CDMI

CENTER FOR DISRUPTIVE MUSCULOSKELETAL INNOVATIONS

Development of Juvenile Scoliosis Spine FE Models to Understand Growth Rod Failure Mechanisms

PI: Aakash Agarwal, PhD
Co-PI: Vijay Goel, PhD
Trainee: Dikshya Parajuli, BS, Ardalan Seyed Vosoughi, BS

University of Toledo

Background

- Scoliosis treatment in juveniles
  - Growing rods
- Complications in growth rods
  - Implant-related complications
  - Fusion complications
  - Skin-related complications
  - Alignment complications
  - Neurologic complications [1]

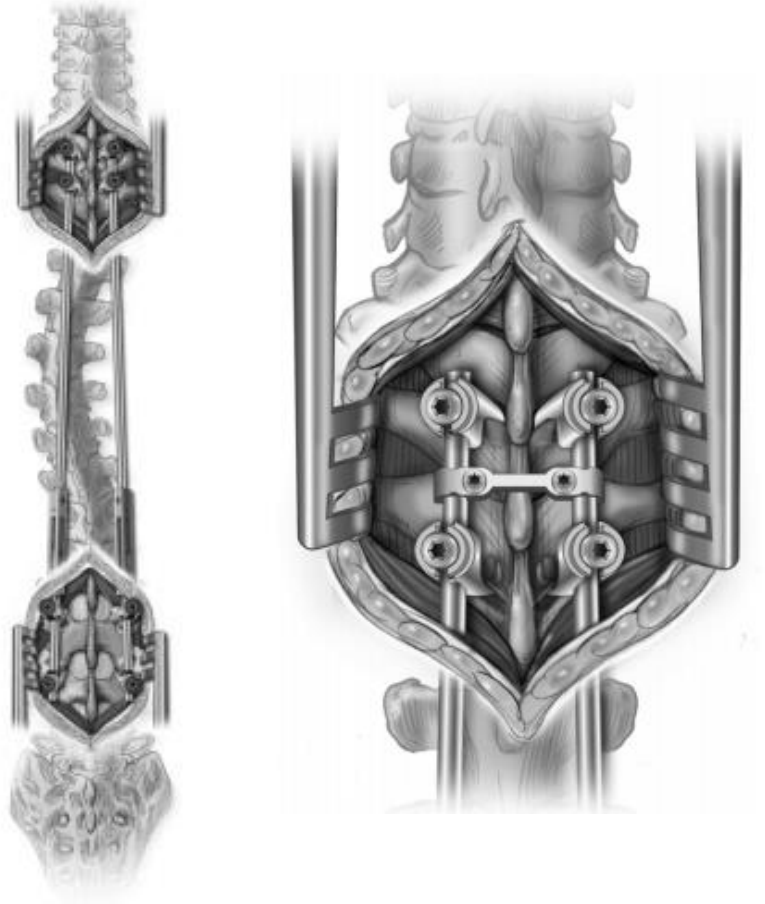


Figure 1. Schematic posterior view of dual growing-rod instrumentation [2].

Clinical Need and Industrial Relevance

- Unfulfilled clinical data
  - High rate of mechanical complications (mostly rod failure) in Growth Rods [1].
  - No standard methodology for pediatric growth rod testing
- Objectives
  - Identify biomechanical parameters in failure modes
  - Provide relevant testing methodology for standardization

Figure 2. Rod fracture in a 6-year-old boy treated with dual GR for progressive scoliosis [1].

Project Aims

- Aim 1-Experimental Model Development and Validation
  - Utilize ASTM F1717 as basis
  - Testing adaptation to accommodate the pediatric growing rod characteristics
- Aim 2-Anatomical Model Development and Validation
  - Develop and validate FE models in patient-specific scoliotic curves
  - Scoliotic spine data provided by FDA
- Aim 3-Parametric Studies
  - Iteration and parametric studies on configurations and materials
  - Identify relevant spinal curvature and device design features

