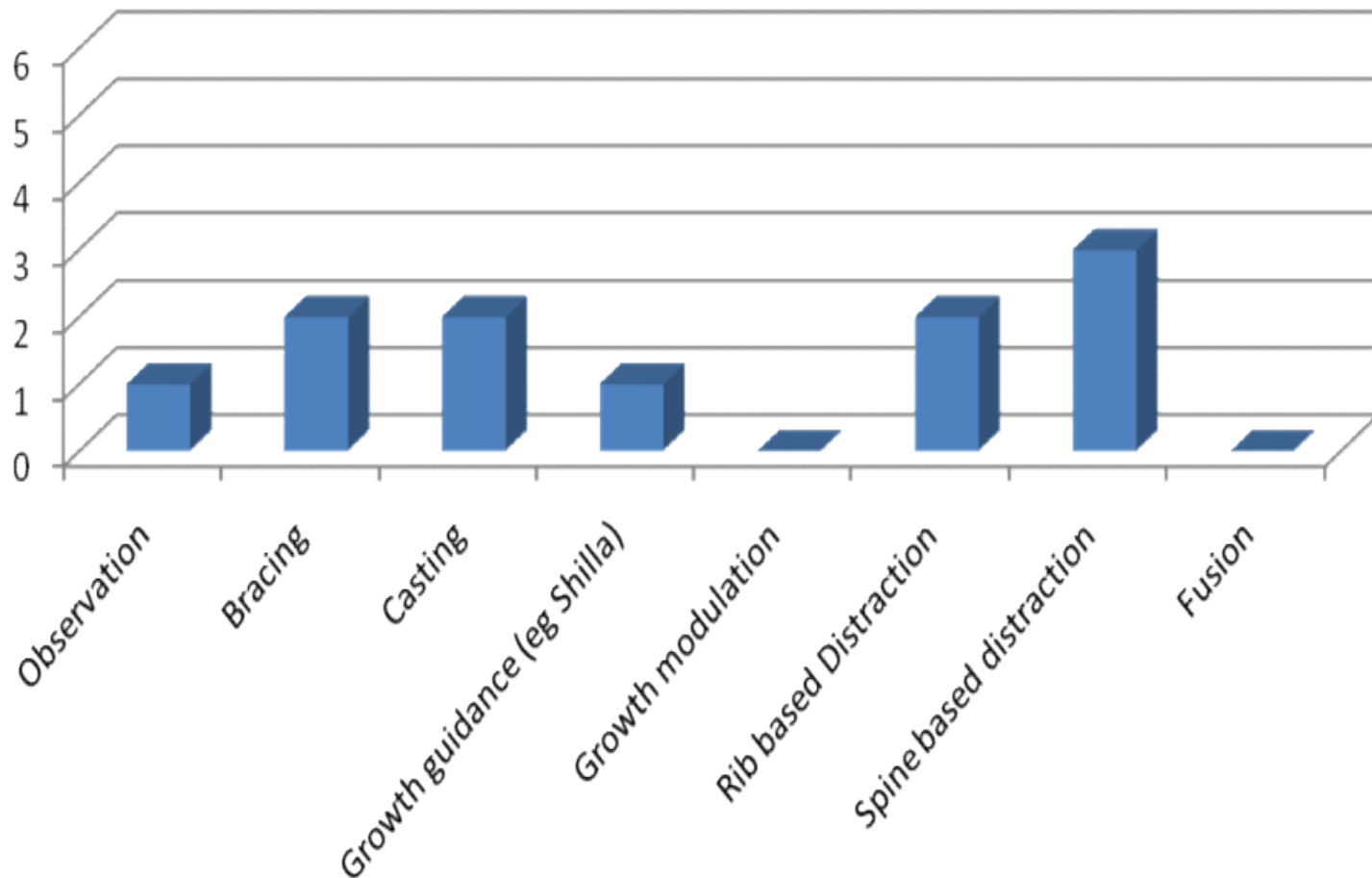
- Given a troubling amount of variability in children with 60 degree curves, future research should focus on developing evidence for treatment in this population
- Similar findings for idiopathic cases



