Can Polymer Sealing Technology With The Ovation Endograft Treat Short Necked AAAs As Well As Fenestrated And Chimney Grafts: What Are The Limitations?

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Disclosures
• Consulting: Endologix, Cook

Late Proximal Neck Failure

Proximal Endoleak at 48 Months in Grafts with Transrenal Fixation

4.00%
6.00%
8.00%
10.00%
12.00%

0.00%
2.00%
4.00%
6.00%
8.00%

Neck <15 mm
Neck 11-15 mm
Neck <11 mm

Late Proximal Neck Failure

Take Home Message

Standard EVAR + Short Neck = BAD!
Take Home Message #2

GET MORE SEAL!

Parallel Grafts

Fenestrated Grafts

What if?

GET MORE SEAL!!

The Science of Seal

Chronic Outward Force: The Force a Self-Expanding Exerts on a Vessel as it Tries to Expand to its Nominal Diameter
An Experimental Evaluation of Device/Arterial Wall Compliance Mismatch for Four Stent-Graft Devices and a Multi-layer Flow Modulator Device for the Treatment of Abdominal Aortic Aneurysms

- Chronic Outward Radial Force (sized graft to a 28 mm aorta)
  - Endurant II = 0.54 N/cm
  - Excluder = 0.34 N/cm
  - Zenith = 0.67 N/cm
- Correlates to an additional 18-36 mmHg of MAP

The Science of Seal

Self Expanding Stent Graft

Chronic Outward Force: The Force a Self-Expanding Exerts on a Vessel as it Tries to Expand to its Nominal Diameter

Late Proximal Neck Failure

2 Years 6 Years

O-Ring Sealing Technology

Insulating Effect

The Science of Seal

Baseline Self Expanding Stent Graft Insulating Polymer Ring

Blood Pressure Blood Pressure Minimal Blood Pressure

Blood Pressure + Stent Outward Radial Force

Aortic Neck Preservation at 5 Years

Aortic Neck Dilatation Over Time

Proximal Neck diameter average expansion (mm)

Baseline 1 Year Growth 2 Year Growth 3 Year Growth 4 Year Growth 5 Year Growth

0.0 2.4 3.6 4.7 5.3

-0.2 0.0 0.2

1.0 2.0 3.0 4.0 5.0

0.0 0.4 0.8 1.2 1.6

0.0 0.4 0.8 1.2 1.6

Monahan JVS 2010: 52: 303-7 N=46. Devices: Cook Zenith


Neck dilatation in proximal neck defined as growth > 3mm at 10mm below renals, 13mm below renals, and 15mm below renals
35% (56/161) of Ovation IDE patients had one or more hostile neck features.

### Hostile Neck Anatomy

#### Ovation Global Pivotal IDE: Hostile Neck Subgroup Analysis

<table>
<thead>
<tr>
<th>Safety</th>
<th>0 to 30 days</th>
<th>31 to 365 days</th>
<th>366 to 730 days</th>
<th>731 to 1095 days</th>
<th>1096 to 1460 days</th>
<th>1461 to 1825 days</th>
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</thead>
<tbody>
<tr>
<td>Freedom from Major Adverse Event</td>
<td>96.4% (54/56)</td>
<td>--</td>
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<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Freedom from Device Related MAE</td>
<td>--</td>
<td>100% (n=56)</td>
<td>100% (n=55)</td>
<td>100% (n=53)</td>
<td>100% (n=45)</td>
<td>100% (n=37)</td>
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<tr>
<td>Freedom from Rupture</td>
<td>100% (n=56)</td>
<td>100% (n=55)</td>
<td>100% (n=53)</td>
<td>100% (n=45)</td>
<td>100% (n=37)</td>
<td>100% (n=31)</td>
</tr>
<tr>
<td>Freedom from Conversion</td>
<td>100% (n=56)</td>
<td>100% (n=55)</td>
<td>100% (n=53)</td>
<td>100% (n=45)</td>
<td>100% (n=37)</td>
<td>100% (n=31)</td>
</tr>
<tr>
<td>Freedom from Type Ia Intervention</td>
<td>100% (n=56)</td>
<td>96.8% (53/55)</td>
<td>100% (n=45)</td>
<td>100% (n=37)</td>
<td>100% (n=31)</td>
<td>100% (n=31)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>30 Day</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
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</thead>
<tbody>
<tr>
<td>Freedom from Type I/III Endoleaks</td>
<td>100% (n=52)</td>
<td>100% (n=47)</td>
<td>100% (n=42)</td>
<td>100% (n=36)</td>
<td>100% (n=29)</td>
<td>100% (n=23)</td>
</tr>
<tr>
<td>Freedom from Migration</td>
<td>Baseline</td>
<td>100% (n=52)</td>
<td>100% (n=42)</td>
<td>100% (n=36)</td>
<td>100% (n=29)</td>
<td>100% (n=23)</td>
</tr>
</tbody>
</table>

### What are the limitations?

#### Raising the Ring?

#### The Collar
Hostile Proximal Neck

Hostile Access Vessels

Low Profile Graft

Endowedge Technique

Proximal Seal

Ovation Endowedge

- 15 Patients
- “Traditional” Neck Length 0-9 mm
  – All within “sealing” diameter at 6 mm
- Two technical complications, requiring parallel grafts.
- No Type I or Neck Dilation at up to 3 years.
Summary

- The Sealing Mechanism of Polymer Ring Devices is much Different than that of Standard Self-Expanding Stent Grafts.
- As such, the Limitations for Self-Expanding Stent Grafts are Unlikely to Apply to Polymer Ring Technology