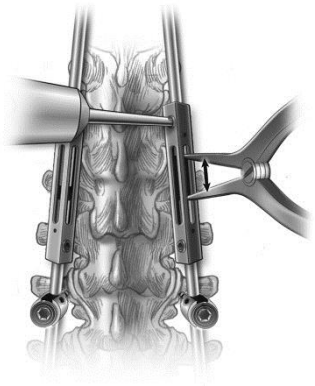
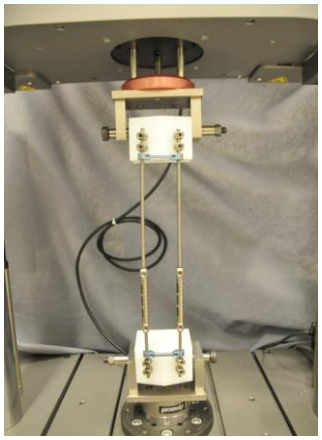
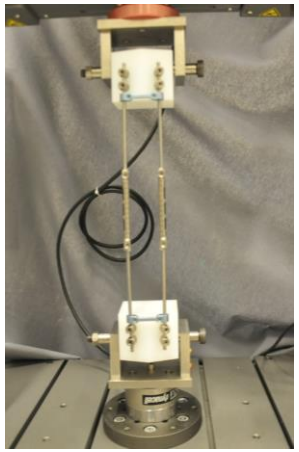
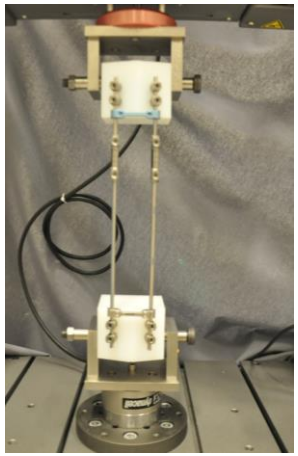


Figure 3. Traditional tandem connector used for early onset scoliosis treatment [2].

Methods: F1717 Constructs (Aim 1)





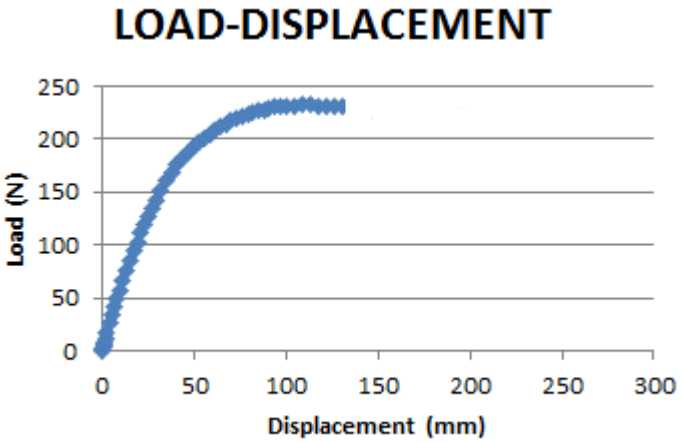


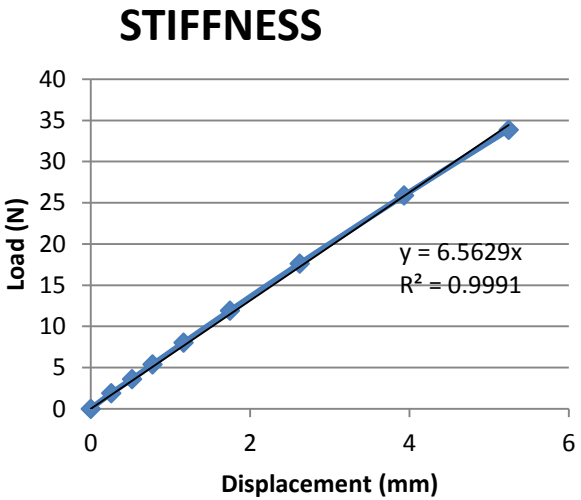
Construct 1: Adjacent to distal anchor

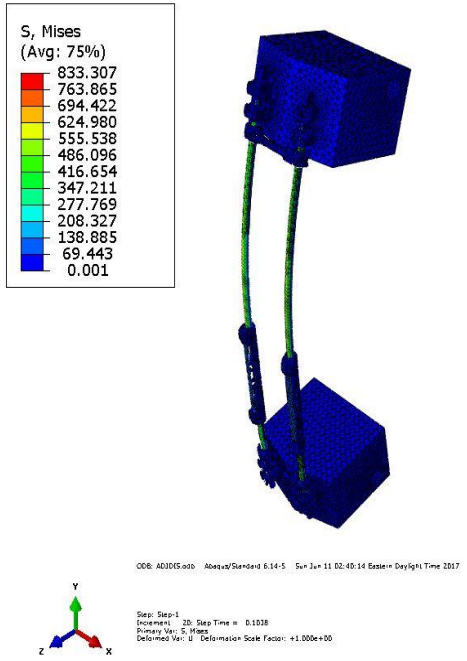
Construct 2: Adjacent to tandem connector

