Spinal Growth Modulation: Biomechancial Principles

How do we optimize design?

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Boston Children's Hospital, Boston MA

Harvard Medical School

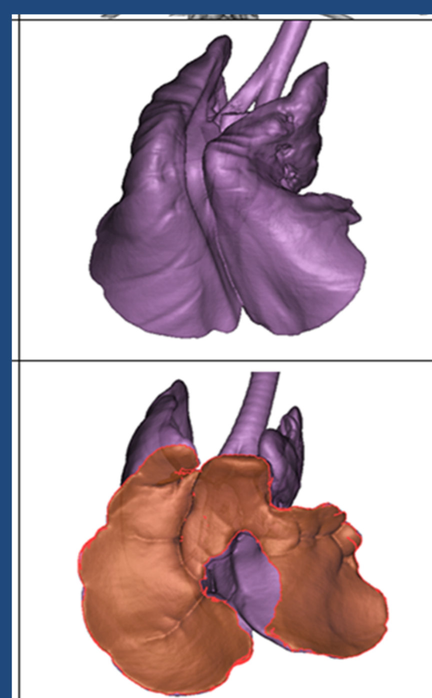
SRS
Scoliosis Research Society

POSNA
The Pediatric Orthopaedic Society of North America

The PROBLEM

- Make “crooked” spine “straight”
- Previous paradigm = instrument + fuse multiple spine levels *early*

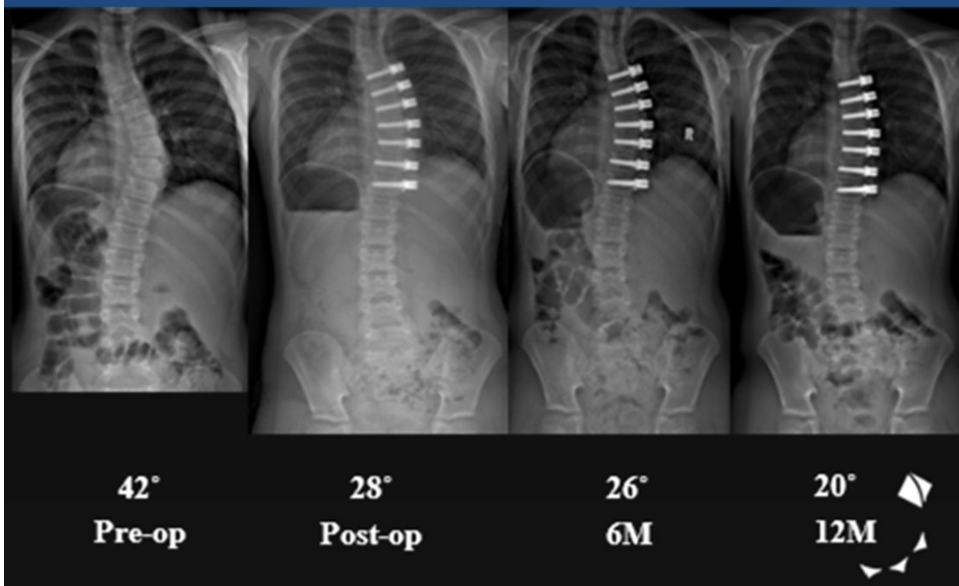
➢ Created straight spine but shortened thorax



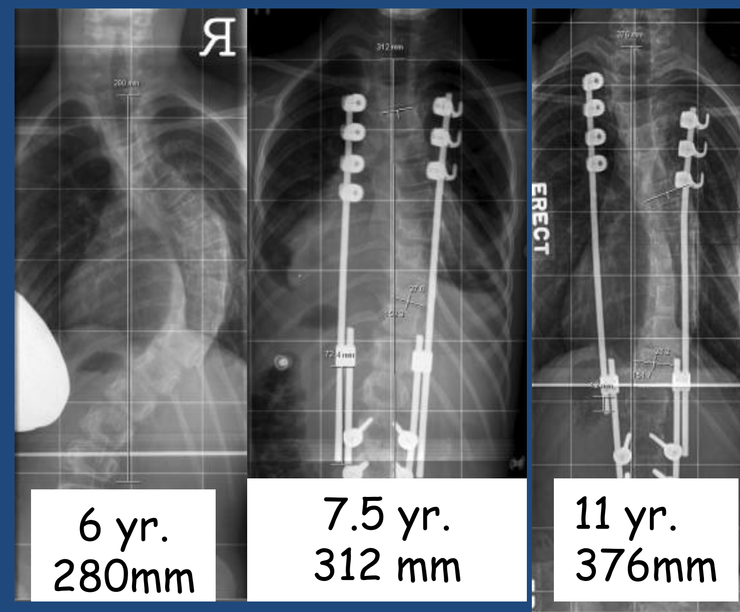
Inhibited growth of lungs and decreased pulmonary function

Modulating Spine Growth

Anteriorly based tether



Posteriorly based distraction

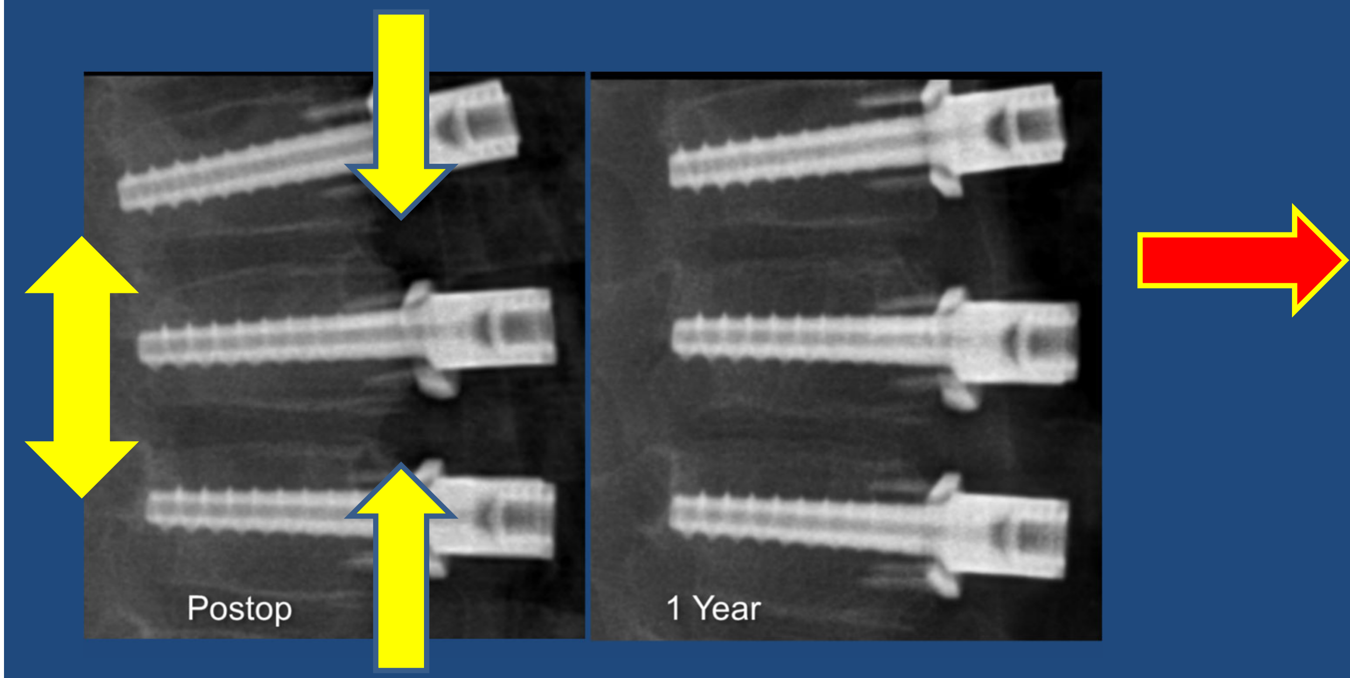


- **Goal: Modulate asymmetrical spinal growth**
  - Maintain motion of spine units
  - Maintain disc physiology
  - Allow growth and development of lung/thorax

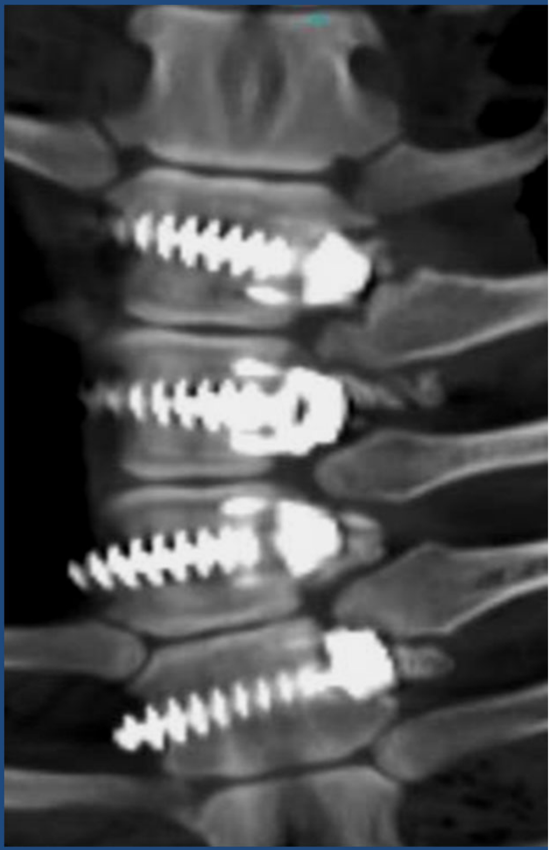
Growth Modulation

Based on Heuter-Volkman principal:

- Depends on loading mode and magnitude applied @ physis or apophysis
  - Tensile force (stress) stimulates growth
  - Compressive force inhibits growth



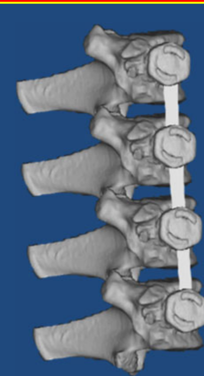
Asymmetric growth

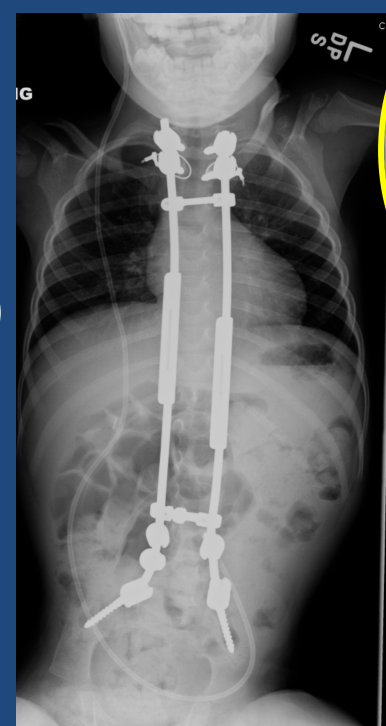


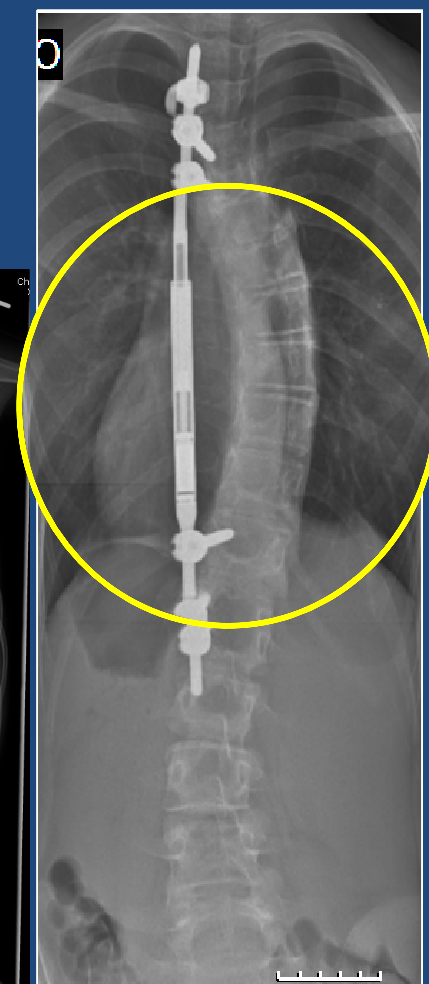
Growth Modulation Systems

Devices Classified based on:

- Placement
  - anterior vs. posterior
- Loading mode
  - tension vs compression
  - static (staples, tethers) vs. dynamic (MAGEC)

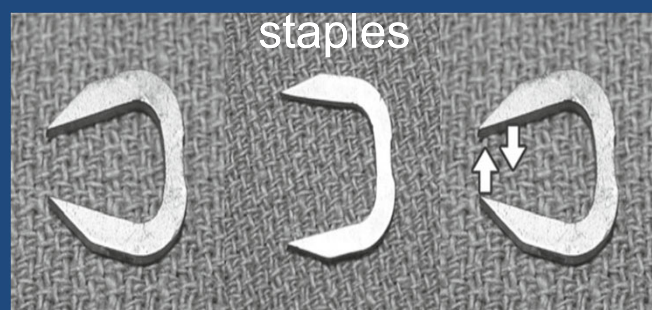






FDA “approved” devices for growth modulation

BUT DO WE KNOW HOW TO USE THESE DEVICES SAFELY AND PREDICTABLY



Engineering Success Measured by Safety and Efficacy

- Predicated on ability of these systems to *predictably* modulate spine growth over specified time interval required to achieve desired clinical effect
- Necessitates specification of defined performance criteria for each device type *a priori* that will then be used for pre-clinical and clinical evaluations

Unique Considerations in Children

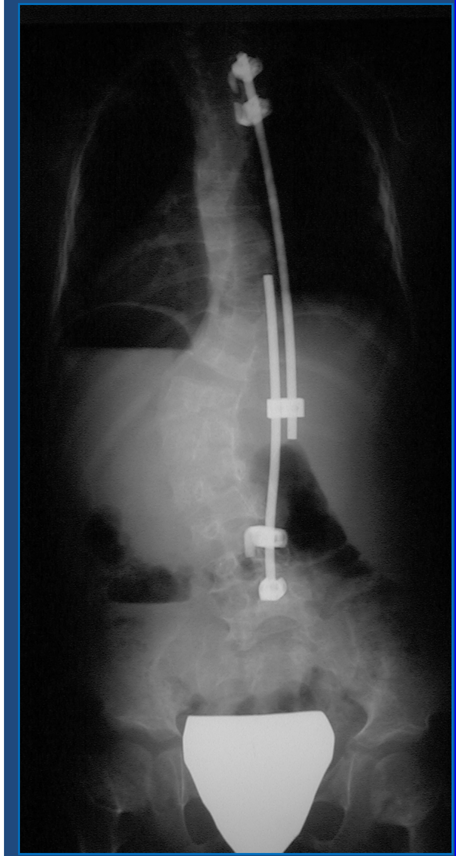
- Multiple sizes of device required to accommodate children over range of heights and weights which change over time with growth
  - performance goals change with child's age
    - reflects evolving physical activity demands
  - performance goals change in same child over time
  - Device must serve dual function for indeterminate number of years without failing
    - maintain correction of spinal deformity
    - modulate growth of spine without inhibiting growth

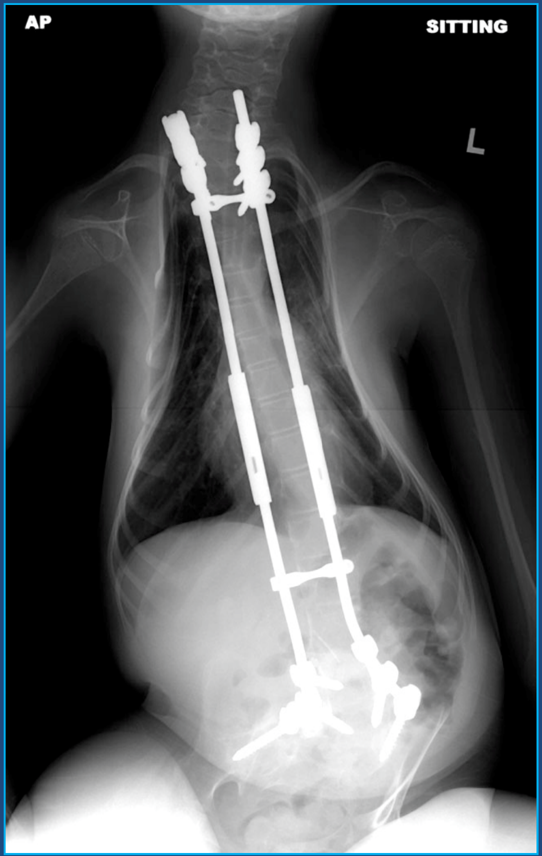
Safety Performance Criteria

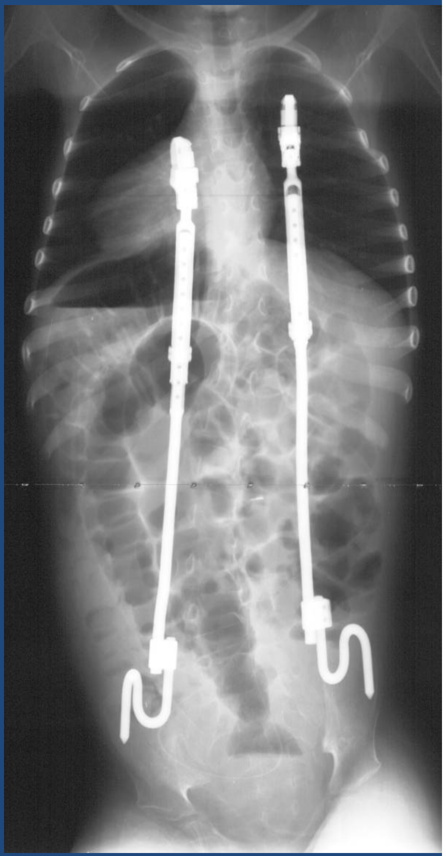
- No standardized test protocols or established performance criteria for Non-Fusion spinal instrumentation
- No predicate adult device for similar indication

SAFETY

Successful Engineering Design
= Avoidance of Device Failure







Controlled by the manufacturer:

