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ABSTRACT

Purpose: To evaluate long-term outcome of GORE EXCLUDER AAA Endoprosthesis (W.L. Gore & Associates, Inc, Flagstaff, Arizona) for elective treatment of infrarenal aortic aneurysms and to evaluate performance of different generations of the device.

Materials and Methods: A retrospective analysis was performed of 248 patients undergoing elective endovascular aneurysm repair with the GORE EXCLUDER between January 2000 and December 2015 in 2 hospitals. Primary endpoint was reintervention-free survival. Secondary endpoints were technical success, overall survival, rupture-free survival, endoleaks, sac diameter change (> 5 mm), limb occlusion, and migration (> 5 mm). Median follow-up time was 26 months (range, 1–190 months).

Results: Assisted primary technical success was 96.8%. Reintervention-free survival for 5 and 10 years was 85.2% and 75.6%, respectively. Independent risk factors for reintervention were technical success ($P < .001$), type I endoleak ($P < .001$), and type II endoleak ($P = .003$). Late adverse events requiring reintervention included rupture (0.4%), limb occlusion (0.4%), and stent migration (0.4%). Type Ia (4.8%), Ib (2.8%), II (35.9%), and V (6.5%) endoleaks were reported throughout follow-up. Sac growth was more prevalent with the original GORE EXCLUDER compared with the low permeability GORE EXCLUDER ($P = .001$) and in the presence of type I, II, and V endoleaks ($P < .05$). Three conversions (1.2%) were performed. Overall survival at 5 and 10 years was 68.4% and 49.0%, with no reported aneurysm-related deaths.

Conclusions: Treatment with the GORE EXCLUDER is effective with acceptable reintervention rates in the long-term and few device-related adverse events or ruptures up to 10 years. Observed late adverse events and new-onset endoleaks emphasize the need for long-term surveillance.

ABBREVIATIONS

AAA = abdominal aortic aneurysm, CI = confidence interval, EVAR = endovascular aneurysm repair, IFU = instructions for use, LFU = lost to follow-up, LP = low permeability GORE EXCLUDER, OP = original permeability GORE EXCLUDER

Endovascular aneurysm repair (EVAR) has become a routinely used procedure for treatment of infrarenal abdominal aortic aneurysms (AAAs). Ongoing improvements in graft design will likely lead to improved long-term outcomes, although long-term data are still scarce. The GORE EXCLUDER (W.L. Gore & Associates, Inc, Flagstaff, Arizona) EVAR device was released in Europe in 1997 and > 250,000 patients have been treated with the device worldwide. Over the course of several years, modifications were made to the original permeability GORE EXCLUDER (OP). In October 2004, the low permeability GORE EXCLUDER (LP) was launched as a response to reported aneurysm enlargement with the OP. The LP has a middle layer with a redesigned polytetrafluoroethylene

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Tables E1–E3 are available online at *www.jvir.org*.

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Table 1. Baseline Characteristics of Patients with an Infrarenal Aortic Aneurysm Treated with the GORE EXCLUDER

Variable	Overall (N = 248)	OP (n = 52)	LP (n = 196)	*P* Value
Patient characteristics				
Mean age, y (SD)	71.2 (8.2)	69.5 (6.8)	71.7 (8.5)	.086
Male sex	216 (87.1%)	47 (90.4%)	169 (86.2%)	.426
Risk factors/comorbidities				
Hypertension	172 (69.4%)	36 (69.2%)	136 (69.4%)	.650
Hyperlipidemia	163 (65.7%)	22 (42.3%)	141 (71.9%)	< .001*
Cardiovascular disease				
Coronary artery disease	116 (46.8%)	27 (51.9%)	89 (45.4%)	.403
Cerebrovascular disease	36 (14.5%)	7 (13.5%)	29 (14.8%)	.808
Peripheral artery disease	23 (9.3%)	5 (9.6%)	18 (9.2%)	.924
Diabetes mellitus	37 (14.9%)	7 (13.5%)	30 (15.3%)	.740
Insulin dependent	7 (2.8%)	3 (5.8%)	4 (2.0%)	.149
Severely reduced kidney function/renal dialysis	7 (2.8%)	0 (0.0%)	7 (3.6%)	.167
Lung disease	62 (25.0%)	10 (19.2%)	52 (26.5%)	.280
Currently smoking	73 (29.4%)	17 (32.7%)	56 (28.6%)	.117
Previous vascular surgery	92 (37.1%)	22 (42.3%)	70 (35.7%)	.396
ASA classification				
I–II	144 (58.1%)	30 (57.7%)	114 (58.2%)	.951
III–IV	104 (41.9%)	22 (42.3%)	82 (41.8%)	.951