Construct 3: Adjacent to mid-construct

Results: Construct 1 (Aim 1)

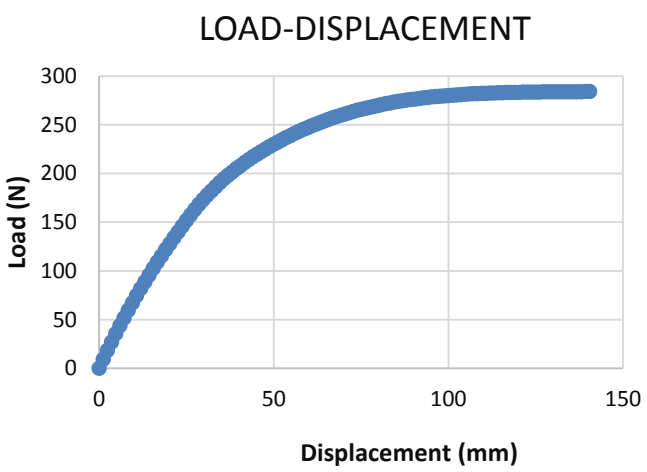


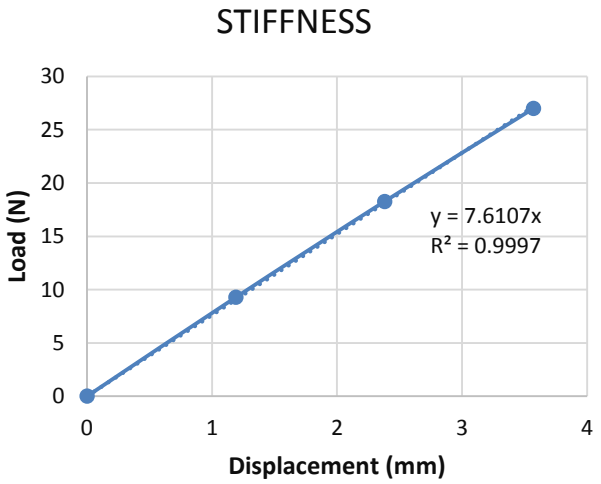


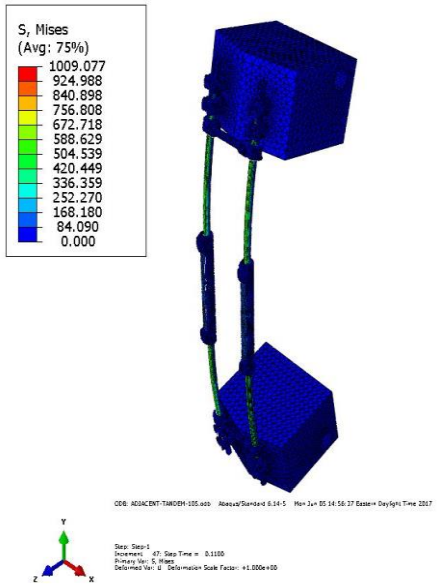


Construct 1: Adjacent to distal anchor

Results: Construct 2 (Aim 1)

