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Case Report

Current Clinical Knowledge on GORE EXCLUDER Conformable Abdominal Aortic Aneurysm Repair Endoprosthesis: A Case Series and Literature Review

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The GORE EXCLUDER Conformable abdominal aortic aneurysm (AAA) Endoprosthesis (CEXC), is currently the newest stent-graft system for treating patients with AAA. CEXC is approved for patients with proximal aortic neck angles ≤90° with a ≥15 mm aortic neck length or proximal aortic neck angles ≤60° with ≥10 mm aortic neck length. The present study describes a clinical series of 5 males with AAA, one of whom had a ruptured infrarenal AAA and a 90° proximal aortic neck angle. All patients were treated with 100% technical success using the CEXC device. Dosimetric data were recorded regarding the total kerma-area product and total fluoroscopy time. During the 30-day follow-up, no device migration or failure was detected, whereas type Ib and II endoleaks were observed in two patients. The type Ib endoleak required re-intervention with limb extension placement, and the type II endoleak was treated with lumbar artery embolization. This clinical series showed that CEXC has no technical defects or AAA-related mortality. We also reviewed the current knowledge on CEXC's clinical outcomes, showing promising technical and clinical results in some studies, even outside the instructions for use. CEXC expands the vascular surgeons' armamentarium against hostile neck anatomy, as it is the only repositionable endovascular aneurysm repair device available. Multicenter, long-term outcome studies should confirm the promising preliminary results of our case series and the literature review.

Key Words: Abdominal aortic aneurysm, Endovascular aortic repair, Ruptured aortic aneurysm, Fluoroscopy, Endoleak

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INTRODUCTION

Aortic neck anatomy is a major determinant of patient suitability for endovascular aneurysm repair (EVAR). Hostile neck anatomy (HNA) is a major determinant of proximal seal failure. An aortic neck is defined as hostile if it meets any one of the following criteria: (1) dilatation greater than or equal to 2 mm within 1 cm below the renals (reverse

taper); (2) angulation ≥60° within 3 cm below the renal arteries; (3) length ≤10 mm; (4) thrombus ≥50% of the circumference; and (5) focal bulge ≥3 mm within the first 1.5 cm below the most caudal renal artery [1]. There are also reports defining proximal necks with lengths of ≤15 mm as HNA because most commercially available endografts require a neck length of at least 15 mm [2,3]. For years, neck hostility toward endograft hosting has highlighted the need for newer devices to counter its features. GORE EXCLUDER Conformable abdominal aortic aneurysm (AAA) Endoprosthesis (CEXC) (W. L. Gore and Associates) is a recent stent-graft, authorized by the U.S. Food and Drug Administration and receiving clearance in December 2020. According to its instructions for use (IFU) [4], AAA patients with an infrarenal neck diameter between 16 mm and 32 mm, a minimum neck length of 15 mm, and a proximal neck angulation of up to 90° are suitable. For less severe angulations (up to 60°), the minimum required neck length is 10 mm. Additionally, iliac artery sizes between 8 mm and 25 mm and an iliac distal vascular seal zone length of at least 10 mm are required. This study aims to provide information about the technical efficacy and early operative outcomes of the CEXC during a case series of 1 urgent ruptured AAA (rAAA) and 4 elective AAA patients treated in our center while reviewing the literature of studies concerning the clinical outcomes of CEXC to date.

The CEXC device was deployed in 5 Caucasian male patients at the Department of Vascular Surgery at the University Hospital of Patras (IRB no. 29/11-07-2018) between November 2021 and January 2022. Approval was obtained from the ethics committee, and patient consent was obtained.

CASES

All patients had infrarenal aneurysms, including an urgent patient with an rAAA. Patient characteristics, risk factors, and comorbidities are shown in Table 1. The aneurysm morphological characteristics, several intra-operative details, and dosimetric data are shown in Table 2. None of the patients had a conical aortic neck or significant aortic neck thrombus or calcification >2 mm and/or >25% of the circumference. Preoperative computed tomography angiography (CTA) was performed in all patients to assess the aortoiliac axis characteristics.

Dosimetric data were recorded for total kerma-area product (KAP) and total fluoroscopy time (FT). Total KAP (mean, 6.49 mGym^2; range, 1.36-20.10 mGym^2) refers to the sum of KAP values during the low-dose fluoroscopy (LDF) and the high-dose fluoroscopy (HDF) modes. Similarly, the total FT (mean, 24.9 min; range, 10.4-59.0 min) corresponds to the sum of FT values during the LDF and HDF modes. HDF, either pulsed (12.5 frames per second) or continuous (30 frames per second), was mainly used during contralateral gate cannulation and included electronic magnification (23 or 17 cm in the plane of the image intensifier) and digital subtraction angiography. In addition, relevant literature was reviewed using MEDLINE, SCOPUS, and ClinicalTrials.gov and Euclinicaltrials.eu databases.

