VEPTR®/VEPTR II™
Vertical Expandable Prosthetic
Titanium Rib: Indications and Limitations

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Objectives

• Define early onset scoliosis and thoracic insufficiency syndrome (TIS)

• Discuss classification system for “growth friendly spine implants”

• Discuss impetus for development of VEPTR device and provide current indications for use of VEPTR

• Discuss where VEPTR may be more beneficial than other growing spine treatment modalities

• Review complications associated with VEPTR and contraindications for use
Disclaimer

- VEPTR®/VEPTR II™ is no longer subject to HDE (humanitarian device exemption); obtained FDA clearance as Class II medical device

- All other devices discussed are not approved growing constructs by the FDA and are used off-label
Early Onset Scoliosis

- Early Onset Scoliosis (EOS) = Scoliosis of any etiology developing before the age of 10

- Age 10 appears to be the logical differentiation

- Treatment principles for children with scoliosis onset at age 5-10 more closely resemble those for children <5 years than >10 years
The Ideal Spine Instrument

- Controls alignment of progressive curves
- Decreases curve over time (when growth potential exists)
- Allows most normal growth of the spine and thorax
- Does not require repeat surgery
- Leaves spine flexible
“Growth Friendly Implants”

- Classification creates a common language and facilitates comparative studies

- Three categories based on forces exerted on the spine:
  - Distraction-based
  - Compression-based
  - Guided growth

“Growth Friendly Implants”

Distraction-Based:

• Mechanically applies a distractive force across a deformed segment

• Anchors at top and bottom of the implants; commonly attaches to spine, ribs, and/or pelvis
“Growth Friendly Implants”

Distraction-Based Examples:

- Spine-based or rib-based growing rods
- VEPTR
- Remotely expandable devices
“Growth Friendly Implants”

Compression-Based:

- Compressive forces applied to the convexity of the curve
- Causing convex growth inhibition
- Compressive force may be generated both mechanically at implantation or over time as the spine grows
“Growth Friendly Implants”

Compression-Based Examples:

- Vertebral staples
- Tethers
“Growth Friendly Implants”

Guided Growth:

• Anchors multiple vertebrae (usually including the apical vertebrae) to rods with mechanical forces, including translation at the time of the initial implant

• Majority of anchors not rigidly attached to the rods, thus permitting longitudinal growth over time.
“Growth Friendly Implants”

Guided Growth Examples:

- Luque trolley
- Shilla
Thoracic Insufficiency Syndrome

- Inability of thorax to support normal respiration or lung growth
- Seen in patients who have severe congenital scoliosis with fused ribs

*Campbell, RM et al. The Effect of Opening Wedge Thoracostomy on Thoracic Insufficiency Syndrome Associated with Fused Ribs and Congenital Scoliosis. JBJS 2005, 86-A:8*
Thoracic Insufficiency Syndrome

- 27 patients; congenital scoliosis with fused ribs.

- Opening wedge thoracostomy with longitudinal lengthening using a chest wall distractor called VEPTR.

The Effect of Opening Wedge Thoracostomy on Thoracic Insufficiency Syndrome Associated with Fused Ribs and Congenital Scoliosis

By Robert M. Campbell Jr., MD, Melvin D. Smith, MD, Thomas C. Massis, MD, John A. Mangos, MD, Donna B. Willey-Courakis, MD, Nuneet Kose, MD, Ricardo F. Pineiro, MD, Marden F. Aldes, DDS, Hua L. Duong, MD, and Jennifer L. Sutker, BS.

Investigation performed at the Thoracic Institute, Christus Santa Rosa Children’s Hospital, San Antonio, Texas.
Thoracic Insufficiency Syndrome

• Mean age 3.2 (0.6-12.5), average follow-up 5.7 years; all progressive congenital scoliosis

• Placement of VEPTR with lengthening every 4-6 months

• Scoliosis 74° → 49°; height of thoracic spine ↑ 0.71 cm/year; patients had congenital scoliosis with fused ribs
Thoracic Insufficiency Syndrome

Fig. 5-A The mean vital capacity at the time of the last follow-up for patients less than two years old at time of surgery (Group A), those two years of age or older at the time of surgery who had no history of spine fusion (Group B), and the three patients who were two years of age or older at time of surgery and had had a prior spine fusion (Group C). There was no significant difference among these three groups. Fig. 5-B The mean percentage of the predicted normal vital capacity at the time of the last follow-up for Groups A, B, and C. There is a significant difference between Groups A and B but not between Groups B and C, with the numbers available.
Thoracic Insufficiency Syndrome

Complications:

- 52 in 22 patients
- Most common complication seen in 7 pts was asymptomatic proximal migration of device through ribs
Thoracic Insufficiency Syndrome

Conclusions:

• Opening wedge thoracostomy & VEPTR directly treat segmental hypoplasia of the hemithorax

• Addresses TIS by lengthening & expanding hemithorax; allows growth of thoracic spine & rib cage

• Corrects most components of chest wall deformity; indirectly corrects congenital scoliosis, no fusion
Which Implant Should I Use?

