Next Generation Endovascular Devices to Treat Thoracoabdominal Aortic Aneurysms

Clayton J Brinster, MD
Vascular Surgery Section
Ochsner Clinic Foundation
TAAA: Crawford Classification

Extent I

Extent II

Extent III

Extent IV

Extent V
TAAA: Open Surgical Exposure
TAAA : times they are a changin
(slowly in the USA)

Drive for less invasive therapy multifactorial:
• many patients unfit for surgical repair
• high morbidity and mortality
• abdominal and thoracic endovascular techniques, operator skill continue to advance
Endovascular TAAA Repair

• First accomplished in 2001 (Chuter)
• Cook t-branch and PMD have shown consistent results since
• Path to commercialization has been slow
• Currently only available in the USA with Physician Sponsored Investigational Device Exemption (PS-IDE) studies
Endovascular TAAA Repair

• Most currently available implantable devices either: custom made
  • 4 – 8 week lag for fabrication
  • Not suitable for all anatomies
• OR physician modified
  • time consuming to construct (elective only)
  • not standardized
TAAA Repair: Continued push for innovation

- All of these factors have contributed to the continued pursuit of less invasive, generalizable solution to TAAA

- Pursuit and development of off-the-shelf devices to treat TAAA is the next frontier
Off-the-shelf Endovascular TAAA

- Developed with “One fits most” philosophy
  - Modular Body with pre-fabricated branches, not fenestrations
- All results have been obtained at high-volume centers of excellence
- SCI remains high 7 – 8%
Three Current OTS Devices Undergoing Clinical Trial
GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE)
GORE TAMBE

• Off-the-shelf, modular, multicomponent system
• Proximal multi-branched aortic component
• Distal bifurcated component, iliac limb extensions
• Side branch component is a specially designed balloon-expandable covered stent-graft, the GORE VIABAHN BX Endoprosthesis
• Three total cases have been reported (trial ongoing)

• All used two retrograde renal portals (femoral) and two antegrade portals (arm) for the celiac axis and superior mesenteric artery (SMA).
Deployment

Femoral and Axillary Approach:

A: Placement of through-and-through preloaded wires

B: Device positioning with antegrade portals above the celiac axis and SMA and retrograde portals below the renal arteries

C: Partial endograft deployment

D: Advancement of guidewires to the left femoral access site using a snare
Deployment

A: Guiding Ansel sheaths placed (7Fr)

Selective catheterization:

celiac trunk (B),

SMA (C),

and renal arteries (D)
Deployment

Balloon dilatation of the proximal neck after device deployment (A)

Placement of renal stent-grafts (femoral access) (B)

Bifurcated distal device and iliac limb deployment (C)

Completion with SMA and celiac stent-grafts (D, E)
The third worldwide case and first USA case (Mayo Clinic, Gustavo Oderich)

Aneurysm (A) and preoperative (B) and postoperative (C) CTA. Artist depiction of the treated aneurysm (D) and the GORE TAMBE
Anticipated 80% of patients with complex abdominal or TAAA will meet the requirement of vessel incorporation.

Limitations:

- excessive angulation
- unsuitable targets because of small diameter
- occlusive disease or early bifurcation
Medtronic Valiant TAAA Stent Graft System

Device objectives

• Create device design and procedure that utilizes ‘standard’ EVAR techniques
• Modular approach for an “off-the-shelf” endovascular solution

Program status

• Over 40 patients total treated
Medtronic Valiant TAAA: Deployment

Thoracic bifurcated component first deployed from a femoral approach

Proximal seal in the thoracic aorta

Visceral manifold deployed within one of the two limbs of the bifurcated thoracic component
Via the visceral manifold: Celiac, SMA, and both renal arteries stented from axillary approach

Remaining limb of the thoracic bifurcation extended distally

Standard infrarenal EVAR to create distal seal
Medtronic Valiant TAAA: Pre/Post

I & II: 5.5 - 7.1cm

III: 5.2 - 8.2cm

IV: 5.3 - 7.2cm

V: 5.2 - 5.7cm
Zenith t-Branch TAAA Platform

- Constructed of self-expanding stainless steel Cook Z stents
- Active fixation
Zenith t-Branch

- t-Branch is a modular, off-the-shelf endograft made up of two parts:
  - 1) a standard 4-branch component
  - 2) distal bifurcated unibody
- Downward facing branches allow for accommodation of most anatomies and cannulation from an axillobrachial approach
Sweet, Chuter et al. JEVTR 2009
SMA Branch
Diameter: 8 mm
Length: 18 mm
Distance from proximal end of graft to distal end of branch: 117 mm
Clock: 12:00

Celiac Branch
Diameter: 8 mm
Length: 21 mm
Distance from proximal end of graft to distal end of branch: 99 mm
Clock: 1:00

Left Renal Branch
Diameter: 6 mm
Length: 18 mm
Distance from proximal end of graft to distal end of branch: 135 mm
Clock: 3:00

Right Renal Branch
Diameter: 6 mm
Length: 18 mm
Distance from proximal end of graft to distal end of branch: 135 mm
Clock: 10:00
Zenith t-Branch – Introduction System

- Similar to previous Cook constructs
- 22 Fr H&L-B One Shot™ Introduction System (7.3 mm ID, 8.5 mm OD)
- Captor Hemostatic Valve
- Flexor Introducer Sheath
Zenith t-Branch Deployment

• Modular body advanced and positioned from a femoral approach
• Branches cannulated from an axillary approach
• Bifurcated iliac component (if necessary) used to achieve distal seal
Case: Ruptured Type III
Postop CTA
Next Generation TAAA Devices: promising, but work to do

- Major paradigm shift over the past decade
- Goal: treat highly complex pathology in a fragile patient population
  - SCI rates remain high (7 – 8%)
- OTS devices could obviate waiting times for appropriate elective and urgent patients
- *Significant number will still require custom-made device repair or OSR until additional device designs become available*
Acknowledgements, Thank you

- Eric Verhoeven, MD, PhD
- Thanos Katsargyris, MD
- Gustavo Oderich, MD
- Randy Bassett, PhD
Next Generation Endovascular Devices to Treat Thoracoabdominal Aortic Aneurysms

Clayton J Brinster, MD
Vascular Surgery Section
Ochsner Clinic Foundation