How stent graft design influences overall AAA sac dynamics and overall therapy success

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Disclosure

Speaker name:
........Ross Milner, MD.................................................................

I have the following potential conflicts of interest to report:

■ Consulting: Endospan, Medtronic, Silk Road, and WL Gore

■ Employment in industry

■ Stockholder of a healthcare company

■ Owner of a healthcare company

■ Other(s)

■ I do not have any potential conflict of interest
Key Factors Determining EVAR Therapy Success

- Freedom From Aneurysm Related Mortality
- No/low incidence of endoleaks
- Freedom from Secondary Procedures
- AAA Sac Regression
Not only sac expansion but any failure of the sac to regress is associated with higher long-term mortality, independent of reinterventions or endoleaks.
Additional Factors Associated with AAA regression

Meta-analysis encompassing 8 studies and 17,096 patients

Compared to patients with non-regressing aneurysms, patients with aneurysm regression experienced

1. Significantly lower hazard of death
2. Significantly lower odds of rupture
3. Significantly lower hazard of secondary interventions and late complications
# Endurant Stent-Graft: Clinical Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Geo</th>
<th>Publication</th>
<th>N</th>
<th>5 year FF ARM</th>
<th>AAA sac decreased or stable at 5 yrs</th>
<th>Type Ia Endoleaks at 5 yrs</th>
<th>5 Year FF 2nd procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>US IDE</td>
<td>🇺🇸</td>
<td>Singh et al. J Vasc Surg 2016</td>
<td>150 pts</td>
<td>99.2%</td>
<td>94.0%</td>
<td>0.0% (0/73)</td>
<td>89.0%</td>
</tr>
<tr>
<td>ENGAGE Registry</td>
<td>🇪🇺</td>
<td>Teijink et al. Eur J Vasc Endovasc Surg 2019</td>
<td>1263 pts</td>
<td>97.8%</td>
<td>89.4%</td>
<td>1.6% (8/501)</td>
<td>84.3%</td>
</tr>
</tbody>
</table>

**Final results of the Endurant Stent Graft System in the United States regulatory trial**

Michael J. Singh, MD,* Robert Fattahian, MD,† Paul Jannetta, MD,‡ William D. Joyal, MD,* Thomas Maitland, MD,* Russell Sammon, MD,* and Michel S. Makaroun, MD,* (for the Endurant U.S. Pivotal Trial Investigators, Pittsburgh and Philadelphia, Pa, Buffalo and New York, NY, Birmingham, Ala, and Louisville, Ky)

*Endurant Medical, Bridgewater, New Jersey.
†Endurant Medical, Bridgewater, New Jersey, and Jeanette, NJ.
‡Endurant Medical, Bridgewater, New Jersey, and Olney, MD.

**Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry**

Kees V. Teijink,* Adam H. Hoey*,† Nils W. Nilsson,* Patrick Fievet,* Steven G. Marmor* and H. Howard†

*Endovascular Group, Radiology, Washington, DC
†Department of Radiology, Hôtel-Dieu, Centre Hospitalier Universitaire, Lille, France

SGEN (Société de Gériatrie et d’Endovascular) France, Société de Radiologie Interventionnelle France, Société Francophone des Angiographes Interventionnels, Société de Radiologie Interventionnelle, France

Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181
Max AAA diameter decreasing by >5 mm

**US IDE**

<table>
<thead>
<tr>
<th>Year</th>
<th>Regression 0-20%</th>
<th>Regression &gt;20%</th>
<th>Total 63.9%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Yr</td>
<td>135</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>2-Yr</td>
<td>131</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>3-Yr</td>
<td>111</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>4-Yr</td>
<td>100</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>5-Yr</td>
<td>83</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

**ENGAGE**

<table>
<thead>
<tr>
<th>Year</th>
<th>Regression 0-20%</th>
<th>Regression &gt;20%</th>
<th>Total 61.4%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Yr</td>
<td>949</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>2-Yr</td>
<td>793</td>
<td>135</td>
<td></td>
</tr>
<tr>
<td>3-Yr</td>
<td>658</td>
<td>111</td>
<td></td>
</tr>
<tr>
<td>4-Yr</td>
<td>586</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>5-Yr</td>
<td>492</td>
<td>83</td>
<td></td>
</tr>
</tbody>
</table>


*Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181*
Endurant Design Features that Influence Therapy Success

- **Tip Capture**: Accurately deploy the proximal edge of the stent-graft
- **M Sealing Stent**: Maximize the support within the seal region
- **Endurant Fabric**: Woven high-density multifilament polyester graft fabric

- **Maximize seal length and secure fixation**
- **Continuous wall apposition and seal durability**
- **Durable hemostatic barrier**

Endurant Design Features that Influence Therapy Success

- Controlled delivery at the intended target zone to maximize seal length
- Controlled release of the suprarenal stent and anchor pins to provide secure fixation and prevent migration

