Is There a Role for Using EOS Technology Beyond Skeletal Maturity?

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Disclosures:

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Nuvasive: speaker

SRS: BOD

Spine Deformity: Associate Editorial Board

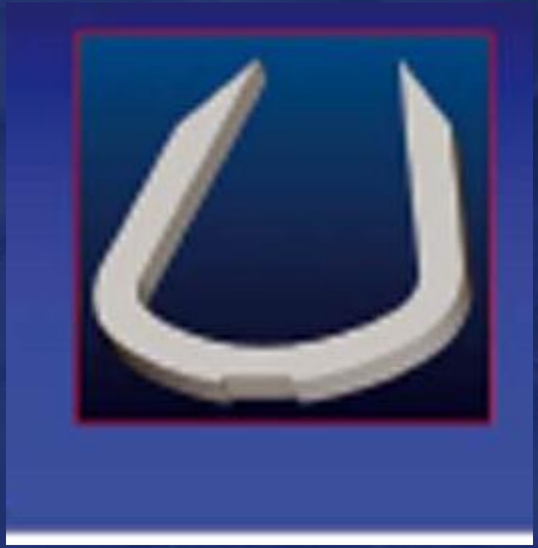
AVBT (tether)

- Thoracoscopic placement, utilizing a posterior non-fusion system in physician-directed manner
- Not FDA approved

"Well, yes, it's a routine procedure—if you routinely have someone slice open your body with sharp instruments and then fiddle with your insides."

Compression Based

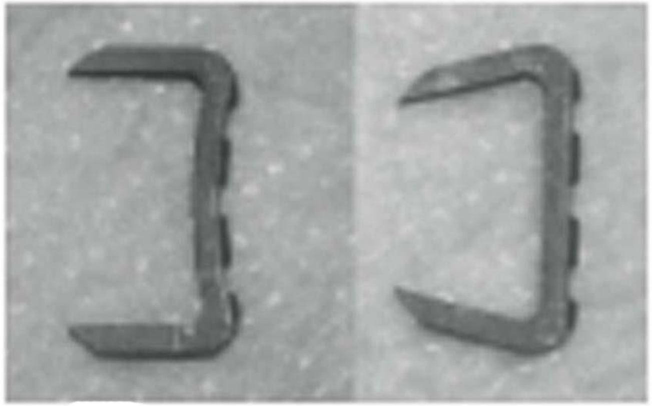
Vertebral Stapling



Anterior Vertebral Body Tethering

Vertebral Body Stapling (VBS)

- –Nitinol shape memory alloy
- –When cold, the prongs are straight
- –Prongs clamp down into the bone in a “C” shape when warmed to body temperature



Braun, et al. Spine 2004; (29) 18: 1980-1989.

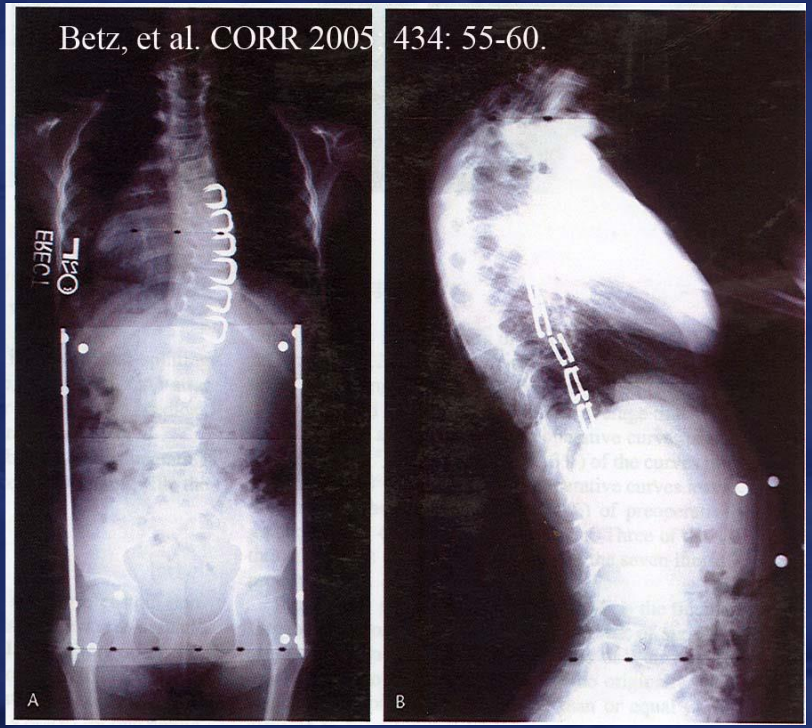
Figure 7. A, Generally, two staples are utilized at each vertebral segment. This can be in the form of two single staples, which allow the flexibility of adding a third anterior staple if desirable. B, However, to facilitate time, a double staple is commonly used.