The first patient of our series had a history of an AAA not indicated for repair 10 years before his operation. Owing to an increase in the aneurysmal sac, as shown in his

Table 1. Age, ethnicity, sex, risk factors, and comorbidities of five male who underwent EVAR with CEXC

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Age (yr)	80	76	82	73	71
Ethnicity	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian
Sex	Male	Male	Male	Male	Male
Smoker	Former	Yes	Former	Former	Former
Alcohol	No	No	Socially	Socially	No
Previous procedures	Adenoidectomy	Bladder papilloma excision	Inguinal hernia repair, cholecystectomy	Quadruple bypass, inguinal hernia repair	Intestinal perforation repair, incisional hernia repair
Hypertension	Yes	Yes	Yes	Yes	Yes
Dyslipidemia	Yes	No	No	Yes	No
Diabetes mellitus	No	No	No	No	No
Coronary artery disease	Yes	No	No	No	No
Chronic kidney disease	No	No	No	No	No
Cerebrovascular disease	No	No	No	No	No
Pulmonary disease	No	No	No	Yes	No

EVAR, endovascular aneurysm repair; CEXC, GORE EXCLUDER Conformable abdominal aortic aneurysm Endoprosthesis (W. L. Gore and Associates).

Table 2. Aneurysm characteristics, operative and dosimetric data of five male who underwent EVAR with the CEXC

		Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Disease status		Asymptomatic	Asymptomatic	Asymptomatic	Ruptured	Symptomatic
Classification		Infrarenal	Infrarenal	Infrarenal	Infrarenal	Infrarenal
Aneurysmal sac diameter[a] (mm)		52.0	54.0	50.2	131.0	58.5
Proximal aortic neck length (mm)		13.0	18.0	20.0	25.0	13.2
Proximal aortic neck diameter (mm)		22.0	27.0	22.5	21.0	25.0
Proximal aortic neck angulation (°)		40.0	12.0	63.0	90.0	33.7
Conical neck		No	No	No	No	No
Neck thrombus or calcification		<2 mm/<25% of circumference	<2 mm/<25% of circumference	<2 mm/<25% of circumference	<2 mm/<25% of circumference	<2 mm/<25% of circumference
Anesthesia type		General	General	General	General	General
Contrast agent volume (mL)		125	150	150	180	200
Procedure duration (min)		115	120	125	180	105
Blood transfusion (unit)		-	-	-	4	-
Postoperative hospitalization (d)		1	1	2	11	1
Kerma-area product[b] ($mGym^2$)	LDF	2.40	0.98	3.33	NA	3.72
	HDF	0.30	0.38	0.46	NA	0.78
	Total	2.70	1.36	3.79	20.10	4.50
Fluoroscopy time (sec)	LDF	786	547	1,253	NA	1,090
	HDF	38	80	66	NA	84
	Total	824	627	1,319	3,540	1,174

EVAR, endovascular aneurysm repair; CEXC, GORE EXCLUDER Conformable abdominal aortic aneurysm Endoprosthesis (W. L. Gore and Associates); LDF, low-dose fluoroscopy; HDF, high-dose fluoroscopy; NA, not available.
[a]Inner wall-to-inner wall. [b]Mobile C-arm fluoroscopy equipment with a maximum field-of-view of 31 cm at the plane of the image intensifier (Philips BV Pulsera; Philips Medical Systems).

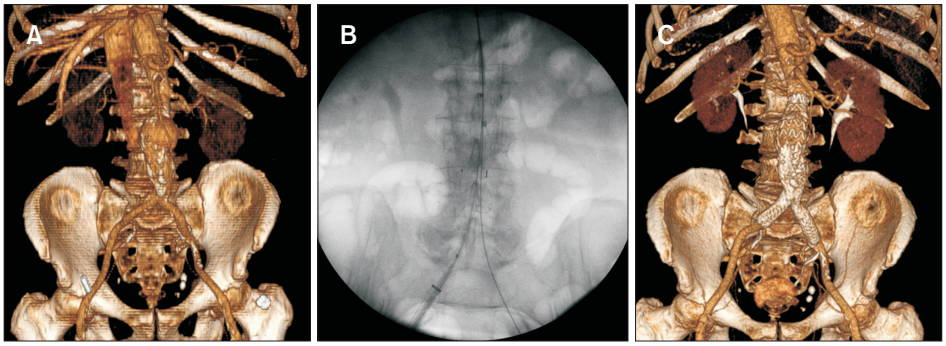

Fig. 1. Case image series from patient 1 presenting the high conformability of GORE EXCLUDER Conformable abdominal aortic aneurysm Endoprosthesis (W. L. Gore and Associates). (A) Preoperative three-dimensional computed tomography angiography reconstruction. (B) Perioperative imaging. (C) Postoperative 30-day follow-up with no evidence of complications.

