Optimizing Accuracy of Aortic Stent Grafts in Short Necks

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Disclosure

Speaker name: Venkatesh Ramaiah, MD

• I have the following potential conflicts of interest to report:
  ✓ Consulting – TriVascular/Medtronic/Cook
  ✓ Will be discussing some off-label use
Aortic neck is generally defined in clinical studies as the longitudinal distance between the first transverse CT slice directly distal to the lowermost renal (D1) artery and the first transverse CT slice (D2) that showed at least a 10% larger outer aortic wall diameter versus the diameter measured directly below the lowermost renal artery.

\[
\frac{D2}{D1} = 1.1
\]
Neck Length for Fixation: Contemporary Look

Suprarenal barbs/anchors/pins used to achieve fixation have almost eliminated migration in pivotal studies – IFU data

<table>
<thead>
<tr>
<th>Item</th>
<th>Zenith Standard Risk</th>
<th>Zenith High Risk</th>
<th>Zenith Roll-In</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft migration (&gt;10 mm)</td>
<td>0.0% (0/162)</td>
<td>0.0% (0/71)</td>
<td>0.0% (0/34)</td>
</tr>
</tbody>
</table>

6.6.4. Migration

The proportion of subjects with a device migration (evidence of proximal or distal movement of the stent graft > 10 mm relative to fixed anatomic landmarks) identified by the imaging core laboratory through 12 months post-treatment was 0% (0 of 161).
Neck Length for Seal

- Metal wire pushes fabric against aortic wall, creating points of contact.
- Parallel walls (aka neck) are required in order to create sufficient points of contact for seal.
- Ovation Prime’s sealing ring provides *continuous* apposition, even in irregular and / or tapered anatomy.
FDA Approved EVAR Devices

- Excluder
- Zenith
- Endologix
- Endurant
- Ovation
- Lombard
Additional CE Mark EVAR Devices

Cordis Incraft®

Bolton Treovance®

Endologix Nellix®
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Can We Apply This To EVAR?

Seal by filling recess using caulking

Sealing by filling aneurysm sac with Nellix system
Do Novel Devices Change the Concept of Neck Length?
O-Ring Sealing Technology

O-Ring Sealing in Proven Engineering Solutions

- O-rings are designed to seal by blocking the flow of fluid between two closely spaced surfaces
  - O-rings create a water-tight seal once two surfaces establish intimate contact
  - O-rings are designed to be flexible to accommodate variation in the two surfaces

O-Ring Sealing in Aorta

- Ovation Prime O-ring is designed to seal by blocking flow of blood between aortic wall and graft
  - Biocompatible polymer delivered to inflate O-ring
  - O-ring designed to conform to irregular luminal surface in aortic neck
  - O-ring insulates aortic neck from blood pressure

Ovation Prime graft sealing colored water in clear tube*
Novel Design Paradigm

The Ovation Prime aortic body is comprised of two key components delivered *sequentially*:

1. Suprarenal stent with integral anchors deployed in stages to secure the system and reduce the risk of migration
2. Biocompatible polymer delivered to inflate novel sealing rings for a robust and conformable seal
The Ovation Prime Aortic Body eliminates stent / material overlap which allows for significant reduction in profile without compromising durability.

Note: Images show graphical representation of a stent graft.
The Ovation System at Arizona Heart

- First experience Feb 8th 2013
- 173 grafts implanted to date
  - 100% technical success
- Initial interest in Ovation System:
  - Short, challenging necks
  - Tight, calcified and tortuous access
AZ Heart Case Study

- 87 yr old female with history of Smoking, Chronic Obstructive Pulmonary Disease, Cerebrovascular Accident and Hyperlipidemia

- Presented with abdomina/back pain and 8 cm AAA aortic aneurysm.

- Small calcified iliacs and a tortuous proximal neck.

