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

A. Katsargyris a, B. Botos a, K. Oikonomou a, M. Pedraza de Leistl b, W. Ritter b, E.L.G. Verhoeven a,*

a Department of Vascular and Endovascular Surgery, Klinikum Nürnberg Süd, Nürnberg, Germany
b Department of Radiology, Klinikum Nürnberg Süd, Nürnberg, Germany

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 ± 9.3 years) were enrolled. Elective abdominal aortic aneurysm (AAA) was the most common indication for treatment (n = 90), followed by common iliac artery aneurysm (n = 5), ruptured AAA (n = 2), type la 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.

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INTRODUCTION

Endovascular aortic aneurysm repair (EVAR) is now widely regarded as the procedure of choice for patients with suitable infrarenal abdominal aortic aneurysm (AAA).1,2 Achieving good proximal sealing represents one of the fundamental prerequisites for both early- and long-term success of EVAR. Accurate proximal stent-graft deployment is therefore of importance, especially in marginally suitable neck anatomies (short neck length, angulated proximal neck).

Since the introduction of EVAR, two decades ago, stent-graft manufacturers have been trying to enhance proximal sealing aiming to increase anatomic eligibility, and to improve early and long-term outcomes of EVAR.3,4 Gore (W.L. Gore & Associates, Flagstaff, AZ, USA) introduced the new C3 Excluder stent-graft to address the issue of proximal deployment accuracy. The new C3 Excluder stent-graft offers a redesigned deployment mechanism that allows for
multiple repositioning, both for level and orientation, prior to final deployment of the stent-graft.

The early use of the new C3 Excluder deployment system in the first 25 patients from GREAT (Global Registry for Endovascular Aortic Treatment) has already been published, and 1-year results of 400 patients included in GREAT are awaited. In this report, we present our single-center experience with the use of the C3 Excluder in 100 patients.

MATERIALS AND METHODS

Patient cohort

In our institution, patients with AAA that are anatomically suitable for EVAR are always considered for endovascular repair. Patients are informed about potential longevity issues of EVAR and the need for life-long surveillance and are also informed about open surgery as an alternative treatment before reaching a final decision. Open surgery is recommended only for minimal risk young patients, or for patients that are not willing to comply with a strict postoperative surveillance protocol. All patients treated with a standard infrarenal stent-graft are enrolled in a prospectively collected database. Data of all patients that were treated with the C3 Excluder stent-graft between August 2010 and July 2013 were analyzed for this study. Patients treated both inside and outside the instructions for use (IFU) were included. Patients were considered to be outside IFU if:

1. the proximal neck length was less than 1.5 cm. This was defined as the distance between the lowest renal artery and the origin of the aneurysmal dilation of the aorta; and/or
2. the infrarenal neck angle was greater than 60 degrees. Neck angle was defined as the angle between the aortic centerline above the lowest renal artery and the centerline between the lowest renal artery and the aortic bifurcation.

The indication for treatment was an AAA of at least 5 cm in diameter (or a smaller AAA in conjunction with a common iliac artery aneurysm of at least 3 cm in diameter). Patients with acute or ruptured AAA or with complications after previous EVAR or open surgery were also included.

All included patients provided written informed consent for their participation in the study. The study was approved by our institution’s ethical committee. The first 74 patients were enrolled in GREAT (Global Registry for Endovascular Aortic Treatment).

Stent-graft design

The C3 Gore Excluder (W.L. Gore & Associates, Flagstaff, AZ, USA) is a third-generation stent-graft featuring an original design with a flexible, catheter-mounted introduction, and active infrarenal attachment with barbs. The deployment mechanism has been modified into a three-step sequence, which enables repositioning of the stent-graft up to three times prior to final release from the delivery catheter. In the first step, the body and contralateral limb are opened. A constraining loop around the body of the stent-graft enables recapturing and repositioning of the proximal trunk both for level and orientation. In the second step the constraining wire is removed after confirmation of correct position. The ipsilateral limb is deployed in a third separate step.

Procedure

All patients had a preoperative stent-graft plan featuring the lengths and diameters of the chosen stent-grafts according to their aortic and iliac dimensions. All procedures were performed in a hybrid operating room with fixed imaging system (Siemens Artis Zeego, Siemens, Erlangen, Germany). General anesthesia and bilateral small femoral cut down access were routinely used. The need for and details of level and/or orientation repositioning were documented for every procedure. Adjunctive procedures (e.g., renal chimney) were also documented. Completion angiography was routinely performed to document the final position of the stent-graft and potential endoleaks. Technical success was defined as successful deployment of the stent-graft with no type I/II endoleak, unintentional coverage of visceral aortic branches or hypogastric arteries at the end of the procedure, and with successful removal of the delivery system. Primary conversion was considered a technical failure.