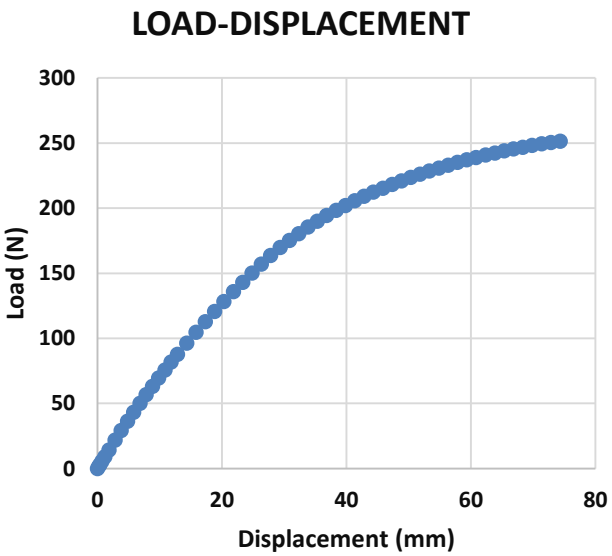


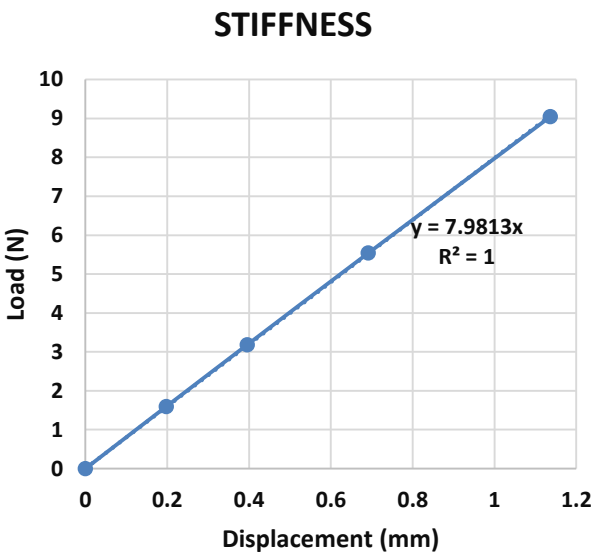


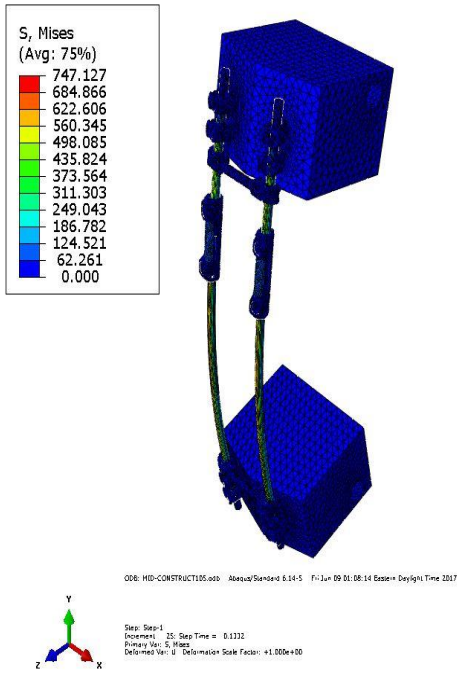


Construct 2: Adjacent to tandem connector

Results: Construct 3 (Aim 1)







Construct 3: Adjacent to mid-construct

Methods: Patient specific model (Aim 2)

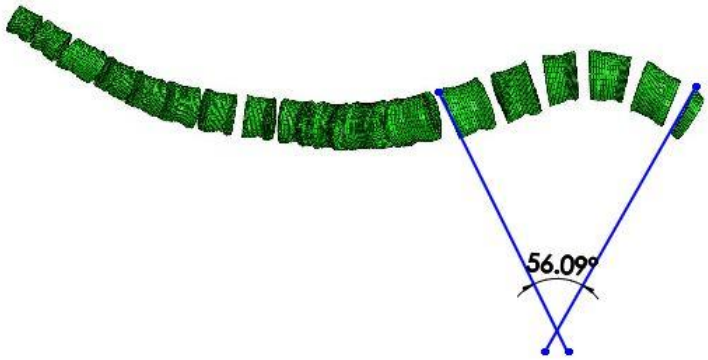
Pre-index surgery Cobb angle = 48
Pre-index surgery kyphosis = 36 deg
Pre-index surgery Lordosis = -56 deg

Tandem connector on each side of construct
Tandem connector length = 80mm
Rod diameter=4.5mm