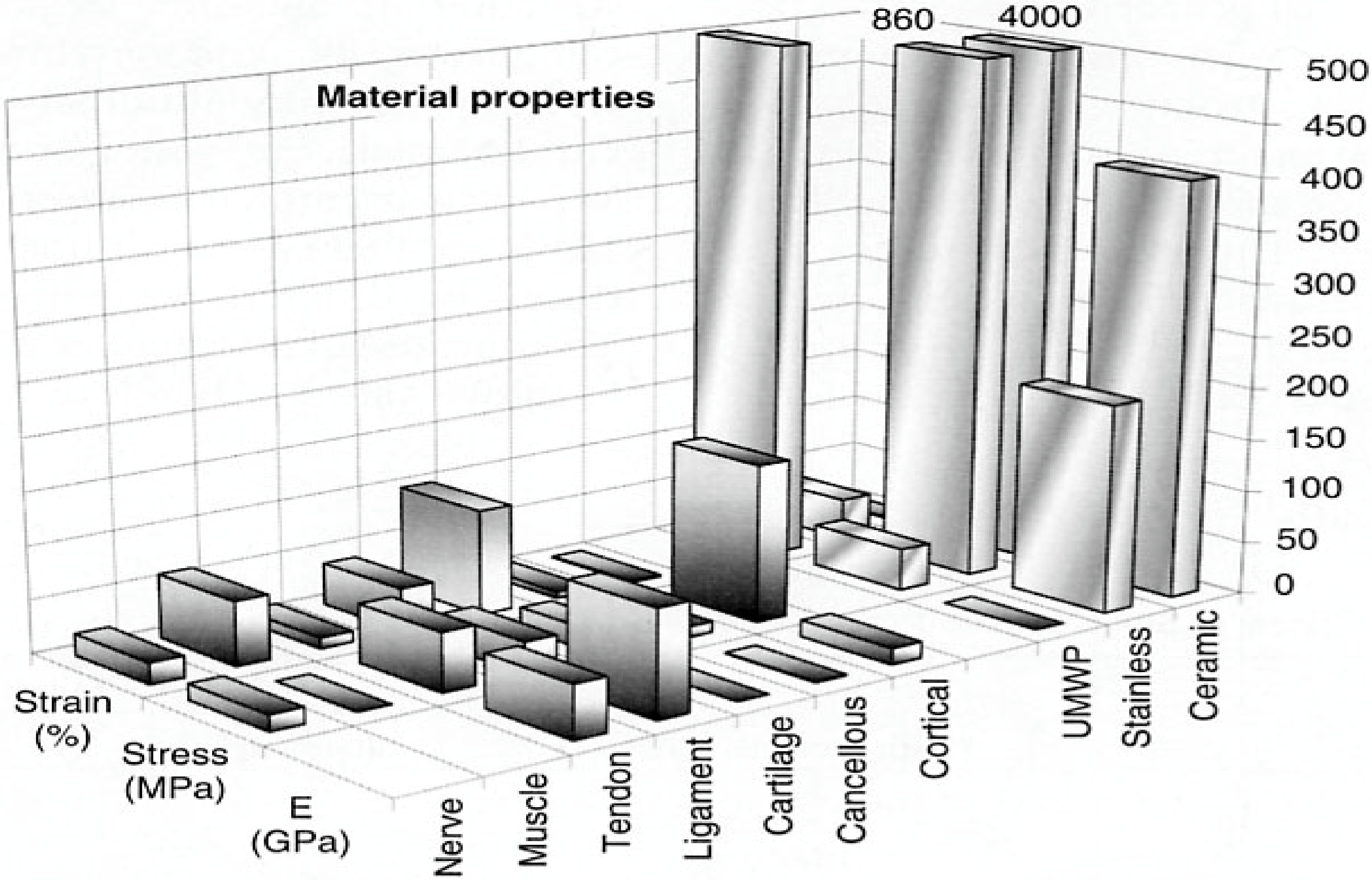
Design Variables

Properties of the device

Material Properties

Structural Geometry

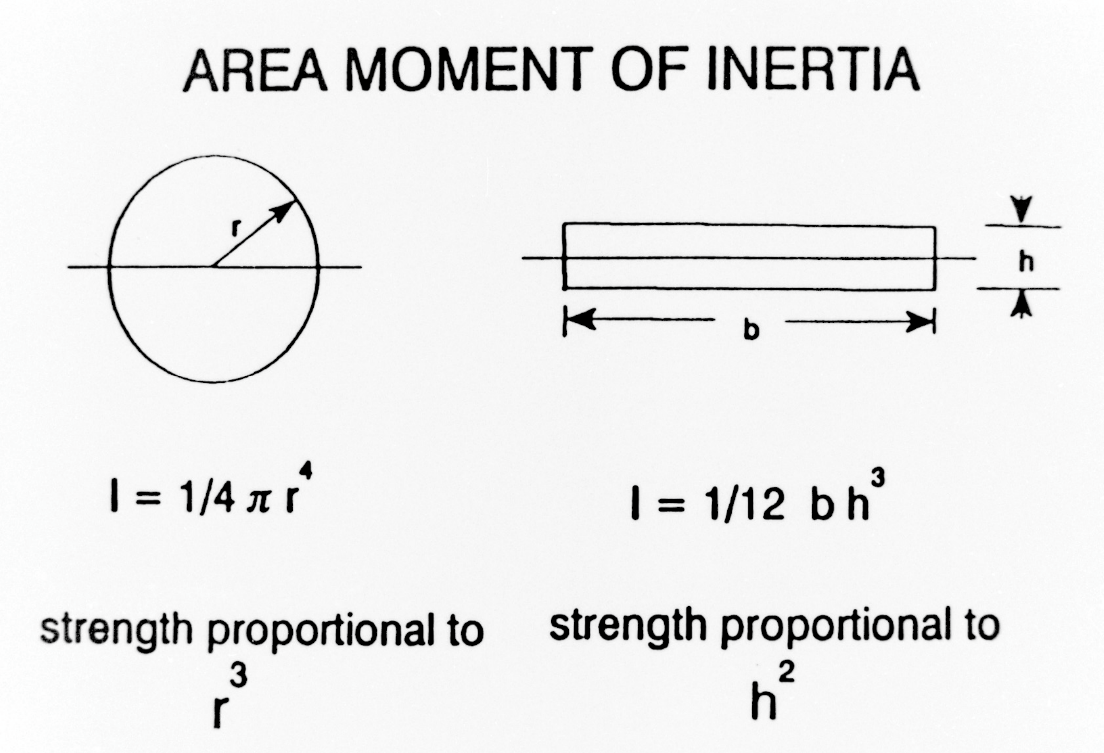
Material Properties
Intrinsic Stiffness and Strength



Geometry: Moment of Inertia

Describes Distribution of Material Relative to a Bending Axis

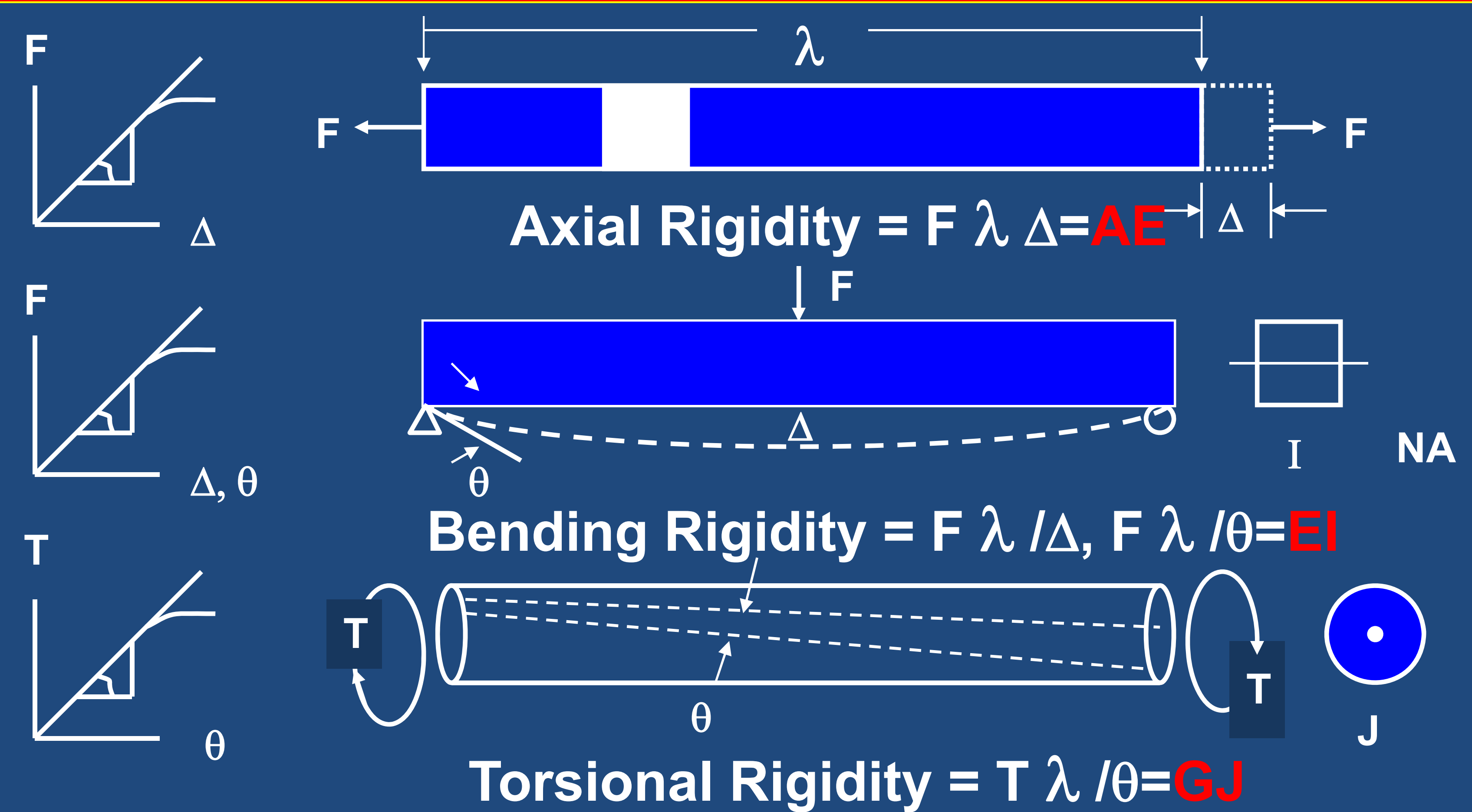
- Varies as 4th power of the distance from bending axis
- 5mm diam rod 1.5x stiffer than 4.5 mm rod



STRUCTURAL RIGIDITY

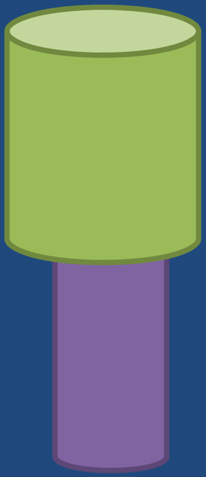
Product of Material Modulus x Geometric Property

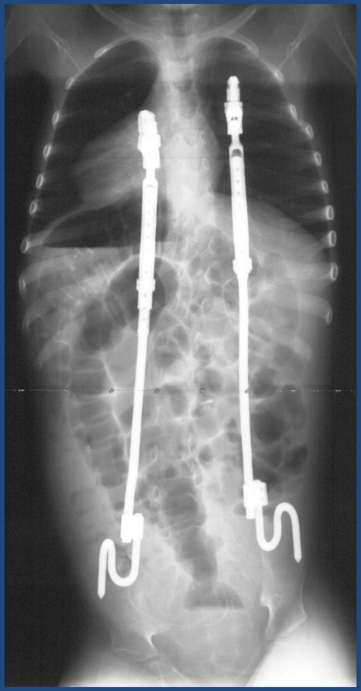
Determines Load Capacity of Rods



AVOID Stress Concentration

- **Abrupt change in geometry or material induces localized stress peak in structure that predisposes to fatigue failure**
- Discontinuities causes stress to be concentrated
  - Highest for small radius
- Mechanically assisted crevice corrosion @ couplings





Controlled by the patient: *Applied Loads*

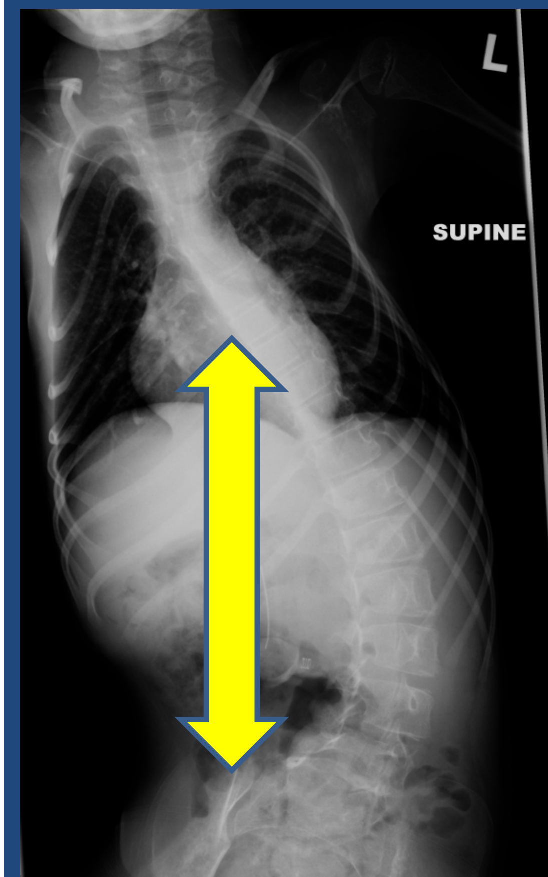
Mode of loading

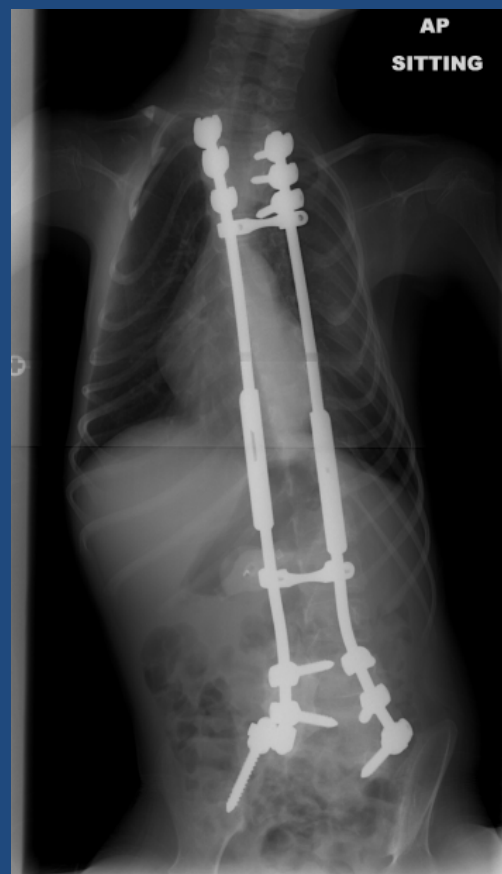
Magnitude of loads

Number of cycles

SUCCESS = DEVICE ABLE TO WITHSTAND APPLIED LOADS

Instrumentation must sustain forces & moments required to correct spinal deformity + those generated during activities of living





Cyclic Compression + Flexion + Torque

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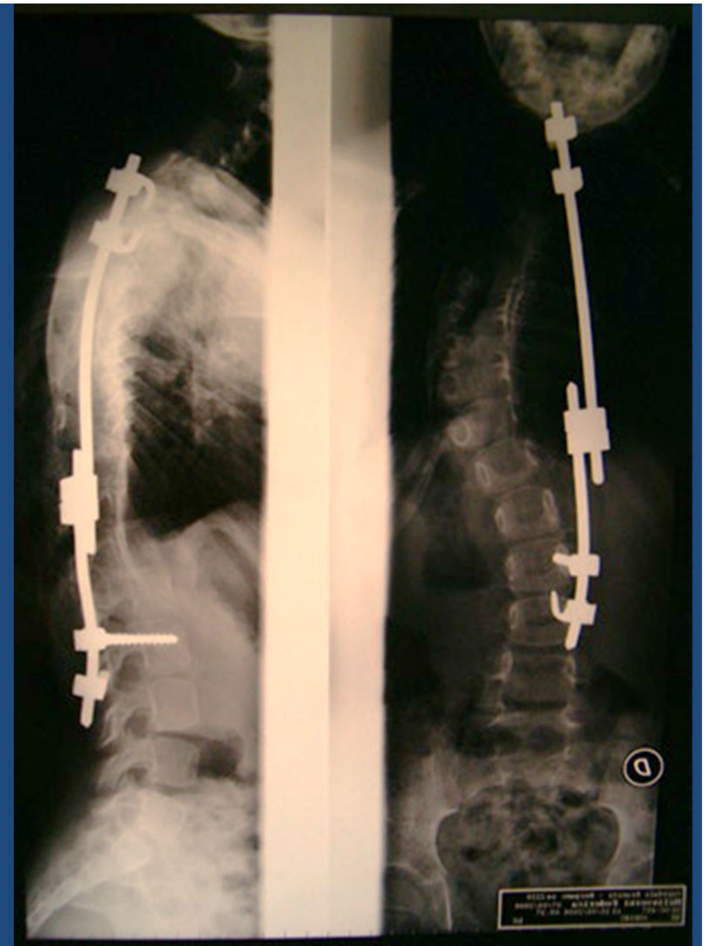
BRIEF ARTICLE

Measurement of forces generated during distraction of growing-rods in early onset scoliosis

Marco Teli, Giuseppe Grava, Victor Solomon, Giuseppe Andreoletti, Emanuele Grismondi, Jay Meswania



RESULTS: Twenty measurements were obtained showing a linear increase of the load with increasing distraction, with a mean peak force of 485 N at 12 mm distraction and a single reading over 500 N. We did not observe bone fractures or ligament disruptions during or after rod elongations. There was one case of superficial wound infection in the cohort.

CONCLUSION: The safe peak force carrying capacity of a motorized device for distraction of growing-rods is 500N.

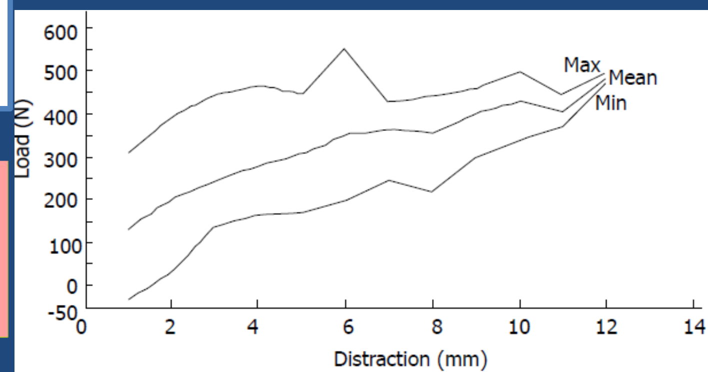


Figure 3 Force/distraction plot: maximum (top curve), mean (middle curve) and minimum (bottom curve) values.

