Prevalence of type II endoleak after elective endovascular aneurysm repair with polytetrafluoroethylene- or polyester-based endografts

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ABSTRACT

Objective: Type II endoleak is the most frequent complication after endovascular abdominal aneurysm repair. Polytetrafluoroethylene and polyester (PE) are the two most commonly used graft materials in endovascular aneurysm repair (EVAR) devices. Biological properties of the material might influence the appearance and persistence of type II endoleak (T2EL). Therefore, the aim of this study was to evaluate potential differences in the prevalence of T2EL after EVAR between polytetrafluoroethylene (PTFE) and PE endografts in patients electively treated for an infrarenal abdominal aortic aneurysm.

Methods: A single-center, retrospective, observational study was conducted between January 2011 and January 2022. Preoperative, procedural, and follow-up data were derived from electronic health records. Imaging included computed tomography scans, and/or duplex ultrasound examination. The primary end point was the prevalence of T2EL diagnosed within 1 year after EVAR. Secondary end points included the prevalence of T2EL throughout follow-up, early (≤30 days) and late (>30 days) T2EL, the rate of T2EL disappearance during the follow-up period, the prevalence of type I and III endoleak, and T2EL-related reinterventions.

Results: Follow-up was available for 394 patients, 245 in the PE and 149 in the PTFE group. The prevalence of T2EL diagnosed within 1 year after endovascular repair was 11.8% in the PE group and 21.5% in the PTFE group ($P = .010$). There was no significant difference in early (≤30 days) and late (>30 days) T2EL between groups ($P = .270$ and $P = .311$). There was no difference in the freedom from endoleak type II reinterventions between groups ($P = .877$).

Conclusions: The prevalence of T2EL after elective EVAR is significantly higher with the use of PTFE-based endografts compared with PE-based endografts. This difference is mostly based on T2EL diagnosed after 30 days of follow-up. (J Vasc Surg 2023;■:1-10.)

Keywords: Abdominal aortic aneurysm; Endovascular abdominal aneurysm repair; EVAR; Endoleak type II; Polytetrafluoroethylene (PTFE); Polyester

Endovascular aneurysm repair (EVAR) is the preferred treatment modality for most infrarenal abdominal aortic aneurysms (AAAs) in patients with a suitable anatomy.[1,2] Despite the lower periprocedural risks compared with open surgical repair, EVAR is also associated with long-term complications and subsequent reinterventions, with various types of endoleaks being the most frequent complication.

The most common type of endoleak is the type II endoleak (T2EL), characterized by collateral backflow outside the endograft in the aneurysm sac derived from aortic branches, usually from the lumbar arteries, the inferior mesenteric artery, or accessory renal arteries. T2ELs are mostly harmless and often spontaneously resolve within the first 6 months after EVAR.[3,4] According to the current guidelines, a secondary intervention may be considered when patients have a persistent T2EL that is associated with clinical significant (>10 mm) growth of the aneurysm sac.[1]

The biological properties of the prosthetic material covering the metal framework of endografts, typically either polytetrafluoroethylene (PTFE) or polyester (PE), might impact the occurrence and/or persistence of T2EL after EVAR.[5] To date, most evidence on the association between one specific prothesis type and the prevalence of T2EL is available of reports of investigational device exemption trials.[6-11] These reports showed a T2EL rate occurring at latest follow-up after EVAR ranging from 4.8% to 40.5% for PTFE endografts and 8.8% to

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28.0% for PE endografts.[6-11] Some studies demonstrated that particular characteristics of the PTFE material could contribute to the risk of developing a T2EL.[12,13] For example, PTFE is associated with antithrombotic and antiadhesive features caused by the negative charge on the surface. These features might cause a persistent T2EL by not thrombosing the collateral backflow in the aneurysm sac.[12,13] Studies to date, however, do not show consistent results.[14,15]

To date, a direct comparison between PTFE and PE endografts on the prevalence of T2ELs after EVAR has not been performed in a single center setting. The aim of the study was to study the impact of endograft material (PTFE or PE) on the occurrence and persistence of T2EL after elective EVAR performed for infrarenal aneurysm.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective analysis
- **Key Findings:** This retrospective analysis showed that the prevalence of type II endoleak (T2EL) is significantly higher when using polytetrafluoroethylene-based endografts (149 patients) compared with polyester-based endografts (245 patients). The biological properties of the graft material used in device design, may play a role in the prevalence of T2ELs after endovascular aneurysm repair.
- **Take Home Message**: The current study showed a higher rate of T2ELs in polytetrafluoroethylene-based endografts, compared with polyester-based endografts, in patients electively treated with endovascular aneurysm repair for an infrarenal abdominal aortic aneurysm, without an impact on the reintervention rates or the aneurysmal sac remodeling.

METHODS

A single-center, retrospective, observational study was performed on consecutive patients who were electively treated with EVAR for an infrarenal AAA between January 2011 and January 2021. Patients were excluded when treatment was fenestrated EVAR, chimney EVAR, thoracic EVAR, iliac branched technology, endovascular aneurysm sealing, or open surgical repair. Patients with a symptomatic or ruptured AAA were also excluded, as were patients who underwent EVAR revision.

