One-year results of the GORE EXCLUDER Conformable AAA Endoprosthesis system in the United States regulatory trial

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ABSTRACT

Objective: To report the 1-year clinical outcomes from the GORE EXCLUDER Conformable AAA Endoprosthesis system in the US regulatory trial.

Methods: The study is a prospective, multicenter, investigational device exemption clinical trial at 31 US sites with core laboratory assessment of imaging and independent event adjudication. The primary safety (incidence of major adverse events at 30 days) and effectiveness end points (successful aneurysm treatment at 1 year) were assessed in a cohort of patients with abdominal aortic aneurysms (AAAs).

Results: We enrolled 80 patients between December 19, 2017, and February, 27, 2019. The mean maximum aortic diameter was 57.7 ± 7.95 mm (range, 42.5-82.7 mm) with an average patient age of 73.5 ± 8.14 years (range, 56-96 years). Overall technical success was 100% (80/80). The mean hospital length stay was 1.2 ± 0.6 days (range, 1-4 days). No primary safety end point events were observed, including no death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, procedural blood loss of more than 1000 mL, or thromboembolic events including limb occlusion or distal emboli. There were no type I or III endoleaks detected on the 1-, 6-, or 12-month follow-up computed tomography scans. There were no stent fractures, device migrations (≥10 mm), AAA ruptures, or conversions to open surgical repair observed. Two patients had AAA sac growth of more than 5 mm at 1 year owing to type II endoleaks. There were no aneurysm-related deaths within the 12-month follow-up, and freedom from aneurysm-related mortality was 100% through 1 year.

Conclusions: The safety and effectiveness of the GORE EXCLUDER Conformable AAA Endoprosthesis system has been demonstrated with 98.5% freedom from primary effectiveness end point events at 1 year and 100% freedom from primary safety end point events assessed through 30 days. (J Vasc Surg 2022;■:1-9.)

Keywords: Abdominal aortic aneurysm; Endograft; Endovascular repair

The use of stent graft technology, along with the development of endovascular techniques, has provided less invasive treatment of abdominal aortic aneurysms (AAA) with lower perioperative morbidity and mortality risks compared with open repair for more than 25 years.[1,2] The evolution of endografts and delivery systems for endovascular repair of AAAs (EVAR) has undergone multiple generations of technological advancements based on physician and engineering feedback to address areas of clinical need and improve deliverability, decrease profile, and promote better conformability to tortuous anatomy.[3] However, a significant remaining challenge for a satisfactory long-term outcome is to improve the performance of these devices in nonideal proximal sealing zones. In particular, short (<15 mm) and highly angulated (>60°) necks can threaten long-term exclusion of the aneurysm even with the current generation of endografts.[4,5]

Most AAA endografts have been designed for use in relatively straight, uniform proximal necks, with all current devices in the United States approved for use in relatively low angulation (≤60°).[6] For this reason, complete wall apposition is often unattainable in anatomies with highly angulated necks because the device cannot be delivered to or conform with this hostile region. As a result, a highly angulated neck may lead to potentially higher rates of proximal type I endoleaks and secondary interventions.[7]

The GORE EXCLUDER AAA Endoprosthesis (EXC) product line has been a part of this treatment paradigm since

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receiving initial Conformité Européene (CE mark) in 1997 (W.L. Gore & Associates, Flagstaff, AZ) with excellent post-market clinical results.[3] The CE mark is the European Union's mandatory conformity marking to regulate the goods sold within the European Economic Area and, when obtained, represents the manufacturer's indication that a product complies with these EU standards. The GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC) builds on the history of the EXC device while incorporating key design features to address remaining unmet clinical needs, specifically issues associated with short (10 to <15 mm) and/or highly angulated aortic necks (>60°-90°).

METHODS

Device description. The EXCC device is a modular stent graft system made of an expanded polytetrafluoroethylene graft and a nitinol stent structure. The trunk portion of the stent is comprised of individual stent rings assembled to the graft in such a way to allow for both angular and diametrical conformability (Fig 1). The device delivery system not only includes the same reconstraintment capability as its predecessor, the GORE C3 Delivery System, but also includes new features unique to the EXCLUDER Conformable device. The most notable of these is the GORE ACTIVE CONTROL System, which includes an angulation feature that allows the user to impart an angle on the proximal end of the device during its staged deployment (Fig 1). This element can be used both before and after the first deployment stage. The EXCLUDER Conformable stent graft system also includes a new EXCLUDER Conformable Aortic Extender. This component uses an individual stent row architecture similar to the EXCLUDER Conformable device, as well as a delivery system that also includes angulation control. The new EXCLUDER Conformable device is used with the current GORE EXCLUDER AAA contralateral limbs and iliac extenders to complete the EVAR system.

The EXCC device has three distinctive features that allow the endograft to be used more effectively in hostile aortic necks. First, the stent graft is designed to be highly conformable and achieve seal within the proximal 10 mm of the device using the proximal stent row and graft with sealing cuff construction. The stent graft design is intended to conform to the shape (angle, taper, etc) of the proximal aortic neck. Conforming to the aortic neck promotes maximal seal across the broad range of aortic morphologies seen in patients with an AAA.

