ENCORE study update: Durability through polymer sealing using the Ovation AAA stent graft system

Hence JM Verhagen, Sean Lyden, Marc Schermerhorn for the ENCORE steering group

Erasmus University Medical Center; Rotterdam, The Netherlands
Disclosures

- Medtronic
- WL Gore
- Abbott
- Terumo
- Endologix
- Arsenal AAA
EVAR’s durability issue

Late Rupture or Reintervention

Survival Benefit Lost


EVAR’s durability issue

- Most common failure mode of EVAR is loss of proximal seal.

- This is especially seen after implants in attachment zones that are aneurysmal.

- A wide neck is a durability issue for EVAR.
Wide neck is durability issue for EVAR

Editor’s Choice — Influence of Proximal Aortic Neck Diameter on Durability of Aneurysm Sealing and Overall Survival in Patients Undergoing Endovascular Aneurysm Repair. Real World Data from the Gore Global Registry for Endovascular Aortic Treatment (GREAT)

Dominic P.J. Howard a,b, Conor D. Marron a, Ediri Sideso b, Phillip J. Puckridge a, Eric L.G. Verhoeven c, James I. Spark a, on behalf of The Global Registry for Endovascular Aortic Treatment (GREAT) Investigators

Eur J Vasc Endovasc Surg (2018) 56, 189—199

Gradual increase in type 1A EL

Increased mortality
Wide neck is durability issue for EVAR

Standard endovascular aneurysm repair in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events

Nelson F. G. Oliveira, MD, Frederico M. Bastos Gonçalves, MD, PhD, Marie Josee Van Rijn, MD, Quirina de Ruiter, MSc, Sanne Hoek, PhD, Jean-Paul P. M. de Vries, MD, PhD, Joost A. van Herwaarden, MD, PhD, and Hence J. M. Verhagen, MD, PhD, Rotterdam, Nieuwegein, and Utrecht, The Netherlands, and Azores and Lisbon, Portugal

J Vasc Surg 2017;65:1608-16.)
Wide neck is durability issue for EVAR

Patients with large neck diameter have a higher risk of type IA endoleaks and aneurysm rupture after standard endovascular aneurysm repair

Nelson F. G. Oliveira, MD, Frederico Bastos Gonçalves, MD, PhD, Klaas Ultee, MD, PhD, José Pedro Pinto, MD, Marie Josee van Rijn, MD, PhD, Sander Ten Raa, MD, PhD, Patrice Mvipatayi, MD, FCS, FRACS, Dittmar Böckler, MD, PhD, Sanne E. Hoeks, PhD, and Hence J. M. Verhagen, MD, PhD, Rotterdam, The Netherlands; Ponta Delgada, Lisbon, and Porto, Australia; and Heidelberg, Germany

J Vasc Surg 2019;69:783-91

3-fold greater risk of type 1A EL

5-fold greater risk of aneurysm rupture & increased mortality
Wide neck is durability issue for EVAR

2019 Systematic Review: Wide neck is a significant risk factor for conventional EVAR

Covelo's et al. J Cardiovascular Surgery

- 6.7x Type 1a endoleak
- 4.10x Neck Related Adverse Events
- 10.07x Sac Expansion
- 5.10x Ruptured AAA
- 1.55x All Cause Mortality
- 1.79x Aneurysm Related Death
EVAR’s durability issue

- Our research showed that the most common failure mode of EVAR in wide necks was loss of proximal seal due to progressive dilatation of the neck.

- We found a yearly rate of neck dilatation between 4-6%.

- The continuous outward radial force by self-expandable stentgrafts may play an important role here.
No continuous outward force

Separates Fixation From Seal

13 mm

Radiopaque Marker
Sealing Ring
No continuous outward force

Polymer EVAR
No Neck Dilatation

Separates Fixation From Seal
Objective

• To determine the impact of polymer sealing on neck-related adverse events by studying the 5-Y outcome of patients treated with the Ovation device

• To compare outcomes of wide necks vs standard necks

Hypothesis

• All patients can be treated safely and durably with the Ovation device
Studies actively following patients per respective protocol: †5 year FU completes in 2020 / ‡5y FU completes in 2019 / *1y FU completes in 2018

Data Cut April 12, 2018. First of multiple, future planned data cuts and sub-analyses.