Evaluating the Extent of Clinical Uncertainty Among Treatment Options for Patients with Early-Onset Scoliosis

Jacqueline Corona, MD, Daniel J. Miller, MD, Jenny Downs, PhD, MSc, Behrooz A. Akbarnia, MD, Randal R. Betz, MD, Laurel C. Blakemore, MD, Robert M. Campbell Jr., MD, John M. Flynn, MD, Charles E. Johnston, MD, Richard E. McCarthy, MD, David P. Roye Jr., MD, David L. Skaggs, MD, John T. Smith, MD, Brian D. Snyder, MD, PhD, Paul D. Sponseller, MD, MBA, Peter F. Sturm, MD, George H. Thompson, MD, Muharrem Yazici, MD, and Michael G. Vitale, MD, MPH

Investigation performed at Columbia University Medical Center, New York, NY

• 315 patient case scenarios
• 8 treatment options grouped into 5 categories: conservative (observation, casting, bracing), growth guidance, growth modulation, distraction instrumentation, and spinal fusion

Which One?

- 11 surgeons (average experience of 22 years) selected treatment

- Purpose was to identify areas of clinical uncertainty and evaluate collective equipoise in treating EOS

- RCTs= Gold standard for EBM but used only in a small portion of literature
Which One?

• Distraction-based instrumentation was treatment of choice for 60° curves with recent curve progression

• Younger children treated with rib or spine-based distraction; older children with spine–based distraction
Which One?

Areas of Focus for Future RCTs:

• Conservative vs. Distraction: Idiopathic EOS with moderate deformity
• Rib vs. Spine Distraction: 3-6 year olds with progressive EOS and hyperkyphosis
• Observation vs. Arthrodesis: 12 year olds who completed lengthening
• Distraction vs. Arthrodesis: 9-year olds with EOS
Indications for VEPTR

• VEPTR/VEPTR II is indicated for skeletally immature patients with severe, progressive spinal deformities and/or three dimensional deformity of the thorax associated with or at risk of TIS

• TIS is the inability of the thorax to support normal respiration or lung growth

• TIS includes patients with progressive congenital, neuromuscular, idiopathic, or syndromic scoliosis
VEPTR in the Literature

Use of Vertical Expandable Prosthetic Titanium Rib (VEPTR) in the Treatment of Congenital Scoliosis Without Fused Ribs

Robert F. Murphy, MD,* Alice Moisan, BSN,† Derek M. Kelly, MD,* †
William C. Warner, Jr, MD,* † Tamekia L. Jones, PhD,‡ and Jeffrey R. Sawyer, MD* †

- Multi-center database identified 25 patients
- 50 month follow-up
- 60% (15) had 41 complications; 68% of complications device related (infection, wound dehiscence, hook migration)
- “VEPTR is an effective treatment for patients with CS without fused ribs, as evidenced by improved radiographic parameters and increased spinal height, with a complication rate which is high but similar to other methods of treatment.”

VEPTR in the Literature

VEPTR to Treat Nonsyndromic Congenital Scoliosis: A Multicenter, Mid-term Follow-up Study

John M. Flynn, MD,* John B. Emanus, MD,† John T. Smith, MD,‡ Randal R. Betz, MD,§ Vincent F. Deeney, MD,|| Neeraj M. Patel, MD, MPH, MBS,¶ and Robert M. Campbell, MD*

- 8 pediatric spine centers; 24 patients; 96% with fused ribs
- 41 month follow-up, 50% had 5 or more expansions
- Most common adverse events were device migration in 7 patients and infection or skin problems in 6 patients
- “VEPTR insertion with expansion thoracoplasty represents a successful treatment paradigm for nonsyndromic congenital spinal deformities.”

VEPTR in the Literature

Use of VEPTR expanded to other diagnoses: syndromic, idiopathic, neuromuscular.


A Potential Advantage?

- 38 patients, 5 centers, >2 year follow-up, at least 3 lengthening procedures, mixed diagnoses

**Figure 1. Cobb angle versus number of lengthenings.**

- “Law of Diminishing Returns” with repeated lengthening of dual growing rods
- Repeated lengthenings → net T1-S1 increase; however, gain tends to ↓ with each lengthening & over time

**Figure 2. T1-S1 gain versus number of lengthenings.**

A Potential Advantage?

• 35 patients, 5 year follow-up, mixed etiology

• Increase in total spine height 20-28 cm by 15th lengthening

• Maintained >75% of expected age-matched spine growth until age 10 years

• Lengthening procedures did not appear to follow law of diminishing returns

Complications

Growing Rods:

- Risk of complication from growing rod ↓13%/year if you wait to start later
- Risk of complication ↑24% for each additional surgery performed

Complications

VEPTR:

• Restrospective review since 2005

• 54 patients, average 7 years at implantation, follow-up 22.5 months

• 74 complications in 54 patients → 137% per patient and 40% per surgery

Complications

VEPTR:

- Literature review of all studies; involved 776 patients with a variety of causes
- Complication rate comparable to previous published studies
- 22% fractures, 28% hook migration, 22% infection, 5% neurologic (almost all brachial plexus)
Complications

Minimizing Complications:

• Correct determination of levels to be fused

• Pre-operative improvement of nutrition status

• Pre- and post-operative respiratory function
Complications

Minimizing Complications:

• Agree with Skaggs et al → intraoperative neural monitoring during VEPTR placement or replacement; not necessarily during expansion

• Do not attempt to correct upper thoracic hyperkyphosis with VEPTR; can’t go beyond 2\textsuperscript{nd} rib
Key Points

- Congenital chest wall/spine deformities are complex! They result in TIS.

- VEPTR developed to address this “exotic scoliosis.”
Key Points

- Weigh incidence of complications against other treatments or against natural progression of untreated

- Optimize nutritional status; G-button if needed

- Pre- and post-operative respiratory function to minimize complication rate
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Thank You!

Questions?