ASA = American Society of Anesthesiologists; LP = low permeability GORE EXCLUDER; OP = original permeability GORE EXCLUDER.
*Significant difference between OP and LP.

microstructure to decrease graft permeability (1). In 2011, the C3 device delivery system was introduced. This delivery system offers the advantage of repositioning the stent graft, resulting in higher accuracy in positioning relative to the renal arteries and improving ease of cannulation through repositioning. The GORE EXCLUDER has been related to low rates of aneurysm-related death and adverse events, but reports on long-term outcomes are scarce (2–5). The principal aim of the present study was to evaluate the long-term results, particularly the reintervention-free survival, of the GORE EXCLUDER in the elective treatment of infrarenal AAAs. In addition, the outcomes of the different generations of the device were evaluated.

MATERIALS AND METHODS

Study Design

Hospital records from patients who underwent EVAR with the GORE EXCLUDER for the treatment of an infrarenal AAA were retrospectively analyzed. All patients electively treated with the GORE EXCLUDER between January 2000 and December 2015 at 2 hospitals were included. Retrospective "patients' files" research is not within the scope of the Dutch WMO (Wet Mensgebonden Onderzoek [law on research involving human subjects]), and a waiver of the Dutch central ethical board was obtained that their review was not necessary. Anonymity of patients' data was maintained during analysis. The local board approved the study protocol. There were 26 patients excluded because the indication was treatment of a symptomatic or ruptured AAA (n = 15), because no follow-up data were available for at least 1 month (n = 4), and because the device was used as a secondary intervention after previous aortic repair (n = 7).

Baseline Demographics

During the study period, 248 patients were electively treated using the GORE EXCLUDER. In this time interval, 1,643 EVAR procedures were performed at the 2 sites. There were 216 men (87.1%) and 32 women (12.9%) with a mean age of 71.2 years ± 8.2 treated with the GORE EXCLUDER identified and included. Baseline demographics and risk factors are summarized in **Table 1**. Cardiovascular risk factors were present in most of the patients, and 41.9% of the patients had a high operative risk (American Society of Anesthesiologists class III or IV). The mean maximum aneurysm diameter was 59.1 mm ± 9.6 (range, 30–96 mm). Three patients with a saccular aneurysm were treated for an aneurysm diameter < 50 mm. The mean infrarenal aortic neck diameter was 22.9 mm ± 2.4, the mean neck length was 32.3 mm ± 11.9, and the mean infrarenal neck angle (beta angle) was 23.6° ± 21.9. A saccular aneurysm was present in 11 patients (4.4%), and an inflammatory aneurysm was present in 3 patients (1.2%). Besides the infrarenal aneurysm, 25 patients (10%) also had a concomitant common iliac artery aneurysm, and 5 patients (2%) also had an internal iliac artery aneurysm. There were 61 patients (24.6%) treated outside the instructions for use (IFU) of the device, mainly owing to the diameter of the common iliac artery, and 4.8% of the patients had a hostile aortic neck anatomy.

Procedural Details and Follow-up

All patients underwent computed tomography (CT) angiography before the procedure. Based on the anatomic suitability, the choice for endovascular treatment with the GORE EXCLUDER was made by a vascular surgeon and an interventional radiologist. Early on, procedures were performed in an operating room using a mobile image intensifier and later on in a dedicated angiosuite, following the IFU. Antibiotic prophylaxis and heparin were given. Follow-up included clinical examination, abdominal radiography, duplex ultrasound scanning, and CT angiography. Surveillance protocols differed slightly between hospitals and evolved over time. In general, a routine follow-up visit occurred at 1–3 months, 12 months, and annually thereafter.

Endpoints and Definitions

The primary endpoint was reintervention-free survival. Secondary endpoints were technical success, overall survival, rupture-free survival, endoleaks, sac change, limb occlusion, and migration (> 5 mm). Technical success was defined according to the reporting standards as successful introduction and deployment of the device and no conversion, death, type I or III endoleak, or graft limb occlusion within 24 hours after the procedure. If unplanned endovascular or surgical procedures were required (during the procedure or within 24 h), the term "assisted primary technical success" was used. Endoleak was defined as described by Chaikof et al (6). Hostile neck anatomy was defined as a neck length < 15 mm, neck diameter > 28 mm, or neck angle > 60°. The maximum AAA diameter as assessed according to the reporting standards for EVAR and an increase or decrease of the aneurysm sac of at least 5 mm were considered significant (6). Diameters were compared with the first imaging study obtained after the procedure and the previous imaging. Hypertension was defined as known history of hypertension or use of antihypertensive medication, with the exception of the use of antihypertensive medication for arrhythmias. Hyperlipidemia and diabetes mellitus were defined as known history of hyperlipidemia or diabetes mellitus or the use of a statin or antidiabetic medication. Severely reduced kidney function was defined as a glomerular filtration rate < 30 mL/min/1.73 m^2. Aneurysm-related mortality was defined per reporting standards as described by Chaikof et al (6) as deaths due to aneurysm rupture, a primary or secondary procedure, or surgical conversion.