Second, the EXCC device includes an advanced reconstrainment mechanism within the delivery system. This reconstrainment mechanism includes the proximal end reconstrainment capability provided in the previous generation EXCLUDER device, but also includes a new secondary constrainment sleeve that holds the diameter of the body of the device distal to the most proximal stent row to approximately 70% of full diameter through the first stage of deployment (Fig 1, *B*). This feature is intended to improve the ability of the device to be finely repositioned by the user after the first stage of deployment. The enhanced ability to reposition the device allows for maximal deployment accuracy, which promotes maximal achieved proximal seal length.

Last, The EXCC device delivery system includes a new angulation feature that allows the user to control the angle of the proximal end of the stent graft with respect to the aorta during deployment (Fig 1, *B* and *C*). This feature is intended to decrease the occurrence of the stent graft deploying at a skewed angle compared with the proximal aortic neck. The ability to deploy the device orthogonally to the aorta promotes achieving maximal seal length within the aortic neck. Although this feature may provide maximal benefit in extremely angled aortic necks—more than 60°—benefit may still be achieved using this feature in aortic necks with angles of 60° or less. In total, the ability to effectively exclude aneurysms in patients with aortic necks as short as 10 mm depends on a stent graft that is designed to create a seal within the proximal 10 mm of the device, as well as the user's ability to deploy the device accurately in an orthogonal manner, such that the entirety of the available healthy aortic neck is used to create the seal.

Study design. This study is a prospective, multicenter, nonrandomized clinical study with two parallel arms designed to evaluate the safety and effectiveness of the EXCC device for the treatment of infrarenal AAA in patients with short aortic necks (≥10 mm) and highly angulated infrarenal aortic necks (≤90°). The two study arms included a short neck arm, which consisted of patients with AAA having aortic neck angulation of 60° or less and an infrarenal aortic neck length of 10 mm or more; and a high neck angulation arm, which included patients with AAAs having aortic neck angulation of less

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, prospective, nonrandomized study
- **Key Findings:** Endovascular treatment of 80 patients with infrarenal abdominal aortic aneurysms treated with the GORE EXCLUDER Conformable AAA Endoprosthesis system endograft system demonstrated 98.5% freedom from the primary effectiveness end point event at 1 year and 100% freedom from primary safety end point events.
- **Take Home Message:** The 1-year results of the latest generation of the W. L. Gore & Associates' endograft system (GORE EXCLUDER Conformable AAA Endoprosthesis system) demonstrated unprecedented safety and effectiveness in the treatment of abdominal aortic aneurysms.