Follow-up

Patients were systematically followed according to our institution’s protocol. All treated patients are discharged with an accompanying letter for their general practitioner stating in detail the appropriate follow-up scheme [exact date and method (CT, U/S) of follow-up]. Over 90—95% of the patients return to our center for clinical and imaging follow-up (inside the hospital or via our out-patient clinic). For patients outside our region (mostly fenestrated and branched and not that many standard EVARs) we obtain the CT images and the relevant follow-up letter and update our database. In case of open issues, we do phone the general practitioner, the referring vascular surgeon, or the patient/patient family.

Patients that had signs of endoleak at completion angiography were followed with computed tomography angiography (CTA) until the endoleak was treated or regressed spontaneously. EVAR patients without endoleak were followed with yearly ultrasound and abdominal X-ray. CTA was reserved for patients in whom ultrasound showed endoleak and/or aneurysm sac enlargement or when stent-graft migration or dislodgement was seen on abdominal X-ray.

Detected endoleaks, stent-graft migration and reintervention needed during follow-up were recorded. Time and cause of death were also documented.

Statistical analysis

SPSS for Windows (version 17.0; SPSS Inc, Chicago, IL, USA) was used for statistical analysis. Variables are presented as mean ± standard deviation (SD) in case of normal distribution, and median plus range if data had a skewed
distribution. Statistical significance was taken at \( p < .05 \). Analyzed outcomes included technical success, number and type of stent-graft repositioning, operative mortality and morbidity, and late procedure-related events with regard to endoleak, stent-graft migration, and reinterventions. Survival and reintervention during follow-up were subjected to Kaplan–Meier analysis.

**RESULTS**

**Baseline data**

Between August 2010 and July 2013, 100 patients (86% male, mean age 71.1 ± 9.3 years) were treated with the new C3 Gore Excluder stent-graft. Patient demographics and risk factors are summarized in Table 1.

Elective AAA was the most common indication for treatment (\( n = 90 \)), followed by common iliac artery aneurysm (\( n = 5 \)), ruptured AAA (\( n = 2 \)), type la endoleak (\( n = 1 \)) and type IV endoleak (\( n = 1 \)) after prior EVAR, and penetrating aortic ulcer (\( n = 1 \)).

In 95 out of 100 patients, C3 implantation was performed as a primary procedure, while the remaining cases were reintervention after prior endovascular (3/100) or open (2/100) aortic procedures.

The mean maximum AAA diameter was 58.4 ± 8.6 mm (range 48–95 mm). Proximal aortic neck had a mean length of 27.4 ± 12 mm (range 10–60 mm) and a mean angulation of 15.8 ± 25° (range 0–90°). A total of 17 of 100 patients were treated outside the IFU for the C3 Excluder stent-graft (Table 2).

**Procedure data**

The procedure was performed under general anesthesia and via femoral surgical cut-down in all cases. One patient with a short necked (10 mm) AAA and severely angulated proximal neck underwent an additional planned right renal artery chimney stenting via left axillary artery introduction (Fig. 1). Median procedure duration was 84 minutes (range 48–335 minutes). Median estimated blood loss (EBL) was 160 mL (range 90–1600 mL). Median fluoroscopy time was 12.4 minutes (range 6–150 minutes) and mean iodinated contrast volume used 104.7 ± 23 mL. The one patient with a very long procedure time and fluoroscopy time (335 and 150 minutes, respectively) had a type IV endoleak after prior EVAR with a Powerlink stent-graft (Endologix, Irvine, CA, USA). This aneurysm was planned for a complete relining with a C3 Excluder stent-graft. Serious difficulties were encountered during wire access, with the guidewire being repeatedly trapped between the struts of the previously implanted Powerlink stent-graft.

**Intraoperative stent-graft repositioning and need for proximal cuff extender**

Sixty-nine proximal trunk repositionings were performed in 49 patients. One repositioning was required in 32 patients, two in 14 patients, and three in three patients. The exact planned position of the proximal trunk was achieved in 98 patients, with the remaining two within 5 mm of the intended location. Adjunctive proximal cuff extender implantation was not required in any of the patients. Readjustment of the length of the ipsilateral limb after complete opening of the proximal trunk in order to preserve the hypogastric artery was performed in three patients. Table 3 summarizes the repositioning data. Repositioning of the proximal trunk and the ipsilateral limb was always possible. The back-up mechanism to open the stent-graft in case of failure of the deployment system was never used. Adverse events related to repositioning maneuvers were noticed in two patients. In one patient, repetitive rotational reorientation of the contralateral gate caused a twist in the ipsilateral limb. This was diagnosed at the 1-month postoperative CTA. Although the patient had good femoral pulses, it was decided to treat him prophylactically. Additional stenting (self-expanding stent 10 × 40 mm, Absolute Pro Vascular, Abbott Vascular, Hessen, Germany) was performed after complete wound healing 2 months postoperatively (Fig. 2). In a second patient, excessive upward readjustment of the ipsilateral limb to preserve the hypogastric artery resulted in upward migration of the proximal trunk, partially covering the left renal artery. This was diagnosed at completion angiography and immediately treated with a chimney stent to secure the left renal artery (Fig. 3).