Preoperative, procedural, and follow-up data were retrospectively derived from the electronic health records of the included patients and entered coded into Research Manager (Deventer, the Netherlands). These data were added to the existing AAA database that is updated every year by collecting retrospective data from the electronic health records of patients. Data acquisition stopped on March 1, 2022. This resulted in at least 1-year follow-up information for every patient in the database. If no 1-year follow-up was available, patients were excluded from the follow-up data analysis. The research was performed according to the declaration of Helsinki. A not-WMO-compulsory declaration (2022-13,485) and local approval (2022-2003) was obtained. Patients received a letter with an objection form if they did not want us to use their data for this project, which they could send in in case of objection.

End points. The primary end point was the prevalence of T2EL diagnosed within 1 year after the EVAR procedure. Secondary end points included the prevalence of T2EL through follow-up after the EVAR procedure, the incidence of early (≤30 days) and late (>30 days) T2EL, the rate of T2EL disappearance during the follow-up period, the prevalence of type I endoleak (T1EL) and type III endoleak (T3EL), and T2EL related reinterventions. The latest available information from the patient records was recorded, resulting in follow-up data from 1 to 10 years. Imaging used for detecting T2EL and evaluating remodeling was Duplex ultrasound (DUS) examination and/or computed tomography angiography (CTA), which were performed at the discretion of the treating physician. Imaging was done 1 month, 6 months, and yearly after EVAR in which standard DUS was used, and a contrast-enhanced CTA was mostly made on indication, in case of endoleaks and/or sac enlargement. T1EL, T2EL, and T3EL were included when they were diagnosed and/or confirmed on postprocedural imaging (CTA or DUS examination). Comparison on all end points were done between two groups of patients[1]: the PTFE group consisting of patients treated with PTFE-based endografts and the PE group consisting of patients treated with PE-based endografts.[2] Patients presenting with a T1EL or T3EL before diagnosis of T2EL were excluded from the follow-up analyses because their presence significantly affects the occurrence of T2EL (because lumbars and the inferior mesenteric artery acts as an outflow vessel).

Sac behavior was analyzed at 1 year and latest available follow-up. If changes were ≤5 mm, coding was stable sac. Shrinkage was coded if diameter was >5 mm smaller and growth was coded if diameter was >5 mm larger at follow-up.

Statistical analyses. The data for continuous variables were presented as mean ± standard deviation or median with interquartile range (IQR) if applicable. The data for discrete variables were presented as a number followed by percentage and 95% confidence interval (95% CI). T2EL was expressed and compared as monthly and yearly rates. Imputation of missing values was not applied. Subgroup analysis was achieved for patients treated with PTFE endografts and PE endografts. Depending on the distribution of the data, parametric or nonparametric tests were used for testing follow-up data, and differences in patient and procedural characteristics. Statistical analysis was performed by using IBM SPSS Statistics (SPSS version 25.0 for windows, IBM Corporation, Armonk, NY). A two-sided P value of <.05 was considered significant.

RESULTS

The original database included 1467 patients. After selection of patients adhering to the inclusion criteria, the study population was 409 patients (Fig 1). The PTFE group included 156 patients (38.1%) and the PE group 253 patients (61.9%). Baseline characteristics are depicted in Table I. The majority of the population was male (84.8%) with a mean age of 73.2 ± 8.1 years. Most patients were classified with American Society of Anesthesiologists score of 2 (44.5%) or 3 (47.8%) and had multiple cardiac vascular risk factors. There were no differences between the groups in the prevalence of cardiovascular risk factors. Baseline aneurysm characteristics are depicted in Table II. The mean maximum AAA diameter before EVAR was 57 ± 9 mm in the PTFE group and 61 ± 10 mm in the PE group ($P = .050$). The majority of the aneurysms was fusiform in both groups (80.3% in the PTFE group and 95.0% in the PE group; $P < .001$). There were no significant differences in the infrarenal neck parameters between groups.

Procedural details

Details of the device type used during the procedure for both groups are presented in Table III. The mean procedure time was 88 ± 37 minutes in the PTFE group and 88 ± 35 minutes in the PE group ($P = .427$). Procedural blood loss was 100 ± 200 mL in the PTFE group and 100 ± 250 mL in the PE group ($P = .334$). A concomitant procedure was performed in 53 patients (13%), 17 (10.9%) in the PTFE group vs 36 (14.2%) in the PE group ($P = .444$). Conversion to open repair occurred in one patient in the PE group (0.5%).

Follow-up data

Two patients died within 2 weeks after the EVAR procedure. One patient developed respiratory insufficiency, which was followed by peritonitis and sepsis and died on postoperative day 8. The other patient had a type Ia endoleak after the procedure. CTA after 3 days because of back pain showed a pseudoaneurysm of the superior mesenteric artery that was subsequently coiled. Hereafter, the kidney function declined, blood pressure became instable, and the patient developed neurological deterioration and died before a new CT scan was gotten.

After excluding patients without 1-year follow-up information available (n = 5), the study sample for follow-up data included 401 patients. Two patients had follow-up in another hospital and three patients died within 1 year after EVAR, one from urosepsis, one from lung cancer, and one unknown cause of death. The mean follow-up time was 3.4 ± 2.9 years in the PE group and 3.6 ± 2.8 years in the PTFE group ($P < .001$). Six patients had a T1EL before diagnosis of T2EL (and two showed a T3EL at the same time); they were excluded from the follow-up analyses.