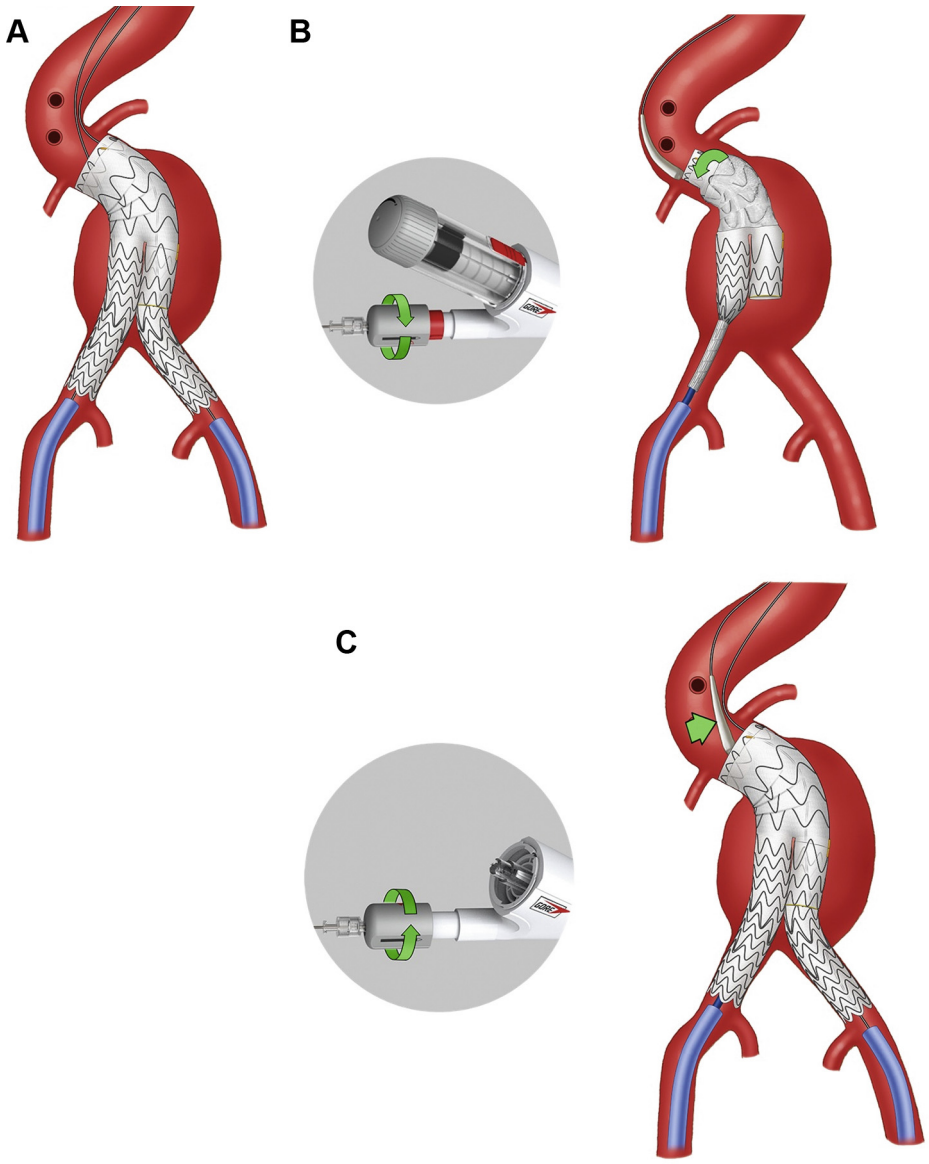

Fig 1. The GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC) and deployment stages **(A)** Fully deployed. **(B)** Angulation while restrained. **(C)** Angulation while unrestrained.

than 60° and 90° or less and an infrarenal aortic neck length of 10 mm or greater. The current study specifically reports the results of the first study arm. The second study arm is still in enrollment and will be reported upon conclusion. The patient population included in the first study arm was not limited to only patients with aortic neck lengths of less than 15 mm because this is a new device and delivery system construction. Rather than study the new device only in a subpopulation that represents a minority of the overall AAA population, it was relevant to study the device across the entire population, inclusive of the short neck subpopulation. The study was powered to determine the safety and efficacy of the device in the broad 10-mm or greater neck length and the 60° or less neck angle population.

A total of 48 clinical investigative sites in the United States participated in this study (Appendix A, online only), with 31 sites enrolling in the short neck arm. Institutional review board approval was obtained at all listed participating institutions (Appendix A, online only) and patients were consented before data collection and analyses.

The study aims to enroll a total of 190 patients, including 80 in the short neck arm and 110 in the high neck angulation arm. This report is the clinical data of all consecutive patients enrolled in the short neck substudy with 12 or more months of follow-up, which led to US Food and Drug Administration (FDA) approval of the device for commercial use. At the time of publication, the FDA has approved the EXCC device for use in

patients with aortic neck lengths of 15 mm or greater and aortic neck angles of 60° or less. The FDA is awaiting additional long-term data to assess approval of the EXCC device for use in patients with aortic neck lengths as short as 10 mm.

The inclusion criteria for the short neck arm were an AAA diameter of more than 5 cm or growth of more than 5 mm in 6 months (or a nonruptured AAA presenting with clinical symptoms), a neck length of 10 mm or greater, and proximal neck angulation of 60° or less. Patients were enrolled into the clinical study provided all inclusion and no exclusion criteria were met. Patients are evaluated through hospital discharge and return for follow-up visits at 1 and 6 months, and annually through 5 years after treatment. All images were reviewed by the Gore Imaging Sciences (GIS) laboratory, a group of film reading experts who provide image reading support for Gore clinical studies, as well as Gore commercial cases.

To support a robust investigation and analysis of device performance, in consideration of complex aortic neck angles, a specific proceduralized neck angle measurement method was created by Gore. The FDA provided input and approval of this method for use in the US clinical trial. The method used three-dimensional reconstruction and centerline delineation of preprocedural aortic imaging. This method defined the neck angle as the most acute change in centerline direction within the infrarenal aortic neck. Any angles originating distal to the infrarenal aortic neck were not included in this measurement.

End points. Primary safety end points were in accordance with Society for Vascular Surgery reporting standards,[8] including death, stroke, myocardial infarction, renal failure, bowel ischemia, paraplegia, respiratory failure, blood loss of more than 1000 mL, and thromboembolic events (including limb occlusions and distal embolic events) within 30 days of the initial procedure. The primary safety analysis included patients who underwent a follow-up examination at or after 30 days after the initial EXCC device implant procedure as well as any patient who experienced safety events at any time during follow-up.

Primary effectiveness end points were technical success of device implantation and freedom from the following events: type I and III endoleaks in the 12-month window, migration (≥10 mm), and AAA enlargement (>5 mm) between the 1- and 12-month window, and AAA rupture and conversion to open surgical repair through 12 months.

The primary effectiveness analysis included patients with both postoperative (no later than 1-month study window) and a 12-month contrast-enhanced computed tomography (CT) scan, as well as any patient with an eligible effectiveness event, regardless of follow-up.

In addition to primary effectiveness end points, a second group of effectiveness end points were assessed, independent of the performance goals. The secondary effectiveness end points were defined as the following: aneurysm-related mortality, stent-fracture based on core laboratory analysis, reintervention, type II and IV endoleaks, index procedure blood loss, index procedure time, and length of initial hospital stay.

Statistical analysis. One-sided exact Clopper-Pearson lower confidence limits for binomial proportions (alpha = 0.05) were constructed to compare the primary safety and primary effectiveness end point results against prespecified performance goals. Additional analyses through 1 year included all patients in the denominator, whereas the primary end point analysis required follow-up past 30 days for primary safety analysis and in the 12-month window for the primary effectiveness analysis. Results are further presented by aortic neck length (<15 mm vs ≥15 mm) as measured by the GIS laboratory.