Statistical Analysis

Mean ± SD and median with range were calculated for normally and skewed distributed variables, respectively. Differences between the different generations of the device were evaluated using the following tests. Nominal variables were compared with the χ^2 test, and continuous variables were analyzed using the independent t test (normal distribution) and Mann-Whitney U test (skewed distribution). Standard Kaplan-Meier statistics have been applied with censoring for patients lost to follow-up (LFU) or not reaching the follow-up time because they were included later in time. Kaplan-Meier analyses were used for survival, reintervention-free survival, and endoleak-free survival. If the standard error was > 10%, the table or life graph was truncated. Additional Cox regression analysis was used to investigate the effect of several variables on survival and reintervention. Two-sided P value < .05 was considered significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp, Armonk, New York).

RESULTS

Perioperative Data

The OP was used in the first 52 consecutive patients (21%). There were 196 patients treated with the LP, and the new C3 delivery system was used in most cases (54%). The device was combined with the GORE EXCLUDER Iliac Branch Endoprosthesis in 2% (n = 5). The procedure was performed under local anesthesia in 52.0%, followed by general (29.8%), regional (14.9%), and combined local and epidural (0.8%) anesthesia; the anesthesia used was unknown in 6 patients (2.4%). Surgical cutdown was used in 212 patients (85.5%), 18 patients (7.2%) were treated with percutaneous technique, and 18 patients (7.2%) had a combination of both techniques. Additional procedures were performed in 42 patients (1 additional procedure in 32 patients, 2 additional procedures in 9 patients, and 3 additional procedures in 1 patient). Additional procedures included embolization of the internal iliac artery (n = 18) and treatment for occlusive disease (n = 15). The median procedural time (including additional procedures) was 118 minutes (range, 46–434 min). Median estimated blood loss was 100 mL (range, 0–1,800 mL), and 6 patients (2.4%) needed a blood transfusion during the procedure or postoperative stay.

Primary technical success was achieved in 231 patients (93.1%). In 3 of 17 technical failures, the device was used outside the IFU. There was no significant difference in success rate for using or not using the C3 delivery system (P = .360), for complying or not complying with the IFU criteria (P = .395), or having or not having a hostile neck anatomy (P = .873). Assisted primary technical success was achieved in 9 more patients, leading to a success rate of 96.8%. Additional procedures to achieve assisted primary technical success were the use of an extension or bridging stent for a type Ia (n = 3), Ib (n=1), or III (n=1) endoleak; extra ballooning of the proximal stent to solve a type Ia endoleak (n = 1); a renal stent owing to proximal migration of the GORE EXCLUDER causing obstruction of the renal inflow (n = 1); and 2 unplanned endarterectomies owing to occlusion and stenosis of the common femoral artery at the end of the procedure. Technical success was not achieved in 8 patients (3.2%) because of persistent type Ia endoleak in 7 patients and type Ib endoleak in 1 patient. Four patients (1.6%) required admission to the intensive care unit, 3

Table 2. Estimated Freedom from Endoleak during Follow-up

Follow-up Time	Type Ia (95% CI)	Type Ib (95% CI)	Type II (95% CI)	Type V (95% CI)	Overall (95% CI)
1 year	96.2% (93.8–98.6)	98.7% (97.3–100.1)	66.5% (60.4–72.6)	99.5% (98.5–100.5)	65.4% (59.3–71.5)
5 years	95.3% (92.4–98.2)	95.1% (91.2–99.0)	60.7% (53.8–67.6)	90.6% (84.9–96.3)	47.8% (39.8–55.8)
10 years	91.5% (83.7–99.3)	95.1% (91.2–99.0)	55.0% (45.0–65.0)	80.3% (69.1–91.5)	31.9% (19.6–44.2)

CI = confidence interval.

patients because of preexisting comorbidities and 1 patient because of congestive heart failure following EVAR. The median hospital stay was 2 days (range, 1–31 d).

