How Are Long-Term EVAR Outcomes Impacted By Extremely Hostile Necks

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I have the following potential conflicts of interest to report:

Medtronic
WL Gore
Philips
Endologix
Arsenal AAA
A stable proximal seal is paramount for AAA exclusion and for limiting complications over time.

Hostile proximal neck characteristics are still the most frequent constraints for EVAR. These include:

- Length, Diameter, Angulation, Contour, and Ca$^{2+}$/Thrombus burden
How are long-term EVAR outcomes impacted by:

• Severe Conicity: ≥20% reverse taper

• Extreme Infrarenal Angulation: >60° to 90°

• Ca²⁺/Thrombus Burden: >20% circumferential
Endurant Stent Graft System:

- Designed for short, challenging proximal necks
  - High conformability
  - Active suprarenal fixation
  - Lower amplitude seal stent
  - Precision deployment
Methods – ENGAGE Registry

Largest Contemporary EVAR Registry with single stent graft (Endurant)

N=1263 pts; Prospective/Consecutive Enrollment (2009-2010)
  - Initiated <1yr post-CE mark, to evaluate Endurant in real-world population

79 Centers, across 30 Countries, on 6 Continents
  - Diverse patient and physician population

Adherence to IFU advised; Off-IFU pts permitted

High-Quality Data
  - 100% data management review
  - Independent data monitoring
  - Independent Clinical Event Committee
Challenging Patient Population

- **SVS 3**: 35.4%
- **Outside IFU**: 17.0%
- **Symptomatic AAA**: 16.2%
- **AAA >7cm**: 15.2%
- **ASA IV**: 10.6%
- **Female**: 10.5%
- **Neck 10mm - <15mm**: 10.0%

*79.5% due to proximal neck parameters*
*Increased risk of graft displacement over time*
*Severe systemic disease; increased complications risk*
*Challenging patients, historically underserved*
*Increased risk for proximal failure*
OBJECTIVE:

To evaluate midterm results (4 yrs) in patients having challenging proximal neck anatomy treated with Endurant

3 subgroup analyses:
- Conical (Reverse Taper) Necks (N=51 pts)
- Angulated Necks (N=112 pts)
- Calcified/Thrombus Necks (N=190 pts)

HYPOTHESIS:

Endurant performs as well in pts w/ challenging neck anatomies as it does in pts w/ standard neck anatomies
**ENGAGE Registry**

**Proximal Neck Sub-Analysis**

<table>
<thead>
<tr>
<th>INITIAL IMPLANT</th>
<th>Neck Conicity (Reverse Taper)</th>
<th>Neck Angulation</th>
<th>Neck Ca(^{2+})/Thrombus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥20%</td>
<td>&lt;20%</td>
<td>P-value</td>
</tr>
<tr>
<td>Successful Delivery and Deployment</td>
<td>100% (51/51)</td>
<td>99.4% (1179/1186)</td>
<td>0.58</td>
</tr>
</tbody>
</table>

Early technical success is not impacted by extreme conicity or angulation. But it is, however, impacted by Ca\(^{2+}\)/thrombus, 5 of 7 pts with unsuccessful delivery and deployment in Ca\(^{2+}\)/Thrombus cohort due to access vessels, not proximal neck.
### Main Body Migration through 4 years not impacted by challenging neck anatomy
<table>
<thead>
<tr>
<th>At 4 Year Follow-Up</th>
<th>Neck Conicity (Reverse Taper)</th>
<th>Neck Angulation</th>
<th>Neck Ca(^{2+})/Thrombus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≥20%</td>
<td>&lt;20%</td>
<td>P-value</td>
</tr>
<tr>
<td>Type Ia Endoleak</td>
<td>0.0% (0/28)</td>
<td>0.5% (3/611)</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>0.0% (0/46)</td>
<td>0.7% (4/582)</td>
<td>0.57</td>
</tr>
<tr>
<td></td>
<td>0.0% (0/86)</td>
<td>0.9% (5/554)</td>
<td>0.38</td>
</tr>
</tbody>
</table>

