GORE® EXCLUDER® AAA Endoprosthesis demonstrates long-term durability

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Disclosure

Speaker name:
Michel Reijnen

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Long term outcome of EVAR

- Long-term data after EVAR are still limited
- Lack of device-specific reporting
- Bias of ongoing introduction of improvements and new devices
- EVAR-1 cohort with mean FU of 12.7±1.5 years;
  - beyond 8 years significantly higher mortality in EVAR group
  - Increased AAA-related mortality mainly attributable to secondary rupture (7% vs 1%)

Influence of Graft Type

EVAR 1 and EVAR 2 Trial

“For the prespecified adjustment variables, there was some evidence to suggest that patients who had a GORE® EXCLUDER® Device experienced significantly lower rates of complications and reinterventions compared with the other graft types.”

Gore Excluder Endoprosthesis

1997  Introduced in Europe
2004  Introduction of the low-permeability expanded PTFE to reduce endotension
2010  Introduction of the C3 delivery system Repositionable for
       - Precise proximal deployment
       - Cannulation of CL limb
2012  The profile is reduced while remaining the same devices; no compromise on durability
Future Introduction of the conformable Excluder
A low-permeability film layer, added in 2004, is the only modification to the GORE® EXCLUDER® AAA Device. Requiring so few changes is unprecedented compared to currently available endografts.
Gore concept and conformability

- **ePTFE & Nitinol**
  - Biocompatible, highly durable, long term performance
  - MRI compatible

- **Sutureless Construction**
  - Stent is heat bonded to graft
  - Optimized for stent nesting

- **Stent design**
  - Sinusoidal pattern
  - Provides nitinol stent support with fewer unsupported gaps, better wall apposition, and limiting kinking and occlusion
Long term outcome Excluder

- 2 Dutch sites
- January 2000 and December 2015
- 248 patients treated with Gore Excluder out of 1643 EVAR procedures
- 87% male with mean age of 71.2 ± 8.2 years
- N=61 (25%) outside the IFU

<table>
<thead>
<tr>
<th>Anatomical characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurysm diameter</td>
<td>59.1 ± 9.6 mm</td>
</tr>
<tr>
<td>Infrarenal neck diameter</td>
<td>22.9 ± 2.4 mm</td>
</tr>
<tr>
<td>Infrarenal neck length</td>
<td>32.3 ± 11.9 mm</td>
</tr>
<tr>
<td>Neck angulation</td>
<td>23.6 ± 21.9°</td>
</tr>
<tr>
<td>Concomitant iliac artery aneurysm</td>
<td>n=30 (12%)</td>
</tr>
</tbody>
</table>

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Long term outcome Excluder

- Median follow-up 26 months (range 1-190 months)
  - ≥ 5 year n=63 (25.4%)
  - ≥ 10 years n=20 (8.1%)

- Estimated re-intervention-free survival:
  - 5 years; 85.2%
  - 10 years 75.6%

- Independent risk factors for re-intervention:
  - Technical success (P < .001)
  - Endoleak type I (P < .001)
  - Endoleak type II (P = .003)
Long term outcome Excluder

Freedom from endoleak

Reintervention for endoleak in 16 patients (6.5%)

- Type Ia  n=6
- Type Ib  n=5
- Type II n=5

<table>
<thead>
<tr>
<th></th>
<th>Type Ia (95% CI)</th>
<th>Type Ib (95% CI)</th>
<th>Type II (95% CI)</th>
<th>Type V (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>96.2% (93.8 - 98.6)</td>
<td>98.7% (97.3 - 100.1)</td>
<td>66.5% (60.4 - 72.6)</td>
<td>99.5% (98.5 - 100.5)</td>
</tr>
<tr>
<td>5 years</td>
<td>95.3% (92.4 - 98.2)</td>
<td>95.1% (91.2 - 99.0)</td>
<td>60.7% (53.8 - 67.6)</td>
<td>90.6% (84.9 - 96.3)</td>
</tr>
<tr>
<td>10 years</td>
<td>91.5% (83.7 - 99.3)</td>
<td>95.1% (91.2 - 99.0)</td>
<td>55.0% (45.0 - 65.0)</td>
<td>80.3% (69.1 - 91.5)</td>
</tr>
</tbody>
</table>

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Long term outcome Excluder

- Re-interventions
  - Aneurysm rupture 0.4%
  - Limb occlusion 0.4%
  - Stent migration 0.4%

- Aneurysm sac growth was more prevalent in:
  - Original Excluder compared to the Low Permeability Excluder (P = .001)
  - Presence of an endoleak type I (P = .002), II (P = .005) and V (P < .001)

- The overall survival at 5 and 10 years after EVAR was 68.4% and 49.0%, without reported aneurysm related deaths
  - In two patients suspect to be AAA-related

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## Long term outcome Excluder