Betz, spine 2004

GROWTH MODULATION

Vertebral Body Stapling (VBS)

- –Placement of a staple on the convex side of the anterior spine to stop development of the curve
- –Development of concave growth plates stabilize the progression of the curve or decrease curve



Vertebral Body Stapling (VBS)

- Spine 2003
  - 10 patients with curves < 50°
  - 60% remained stable, 40% progressed

- Cudihhy *Biomed Research Intl 2015*
  - not effective for T >35 and equal to bracing for lumbar

- Cahill *Spine Deformity 2018*
  - IS 7-15 yo, R0-1, min 2yr f/u
  - 20-35 degrees thoracic curves, 20-45 deg lumbar curves
  - 74% thoracic, 82% lumbar success (<10 deg progression)
  - 5/63 loose, 4/63 broken, 4/63 overcorrected
  - 2 SMA syndrome
  - **9/63 (14%) → fusion**

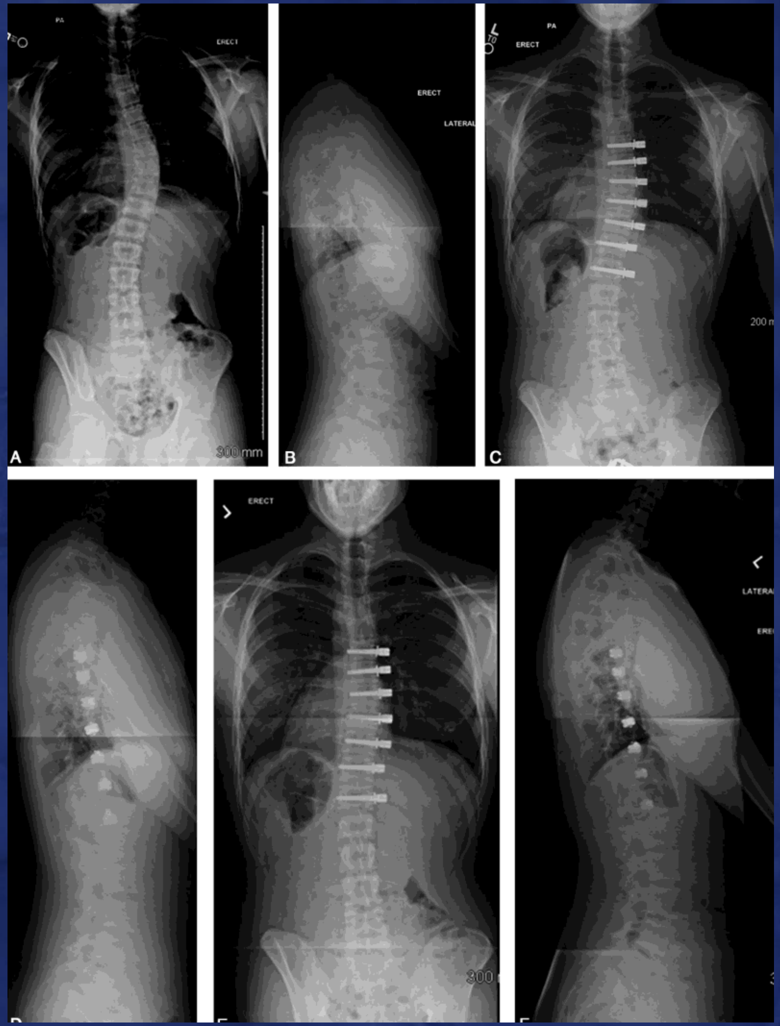
Tethers: Animal Research

- Braun 2006
  - Mechanical creation of scoliosis in immature goats using tethers
- Newton (multiple pubs)
  - bovine/porcine models
  - excellent radiographic and histologic evaluation

Braun, et al. JBJS 2005; 87 (9): 2038-2051.

VBT early clinical data

- Samdani Spine J 2014
  - 32 pts,1 yr f/u
  - 42→21 →17 deg
  - 2 pts overcorrected and still Risser 0-2



VBT early clinical data

- Pahys, Samdani et al paper 202 IMAST 2015
  - 100 cases, no major complications at 30d

- Wong et al paper 195 IMAST 2015
  - 5 girls age 9-12 R0, 34 mo f/u (24-42)
  - Cobb 40→24→18→20→at 34 mo
  - Youngest patients saw complete curve correction at 24 mo but adding on affect after TRC closure

Anterior Spinal Growth Tethering for Skeletally Immature Patients with Scoliosis

A Retrospective Look Two to Four Years Postoperatively

Peter O. Newton, MD, Dylan G. Kluck, MD, Wataru Saito, MD, PhD, Burt Yaszay, MD, Carrie E. Bartley, MA, and Tracey P. Bastrom, MA