Study group

Ovation
Global Pivotal Trial
5 YEARS

Ovation
Pivotal Trial
CAP
5 YEARS

Ovation
Pivotal Trial
De Novo
5 YEARS

Ovation
EU Post Market
Study
5 YEARS

LIFE
Fast Track EVAR
30 DAYS

LUCY
Study
1 YEAR

ENCORE
EffectiveNess of Custom Seal with Ovation: Review of the Evidence
Study design

- Retrospective analysis of 6 prospectively enrolled studies
- 1296 patients
- Standardized follow-up, Median follow-up: 3 year (30d – 5Y)

- **Study group:** 242 patients (19%) treated with 34mm Ovation device
- **Controls:** Remaining population
## Baseline characteristics

<table>
<thead>
<tr>
<th>DEMOGRAPHICS</th>
<th>34AB</th>
<th>&lt;34 AB</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>74 ± 8</td>
<td>73 ± 8</td>
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</tr>
<tr>
<td>Male</td>
<td>83%</td>
<td>80%</td>
<td>ns</td>
</tr>
<tr>
<td>Female</td>
<td>17%</td>
<td>20%</td>
<td>ns</td>
</tr>
<tr>
<td>ASA Class 1/2</td>
<td>36%</td>
<td>35%</td>
<td>ns</td>
</tr>
<tr>
<td>Class 3/4/5</td>
<td>64%</td>
<td>65%</td>
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<tr>
<td>BMI</td>
<td>28 ± 5</td>
<td>28 ± 5</td>
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<table>
<thead>
<tr>
<th>MEDICAL HISTORY</th>
<th>34AB</th>
<th>&lt;34 AB</th>
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<tbody>
<tr>
<td>CHF</td>
<td>2%</td>
<td>4%</td>
<td>ns</td>
</tr>
<tr>
<td>COPD</td>
<td>33%</td>
<td>28%</td>
<td>ns</td>
</tr>
<tr>
<td>MI</td>
<td>14%</td>
<td>17%</td>
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<tr>
<td>Diabetes</td>
<td>17%</td>
<td>18%</td>
<td>ns</td>
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<tr>
<td>CVA (Stroke)</td>
<td>5%</td>
<td>6%</td>
<td>ns</td>
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<tr>
<td>Thoracic Aneurysm</td>
<td>2%</td>
<td>2%</td>
<td>ns</td>
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<tr>
<td>Family History AAA</td>
<td>10%</td>
<td>14%</td>
<td>ns</td>
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<tr>
<td>Current Tobacco Use</td>
<td>48%</td>
<td>26%</td>
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## Anatomical characteristics

<table>
<thead>
<tr>
<th>Baseline Aortoiliac Characteristics</th>
<th>34AB</th>
<th>&lt;34 AB</th>
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</thead>
<tbody>
<tr>
<td>Maximum Sac Diameter (mm)</td>
<td>57 ± 9</td>
<td>54 ± 9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Neck Angulation (°)</td>
<td>22 ± 20</td>
<td>18 ± 18</td>
<td>ns</td>
</tr>
<tr>
<td>Proximal Neck length (mm)</td>
<td>19 ± 10</td>
<td>25 ± 12</td>
<td>&lt;0.001</td>
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<tr>
<td>Aortic Neck Dia Lowest Ostium, IR (mm)</td>
<td>25 ± 3</td>
<td>22 ± 9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic Neck Dia Ovation Sealing Zone, IR + 13</td>
<td>28 ± 2</td>
<td>22 ± 3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Distal Common Iliac Dia (mm)</td>
<td>14.5 ± 4</td>
<td>13.5 ± 3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>External Iliac Artery Dia (mm)</td>
<td>8 ± 2</td>
<td>8 ± 2</td>
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</table>
### Procedural characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>34AB</th>
<th>&lt;34 AB</th>
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<tbody>
<tr>
<td>Technical success</td>
<td>100%</td>
<td>99.7</td>
<td>ns</td>
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<tr>
<td>Procedure time, minutes</td>
<td>98 (43, 226)</td>
<td>94 (33, 371)</td>
<td>ns</td>
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<tr>
<td>Bilateral Percutaneous Access</td>
<td>58%</td>
<td>65%</td>
<td>0.05</td>
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</table>
Mortality

All cause mortality

AAA related mortality
Rupture, conversion

Rupture

Conversion
Endoleak, Re-intervention

Type 1A

Proximal device reintervention
Conclusion

- EVAR using proximal polymer sealing does not seem to induce neck dilatation like other endografts.

- In contrast to self-expanding EVAR devices, patients treated with the largest size Ovation do not suffer from more complications compared to standard diameter devices.

- This analysis suggests that Ovation is a durable EVAR option, even in wide neck anatomy.

- Further investigation is needed to understand why Ovation follows a different clinical course.
Thank you
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