Innovative device design and delivery systems – exploring current and future device capabilities

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Disclosure

Speaker name:

Dittmar Böckler

I have the following potential conflicts of interest to report:

[X] 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
Achilles' Heel of EVAR

- Reinterventions
- Ongoing risk of rupture

- Endoleak
- AAA sac enlargement
- Migration
Hostile Neck Anatomy

Neck angulation ($\alpha$ and $\beta$)

Neck length

Associated thrombus

Tapered configuration

Complex morphology
Reintervention Rates - Neck Anatomy

Reintervention Rates:
Hostile vs. Favorable Neck Anatomy

Stather PW et al. Outcomes in Endovascular Aneurysm Repair in Patients with Hostile Neck Anatomy
*Eur J Vasc Endovasc Surg* 2012; 44: 556-61
Neck Morphology and Gender

- Only 50% of women and 70% of men have suitable neck criteria for potential treatment with EVAR

- Women are 8 times more likely to have an infrarenal neck length < 10 mm and angulation > 45°

> The two main factors driving ineligibility are both infrarenal neck length and angulation
GREAT Registry (n=400 : C3 Excluder)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck Length &lt;1.5cm</td>
<td>32/396</td>
<td>8.1%</td>
</tr>
<tr>
<td>Neck Angulation &gt; 60</td>
<td>47/380</td>
<td>12.4%</td>
</tr>
<tr>
<td>Neck Angulation &gt; 90</td>
<td>7/380</td>
<td>1.8%</td>
</tr>
<tr>
<td>Neck Length &lt;1.5 cm and Neck Angulation &gt;60</td>
<td>11/378</td>
<td>2.9%</td>
</tr>
<tr>
<td>Neck Length &lt;1.5 cm and Neck Angulation &gt;90</td>
<td>3/378</td>
<td>0.8%</td>
</tr>
<tr>
<td>Significant Calcification at Landing Zones</td>
<td>67/398</td>
<td>16.8%</td>
</tr>
<tr>
<td>Significant Thrombus at Landing Zones</td>
<td>44/398</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

17% out of IFU (68 / 400)
How to Achieve Effective EVAR in Challenging Proximal Necks?
Innovative device design: Repositionable C3 Excluder
C3 Excluder Repositioning

- is for level and orientation in challenging neck anatomies
- allows rotation for relocation of contralateral gate and cannulation
- adapts of length of ipsilateral limb
Early outcome of endovascular aneurysm repair in challenging aortic neck morphology based on experience from the GREAT C3 registry

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The New C3 Gore Excluder Stent-graft: Single-center Experience with 100 Patients

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WHAT THIS PAPER ADDS
This is the largest single-center experience with the use of the new C3 Gore Excluder stent-graft. The C3 Gore Excluder has a redesigned deployment mechanism that allows for multiple repositioning, both for level and orientation, prior to final deployment. This study shows that repositioning before final stent-graft deployment is feasible and safe in “real life” conditions. This new capability for multiple repositioning is frequently used in clinical practice and results in precise proximal deployment. Occasionally, however, adverse events can occur when excessive repositioning is attempted.

Objectives: To present results from the first 100 patients treated with the new C3 Gore Excluder stent-graft in a single institution.

Methods: All patients treated with the C3 Excluder stent-graft between August 2010 and July 2013 in our institution were included. Patient demographics, treatment indication, need for intraoperative stent-graft repositioning, immediate technical success, survival, endoleak and migration rate, and need for reintervention during follow-up were analyzed.

Results: A total of 100 patients (86% male, mean age 71.1 ± 5.3 years) were enrolled. Elective abdominal aortic aneurysm (AAA) was the most common indication for treatment (n = 90), followed by common iliac artery aneurysm (n = 3), ruptured AAA (n = 2), type II endoleak (n = 1), and type IV endoleak (n = 1) after prior EVAR, and penetrating aortic ulcer (n = 1). Technical success was achieved in 98 patients. In two patients a small type I endoleak persisted at completion angiography, but had disappeared at the first control computed tomography angiogram. Stent-graft repositioning after initial deployment was required in 49 patients, almost equally distributed for level and contralateral gate reorientation. Exact positioning of the proximal trunk was achieved in 98 patients, with the remaining two cases within 5 mm of the intended location. Adverse events related to repositioning maneuvers were noticed in two cases. Mean follow-up duration was 12.2 ± 9.4 months (range 0–36 months). Eight patients died, none from aneurysm related causes. Cumulative patient survival was 96.2 ± 2.1% at 1 year, and 84 ± 6.1% at 2 years, respectively. No migration, or type I or III endoleak was detected during follow-up. Estimated freedom from reintervention was 96 ± 2.4% at 1 year, and 91 ± 5.2% at 2 years, respectively.