<table>
<thead>
<tr>
<th></th>
<th>Poublon (n=248)</th>
<th>Maleux (n=121)</th>
<th>Bastos Gonçalves (n=144)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anatomy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm diameter</td>
<td>59.1 ± 9.6 mm</td>
<td>58.1 ± 11.8</td>
<td>60 (54-70)</td>
</tr>
<tr>
<td>Infrarenal neck diameter</td>
<td>22.9 ± 2.4 mm</td>
<td>21.6 ± 2.2</td>
<td>24 (22.2-25)</td>
</tr>
<tr>
<td>Infrarenal neck length</td>
<td>32.3 ± 11.9 mm</td>
<td>32.9 ± 13.3</td>
<td>28.5 (21-42)</td>
</tr>
<tr>
<td>Follow-up (mean)</td>
<td>2.2 (0-15.8)</td>
<td>5.0 ± 3.1</td>
<td>5.0 (3.1-6.4)</td>
</tr>
<tr>
<td><strong>Survival</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-year</td>
<td>68%</td>
<td>75%</td>
<td>62%</td>
</tr>
<tr>
<td>10-year</td>
<td>49%</td>
<td>58%</td>
<td>39%</td>
</tr>
<tr>
<td><strong>Re-interventions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12%</td>
<td>15%</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Intervention free survival</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-year</td>
<td>85%</td>
<td>90%</td>
<td>NA</td>
</tr>
<tr>
<td>10-year</td>
<td>76%</td>
<td>78%</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Endoleak</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ia</td>
<td>5%</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Ib</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>II</td>
<td>36%</td>
<td>32%</td>
<td>23%</td>
</tr>
<tr>
<td>III</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Endotension</td>
<td>7%</td>
<td>9%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Limb occlusion</strong></td>
<td>0.4%</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Poublon et al. J Vasc Intervent Radiol, in press
### Long term outcome Gore Excluder

#### Re-interventions

<table>
<thead>
<tr>
<th>Indication for reintervention</th>
<th>Poublon (n=248)</th>
<th>Maleux (n=121)</th>
<th>Bastos Gonçalves (n=144)</th>
<th>Overall (n=513)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reinterventions</td>
<td>N=34</td>
<td>N=18</td>
<td>N=39</td>
<td>18%</td>
</tr>
<tr>
<td>Insufficient proximal seal</td>
<td>N=7</td>
<td>N=2</td>
<td>N=10</td>
<td>4%</td>
</tr>
<tr>
<td>Insufficient distal seal</td>
<td>N=7</td>
<td>N=2</td>
<td>N=9</td>
<td>4%</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>N=9</td>
<td>N=4</td>
<td>N=8</td>
<td>4%</td>
</tr>
<tr>
<td>Infolding of the proximal graft</td>
<td>N=1</td>
<td>N=2</td>
<td>N=0</td>
<td>0.6%</td>
</tr>
<tr>
<td>Limb kinking</td>
<td>N=0</td>
<td>N=1</td>
<td>N=0</td>
<td>0.2%</td>
</tr>
<tr>
<td>Limb occlusion</td>
<td>N=1</td>
<td>N=1</td>
<td>N=1</td>
<td>0.6%</td>
</tr>
<tr>
<td>Endotension</td>
<td>N=3</td>
<td>N=5</td>
<td>N=8</td>
<td>3%</td>
</tr>
<tr>
<td>Conversion</td>
<td>N=1</td>
<td>N=1</td>
<td>N=4</td>
<td></td>
</tr>
<tr>
<td>relining</td>
<td>N=3</td>
<td>N=4</td>
<td>N=2</td>
<td></td>
</tr>
<tr>
<td>fenestration</td>
<td>N=0</td>
<td>N=0</td>
<td>N=2</td>
<td></td>
</tr>
<tr>
<td>Endograft Infection</td>
<td>N=0</td>
<td>N=1</td>
<td>N=1</td>
<td>0.4%</td>
</tr>
</tbody>
</table>
Endotension

- Maleux et al.: In all of the patients with endotension an original permeability stentgraft was implanted.

- Bastos Gonçalves et al.: The generation of implanted endoprosthesis (OD vs. LP) was significantly associated with the risk of sac growth.

- Poublon et al.: Sac growth was more prevalent with the Original Gore Excluder compared to the Low Permeability Excluder (P=.001).

Poublon et al. J Vasc Intervent Radiol, in press
Mortality

• Maleux et al.:
  • the majority died from cancer (19/35)
  • No AAA-related mortality

• Bastos Gonçalves et al.:
  • The estimates for AAA-related death or rupture (including 30 days) were 2.4% at 5 years and 2.4% at 10 years
  • One death related to rAAA in conjunction with infection

• Poublon et al.:
  • Malignancy most frequent cause of death (28%)
  • No reported AAA-related mortality although two deaths were suspected to be aneurysm related

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Gore Excluder and conformability

- Excluder is related to very low incidence of:
  - Limb occlusions 0 - 2%
  - Kinking 0 - 1%
  - Distal migration 0 - 4%

- Relation between aorto-iliac morphology and complications has been established with more graft related complications in:
  - Higher infrarenal neck angulation
  - Higher common iliac artery tortuosity
Gore Excluder and conformability

- Anatomical fit between patient and stent graft may be an important factor for success of treatment

- EVAR devices do reduce the aorto-iliac tortuosity;
  - Conformability; Zenith < Endurant < Excluder
  - Conformability ; Cook IBD < Gore IBE

C3 delivery system

- Option for re-positioning
- August 2010 and December 2012
- 400 patients (86.8% male, mean age 73.9 ± 7.8 years)
- Technical success 99%
- Graft repositioning in 192/399 (48%) patients, most frequently for level readjustment with regard to the renal arteries
- Mean follow-up 15.9 ± 8.8 months
- Estimated freedom-from-reintervention
  - 1 year  95% (95% CI 92-97%)
  - 2 years 92% (95% CI 87-95%)

Conclusions

- The Gore Excluder has demonstrated its durability at the long-term with acceptable re-intervention rates and low AAA-related adverse events.
- Late new-onset endoleaks are observed and emphasize the need for long-term surveillance.
- The high conformability of the Gore Excluder may attribute to its low limb occlusion rates.
- The introduction of the C3 delivery system could further reduce the re-intervention rates.
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