Investigation performed at Rady Children's Hospital, San Diego, California

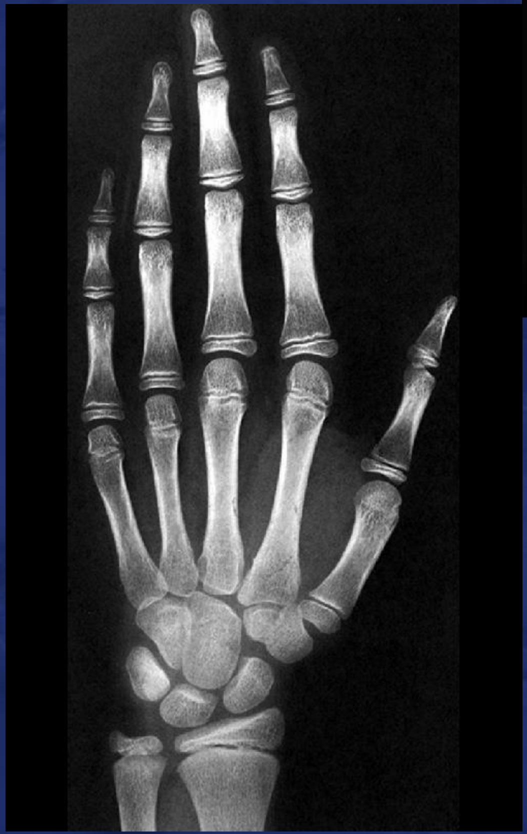
Background: Anterior spinal growth tethering (ASGT) has been shown to alter spinal growth with the potential to correct scoliosis while maintaining spine flexibility. The purpose of this study was to report the 2 to 4-year outcomes of ASGT in skeletally immature patients with thoracic scoliosis.

Methods: We conducted a retrospective review of patients with thoracic scoliosis who underwent ASGT with a minimum of 2 years of follow-up. Patient demographics, perioperative data, and radiographic outcomes are reported. A "successful" clinical outcome was defined as a residual curve of <35° and no posterior spinal fusion indicated or performed at latest follow-up.

Results: Seventeen patients met the inclusion criteria. The etiology was idiopathic for 14 and syndromic for 3. The mean follow-up was 2.5 years (range, 2 to 4 years). Preoperatively, all patients were at Risser stage 0, with a mean age at surgery of 11 ± 2 years (range, 9 to 14 years). There was an average of 6.8 ± 0.5 vertebrae tethered per patient. The average thoracic curve magnitude was 52° ± 10° (range, 40° to 67°) preoperatively, 31° ± 10° immediately postoperatively, 24° ± 17° at 18 months postoperatively, and 27° ± 20° at latest follow-up (51% correction; range, 5% to 11[illegible]%). Revision surgery was performed in 7 patients: 4 tether removals due to complete correction or overcorrection, 1 lumbar tether added, 1 tether replaced due to breakage, and 1 revised to a posterior spinal fusion. In 3 additional patients, posterior spinal fusion was indicated due to progression. Eight (47%) of the patients had a suspected broken tether. Ten (59%) of the 17 were considered clinically successful.

Best candidates?

- Smaller <u>flexible</u> (<30) curves- 45-60 deg
- Not too much rib deformity
- Failed bracing
- Sanders between 2 and 4
- Enough growth, but not *too* much



