Update from the Endurant global clinical experience

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I have the following potential conflicts of interest to report:

- Consulting and speakersfee
  - WL Gore & Associates
  - Medtronic
  - Medtronic

- Unrestricted research grants
  - Medtronic
  - Abbott Vascular
The Endurant Experience

In the U.S.
- IDE: 150 patients
- AUI Arm: 44 patients
- IDE + ENGAGE PAS: Post-Market (EU trial) - 328 patients

Internationally
- First In Man (EU trial): 40 patients
- Continued Access (EU trial): 40 patients
- ENGAGE Registry: 1263 patients

~2000 Patients
US IDE Trial

Primary Endpoint (composite)

• **Safety**: Safety – the proportion of subjects who have no MAE reported within 1 month (Day 0 – Day 30) from the index procedure.

• **Efficacy**: Successful aneurysm treatment within 12 months of procedure.

150 patients

4 year follow-up
ENGAGE Registry

International multicenter registry: 1263 patients
30 countries, 79 sites
ENGAGE Registry

Patients consecutively enrolled
Follow-up: 30-day, annual visits through 5 years
Extensive monitoring on-going
  100% data management review
  Independent data monitoring (100% endpoints)
  Independent Clinical Event Committee

High quality registry data
**Baseline Characteristics**

**U.S. IDE**

Mean age: $73.1 \pm 8.0$ years (min 52, max 88)

<table>
<thead>
<tr>
<th>ASA Classification</th>
<th>N=150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>2.0%</td>
</tr>
<tr>
<td>Class II</td>
<td>49.3%</td>
</tr>
<tr>
<td>Class III</td>
<td>48.7%</td>
</tr>
<tr>
<td>Class IV</td>
<td>0%</td>
</tr>
</tbody>
</table>

**ENGAGE**

Mean age: $73.1 \pm 8.1$ years (min 43, max 93)

<table>
<thead>
<tr>
<th>ASA Classification</th>
<th>N=1262</th>
</tr>
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<tbody>
<tr>
<td>Class I</td>
<td>0% (76)</td>
</tr>
<tr>
<td>Class II</td>
<td>41.8% (528)</td>
</tr>
<tr>
<td>Class III</td>
<td>41.5% (524)</td>
</tr>
<tr>
<td>Class IV</td>
<td>10.6% (134)</td>
</tr>
</tbody>
</table>
Infrarenal Neck >60°
ASA IV
Symptomatic AAA
Outside IFU
10,2%
12,0%
10,6%
35,4%
16,2%
10,5%
17,8%
15,2%

% Patient Cohort

Mean (mm)
60.3 ± 11.6

Anatomic factors associated with worse EVAR outcomes

Challenging/Real World Population

Patient Baseline Characteristics n=1263
Freedom from AAA-Related Mortality

Durable Clinical Performance Out to 4 Years

U.S. IDE

ENGAGE

99.2 %
4 yrs

98.4 %
4 yrs
Freedom from secondary intervention

Durable Clinical Performance out to 4 Years

U.S. IDE

ENGAGE

90.0 %
4 yrs

87.3 %
4 yrs
**US IDE and ENGAGE**

Durable Clinical Performance Out to 4 Years

Endurant performs equally well in standard EVAR anatomy and real-world patient population

<table>
<thead>
<tr>
<th>US IDE Trial</th>
<th>1 year</th>
<th>2 year</th>
<th>3 year</th>
<th>4 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Implant Rupture</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Conversion to Open Surgery</td>
<td>0%</td>
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### US IDE and ENGAGE
Durable Clinical Performance Out to 4 Years

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<th>3 year</th>
<th>4 year</th>
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</thead>
<tbody>
<tr>
<td>Type I Endoleak</td>
<td>0%</td>
<td>0.8%</td>
<td>0.9%*</td>
<td>0%</td>
</tr>
<tr>
<td>Migration</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Stent Graft Wire Form Fracture</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Stent Graft Occlusion</td>
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<td>2.3%</td>
<td>1.7%</td>
<td>1.8%</td>
<td>0.7%</td>
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Source: Endurant BIFUR APR2014 and ENGAGE Registry - Data on File at Medtronic.
* One subject experienced a new Type I endoleak at the 3 year time frame which led to an aneurysm expansion. The subject refused intervention and voluntarily entered hospice, and expired on day 1212 due to an aneurysm rupture.
Consistent Performance in Straight-Forward and Challenging Anatomies

