Financial Disclosures

- None

Clinical Trials Disclosure

Principal Investigator:

1. PYTHAGORAS (Lombard Medical)
2. ENDORFIX (Lombard Medical)
3. ANCHOR (Aptus Endosystems)
4. RELAY (Bolton Medical National PI)
5. Vascular Registry (MALASHOPKINS)
6. PYTHAGORAS: Post approval registry (Lombard)

Aorfix

- Highly flexible ring stent design
- 4 pairs of barbs for active fixation
- 8mm long sealing bond
- Woven polyester graft
- Usually placed trans-renally
- Proximal end is stabilized by delivery system throughout deployment

Aorfix Use

Pythagoras Trial of Aorfix in Highly Angled Necks

- The first IDE trial to assess an EVAR device in highly angled necks
- Includes 151 patients with neck angles greater than 60°
- 42 of those patients had neck angles > 90°
- Almost all 5 year data has now been collected
EVAR-specific Results – 2 years

<table>
<thead>
<tr>
<th></th>
<th>Aorfix™ All</th>
<th>Aorfix™ 60-110°</th>
<th>Aorfix™ &lt;60°</th>
<th>SVS control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>218</td>
<td>151</td>
<td>67</td>
<td>323</td>
</tr>
<tr>
<td>Freedom from SVS-defined MAE (2 yr)</td>
<td>73%</td>
<td>70%</td>
<td>79%</td>
<td>55% (1 yr)</td>
</tr>
<tr>
<td>Mortality (2 yr)</td>
<td>11%</td>
<td>14%</td>
<td>5%</td>
<td>NA</td>
</tr>
<tr>
<td>Sac shrinkage (5mm 2yr)</td>
<td>54%</td>
<td>54%</td>
<td>55%</td>
<td>-</td>
</tr>
<tr>
<td>Sac expansion (5mm 2yr)</td>
<td>5%</td>
<td>5%</td>
<td>4%</td>
<td>-</td>
</tr>
<tr>
<td>Type I/III leak (2 yr)</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>-</td>
</tr>
<tr>
<td>Migration (2 yr)</td>
<td>3%</td>
<td>4%</td>
<td>2%</td>
<td>-</td>
</tr>
<tr>
<td>Wire Fracture (2 yr) (pre-Nitinol change)</td>
<td>14%</td>
<td>16%</td>
<td>10%</td>
<td>-</td>
</tr>
</tbody>
</table>

Freedom from Aneurysm-Related Mortality: Intent to Treat Basis

- Test subjects older: EVAR 76 ±8, vs 69 ±7 years, p=0.001

Performance of The Aorfix Endograft in Severely Angulated Proximal Necks in the PYTHAGORAS U.S. Clinical Trial

Pythagoras: Results at 3 years

<table>
<thead>
<tr>
<th></th>
<th>Aorfix™ 60-110°</th>
<th>Aorfix™ &lt;60°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from SVS-defined MAE (3 yr)</td>
<td>21.9% [151]</td>
<td>13.4% [67]</td>
</tr>
<tr>
<td>Mortality</td>
<td>21.9% [151]</td>
<td>13.4% [67]</td>
</tr>
<tr>
<td>Sac shrinkage (5mm)</td>
<td>55.3% [85]</td>
<td>60.5% [43]</td>
</tr>
<tr>
<td>Sac expansion (5mm)</td>
<td>7.1% [85]</td>
<td>7.0% [43]</td>
</tr>
<tr>
<td>Type I/III leak</td>
<td>0.0% [76]</td>
<td>0.0% [38]</td>
</tr>
<tr>
<td>Migration</td>
<td>7.1% [85]</td>
<td>8.4% [43]</td>
</tr>
<tr>
<td>Wire Fracture (pre-Nitinol change)</td>
<td>21.4% [84]</td>
<td>12.8% [30]</td>
</tr>
</tbody>
</table>

When does Aorfix not work?

- IFU Aortic Considerations (USA)
  - Indications:
    - Aortic diameters 19mm to 29mm
    - Neck center-line length ≥ 15mm
    - Neck angulations ≤ 90°
  - Warning & Precaution
    - Necks with diameter change ≥ 5mm over 15mm length can increase risk of migration
    - Placement ≥ 8mm below distal renal can increase risk of migration
**Short Neck – IFU Needs 15mm**

Core Lab Measurement: Neck Angle 94°, length 9mm

Pre-Op Post-Op 1 Year

Core Lab Measurement: Neck Angle 75°, length 21mm

Post-Op 2 Year 4 Year

Length projecting into Iliac 25

Diameter 19

Diameter 5mm proximal 23

Diameter 10mm proximal 24

**Limb Migration**

**IFU needs 15mm Distal Landing Zone**

Post-Op 2 Year 4 Year

**Aorfix Fishmouth**

- When overdilated, proximal end of stent graft has a fish-mouth shape
- Preferably place trans-renal in region of highest aortic stability
- Pay attention to oblique imaging angle for correct renal alignment
- Leave flush catheter in place

<table>
<thead>
<tr>
<th>Renal Stenosis Arising from Occlusions Renal Stent Place/Ad</th>
<th>5 [2.4%]</th>
<th>6 [2.9%]</th>
<th>1 [0.5%]</th>
<th>3 [1.4%]</th>
<th>4 [1.9%]</th>
<th>1 [0.5%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Graft</td>
<td>3 [1.4%]</td>
<td>1 [0.5%]</td>
<td>4 [1.9%]</td>
<td>1 [0.5%]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of cuff or Palmaz stent</td>
<td>4 [1.9%]</td>
<td>1 [0.5%]</td>
<td>5 [2.4%]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existing Renal Stenosis</td>
<td>0 [0%]</td>
<td>6 [2.9%]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4 [1.9%]</td>
<td>6 [2.9%]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Aorfix Oversizing**

- Oversize by 10% to 30%
- No difference in complication rates between 10% to 20% oversize and 20% to 30%
- Don't undersize!

**Case Example: Courtesy Dr Muhs**
Case Example: Courtesy Dr Hodgson

Conclusions

- Tortuous anatomy can have multiple complex features: understand the anatomy well in 3-D before surgery
- Aorfix is safe and effective in treating highly angled necks and provides a well proven option in treating aortic or iliac tortuosity
- Complications are associated with straying from the IFU

Thank you!

VEITH Symposium
Connecting the Vascular Community