The overall prevalence of T2EL through 1 year after EVAR was 15.5% (61/394; 95% CI, 11.9%-19.1%); in the PE group 11.8% (29/245; 95% CI, 8.6%-15.0%) and 21.5% in the PTFE group (32/149; 95% CI, 17.4%-25.6%) (P for difference between groups = .010) (Table IV). The overall T2EL rate through 2 years after EVAR was 17.8% (70/394; 95% CI, 14.0%-21.6%); 14.7% in the PE group (36/245; 95% CI, 11.2%-18.2%) and 22.8% in the PTFE group (34/149; 95% CI, 18.7%-26.9%) ($P = .041$). At latest follow-up, the overall T2EL rate was 23.1% (91/394; 95% CI, 18.9%-27.3%); 18.4% in the PE group (45/245; 95% CI, 14.6%-22.2%) and 30.9% in the PTFE group (46/149 (95% CI, 26.3%-35.5%) ($P = .004$).

The overall early T2EL rate was 8.1% (32/394; 95% CI, 5.3%-10.7%); in the PE group 6.9% 17/245; 95% CI, 4.4%-9.4%) and 10.1% in the PTFE group (15/153; 95% CI, 6.9%-12.7%) ($P = .270$). The overall late T2EL rate was 15.7% (62/394; 95% CI, 1212%-19.3%); 14.3% in the PE group (35/245; 95% CI, 10.8%-17.8%) and 18.1% in the PTFE group (35/153; 95% CI, 14.3%-21.9%) ($P = .311$).

Of the 91 T2ELs, 55 T2ELs (60.4%) spontaneously resolved during follow-up. The mean time until the disappearance was 29.4 ± 27.6 months in the PTFE group and 31.1 ± 28.0 in the PE group ($P = .819$).

Reinterventions for T2ELs. There were four reinterventions performed for T2Els within 1 year after EVAR, two in the PTFE group and two in the PE group ($P = .733$). At latest follow-up, there were 10 reinterventions for T2ELs in the entire study group, 5 in the PTFE group and 5 in the PE group. These reinterventions included coiling of the inferior mesenteric artery, coiling of the iliolumbar artery, coiling of the internal iliac artery, coiling of a T2EL, and CT-guided puncture with tissucol in the PE group. In the PTFE group, coiling and embolization of the inferior mesenteric artery, coiling of the internal iliac artery right, and extension of the stent until the external iliac artery, coiling of a T2EL, CT-guided tissucol injection, and coiling of the iliolumbar artery left and right was performed. The median time to the first reintervention for T2ELs was 1240 days (IQR, 351-2119 days) for the PTFE group and 459 days (IQR, 134-658 days) for the PE group ($P = .421$). After these reinterventions, four patients were diagnosed with a T2EL again during the follow-up period, three patients in the PTFE group and one patient in the PE group. At the latest follow-up, in the PE group, three patients had expansion (>5 mm) of the aneurysm sac, one patient had shrinkage (>5 mm) of the aneurysm sac, and one patient was diagnosed with a stable (no shrinkage or expansion) aneurysm sac. In the PTFE group, two patients had expansion (>5 mm) of the aneurysm sac, two patients had shrinkage (>5 mm) of