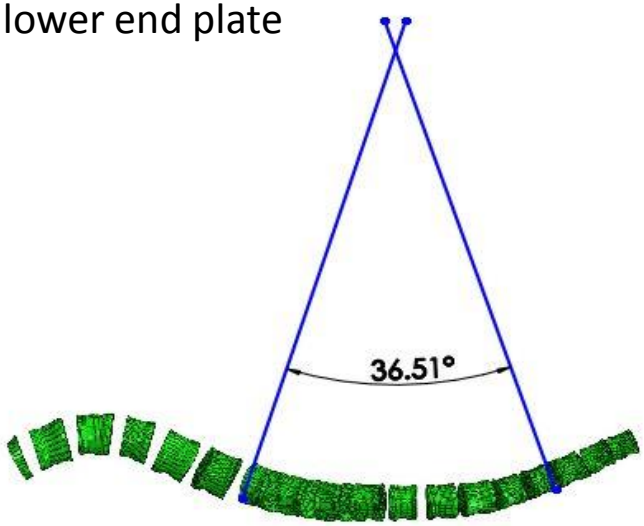
Methods: Patient specific model (Aim 2)

CENTER FOR DISRUPTIVE MUSCULOSKELETAL INNOVATIONS

- Pre-index Lordosis angle: -56°
- Model angle: -56.09°
- Vertebral levels used to measure the Lordosis angle: L1 upper end plate to S1 upper end plate

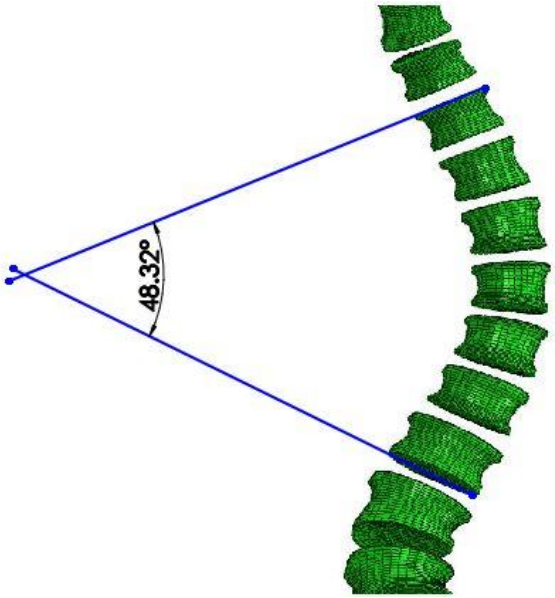


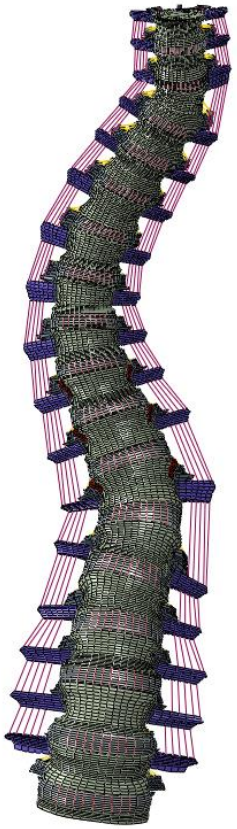
- Pre-index Kyphosis angle: 36°
- Model angle: 36.51°
- Vertebral levels used to measure the Kyphosis angle: L4 upper end plate to T12 lower end plate



Methods: Patient specific model (Aim 2)

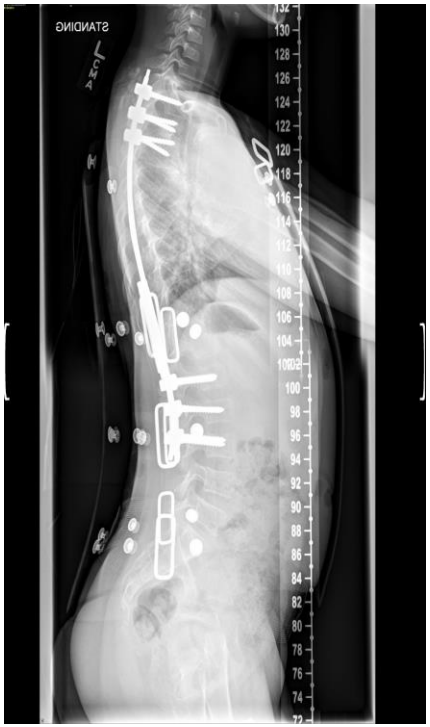
- Pre-index Cobb angle: 48°
- Model Cobb angle: 48.32°
- Vertebral levels used to measure the Cobb angle: T5 upper end plate to T11 lower end plate