- Very tight narrow distal aorta (8mm X 10mm on CT)
# Aortic Neck

<table>
<thead>
<tr>
<th>Inferior Renal Artery (IR) (Right or Left)</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aortic Diameter (ID) Measurement</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Device Recommendation</strong></td>
<td></td>
</tr>
<tr>
<td>IR+13</td>
<td>23.2 x 31.5 (27.4)</td>
</tr>
<tr>
<td>IR+16</td>
<td>30.2 x 35.7 (33.0)</td>
</tr>
<tr>
<td><strong>Additional Landmarks</strong></td>
<td></td>
</tr>
<tr>
<td>IR+20</td>
<td>34.8 x 38.1 (36.2)</td>
</tr>
<tr>
<td>IR+45</td>
<td>24.2 x 28.2 (26.2)</td>
</tr>
<tr>
<td>IR+80</td>
<td>13.5 x 19.4 (16.5)</td>
</tr>
<tr>
<td>IR+116 Native Bifurcation</td>
<td>7.6 x 9.5</td>
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</table>
Narrow Distal Aorta
• 8mm X 10mm

Significant calcium in bilateral external iliacs
Sealing rings visible due to remaining contrast in polymer
On 30 day CT
AZ Heart Case Study

- 82 year old female with history of breast cancer and hypothyrodism

- Enlarging infra-renal abdominal aortic aneurysm, 5.6 x 6.5 cm at the time of surgery

- Tight and tortuous access vessels
AZ Heart Case Study

- 80 year old female with history of Diabetes Mellitus, Renal insufficiency (creatinine 3.4), Hypertension and Right Breast Cancer

- Presented with a 6.1 cm AAA

- Challenging anatomy:
  - A short, <10 mm, wide reversed taper neck
  - Severely calcified aortic bifurcation and iliacs

- Prohibitive risk for open surgical repair

- Due to the patient’s compromised kidney function IVUS used to limit contrast
77 yr old with 6cm AAA referred for fenestrated graft
Sealed with Ovation
Ovation System at AZ Heart - Results

- **173** grafts implanted to date:
- 100% technical success rate
- One groin complication (pseudo aneurysm) resolved with ultrasound guided injection of thrombin.
- 1 External Iliac Artery complication (minor rupture due to pre dilatation) treated by covering with Iliac Limb
- Four intra-operative Type IA endoleaks in extremely challenging cases. All endoleaks were treated & resolved at initial implantation.
  - Three by placing a Palmaz stent
  - One resolved by Palmaz Stent and placing coils between the proximal and distal sealing rings.
AZ Heart Case Study

- 77 year old male
- 8.5 cm symptomatic aneurysm
AZ Heart Case Study
AZ Heart Case Study

6 Month Follow-up
AZ Heart Case Study

6 Month Follow-up
70 yr old with 5.7cm AAA
Ovation System at AZ Heart – Results

- 173 grafts implanted to date:
- No late Type I endoleaks
- No Type III, IV endoleaks
- One limb occlusion. Secondary to CFA/Closure
- No secondary interventions
- Average length of stay – 1.3 day
- 95% percutaneous.
- We are in the process of analyzing 1 year follow up data in terms of freedom from rupture, freedom from re-intervention, survival and sac shrinkage
AZ Heart Experience

Initial interest in Ovation System: Enable treatment of the most challenging anatomies

- Current status: Primary option for EVAR
- Ease and accuracy of deployment
- 14F OD Facilitates closure post PEVAR – now our preferred access method
- Patient outcomes have been extremely favorable in challenging and straightforward cases alike

- Looking ahead: Customized polymer seal offers opportunity for further enhancements to aortic disease management
The Workhorse System
Versatility of the Ovation Prime® System in challenging and straightforward anatomies.

Venkatesh G. Ramaiah, MD, FACS; Syed M. Hussain, MD; Jennifer L. Ash, MD; Ayman Jamal, MD; Ravi Hasanadka, MD; and Thomas King, DO

Endovascular TODAY
PROTECT THE NECK

September 2014
## Comparing Techniques

### Fenestrated Grafts
- More Anatomic branch revascularization
- Needs more planning
- Custom made
- Can be technically more difficult
- Fractures/Migration
- On Label

### Chimney Grafts
- “Off the shelf”
- Suitable for Urgent AAA cases
- Cheaper
- Possibly easier/Access smaller
- Can get guttering effect and compression
- Off Label

“Both techniques have good reported success rates”
Facilitate EVAR for Off-Label Aneurysmal Necks in Urgent Setting and/or High Risk Patients

CT axial image of bilateral chimneys
82 yr old with Symptomatic 8.2cm Aneurysm
Fenestrated Aortic Grafting
Questions?
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