RESULTS

A total of 80 patients (88.8% male) met all the inclusion criteria and were enrolled. The mean age was 73.5 ± 8.14 years (range, 56-96 years), and 75 patients were White (93.8%) (Table I). The risk factors for the patients enrolled are listed in Table I. The mean aortic diameter was 57.7 ± 7.95 mm (range, 42.5-82.7 mm); other anatomic characteristics are listed on Table II.

Procedural details. All 80 patients underwent a successful EVAR with the EXCC device. Details of the EXCC implantation procedure are presented in Table III. General anesthesia was used for 72 patients (90.0%). A majority of the 80 patients had percutaneous access for both left and right sides (87.5% and 90.0%, respectively). There were two procedure-related serious adverse events within the study population evaluated during the 12-month window. One patient experienced an incision site ecchymosis on postoperative day 3, which resolved without treatment and sequelae 14 days after EVAR. A second patient experienced a right femoral artery pseudoaneurysm during the index procedure that was treated with surgical repair during the index procedure and resolved without sequela on the same day. The mean procedure time was 89.1 ± 37.9 minutes (range, 33-251 minutes), and heparin was administered to 79 patients (98.8%). The mean blood loss was 75.6 ± 121.7 mL (range, 0-1000 mL). Technical operative success was achieved in all patients (100%) (Table IV). The mean hospital stay was 1.2 ± 0.6 days (range, 1-4 days). An intensive care unit stay was required in 11.3% of patients for a mean length of 14.1 ± 15.3 hours (range, 0-51 hours). Hospital survival was 100% and the mean time to return to normal daily activities was 23.7 ± 27.1 days (range, 0-174 days).

Table I. Baseline demographic and anatomic characteristics

Characteristics	n = 80	
Sex at birth		
Male	71 (88.8%)	
Female	9 (11.3%)	
Ethnicity		
Not Hispanic or Latino	75 (93.8%)	
Hispanic or Latino	1 (1.3%)	
Unknown	4 (5.0%)	
Race		
White	75 (93.8%)	
Black	3 (3.8%)	
Asian	1 (1.3%)	
Native American or Alaska Native	0	
Hawaiian or Pacific Islander	0	
Other	2 (2.5%)	
Age, years		
n	80	
Mean ± SD	73.5 ± 8.14	
Median	73.5	
Range	56.0-96.0	
BMI, kg/m^2		
n	80	
Mean ± SD	29.5 ± 5.05	
Median	28.5	
Range	21.6-46.1	
Maximum aortic diameter,[a] mm		
Mean ± SD	57.7 ± 7.95	
Range	42.5-82.7	
Length from LRA to left internal/external bifurcation,[a] mm		
Mean ± SD	191.8 ± 20.7	
Range	147.4-247.1	
Length from LRA to right internal/external bifurcation,[a] mm		
Mean ± SD	191.9 ± 20.4	
Range	153.9-244.9	
Aortic neck length, proximal,[b] mm		
Mean ± SD	23.9 ± 13.07	
Range	10.0-95.0	
Infrarenal aortic proximal neck angle,[b] °		
Mean ± SD	35.7 ± 14.55	
Range	3.0-59.0	
Common iliac diameter[c]	Right	Left
Mean ± SD	13.2 ± 2.8	13.2 ± 3.2
Range	8.0-19.0	8.4-25.0
External iliac diameter[c]	Right	Left
Mean ± SD	8.5 ± 1.5	8.5 ± 1.4
Range	6.0-12.6	5.9-13.0

GIS, Gore imaging sciences; *LRA*, lowest renal artery; *SD*, standard deviation.
[a]Core laboratory measurements.
[b]GIS measurement.
[c]Site measurements.

Primary safety end point. Of the 80 enrolled patients, 79 patients completed the required assessments to be evaluated for the primary safety end point, with one not complying with the follow-up requirements. No primary safety end point events (death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, procedural blood loss of >1000 mL, or thromboembolic events, including limb occlusion and distal embolic events) were observed. The percentage of patients free from a primary safety end point event was 100%. The lower confidence limit for freedom from primary safety end point events was 96.3%, which exceeded the performance goal of 79%.

Primary effectiveness end point. Sixty-six patients were eligible for the primary effectiveness end point analysis by having an event or by meeting the inclusion criteria and had the required contrast-enhanced CT scan completed at each time point. Follow-up imaging data reviewed by the core laboratory are summarized in Table IV. The percentage of patients free from a primary effectiveness end point event was 98.5% for patients. The lower confidence limit for freedom from primary effectiveness end point events was 93.0%, which exceeded the performance goal of 80%.

No type I or type III endoleaks were detected on the 1-, 6-, or 12-month follow-up CT scans. No wire fractures, device migrations, or AAA ruptures were observed through the 12-month follow-up window (Table IV).

CT scan data were available for 74 patients and 73 patients to determine maximum aneurysm diameter changes within the 6-month follow-up and within the 12-month follow-up, respectively. Within the 12-month follow-up window, 27 patients (37.0%) showed a decrease of 5 or more mm in aneurysm diameter, 45 patients (61.6%) showed no change, and 1 patient (1.4%) showed aneurysm growth (Table IV). Type II endoleaks were found in the two patients who showed aneurysm growth. Through 12 months of follow-up, there were four nonaneurysmal deaths with causes attributed to ascites, pneumonia, septic shock, and cardiomyopathy. Freedom from all-cause mortality was 96.2% (95% confidence interval, 88.6%-98.7%) through 1 year (Fig 2).