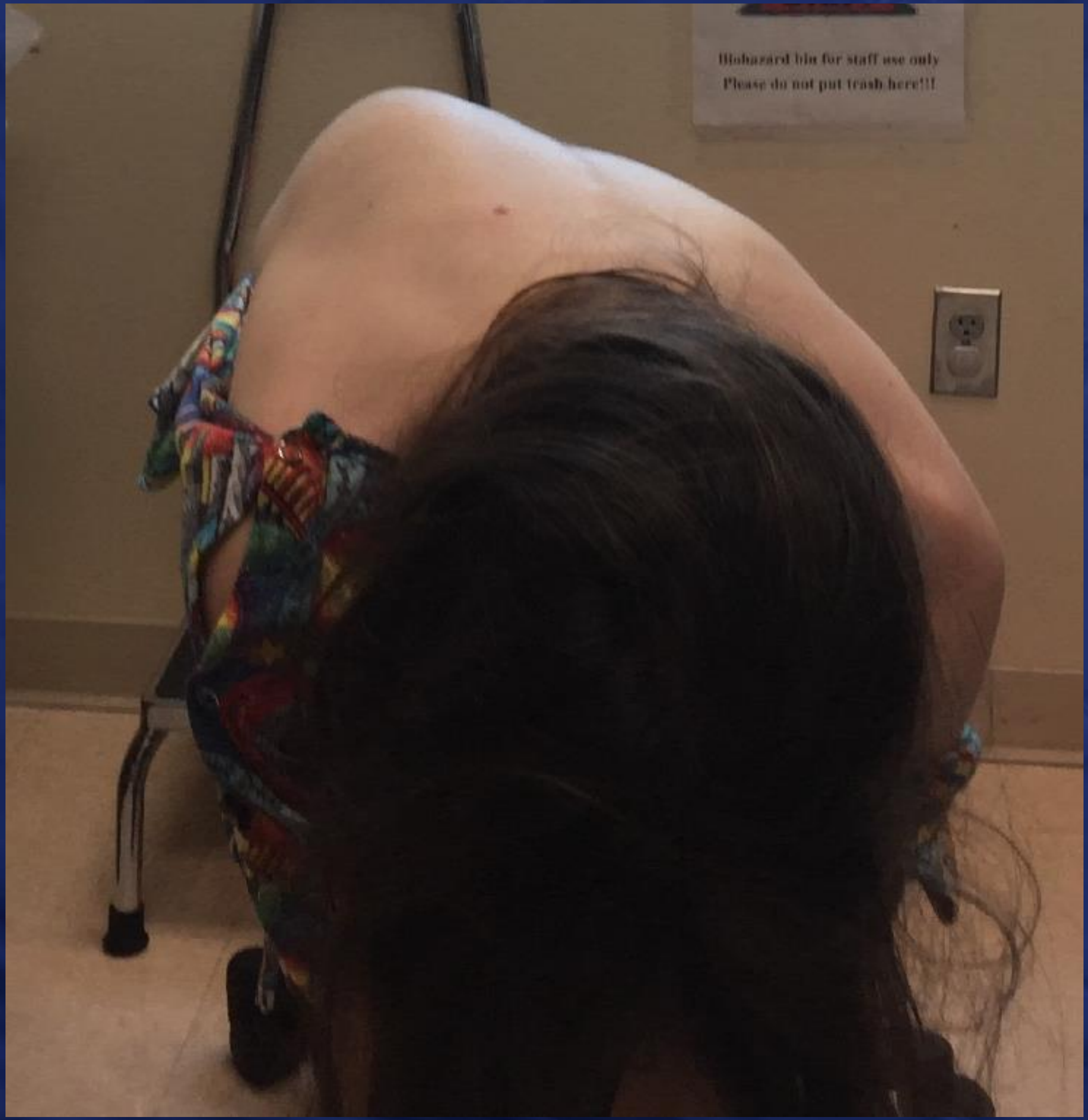
Predictability?

College of Medicine
Department of Orthopaedics & Rehabilitation
UNIVERSITY *of* FLORIDA