most recent ultrasound, CTA confirmed the indication for EVAR (Fig. 1A). A CECX device was successfully deployed using the C3 delivery system, as confirmed using intraoperative fluoroscopy (Fig. 1B), with no technical or clinical complications. The patient was discharged on the first postoperative day and followed up. At the 30-day follow-up, CTA revealed no complications (Fig. 1C).

The second patient in our series was diagnosed with a 40 mm AAA six years prior, during an examination for a known urinary bladder papilloma. The AAA was followed-up and demonstrated an aneurysmal sac expansion measuring 54 mm on CTA, thus requiring intervention. Optional repositioning of the C3 delivery system was not required. No technical or clinical issues were encountered in this case. No complications were detected postoperatively or during the 30-day follow-up period using CTA.

The third patient had a 50 mm AAA with a neck angle of 63° and a neck length of 20 mm. Despite the high angulation of the aortic neck (>60°), the device was successfully deployed; postprocedure aortography revealed the lack of any type of endoleak and confirmed its successful placement. The C3 delivery system's angulation control feature aided in appropriate graft placement without clinical or technical issues. No complications occurred during the patient's two-day in-hospital stay, and no migration was detected on the 30-day postoperative follow-up.

The fourth patient was transferred from another hospital to our emergency department with suspected rAAA. The patient was hemodynamically stable with reported vital signs of blood pressure 163/81 mmHg, pulses 82/min, respiratory rate 17/min, and temperature 37.3°C. Preoperatively, the rAAA was confirmed using CTA, which revealed an engulfed retroperitoneal hematoma. The patient was transferred to the operating theatre on the afternoon of the same day, 15 hours later. Regardless of the risk factors and ruptured state of the AAA, device apposition and positioning were appropriately performed without technical issues (Fig. 2). The patient underwent standard EVAR because of the engulfed state of the rupture and was hemodynamically stable. Aortic occlusion balloon was not required. Upon completion of the operation, no endoleaks, migration, or abdominal compartment syndrome were observed. During his 11-day postoperative management, the patient developed acute kidney injury, possibly due to a hematoma pressing the left ureter, and gouty arthritis, both of which were treated successfully. At the 30-day follow-up, the patient was free of additional complications. At the 3-month follow-up, a type II endoleak was detected with no sac enlargement and was treated with lumbar artery embolization. The patient also underwent a one-year follow-up at our center by computed tomography without intravenous contrast due to renal impairment, where no sac enlargement was reported.

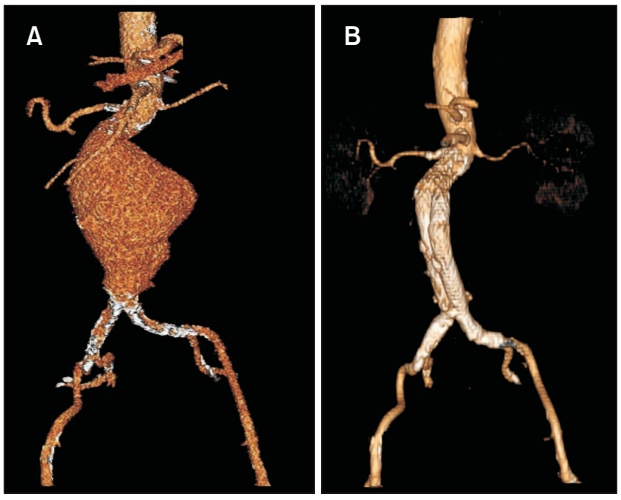

Fig. 2. Case image series from patient 4 (endovascular repair of ruptured abdominal aortic aneurysm [AAA]). (A) Preoperative three-dimensional computed tomography angiography (CTA) reconstruction showcased the severe angulation (90°) of the proximal aortic neck. (B) GORE EXCLUDER Conformable AAA Endoprosthesis (W. L. Gore and Associates)'s high conformability in the postoperative 4-month follow-up CTA.

