Why Sac Regression Matters: 
How Our Experience with Endurant 
Informs Our Practice

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Key Determinants of EVAR Therapy Success

Long-term success for EVAR is mostly dependent on:

- Incidence of significant endoleaks
- Positive AAA sac dynamics
Recent Interest in AAA Sac Dynamics

1- year Sac Dynamics Associated with 5 – year Mortality

VSGNE, 2003 – 2011
N=2,437 EVAR patients

Stable or regressing sacs
Sac expansion

Clinical signals indicate that sac regression is associated with better long-term outcomes


1- year Sac Dynamics Associated with 5 - and 10 - year Mortality

VQI, 2003 – 2017
N=14,827 EVAR patients

Long-term Survival

P < 0.01 for all comparisons. SE<0.1

5-year
87%
86%
79%

10-year
78%
69%
61%

n = 14,817 in VQI study

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Pts with no shrinkage had significantly more secondary interventions than those with moderate and major shrinkage.

Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair

F. Bastos Gonçalves¹,², H. Baderkhan⁴, H. J. M. Verhagen¹, A. Wanhainen⁴, M. Björling⁵, R. J. Stoker², S. E. Hoeks² and K. Mani⁴

*BJS 2014; 101: 802–810
5YR US IDE Trial Results

- **Max Sac Diameter Decrease**
- **Max Sac Diameter Increase**

**Sac Regression**

**Sac Expansion**

- **AneuRx**
- **Talent**
- **Endurant**

Singh et al., J of Vasc Surg. 2016
Turnbull et al., J Vasc Surg. 2010;51:574-41
AneuRx™ Clinical Update 4th Ed 2007

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### Consistent Sac Regression Rates with Endurant

**5 YR SAC REGRESSION RATES**

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<tbody>
<tr>
<td><strong>Rate</strong></td>
<td>66%</td>
<td>61%</td>
<td>67%</td>
<td>61%</td>
<td>63%</td>
<td>72%</td>
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**ENGAGE OUS Registry**

- **per IFU**
- **Real World**

Teijink et al EJVS 2019

MDT data on file

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Excellent long-term outcomes with Endurant in challenging anatomies up to 11 years of follow-up

<table>
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<tr>
<th>Aneurysm Diameter Change</th>
<th>Follow-up n = 180</th>
<th>Increase ≥ 5mm (n)</th>
<th>Stable (n)</th>
<th>Decrease ≥ 5mm (n)</th>
</tr>
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<tbody>
<tr>
<td>0 – 2 years</td>
<td>1</td>
<td>31</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>2 – 5 years</td>
<td>8</td>
<td>19</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>&gt;5 years</td>
<td>12</td>
<td>16</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>21 (11.7%)</td>
<td>66 (36.7%)</td>
<td>93 (51.6%)</td>
<td></td>
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</table>

Glen L. Benveniste et al. "Long-term Results of 180 Consecutive Patients with Abdominal Aortic Aneurysm Treated with the Endurant Stent Graft System; Ann Vasc Surg 2020; 1–9
Endurant Design Features that Influence Therapy Success

- **Tip Capture**
  - Accurately and reliably align the proximal edge of the stent-graft
  - Low need for intra-op adjuncts

- **M Sealing Stent**
  - Maximizes the seal
  - Low type Ia endoleak rates

- **Endurant™ Fabric**
  - Woven High Density multifilament polyester graft fabric
  - Positive AAA remodeling

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ENGAGE OUS Registry – Sac Dynamics

1263 Patients
30 Countries
6 Continents

REAL WORLD PATIENTS
Limited inclusion/exclusion criteria

REAL WORLD PRACTICE
Limited procedural specifications - Standard follow-up

SAC DYNAMICS AT 5 YEARS

61.4% of AAA had sac diameter decrease at 5 years

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ENGAGE OUS Registry
Freedom from All Cause Mortality

- Decrease 80.0%
- Stable 71.9% \( (p=0.007) \)
- Increase 62.6% \( (p=0.010) \)

p-values are for comparisons to the sac decrease group

Bockler et al, ESVS 2020
MDT data on file

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ENGAGE OUS Registry
Freedom from Major Adverse Events

- Decrease 75.7%
- Stable 67.0% (p=0.007)
- Increase 55.6% (p=0.004)

No. at risk:
- 441
- 423
- 380
- 347
- 314
- 190

Time from Implant (Days):
- 0
- 366
- 732
- 1097
- 1462
- 1827

p-values are for comparisons to the sac decrease group

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ENGAGE OUS Registry: Freedom from Secondary Endovascular Procedures

- Decrease 89.8%
- Stable 82.5% (p=0.008)
- Increase 63.1% (p<0.0001)

No. at risk:
- 441
- 418
- 379
- 342
- 303
- 185
- 462
- 431
- 363
- 314
- 265
- 154
- 46
- 37
- 29
- 23
- 19
- 13

Time from Implant (Days):
- 0
- 366
- 732
- 1097
- 1462
- 1827

p-values are for comparisons to the sac decrease group

Bockler et al, ESVS 2020
MDT data on file
## AAA Sac Dynamics Conclusions

- Large EVAR registries show associations between sac dynamics and long-term mortality, with sac regression correlated to improved overall survival.

- Separation of fixation (supra-renal) and sealing (infra-renal) provides durable proximal performance which leads to favorable results including sac regression.

- Endurant features drive low endoleak and high sac regression rates while expanding on-label patient applicability.

- ENGAGE registry showed a significantly better survival, FF Secondary procedures and MAEs for pts with sac regression.
Thank you

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