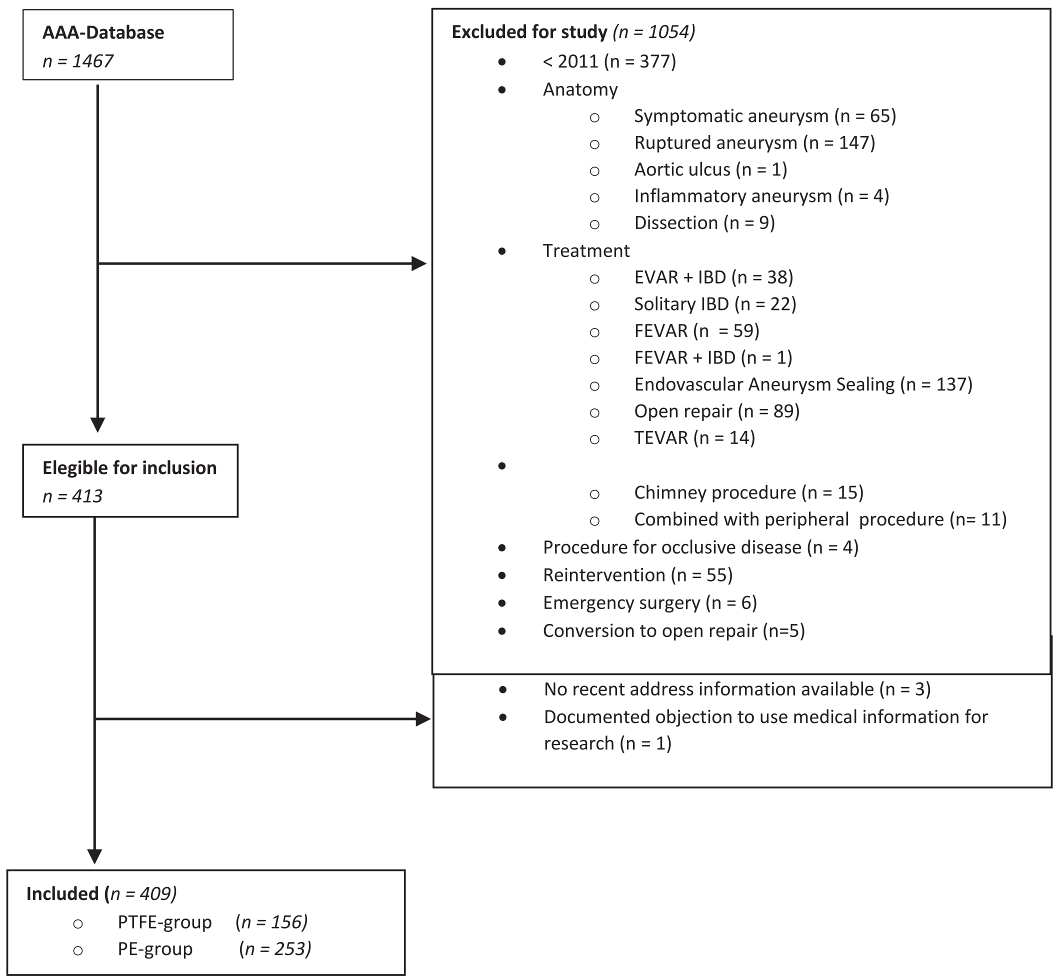

Fig 1. Flow chart of included study participants. *AAA*, Abdominal aortic aneurysm; *EVAR*, endovascular aneurysm repair; *IBM*, internal branched device; *FEVAR*, fenestrated endovascular aneurysm repair; *TEVAR*, thoracic endovascular aneurysm repair; *PTFE*, polytetrafluoroethylene; *PE*, polyester.

the aneurysm sac and, one patient was diagnosed with a stable (no shrinkage or expansion) aneurysm sac. The reintervention for T2EL-free survival is depicted in Fig 2.

T1EL and T3EL

At the latest follow-up, 27 patients were diagnosed with a T1EL and 4 with a T3EL. There were 15 patients—6 in the PTFE group and 9 in the PE group—who were diagnosed with a procedural T1EL that was no longer visible during the follow-up period. There were two patients, both in the PE group, who were diagnosed with a procedural T3EL, which was no longer visible during the follow-up period.

Thirteen patients—6 in the PE group and 7 in the PTFE group—were diagnosed with a T1EL or T3EL during follow-up after they were diagnosed with a T2EL. Ten patients were diagnosed with a T1EL—1 patient with a T3EL, 1 patient with both a T1EL and T3EL on the same day, and 1 patient with both T1 and T3, but on different dates. Five patients underwent reintervention for the treatment of a T1EL and or T3EL. These reinterventions included PTA for a type Ia endoleak, the placement of extensions together with coiling, and an emergency surgical procedure performed in another hospital.

In two patients, one in the PTFE group and one in the PE group, both a T1EL and T2EL were diagnosed at the same follow-up day. One patient in the PE group underwent reintervention for treatment of the T1EL. This reintervention included the placement of an aortic cuff.

Sac behavior over time

Overall, at the 1-year follow-up no differences in sac behavior was found between PTFE and PE grafts ($P = .425$). In the entire group, 58.1% (n = 229) of aneurysm sacs showed shrinkage compared with baseline diameter, 55.7% in the PTFE group and 59.6% in the PE group. Growth was registered in 1.8% of patients (n = 7), four in the PTFE group (2.7%) and three (1.2%) in the PE group, and stable sac behavior was seen in 39.1% (n = 154), 41.6% in the PTFE group and 37.6% in the PE group.

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Table I. Baseline characteristics of the study population overall and by prosthesis type

Characteristics	Overall (n = 409)	PTFE (n = 156)	PE (n = 253)	*P* value
Male gender	347 (84.8)	127 (81.4)	220 (87)	.13
Age, years	73.2 ± 8.1	72.0 ± 8.5	73.9 ± 7.8	.13
Body mass index, kg/m^2	26.7 ± 4.2	27.0 ± 4.0	26.5 ± 4.2	.27
ASA score				.85
1	2 (0.5)	1 (0.7)	1 (0.4)	
2	178 (44.5)	69 (45.1)	109 (44.1)	
3	191 (47.8)	74 (48.4)	117 (47.4)	
4	29 (7.3)	9 (5.9)	20 (8.1)	
Cardiac history	198 (52.9)	70 (51.1)	128 (54.0)	.59
Hypertension	290 (71.3)	105 (67.3)	185 (73.3)	.17
Hyperlipidemia	290 (78.4)	106 (72.6)	184 (82.1)	**.029**
Diabetes mellitus	77 (18.9)	29 (18.7)	48 (19.0)	.93
Current tobacco use	136 (34.8)	48 (31.6)	88 (36.8)	.29
Pulmonary disease	81 (22.3)	34 (24.1)	47 (21.1)	.50
Renal disease	126 (31.5)	50 (32.5)	76 (30.9)	.74
eGFR, mL/min/1.73 m^2	67.3 ± 18.5	68.3 ± 16.7	66.7 ± 19.5	.052
Lipid-lowering medication	259 (63.3)	99 (63.5)	160 (63.2)	.96
Anti coagulant medication	292 (71.4)	108 (69.2)	184 (72.7)	.45
Platelets	263 (64.3)	99 (63.5)	164 (64.8)	.48
Vitamin K antagonists	66 (16.1)	19 (12.2)	47 (18.6)	.12
Direct oral anticoagulant	26 (6.4)	13 (8.3)	13 (5.1)	.15

ASA, American Society of Anesthesiologists; *eGFR*, estimated glomerular filtration rate calculated by MDRD equation; *PE*, polyester *PTFE*, polytetrafluoroethylene.
Data are presented as number (%) or mean ± standard deviation.