Spine

SPINE Volume 36, Number 26, pp 2299–2303

DEFORMITY

The "Law" of Diminishing Growth

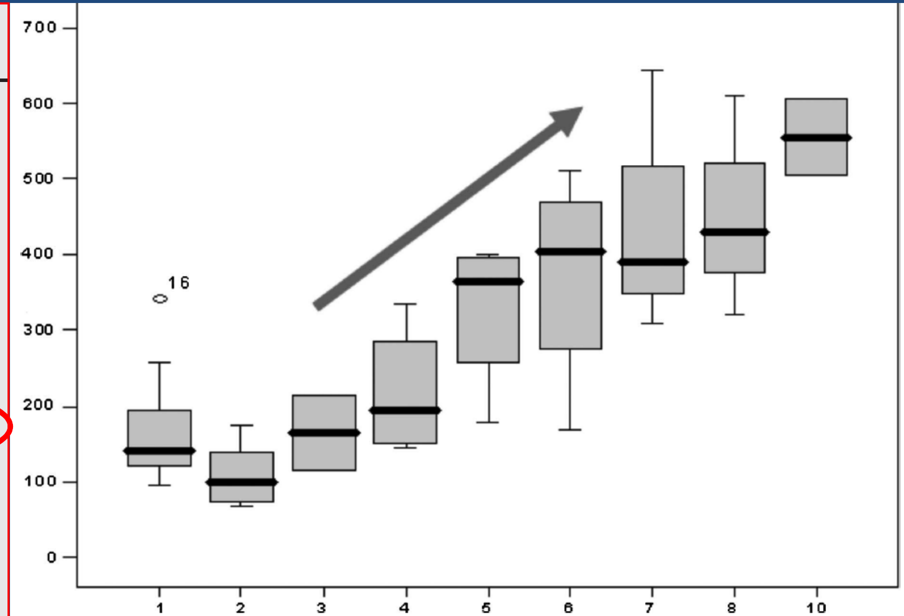
In Vivo Distraction Force and Length Measurements of Growing Rods

Which Factors Influence the Ability to Lengthen?

Hilali M. Noordeen, FRCS (Orth),* Suken A. Shah, MD,† Hazem B. Elsebaie, FRCS, MD,‡ Enrique Garrido, EBOT, MRCS,* Najma Farooq, FRCS (Tr & Orth),* and Mohannad Al Mukhtar, MRCS*

Key Points

- There is a significant increase in distraction forces in growing-rod constructs with subsequent lengthening.
- Apical fusion increases the force needed to distract the rods significantly.
- The amount of length gained with each distraction decreases with time and with serial distractions.
- Instrumentation design must accommodate the forces generated and the trends observed in this study to minimize failure.



"Law of Diminishing Growth" Explained

Corrective moment = Distractive Force x Moment Arm (lateral offset)

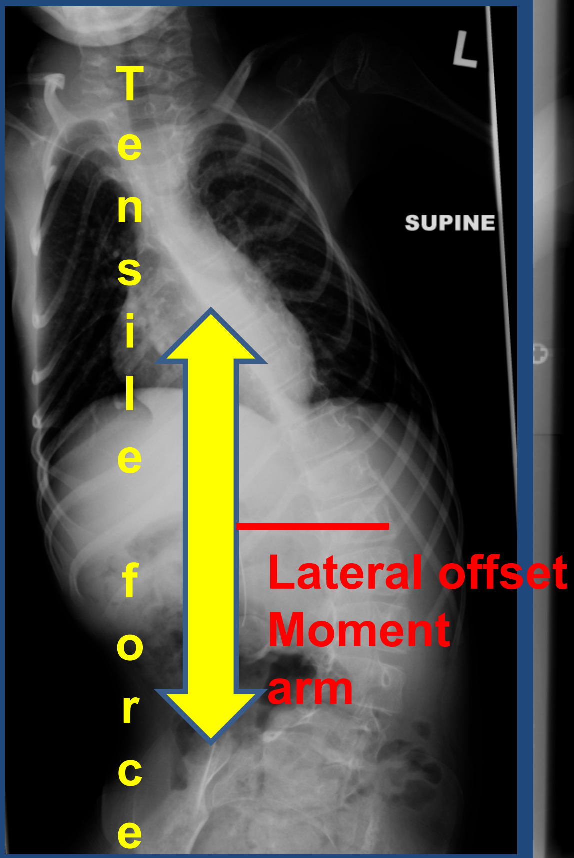
As the scoliosis decreases
the lateral offset becomes smaller
thereby decreasing the moment arm

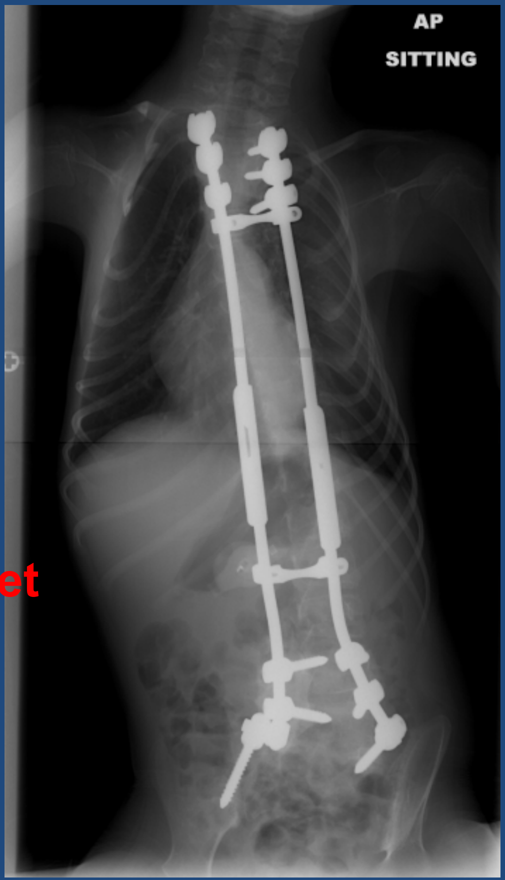
To maintain a constant corrective
moment - the distractive force must
increase proportionately

Ultimately, tension applied to "straight"
spine ("no more slack")

Upper limit of the distractive force
determined by the material properties
of the bone – anchor interface

In addition there is CREEP or
continued viscoelastic deformation in
response to the applied static load



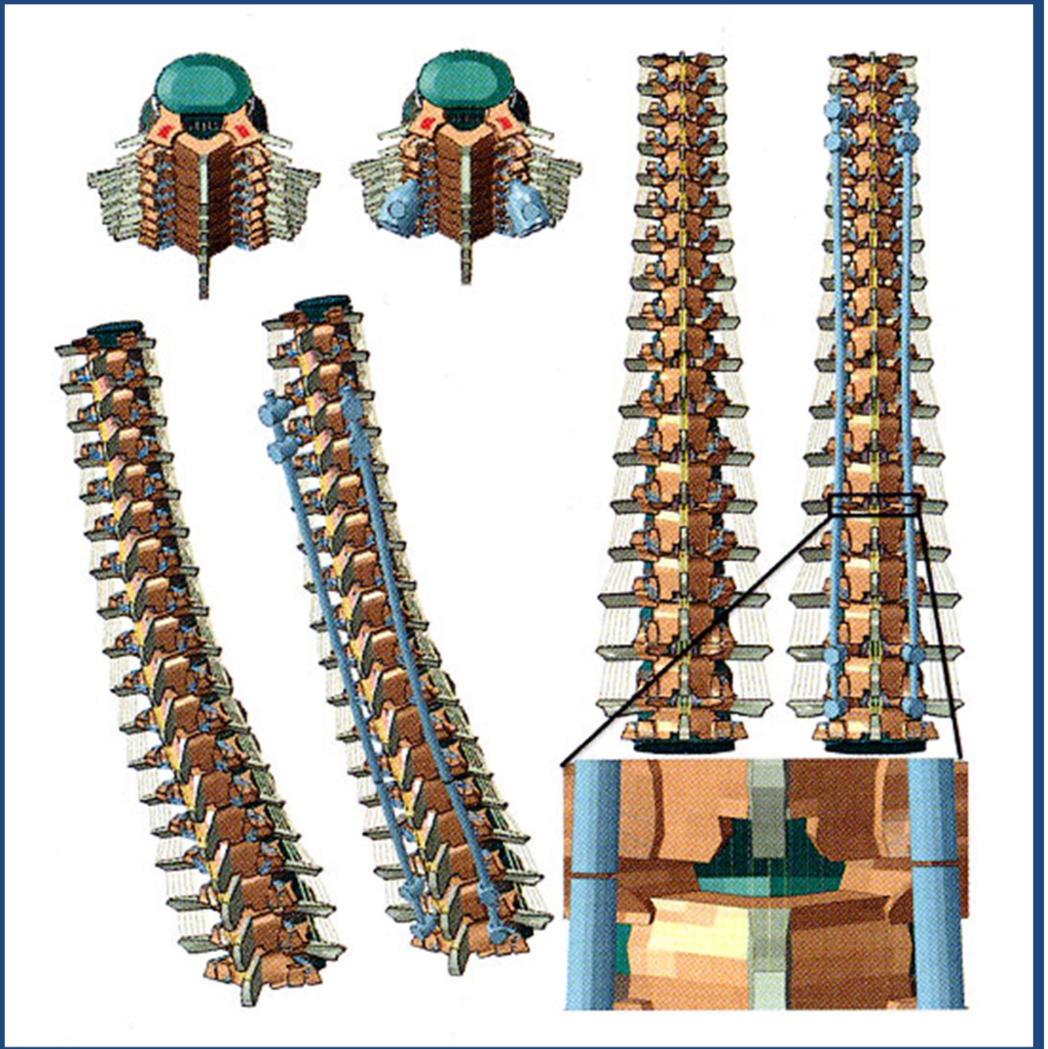


Finite Element Study to determine optimal interval between sequential distractions to minimize rod failure

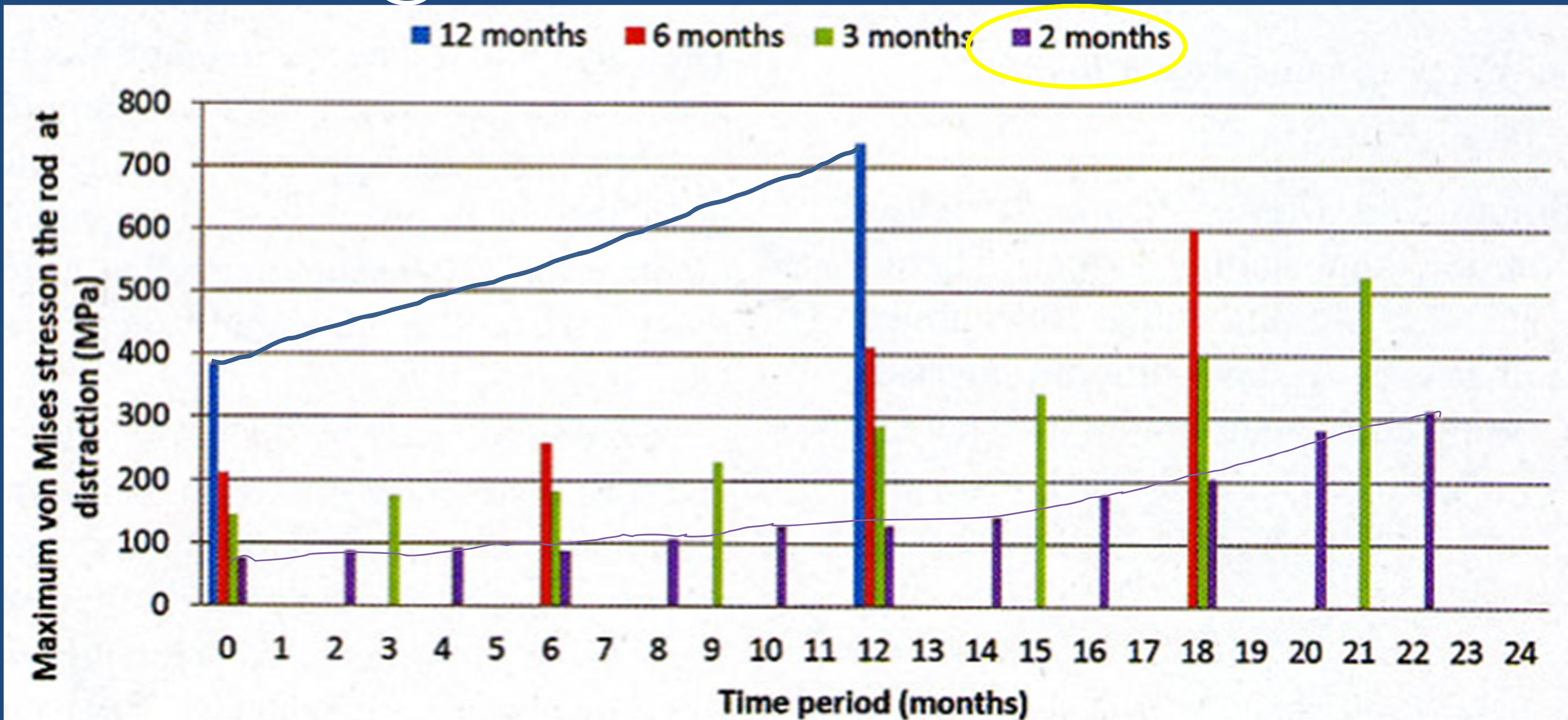
(Agarwal et al. Spine Deformity 2:430-36; 2014)

- FEM juvenile spine instrumented with dual growing rods
  - Appropriate material properties for bone, connective tissues
    - Elastic and Viscoelastic
  - Applied appropriate distraction to mimic growth over time interval
- Compared Von Mises stresses on rods for different time intervals between distractions

➢ 12 mo, 6 mo, 3 mo, 2 mo



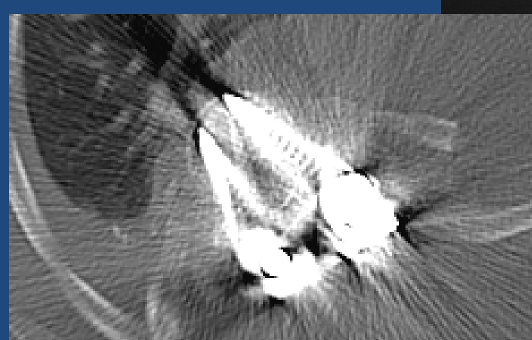
Maximum Von Mises stress on rod after sequential distractions @ different time intervals over 24 months

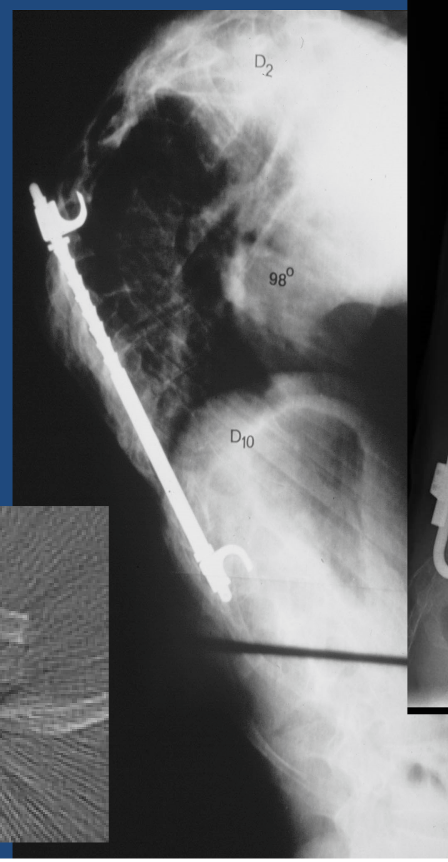


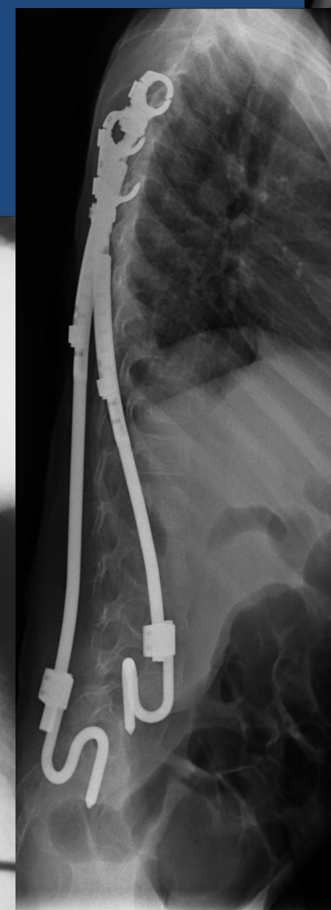
- ↑ Stress with progressive lengthening for all time intervals
  - Highest rod stress @ 12 mo interval (x2),
  - Lowest rod stress @ 2 mo interval (x12)
- Shorter time intervals between subsequent lengthening decreases rod stress for same height gain

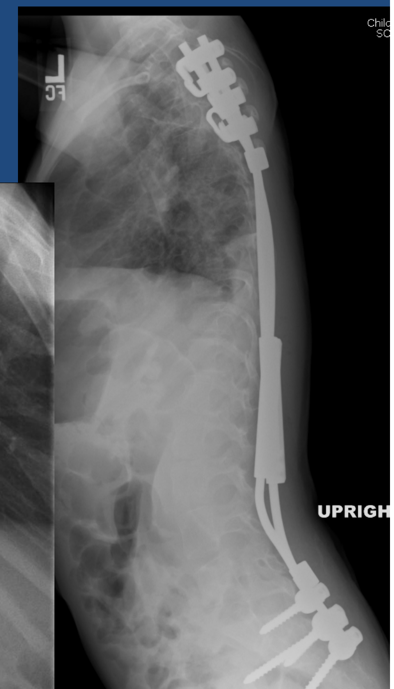
Properties of bone-anchor interface

- Screws (rigid) vs. hooks (semi-constrained)
  - Hook anchor allows motion at bone interface
  - relieves stress/energy similar to airplane wing
- Bone quality affects stability of bone anchor
  - Bone stiffness and strength vary with (density)^2



