Endovascular Custom Seal with Ovation Alto: Review of the Evidence for Avoiding FEVAR or Parallel Graft Use

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Disclosures

- Consultant – Abbott Vascular, Boston Scientific, Endologix, PQ Bypass, Spectranetics/Phillips, Shockwave Medical
- VIVA Physicians 501c3 Board Member

5 Year Clinical Performance

ENCORE Study Design and Methodologies

- Pooled, retrospective analysis of 6 prospectively enrolled studies*
  - 1,296 patients
  - Treatment from 2009 – 2017
  - Global cohort (US, Europe, South America)
    - 160 Centers and 339 Investigators
    - Standardized variable definitions across each study
    - Standardized follow-up intervals across studies for K-M calculations
  - Median follow-up across studies = 1034 days (30d – 5y)

Vascular Characteristics

46% had one or more complex anatomic characteristic

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD</th>
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<tbody>
<tr>
<td>Neck Length (mm)</td>
<td>24.3 ± 12.2</td>
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<tr>
<td>Fas Neck Dia R (mm)</td>
<td>12.5 ± 3.2</td>
</tr>
<tr>
<td>Fas Neck Dia RV (mm)</td>
<td>7.0 ± 3.3</td>
</tr>
<tr>
<td>Juxtarenal Neck Angulation (°)</td>
<td>19 ± 19</td>
</tr>
<tr>
<td>Max AAA Dia (mm)</td>
<td>53.9 ± 9.1</td>
</tr>
<tr>
<td>Common Iliac Artery Dia (mm)</td>
<td>15.7 ± 3.5</td>
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<tr>
<td>Ext Iliac Artery Min Dia (mm)</td>
<td>8.0 ± 2.0</td>
</tr>
</tbody>
</table>

Freedom from Mortality

98.9% FF AAA-Related Mortality
78.9% FF All-Cause Mortality
**Freedom from Rupture, Conversion**

- Three (3) Ruptures
  - Day 29, Type Ib EL with contained iliac artery rupture, treated with bypass and limb extension
  - Day 1486, Rupture, death due to COPD, renal failure
  - Day 1497, Contained rupture with hematoma, death due to COPD

- 99.5% FF Rupture
- 99.2% FF Conversion

**5y Freedom from Endoleak**

- 96% FF Type Ia Endoleak
- 99% FF Type Ib Endoleak
- 99% FF Type III Endoleak

**5y Freedom from Reintervention**

- FF Reintervention for Type Ia EL

**Freedom from Device-Related Reintervention**

- 97.2% for Occlusion

**Next Generation Polymer EVAR: Ovation Alto**

- Sealing closer to the renals
- Elevated sealing ring (7mm)
- Integrated balloon
- Integrated cross-over port for easier gate cannulation

The Ovation Alto is not approved in any market; Ovation Alto is an investigational device in the United States, limited by federal (or United States) law to investigational use only.

**Next Generation Polymer EVAR: Ovation Alto**

- **Ovation Alto**
  - Advanced Stent Graft System
  - Sealing closer to the renals
  - Elevated sealing ring (7mm)
  - Integrated balloon
  - Integrated cross-over port for easier gate cannulation

**ELEVATE**

- Expanding patient applicability with polymer sealing Ovation Alto stent graft
- 75 patients / 12 US Centers
- Enrollment Mar 2017 – Feb 2018

The Ovation Alto is not approved in any market; Ovation Alto is an investigational device in the United States, limited by federal (or United States) law to investigational use only.
Conclusions

• Short conical necks issue for standard EVAR
• Polymer EVAR with Ovation
  ◦ Broad anatomic applicability, on-IFU
  ◦ Durable 5y outcomes (ENCORE)
  ◦ 99% FF rupture, conversion, AAA-related mortality
  ◦ 96% FF Type Ia endoleak; 98% freedom from reintervention for Type Ia endoleak
• Ovation Alto ELEVATE IDE follow-up underway