Early Multicenter Experience with the Gore Ascending Aortic Off-the-Shelf Endograft: Indications, Contraindications, Advantages and Results

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Disclosures
- Consultant WL Gore

Ascending Aorta
- No minimally invasive devices approved for the ascending aorta
- Is difficult location to treat due to curvature, motion and access
  - Right next to the aortic valve, coronary arteries and left ventricle on the proximal end of the ascending and the brachiocephalic artery distally
  - Rough location for emboli

Challenges of the Ascending Aorta
- Specific challenges of the Ascending Aorta that Endovascular Solutions must contend with:
  - Motion induced by the cardiac cycle
  - High flow conditions (volume and velocity)
  - High degrees of tortuosity and curvature
  - Proximal and Distal landing targets

E/C Use in Current TBE EFS
- Pros:
  - Speed
  - Patient risk/benefit analysis
    - For patients with no other options
- Cons:
  - Not a regulatory pathway
  - Not a study
    - No required follow-up

PS-IDE
- Pros:
  - Speed
  - Cost effective
  - One site to support
  - Physician/hospital driven
- Cons:
  - Less industry control/involvement
  - Typically limited to 1 site
  - Not as much of a partnership, less conducive to device iterations
**New Type A EFS**

- **Pros:**
  - Multi-center prospective industry sponsored
  - IDE protocol – indication driven
  - Ability to make design modifications during study
  - Transparent process for subject protect
  - In-house clinical resources available

- **Cons:**
  - Slower

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**ARISE: Evaluation of the GORE® Ascending Stent Graft in the Treatment of DeBakey Type I/II Aortic Dissection (TBE14-02)**

- First industry sponsored FDA approved trial for endovascular repair in the ascending aorta
- Focused goal of this EFS is to assess the feasibility of endovascular repair of Type A dissections

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**Early Feasibility Study for Endovascular Repair of DeBakey Type I/II Dissection**

**National Principal Investigator**  
Michael Reardon, MD  
Houston Methodist Hospital

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<thead>
<tr>
<th>Site</th>
<th>Principal Investigator</th>
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<tbody>
<tr>
<td>Houston Methodist Hospital</td>
<td>Jean Bismuth, MD</td>
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<td>Memorial Hermann Heart &amp; Vascular</td>
<td>Anthony Estrera, MD</td>
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<td>Institute</td>
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<td>St. Luke's Health Baylor</td>
<td>Joseph Coselli, MD</td>
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<td>Cleveland Clinic</td>
<td>Eric Roselli, MD</td>
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<tr>
<td>Hospital at University of Pennsylvania</td>
<td>Nimesh Desai, MD</td>
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<td>University of Michigan</td>
<td>Himanshu Patel, MD</td>
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**Gore Type A Early Feasibility Study**

**High Level Inclusion Criteria**

- Primary entry tear must be in the ascending aorta and ≥2cm distal to the most distal coronary artery ostia
- High surgical risk for open repair
- Must have good quality imaging for screening

**Notable Exclusion Criteria**

- Moderate to severe aortic insufficiency
- Known degenerative connective tissue disease, e.g. Marfan’s or Ehler-Danlos Syndrome

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**ARISE Trial**

- Patient Population: DeBakey Type I/II dissections
- Currently approved for up to 10 patients, 6 sites
- Study Device: GORE® Ascending Stent Graft
  - Prior study device, TBE Aortic Extender, is no longer the primary treatment device
  - The Gore TBE System will be available for distal repair as needed

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**First Case**

Presentation - 4/21/2016, Houston Methodist

- 61 y/o Male, DeBakey Type 1 Aortic Dissection
- Procedure
  - Four devices of 45mm were stacked proximal to distal
    - Rapid pacing for most proximal extender deployment
- Post-Treatment
  - False lumen in the ascending aorta was excluded and the endovascular repair of the Type A was achieved

**Lessons Learned**

- Procedural
  - Outer curve coverage
  - Device orthogonality to STJ
**Initial Study Device**

- The Aortic Extender from the Gore Thoracic Branch Endoprosthesis System is being used to line the dissection and stabilize the entire ascending aorta, mimicking surgical repair.
- The rest of the TBE system is available for distal extension to cover any distal tears in the arch and DTA that may provide flow to the ascending false lumen.

**Next Generation Device**

- Staged deployment
  - Slow, controlled – flow through device
  - Fixed on catheter until physician releases

**GORE® Ascending Stent Graft**

- **Device Dimensions**
  - Diameter: 31/34/37/40/45 mm
  - Treatment range: 24 – 42 mm

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**Anatomical Criteria – Length**

- **Length Criteria**
  - L1 – Outer curve distance from the most distal coronary to the most proximal entry tear must be ≥ 20mm
  - L2 – Characterize the outer curve distance from the distal edge of the ascending entry tear to the brachiocephalic artery. If ≤ 20mm, a Zone 0 TBE Aortic Component and Side Branch may be needed for distal seal
  - L3 – Outer curve distance from the most distal coronary artery to the proximal edge of the brachiocephalic artery must be long enough to accommodate the ASG (7/8cm or 10cm)
- **NOTE:** Proximal entry tear must be in the ascending aorta

**Anatomical Criteria – Diameter**

- **Proximal landing zone**
  - Proximal 2cm of the ascending aorta (or proximal extent of target deployment)
    - Measure max true lumen diameter (A, B, C)
      - Use this to determine device size with oversizing based on sizing chart
    - Measure total average aortic diameter (D, E, F)
      - Confirm that device will be in apposition with the total aortic diameter to avoid dislodgement or migration of the stent due to lack of mechanical integrity of the dissection septum of the true lumen. If chosen device will not be in apposition with total aortic diameter, upsize to ensure apposition in landing zone
Background on ARISE EFS Sizing

- Sizing in a Type A Dissection
  - Sizing in a Type B dissection is based off proximal non-dissected aorta in landing zone
  - Type A dissections have no proximal non-dissected aorta in nearly all cases
  - Open surgical repair sews in a vascular graft diameter that would roughly match the native ascending aorta diameter prior to dissection (often based on LVOT diameter)
  - After much discussion between early physician investigators, initial sizing recommendations for stent grafting in an ascending dissection for the EFS was to use TEVAR oversizing based on the maximum true lumen diameter

Anatomical Criteria – Diameter

- Distal landing zone
  - Distal 2cm of the ascending aorta (or distal extent of target deployment)
  - Measure max true lumen diameter (G, H, I)
    - Use this to determine device size with oversizing based on sizing chart
  - Measure total average aortic diameter (J, K, L)
    - Confirm that device will be in apposition with the total aortic diameter to avoid dislodgement or migration of the stent due to lack of mechanical integrity of the dissection septum of the true lumen. If chosen device will not be in apposition with total aortic diameter, consider up sizing

Early Feasibility Study for Endovascular Repair of DeBakey Type I/II Dissection

- Study Status:
  - Currently enrolling
  - 8/14 Patients enrolled to date
    - 8 trial subjects (4 with ASG)
      - 5 females, 3 males
  - DeBakey Aortic Dissection Type
    - 5 Type I aortic dissection
    - 3 Type II aortic dissection
  - Successful access
  - Successful device deployment
  - Successful device delivery
  - Successful retrieval of device delivery system
  - Successful tear exclusion

Conclusions

- Patients with limited treatment options gain access to technology that could positively impact their survival and/or quality of life
- Early feedback from the trials allows early adjustments to device designs
- Rapid refinement of device design reduces time to commercial release of a fit for use device