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**Table 2. Patients treated outside instructions for use.**

<table>
<thead>
<tr>
<th>Indication(s) outside IFU</th>
<th>Patient N (%)</th>
</tr>
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<tbody>
<tr>
<td>Neck length &lt;1.5 cm</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>Neck angulation &gt;60</td>
<td>2 (8%)</td>
</tr>
</tbody>
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Perioperative outcome

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 CTA. Intraoperative and 30-day mortality was zero. Postoperative complications occurred in five patients. One patient developed a capsular hematoma of the right kidney, caused by wire manipulation (accidental catheterization of the right renal artery). This hematoma was treated conservatively with success. One patient suffered an acute myocardial infarction requiring coronary angiography. One patient developed temporary acute renal failure due to a contrast reaction. Finally, two patients developed a groin hematoma treated conservatively in both cases.

Admission to the ICU was required in eight patients, in two of them for longer than 24 hours. Reasons for ICU admission were severe chronic obstructive pulmonary disease in two patients, capsular hematoma of the kidney, renal function surveillance due to high preoperative creatinine values, prolonged procedure duration preventing immediate postoperative extubation, preoperative cardiovascular collapse, postoperative hypotension with ST depression in the electrocardiogram, and difficult intubation due to rheumatoid arthritis causing edema of the vocal cords.

Table 3. Summary of proximal trunk repositioning data.

<table>
<thead>
<tr>
<th>Number of patients required trunk repositioning</th>
<th>49 (49%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Episodes of trunk repositioning</td>
<td>69</td>
</tr>
<tr>
<td>Episodes of ipsilateral limb length readjustment</td>
<td>3</td>
</tr>
<tr>
<td>Reasons for proximal trunk repositioning</td>
<td></td>
</tr>
<tr>
<td>Positioning closer to renal arteries</td>
<td>23/69 (33%)</td>
</tr>
<tr>
<td>Positioning lower to uncover the renal arteries</td>
<td>12/69 (17.4%)</td>
</tr>
<tr>
<td>Contralateral gate positioning</td>
<td>34/69 (49.3%)</td>
</tr>
<tr>
<td>Number of repositions per case</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.7 (0.8)</td>
</tr>
<tr>
<td>Range</td>
<td>(0.0–3.0)</td>
</tr>
</tbody>
</table>

Mean hospital stay including preoperative admission day(s) was 5.9 ± 1.7 days. All patients left hospital in good condition. No secondary intervention was required within 30 days of the procedure.

Follow-up

Mean follow-up duration was 12.2 ± 9.4 months (range 0–36 months). Two patients were lost from follow-up, both after 1 year. One was referred to us from another country, and one suffered a stroke and refused further clinical examination and imaging. Eight patients died during follow-up, none from aneurysm-related causes. Two patients died of acute myocardial infarction, two of pulmonary infection, one of sepsis, one of amyotrophic lateral sclerosis, one due to traumatic brain injury, and one due to complications following hip fracture. Cumulative patient survival estimated by Kaplan—Meier was 96.2 ± 2.1% at 1 year, and 84 ± 6.1% at 2 years (Fig. 4A). During follow-up, no migration or type I or III endoleak was detected and no patient required conversion to open repair. A total of eight type II endoleaks were observed during follow-up. Two of them were treated with lumbar artery embolization, while the remaining six were followed, as there was no AAA sac enlargement. Reintervention during follow-up was required in four patients, including the two previously mentioned lumbar artery embolizations and the preventive stenting of the ipsilateral limb twist. The last reintervention was the chimney stent for the left renal artery: this one occluded at 5 months and was immediately restented with success. Estimated freedom from reintervention was 96 ± 2.4% at 1 year, and 91 ± 5.2% at 2 years, respectively (Fig. 4B).

DISCUSSION

Accurate proximal stent-graft deployment is essential in both standard and challenging proximal necks, in order to achieve initial, but also long-term success of EVAR. To address this issue, Gore recently revised the Excluder stent-graft, introducing the new C3 Excluder, featuring a deployment mechanism that allows multiple reconstraining and repositioning of the stent-graft before final deployment. The new C3 deployment mechanism enables multiple readjustments of the Excluder stent-graft for (a) proximal level, (b) orientation,

and (c) distal level of the ipsilateral limb. The ability to reposition the stent-graft for proximal level enables accurate deployment with regard to the renal arteries. This is an advantage both for inexperienced clinicians (second and third chance for deployment at the right level), and for experienced clinicians (in case of challenging neck anatomy). The option for rotational readjustment can be useful in cases of difficult contralateral gate cannulation, where the proximal trunk can be reconstrained and the gate reoriented to a more convenient location for catheterization. Finally, the separate deployment of the ipsilateral limb allows for limb length adaptation. The ipsilateral limb can be readjusted for level by meticulously pushing the delivery catheter upwards during slow controlled deployment. This can correct inadvertent overstenting of the hypogastric artery.