Table II. Baseline aneurysm characteristics overall and by prosthesis type

	Overall (n = 409)	PTFE (n = 156)	PE (n = 253)	*P* value
Maximum diameter, mm	60 ± 10	57 ± 9	61 ± 10	.050
Infrarenal aortic neck diameter, mm	24 ± 4	23 ± 3	25 ± 4	.11
Infrarenal aortic neck length, mm	29 ± 13	32 ± 13	28 ± 12	.60
Angles between AAA and neck,°	42 ± 21	43 ± 21	41 ± 21	.99
Right common iliac artery diameter, mm	17 ± 8	18 ± 9	17 ± 7	.082
Left common iliac artery diameter, mm	16 ± 6	16 ± 7	16 ± 5	.17
Right external iliac artery diameter, mm	9 ± 2	10 ± 2	9 ± 2	.73
Left external iliac artery diameter, mm	9 ± 2	9 ± 2	9 ± 2	.95
Type of aneurysm				**<.001**
Fusiform	366 (89.5)	125 (80.1)	241 (95.3)	
Saccular	43 (10.5)	31 (19.9)	12 (4.7)	

AAA, Abdominal aortic aneurysm; *PE*, polyester *PTFE*, polytetrafluoroethylene.
Data are presented as number (%), mean ± standard deviation.
Bold indicates a two-sided *P* value of <.05 was considered significant.

At the latest available follow-up, again no differences in sac behavior were found between PTFE and PE grafts ($P = .131$). Overall, 62.9% (n = 248) showed shrinkage of the aneurysm sac compared with baseline, 58.4% in the PTFE and 65.7% in the PE group. Growth was reported in 6.1% (n = 24), 8.7% in the PTFE and 4.5% in the PE group. The remainder (30.2%, n = 119) showed stable sac behavior, 32.9% in the PTFE and 28.6% in the PE group.

The rate of ELT2 at the 1-year follow-up and at latest follow-up was highest in growing sacs and lowest in shrinking aneurysm sacs, as shown in Fig 3 ($P < .001$ for both).

Table III. Details of the device type used during the procedure overall and by prosthesis type

	PTFE (n = 156)	PE (n = 253)
Device type	Gore Excluder, 129 (82.7) Endologix AFX, 23 (14.7) Ovation 2, (1.3) Endologix Powerlink, 2 (1.3)	Medtronic Endurant, 239 (94.5) Endurant EVO, 7 (2.8) Vascutek anaconda 4, (1.6) Cook, 2 (0.8)
		Treo Bolton Medical, 1 (0.4)

PE, Polyester *PTFE*, polytetrafluoroethylene.
Data are presented as number (%).

Table IV. The incidence of postprocedural T1EL, T2EL, and T3EL at the 1-month, 1-year, 2-year, and latest follow-up overall and by prosthesis type

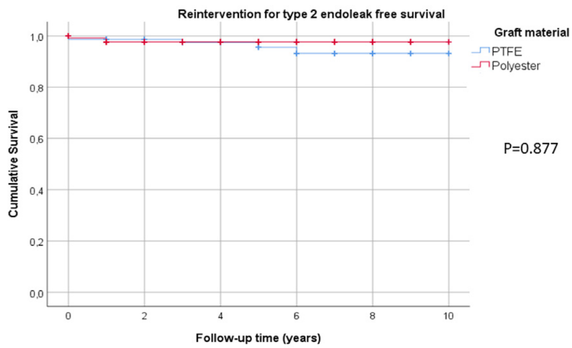
	Overall (n = 394)	PTFE (n = 149)	PE (n = 245)	*P* value
1 Month				
No endoleak	357 (90.6)	131 (87.9)	226 (92.2)	.15
T1EL	5 (1.3)	3 (2.0)	2 (0.8)	.30
T2EL	32 (8.1)	15 (101)	17 (6.9)	.27
T3EL	0 (0.0)	0 (0.0)	0 (0.0)	-
1 Year				
No endoleak	326 (82.7)	115 (77.2)	211 (86.1)	**.02**
T1EL	11 (2.8)	5 (3.4)	6 (2.4)	.60
T2EL	61 (15.5)	32 (21.5)	29 (11.8)	**.010**
T3EL	0 (0.0)	0 (0.0)	0 (0.0)	-
2 Year				
No endoleak	316 (80.2)	112 (75.2)	204 (83.3)	**.050**
T1EL	13 (3.3)	7 (4.7)	6 (2.4)	.23
T2EL	70 (17.8)	34 (22.8)	36 (14.7)	**.041**
T3EL	1 (0.3)	1 (0.7)	0 (0.0)	.20
Latest follow-up				
No endoleak	291 (73.9)	103 (69.1)	188 (76.7)	.10
T1EL	27 (6.9)	8 (5.4)	19 (7.8)	.36
T2EL	91 (23.1)	46 (30.9)	45 (18.4)	**.004**
T3EL	4 (1.0)	3 (2.0)	1 (0.4)	.12

PE, Polyester *PTFE*, polytetrafluoroethylene; *T1EL*, endoleak type 1; *T2EL*, endoleak type II; *T3EL*, endoleak type 3.
Data are presented as number (%).
Bold indicates a two-sided *P* value of <.05 was considered significant.

An overview of the diameters at all available follow-up moments (and mean follow-up times) are depicted in Table V, including the percentage of CT scans performed. At the early follow-up moments, approximately 10% to 16% of patients had a CT scan. At later follow-up times (after follow-up 6; mean, 3.1 years) the percentage of patients with CT scans increased.