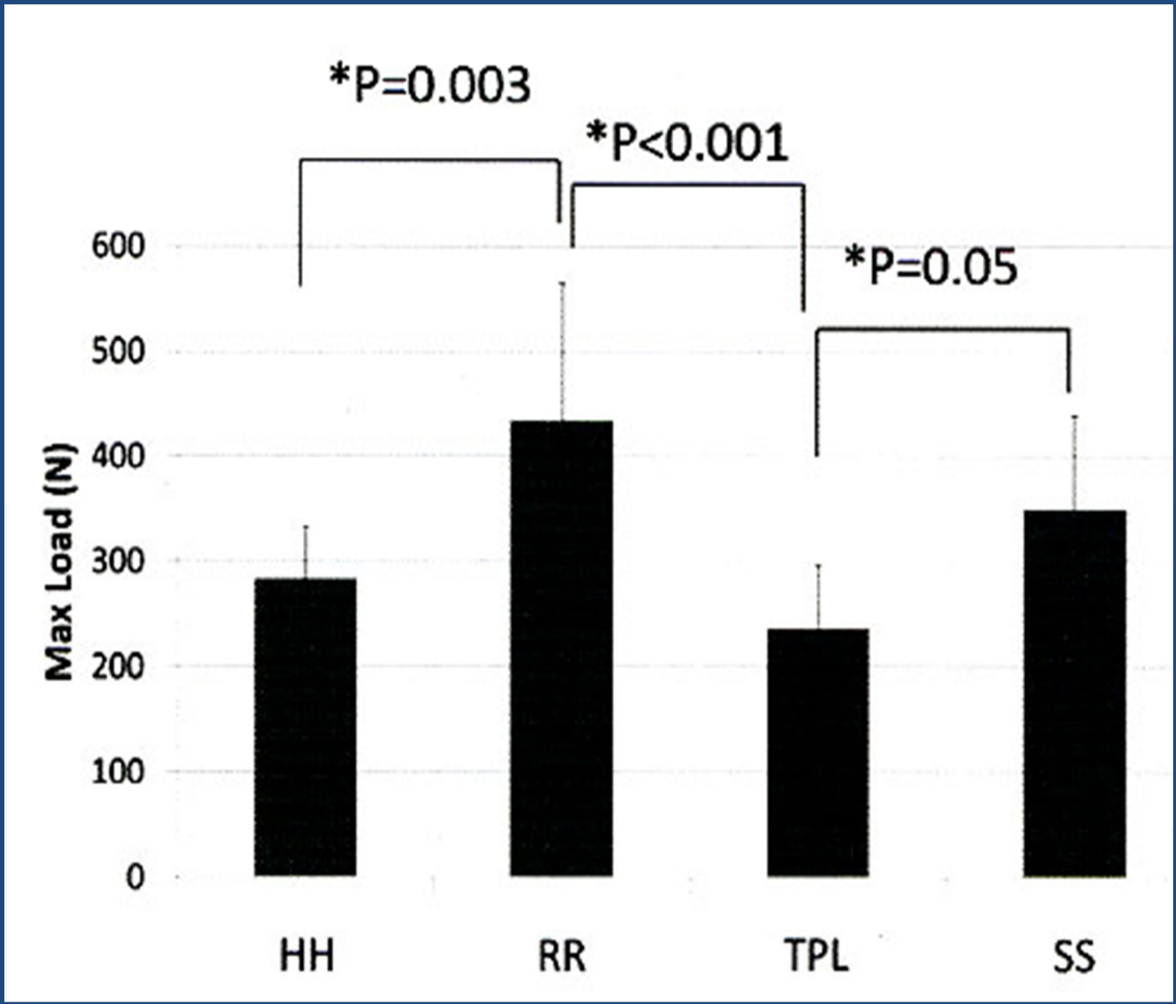






Comparison of anchor construct strength
(Akbarnia et al. Spine Deformity 2:437-43; 2014)

- Rib based (RR) and Pedicle Screw (SS) based constructs had highest ultimate strength, but variable performance
- Laminar hook (HH) and transverse process hook (TPL) constructs had lower ultimate strength but less variable performance



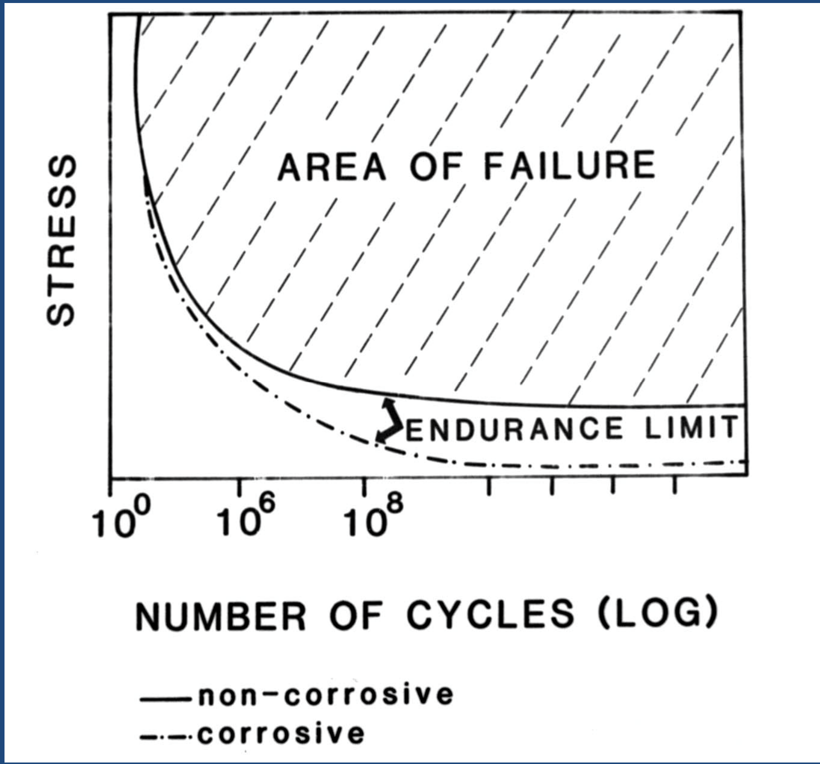
Fatigue

How many loading cycles must the implant withstand over 5-10 year course for growing child ?

- 6 mos of low intensity activity such as walking = 900,000 – 1,350,000 cycles

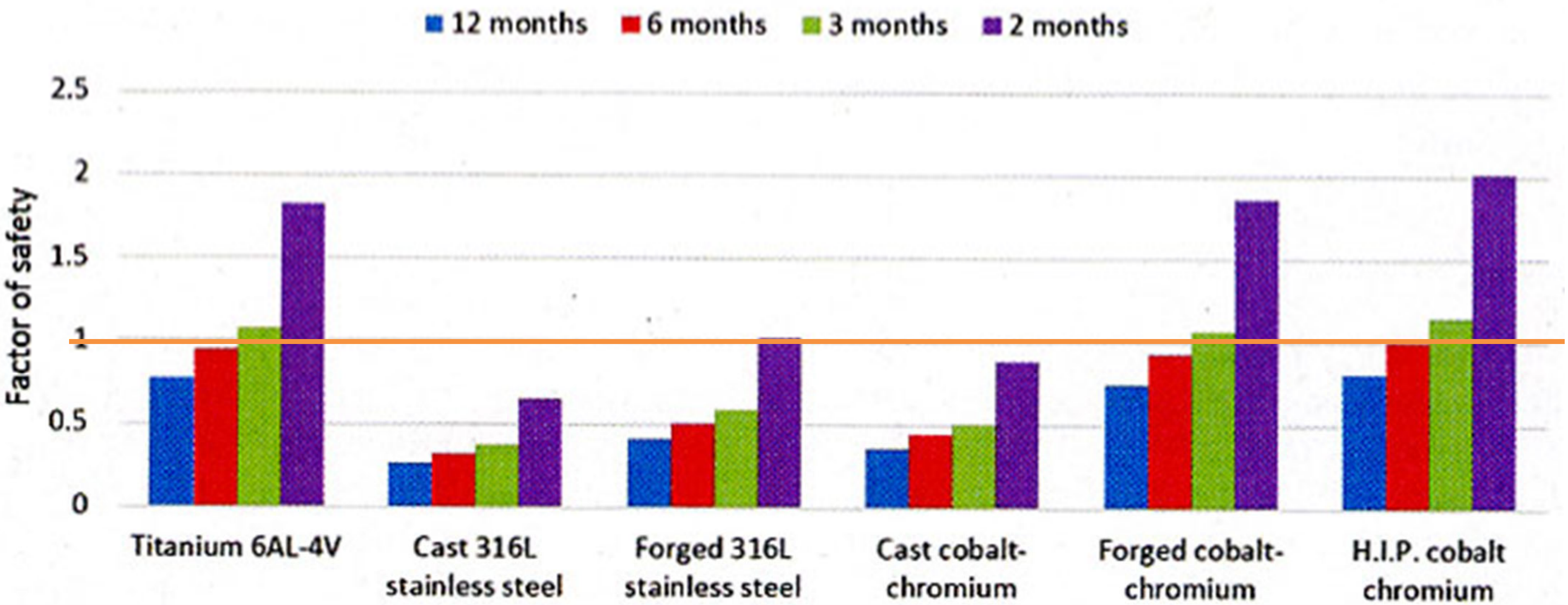
Is 5 million cycles enough ?

- σ-N curve: Number of loading cycles N required to fail specimen vs max stress attained during cyclic testing
- **Endurance Limit:** stress below which cyclic fatigue of material does not occur (even at infinite N)



Factor of Safety (Fatigue strength / Max Von Mises Stress on rod over 24 mos sequential lengthening) for different materials

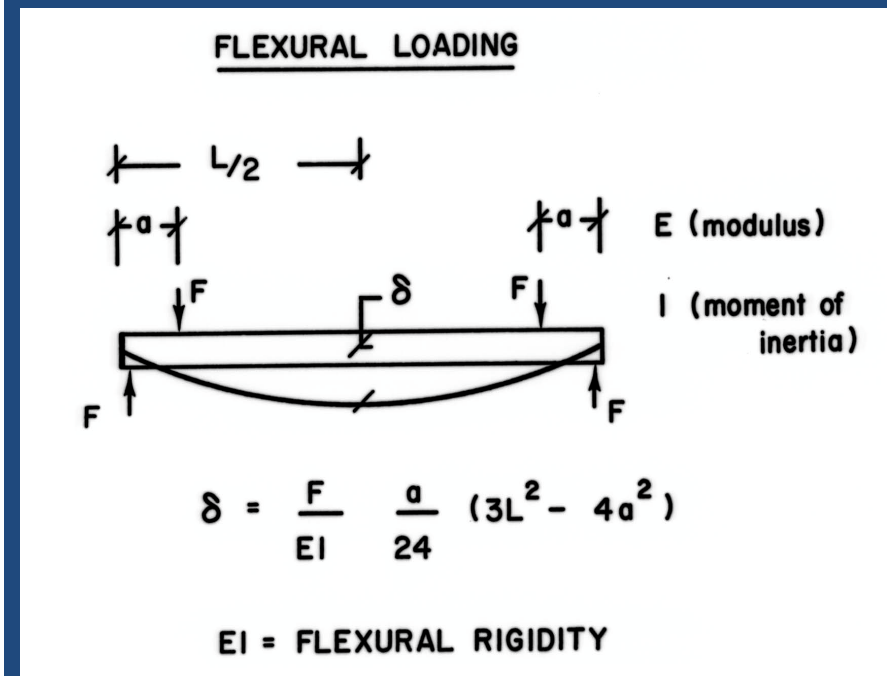
A. Agarwal et al. / Spine Deformity 2 (2014) 430–436



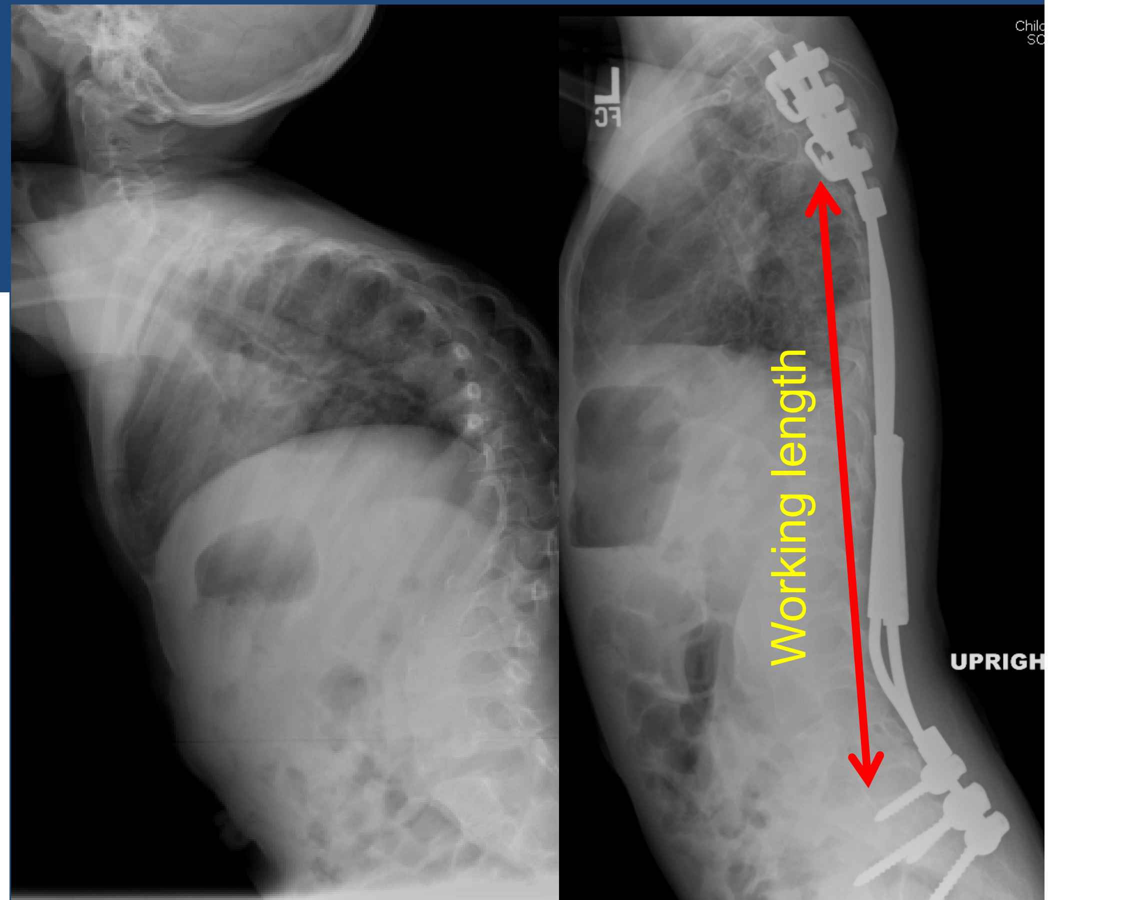
- Lengthening intervals > 2 mos, result in rod stresses approaching fatigue limit
- Ti & Cobalt chrome rod fail after 7 yrs walking (10 million cycles)
- Stainless steel and cast cobalt chrome fail in less time

Other Factors Affecting Construct Stability

- Rod deflection varies as (working length)^2
- Working length and applied load/moment increase w/ lengthening



Working length = unsupported length

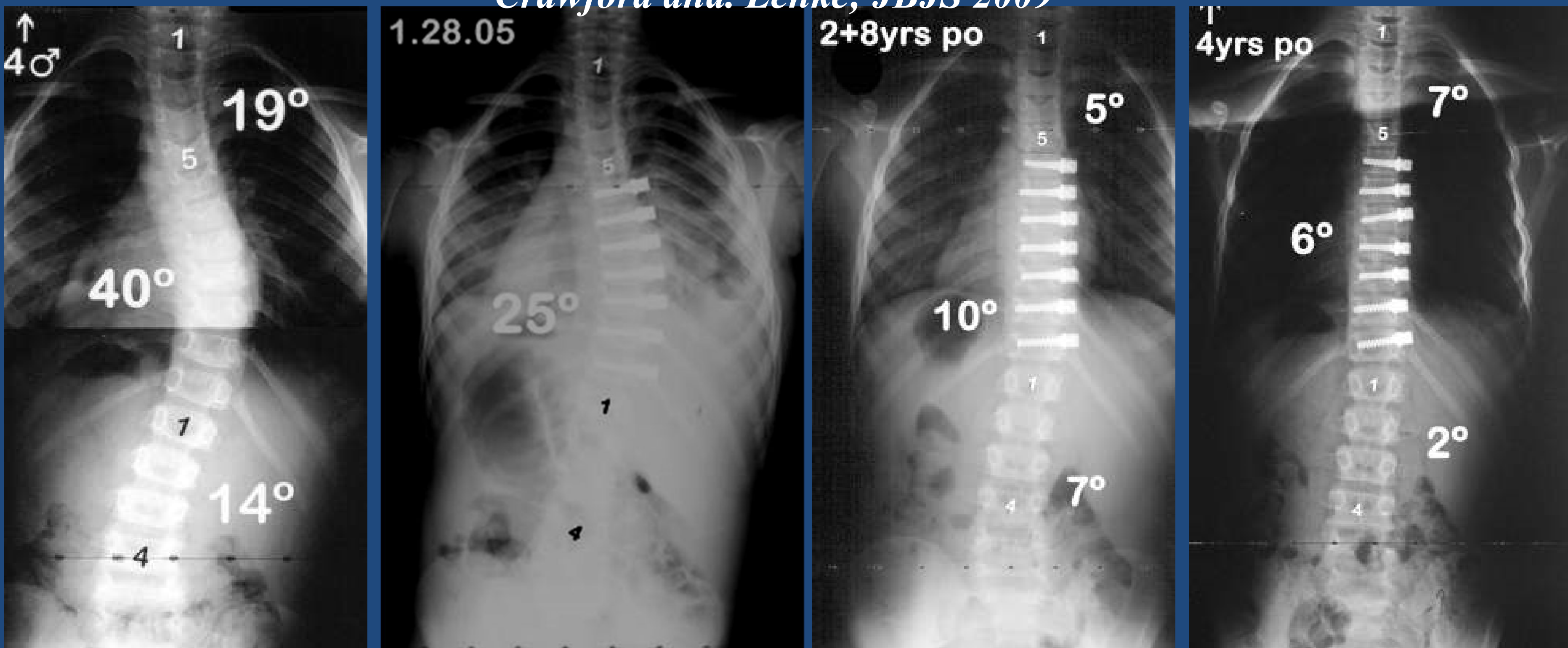


<u>Efficacy of Growth Modulation</u>:

Success = Reliable Prediction Spine Morphology @ Maturity

..“1.4 deg per year per level” – BUT patient went on to over correction on further follow-up