Thank you

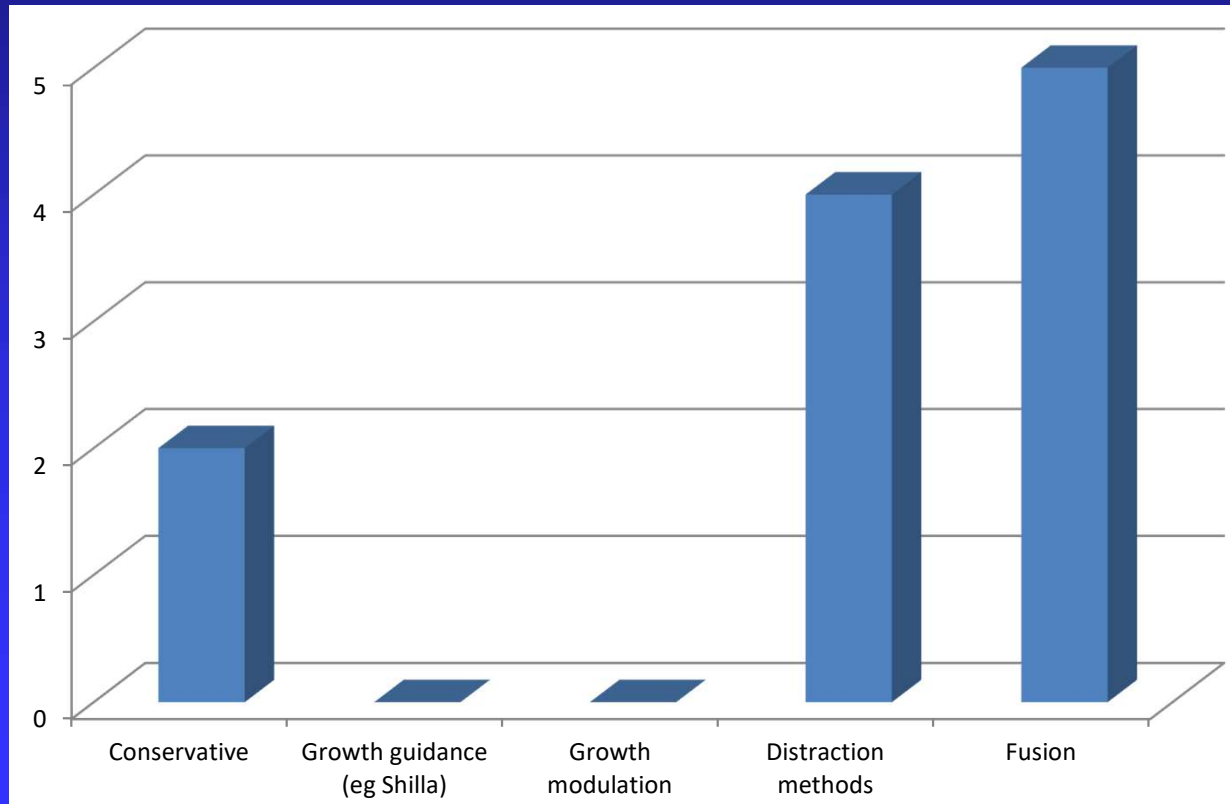
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Example of Case with Complete Equipoise



Example of Case with Complete Equipoise

Distraction/fusion equipoise: High tone, 9 year old, 90 degree Cobb, 0 deg prog past 6m, respiratory involvement, rigid spine and chest wall involvement