The intraoperative and 30-day mortality was zero. Early postoperative complications included groin hematomas (n = 24; 9.7%) and wound infections (n = 10; 4.0%). In 4 patients, the complication was related to adjunctive procedures (n = 2) or reintervention (n = 2). Five patients (2.0%) were readmitted; 3 patients had a wound infection, of which 1 patient also had lower limb ischemia; 1 patient had abdominal and chest pain that turned out to be dyspepsia; and 1 patient had loss of consciousness and confusion with unknown underlying etiology.

Follow-up

The median follow-up of the total population was 25.6 months (mean 42.3 months; range, 1–190 months). Patients treated with the OP and LP had a median follow-up of 77.4 months (mean 85.7 months; range, 1–190 months) and 21.0 months (mean 30.9 months; range, 1–129 months), respectively. Follow-up time was ≥ 5 years in 63 patients (25.4%) and ≥ 10 years in 20 patients (8.1%).

There were 7 patients LFU (**Table E1** [available online at *www.jvir.org*]). One patient went to another hospital, and no information could be obtained. No documentation was found for the other 6 patients LFU, including no information found in hospital records (over 3 years no information after last documented visit). Follow-up imaging was available in 142, 126, and 49 patients after 1, 2, and 5 years. Imaging consisted of CT angiography, duplex ultrasound, and plain x-ray in 12%, 93%, and 71% at 1-year follow-up; 14%, 97%, and 69% at 2-year follow-up; and 10%, 98%, and 78% at 5-year follow-up (**Tables E2**, **E3** [available online at *www.jvir.org*]).

Endoleak

At the end of the EVAR procedure, 7 patients (2.8%) had a type Ia endoleak, 1 patient (0.4%) had a type Ib endoleak, and 29 patients (11.7%) had a type II endoleak. During the follow-up period, 5 type Ia endoleaks and 1 type Ib endoleak resolved spontaneously; 2 type Ia endoleaks persisted over time and required reintervention. There were no type IV endoleaks.

New type Ia, Ib, and V endoleaks developed in 5 (2%), 6 (2.4%), and 16 (6.5%) patients during the follow-up period. New-onset type Ia, Ib, and V endoleaks manifested a median 32 (range, 4–136), 19 (range, 1–53), and

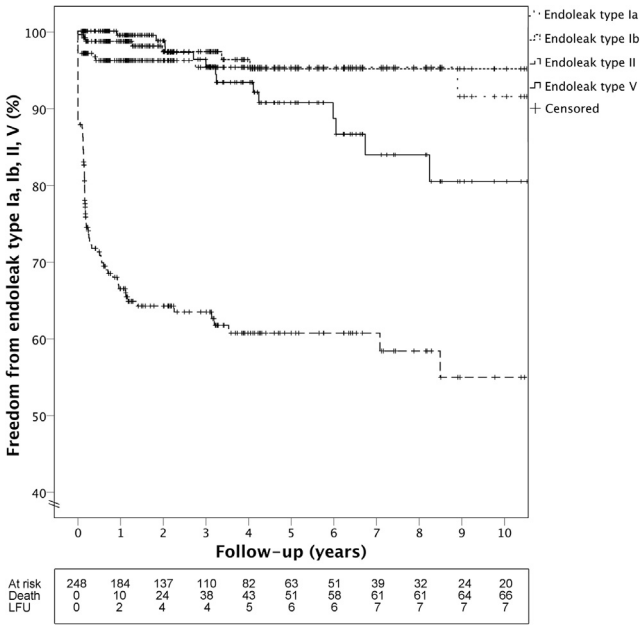

Figure 1. Freedom from endoleak type Ia, Ib, II, and V.

43 (range, 11–146) months after the procedure. During follow-up, a type II endoleak was first seen after a median of 2 months (range, 0-100 months) in 60 patients (24.2%). No type III endoleaks were observed. The overall estimated endoleak-free survival during follow-up was 65.4% (95% confidence interval [CI], 59.3%–71.5%) at 1 year, 47.8% (95% CI, 39.8%–55.8%) at 5 years, and 31.9% (95% CI, 19.6%–44.2%) at 10 years (**Table 2**). **Figure 1** shows the estimated freedom from type Ia, Ib, II, and V endoleak. Type V endoleaks were observed in 6.5% of the patients with a significant difference between the OP and LP in favor of the LP ($P = .021$).

