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

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AVBT (tether)

• Thoracoscopic placement, utilizing a posterior non-fusion system in physician-directed manner

• Not FDA approved
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
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 $< 50^\circ$
  - 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%) $\rightarrow$ 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
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 Yasay, 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 preoperative curve magnitude was 52° ± 10° (range, 40° to 67°) preoperatively, 31° ± 19° immediately postoperatively, 24° ± 17° at 18 months postoperatively, and 27° ± 20° at latest follow-up (51% correction; range, 5% to 116%). 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 flexible (<30) curves- 45-60 deg
- Not too much rib deformity
- Failed bracing
- Sanders between 2 and 4
- Enough growth, but not too much
Predictability?
AC: 7 yo EOS

9 yo

10 yo
MB: 11 yo R0

Note change in L4
Sagittal alignment?
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?
- Motion preserving
- Effect on discs/facets long term

- Yes but may require >1 procedure
- Undocumented, and clinical relevance unknown if true
- 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

Nothing in life is to be feared, it is only to be understood.

Marie Curie
Thank you