Gore C-TAG Thoracic Branch Endoprosthesis – First Case Experience

Session 6: Arch Repair
Critical Issues in Aortic Endografting 2014
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• Research/Research Grants, Clinical Trial Support
  – W. L. Gore
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• Consulting Fees/Honoraria
  – W. L. Gore
  – Abbott Vascular
  – Medtronic

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  – CVRx
  – Enopace
  – TriVascular
  – Cytograft Tissue Engineering
  – Microfabrica
  – 480 Medical
  – Arsenal
  – Intact Vascular

• Officer, Director, Board Member or other Fiduciary Role
  – VIVA Physicians Group

• Speaker’s Bureau
  – None
Device Overview

TBE Device
- Aortic Component
- Side Branch (SB) Component
- Aortic Extender (Optional)

Additional TBE accessory
- GORE® DrySeal Side Branch Introducer Sheath (SBIS)
TAG® Branched Thoracic Endoprosthesis
GORE® TAG® Thoracic Branch Endoprosthesis (TBE)

Zone 2  
Zone 1  
Zone 0
Zone 1 and Zone 2 TBE
Zone 0 TBE, also for suitable Zone 1/2 anatomy
TBE Aortic Component

• Incorporates internal portal allowing seal and fixation of the SB Component
• Device diameters:
  – 21 – 53 mm
• Aortic treatment range:
  – 16 – 48 mm
TBE Aortic Component

Delivery system

• Aortic lumen
• Side branch lumen
  • Removable Guidewire Tube (RGT)
    – Aids in passage of guidewire through internal portal
TBE SB Component

Branch Vessel Segment

CBAS® lumen

Tapered Flex Segment

Internal Portal Segment
SB Component

• **Internal Portal Segment**
  – 3 “anchors” prevent SB migration into vessel
  – 8 or 12 mm diameter
    • Must use 12mm for Zone 0

• **Branch Vessel Segment**
  – Zone 1-2
    • Device diameters: 8 – 17 mm
    • Treatment range: 6 – 15 mm
  – Zone 0
    • Device diameters: 15 – 20 mm
    • Treatment range: 11 – 18 mm
Step 1:
- Insert guidewires in aorta and branch vessel

Step 2:
- Introduce aortic component over both guidewires into position within the arch

Step 3:
- Deploy aortic component and withdraw catheter

Step 4:
- Advance introducer sheath and dilator

Step 5:
- Advance and deploy branch component
Zone 2 US Feasibility Trial

- **Patients:**
  - Descending thoracic aortic aneurysms requiring placement of the proximal extent of the aortic stent graft in Zone 2

- **Primary Endpoints:**
  - Successful access and deployment of TBE
  - Primary patency of side branch assessed by angiography at conclusion of procedure

- **Secondary Endpoints:**
  - One month Core lab analysis
    - Side branch primary patency assessed
    - Device-related endoleaks

- 6 sites
- 20 to 40 patients
- 5 year follow-up
# Zone 2 Feasibility Trial

<table>
<thead>
<tr>
<th>Investigational Sites</th>
<th>Site PI</th>
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<tbody>
<tr>
<td>Leland Stanford Junior University</td>
<td>Michael Fischbein, MD</td>
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<tr>
<td>University of Pittsburgh Medical Center</td>
<td>Michael Singh, MD</td>
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<td>The Hitchcock Foundation</td>
<td>Mark Fillinger, MD</td>
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<td>Mayo Clinic-Rochester</td>
<td>Gustavo Oderich, MD</td>
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<td>University of Pennsylvania</td>
<td>Joseph Bavaria</td>
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<td>University of Michigan</td>
<td>Himanshu J. Patel, MD</td>
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1st GORE® TAG® TBE Case

Patient Info
- 84yo woman
- 61mm diameter fusiform aneurysm
- Prophylactic spinal drain

Case Plan
1. Distal CTAG (40mm x 20cm)
2. TBE Aortic Component (45mm x 10cm)
3. TBE SB Component (8mm x 12mm x 6cm)
4. Bridging CTAG (45mm x 10cm)

Courtesy of UMich
Dr Patel, Williams, and Eliason
Final Aortagram

Procedure Summary

• Successful access and deployment of TBE
• Patent side branch
• No procedural endoleaks

Courtesy of UMich
Dr Patel, Williams, and Eliason
1st GORE® TAG® TBE Case

1 mo follow up
- Side branch patent
- No serious adverse events related to device

Courtesy of UMich
Dr Patel, Williams, and Eliason
1st GORE® TAG® TBE Case

1 month follow up

• Type II endoleak

Courtesy of UMich
Dr Patel, Williams, and Eliason
3rd GORE® TAG® TBE Case

Patient Info
- 84yo man
- 63mm fusiform aneurysm

Case Plan
1. Distal CTAG (40mm x 10cm)
2. TBE Aortic Component (45mm x 10cm)
3. TBE SB Component (8mm x 15mm x 6cm)

Courtesy of UPMC
Dr Makaroun and Singh
3rd GORE® TAG® TBE Case

Procedure Summary

• Successful access and deployment of TBE
• Patent side branch
• No endoleaks

• AC deployment video

Courtesy of UPMC
Dr Makaroun and Singh
3rd GORE® TAG® TBE Case

1 mo follow up
- Side Branch Patent
- No endoleaks

Courtesy of UPMC
Dr Makaroun and Singh
84-year-old man with dumbbell aneurysm configuration
1. 37 mm CTAG TBE (8 mm portal)
2. 12 mm x 6 cm branch
3. 34 mm x 20 cm distal CTAG
4. 40 mm x 10 cm bridging CTAG
Primary Endpoint for all patients (Site reported):
  – Successful access and deployment of TBE
  – Procedural side branch patency

Secondary Endpoint for 5 patients (Core lab):
  – Side branch primary patency
  – Device-related endoleaks
    • 1 Procedural Type 1 endoleak
      – Resolved without re-intervention at 1 month
  – Non-device-related endoleaks
    • 1 Type 2 endoleak at 1 month

• No deaths or neurological events
Zone 0/1 Early Feasibility Trial

- Received FDA approval early May
- FDA “Innovation Pathway”
- Evaluating new clinical application
  - Aortic arch aneurysms (Zone 0 and 1)

Clinical protocol
- Start enrollment after 5 patients with 30 day follow-up in Zone 2
- Phase 1 – Distal vessel(s) revascularization
- Phase 2 – Endovascular procedure
Zone 0/1 Early Feasibility Trial

• Patients:
  – Descending thoracic aortic aneurysms requiring placement of the proximal extent of the aortic stent graft in Zone 0/1

• Primary Endpoints:
  – Successful access and deployment of TBE
  – Primary patency of side branch assessed by angiography at conclusion of procedure

• Secondary Endpoints:
  – One month Core lab analysis
    • Side branch primary patency assessed
    • Device-related endoleaks

• 6 sites (same sites)
• Up to 10 patients
• 5 year follow-up
Summary

The cTAG TBE is composed of an aortic and branch component for treatment of aortic arch lesions involving zones 2, 1, and 0.

Initial clinical experience for zone 2 aneurysms is encouraging:

– Successful access and deployment of TBE
– Procedural side branch patency

Anticipated application of the technology for other zone 2 pathologies (dissection, trauma, etc.) and more proximal zones 1 and 0 aortic disease awaits further clinical outcomes and FDA guidance.