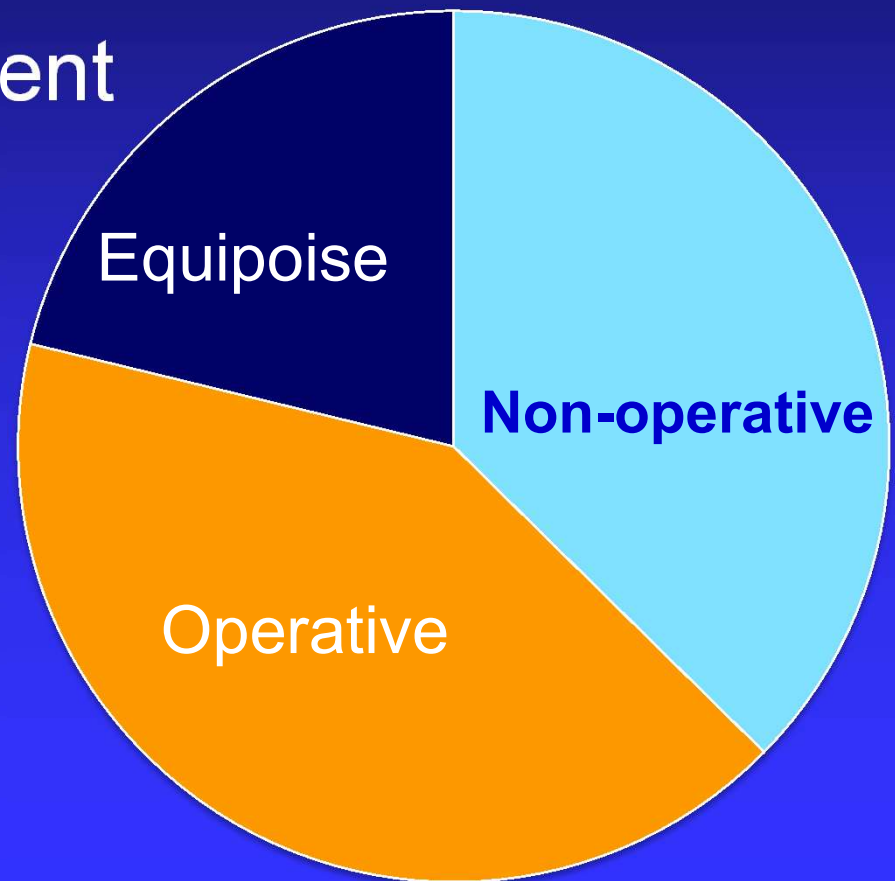




Results – High Tone NMS

What did we agree on?

- There was *consensus* for:
 - Non-operative treatment in 30/114 (26.3%)
 - Operative Treatment in 41/114 (41.4%)
 - Respiratory involvement (p=0.001)
 - Chest wall (p=0.051) involvement



Methods

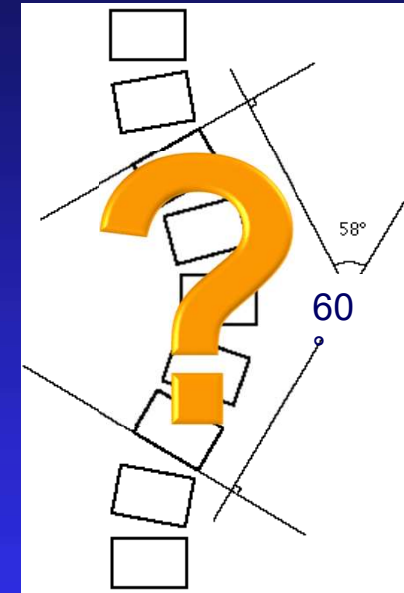
EOS Treatment Preference Survey

- Semi-structured interviews to identify key variables (e.g. diagnosis, age, progression)
- Theoretical patient scenarios created
- Group to identify “cut points” for decision making via online tool
- Quantitative analysis
- Nominal Group Process in ICEOS to finalize

Results – General Themes

Factors Associated with Management Choice

- Strong relationship between Cobb angle and type of management ($p < 0.001$)
 - 100% of 30° curves managed conservatively
 - 75 % of 60° curves showed equipoise
 - 97.9% of 90° curves were managed surgically



Surgeons were strongly influenced by Cobb angle when deciding between non-surgical vs. surgical treatment options

Discussion

Implications for Future Research

- Retrospective analysis of existing databases should focus on the management of Neuromuscular EOS in cases where high degrees of uncertainty were identified (e.g. children with slowly progressing 60° curves of ages)
- This study provides an impetus and ethical justification for randomized clinical trials in cases where there is no evidence that one treatment option will provide a better outcome than another
- Efforts are underway to understand what clinical variables drive decision making when choosing between:
 - The non-surgical treatments (observe vs. brace vs. cast)
 - The surgical treatments (growth guidance vs. growth modulation vs. rib-based distraction vs. spine-based distractions vs. fusion)