Conclusions: The new C3 Excluder stent-graft provides excellent short-term outcomes and offers important advantages in terms of stent-graft repositioning to achieve high proximal deployment accuracy. Longer follow-up is required to confirm improved long-term outcome compared with the previous generation Excluder stent-graft.

Keywords: Abdominal aortic aneurysm, EVAR, Gore Excluder, Re-Ro-Positioning, Proximal deployment
Real-world Performance of the New C3 Gore Excluder Stent-Graft: 1-year Results from the European C3 Module of the Global Registry for Endovascular Aortic Treatment (GREAT)

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WHAT THIS PAPER ADDS

The C3 Gore Excluder stent-graft has a redesigned deployment mechanism that allows for multiple repositioning, both for level and orientation, prior to final deployment. One of the modules of the GREAT registry was designed to monitor the “real-world” performance of the C3 Gore Excluder. The present report presents the combined experience of 13 European centers with the use of the C3 Gore Excluder on 400 patients. The early results show that repositioning before final stent-graft deployment is feasible, safe, and useful in “real-life” conditions, contributing to precise proximal deployment. Longer follow-up will show whether more precise proximal deployment results in better EVAR durability and reduced need for reintervention.

Objectives: The European C3 module of the Global Registry for Endovascular Aortic Treatment (GREAT) provides “real-world” outcomes for the new C3 Gore Excluder stent-graft, and evaluates the new deployment mechanism. This report presents the 1-year results from 400 patients enrolled in this registry.

Methods: Between August 2010 and December 2012, 400 patients (86.8% male, mean age 73.9 ± 7.8 years) from 13 European sites were enrolled in this registry. Patient demographics, treatment indication, case planning, operative details including repositioning and technical results, and clinical outcome were analyzed.

Results: Technical success was achieved in 396/400 (99%) patients. Two patients needed intraoperative open conversion, one for iliac rupture, the second because the stent-graft was pulled down during a cross-over catheterization in an angulated anatomy. Two patients required an unplanned chimney renal stent to treat partial coverage of the left renal artery because of upward displacement of the stent-graft. Graft repositioning occurred in 192/399 (48.1%) patients, most frequently for level readjustment with regard to the renal arteries, and less commonly for contralateral gate reorientation. Final intended position of the stent-graft below the renal arteries was achieved in 96.2% of patients. Thirty-day mortality was two (0.5%) patients. Early reintervention (≤30 days) was required in two (0.5%) patients. Mean follow-up duration was 15.9 ± 8.8 months (range 0–37 months). Late reintervention (>30 days) was required in 26 (6.5%) patients. Estimated freedom from reintervention at 1 year was 95.2% (95% CI 92.3—97%), and at 2 years 91.5% (95% CI 86.8—94.5%). Estimated patient survival at 1 year was 96% (95% CI 93.3—97.6%) and at 2 years 90.6% (95% CI 85.6—93.9%).

Verhouven E et al EJVES 2014, 58 (August):131-37
Real-world Performance of the New C3 Gore Excluder Stent-Graft: 1-year Results from the European C3 Module of the Global Registry for Endovascular Aortic Treatment (GREAT)


Objective: The C3 Gore Excluder stent-graft has a redesigned deployment mechanism that allows for multiple repositionings. This study assesses the real-world performance of the C3 module in 396 patients included in the GREAT registry.

Methods: The registry included 400 patients with various aortic pathologies treated with the C3 stent-graft. Technical success was achieved in 99% of patients. Proximal deployment was successful in 96% of cases, and no device-related failures were reported. Reintervention rates were low, with 6.5% of patients requiring reintervention within 30 days of treatment.