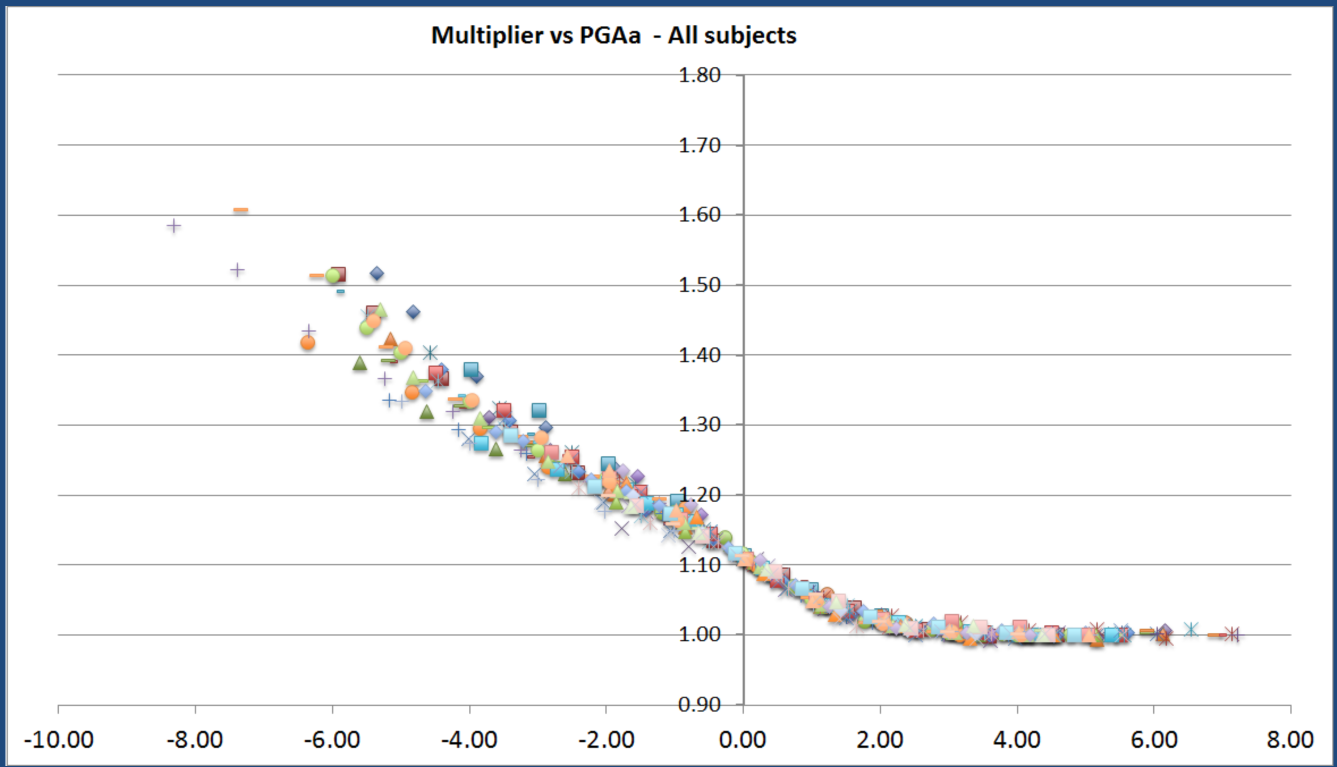
Crawford and. Lenke; JBJS 2009



Need to understand

- Spinal growth of normal spine vs. deformed spine
- Mechanical transduction *signal* (magnitude stress / strain, # cycles) that modulates spine growth in normal vs. deformed

Predicting Remaining Spine Growth



Jim Sanders, MD

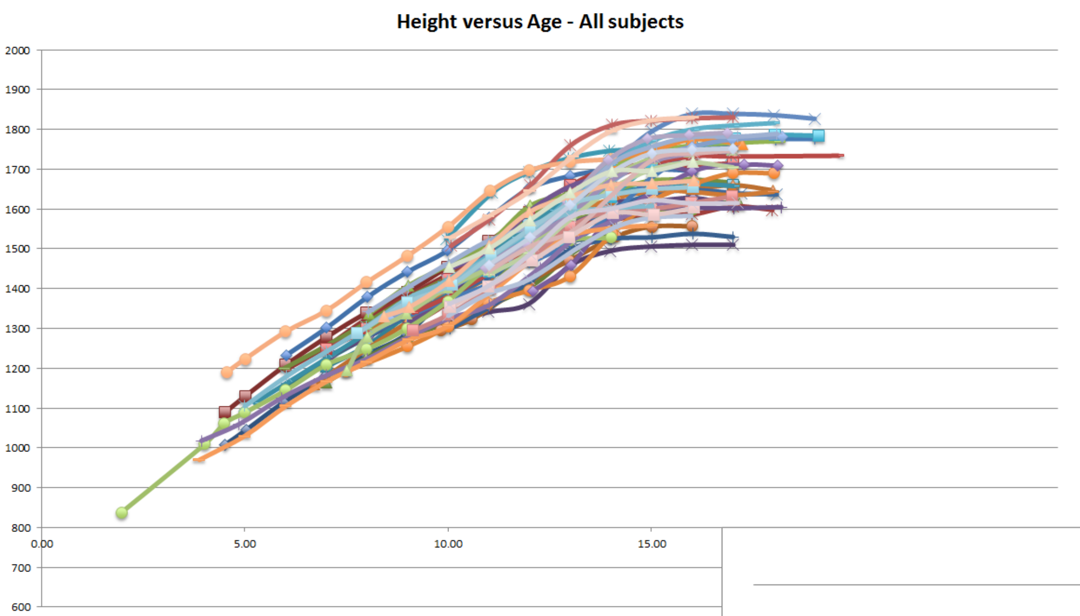
University of Rochester

Golisano Children's Hospital at Strong

T. Wingate Todd, MD

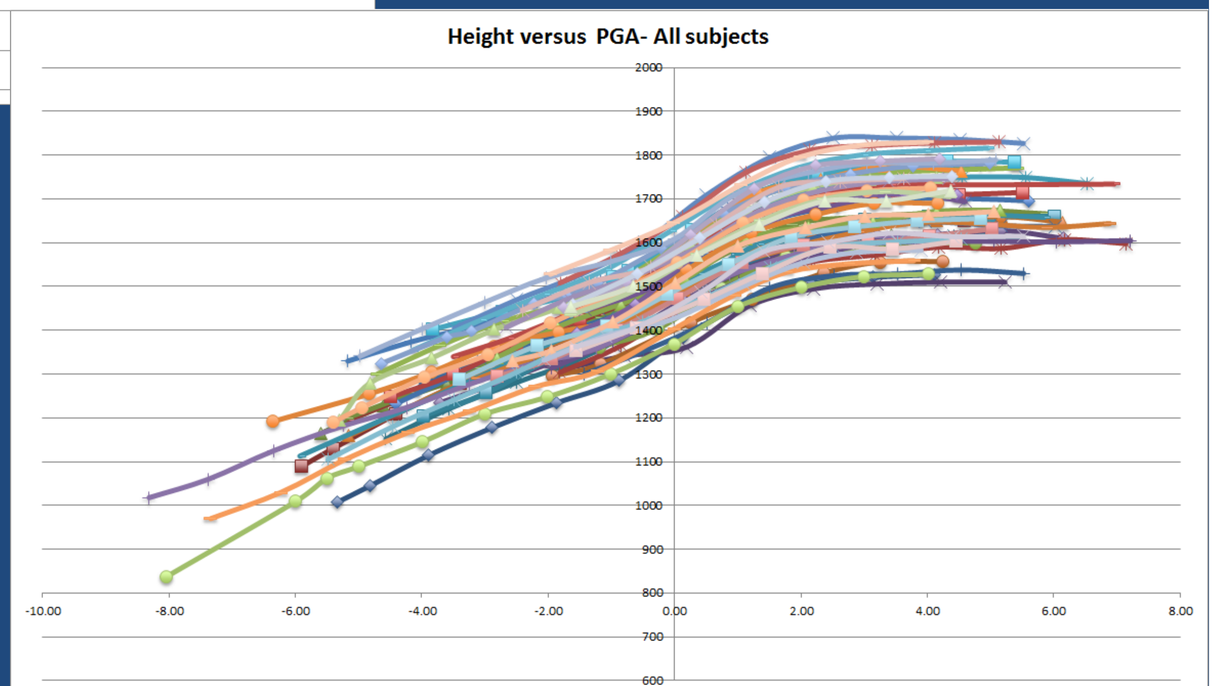
- Largest, most complete collection skeletal radiographs from longitudinal cohort of children through growth – began with >4000
- Healthy Cleveland Children 1929-1942
- Examined every mo until 1yr old, every 6mo until 5yrs then annually
- Each visit:
  - Radiographs left hand, elbow, hip, shoulder, knee, foot
  - Anthropometrics – height, weight, segment measurements

Height Relative to Peak Growth Age

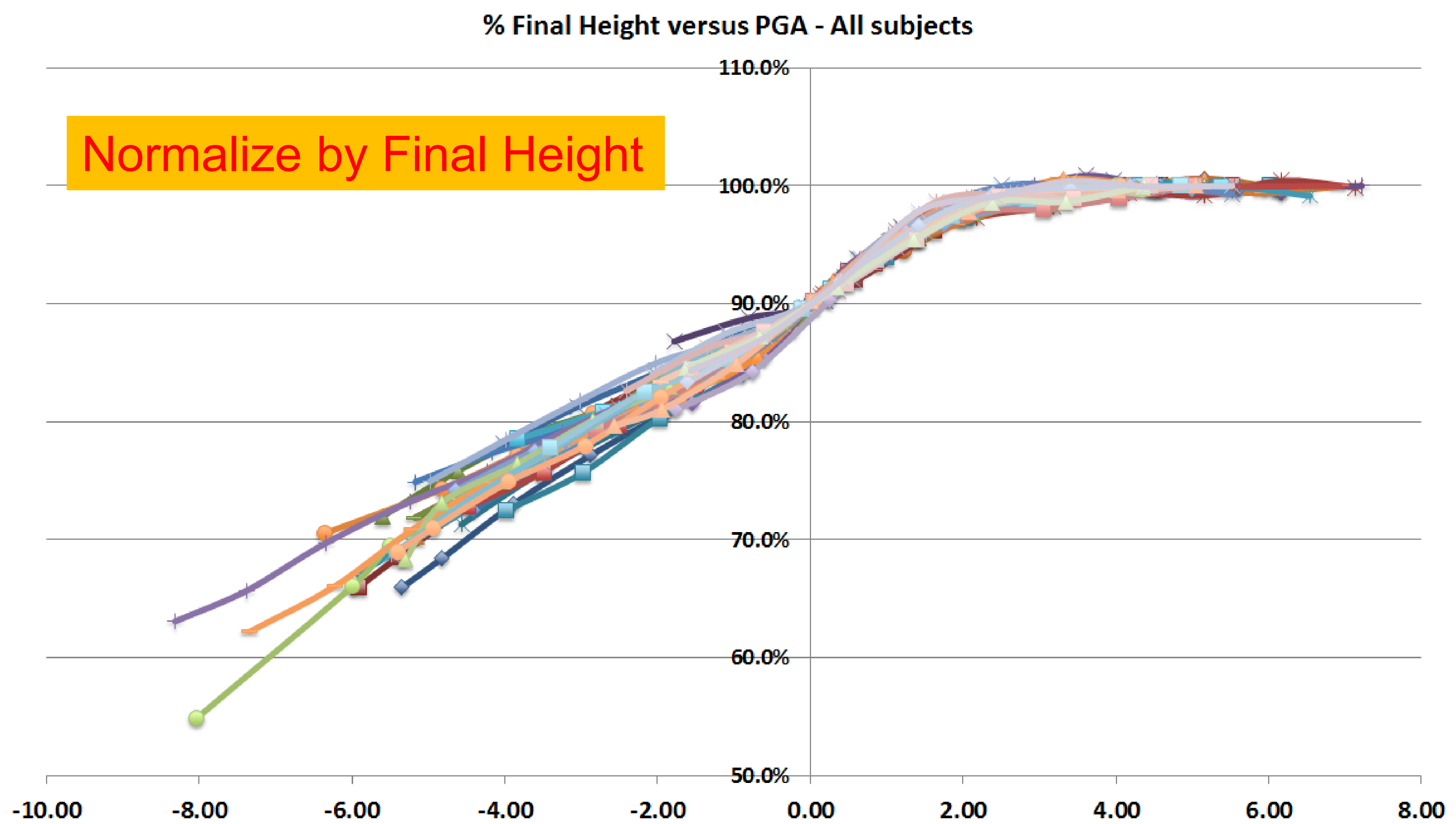


Shift each curve to age at which peak growth occurred

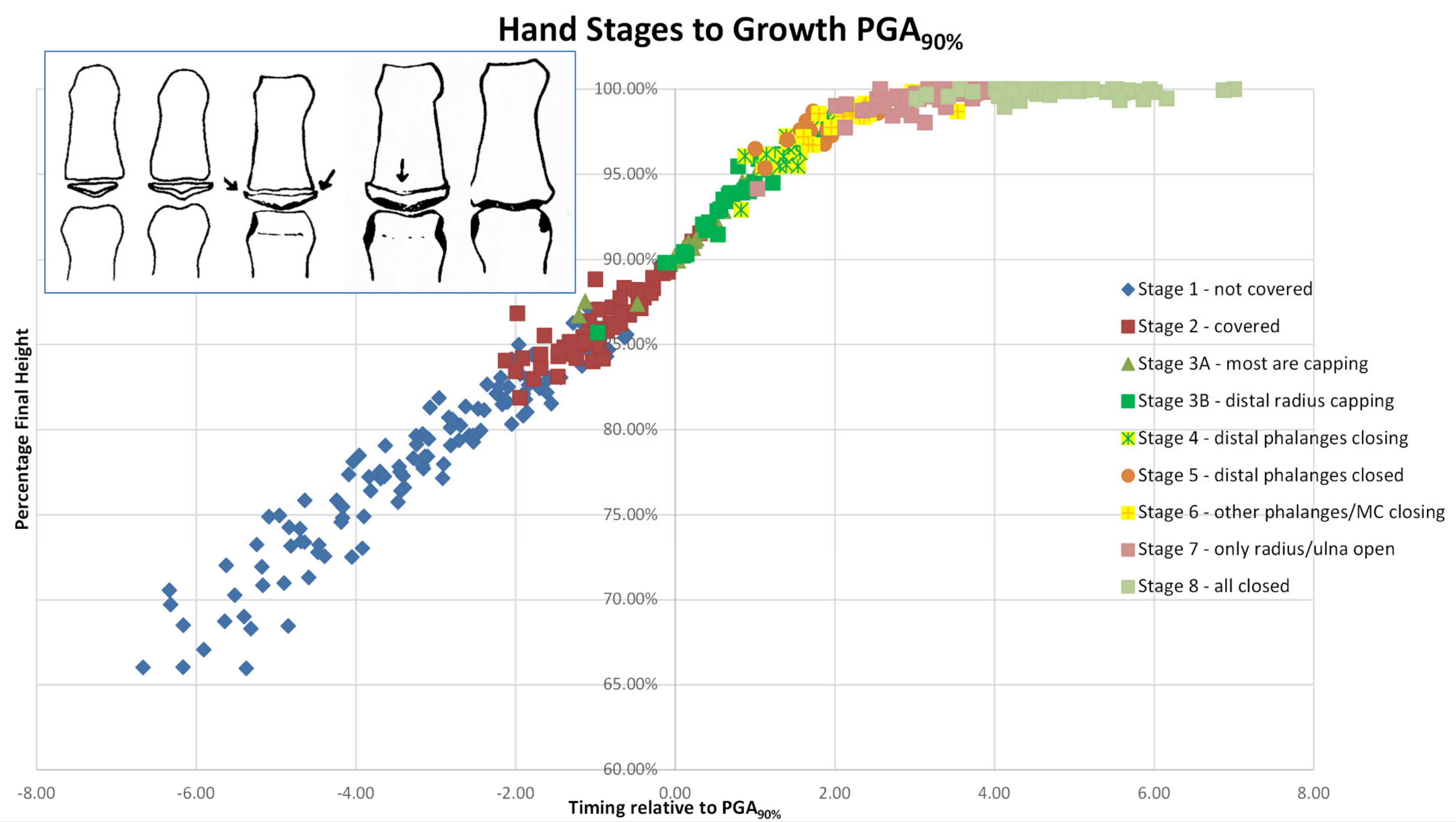
All growth curves can be "fit" to same relationship



Height Plotted Relative to Final Height

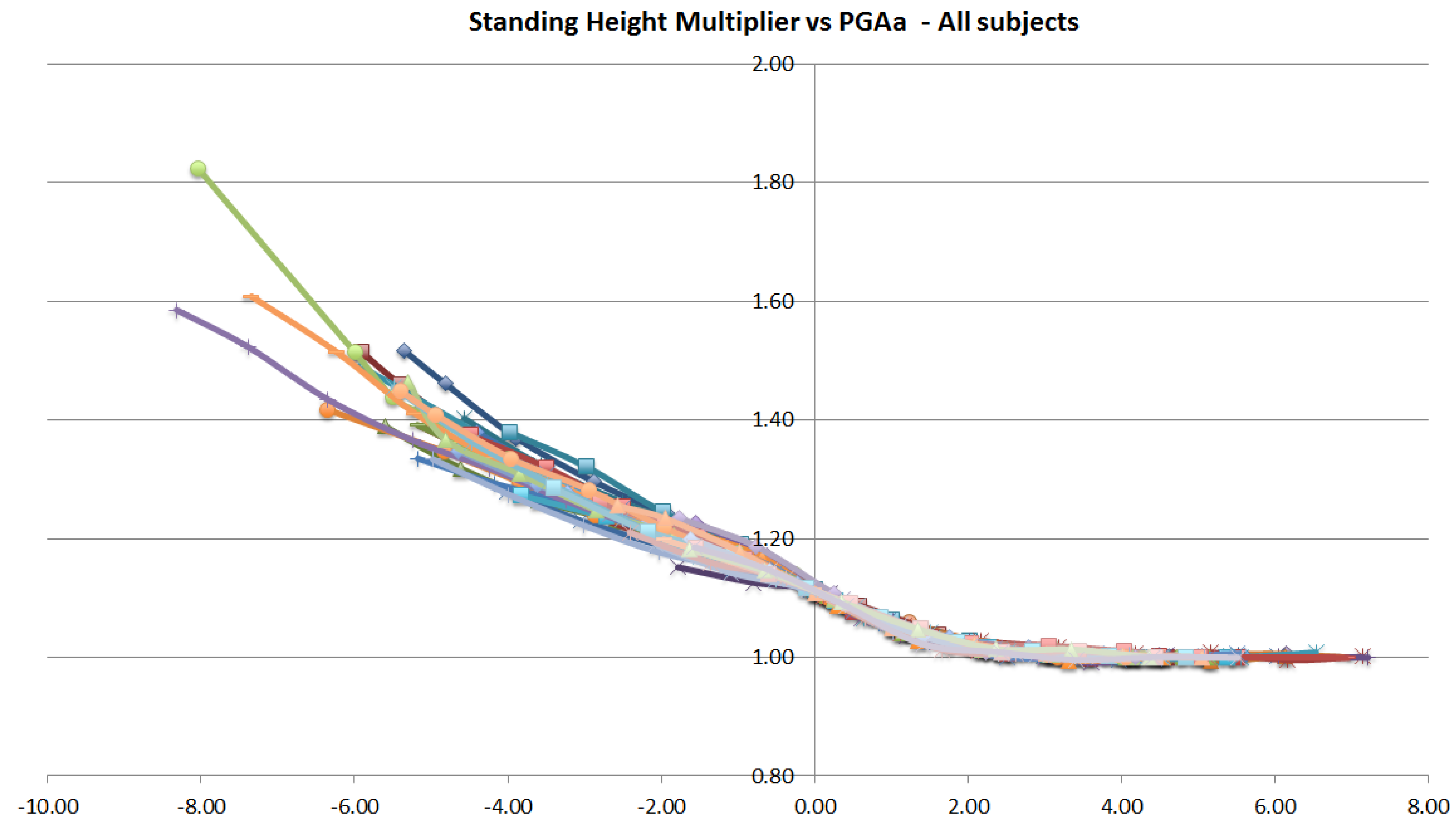


Height Velocity Distributed According to Skeletal Maturity



Reciprocal = relative growth remaining

Provides a multiplier for predicting further growth



Open Questions

- How well does this model modern cohort of children, racial diversity
- How well does this model spine growth for a child with scoliosis, syndrome, chronic disease
- Where is the growth occurring – vertebra vs. IVD
- Will need algorithm that derives number of vertebrae that should be “tethered” and for how long to achieve ultimate correction