DISCUSSION

The present study shows that the prevalence of T2EL is significantly higher when using PTFE-based endografts compared with PE-based endografts. The significantly higher prevalence is found through the 1-year, 2-year, and latest follow-ups after EVAR. Data from the present study indicate that biological properties of the graft material used in the design of EVAR devices may play a role in the prevalence of complications after EVAR, in this case the occurrence of T2EL. The clinical importance of T2EL has been a matter of debate ever since the introduction of EVAR. Although they rarely cause an aneurysm rupture, still many reinterventions are performed to treat T2EL. These reinterventions, in turn, are not always successful and do carry a risk for the patient. There was a randomized controlled trial that investigated an intervention to prevent T2EL; Samura et al[16] randomized patients at risk for T2EL between standard EVAR and



PTFE	0	1	3	5	8	10
No. At Risk	149	132	82	50	21	3
Freedom from EL2 reintervention (%)	100	98.7	97.5	95.6	93.2	93.2
SE	-	0.009	0.015	0.024	0.033	0.033
Polyester	0	1	3	5	8	10
No. At Risk	245	192	130	87	28	2
Freedom from EL2 reintervention (%)	100	97.7	97.7	97.7	97.7	97.7
SE	-	0.010	0.010	0.010	0.010	0.010

Fig 2. Reintervention for T2EL-free survival for both study groups. *EL,* Endoleak; *EL2,* type II endoleak; *PTFE,* polytetrafluoroethylene; *PE,* polyester; *SE,* standard error.

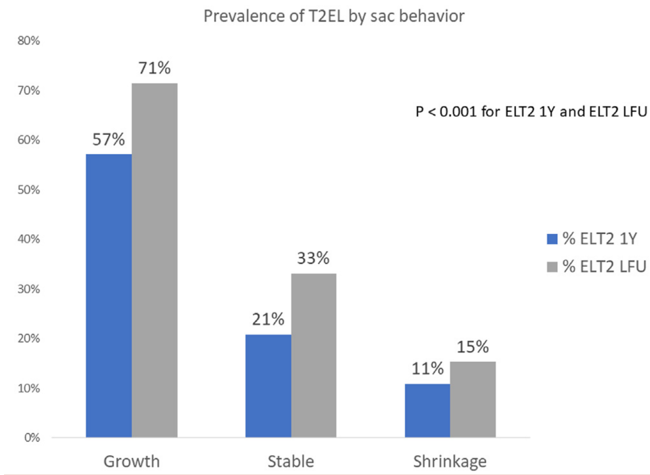


Fig 3. Prevalence of ELT2 by sac behavior. *ELT2,* Type II endoleak; *1Y,* 1-year follow-up; *LFU,* last follow-up available.

EVAR with embolization of the inferior mesenteric artery. They showed that preventive embolization resulted in fewer T2EL through 12 months of follow-up, which was accompanied by more aneurysm sac shrinkage.[16] Recently, it has been shown that shrinking aneurysms after EVAR are related to better outcomes compared with stable aneurysms, with regard to all-cause mortality, complications and re-interventions. T2EL are related to less aneurysm shrinkage after EVAR[17]; consequently, the higher incidence of T2EL observed with PTFE-based endografts may become relevant from this perspective. The current study does show a higher incidence of T2EL in PTFE grafts, however, without differences in sac behavior at 1 year and at latest follow-up between both graft types. A more in-depth analysis of the prevalence of T2EL in growing, stable, and shrinking aneurysm sacs showed the lowest rate of T2EL in the shrinking aneurysm sacs. Currently, methods of active sac management—filling the sac in conjunction with EVAR—are under study and may, therefore, be more relevant in these types of endografts. However, before drawing robust conclusions, prospective data are needed. The ADVANCE trial comparing the Endurant endograft with the Excluder endograft, which will start enrolling patients in 2023, will provide Class 1 evidence on the relation between graft types, T2EL, and sac remodeling.

The prevalence of T2EL depends on the timing and the mode of imaging. This factor may well explain the wide range in reported rates of T2EL in the literature. From a theoretical pathophysiological point of view, all patients with patent side branches will have a T2EL immediately after deployment of the EVAR device, whether it is visible on fluoroscopy or not. Moments after completion of EVAR, the patients in whom all flow thromboses, as well as the small percentage of patients without patent lumbar or inferior mesenteric arteries before EVAR, are truly free from T2EL. Subsequent follow-up DUS or CTA studies are current methods to assess the natural history of T2EL. Reporting freedom from T2EL could be illustrative, but several issues prohibit a valid Kaplan-Meier analysis: if T2EL is missed by imaging (false negative), freedom is mistakenly assumed; Kaplan-Meier analysis requires an irreversible end point (which closure of T2EL is probably not); and definition of censoring and populations at risk (type I or type III endoleak disturbs the natural history of T2EL) should be agreed upon. Current practice is to perform DUS examination first at follow-up visits and only perform CTA when problems are suspected, like an endoleak. The rate of endoleaks might be higher than currently shown, because the majority of imaging was DUS during the early follow-up phase, but the rate of CTAs increased with longer follow-up duration.