An overview of the aneurysm sac size change is provided in **Table 3**. More diameter decrease was seen with the use of the LP (mean decrease 10.2 mm; 17.5%) compared with the OP (mean decrease 2.0 mm; 3.0%). Sac growth was observed during the follow-up period in 28.8% of patients treated with the OP and in 7.7% of patients treated with the LP ($P \leq .001$). When adjusting the follow-up time difference between the OP and LP (only patients with a follow-up ≥ 5 y), 50.0% of patients treated with the OP and 18.2% of patients treated with the LP showed sac growth during follow-up ($P = .007$). Type I ($P = .048$), II ($P \leq .001$) and V ($P \leq .001$) endoleaks were risk factors for sac growth. Patients with an aneurysm

Table 3. Absolute Aneurysm Sac Diameters and Changes during Use of Original GORE EXCLUDER Compared to Low Permeability GORE EXCLUDER

Time Period	OP			LP		
	No. Patients	Mean Diameter, mm	Mean Difference, mm (%)*	No. Patients	Mean Diameter, mm	Mean Difference, mm (%)*
Preoperative	51	56.9		196	59.6	
Initial postoperative	52	55.1		194	56.6	
1 year	45	50.5	−3.9 (6.7%)	149	49.4	−6.5 (11.3%)
2 years	35	52.3	−2.5 (4.3%)	82	48.4	−7.5 (13.1%)
3 years	31	50.8	−2.4 (4.3%)	61	47.8	−9.3 (15.9%)
4 years	28	50.7	−2.8 (4.6%)	42	49.1	−7.9 (13.8%)
5 years	18	53.2	+0.9 (1.6%)	28	50.0	−9.0 (15.4%)
6 years	22	51.9	−2.8 (5.1%)	22	45.5	−12.0 (22.0%)
7 years	17	51.5	−1.7 (2.5%)	13	50.1	−8.3 (13.8%)
8 years	15	53.3	−1.1 (0.4%)	10	45.7	−13.0 (21.2%)
9 years	16	53.8	−1.5 (1.8%)	5	43.4	−10.6 (18.3%)
10 years	13	50.8	−1.8 (2.1%)	2	37.0	−18.0 (30.2%)
Total mean			−2.0 (3.0%)			−10.2 (17.5%)

LP = low permeability GORE EXCLUDER; OP = original permeability GORE EXCLUDER.
*Mean differences in diameter and percentage within patients compared with initial postoperative measurement.

Table 4. Details of Adverse Events and Reinterventions

Time Period	No. Patients (%)	Adverse Event	Reintervention
< 30 days	2 (0.8)	Ischemia (< 24 h)	Endarterectomy
	1 (0.4)	Pulsation swelling (femoral hernia)	Reexploration
	1 (0.4)	Groin hematoma/infection	Reexploration/cleaning
> 30 days	6 (2.4)	Endoleak type Ia	Cuff extension (n = 4), conversion to open repair (n = 2)
	6 (2.4)	Endoleak type Ib (rupture n = 1)	Iliac extension (n = 4), embolization with glue (n = 1), iliac extension and embolization (n = 1)
	9 (3.6)	Endoleak type II	Embolization (coil or glue) (n = 7), open procedure (n = 1), not successful (n = 1)
	3 (1.2)	Endoleak type V	Relining
	1 (0.4)	Swelling groin (femoral hernia)	Reexploration
	1 (0.4)	Short proximal sealing	Cuff extension
	1 (0.4)	Progression of disease	Iliac extension and internal iliac artery coiling (n = 1)
	1 (0.4)	Folding proximal stent graft	Proximal stent graft extension
	1 (0.4)	Migration	Cuff extension proximal
	1 (0.4)	Limb occlusion	Iliofemoral crossover bypass

diameter of > 60 mm showed more decrease in aneurysm sac diameter than patients treated for a smaller aneurysm ($P = .022$). There was no difference in the total amount of patients that showed sac decrease between the LP (50.5%) and the OP (42.3%), and a comparable percentage of patients showed no change in sac diameter during follow-up (LP, 42.9%; OP, 38.5%).

Reinterventions and Adverse Events

During the follow-up period, 34 reinterventions were performed in 30 patients (12.1%), of which 4 were performed within 30 days after the procedure. In 24 patients, the reason for reintervention was the presence of an endoleak (6 had type Ia, 6 had type Ib, 9 had type II, and 3 had type V endoleak). An overview of the adverse events and reinterventions is provided in Table 4. Two reinterventions were required within 24 hours of the initial procedure because of acute lower limb ischemia after the use of a closure device (n = 1) and after a difficult closure with overstitching (n = 1) resulting in stenosis and occlusion of the common femoral artery. The median time until the first reintervention was 13.4 months (range, 0–139 months). Sixteen (47.1%) of the reinterventions were performed within the first year. The estimated reintervention-free survival for 1, 5, and 10 years was 93.6% (95% CI, 90.3%–96.9%), 85.2% (95% CI, 79.1%–91.3%), and 75.6% (95% CI, 65.8%–85.4%) (Fig 2). Independent risk factors for reinterventions were lack of primary technical success ($P < .001$), type I endoleak ($P < .001$), and type II endoleak ($P = .003$). Treatment outside the IFU or with a hostile neck anatomy did not