Normal Spine Growth for EACH Vertebra

Data from CHOP Radiology Database

Normal Chest CT scans male and female children aged 1-19 years

Sriram Balasubramanian, PhD
Orthopedic Biomechanics Laboratory
Drexel University, Philadelphia, PA

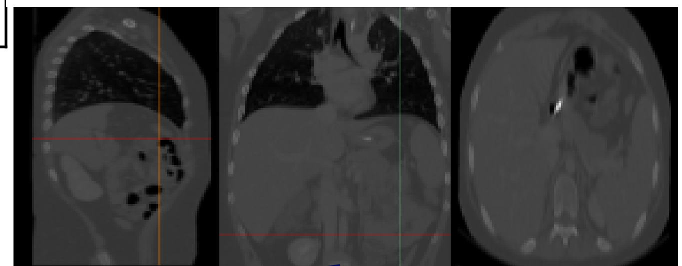
Methods

IRB Approval

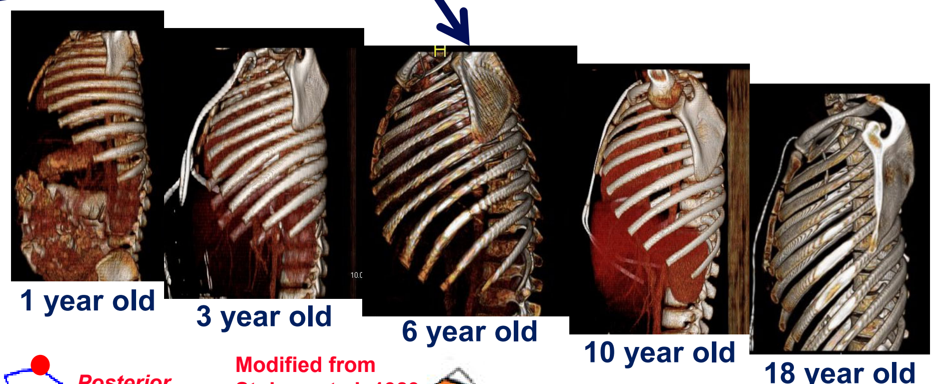
N = 13 AIS SUBJECTS		
Age (Yrs)	**11-13**	**14-16**
M	1	2
F	6	4

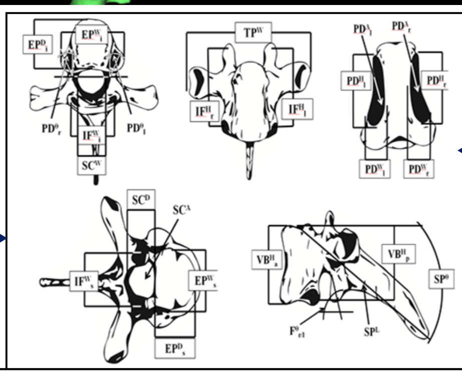
N=100 NORMATIVE SUBJECTS							
Age (Yrs)	**1**	**3**	**6-9**	**10**	**12-14**	**15-16**	**18**
M	7	5	6	6	7	8	6
F	9	5	7	5	7	11	5

COMPUTED TOMOGRAPHY (CT) SCANS

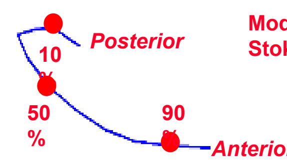


MIMCS BASED 3D RECONSTRUCTIONS





Thoracic vertebrae -- vertebral bodies (VB), spinous (SP) and transverse process (TP), and inter-facet (IF) dimensions. Height (H), width (W), depth (D), length (L), area (A), angle (θ), anterior (a), posterior (p), superior (s), inferior (i), right (r) and left (l)

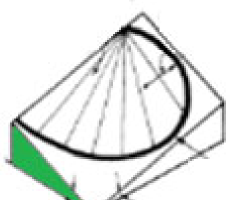


Rib apparent curvature

Modified from Stokes, et al. 1989

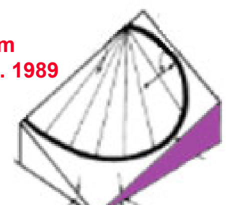
Enclosed Area

MATLAB CODE FOR GEOMETRIC QUANTIFICATION

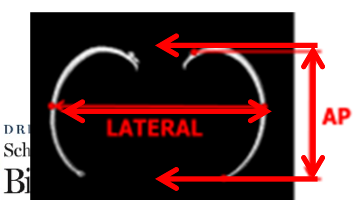


Frontal Angle

Modified from Stokes, et al. 1989



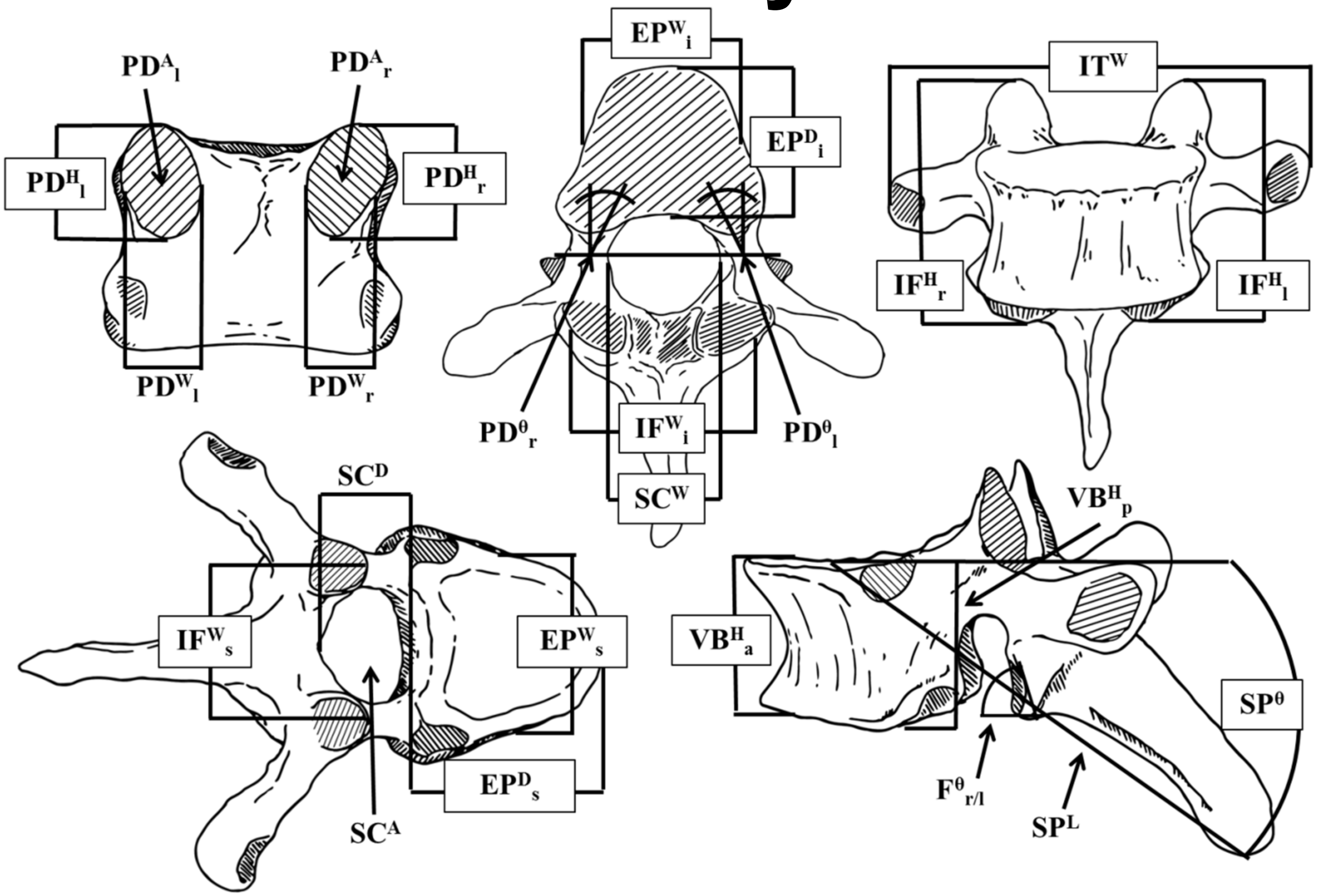
Lateral Angle



Thoracic Index

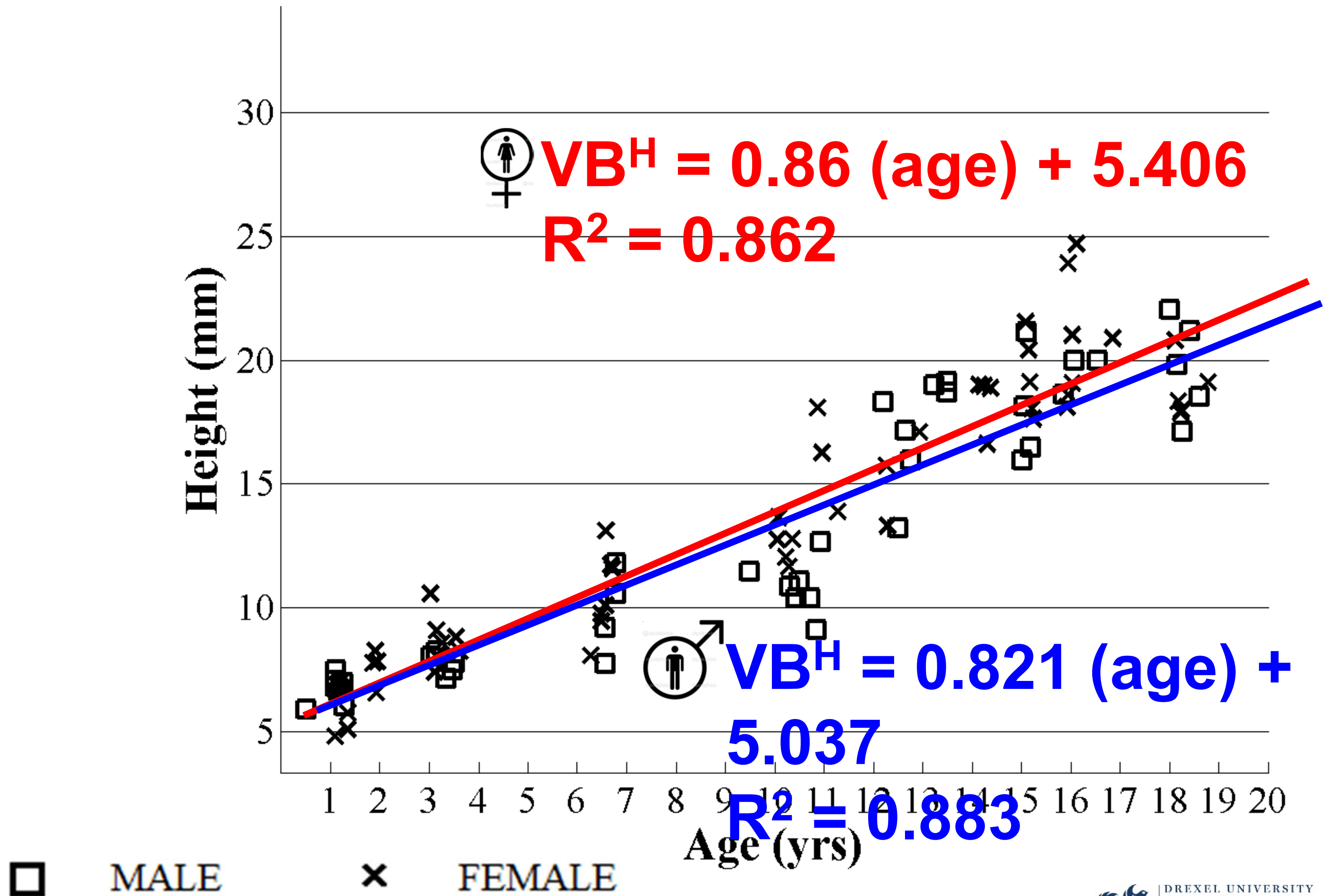
Science and Health Systems

Vertebra Geometry Parameters

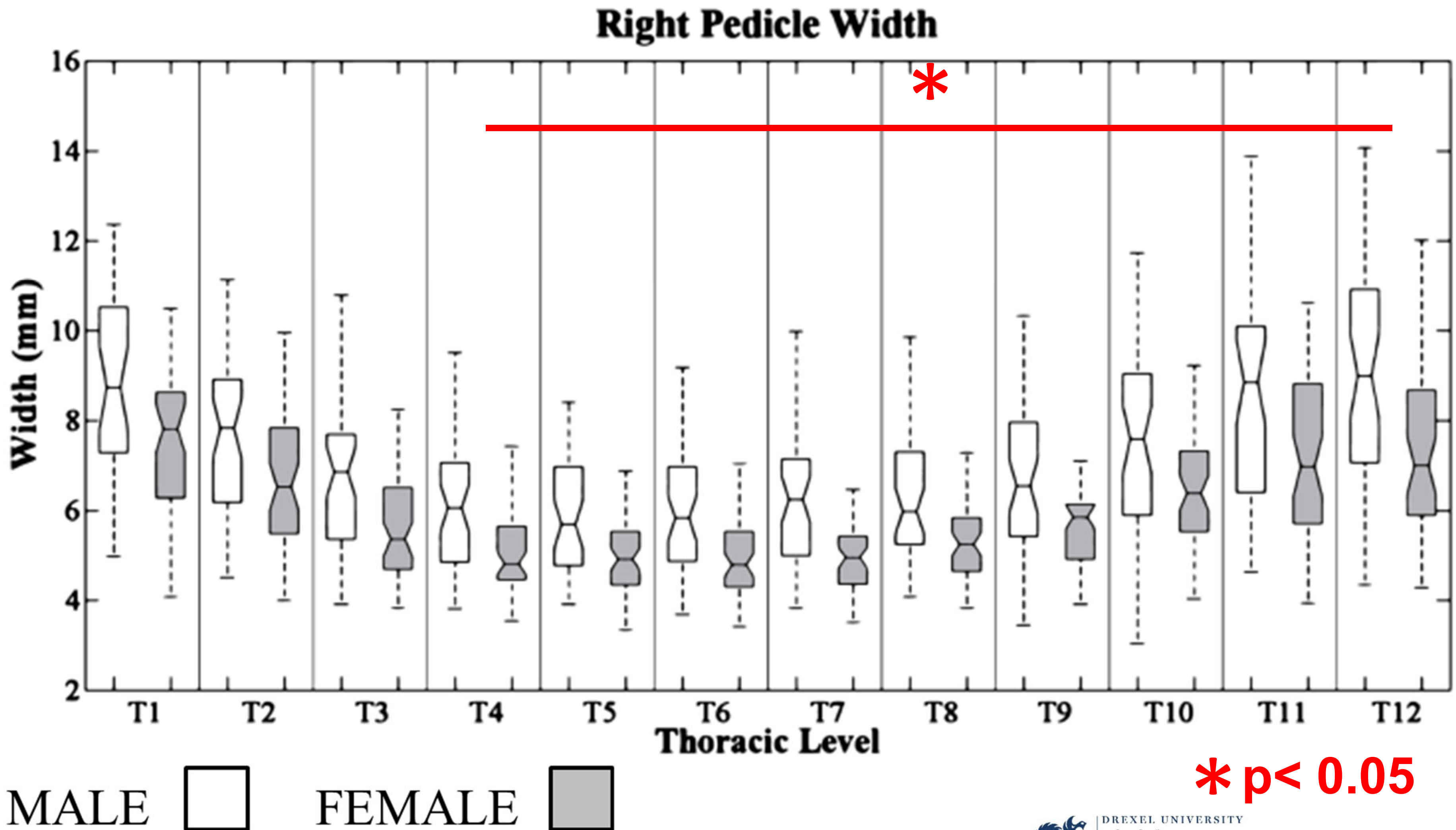


- Automated Landmark identification from 3D point cloud data
- Automated vertebral geometry parameter measurements, plots and statistical analysis

Ant. Vertebral body height correlates significantly with age at all levels (excpt T5)