The reasons why T2EL are more prevalent in PTFE-based endografts is unclear. As mentioned, the antithrombotic and antiadhesive features of PTFE, caused by the negative charge on the surface, may play a role; however, other factors could be involved. In addition, the clinical consequences of the observed differences are unclear. Whether the higher incidence of T2EL also leads to more complications and/or more reinterventions, or a more favorable sac remodeling after EVAR at long-term follow-up, remains to be studied.[12,13] Other, relatively old, studies investigated differences in the prevalence of T2EL, but in those studies, devices were not analyzed together based on the material; device-specific outcomes were reported. One study indicated that there may be more T2EL with the use of PTFE-based endografts,[15] whereas another study only reported early T2EL

Table V. Overview of the diameters, mean FU time, and percentage of computed tomography (*CT*) scans during follow-up

	Diameter						FU time			Imaging modality		
	All		PTFE		PE							
	No.	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	All	PTFE	PE	All	PTFE	PE
Baseline diameter, mm	407	59.3 (9.9)	149	56.7 (9.1)	245	60.9 (10.0)	-	-	-	100%	100%	100%
Sac diameter 1 year, mm	390	51.4 (11.3)	149	49.0 (10.6)	241	52.9 (11.5)	-	-	-	-	-	-
Sac diameter at last FU, mm	391	49.9 (14.7)	149	47.8 (14.2)	242	51.3 (14.9)	-	-	-	-	-	-
Diameter FU 1, mm	373	55.8 (9.5)	138	52.7 (9.0)	230	57.6 (9.3)	1.2 (0.9)	1.2 (0.8)	1.3 (0.9)	43 (12.3)	14 (10.9)	29 (13.2)
Diameter FU 2, mm	355	52.2 (10.2)	136	49.5 (9.4)	213	54.0 (10.3)	7.0 (3.5)	6.9 (3.3)	7.0 (3.6)	40 (12.2)	20 (16.0)	20 (9.8)
Diameter FU 3, mm	296	50.0 (11.1)	113	48.2 (10.8)	177	51.2 (11.2)	14.6 (7.5)	14.4 (9.7)	14.7 (5.6)	36 (12.4)	15 (13.4)	21 (11.8)
Diameter FU 4, mm	256	49.2 (12.1)	100	48.3 (11.7)	151	49.8 (12.4)	1.5 (0.9)	1.5 (1.1)	1.5 (0.8)	29 (11.3)	18 (17.6)	11 (7.1)
Diameter FU 5, mm	220	47.4 (11.9)	84	47.0 (11.6)	131	47.6 (12.1)	2.3 (1.1)	2.1 (1.2)	2.4 (1.0)	30 (13.4)	10 (11.1)	20 (14.9)
Diameter FU 6, mm	194	47.2 (13.9)	73	46.8 (12.0)	116	47.5 (15.1)	3.1 (1.3)	3.0 (1.5)	3.2 (1.2)	22 (11.5)	7 (9.5)	15 (12.7)
Diameter FU 7, mm	153	47.1 (15.1)	60	46.3 (13.6)	89	47.6 (16.1)	3.9 (1.3)	3.7 (1.3)	4.0 (1.3)	27 (16.8)	11 (16.7)	16 (16.8)
Diameter FU 8, mm	115	46.7 (12.8)	39	46.9 (13.0)	73	46.5 (12.8)	4.5 (1.4)	4.4 (1.5)	4.6 (1.3)	26 (20.8)	11 (22.4)	15 (19.7)
Diameter FU 9, mm	108	49.5 (15.0)	38	49.2 (13.7)	68	49.7 (15.8)	4.9 (1.5)	4.8 (1.6)	5.0 (1.4)	21 (19.1)	9 (20.0)	12 (18.5)
Diameter FU 10, mm	88	48.6 (13.7)	34	50.3 (13.8)	52	47.4 (13.7)	5.6 (1.7)	5.3 (1.8)	5.9 (1.6)	19 (21.6)	11 (28.9)	8 (16.0)
Diameter FU 11, mm	62	50.6 (13.3)	23	48.5 (11.4)	39	51.8 (14.3)	6.2 (1.7)	6.1 (1.8)	6.3 (1.6)	15 (25.4)	4 (16.7)	11 (31.4)
Diameter FU 12, mm	43	51.8 (13.7)	14	50.1 (13.7)	29	52.7 (13.8)	6.5 (1.5)	6.6 (1.8)	6.4 (1.4)	11 (28.2)	4 (33.3)	7 (25.9)
Diameter FU 13, mm	32	51.7 (15.4)	11	47.0 (13.1)	21	54.1 (16.2)	6.8 (1.5)	7.0 (1.5)	6.7 (1.6)	5 (20.0)	-	5 (31.3)
Diameter FU 14, mm	23	53.1 (15.3)	9	47.7 (9.1)	14	56.6 (17.7)	7.1 (1.7)	7.0 (1.7)	7.1)1.7)	6 (35.3)	4 (50.0)	2 (22.2)
Diameter FU 15, mm	14	55.4 (15.5)	6	48.7 (9.5)	8	60.5 (17.8)	7.2 (1.7)	6.8 (1.3)	7.4 (1.9)	4 (40.0)	2 (40.0)	2 (40.0)
Diameter FU 16, mm	8	70.3 (25.3)	4	96.3 (29.5)	4	71.3 (25.0)	7.7 (1.9)	7.8 (1.9)	7.6 (2.1)	4 (57.1)	2 (50.0)	2 (66.7)
Diameter FU 17, mm	6	66.3 (14.7)	4	58.0 (7.5)	2	83.0 (8.5)	7.5 (1.4)	7.5 (1.3)	7.5 (2.1)	3 (75.0)	2 (66.7)	1 (100.0)
Diameter FU 18, mm	4	690. (10.2)	3	64.7 (6.7)	1	82.0	8.3 (1.5)	8.0 (1.7)	9.0	3 (75.0)	2 (66.7)	1 (100.0)
Diameter FU 19, mm	4	68.3 (11.4)	3	63.7 (8.3)	1	82.0	8.5 (1.3)	8.3 (1.5)	9.0	2 (100.0)	1 (100.0)	1 (100.0)
Diameter FU 20, mm	2	59.0 (1.4)	2	59.0 (1.4)	0	-	8.0 (0.0)	8.0 (0.0)	-	1 (100.0)	1 (100.0)	-

