A new off-the-shelf branched Gore endograft for TAAA: early clinical experience

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DISCLOSURE

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Consultant: Gore & Associates, Medtronic
Clinical research study (Phase I):

“Initial Feasibility Assessment of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) in the Treatment of Crawford Type III & IV and Safi Type V Thoracoabdominal Aortic Aneurysms and Abdominal Aortic Aneurysms Involving the Renal Arteries”

Study Design:
This is a non-randomized, multicenter study designed to assess the initial feasibility of the GORE® EXCLUDER® Juxtarenal and Thoracoabdominal Branched System (TAMBE Device)

Study Objective:
Assess the initial safety of the TAMBE Device implantation procedure in juxtarenal and thoracoabdominal aortic aneurysm subjects
## 1 year FU

<table>
<thead>
<tr>
<th></th>
<th>CASE 1</th>
<th>CASE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak/Type I / III</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MAE</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Treated Branch Patency</td>
<td>4/100%</td>
<td>4/100%</td>
</tr>
<tr>
<td>Treated Branch Stenosis/Separation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Late SCI</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Case 1
- ATS, female, 68y
- Juxtarenal 52mm AAA
- Hypertension
- COPD

Case 2
- LC, male, 56y
- Juxtarenal 55mm AAA
- Hypertension
Case 1

Case 2

(1 year FU)
# Results

<table>
<thead>
<tr>
<th></th>
<th>CASE 1</th>
<th>CASE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia time</td>
<td>300 min</td>
<td>280 min</td>
</tr>
<tr>
<td>Procedure time</td>
<td>230 min</td>
<td>245 min</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>76 min</td>
<td>93.5 min</td>
</tr>
<tr>
<td>Blood loss</td>
<td>350 cc</td>
<td>400 cc</td>
</tr>
<tr>
<td>Endoleak</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Major Adverse Event</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>LOS/ICU</td>
<td>4 days / (24h)</td>
<td>3 days / (24h)</td>
</tr>
</tbody>
</table>
TAMBE Configurations

• First patients were treated using Retrograde configuration
• Focus on: Device ease of use (e.g., procedure time). Anatomic applicability
• Antegrade device must be incorporated into trial in 2016
Device Components: Aortic Component

- **Aortic Component:**
  - 26, 31, 37 mm proximal diameter
  - Same oversizing as CTAG
  - Proximal anchors (reconstrainable)
  - 20 mm distal diameter
  - 215 mm length

- **SMA & Celiac:** 8 mm Antegrade Portals
- **Renals:** 6 mm Retrograde Portals

- SMA & Celiac: 8 mm Antegrade Portals
- All portals are 10 mm in length
- Renals: 6 mm Retrograde Portals

50 mm seal length
85 mm portal to portal length (outlet to outlet)
TAMBE Device Features

Pre-cannulated side branch portals

Tri-lumen catheter to facilitate through-and-through guidewires and prevent entanglement

Tri-Lumen Catheter
0.035” wire
0.014/0.018” wires (2x)
TAMBE Device Features (Antegrade & Retrograde)

Multi-stage deployment with proximal, distal, and rotational repositionability to aid in branch vessel access and deployment accuracy.
Conformable, kink-resistant side branch components with CBAS® (Heparin Surface)
- GORE® VIABAHN BX Endoprostheses
- GORE® VIABAHN Endoprostheses (+7,5cm)
• Pre-clinical testing of branch flow using:
  – Computational Fluid Dynamics (CFD)
  – Benchtop pressure drop (ΔP) and volumetric flow rate (Q) measurements
  – Particle imaging velocimetry (PIV)
• Data indicate that for both antegrade and retrograde renal configurations:
  – Pressure drops are well below clinically relevant thresholds
  – Perfusion to the kidneys is maintained throughout the cardiac cycle
  – There is complete “washout” during the cardiac cycle (i.e., there are no flow stagnation zones)

• TAMBE - branch patency and kidney function 1 year FU: no problems related to branch perfusion
Summary

• The use of TAMBE in the first two implants demonstrated safety and efficacy in the exclusion of aneurysm sac and the preservation of visceral and renal arteries.

• The TAMBE device is the only “all in one” pre-cannulated off the shelf system, including aortic component and side branch stent graft.

• The initial results (1 year FU) are promising, longer term outcomes are needed to confirm this early experience.