**AAA Sac Change at 4 Yrs**

**US IDE Controlled Trial\(^1\)**

- Increase: 2.0%
- Stable: 32.0%
- Decrease: 62.0%

**Core Lab**

98.0% Decrease >5 mm/Stable

**AAA Sac Change at 3 Yrs**

**ENGAGE Real World\(^2\) Registry**

- Increase: 9.0%
- Stable: 32.6%
- Decrease: 58.4%

**Site Reported**

91.0% Decrease >5 mm/Stable
US IDE and ENGAGE
Durable; consistent performance in straight-forward and challenging anatomies

US IDE at 4 Yrs
- No ASA IV patients
- No outside IFU
- No symptomatic AAA
- 99.2% freedom from aneurysm-related mortality
- 90.0% freedom from secondary procedure

ENGAGE Registry at 4 Yrs
- Yes ASA IV patients
- Yes outside IFU
- Yes symptomatic AAA
- 98.4% freedom from aneurysm-related mortality
- 87.3% freedom from secondary procedure
<table>
<thead>
<tr>
<th>Criteria</th>
<th>Endurant</th>
<th>Talent</th>
<th>Zenith Flex</th>
<th>Gore Excluder</th>
<th>Vascutek Anaconda</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Treatable Neck Length</td>
<td>10mm</td>
<td>10mm</td>
<td>15mm</td>
<td>15mm</td>
<td>15mm</td>
</tr>
<tr>
<td>Maximum Treatable Infrarenal Angulation</td>
<td>75°</td>
<td>60°</td>
<td>60°</td>
<td>60°</td>
<td>60°</td>
</tr>
<tr>
<td>Max Treatable Aortic Neck Diameter</td>
<td>32mm</td>
<td>32mm</td>
<td>32mm</td>
<td>28mm</td>
<td>31mm</td>
</tr>
<tr>
<td>Max Treatable Iliac Diameter</td>
<td>25mm</td>
<td>22mm</td>
<td>20mm</td>
<td>18mm</td>
<td>21mm</td>
</tr>
<tr>
<td># of Main Body Configurations</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Min Access Profile (28mm graft)</td>
<td>20F</td>
<td>22F</td>
<td>23.5F</td>
<td>21F</td>
<td>22.5F</td>
</tr>
</tbody>
</table>
## Endurant’s Performance Compares Favorably to Landmark EVAR Trials (2 year data)

<table>
<thead>
<tr>
<th></th>
<th>Enrollment</th>
<th>Primary Devices</th>
<th>Secondary Intervention</th>
<th>Conversion</th>
<th>Aneurysm-related Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DREAM</strong></td>
<td>2000-2003</td>
<td>Zenith Talent Excluder</td>
<td>12%</td>
<td>1.7%</td>
<td>2.1%</td>
</tr>
<tr>
<td>**OVER ***</td>
<td>2002-2008</td>
<td>Zenith Excluder AneurRx</td>
<td>13.7%</td>
<td>&lt;1.5%</td>
<td>2.1%</td>
</tr>
<tr>
<td><strong>Endurant U.S. IDE</strong></td>
<td>2008-2009</td>
<td>Endurant</td>
<td>6.1%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>ENGAGE</strong></td>
<td>2009-2011</td>
<td>Endurant</td>
<td>7.7%</td>
<td>0.8%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

*Mala MB et al. Semin Vasc Surg 2010;23:165-169*
CONCLUSION I:
Midterm Evidence for Endurant EVAR Durability

Does it seal? YES
Most AAAs shrink or stable? YES
Proximal device security? YES
Rare instances of:
  Rupture  YES
  Conversion
  AAA related mortality
CONCLUSION II: Summary ENGAGE 4 Year Analysis

Encouraging midterm results at 4 year ENGAGE data

No main body device migrations

Low rates of endoleak Type I 2.5%

87.3% of AAA sacs stable or decreasing in size

Freedom from 2nd procedures at 4 years is 91%.

Most 2nd procedures occur in 1st year.
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