Results: The 1-year freedom from reintervention was 95.2% (95% CI 92.3–97%). The cumulative patient survival at 1 year was 96% (95% CI 93.3–97.6%). The freedom from reintervention at 2 years was 91.5% (95% CI 86.8–94.5%). No device-related failures were observed during follow-up.

Conclusions: The C3 Gore Excluder stent-graft demonstrates excellent real-world performance, with low reintervention rates and high patient survival. The redesigned deployment mechanism provides flexibility for repositioning, which is beneficial in managing complex aortic anatomy.
Real-world Performance of the New C3 Gore Excluder Stent-Graft: 1-year Results from the European C3 Module of the Global Registry for Endovascular Aortic Treatment (GREAT)

E.L.G. Verhoeven 1,*, A. Katsargyris 2, P. Bachoo 3, T. Larzon 4, R. Fisher 5, D. Ettles 6, J.R. Boyle 7, J. Brunkwall 8, D. Böckler 9, H.-J. Florek 1, A. Stella 1, P. Kasprzak 1, H. Verhagen 2, V. Rambau 2, on behalf of the GREAT European C3 Module Investigators

Number of patients reporting trunk repositioning

<table>
<thead>
<tr>
<th>Reasons for repositioning</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning closer to renal arteries</td>
<td>67%</td>
</tr>
<tr>
<td>Contralateral gate positioning</td>
<td>19%</td>
</tr>
<tr>
<td>Other</td>
<td>14%</td>
</tr>
</tbody>
</table>

Mean (SD) repositions per case

1.5 (0.7)

Number of repositions per case

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>123 (64%)</td>
</tr>
<tr>
<td>2</td>
<td>54 (28.1%)</td>
</tr>
<tr>
<td>3</td>
<td>12 (6.3%)</td>
</tr>
<tr>
<td>4</td>
<td>3 (1.6%)</td>
</tr>
</tbody>
</table>

Catheterization in an angulated anatomy. Two patients required an unplanned chimney renal stent to treat partial coverage of the left renal artery because of upward displacement of the stent-graft. Graft repositioning occurred in 192/399 (48.1%) patients, most frequently for level readjustment with regard to the renal arteries, and less commonly for contralateral gate reorientation. Final intended position of the stent-graft below the renal arteries was achieved in 96.2% of patients. Thirty-day mortality was two (0.5%) patients. Early reintervention (≤30 days) was required in two (0.5%) patients. Mean follow-up duration was 15.9 ± 8.8 months (range 0–37 months). Late reintervention (>30 days) was required in 26 (6.5%) patients. Estimated freedom from reintervention at 1 year was 95.2% (95% CI 92.3–97%), and at 2 years 91.5% (95% CI 86.8–94.5%). Estimated patient survival at 1 year was 96% (95% CI 93.3–97.6%) and at 2 years 90.6% (95% CI 85.6–93.9%).
Current device capabilities:
Implantation Strategy for Challenging Necks

- Choose ipsilateral side for...
  - “C” shape not “S”
- Orientate the Excluder ...
  - flexible plane accommodates the angulation
- Beware of
  - tortuous iliacs which may disrupt rotational control
  - x-leg configuration
  - avoid helicoptering!
Threatened renal vessel

- Moderate coronal/saggital angulation
- Correct for LRA
- Position of deployment threatened RRA

Effective repositioning

“Hypotenuse Effect”
Effect of Neck Angle on Sealing Zone

In highly angulated aortic necks, centerline is not a good indicator of the actual sealing zone.
Future device capabilities:

C3 Conformable Excluder (CECX)

Repositionable AND Modifiable!
Future device capabilities:

C3 Conformable Excluder (CECX)
Summary

- Proximal neck anatomy continues to be the major determinant for suitability of patients for EVAR

- Current device capabilities e.g. repositioning provide accurate placement and allows initial aggressive deployment

- Literature shows promising results for C3 Excluder as an example of a innovative new generation device design

- Future device capabilities e.g. new conformable Excluder (CECX) with modifiable body has potential to widen IFU and improves results

- Clinical data and time line is not yet available
Innovative device design and delivery systems – exploring current and future device capabilities

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