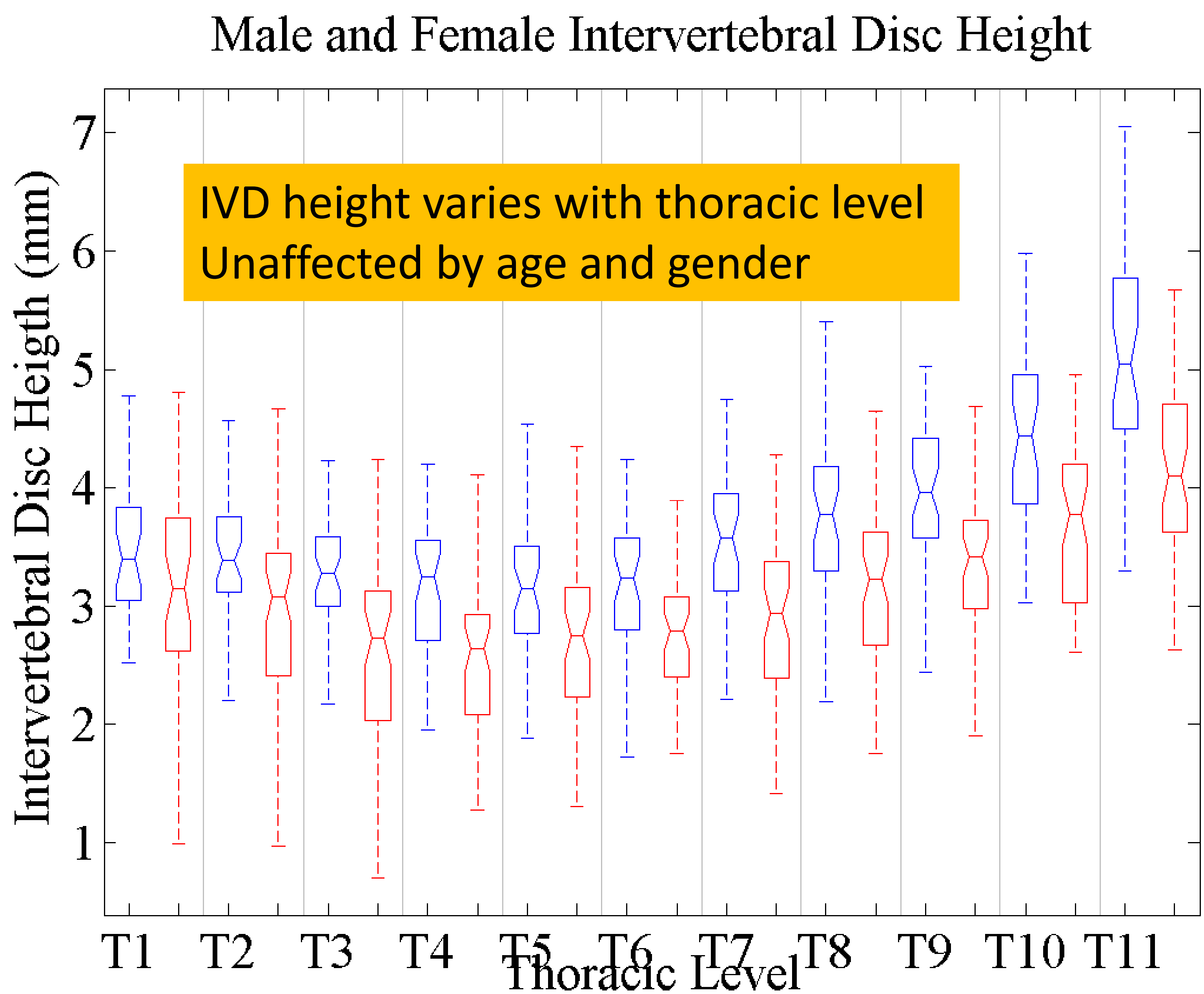


Pedicle width significantly varies between genders from T4 – T12

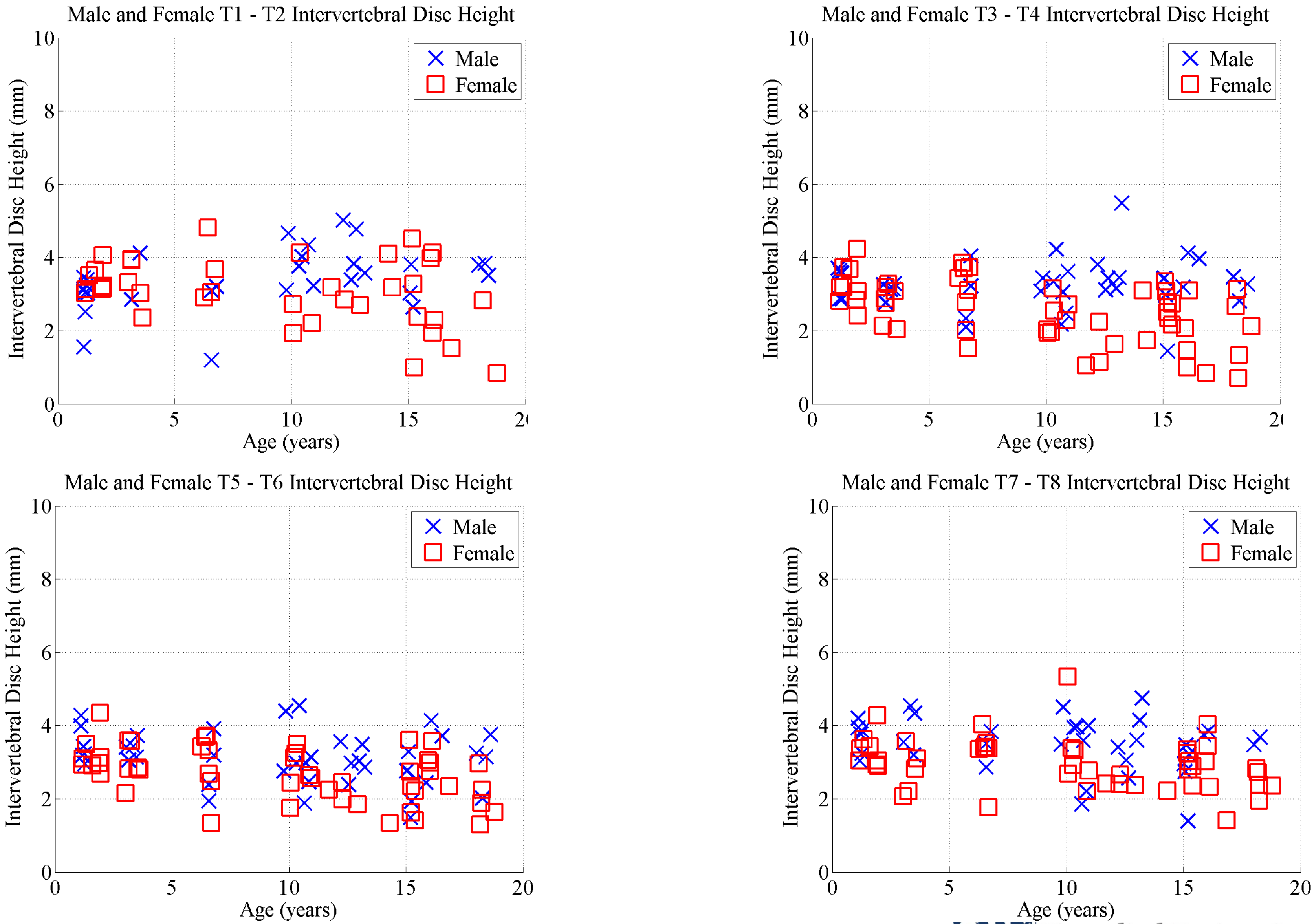


* $p < 0.05$

Presented at the 2013 BMES Conference, Seattle, WA

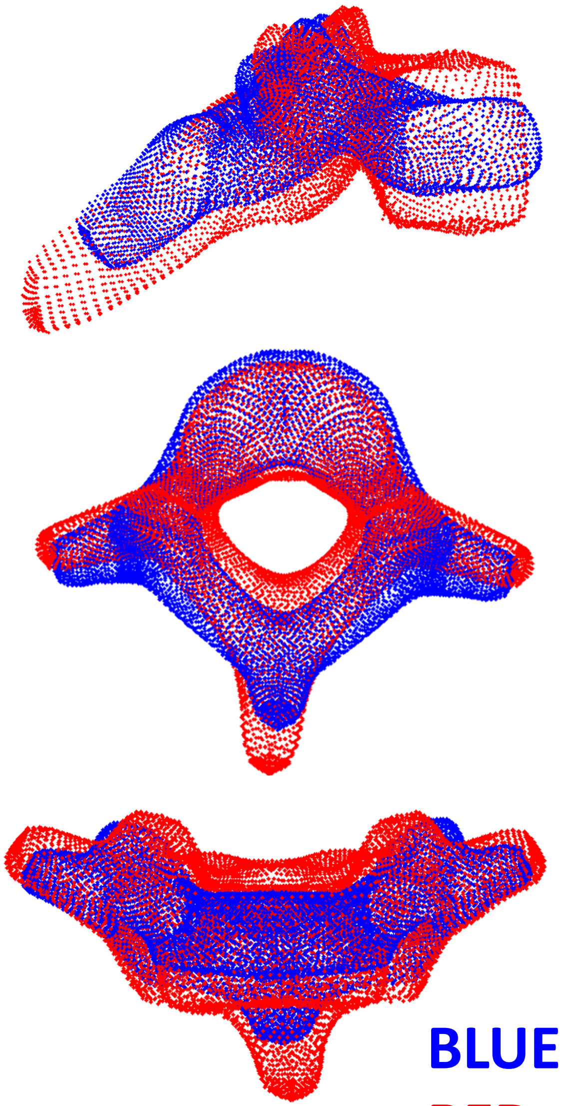

Male and Female Intervertebral Disc Height
IVD height varies with thoracic level
Unaffected by age and gender
Intervertebral Disc Heigth (mm)
1
2
3
4
5
6
7
T1
T2
T3
T4
T5
T6
T7
T8
T9
T10
T11
Thoracic Level

Thoracic intervertebral disc height varies with level
Unaffected by age and gender



Biomedical Engineering,
Science and Health Systems

Upper-Thoracic (T1 – T3)

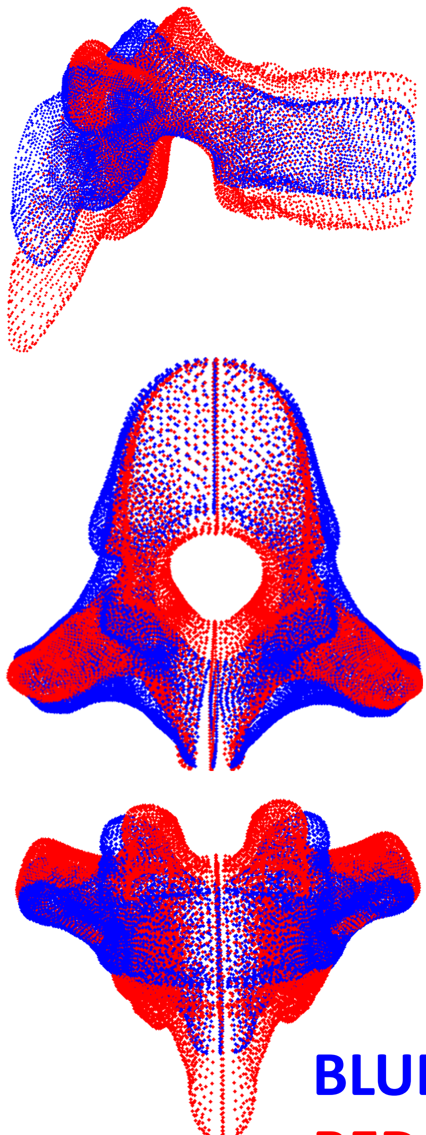


- Axial elongation of the vertebral body relative to other structures (shift in height to depth ratio)
- Increase in inferior facet angles
- Elongated Spinous process

BLUE – 1 YEAR OLD

RED – 19 YEAR OLD

Mid-Thoracic (T4 – T9)

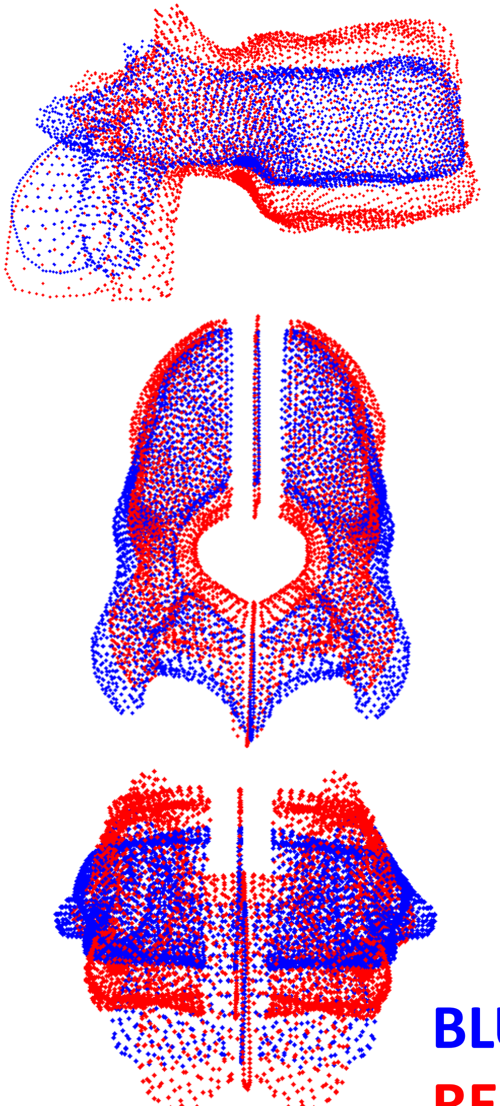


- Scaling of most vertebral features outward from spinal canal
- Increase in coronal transverse process angles
- Inferior and posterior spinous process lengthening

BLUE – 1 YEAR OLD

RED – 19 YEAR OLD

Lower-Thoracic (T10 – T12)



- Axial elongation of vertebra
- Enlarging of vertebral body relative to other structures
- Relative shortening of distance between vertebral body and facets

BLUE – 1 YEAR OLD

RED – 19 YEAR OLD

Vertebra Morphology

- Vertebral body, Pedicles, Facets, Transverse and Spinous process dimensions vary with age
- Spinal canal depth does not vary with age
- Pedicle width significantly varies with sex (T4 –12)
- No other vertebral geometry that depend on sex
- Asymmetries observed in vertebral body heights, endplate width & depth, and facet widths

Successful Prediction of Spine Morphology @ Maturity Requires Understanding Mechanism of Mechanicotransduction

- What is interplay between mechanics and biology?
- Must understand how manipulation of stress state predictably affects biology
  - What is the stress/strain stimulus that Hueter Volkman Principal is operative)

Finite Element Model To Predict Scoliosis Progression and Correction

J. Clin PhD, C.E. Aubin *Ph.D., P.Eng.*, S. Parent *MD, PhD*

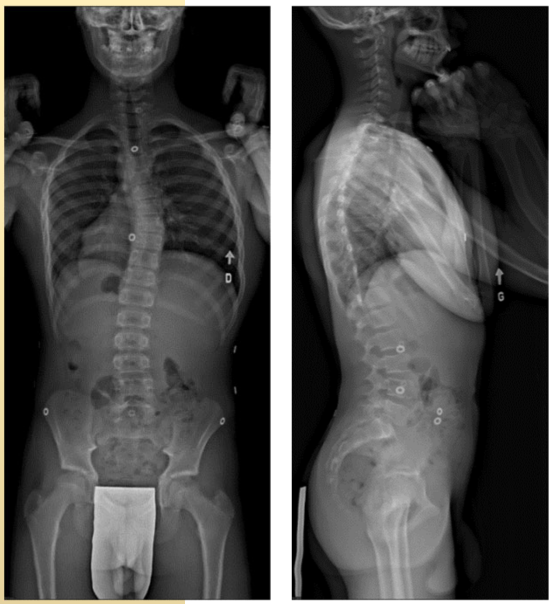
Spine
SPINE Volume 40, Number 6, pp 369-376

BIOMECHANICS

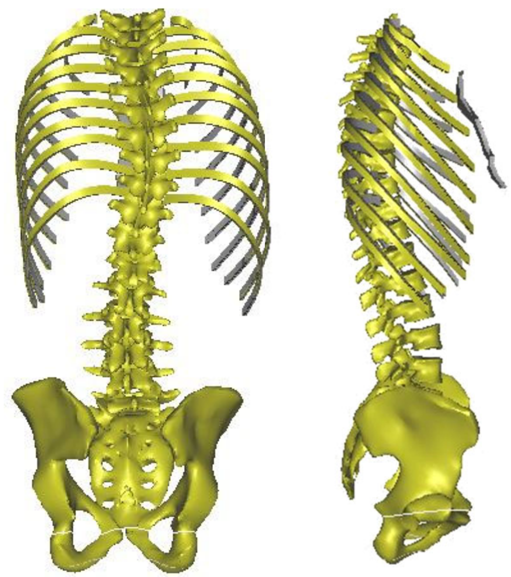
Biomechanical Simulation and Analysis of Scoliosis Correction Using a Fusionless Intravertebral Epiphyseal Device

Julien Clin, PhD,*† Carl-Éric Aubin, PhD, P.Eng.,*† and Stefan Parent, MD, PhD†

bi-planar calibrated radiographs



3D Reconstruction



Finite Element Model

Vertebrae, Discs; Articular joints; Ligaments; Rib cage; Soft tissues; Pelvis; Growth plates

POLYTECHNIQUE MONTRÉAL

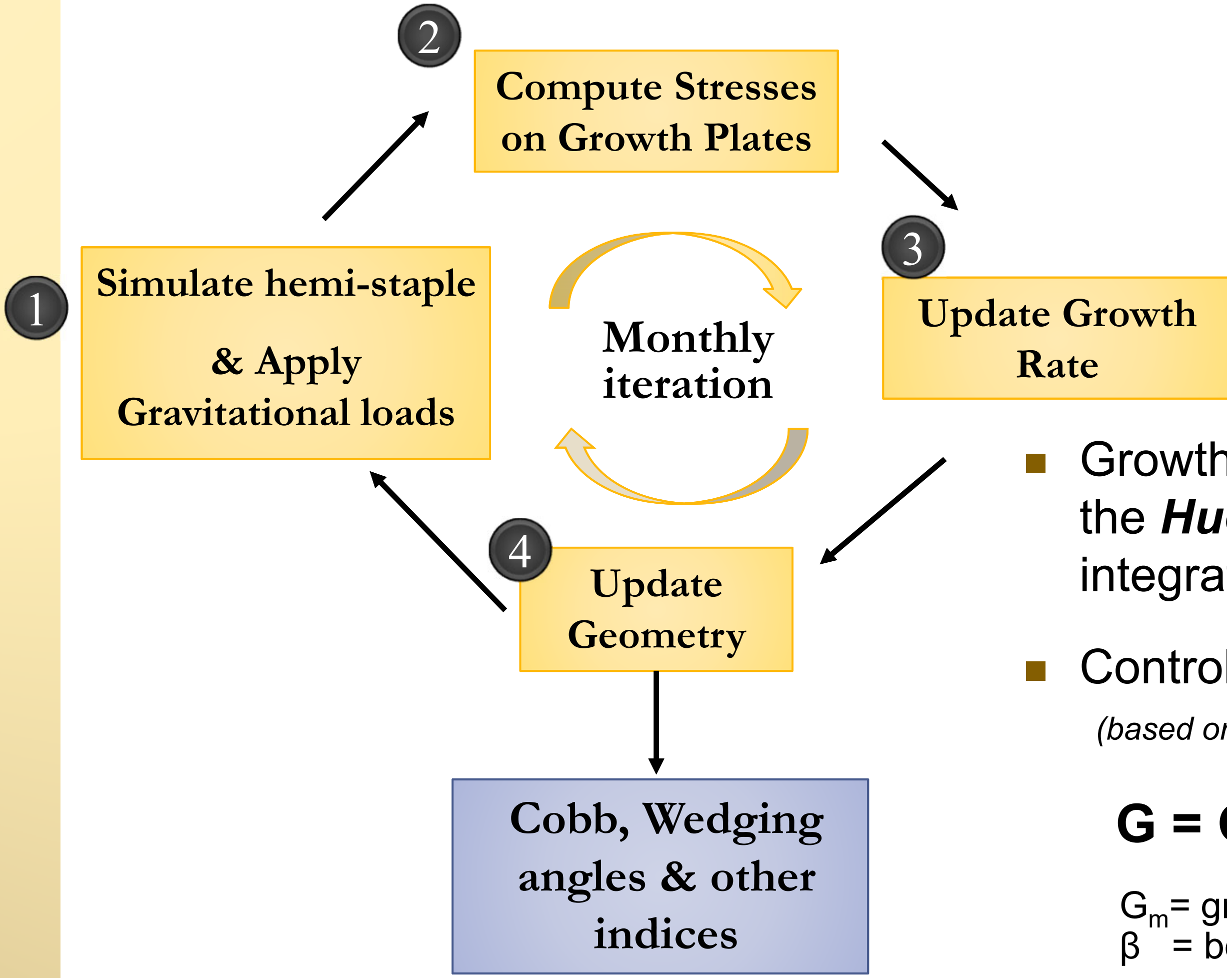
NSERC-Medtronic Industrial Chair in Spine Biomechanics