AC: 7 yo EOS

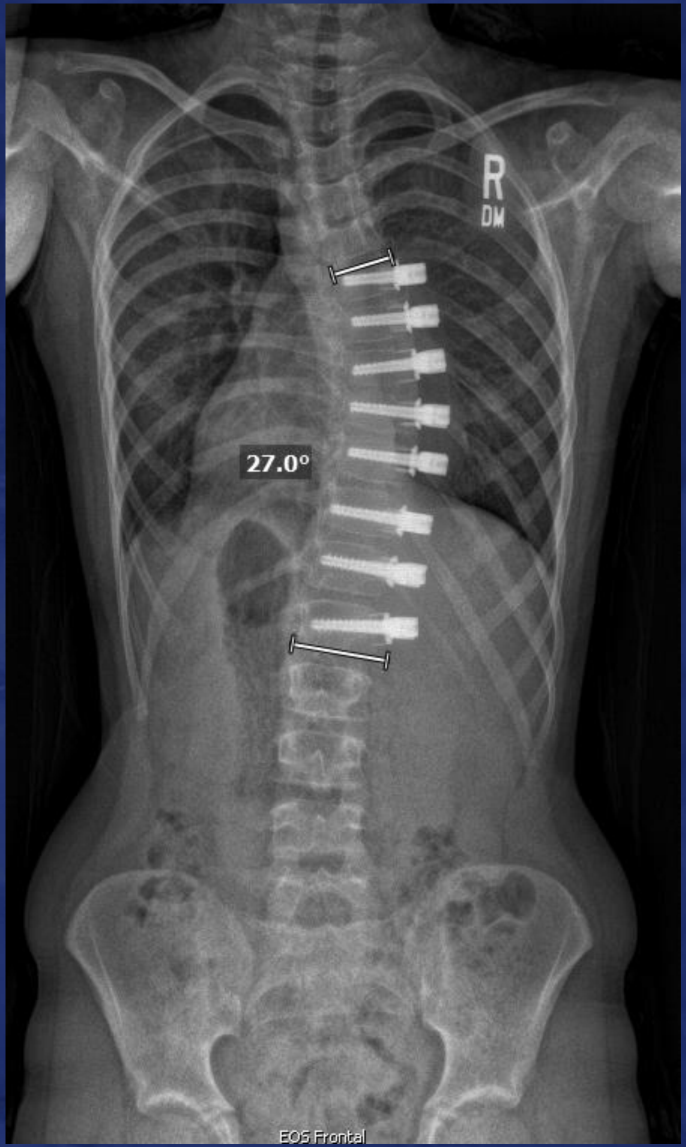
9 yo

10 yo

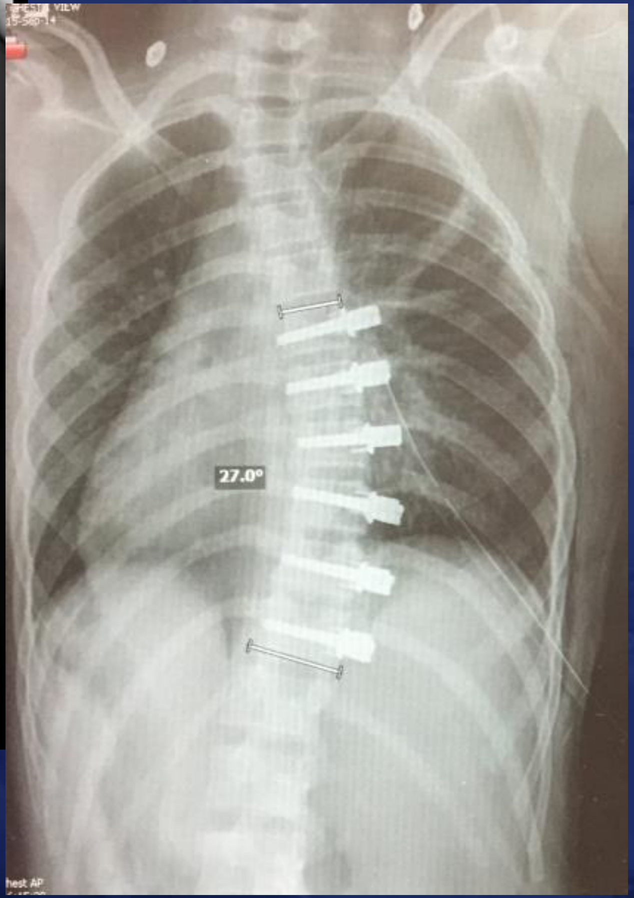

Biohazard bin for staff use only
Please do not put trash here!!!