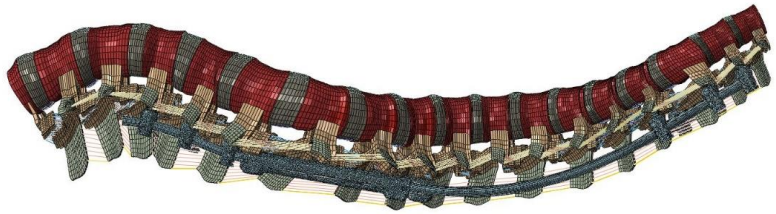
Methods: Patient specific model (Aim 2)

- Instrumented levels on the left pedicles
  - T2, T3, T4 Proximal foundation
  - L1, L2, L3 Distal foundation
- Instrumented levels on the right pedicles
  - T3, T4 Proximal foundation
  - L1, L2, L3 Distal foundation



Post-index Cobb angle= 37 deg
Post-index kyphosis = 42 deg
Post-index Lordosis = -53 deg

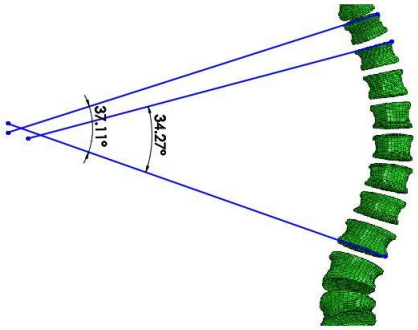
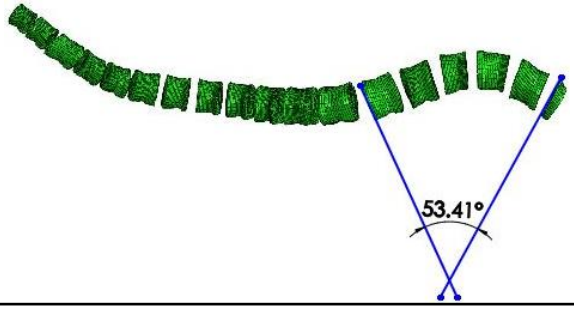
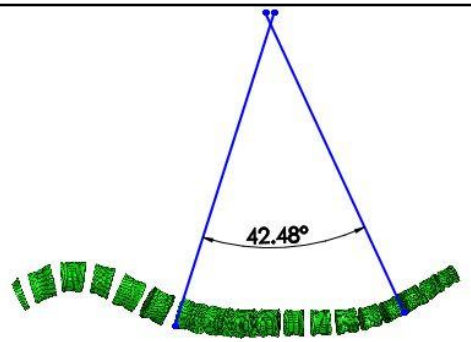
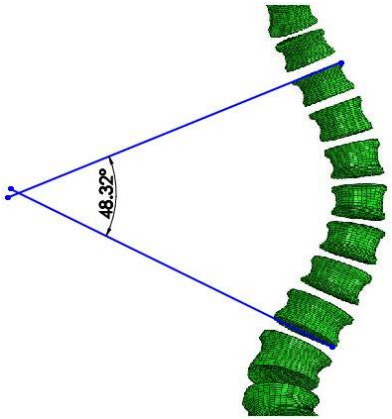
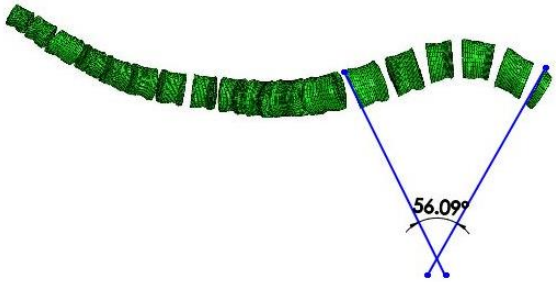
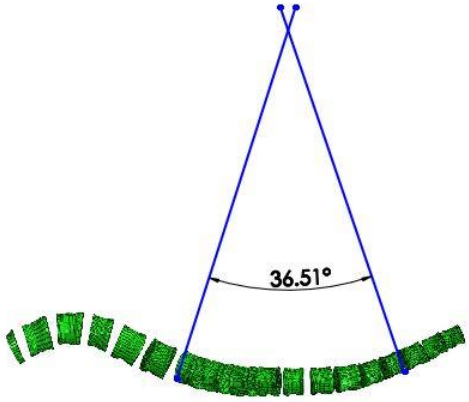
Boundary Conditions:
- Tandem connector fixed in the middle
- 15 mm rod distraction on both sides