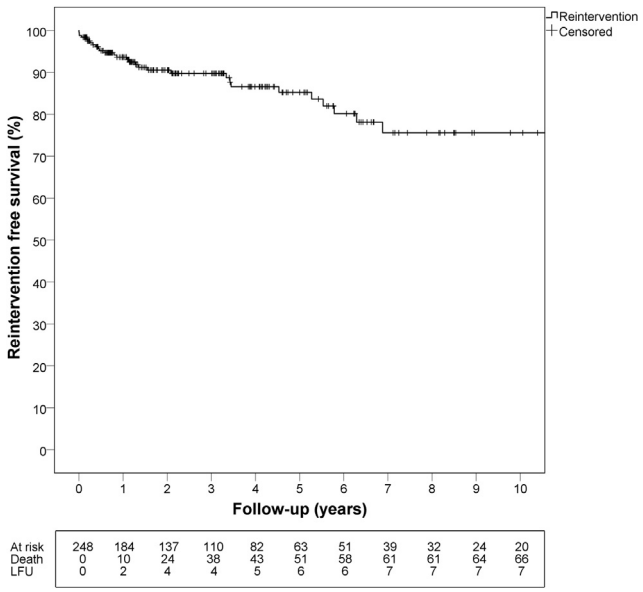

Figure 2. Reintervention-free survival.

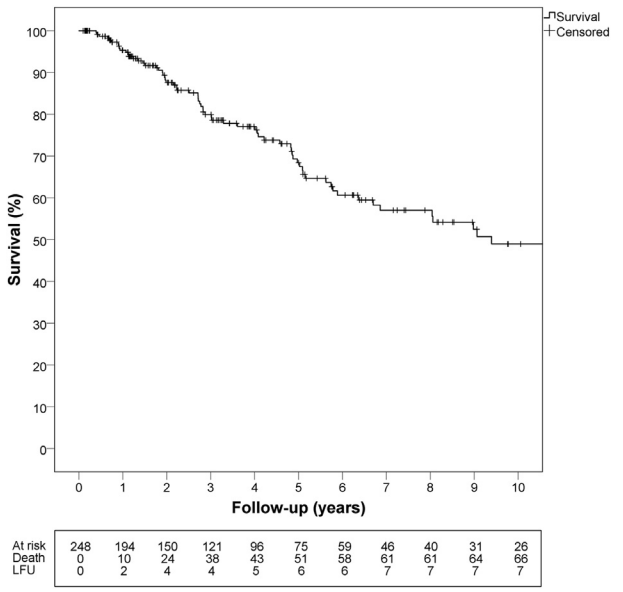

Figure 3. Overall survival.

appear to be a predictor for reintervention ($P = .132$ and $P = .166$, respectively). Also, the generation of device used did not significantly correlate with the reintervention rate (OP vs LP, $P = .076$; C3 vs no C3, $P = .636$).

Migration or dislocation of the stent occurred in 3 patients and led to a reintervention in 2 patients; the third patient was left untreated because there was no sign of a proximal endoleak, and there was a long sealing length. The 1-year and 5-year limb primary and secondary patency rates were 99.6% and 99.6%, respectively, at both time points. There was only 1 patient with limb occlusion who was treated with an iliofemoral crossover bypass after 3 months of follow-up. One patient had a late aneurysm rupture (after 21 months) secondary to a type Ib endoleak and was successfully treated with an extension of the limb and coiling of the internal iliac artery. Three conversions were needed because of aneurysm enlargement with type Ia and II endoleak. Of the 89 type II endoleaks, 49 spontaneously disappeared during follow-up, and 9 reinterventions were performed. In 15 of 89 patients, the endoleak was associated with sac enlargement; in 5 patients, it was associated with another endoleak (type Ib, n = 3; type Ia, n = 1; type V, n = 1). No stent fractures or stent infections were observed.

During the follow-up period, 22 patients (8.9%) developed peripheral arterial disease, and 8 needed an intervention. Five patients (2.0%) had an aneurysm of vessels of the lower extremities, and 3 needed an intervention. Finally, 30 patients (12.1%) developed cancer, 29 patients (11.7%) developed cardiac symptoms, and 13 patients (5.2%) developed neurologic symptoms.