The fifth patient in our series was a smoker with a medical history of hypertension on triple therapy (calcium channel blockers, anti-angiotensin II, and diuretics) for 20 years. Five years earlier, the patient underwent ultrasound for a postoperative incisional hernia, which revealed a 35 mm diameter AAA. Since then, he has been on routine ultrasound follow-ups, with the latter showing an increase in the aneurysm diameter. Subsequently, the patient underwent CTA to confirm the increase in AAA and make a decision for repair. Despite the short aortic neck (<15 mm), the device was deployed as intended without requiring C3 repositioning. Intra-operative angiography confirmed the appropriate positioning. Technical and clinical success was achieved. The

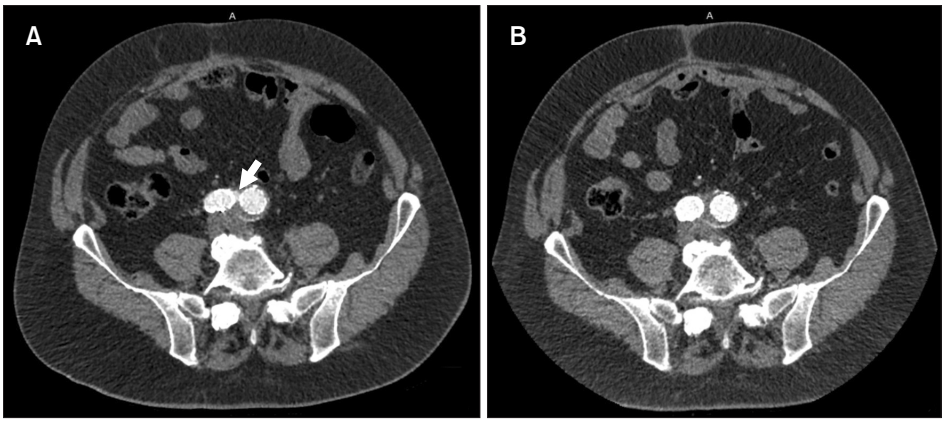

Fig. 3. Case image series from patient 5. (A) Type Ib endoleak during the 30-day follow-up that required reintervention (arrow). (B) No sign of endoleak at the 3-month follow-up.

patient was discharged on the following day. At the 30-day follow-up using CTA, the patient was diagnosed with a type Ib endoleak of the right iliac artery with no significant sac enlargement (<5 mm; Fig. 3A), which required reintervention. An Excluder limb endoprosthesis was implanted in the right common iliac artery with technical and clinical success. During the 3-month follow-up, no endoleaks were reported on CTA (Fig. 3B).

DISCUSSION

In our study, although four of the five patients fell outside the standard IFU, the technical success rate was 100% without type I or III endoleaks intraoperatively, while in-hospital mortality was 0%. One (patient 4) underwent endovascular repair of rAAA. This patient had a right-angled (90°) proximal aortic neck that was successfully addressed because of the high applicability of the device. During the first follow-up, there were two cases of endoleaks: type Ib (patient 5) and type II (patient 4). Type Ib endoleak required reintervention; type II endoleak in rAAA did not exhibit sac enlargement, but it was treated with lumbar artery embolization 3 months after initial EVAR.

This study determined the perioperative radiation dose in terms of total KAP and total FT in 5 cases of CEXC (Table 2). Dosimetric records must be kept and reported because high absorbed doses are related to increased radiation-induced cancer risk or deterministic effects such as skin erythema and fertility impairment. Detailed information on the detrimental effects of ionizing radiation during EVAR has been reported previously [5]. A pilot study of 32 patients treated with the predecessor of CEXC, the C3 Excluder repositionable device, was recently conducted. The median total KAP and total FT values recorded were equal to 2.42 mGym^2 and 12.6 minutes, respectively [6]. The total KAP (median, 3.79 mGym^2) and total FT (median, 19.6 minutes) values in the current study were remarkably higher (56.6% for KAP and 55.5% for FT) than those of the pilot study. Although a direct comparison would not be appropriate, these differences were mainly due to the inclusion of rAAA patients in the current study due to the difficulty in contralateral limb cannulation (Table 2).

In 2019, Rhee et al. [7] reported the first CEXC case series to note the advantages of the new-generation endograft regarding deployability and applicability while utilizing the device's optional features.