Results: Pre & Post index angles (Aim 2)

CENTER FOR DISRUPTIVE MUSCULOSKELETAL INNOVATIONS

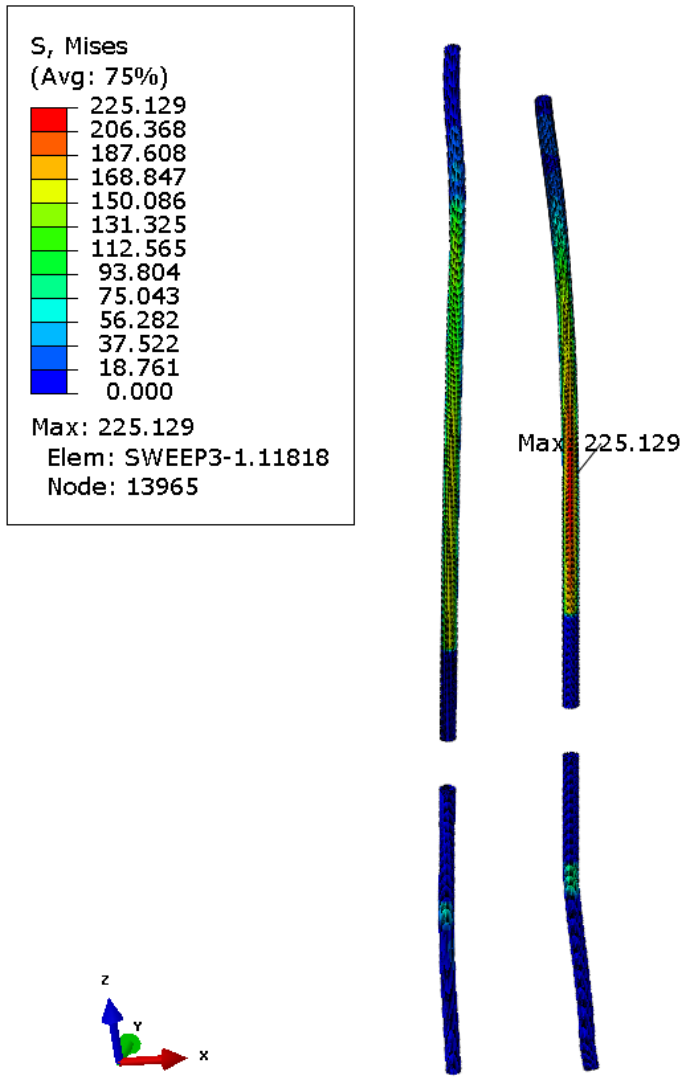
- Both concave and convex rods were distracted 15 mm to predict changes in the various angles

	Cobb Angle	Lordosis Angle	Kyphosis Angle
Post-index angles			
Pre-index angles			

Results: Rod Distraction (Aim 2)

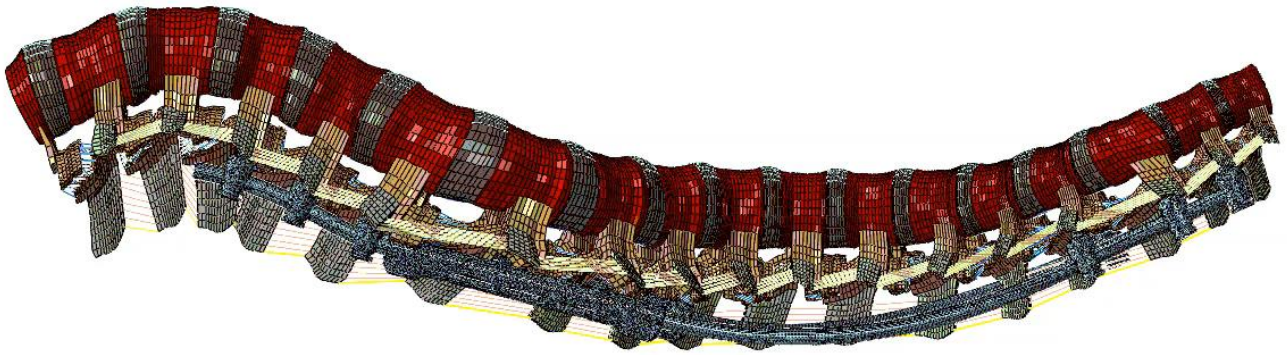
Maximum von Mises stress after rods distraction