Type Ia EL at 4 years not impacted by challenging neck anatomy
## ENGAGE Registry

### Proximal Neck Sub-Analysis

<table>
<thead>
<tr>
<th>Through 4 Year F/U</th>
<th>Neck Conicity (Reverse Taper)</th>
<th>Neck Angulation</th>
<th>Neck Ca(^{2+})/Thrombus</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>≥20%</td>
<td>&gt;60-90°</td>
<td>&gt;20%</td>
</tr>
<tr>
<td></td>
<td>&lt;20%</td>
<td>≤60°</td>
<td>≤20%</td>
</tr>
<tr>
<td></td>
<td>P-value</td>
<td>P-value</td>
<td>P-value</td>
</tr>
<tr>
<td>2(^{nd}) Procedure for Type I/III Endoleak</td>
<td>7.8% (4/51)</td>
<td>5.6% (6/108)</td>
<td>4.3% (8/185)</td>
</tr>
<tr>
<td></td>
<td>3.5% (41/1186)</td>
<td>3.3% (35/1074)</td>
<td>3.6% (37/1025)</td>
</tr>
<tr>
<td></td>
<td>0.10</td>
<td>0.21</td>
<td>0.64</td>
</tr>
</tbody>
</table>

2\(^{nd}\) procedures for Type I/III through 4 years not impacted by challenging neck anatomy
**ENGAGE Registry**

**Proximal Neck Sub-Analysis**

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<tbody>
<tr>
<td></td>
<td>≥20%</td>
<td>&lt;20%</td>
<td>P-value</td>
</tr>
<tr>
<td>Rupture</td>
<td>0.0% (0/51)</td>
<td>0.9% (1/108)</td>
<td>0.49</td>
</tr>
</tbody>
</table>

Rupture rate not impacted by extreme conicity or angulation
But it is impacted by Ca\(^{2+}\)/thrombus,

2 of 4 pts with rupture in Ca\(^{2+}\)/Thrombus cohort due to type III separations, not proximal neck
Through 4 Year F/U

<table>
<thead>
<tr>
<th>Conversion</th>
<th>Neck Conicity (Reverse Taper)</th>
<th>Neck Angulation</th>
<th>Neck Ca(^{2+})/Thrombus</th>
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<tr>
<td></td>
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<td>&gt;60°-90°</td>
<td>&gt;20%</td>
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<tr>
<td></td>
<td>&lt;20%</td>
<td>≤60°</td>
<td>≤20%</td>
</tr>
<tr>
<td></td>
<td>P-value</td>
<td>P-value</td>
<td>P-value</td>
</tr>
<tr>
<td>0.0%</td>
<td>(0/51)</td>
<td>0.9%</td>
<td>1.1%</td>
</tr>
<tr>
<td>1.1%</td>
<td>(13/1186)</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>0.45</td>
<td></td>
<td>0.86</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Conversion to Open Repair through 4 years not impacted by challenging neck anatomy
Current analysis demonstrates Endurant performs as well in patients with very challenging proximal neck characteristics as it does in more standard anatomies, with similar 4 year outcomes in:

- Extremely reverse tapered necks ($\geq 20\%$ diameter change)
- Highly angulated necks ($>60^\circ-90^\circ$ infrarenal angulation)
- $Ca^{2+}$/Thrombus burdened necks ($>20\%$ circumferential)
In Conclusion

- Challenging proximal neck characteristics have historically impacted the long-term durability of EVAR.
- Few studies of significant sample size and rigorous outcomes data could analyze reliably the performance of contemporary endografts in real-world patients.
- Insights from the ENGAGE Registry demonstrate the durable performance of Endurant in both standard and extreme infrarenal anatomies through 4 years.
- The reliability of Endurant’s performance in these patient populations is encouraging.
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