Early Experience with the new GORE EXCLUDER Conformable AAA Endoprosthesis with Active Neck Angulation Control

How it works and early IDE trial experience

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Disclosures

• WL Gore: Consultant, PI clinical trial, Research Grants
• Medtronic: Research Grants
• Cook: Research Grants
• Boston Scientific: Consultant, MAB, Research Grants
• GE Healthcare: Consultant

Primary Predictor of EVAR FAILURE

The First EVAR Frontier...

Design
• < 60° aortic necks
• 15mm neck length

Limitations
• Not intended for short or severely angulated proximal necks
• High incidence of Type 1A endoleaks
• Increased long term risk of rupture

Reality

Even in most large volume tertiary care centers....
~80% of all EVAR treated patients have at least a 10 mm proximal neck

How can we achieve better results in hostile necks?

Control and conformability must be built into the endovascular system

What would this achieve?

1. Entire use of landing zones
every mm of usable is neck used
2. Stabilization of device and delivery system during deployment
3. Conforming of the endovascular device to the native proximal aortic anatomy
A new conformable endovascular abdominal device

GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL

- 16 Fr for most trunks
- Proximal Fixation
- The trunk length is 5.5-6.5 cm
- Ability to conform to proximal neck angles up to 90°
- Achieve seal in short (≥ 10 mm) proximal necks
- Ability to reposition the device
- Mechanism to adjust device angulation
  - Refine and customize placement
  - Orthogonal positioning

AAA 13-03: US IDE Clinical Trial

- Short neck arm: Subjects with abdominal aortic aneurysms having aortic neck angulation ≤ 60° and infrarenal aortic neck length ≥ 10 mm
- High neck angulation arm: Subjects with abdominal aortic aneurysms having aortic neck angulation > 60° and ≤ 90° and infrarenal aortic neck length ≥ 10 mm
### AAA 13-03: US Clinical Trial Update

**Study Objective**
Assess the safety and effectiveness of the CEXC Device for the treatment of infrarenal AAA

- 48 U.S. sites
- Current Study Enrollment = 106
  - Short neck arm: 77 patients
  - High neck angulation arm: 29 patient

**Primary Safety Endpoint:**
- Composite of any of the following events through 30 days post-treatment:
  - Death
  - Stroke
  - Myocardial Infarction
  - Bowel Ischemia
  - Paraplegia
  - Respiratory Failure
  - Renal Failure
  - Blood Loss > 1000 mL
  - Thromboembolic Events (including limb occlusion and distal embolic events)

**Primary Effectiveness Endpoint:**
- Treatment success, defined as technical success (defined as successful access and deployment of all required CEXC device components) and freedom from the following events:
  - Type I endoleak
  - Type II endoleak
  - Migration (10 mm or more)
  - AAA enlargement ≥ 5 mm with or without intervention
  - AAA rupture
  - Conversion to open repair

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**First IDE trial patient (December 2017)**
- 77 yo male
- Retired machine craftsman
- Immigrated to Brooklyn 15 years ago from Odessa, Ukraine
- Rapid growth AAA (4.1 – 4.8cm) in 6 months

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**High Neck Angulation Arm**
- 71 y.o. male
- 8.5 cm AAA
- Turned down at 2 other NYC hospitals for EVAR/FEVAR
- Came for 3rd opinion
- 82 degree angulation
- 11 mm proximal neck
- Extremely tortuous iliacs
Baseline Demographic Characteristics - Both Substudies

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of Subjects</th>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Enrolled Subjects</td>
<td>105</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex at Birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>89 (84.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (15.2%)</td>
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</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>100 (95.2%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>1 (1.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>4 (3.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>99 (94.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>4 (3.8%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hawaiian or Pacific Islander</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
<td>73.5 (8.2)</td>
<td>74.0</td>
<td>(56.0, 96.0)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td>90.6 (19.0)</td>
<td>88.5</td>
<td>(53.2, 145.2)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td></td>
<td>174.5 (9.3)</td>
<td>175.3</td>
<td>(144.4, 199.4)</td>
</tr>
<tr>
<td>BMI (kg/m^2)</td>
<td></td>
<td>29.7 (5.7)</td>
<td>28.7</td>
<td>(17.6, 53.3)</td>
</tr>
</tbody>
</table>

Summary of Pre-Treatment Measurements (Site Data) - Both Substudies

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Number of Subjects</th>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic diameter at proximal implantation site (mm)</td>
<td>105</td>
<td>21.5 (2.7)</td>
<td>21.0</td>
<td>(16.0, 29.0)</td>
</tr>
<tr>
<td>Aortic neck length (proximal aortic neck length, mm)</td>
<td>105</td>
<td>27.4 (14.0)</td>
<td>25.0</td>
<td>(10.0, 90.0)</td>
</tr>
<tr>
<td>Infrarenal aortic proximal neck angle (degrees)</td>
<td>105</td>
<td>46.0 (23.9)</td>
<td>47.0</td>
<td>(0.0, 90.0)</td>
</tr>
</tbody>
</table>

Summary of Treatment Data - Both Substudies

<table>
<thead>
<tr>
<th>Procedure Time (minutes)</th>
<th>Number of Subjects</th>
<th>Mean (Std Dev)</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fluoro Time (minutes)</td>
<td>104</td>
<td>19.5 (15.4)</td>
<td>16.0</td>
<td>(8, 148)</td>
</tr>
<tr>
<td>Contrast Used During Procedure (mL)</td>
<td>104</td>
<td>96.3 (80.8)</td>
<td>80.0</td>
<td>(14, 788)</td>
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</tbody>
</table>
Summary of Device Usage Data at Initial Treatment - Both Substudies

<table>
<thead>
<tr>
<th>EXCLUDER Device Components</th>
<th>Number of Subjects Implanted</th>
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</thead>
<tbody>
<tr>
<td>Trunks</td>
<td>104 (100.0%)</td>
</tr>
<tr>
<td>Contralateral Legs</td>
<td>102 (97.8%)</td>
</tr>
<tr>
<td>Aortic Extenders</td>
<td>8 (7.7%)</td>
</tr>
<tr>
<td>Iliac Extenders</td>
<td>9 (8.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Devices Implanted</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.0%</td>
</tr>
<tr>
<td>2</td>
<td>44.2%</td>
</tr>
<tr>
<td>3</td>
<td>44.2%</td>
</tr>
<tr>
<td>4</td>
<td>9.6%</td>
</tr>
<tr>
<td>5</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

Number of Devices Per Subject

- Mean and Std: 2.7 (0.7)
- Median: 3.0
- Range: 1-5

Summary

- First in human performed Dec 19, 2017
- 106 patients enrolled in IDE trial
- Short Neck Study enrollment near completed
- 30 day and 6 month site reported results appear uneventful thus far
- High Neck Angle (60-90 degrees) Study is enrolling
- Ultimately try to answer the question of what to do with short and angulated proximal necks