- 15 mm of rod distraction were applied on both rods
- On the convex proximal rod
- The value is 225 MPa



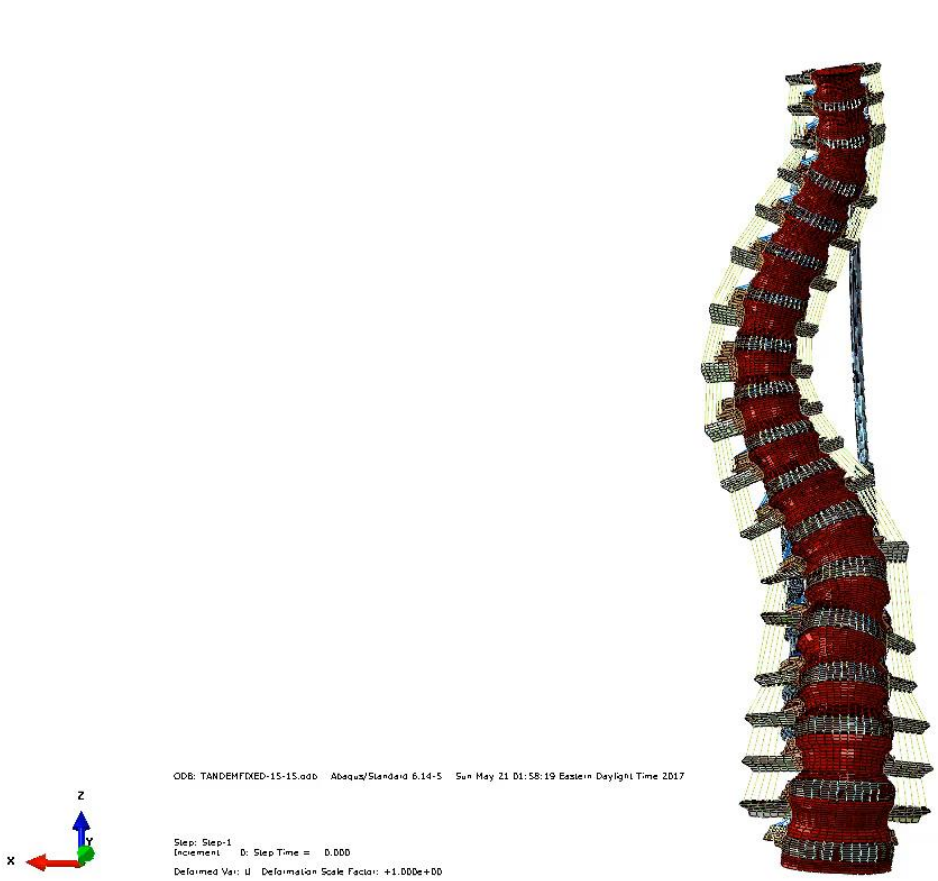
Results: Rod Distraction (Aim 2)

(Sagittal View)



Results: Rod Distraction (Aim 2)

(Coronal View)



Conclusion

1. Validation complete: Mechanical characters for different constructs matches the FDA experimental data. **(Aim 1 executed)**

2. Patient specific model development complete for patient 1 **(Aim 2 partially executed)**

3. Index surgery only: Maximum stresses on convex rod **(Aim 2 partially executed)**

Timeline

Develop spine models and simulate the index surgery	Aug, 2016
Data Analyses, publications (abstracts and manuscripts) and report	Sep, 2017

Acknowledgement

- Dr. Aakash Agarwal, PhD
- Dr. Agarwal, MD
- Dr. Goel, PhD
- Industrial Advisory Board

Thank you for your attention

Research, Product Development
and Evaluation: Partnership with Industry