Table II. GORE EXCLUDER Conformable AAA Endoprosthesis system (*EXCC*) procedure details in short neck substudy

Variable	Patients initiating EXCC procedure (n = 80), n (%)
Endovascular access method on left side	
Percutaneous	70 (87.5)
Cutdown	10 (12.5)
Cutdown and conduit	0 (0.0)
Endovascular access method on right side	
Percutaneous	72 (90.0)
Cutdown	8 (10.0)
Cutdown and conduit	0 (0.0)
Anesthesia method[a]	
General	72 (90.0)
Regional	4 (5.0)
Local	3 (3.8)
Procedure time, minutes	
Mean ± SD	89.1 ± 37.9
Range	33-251
Blood loss, mL	
Mean ± SD	75.6 ± 121.7
Range	0-1000
Total fluoro time, minutes	
Mean ± SD	16.4 ±7.4
Range	8-42
Contrast used during procedure, mL	
Mean ± SD	82.2 ±32.7
Range	14-200
Any blood transfusion	1 (1.3)
Heparin administered	79 (98.8)
Procedure survival	80 (100.0)
Return to normal activities, days	
Mean ± SD	23.7 ±27.1
Range	0-174

SD, Standard deviation.
[a]One patient received monitored anesthesia care, not elsewhere included in this table.

Table III. Technical results

No. of enrolled patients	n = 80, n (%)
Technical success	80 (100.0)
Femoral artery access obtained	80 (100.0)
EXCC device successfully deployed within the proximal neck seal zone	80 (100.0)
Delivery catheters successfully removed	80 (100.0)
EXCC device patent and free from significant twist, kinks, or obstruction (>30% luminal stenosis) upon final deployment	80 (100.0)
Absence of type I or type III endoleak on completion angiography	80 (100.0)
Access site closure successful (either surgical or percutaneous)	80 (100.0)
Achieved proximal seal without need for proximal extension cuff	74 (92.5)

EXCC, GORE EXCLUDER Conformable AAA Endoprosthesis system.

Secondary effectiveness end point. Two patients (2.5%) required reintervention within the 1-year follow-up period. One reintervention was on postoperative day 222 for treatment of a type II endoleak from the inferior mesenteric artery with coil embolization. The same patient had an additional type II endoleak reported from a lumbar artery, which was treated with a second coil embolization on postoperative day 283. The second patient who required a reintervention had a stenosis of the right common iliac artery distal to the endograft, which was treated with a bare metal self-expanding stent on postoperative day 44. Events for both patients resolved subsequently without sequelae.

Thirty-four patients (43.6%) had a core laboratory-reported type II endoleak and six (7.7%) had an indeterminate endoleak reported. There were no type I, III, or IV endoleaks reported through 12 months of follow-up (Table IV). There were no aneurysm-related deaths within the 12-month follow-up window and freedom from aneurysm-related mortality was 100% through 1 year (Fig 2). Additionally, there were no wire fractures, nonpatent device components, extrusions, erosions, lumen obstructions, or device compressions based on core laboratory standardized analyses (Table IV).

Aortic neck length subgroup analysis. There were 23 patients with an aortic neck length of less than 15 mm and 57 patients with a neck length of 15 mm or more as measured by GIS eligible for primary effectiveness analysis. Freedom from primary effectiveness end point event at 1 year was 17 of 17 (100%) in the subgroup with a neck length of less than 15 mm and 48 of 49 (98.0%) in the subgroup with a neck length of 15 mm or greater. Twelve-month AAA enlargement of 5 mm or more rates were 0 of 20 (0%) (neck length of <15 mm) and 1 of 53 (1.9%) (neck length of ≥15 mm), as measured by the core laboratory. Through 12 months, no patients with a neck length of less than 15 mm and two (3.5%) patients with a neck length of 15 mm or greater underwent reinterventions. In the subgroup with a neck length of less than 15 mm, 6 of the 22 patients (27.3%) had a type II endoleak and one patient (4.5%) had an indeterminate endoleak.

Table IV. Core laboratory follow-up imaging findings

Variable	Post-treatment follow-up period			
	1 month, n (%)	6 months, n (%)	12 months, n (%)	Total, n (%)
Patients	80	79	79	80
Patients with CT scan	79	75	74	80
Endoleak	33/75 (44.0%)	25/70 (35.7%)	21/67 (31.3%)	36/78 (46.2%)
Type I	0/75	0/70	0/67	0/78
Type IA	0/75	0/70	0/67	0/78
Type IB	0/75	0/70	0/67	0/78
Type II	31/75 (41.3%)	24/70 (34.3%)	18/67 (26.9%)	34/78 (43.6%)
Type III	0/75	0/70	0/67	0/78
Type IV	0/75	0/70	0/67	0/78
Indeterminate	3/75 (4.0%)	1/70 (1.4%)	3/67 (4.5%)	6/78 (7.7%)
Patients with diameter change data (from baseline)	–	74	73	–
Change in maximum abdominal aortic diameter from baseline				
≥5 mm decrease	–	26 (35.1%)	27 (37.0%)	–
No change	–	47 (63.5%)	45 (61.6)	–
≥5 mm increase	–	1 (1.4%)	1 (1.4%)	–
AAA rupture	0/77	0/72	0/69	0/80
Migration	0/79	0/75	0/73	0/80
Wire fracture[a]	0/73	0/69	0/71	0/80
Extrusion/erosion	0/79	0/75	0/73	0/80

AAA, Abdominal aortic aneurysm; *CT*, computed tomography.
[a]Wire fracture was considered assessed and included in denominator if any fracture was present or, at a minimum, the nonoverlap areas of investigational device could be assessed.