<table>
<thead>
<tr>
<th></th>
<th>US IDE</th>
<th>ENGAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Implantation</td>
<td>99.3% (149/150)</td>
<td>99.4% (1255/1262)</td>
</tr>
<tr>
<td>Use of Prox Extension</td>
<td>2.0% (3/150)</td>
<td></td>
</tr>
<tr>
<td>Main Body Migrations at 5 years</td>
<td>0%</td>
<td>Main Body Migration at 5 Years</td>
</tr>
</tbody>
</table>

Stokmans et al. Eur J Vasc Endovasc Surg 2012;44:369-75
Endurant Design Features that Influence Therapy Success

- M-stent design optimizes seal zone contact with uniform apposition against the vessel wall
- Self-expanding nitinol stent maximizes circumferential conformability and maintains a dynamic, continuous seal resulting in low type I endoleak rates

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>2 year</th>
<th>3 year</th>
<th>4 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US IDE Type Ia (core lab)</strong></td>
<td>0.0% (0/132)</td>
<td>0.8% (1/121)</td>
<td>0.0% (0/93)</td>
<td>0.0% (0/2)</td>
<td>0.0% (0/73)</td>
</tr>
<tr>
<td><strong>ENGAGE Type Ia</strong></td>
<td>0.3% (3/1034)</td>
<td>0.5% (4/856)</td>
<td>0.7% (5/705)</td>
<td>0.7% (4/614)</td>
<td>1.6% (8/501)</td>
</tr>
</tbody>
</table>

Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181
Endurant Design Features that Influence Therapy Success

- Designed to minimize blood permeability while optimizing flexibility and durability

<table>
<thead>
<tr>
<th>ENGAGE</th>
<th>1 year</th>
<th>2 year</th>
<th>3 year</th>
<th>4 year</th>
<th>5 year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type II Endoleaks</strong></td>
<td>9.2% (95/1034)</td>
<td>8.4% (72/856)</td>
<td>8.5% (60/705)</td>
<td>7.7% (47/614)</td>
<td>7.2% (36/501)</td>
</tr>
<tr>
<td><strong>Type III Endoleaks</strong></td>
<td>0.2% (2/1034)</td>
<td>0.6% (5/856)</td>
<td>0.1% (1/705)</td>
<td>0.2% (1/614)</td>
<td>0.4% (2/501)</td>
</tr>
<tr>
<td><strong>Type IV Endoleaks</strong></td>
<td>0.1% (1/1034)</td>
<td>0.0% (0/856)</td>
<td>0.0% (0/705)</td>
<td>0.0% (0/614)</td>
<td>0.0% (0/501)</td>
</tr>
</tbody>
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Teijink et al. Eur J Vasc Endovasc Surg 2019;58:175-181
ENGAGE: Type II Endoleaks and Sac Dynamics

### NO ENDOLEAK (N=893)

![Bar chart showing the percentage of cases with regression, stable, and enlargement over 1 to 5 years.

- **1-Yr**: Regression 674, Stable 152, Enlargement 67
- **2-Yr**: Regression 558, Stable 152, Enlargement 67
- **3-Yr**: Regression 452, Stable 152, Enlargement 67
- **4-Yr**: Regression 405, Stable 152, Enlargement 67
- **5-Yr**: Regression 341, Stable 152, Enlargement 67

### ISOLATED TYPE II PTS (N=197)

![Bar chart showing the percentage of cases with regression, stable, and enlargement over 1 to 5 years.

- **1-Yr**: Regression 165, Stable 123, Enlargement 96
- **2-Yr**: Regression 140, Stable 123, Enlargement 96
- **3-Yr**: Regression 123, Stable 123, Enlargement 96
- **4-Yr**: Regression 109, Stable 123, Enlargement 96
- **5-Yr**: Regression 96, Stable 123, Enlargement 96

Endograft Fabric Material and Type II Endoleaks

<table>
<thead>
<tr>
<th>Published US IDE Results*</th>
<th>1-Year Type II Endoleak Rate</th>
<th>5-Year Type II Endoleak Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyester Graft #1</td>
<td>4.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Polyester Graft #2</td>
<td>9.1%</td>
<td>4.1%</td>
</tr>
<tr>
<td>ePTFE Graft #3</td>
<td>20.2%</td>
<td>12.3%</td>
</tr>
<tr>
<td>ePTFE Graft #4</td>
<td>35.7%</td>
<td>14.3%</td>
</tr>
</tbody>
</table>

Rates of type II Endoleaks may vary by graft material*

*Results are taken from independent clinical studies for illustration purpose only and are not based on statistical analysis. Results may differ in a head-to-head study.

Type II Endoleaks are associated with higher rates of secondary procedures¹

• Successful AAA therapy w/stent grafts traditionally determined by freedom from mortality, no endoleaks/need for secondary intervention
  • Importance of sac regression highlight in studies showing patients with non-shrinking aneurysm sacs have an increased mortality
  • Endoleaks, including type II, have a negative impact on sac regression
• Endurant design features influence AAA sac dynamics and therapy success
  • Accurate deployment mechanism
  • Robust seal stent
  • Low permeability polyester graft material
• Endograft design plays important role in success of endovascular AAA therapy