Thoracic and Abdominal Aortic Aneurysm Grafts: Lessons from the Past, Designs for the Future

Robert M. Bersin, MD, MPH
Medical Director, Endovascular Services
Seattle Cardiology and Swedish Medical Center
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The following relationships exist related to this presentation:

Name of Company: Cook Inc. C, P
Name of Company: Cordis Endovascular AB,C, EI, P, SB
Name of Company: Medtronic Vascular P
Name of Company: W.L. Gore C, P

Off label use of products will be discussed in this presentation: Use of endografts for aortic dissection, ascending, arch and thoracoabdominal aneurysms
First AAA Endograft Implant 1990

EVT ANCURE® Endograft

Features

One-piece
Conformable graft design
Platinum radiopaque markers
ENDO-HOOKS™ Attachment System

25 Fr inner diameter
**EVAR - Profile and Anatomic Coverage of Current Devices**

<table>
<thead>
<tr>
<th>Device</th>
<th>Profile (O.D.)</th>
<th>Anatomic Coverage</th>
<th>Profile (O.D.)</th>
<th>Anatomic Coverage</th>
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</thead>
<tbody>
<tr>
<td>Medtronic AneuRx</td>
<td>21/22Fr</td>
<td>≈50%</td>
<td>22/23Fr</td>
<td>≈75%</td>
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<tr>
<td>Medtronic Talent</td>
<td>22/23Fr</td>
<td>≈75%</td>
<td>20/21Fr</td>
<td>≈60%</td>
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<tr>
<td>Gore Excluder</td>
<td>20/21Fr</td>
<td>≈60%</td>
<td>21/24Fr</td>
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<tr>
<td>Cook Zenith</td>
<td>21/24Fr</td>
<td>≈75%</td>
<td>20/22Fr</td>
<td>≈40%</td>
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<tr>
<td>Endologix Powerlink</td>
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Aortic Endografts
Current Limitations

- Proximal neck diameters
  - 18-32 mm (Talent—34 mm, Zenith—36 mm)
- Proximal neck lengths (supra and infra renal attachment)
  - 5-15 mm
- Iliac artery size for delivery
  - 6-9 mm
- Iliac artery attachment site diameter
  - 8-20 mm diameter
- Angle of neck to aneurysm <60°
Aptus Endostapling AAA Device

FIM 7-30-05 Venezuela
STAPLE-2 US IDE Pivotal Trial Completed
Next Generation Endografts

Aorfix Endograft (N=20)

The ARBITER II Trial (N=232)
Fenestrated Endografts

Proximal Neck 5 mm

Courtesy of T. Ohki
Multi-Branched Endografts
Nellix AAA Therapy: A No Neck Solution?

1. Two Delivery Catheters access the Aneurysm
2. Sheaths are retracted to expose Endografts and Endoframes mounted on Balloons
3. Balloons are inflated to expand Endoframes. Endografts are then filled with Polymer
4. Balloons are removed and Endoprosthesis is delivered. Extension cuffs are used per patient’s anatomical needs.
Nellix Device

Polymer Fill
The Unmet Need for Percutaneous Access

Small Caliber Iliacs

Extreme Tortuosity
Endurant Endograft

Design Characteristics

- Three-piece modular
- Suprarenal stent with hook fixation
- More flexible main body and limbs
- Lower-profile delivery: 18- and 20-F OD
- Treats shorter and more angulated necks
Next Generation LP EVAR Devices

Common Design Characteristics

- Three-piece modular
- Suprarenal stent with hook fixation
- Lower-profile delivery: 12-16F OD
AneuRx Thoracic Stent-Graft System
AneuRx Thoracic Stent-Graft System
Thoracic Endografts

WL Gore TAG thoracic device

Cook TX2 thoracic device

Medtronic TALENT thoracic device
Descending Thoracic Aneurysm with Acute Dissection
Stanford Type B Dissection

26 mm proximal neck diameter by CTA
30 mm proximal neck diameter by IVUS
33 mm distal neck diameter at 20 cm

34 mm x 20 cm Gore TAG device
Acute Proximal Endograft Collapse
Curved TAG Endograft

Clinical Trials

- 08-01 Acute Type B Dissection
- 08-02 Traumatic Transection
- 08-03 Aneurysm of the DTA
Medtronic Thoracic Device Portfolio

**Talent Thoracic Xcelerant**
- Approved U.S. '08
- 5-peak proximal bare spring with radial force
- Diameters (22-46mm)
- Lengths (110 – 116mm)
- 22F, 24F, 25F
- Pros: accuracy, ease of use, >20K implants WW

**Talent Thoracic Captivia**
- IDE trial completed
- 5-peak bare spring, proximal tip capture delivery, hydrophilic coating
- Lengths to 200mm
- Pros: Tip capture, improved accuracy, easier iliac access, longer lengths

**Valiant on Captivia**
- CE Mark October '09
- 8-peak proximal bare spring, no connecting bar, tip capture delivery, hydrophilic coating
- Pros: Tip capture, accuracy, increased patient applicability in more challenging cases, high conformability, #1 TEVAR device OUS
TX2 with Pro-Form

Original TX2
- Trigger-wires constrain the PROXIMAL end of the sealing stent

TX2 with Pro-Form
- Trigger-wires constrain PROXIMAL and DISTAL end of the sealing stent
Zenith TX2 with Pro-Form

Addresses the “Bird’s Beak” effect

Original TX2 with Trigger-wires pulled

TX2 with Pro-Form with Trigger-wires pulled
Next Generation TX2  
TX2-Low Profile

<table>
<thead>
<tr>
<th>Graft Diameters</th>
<th>Introducer</th>
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<tbody>
<tr>
<td>ID</td>
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<tr>
<td>18 – 30 mm</td>
<td>16 Fr</td>
</tr>
<tr>
<td>32 – 40 mm</td>
<td>18 Fr</td>
</tr>
<tr>
<td>42 – 46 mm</td>
<td>20 Fr</td>
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Proximal Component

Distal Component
TX2 Dissection Device

Bare Z’s - Stainless steel stacked stent bodies connected with 5.0 Prolene
- 46 mm diameter X 3 lengths: 82, 123, 164 mm
- very low radial force; expand over time
- STABLE Trial is adding 36 mm bare stent and TX2 with Pro-Form
Chuter Arch Branched Device
Ascending Aortic Devices

TX2-LP Devices (28 - 46 mm)