The Gore Excluder Conformable Device (CEXC) for EVAR with unfavorable neck anatomy: The European experience from the EXCeL Registry

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Disclosure
Marc RHM van Sambeek
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There’s no univocal definition.
In general:

- Neck length ≤ 15 mm?
- Neck angulation ≥ 60°?
- Double angled necks?
- Irregular (thrombus, bulge, calcium).Liberalized interpretation of the instructions for use

- Wide (> 28 mm)?
- Or outside instructions for use?

Endoleak
Migration
Rupture

The literature on hostile neck

NEGATIVE

Liberalized interpretation of the instructions for use is associated with increased risk of aneurysm sac enlargement, which can lead to re-intervention and rupture of the aneurysm.

In a meta-analysis it was demonstrated that patients treated with hostile neck anatomy were at significantly increased risk for operative morbidity, additional adjunctive procedures at treatment, Type I endoleak at one year, and aneurysm related mortality at one year.

The literature on hostile neck

POSITIVE

Real-world, global experience shows promising results and indicates that endovascular AAA repair is safe and effective in patients with challenging aortic neck anatomy.

Emergency EVAR provides excellent results for treatment of RAAA patients with both FNA and HNA.
EVAR in RAAAs with HNA is technically feasible and safe in experienced endovascular centres.
Broos PP, et al. EJVES 2015;50:313-319

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.

CE mark: 2018
**Experience matters**

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

**First EU implants 9/11-2018**

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

150 consented subjects from 11 high-volume sites across Europe will be included.

**EXCeL Registry**

- Number of patients: 10
- Age: 77 (64-87) years
- AAA diameter: 59 (52-64) mm
- Neck angulation: 17-79 degrees
- Number of repositioning: 1 (0-2)
- Active angulation of device: 4 out of 10 cases
- Type I endoleak at compl.: 0 (1 corrected before compl.)
- Length of hospital stay: 2.7 (2-5) days
Conclusion

EVAR continues to evolve as the treatment option for AAA

New generation devices will extend the applicability of EVAR