Controlled conformability to make it possible: the EXCeL Registry

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Disclosure

Speaker name:

Marc van Sambeek

I have the following potential conflicts of interest to report:

Consulting and speakersfee
- WL Gore & Associates
- Medtronic

Unrestricted research grants
- Medtronic
- W.L Gore & Associates
- Philips Medical Systems
Anatomical challenges

Risks of a hostile neck

Which are the risks related to treatment of a hostile neck?

Endoleak
Migration

Aneurysm rupture
Effect of neck angulation

Coronal & sagittal angulation

Correction for renals

Conformable & respositionable

Courtesy of Prof. Dr. D. Böckler
Effect of neck angulation

Coronal & sagittal angulation

Correction for renals

Conformable & respositionable

Courtesy of Prof. Dr. D. Böckler
New developments

EVAR continues to evolve as a treatment option for AAA. New devices which are specifically designed to perform adequately across the spectrum of potential anatomic presentations for infra-renal EVAR are needed.
New developments

GORE® EXCLUDER® Conformable AAA Endoprosthesis

The IFU anatomic criteria
- $\geq 15\text{mm}$ proximal neck length and $\leq 90^\circ$ proximal neck angulation
- $\geq 10\text{mm}$ proximal neck length and $\leq 60^\circ$ proximal neck angulation

[Images of medical illustrations related to the endoprosthesis]
First EU implants 9/11-2018

EXCeL Registry is a multi-center, post-market, non-interventional, non-randomized, single-arm, prospective observational study.

Follow-up 3 years

150 consented subjects from 11 high-volume sites across Europe will be included.
### EXCeL Registry Inclusions

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>&lt; 60° Neck Angulation</th>
<th>60-90° Neck Angulation</th>
<th>&gt; 90° Neck Angulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 15 mm</td>
<td>Inside IFU</td>
<td>Inside IFU</td>
<td>Challenging anatomy</td>
</tr>
<tr>
<td>10-15 mm</td>
<td>Inside IFU</td>
<td>Challenging anatomy</td>
<td>Extreme anatomy</td>
</tr>
<tr>
<td>5-10 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Inside IFU**

**Challenging anatomy**

**Extreme anatomy**

**Department of Vascular Surgery**

**Department of Cardiovascular Biomechanics**

**TU/e Technische Universiteit Eindhoven University of Technology**
### EXCeL Registry

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>21</td>
</tr>
<tr>
<td>Age</td>
<td>64-87 years</td>
</tr>
<tr>
<td>AAA diameter</td>
<td>52-91 mm</td>
</tr>
<tr>
<td>Neck angulation</td>
<td>17-80 degrees</td>
</tr>
<tr>
<td>Number of repositioning</td>
<td>Average 1.4 (0-3)</td>
</tr>
<tr>
<td>Active control of device</td>
<td>12 out of 21 cases</td>
</tr>
<tr>
<td>Type I endoleak at compl.</td>
<td>0 (1 corrected before compl.)</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>2.4 (2-5) days</td>
</tr>
</tbody>
</table>
Conclusion

EVAR continues to evolve as the treatment option for AAA

New generation devices will extend the applicability of EVAR
Controlled conformability to make it possible: the EXCeL Registry

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