Optimizing the accuracy of the Trivascular Ovation aortic aneurysm stent graft in short neck situations:
A novel pre-deployment use of contrast enhanced visualization of the main body seal zone

Steve Henao MD
New Mexico Heart Institute
Albuquerque, New Mexico USA
Disclosure

x medical educator, Trivascular
Limitations of Conventional Infrarenal EVAR

Key Findings

- Nearly 35% of men and 60% of women remain ineligible for EVAR solely based on anatomical requirements.
- Inadequate neck length was a main driver of ineligibility (25% with <10mm).
- Treatment options limited to surgical repair, fenestrated / branched endografts, off-label EVAR, or watchful waiting.

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Current FDA-Approved EVAR Devices – Sealing Mechanism

Self-Expanding

Gore
Endologix
Lombard
Medtronic
Cook

Polymer Ring
TriVascular
# Indication Statements vs. Anatomical Characteristics*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Indication Statement</th>
<th>Anatomical Characteristics</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Self-Expanding Stent IFU</td>
<td>Ovation Prime System IFU</td>
</tr>
<tr>
<td>Neck Length, mm</td>
<td>&gt; 10 - 15</td>
<td>No conventional length requirement</td>
</tr>
<tr>
<td>Neck Diameter, mm</td>
<td>18 - 32mm</td>
<td>16 - 30mm</td>
</tr>
<tr>
<td>Neck Angulation, °</td>
<td>&lt; 45 – 60</td>
<td>&lt; 45 – 60</td>
</tr>
<tr>
<td>Access vessel diameter, mm</td>
<td>&gt; 6–7</td>
<td>&gt; 4.7</td>
</tr>
</tbody>
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*Data from Morrison et al.1 and Sweet et al.2 Values are median or mean (interquartile range). Abbreviations: IFU, instructions for use.
Limitations of Short Necks (<10mm)

Even in patients who qualify for EVAR, short aortic necks remain the greatest limitation to achieving adequate proximal seal and durable aneurysm exclusion.

In a study of 3,500 patients from the EUROSTAR registry, patients with aortic necks < 10 mm had a fourfold greater risk of proximal endoleak through 30 days of follow-up compared to those with necks > 15 mm².

AbuRahma and colleagues identified proximal endoleaks in approximately 50% of patients with aortic neck lengths < 10 mm at a mean of 2 years of follow-up³.

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The Ovation Prime System at New Mexico Heart Hospital

First experience April 2013
Initial interest in Ovation Prime System:
- Small Profile
- Cost

### PATIENT PROFILE

| Age (Yrs) | Mean | 74.9 |
| Gender | Male | 71.1% |

### PROCEDURE DATA

| Device Time (mins) | Mean | 41.9 |
| Anesthesia Type | General | 97.8 |
| Primary Vessel Access | Percutaneous | 88.9% |
| ICU Stay (Hours) | Mean | 22.2 |
| Hospital Stay (Hours) | Mean | 22.2 |

### ANATOMICAL DATA

| Access Vessels (<7mm) | <7mm | 24.4% |
| Short Necks (<15mm) | <15mm | 35.5% |
| Moderate / Severe Calcium >25% circumferential | 46.6% |
| Moderate / Severe Thrombus >25% circumferential | 28.8% |
Case 1
Case 2
Case 3
Case 4
Pre-polymer visualization

• optimizes the placement of the unique seal ring of the Ovation stent graft system
• allows for more accurate positioning of the seal zone by directly visualizing the conforming o-ring against the aortic wall
• potentially further expands the utility of the device in patients with challenging neck anatomy
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