In the subgroup with a neck length of 15 mm or greater, 28 of 56 patients (50.0%) had a type II endoleak and 5 (8.9%) patients had an indeterminate endoleak to date.

DISCUSSION

EVAR is the preferred treatment method for patients with AAAs who meet the anatomical requirements, despite evidence on randomized clinical trials of lack of long-term survival advantage compared with open surgical repair.[9,10]

When used under the instructions for use (IFU), EVAR is associated with lower rate of technical failure, endoleaks, and secondary interventions.[11-13] Unfortunately, endovascular devices are used frequently with liberal anatomical criteria and outside IFU, which has resulted in higher rate of secondary interventions.[14-18] Two anatomical factors have limited the application of infrarenal devices: short sealing zones and angulation.[19,20] Sweet et al[21] concluded that "shorter infrarenal AAA neck length will have the greatest impact on expanding on-label EVAR regardless of gender." These unmet clinical needs culminated with the development of the EXCC device specifically intended to treat patients with short and highly angulated necks. The need for an infrarenal AAA endovascular device which would allow physicians to safely treat patients with relatively hostile necks was born out of clinical necessity. More than 80% of all patients with an AAA are infrarenal.[4] Of these, the majority have a proximal infrarenal sealing zone of 10 mm or greater.[8] However, the earlier generations of the EVAR devices were designed for infrarenal sealing zones of greater than 15 mm. The EXCC device was specifically engineered to seal with a 10-mm length of infrarenal neck with up to 90° of angulation.

The results of the present study are outstanding through the first year after implantation, with 100% freedom from the primary safety end points and 98.5% freedom from the primary effectiveness end point events. Notably, highly accurate deployment of the EXCC device in challenging necks was reproducible, as evidenced by the perfect technical results achieved across all sites and further highlighted by the observation that majority of the proximal seal was achieved (92.5%) without the need for proximal extension cuff (Table III). This immediate technical and clinical success was preserved through the first year after implantation with no type I or III endoleaks, no migration, and reinterventions for type II endoleaks in the only two patients experienced a small sac expansion in the study. Although the long-term durability of short neck EVAR with EXCC remains to be determined, it is encouraging that freedom from aneurysm sac growth was observed in 98.6% of patients at 12 months.

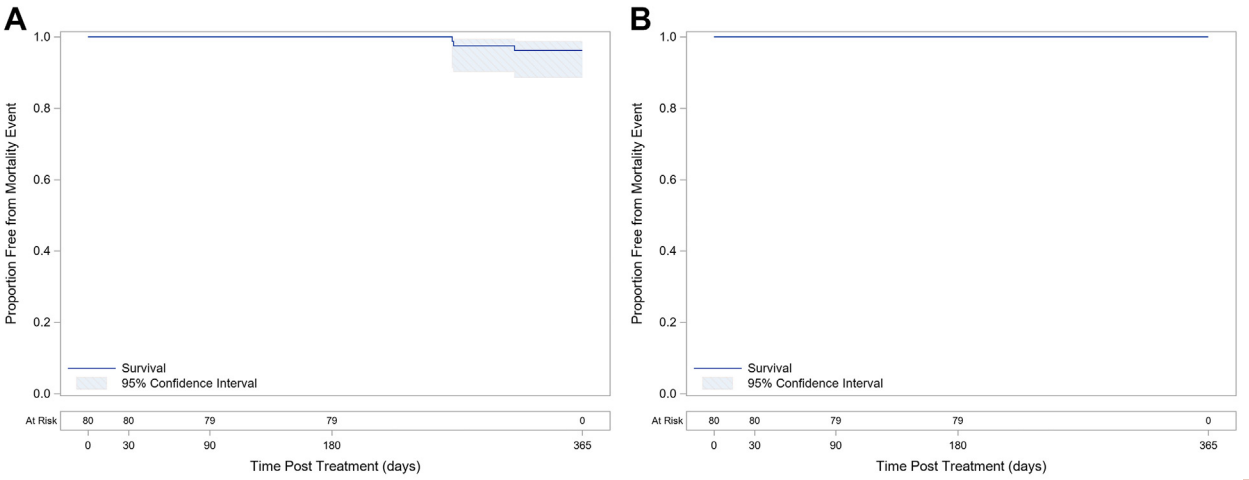

Fig 2. One-year freedom from **(A)** all-cause mortality and **(B)** aneurysm-related mortality.

