Multibranched Endovascular Device for Treating
AAAs:
Recent Technical Modifications and Clinical Experience

Mark A. Farber, MD FACS
Chief, Division of Vascular Surgery
Professor of Surgery and Radiology
Director, Aortic Network
University of North Carolina
Chapel Hill, NC

Design Partnership for Endovascular Treatment of Thoracoabdominal Aortic Aneurysms
GORE partnered with physicians to design an off-the-shelf endoprosthesis for treatment of thoracoabdominal and complex abdominal aortic aneurysms
Large anatomic datasets and proven GORE technology were studied to enable multiple designs that were evaluated pre-clinically to identify the final designs
* Gore EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE)*

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.

Disclosures

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Cook Medical</th>
<th>WL Gore</th>
<th>Medtronics</th>
<th>Endologix</th>
<th>Centerline Biomedical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Support, Clinical Trials, Consulting</td>
<td>Clinical Trials, Consulting</td>
<td>Clinical Trials, Consulting</td>
<td>Clinical Trials, Consulting</td>
<td>Consulting</td>
<td></td>
</tr>
<tr>
<td>Received</td>
<td>Grants, Honoraria</td>
<td>Honoraria</td>
<td>Honoraria</td>
<td>Honoraria</td>
<td>Stock Options</td>
</tr>
</tbody>
</table>

Clinical Considerations for TAMBE
- Procedural steps need to be simple
- Anatomical screening and case planning must be thoughtful
- Aortic coverage should be minimized
- Diverse anatomical conditions must be accommodated

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.

**t-Branch**
- Four vessel design
- Branches
  - CA - 8 mm 1 o’clock
  - SMA 8 mm 12 o’clock
  - RRA - 6 mm 10 o’clock
  - LRA - 6 mm 3 o’clock

DTA coverage above CA: 6.5 cm

Gore TAMBE
- DTA coverage above CA: 6.5 cm

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.
Sequential Deployment and Integrate Access

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.

TAMBE Device Features (Antegrade & Retrograde)

- Conformable, kink-resistant side branch components with CBAS® Heparin Surface
- GORE® VIABAHN BX Endoprosthesis

Technical Aspects and 30-day Outcomes of the Prospective Early Feasibility Study of the GORE® EXCLUDER® Thoracoabdominal Branched Endoprosthesis (TAMBE)

Gustavo Oderich, MD, Mark Farber, MD, Pierre Silveira, MD, et al

Rochester, MN, Chapel Hill, NC, Florianopolis SC

Accepted: In Press

Procedure Details

<table>
<thead>
<tr>
<th>Procedure Time (minutes)</th>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>287.6 (126.1)</td>
<td>254</td>
<td>254</td>
<td>(149,678)</td>
</tr>
</tbody>
</table>

Anesthesia Method

- General 16(100.0%)

Contrast Used During Procedure (mL)

<table>
<thead>
<tr>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>200.6(114.5)</td>
<td>184</td>
<td>(44,490)</td>
</tr>
</tbody>
</table>

Estimated Blood Loss During Procedure (mL)

<table>
<thead>
<tr>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>623.8(531.8)</td>
<td>350</td>
<td>(100,1700)</td>
</tr>
</tbody>
</table>

Transfusion Required

- 4(40.0%)

Length of Stay (days)

<table>
<thead>
<tr>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1(2.8)</td>
<td>4</td>
<td>(2,12)</td>
</tr>
</tbody>
</table>

Clinical Experience

16 Implants Worldwide

- Florianopolis - 6
- Mayo Clinic - 5
- UNC - 2
- UPMC - 1
- Mt Sinai - 1
- Dartmouth - 1

Pararenal: Type IV - 75%;25%

Retrograde design replaced by Antegrade design in Spring 2016

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.
Preliminary Data: Technical Success

<table>
<thead>
<tr>
<th>Subjects Initiating TAMBE Procedure</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>15 (93.8%)</td>
</tr>
<tr>
<td>Successful access to the necessary arterial sites</td>
<td>16 (100.0%)</td>
</tr>
<tr>
<td>Successful deployment of all required TAMBE Device components and any required accessory components</td>
<td>16 (100.0%)</td>
</tr>
<tr>
<td>Patency of all required TAMBE Device components and any required accessory components on completion angiography</td>
<td>15 (93.8%)</td>
</tr>
<tr>
<td>Absence of surgical conversion within 24 hours of initiation of the procedure</td>
<td>16 (100.0%)</td>
</tr>
</tbody>
</table>

Preliminary Data: 30 Day Primary Safety Endpoints

<table>
<thead>
<tr>
<th>Subjects enrolled and on Study for 30 Days</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects With Any Event</td>
<td>5 (31.3%)</td>
</tr>
<tr>
<td>Number of Events</td>
<td>5</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>1</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
<td>0</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0</td>
</tr>
<tr>
<td>Procedural Blood Loss ≥1000 mL</td>
<td>4 (25.0%)</td>
</tr>
</tbody>
</table>

CEC adjudicated all events and determined that 4 procedural blood loss events met the "severe safety" definition.

Short-term Outcomes

- Mean F/U 17.7 months
- Overall Survival 92.3%
- One patient presented @ 4.1 months with MSOF from CA, SMA and LRA branch occlusion.
- No TAMBE related device causes identified on autopsy
- Serious Adverse Events: 46.2%
- Involving: vascular, cardiac and gastrointestinal systems
- AKI: 23%
- No Type I or III endoleaks during follow-up

*Data Analysis 12/17

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.

Branch Vessel Occlusions

- Patients: 3 of 16 patients
- 7 branch vessels
- Patient 1: Loss of RRA branch during index procedure
  - Presented in MSOF and remaining 3 branches occluded (POD 123)
- Patient 2: POD 682 with AKI/Renal Failure sequential renal artery branch occlusion related to severe dehydration
  - Tx: Hepatorenal bypass
- Patient 3: Unilateral renal artery occlusion (POD 144)
  - Managed with lysis and stenting
  - Noted to have contralateral renal artery stenosis POD 46
- No difference in occlusion rates (AG/RG) p=NS

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.

Outcomes

- Technical Success was 93.8%
  - One intra-procedural right renal artery occlusion
  - Likely secondary to dissection
- Primary safety endpoints occurred in 4 patients
  - EBL > 1000 mls
  - DrySeal Flex was not available during the feasibility trial

Caution: TAMBE is an Investigational Device. Limited by United States law to investigation use only.
Conclusions

- TAMBE device has completed its feasibility study with similar results for complete endovascular repair of TAAAs
- Longer follow-up and a Pivotal study are planned in pursuit of FDA approval