The TriVascular Ovation Experience at Arizona Heart

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Disclosure

Speaker name: Venkatesh Ramaiah, MD

- I have the following potential conflicts of interest to report:
  - Consulting - TriVascular
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - Other(s)
  - I do not have any potential conflict of interest
FDA Approved EVAR Devices

Excluder  Zenith  Endologix  Endurant  Ovation  Lombard
Additional CE Mark EVAR Devices

Cordis Incraft®

Bolton Treovance®

Endologix Nellix®
Ovation Prime® Abdominal Stent Graft

Tri-modular design

Suprarenal nitinol stent with integral anchors for fixation

Low-viscosity, radiopaque, fill polymer

13-14F OD conformable iliac limbs

14F OD main body

Inflatable rings for optimal seal

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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

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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
Novel Design Paradigm

The Ovation Prime Aortic Body eliminates stent / material overlap which allows for significant reduction in profile without compromising durability.
Long-Term Data on O-Ring Sealing Technology

Professor John P. Fletcher
University of Sydney, Department of Surgery, Westmead Hospital, Sydney, Australia

- 12 patients followed for mean of 8 years and 2 months
- No AAA related deaths
- 3 deaths (25%) 54 to 93 months after EVAR from cancer, cardiac and respiratory failure
- No late Type I Endoleaks

International Society for Vascular Surgery
February 2013 Poster Presentation
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

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The Ovation System at Arizona Heart

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

- 80 year old male with history of Coronary Artery Disease, Carotid stenosis and PVD

- Presented with asymptomatic 5.1 cm AAA.
AZ Heart Case Study

- 87 yr old female with history of Smoking, Chronic Obstructive Pulmonary Disease, Cerebrovascular Accident and Hyperlipidemia
- Presented with abdominal 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)</th>
<th>Aortic Diameter (ID) Measurement</th>
<th>Device Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Right or Left)</td>
<td></td>
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</tr>
<tr>
<td>IR+13</td>
<td>23.2 x 31.5 (27.4)</td>
<td>34mm</td>
</tr>
<tr>
<td>IR+16</td>
<td>30.2 x 35.7 (33.0)</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Additional Landmarks</th>
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<tbody>
<tr>
<td>IR+20</td>
<td>34.8 x 38.1 (36.2)</td>
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</tr>
<tr>
<td>IR+45</td>
<td>24.2 x 28.2 (26.2)</td>
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<tr>
<td>IR+80</td>
<td>13.5 x 19.4 (16.5)</td>
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<tr>
<td>IR+116</td>
<td></td>
<td>7.6 x 9.5</td>
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<tr>
<td>Native Bifurcation</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 hypothyroidism

- Enlarging infra-renal abdominal aortic aneurysm, 4.6 x 5.5 cm at the time of surgery

- Tight and tortuous access vessels
# Aortic Neck

<table>
<thead>
<tr>
<th>Inferior Renal Artery (IR)</th>
<th>Left</th>
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<tr>
<td><strong>Aortic Diameter (ID) Measurement</strong></td>
<td><strong>Device Recommendation</strong></td>
</tr>
<tr>
<td>IR+13</td>
<td>27.0x32.7 (29.9)</td>
</tr>
<tr>
<td>IR+16</td>
<td>26.3x34.0 (30.2)</td>
</tr>
</tbody>
</table>

## Additional Landmarks

| IR+20 | 27.4x33.6 (30.5) |
| IR+45 | 26.3x29.1 (27.7) |
| IR+80 | 20.4x30.0 (25.2) |
| IR+147 Native Bifur | 16.2x17.1 |
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
Ovation at AZ Heart - Results

- 143 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.
Ovation at AZ Heart - Results

- 143 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
Percutaneous Endovascular AAA Repair with Local Anesthesia

10 F Prostar XL™

Access site

Access site
Questions?
U.S. INDICATIONS FOR USE: The TriVascular Ovation/Ovation Prime Abdominal Stent Graft Systems are indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories; proximal aortic landing zone: with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

CONTRAINDICATIONS: The TriVascular Ovation and Ovation Prime Abdominal Stent Graft Systems are contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the system’s Instructions for Use. Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

CE marked. Please refer to current Ovation® and Ovation Prime™ Instructions for Use.
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