44.8°

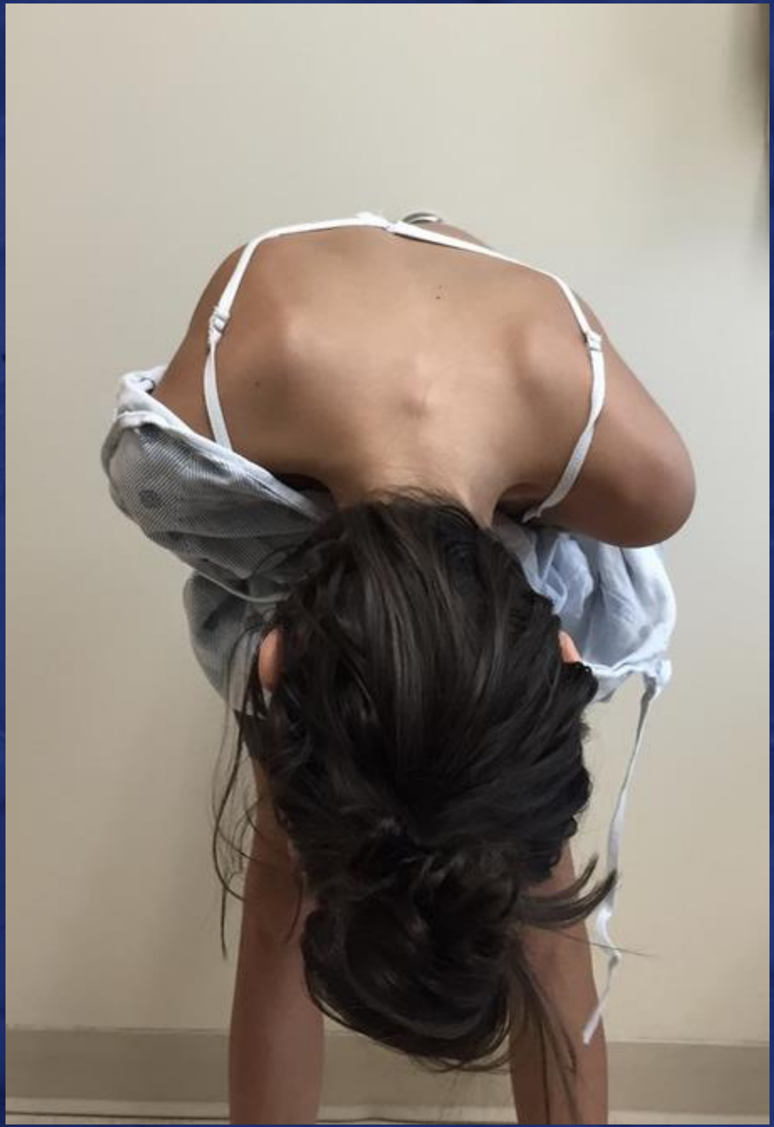

R
RAN


R
DM
27.0°
EOS Frontal

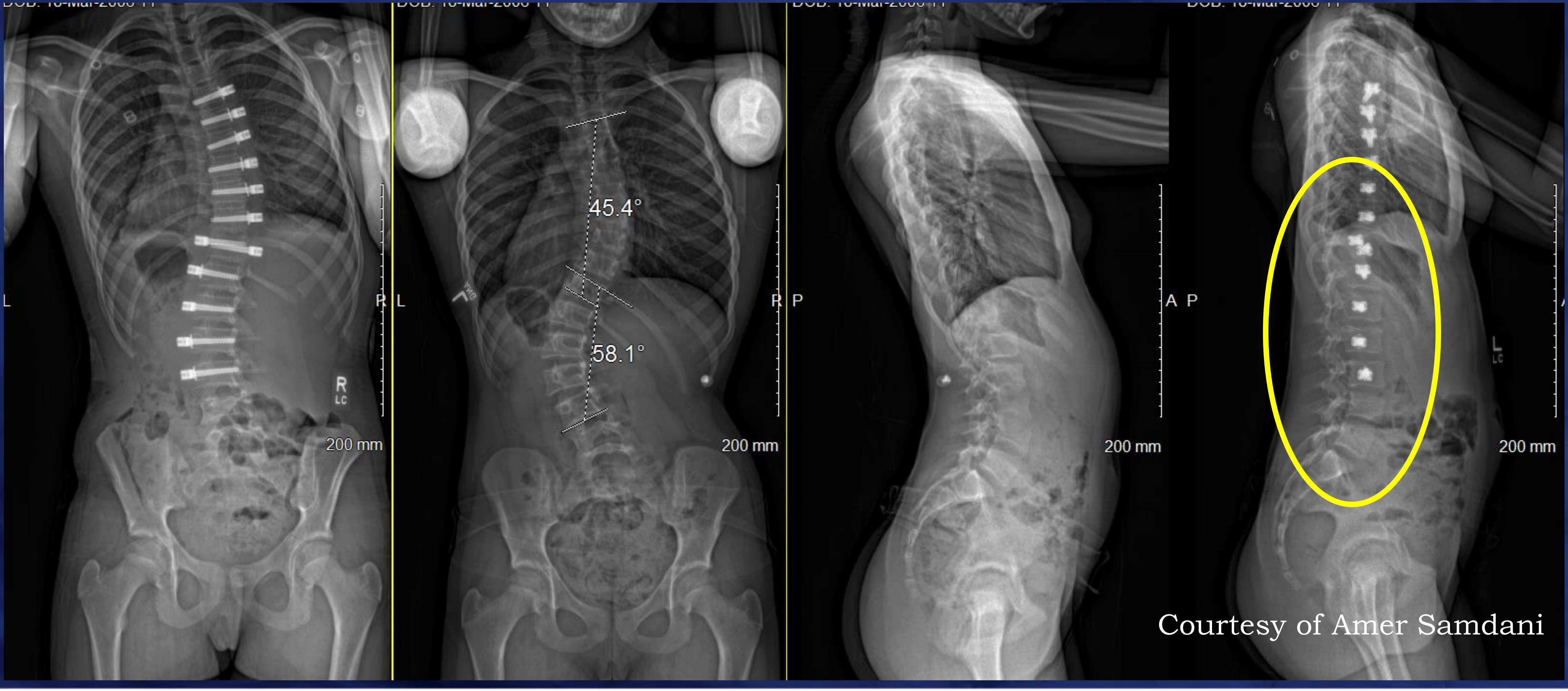
MB: 11 yo R0



Note change in L4



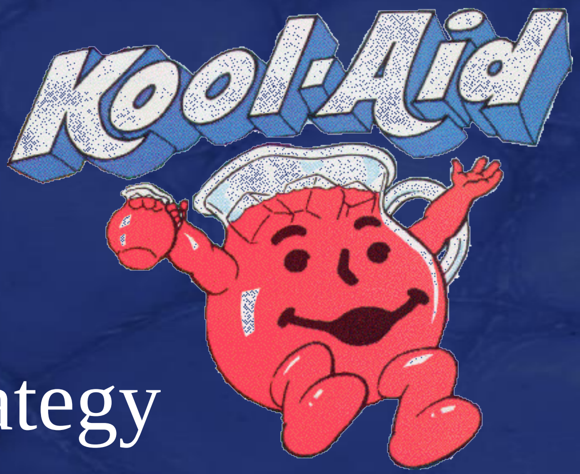
Sagittal alignment?