FU, Follow-up; *SD*, standard deviation.
[a]Mean in months for follow-up 1-3 and in years for follow-up 4-20.

rate for PTFE-based grafts, but could not confirm long-term results.[14] Because different prostheses were included in our analyses, we additionally analyzed the results of the Endurant vs Excluder only. There was a significantly greater prevalence of T2EL for the PTFE (Gore Excluder) through 1 year; 24.2% for the Excluder and 11.2% for the Endurant prosthesis ($P = .001$), with no difference in the rate of reinterventions ($P = .689$). The prevalence of T2EL at latest follow-up was 33.9% for the Excluder and 17.7% for the Endurant prosthesis ($P = .001$), with no difference in the rate of reinterventions ($P = .307$).

A factor that might play a role is the aneurysm type. In the PTFE group, the percentage of saccular aneurysms (19.9%) was significantly higher compared with the PE group (4.7%). In saccular aneurysms, there may be a lack of feeding vessels in the aneurysm sac, especially when they are anteriorly directed. In other words, there may be a lower likelihood of the development of T2EL in saccular aneurysms. Other investigators might argue that a higher rate of T2EL would be observed in saccular aneurysms because they tend to be associated with less preoperative mural thrombus. Although we do not have information on the direction of the saccular aneurysms, we analyzed the prevalence of T2EL by type of aneurysm. The prevalence of T2EL through 1 year of follow-up was 19.0% in saccular aneurysms and 15.1% in fusiform aneurysms ($P = .499$). Thus, the hypothesis that there would be fewer T2ELs in saccular aneurysms because of the lack of feeding vessels does not apply in our data. In fact, the percentage of T2EL is a bit higher in saccular aneurysms compared with fusiform aneurysms. T2EL through 1 year of follow-up is a bit more prevalent in saccular aneurysms treated with a PE graft (16.7%) compared with fusiform aneurysms treated with a PE graft (11.6%; $P = .595$). Looking at PTFE grafts, the prevalence of T2EL was 20.4% in saccular aneurysms and 21.8% in fusiform aneurysms ($P = .826$). These results fit to the hypothesis of there being fewer T2EL in saccular aneurysms, although not significant, and in PTFE grafts only.

In the current study, the PTFE group contained more saccular aneurysms, which might have accounted for a lower rate of T1EL in this group. The T1EL rate was 5.4% (n = 8) in the PTFE group and 7.8% (n = 19) in the PE group ($P = .363$); this assumption does not apply to our data.

Other factors than graft material, may also play a role in the prevalence of T2EL after EVAR.[15,18] For example, Ferreira et al. suggest that patients with postimplantation syndrome had fewer T2Els after EVAR, compared with patients without postimplantation syndrome.[18] Inflammation is known to increase procoagulant factors and also inhibits the natural anticoagulant pathways, causing a thrombotic tendency.[19] The study from Hynes et al[20] found evidence that endovascular repair has adverse effects, especially cardiac and aortic dysfunction. They concluded that the overall contrast of the prosthesis is related to these adverse effects, rather than the material used (PE of PTFE).[20] These results may be interesting topics for further research. A meta-analysis found no increased risk for PTFE-based endografts compared with PE-based endografts on the prevalence of T2EL.[17] A limitation of this review is that only randomized controlled trials were included and other clinical studies were excluded. This factor could cause the discrepancy with our study in the prevalence of T2EL.[17]

Limitations. This study was limited by its retrospective nature, making it susceptible to incomplete and missing data, which could have influenced the analysis. It would have increased the value of this study if data on the patency and diameters of the inferior mesenteric artery and lumbar arteries were available. However, because of the retrospective design, these data were not available. To minimize the impact of bias, there were predefined definitions of the follow-up events. Furthermore, patient selection may have caused a bias in the current study. All patients were discussed in a multidisciplinary meeting, but the final device selection was based on a combination of anatomical features, surgeon preference, and availability. One of the strengths of this study is that every effort was taken for blind retrieval, assessment, and analysis of outcomes.

CONCLUSIONS

The current study showed a higher rate of T2EL in PTFE-based endografts compared with PE-based endografts in patients electively treated with EVAR for an infrarenal AAA. Primary freedom from branch perfusion instead of T2EL rates could be an interesting new way of analyzing the influence of endograft material on continued perfusion of lumbar and inferior mesenteric arteries after EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: MR, SH, JB
Analysis and interpretation: MK, SH, JB
Data collection: MK
Writing the article: MK, SH
Critical revision of the article: MR, SH, JB
Final approval of the article: MR, MK, SH, JB
Statistical analysis: MK, SH, JB
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DISCLOSURES

M.M.P.J.R is a research consultant for W. L. Gore & Associates, Medtronic, Terumo Aortic, and Artivion.

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