Polytechnique Excellence Research Chair in Orthopedic Engineering

CHU Sainte-Justine
Mother and Child University Hospital Center
For the love of children

Université de Montréal

Analytic Model of Growth Dynamics



- Growth dynamics governed by the ***Hueter-Volkmann*** principle integrated in FEM
- Controlling equation:

  (based on Stokes 90 & Villemure 02):

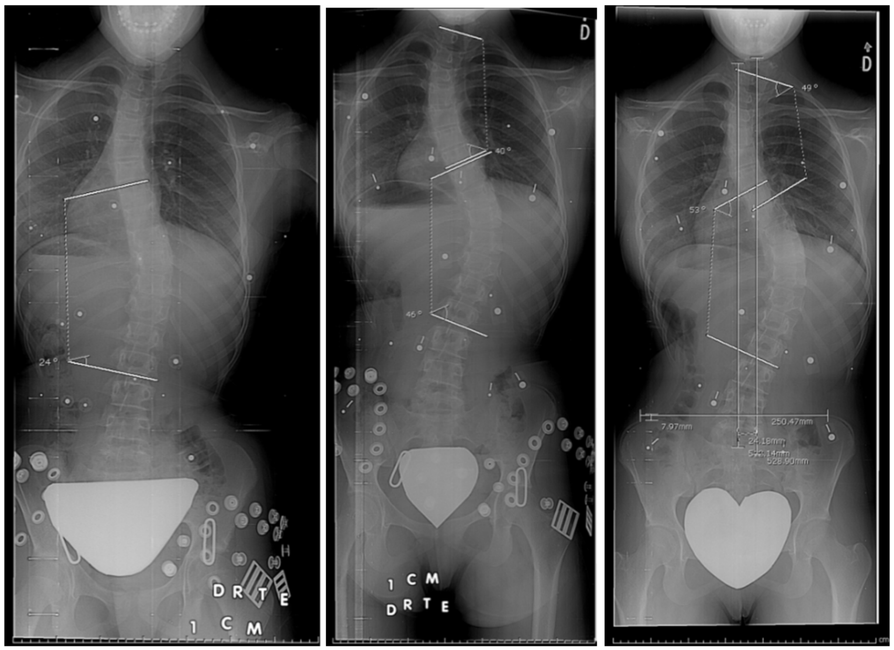
$$G = G_m \, [1 - \beta \, (\sigma - \sigma_m)]$$

G_m = growth rate (0.8-1.1 mm/year)
β = bone sensitive factor (1-3 MPa^{-1})
σ = stress in pathologic spine
σm = normal stress

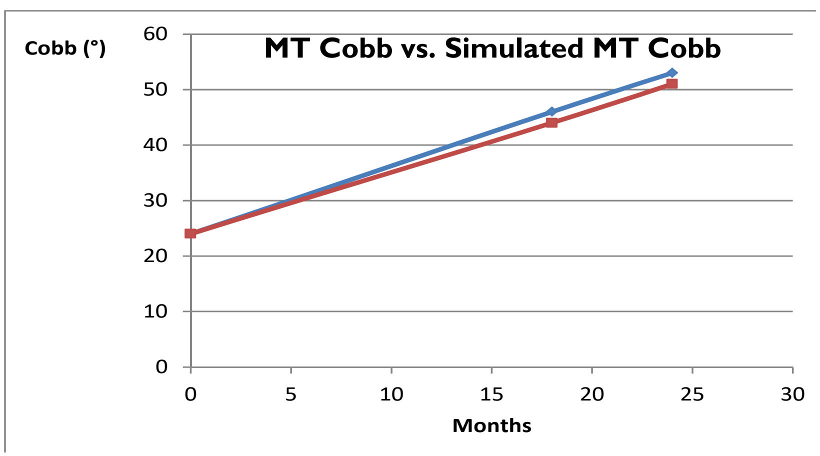
- Validated model to predict scoliotic progression (Villemure 2002, Stokes 2007, Lin 2011)

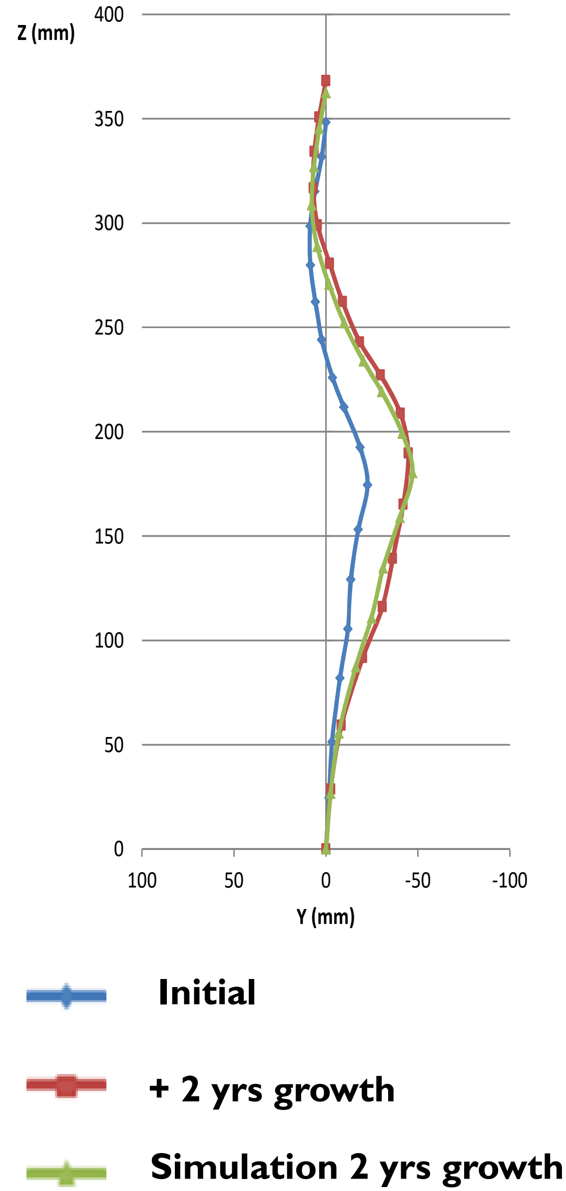
Growth Modeling Validation

(2 yrs growth simulation: creation of scoliosis)



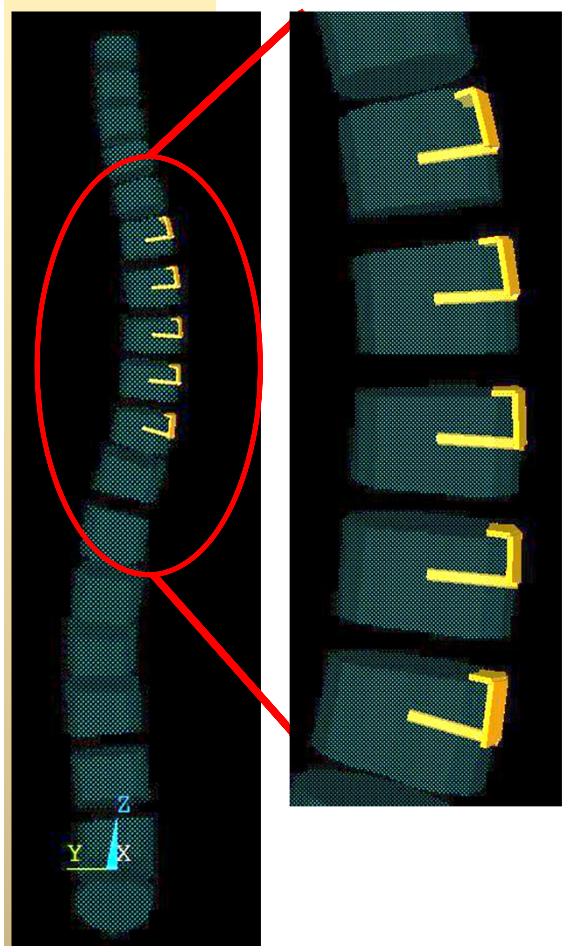
Sept. 2004 | April 2006 | Sept. 2006



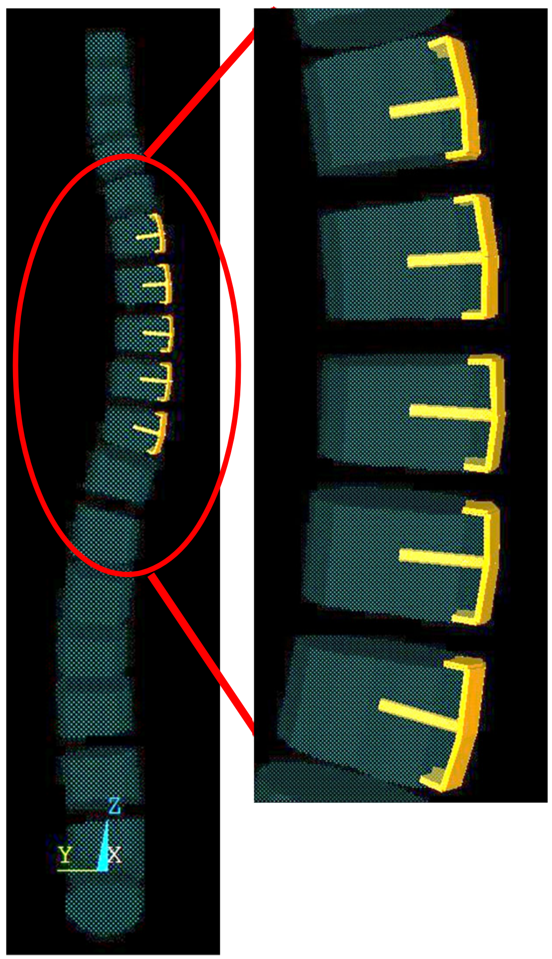


Growth Modulation: configuration tested

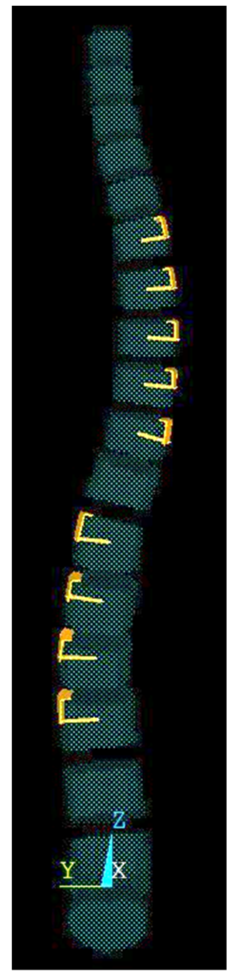
Config #1:
5 instrumented levels
(MT spine)
Single growth plates



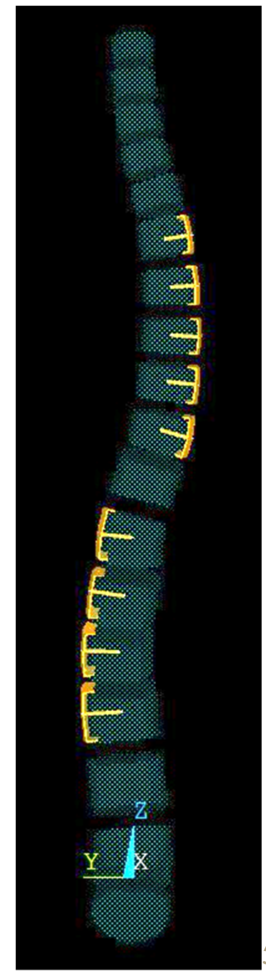
Config #2:
5 instrumented levels
(MT spine)
Both growth plates

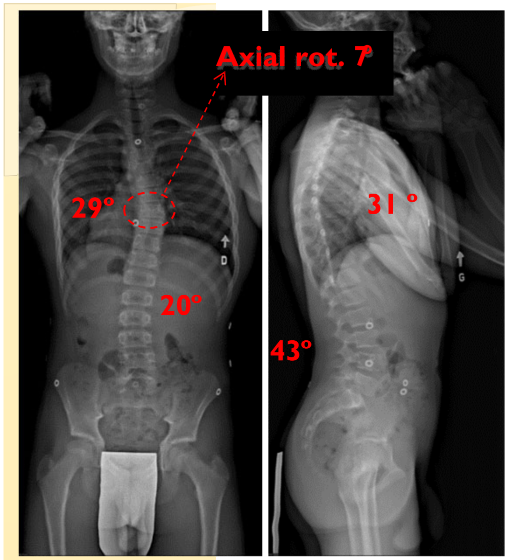


Config #3:
9 instr. levels
(MT & TL/L spines)
Single growth plates

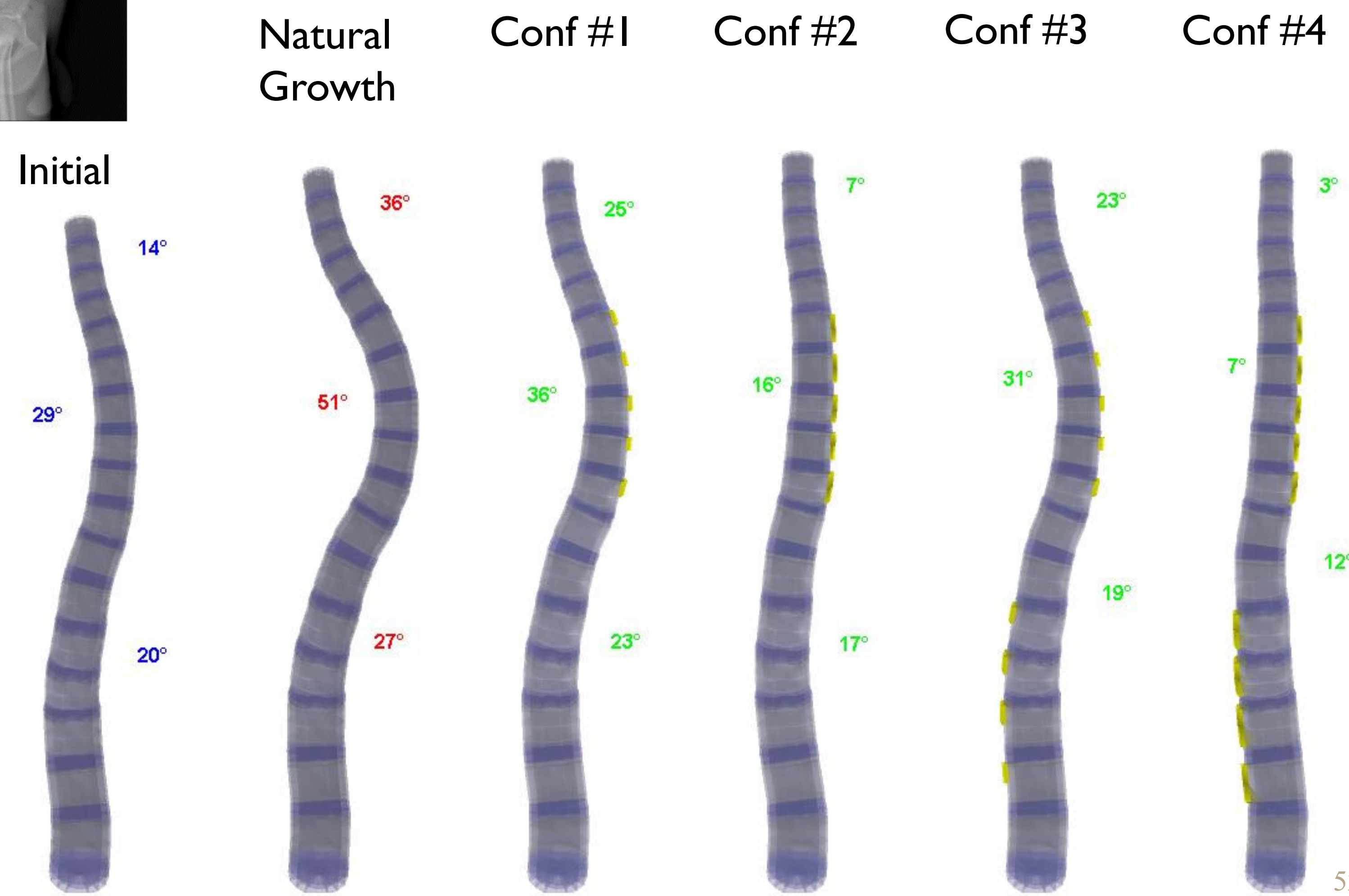


Config #4:
9 instr. levels
(MT & TL/L spines)
Both growth plates





Growth Modulation 2 yr simulation: correction of scoliosis using different configurations



Successful Device for Spine Growth Modulation MUST

- Be able to withstand applied loads & moments required to correct the spinal deformity and support those generated during activities of daily living

- Able to *predictably* modulate spine growth over the specified time interval required to achieve desired clinical effect

Thank You

SRS
Scoliosis Research Society

POSNA
The Pediatric Orthopaedic Society of North America