Courtesy of Amer Samdani

Anterior Vertebral Body Tethering

- Advantages over PSF
  - can completely correct using growth
  - less soft tissue disruption
  - better ROM (?)



- Commenced without clear strategy
  - Leave it in?
  - Take it out?

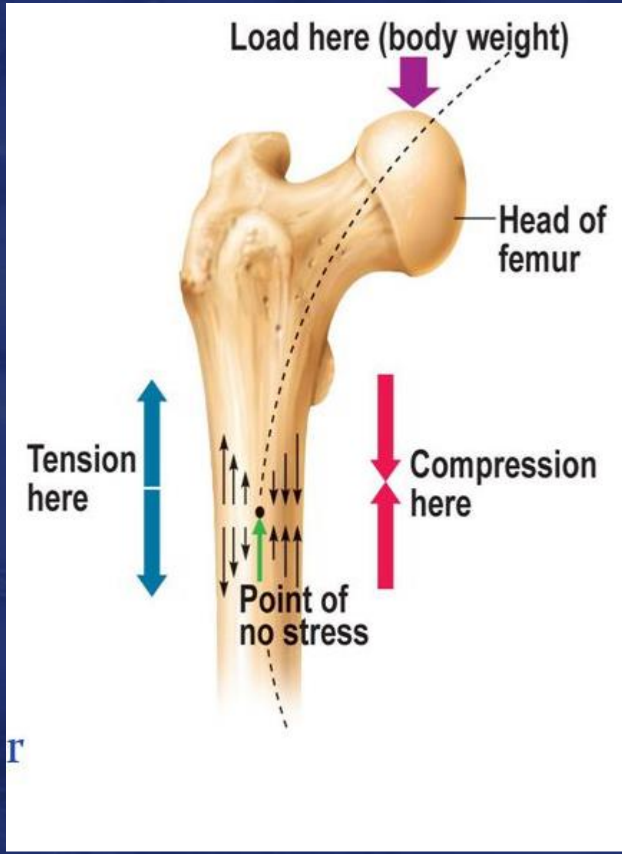
What is Known About Theoretical Advantages?

- Minimally invasive?
- Yes but may require >1 procedure
- Motion preserving
- Undocumented, and clinical relevance unknown if true
- Effect on discs/facets long term
- Uncertain- may still end up with fusion for pain or progression

What About Adults?

- Wolff's law: a bone remodels in response to forces or demands placed upon it

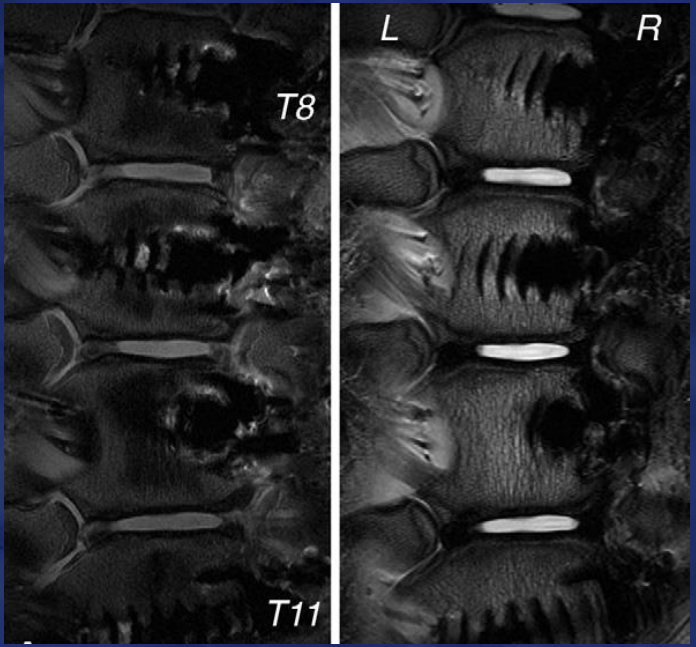
- Bone remodeling: reshaped by the independent action of osteoblast and osteoclasts.



- Growing vertebrae can change shape
- No published data on ability of scoliotic adult spine to remodel
- No published data on use of growth modulation in adults

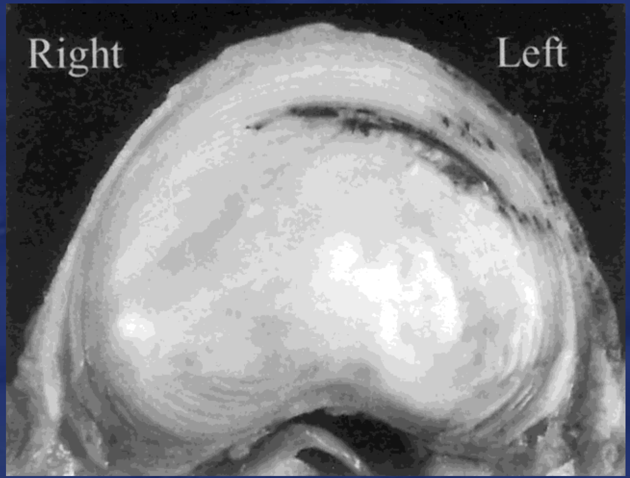
Effects on Discs and Vertebra?