Survival

The overall survival, as estimated by Kaplan-Meier analysis, was 95.3% (95% CI, 92.6%–98.0%) at 1 year, 68.4% (95% CI, 60.8%–76.0%) at 5 years, and 49.0% (95% CI, 39.0%–59.0%) at 10 years (Fig 3). During the follow-up period, 76 patients (30.6%) died. No aneurysm-related deaths were observed, although 2 deaths were suspected to be aneurysm related. Cause of death was unknown in 48.7% of patients (n = 37). The most frequent known causes of death were malignancy in 28% (n = 21) cardiac failure in 7% (n = 5), renal failure in 4% (n = 3), and sepsis in 4% (n = 3). Independent risk factors for mortality were age ($P = .001$), coronary artery disease ($P = .020$), and hyperlipidemia ($P < .001$).

DISCUSSION

The present study shows that elective treatment of an infrarenal AAA with the GORE EXCLUDER is effective with acceptable long-term reintervention rates and few device-related adverse events or ruptures over up to 15 years of follow-up. With a mean follow-up time of 3.5 years and 63 patients with a follow-up time > 5 years, this study presents some of the longest follow-up data with the GORE EXCLUDER and a comparison of the OP, LP, and C3 delivery device.

The assisted primary technical success rate was 96.8% with no mortality within 30 days. This technical success rate is in accordance with other research of the device, with even higher reported rates of technical success for the GORE EXCLUDER featuring the C3 delivery system (98%–99%) (3,5). As reported by Stather et al (7), a hostile neck anatomy is particularly associated with a decrease in technical success. In the present study, no significant difference was found between patients with a favorable or hostile neck anatomy with regard to technical success rates, although only a few patients (4.8%) met the criteria for hostile neck anatomy.

The present series is likely to be subjected to selection bias, as the choice for the device could not be deducted

from the case files and depended on physician preference, which could have changed over time. Only 13% of patients undergoing EVAR in the study group were treated with the GORE EXCLUDER during the inclusion years, which suggests a selection bias. Owing to the fact that there were no selection protocols, the selection criteria were not clear and could not be deduced from the case files. In addition, these criteria could have been different between the sites and physicians and may have changed over time. Overall, the neck anatomy of the treated aneurysm seemed favorable, although 25% of patients were treated outside the IFU.

As reported by midterm and long-term studies of the GORE EXCLUDER, reintervention rates are 9%–15% (4,8,9). Described risk factors for reintervention are endoleaks, especially type I; ruptures; endotension; use of the OP; aneurysm sac size > 5.5 cm; limb thrombosis; and migration (9–12). In this study, reinterventions were performed in 30 patients for whom follow-up data were available; 16 reinterventions were performed within the first year after the procedure. Independent risk factors for reinterventions were failure to achieve primary technical success, type I endoleaks, and type II endoleaks. Limb occlusion was extremely rare.

The estimated intervention-free survival after 5 and 10 years was 85.2% and 75.6%, respectively. This is in the same range as previously published research (86.5% and 90% at 5 years and 77.7% at 10 years) (4,8). Late ruptures after EVAR, although uncommon, have been described as a cause of late reintervention and death (9,12). In this study, 1 patient presented with a late rupture caused by a late type Ib endoleak and needed a redo endovascular repair. No aneurysm-related death was observed. However, this might be an underestimation considering previous reported midterm results with an aneurysm-related mortality rate of approximately 1.5% and the fact that owing to the retrospective design of the study the cause of death was often missing (8,9). In this series, 2 patients who presented with a late endoleak in combination with aneurysmal sac growth died within 4 months after diagnosis of the sac growth. A rupture as cause of death cannot be ruled out in these patients.

During the follow-up period, 76 patients (30.6%) died. Independent risk factors associated with death were older age, prevalent coronary artery disease, and hyperlipidemia with an estimated survival of 68.4% and 49.0% at 5 and 10 years. These survival rates are lower than previously described by Pratesi et al (8) and Maleux et al (4) (74.5%–88.5% at 5 y and 57.8% at 10 y). It is unclear why the life expectancy is lower in this group. It might be that patients had more comorbidities; however, patient characteristics are difficult to compare with other studies.