Whether short neck AAA should be treated with infrarenal seal devices or more complex constructs such as fenestrated endografts remains an important question at this time. Other commercially approved infrarenal devices with short-neck indications in the United States include Endurant (≥10 mm) (Medtronic, Minneapolis, MN) and Alto (≥7 mm) (Endologix, Irvine, CA). Although the 1-year outcomes from the Endurant pivotal trial were excellent, the mean neck length in the trial was 26.5 mm, with only 10% of the enrolled patients having neck between 10 and 15 mm.[22]

The alternative approach of using fenestrated grafts to raise the seal zone above the renal arteries is a well-accepted strategy, mostly based on the behavior of hostile necks over time following outside IFU EVAR, using previous generation infrarenal devices. The only commercially approved fenestrated endograft in the United States for short-neck AAA (≥4 mm), Zenith Fenestrated (ZFEN) (Cook Medical, Bloomington, IN), has recently completed its 5-year follow-up, confirming its overall safety and efficacy.[23] Comparing the 5-year ZFEN follow-up data with the present 1-year EXCC follow-up study, the longer procedure time (236 ± 81 minutes for ZFEN vs 89.1 ± 37.9 minutes for EXCC) as well as high reintervention rates (30%) to maintain renal branch patency are areas of interest that will require further evaluation, as long-term follow-up data on the EXCC are collected. Notwithstanding the concerns regarding the natural history of hostile necks after infrarenal EVAR, the choice between fenestrated endografts and dedicated infrarenal technology designed and evaluated for challenging neck anatomy is undoubtedly complex. There is no clear advantage of an infrarenal fixation versus a suprarenal fixation EVAR system in the literature. Previous studies have demonstrated equivalence in hostile aortic necks.[24]

Anatomic features such as suprarenal aortic angulation, viscerorenal vessel disease, and infrarenal neck characteristics should all be considered in the context of the overall burden of comorbidities of each patient. Nevertheless, the current study clearly demonstrates that EXCC (which is an infrarenal aortic sealing device with infrarenal fixation) provides the operator with the ability to use the entire length of available neck through accurate and reproducible orthogonal deployment. The incidence of type II endoleaks was relatively high in this study; only two patients with type II endoleaks experienced sac expansion during the 1-year study period. Close long-term tracking of these patients will determine the significance of the type II endoleaks related to the EXCC. It should be noted that the rate observed in the present study, however, is comparable with that published for the EXC device in contemporary series.[25]

Although the current study provides excellent data on the performance of EXCC in patients with an AAA, including those with short aortic necks (≥10 mm), future data on the highly angulated neck arm of the study currently enrolling will also provide impactful data. It is this subset of patients with angulated necks that the conformable stent graft design and unique active angulation capability of the EXCC device may prove to be even more beneficial.

CONCLUSIONS

The EXCC device enables safe and effective treatment of infrarenal AAAs (proximal sealing zone of >10 mm and a neck angle of ≤60°) with encouraging 1 year outcomes. Its performance in highly angulated necks as well as long-term durability are pending.

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AUTHOR CONTRIBUTIONS

Conception and design: RR

Analysis and interpretation: RR, GO, SH, CL, PM, EM, JM

Data collection: Not applicable
Writing the article: RR, GO, SH, CL, PM, EM, JM
Critical revision of the article: RR, GO, SH, CL, PM, EM, JM
Final approval of the article: RR, GO, SH, CL, PM, EM, JM
Statistical analysis: JM
Obtained funding: Not applicable
Overall responsibility: RR