The present experience on 100 patients shows that the new deployment system enables easy and safe repositioning of the proximal trunk. Repositioning was always possible when attempted. The exact influence of repositioning on outcomes is difficult to assess. Proximal deployment accuracy although subjectively assessed by the operator was high (98% deployment at the exact desired position). A more objective indication of proximal deployment improvement is the zero use of proximal cuffs (but biased in a positive way, as indication for standard EVAR are strict, and fenestrated EVAR is employed with low threshold). Compared with older EVAR series, where proximal cuffs were used in up to 19% of cases, this represents a clear improvement in proximal deployment accuracy.

Although no failures to reposition the stent-graft were encountered in this patient cohort, risks associated with excessive repositioning maneuvers can occasionally arise. Reconstraining the stent-graft and upward level repositioning may be difficult in narrow and/or angulated neck anatomy, although no adverse events were noticed in this cohort. Excessive rotational reorientation may cause twist of the ipsilateral limb. Moreover, proximal position can be lost during rotational reorientation requiring new repositioning for level. Finally, excessive upward readjustment of the ipsilateral limb, aiming to avoid hypogastric artery overstenting, may result in upward migration of the proximal trunk.

Based on current clinical experience, relevant advice was developed to eliminate these repositioning associated risks. In narrow and/or angulated neck anatomy, where upwards repositioning of the stent-graft can be difficult, the stent-graft should be deployed at the level of the renal arteries or higher, with lower repositioning if needed. Positioning the stent-graft deliberately above the renal arteries is also useful in relining procedures after previous EVAR with limited working length due to the high neo-bifurcation. Once catheterization of the contralateral limb has been achieved the stent-graft can be pulled down below the renal arteries. Ipsilateral limb twist due to extensive rotational reorientation can be identified and corrected during slow deployment under fluoroscopy. Finally, attention should be paid to confirm that the proximal edge of the stent-graft remains in position during pushing-up of the ipsilateral limb to adjust its length. It is however fair to say that in the one case this misfortune happened, the limb was pushed upwards far too high.

With the new C3 Excluder stent-graft a new (optional) deployment sequence was developed. Briefly, after proximal trunk deployment, contralateral gate cannulation is attempted, if required, with reorientation of the stent-graft. Upon successful catheterization, the proximal position is controlled by angiography and the stent-graft repositioned for level if needed. Thereafter the proximal trunk is completely opened and the ipsilateral limb deployed. This approach was initially used, aiming for quicker catheterization of the contralateral gate and reduced fluoroscopy duration. With more experience, however, we have become more conservative again and allow for some time for catheterization, in order to avoid repetitive reorientation and possible torsion of the ipsilateral limb. An overall repositioning rate of 49% is therefore a bit excessive.

Figure 2. (A) Twisting causing stenosis of the ipsilateral limb (arrow) after repeated reorientation maneuvers to facilitate contralateral gate cannulation. (B) Successful treatment with a bare stent.

Seventeen percent of the patients of this series were treated outside C3 Excluder’s IFU. Delivery and deployment of the stent-graft did not seem to be influenced by these wider inclusion criteria. The stent-graft was successfully deployed at the exact planned position in 16 out of 17 (94%) cases outside the IFU. No significant difference in the need for repositioning was noticed between cases outside IFU and those within IFU (49.4% vs. 50.6%). Despite these early encouraging results, longer follow-up is required to prove durability of treatment outside IFU.

The perioperative and short-term outcomes of this study, including zero 30-day mortality and reintervention, and low
reintervention during 1-year follow-up, compare well with the landmark EVAR-1 and DREAM trials. This observation might imply that outcomes of EVAR as reported in older studies may not accurately reflect the current status of the technique, if applied with care and in the right patients. Short-term outcomes of EVAR have certainly improved over the years due to better device technology and accumulated clinical experience.

CONCLUSIONS

The use of the new C3 Excluder stent-graft in 100 patients in our institution showed excellent short-term outcomes. The new opportunity for multiple repositioning before definitive stent-graft opening is frequently useful in clinical practice and results in precise proximal deployment. Longer follow-up is needed to confirm improved durability and reduced need for late reintervention.

CONFLICT OF INTEREST

Eric L. G. Verhoeven has received educational grants and is a consultant for Cook Inc., W.L. Gore & Associates, Siemens and Atrium-Maquet.

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REFERENCES