The overall estimated freedom from endoleaks was 47.8% at 5 years and 31.9% at 10 years. These low numbers of freedom from endoleaks can be explained by the high rate of patients who had a type II endoleak (35.9%) at some point during follow-up. Only 9 patients (3.6%) required a reintervention for a type II endoleak. The incidence of immediate type II endoleak is seemingly low and could have been an underestimation given the precipitous drop to 70% freedom from type II endoleak in **Figure 1** at early follow-up. Throughout the follow-up period, type Ia, Ib, II, and V endoleaks were reported in 4.8%, 2.8%, 35.9%, and 6.5% of patients. Aneurysmal sac growth was more often seen in the presence of an endoleak and with the use of the OP. In contrast, more sac diameter shrinkage was seen with the use of the LP, emphasizing the success of the modification of the device. Similar results were described by Hogg et al (13), who focused on sac behavior, and by Tanski et al (2) and Krajcer et al (14), who focused on the difference between the OP and LP devices.

No difference in outcome of patients who were treated within or outside the IFU of the device was observed. No further subanalysis of the various anatomic factors regarding why these patients were outside the IFU was performed, as they had 1, 2, or multiple causes, and therefore the sample sizes would be very small and biased.

In 2011, the C3 delivery system was introduced allowing multiple repositioning maneuvers of the stent graft before deployment. Challenging anatomy is associated with poorer short-term outcomes (7). Previous studies have demonstrated easy and safe repositioning of the proximal trunk with high proximal deployment accuracy (98.0% and 96.2% at the exact desired position) and good midterm clinical outcomes also in patients with unfavorable neck anatomy (3,5,15,16). In this study, 132 patients were treated with the C3 delivery system, and no significant difference in favor of the C3 delivery system compared with the older generations was observed with regard to technical success, type Ia endoleaks, or reinterventions.

The present study has some limitations. It is a retrospective study with data collected as available, and therefore some data were missing or causes of death were unknown. Only 63 of 118 patients completed > 5 years of follow-up. In 39 cases, the patient died within this period, and the remaining patients were LFU. Patients were included over a long time interval, and thus data may have been biased by the early days of experience with this device and the changes of the device itself. The rate of sac size change might be overestimated or underestimated because of a small error in size comparison. Measurements were performed by different physicians, and thus interobserver variability could be an issue. Although the total sample size was reasonable, some subgroup analyses could be slightly biased because of the small sample size.

In conclusion, the present study has shown that the GORE EXCLUDER EVAR device has demonstrated its durability over the long-term with acceptable reintervention rates and low aneurysm-related adverse events and mortality. Late new-onset endoleaks were observed and emphasize the need for long-term surveillance.

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Table E1. Number of Patients LFU per Follow-up Visit

Follow-up Visit	No. Patients Lost
3 months	1
9 months	1
18 months	2
4 years	1
5 years	1*
7 years	1
Total	7

LFU = lost to follow-up.
*Other hospital documented last follow-up.

Table E2. Overview per Year of Number of Patients Available for Follow-up, Deceased Patients and Patients LFU

Year	No. Patients Alive	No. Patients with Available Follow-up	No. Patients Died during Study Period	No. Patients LFU
0	248	248	0	0
1	194	194	10	2
2	150	117	14	2
3	121	92	14	0
4	96	70	5	1
5	75	46	8	1
6	59	44	7	0
7	46	30	3	1
8	40	25	0	0
9	31	21	3	0
10	26	15	2	0

LFU = lost to follow-up.

Table E3. Overview of Number of Patients per Follow-up Visit Including Collected Imaging Modalities

Follow-up Visit	No. Patients Completed Follow-up	Imaging Available		Often Combined Imaging	
		Overall	CT Angiography	Duplex Ultrasound	X-Ray
1 month	107	107 (43.1%)	50 (46.7%)	43 (40.2%)	14 (13.1%)
3 months	173	173 (69.8%)	126 (72.8%)	68 (39.3%)	9 (5.2%)
6 months	79	79 (31.9%)	19 (24.1%)	67 (84.8%)	33 (41.8%)
9 months	64	64 (25.8%)	13 (20.3%)	54 (84.4%)	15 (23.4%)
12 months	142	141 (56.9%)	17 (12.1%)	131 (92.9%)	100 (70.9%)
18 months	75	75 (30.2%)	11 (14.7%)	72 (96.0%)	34 (45.3%)
2 years	126	124 (50.0%)	17 (13.7%)	120 (96.8%)	86 (69.4%)
3 years	102	103 (41.8%)	14 (13.6%)	98 (95.1%)	63 (61.2%)
4 years	76	75 (30.2%)	8 (10.7%)	68 (90.7%)	50 (66.7%)
5 years	49	49 (19.8%)	5 (10.2%)	48 (98.0%)	38 (77.6%)