- In immature spine, changes in both
  - Newton *Spine Deformity 2013, JBJS 2011*
  - physes thinner on the instrumented side
  - tethered discs thinner than sham, but demonstrated no contralateral to instrumented-side thickness difference
  - wedging of discs reversed (wider on tether side)
  - nucleus healthy but annulus dehydrated



Discs are sensitive

- Newell J *Mechanical Behavior Biomed Mat 2017*
  - under compression, annulus becomes stiffer
  - under tension, annulus becomes weaker
- Even needlestick injury to annulus causes progressive damage
  - Fazzalari *Spine 2001*
- Can a disrupted/degenerating disc preserve normal motion?



So What if it Fails?

- If tether is achieving the correction and tether fails?
  - recurrence?
  - pain?
- Repetitive thoracoscopic procedures?
  - pulmonary function?

Reasons to use new technology

- Advance patient care

- Other pressures can create potential conflict

Suggested Process for Understanding Before Dissemination

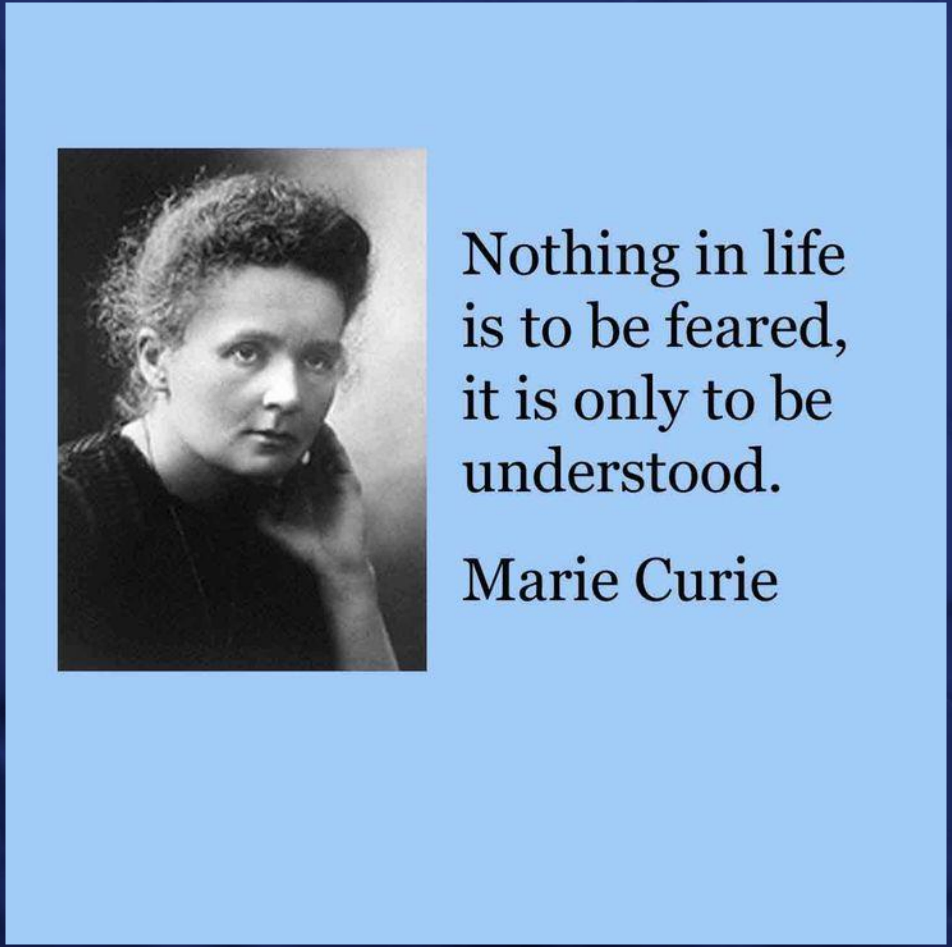
- Experimental work must be conducted under guidelines
- Physician, industry or society directed IDE, carefully controlled enrollment and monitored outcomes
  - Could be a subset within a registry
- Independent selection of requirements for sites for participation.

Downsides of "Understand then Disseminate"

- Time consuming
- Impractical
  - Randomization difficult
  - Effects unknown for years

- Expensive
- Limits on creativity/ ingenuity
  - (loss of crowdsourcing effect) slows down improvements
- Liability issues

Our Job



Understand then disseminate

Protect patients and develop a potentially beneficial technology safely

Thank you