In a recent study comparing patient eligibility rates for EVAR [8], CEXC had the best morphological applicability (65%), which is particularly important considering that its predecessor had an eligibility rate of only 45%. CEXC also has the feature of being compatible with deployment with the C3 system. This allows the proximal end of the endoprosthesis to be reconstrained after implantation, enabling the device to be rotated or relocated cranially or caudally as needed. Repositioning the endograft may allow easy contralateral gate cannulation and placement closer to the lowest renal artery, thereby minimizing the likelihood of insufficient sealing and associated problems such as endoleaks and graft migration. A recent study at our center showed that it has important safety characteristics related to accurate placement of the renal arteries and equivalent long-term effectiveness [9]. In addition, the new endograft introduces a promising Active Control system (W. L. Gore and Associates) that provides optional angulation control during the deployment procedure for patients with severe AAA neck angulation [10]. Finotello et al. [11] reported an initial clinical experience at their center, which showed an absence of type I endoleaks through a 30-day follow-up, confirming the safety and effectiveness of the CEXC device against challenging aortic necks. The high conformability of the device was confirmed even in the presence of angulated necks owing to the absence of significant changes between the preoperative and postoperative aortic curvature analysis.

A recent study by the Scottish Vascular Center reported technical and clinical results using CEXC's active control system against HNA [12]. This study included a cohort of 24 patients who were followed-up for up to 12 months using CTA. The technical success rate was 100%, and no morbidity or serious adverse effects were reported. At the 3-month follow-up, 7 patients (29.2%) experienced type II endoleaks without reintervention. One patient (4.2%) had a type Ib endoleak requiring graft limb extension, one had a right common femoral artery dissection requiring open surgery, and one needed right iliac limb extension because of the risk of developing a type Ib endoleak. At the 12-month follow-up, type I endoleaks were absent; however, two type II endoleaks requiring embolization were identified. In a 2021 CEXC preliminary experience study, it was stated that the device should be thought of as a suitable alternative for patients with severe proximal aortic neck angulation (≥70°) since its active angulation system might pre-curve the proximal portion of the endograft and adapt well to this kind of architecture [3].

In 2022, one-year outcomes of CEXC were reported for a cohort of 80 patients enrolled in a U.S. clinical trial between 2017 and 2019. The safety and efficacy of CEXC, when used inside the IFU, have been proven, with 100% freedom from primary safety endpoint events evaluated after a 30-day follow-up and 98.5% freedom from primary effectiveness endpoint events at a 1-year follow-up [10].

Although CEXC studies to date typically follow the man-

ufacturing company's IFU, in a recent study, Mascoli et al. [13] confirmed excellent outcomes of 30-day morbidity and mortality, even when used outside the IFU. In this study, 44% of the patients had HNA with a severely angulated neck (≥90°); however, no reintervention was reported in the follow-up period of the 31 patients enrolled in this study, of whom 24% were followed up for more than 24 months. In addition, according to the meta-analysis by Antoniou et al. [14], up to 40% of patients are treated outside the IFU, usually because of the hostility of the AAAs' neck, which is an aspect of AAAs that CEXC promises to counter. The above results indicate that CEXC has increased applicability compared to other endografts.

Despite these promising results, CEXC to be further studied because there is a lack of comparative and post-market long-term clinical studies with significant results [15]. An EXcluder Conformable real Life (EXCeL) prospective observational study with a 3-year follow-up is awaited to be completed by 2025 [16]. A prospective, non-randomized, international multicenter study of two parallel sub-studies (short neck and high angulation) is estimated to be completed by 2026 [17]. The British Society of Endovascular Therapy ConformabLe EndoVascular Aneurysm Repair (BSET-CLEVAR) study, which is awaited to be completed, will introduce us to the first study with a 1-year follow-up on the CEXC with ACTIVE CONTROL System device [18].

In conclusion, the current clinical knowledge in the literature shows encouraging early results for GORE's new generation AAA endograft, with a 100% technical success rate and freedom from AAA-related mortality. CEXC increased our armamentarium owing to its increased patient applicability, allowing more patients to choose EVAR. Furthermore, multicenter studies with long-term outcomes are needed to confirm our promising results.

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CONFLICTS OF INTEREST

In addition to what is described in the funding section, no potential conflict of interest relevant to this article was reported.

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Concept and design: CFP, FOE, SKK. Analysis and interpretation: CFP, FOE, KGM. Data collection: CFP, ALT, CPD, KGM. Writing the article: CFP, FOE, ALT. Critical revision of the article: CFP, PEZ, SKK. Final approval of the article: all authors. Statistical analysis: none. Obtained funding: SKK. Overall responsibility: GSP, SKK.

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