REFERENCES

1. Lederle FA, Kyriakides TC, Stroupe KT, Freischlag JA, Padberg FT Jr, Matsumura JS, et al. Open versus endovascular repair of abdominal aortic aneurysm. N Engl J Med 2019;380:2126-35.
2. van Schaik TG, Yeung KK, Verhagen HJ, de Bruin JL, van Sambeek MRHM, Balm R, et al. Long-term survival and secondary procedures after open or endovascular repair of abdominal aortic aneurysms. J Vasc Surg 2017;66:1379-89. Erratum in: J Vasc Surg 2018;67:683.
3. Verhoeven ELG, Katsargyris A, Bachoo P, Larzon T, Risher R, Ettles D, et al. 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). Eur J Vasc Endovasc Surg 2014;48:131-7.
4. Maudet A, Daoudal A, Cardon A, Clochard E, Lucas A, Verhoye JP, et al. Endovascular treatment of infrarenal aneurysms: comparison of the results of second- and third-generation stent grafts. Ann Vasc Surg 2016;34:95-105.
5. AbuRahma AF, Campbell J, S tone PA, Nanjundappa A, Jain A, Dean LS. The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair in patients. J Vasc Surg 2009;50:738-48.
6. Rhee R, Peterson B, Moore E, Lepore M, Oderich G. Initial human experience with the Gore Excluder Conformable AAA endoprosthesis. J Vasc Surg Cases Innov Tech 2019;29:319-22.
7. Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-55.
8. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002;35:1048-60.
9. Antoniou GA, Antoniou SA, Torella F. Editor's choice — endovascular vs. open repair for abdominal aortic aneurysm: systematic review and meta-analysis of updated peri-operative and long term data of randomised controlled trials. Eur J Vasc Endovasc Surg 2020;59:285-397.
10. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet 2016;388:2366-74.
11. Singh M, Fairman R, Anain P, Jordan W, Maldonaldo T, Samson R, et al. Final results of the Endurant Stent Graft System in the United States regulatory trial. J Vasc Surg 2016;64:55-62.
12. Swerdlow NJ, Lyden SP, Verhagen HJM, Schermerhorn ML. Five-year results of endovascular abdominal aortic aneurysm repair with the Ovation abdominal stent graft. J Vasc Surg 2020;71:1528-37.
13. Rhee RY, Eskandari MK, Zajko AB, Makaroun MS. Long-term fate of the aneurysmal sac after endoluminal exclusion of abdominal aortic aneurysms. J Vasc Surg 2000;32:689-96.
14. Charbonneau P, Hongku K, Herman CR, Habib M, Girsowics E, Doonan RJ, et al. Long-term survival after endovascular and open repair in patients with anatomy outside instructions for use criteria for endovascular aneurysm repair. J Vasc Surg 2019;70:1823-30.
15. Herman CR, Charbonneau P, Hongku K, Dubois L, Hossain S, Lee K, et al. Any nonadherence to instructions for use predicts graft-related adverse events in patients undergoing elective endovascular aneurysm repair. J Vasc Surg 2018;67:126-33.
16. Hwang D, Park S, Kim HK, Lee JM, Huh S. Reintervention rate after open surgery and endovascular repair for nonruptured aortic aneurysms. Ann Vasc Surg 2017;43:134-43.
17. Nakai M, Sato M, Sato H, Sakaguchi H, Tanaka F, Ikoma A, et al. Midterm results of endovascular abdominal aortic aneurysm repair: comparison of instruction-for-use (IFU) cases and non-IFU cases. Jpn J Radiol 2013;31:585-92.
18. Oliveira-Pinto J, Oliveira N, Bastos-Goncalves F, Hoeks S, VAN Rijn MH, Ten Raa S, et al. Long-term results of outside "instructions for use" EVAR. J Cardiovasc Surg (Torino) 2017;58:252-60.
19. de Vries JPPM. The proximal neck: The remaining barrier to a complete EVAR world. Semin Vasc Surg 2012;25:182-6.
20. Antoniou GA, Georgiadis GS, Antoniou SA, Kuhan G, Murray D. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. J Vasc Surg 2013;57:527-38.
21. Sweet MP, Fillinger MF, Morrison TM, Abel D. The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2011;54:931-7.
22. Makaroun MS, Tucheck M, Massop D, Henretta J, Rhee R, Buckley C, et al. One year outcomes of the United States regulatory trial of the Endurant Stent Graft System. J Vasc Surg 2011;54:601-8.
23. Oderich GS, Farber MA, Schneider D, Makaroun M, Sanchez LA, Schanzer A, et al. Final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms. J Vasc Surg 2021;73:1128-38.
24. Hager ES, Cho JS, Makaroun MS, Park SC, Chaer R, Marone L, et al. Endografts with suprarenal fixation do not perform better than those with infrarenal fixation in the treatment of patients with short straight proximal aortic necks. J Vasc Surg 2012;55:1242-6.
25. Meshii K, Sugimoto M, Niimi K, Kodama A, Banno H, Komori K. The association between perioperative embolization of hypogastric arteries and type II endoleaks after endovascular aortic aneurysm repair. J Vasc Surg 2021;73:99-107.

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Additional material for this article may be found online at www.jvascsurg.org.

APPENDIX A (online only).

GORE EXCLUDER Conformable AAA Endoprosthesis system (EXCC) investigators

Site	Principal investigator
Baptist Cardiac and Vascular Institute Miami, FL	Alex Powell, MD
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(Continued)

Continued.

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Research Foundation SUNY Buffalo Buffalo, NY	Maciej Dryjski, MD

Supplementary Table (online only). Site-reported patient risk factors

	Total
No. of enrolled patients	80
ASA classification	
I	7 (8.8%)
II	31 (38.8%)
III	39 (48.8%)
IV	3 (3.8%)
V	0 (0%)
NYHA functional classification	
I	31 (38.8%)
II	11 (13.8%)
III	1 (1.3%)
IV	0 (0%)
No cardiac disease	37 (46.3%)
SVS risk score	
Diabetes	
0	63 (78.8%)
1	10 (12.5%)
2	7 (8.8%)
3	0 (0%)
Tobacco use	
0	44 (55.0%)
1	16 (20.0%)
2	17 (21.3%)
3	3 (3.8%)
Hypertension	
0	21 (26.3%)
1	26 (32.5%)
2	24 (30.0%)
3	9 (11.3%)
Hyperlipidemia	
0	13 (16.3%)
1	10 (12.5%)
2	3 (3.8%)
3	54 (67.5%)
Cardiac status	
0	53 (66.3%)
1	12 (15.0%)
2	14 (17.5%)
3	1 (1.3%)
Carotid disease	
0	72 (90.0%)
1	7 (8.8%)
2	1 (1.3%)
3	0 (0%)
Renal status	
0	69 (86.3%)
1	11 (13.8%)
2	0 (0%)
3	0 (0%)
Pulmonary status	
0	57 (71.3%)
1	9 (11.3%)
2	13 (16.3%)
3	1 (1.3%)
Summary SVS risk score	
n	80
Mean ± SD	5.8 ± 3.2
Median	6.0
Range	(0-14)

ASA, American Society of Anesthesiologists; *NYHA*, New York Heart Association; *SVS*, Society for Vascular Surgery.