Patency Matters

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Disclosure

Speaker name: David J. Minion, MD

I have the following potential conflicts of interest to report:

- Consulting – TriVascular Medical Educator [X]
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Anatomic Challenges
Proximal Neck

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No Glory In Access

Rupture  

Limb Occlusion

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Limb Occlusions

• Incidence approximately 1 to 8%
• Can lead to limb loss (Rare)
• Risk Factors
  – Small iliacs
  – Calcified iliacs
  – Tortuosity
  – Extension into external iliac
Persistent EVAR Challenges

Characteristics of Hostile Access Anatomy

• Narrow (<6mm)
• Occluded
• Tortuous
• Calcified
• Aneurysmal

40% Patients < 6mm*
M2S Database – 43,000 CT Scans

55% Female Patients <6mm**
(CHAP) Collaborative effort – 1,063 CT Scans

*N derived from M2S Measurement Database of 43,000 AAA CT Scans
**New England Society for Vascular Surgery, Matthew P. Sweet, MD et al.
The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair Clinician-FDA Collaborative effort, Characterization of Human Aortic Anatomy Project (CHAP), 1063 CT Scans

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Angulation and Stenosis

110 degrees
Angulation and Stenosis
Angulation and Stenosis
Angulation and Stenosis
Angulation and Stenosis
Optimizing Limb Design for Improved Patency
## Optimal Graft Material

<table>
<thead>
<tr>
<th>Feature</th>
<th>PTFE</th>
<th>PET/Dacron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical Name</strong></td>
<td>Polytetrafluoroethylene</td>
<td>Polyethylene Terephthalate (Polyester)</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Excellent</td>
<td>Good</td>
</tr>
<tr>
<td><strong>Chemical Resistance</strong></td>
<td>Excellent</td>
<td>Good</td>
</tr>
<tr>
<td><strong>Friction</strong></td>
<td>Exceptionally Low</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td>Very compliant with small amounts of porosity</td>
<td>Very rigid plastic</td>
</tr>
<tr>
<td><strong>Architecture</strong></td>
<td>Can be formed into complex 3D shapes</td>
<td>Must be woven/knitted to create flexible grafts</td>
</tr>
<tr>
<td><strong>Porosity</strong></td>
<td>Contains blood (if porosity low enough)</td>
<td>Not liquid tight; Must be pre-clotted or coated to contain blood</td>
</tr>
<tr>
<td><strong>Ingrowth</strong></td>
<td>Permeability can be controlled to enhance or inhibit ingrowth</td>
<td>Yes</td>
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It’s Different Than Open Repair
## Optimal Graft Material

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Optimizing Limb Design for Improved Patency

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Bending a Tube

10 cm

14 mm

7.8 cm

10 cm
Helical vs Discreet Rings
Helical vs Discreet Rings

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Helical vs Discreet Rings
# Effectiveness Rates at 1-year

<table>
<thead>
<tr>
<th></th>
<th>TriVascular Ovation IDE</th>
<th>Medtronic Endurant IDE</th>
<th>Cook Zenith Flex IDE</th>
<th>Cook LP IDE¹</th>
<th>Endologix PowerLink IDE</th>
<th>Gore Excluder Combined IDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Enrolled</td>
<td>161</td>
<td>150</td>
<td>200</td>
<td>120</td>
<td>192</td>
<td>565</td>
</tr>
<tr>
<td>Type I Endoleak</td>
<td>0%</td>
<td>0%</td>
<td>0.6%</td>
<td>0%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Migration</td>
<td>0%</td>
<td>0%</td>
<td>2.5%</td>
<td>0%</td>
<td>1.6%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Limb Occlusions²</td>
<td>1.2%</td>
<td>2.7%</td>
<td>3.0%</td>
<td>7.7%</td>
<td>3.2%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Subjects Requiring Re-interventions²</td>
<td>6.2%</td>
<td>6.7%³</td>
<td>11.0%</td>
<td>Not Reported</td>
<td>9.9%</td>
<td>11.7%</td>
</tr>
</tbody>
</table>

Sources: Data Rates pulled from Instructions For Use (IFU) and Annual Clinical Updates
1- Cook LP data pulled from SVS Podium Presentation in June 2012
2- Based on Investigator Reported Events
Ovation Global Pivotal Trial
Anatomical Characteristics

- Over 50% of patients treated had minimum access vessel <7mm in diameter
  - Smallest vessel diameter treated = 3.2mm

*Based on core lab reported measurements
The Benefit of Low Profile
Unsurpassed Engineering

Top

Bottom

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Thank You
INDICATIONS FOR USE: The TriVascular Ovation platform (including Ovation, Ovation Prime and/or Ovation iX Abdominal Stent Graft Systems) is 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 25 mm (no greater than 20 mm for Ovation/Ovation Prime).

CONTRAINDICATIONS: The 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 systems’ Instructions for Use.

Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

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NOTE: Not all product components are available in every country. Please consult with your TriVascular representative to confirm product availability.

CE marked. Please refer to current product Instructions for Use.
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