Title

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Low-profile endografts are associated with increased risk of type I/III endoleaks at midterm follow-up of 1220 physician-modified fenestrated, branched endovascular repairs for complex abdominal and thoracoabdominal aortic aneurysms

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ABSTRACT

Objective: Physician-modified endografts (PMEGs) are widely used for complex abdominal and thoracoabdominal aortic repairs, offering versatility in patient-specific stent graft configurations. Low-profile (LP) endografts improve deliverability and decrease access site complications compared with standard-profile (SP) devices. However, concerns have been raised about the long-term durability of certain LP devices. Although LP devices have been incorporated into PMEGs at many centers, data on their impact on outcomes are limited. Therefore, this study compared outcomes of LP and SP endografts used with PMEGs using an international multicenter database.

Methods: A retrospective analysis of data on patients who received PMEGs at 19 international centers from 2009 to 2022 was conducted. Patients were grouped by LP or SP aortic endografts used for modification. Baseline patient characteristics, aortic pathologies, modification techniques, and outcomes were compared. Primary outcomes included technical success, 30-day mortality, and type I and III endoleaks. The secondary outcomes were major adverse events, access site complications, all-cause and aneurysm-related mortality, and target vessel instability during follow-up.

Results: Among 1220 patients included (393 LP, 827 SP), the LP group was older and had higher rates of congestive heart failure, any history of smoking, and an American Society of Anesthesiologists risk score of ≥3. LP devices were more commonly used in elective cases; with short neck aneurysms, postdissection aneurysms, and prior endovascular repairs; and during the latter one-half of the study period. Reinforced fenestration was the most common modification in both groups, with directional branches and preloaded components more common in the LP groups. The LP group required fewer access conduits and a lower radiation dose. There was no difference in technical success (92.5 LP vs 94.5% SP; $P = .19$), mortality (4.1 LP vs 6.8% LP; $P = .06$), major adverse events (23.1 LP vs 25.7% SP; $P = .38$), and access-site complications (8.1 LP vs 11.7% SP; $P = .06$) at 30 days as well as all-cause and aneurysm-related mortality and target vessel instability during follow-up. However, at a median follow-up of 20 months, significantly more type I or III endoleaks (23% LP vs 13% SP; $P < .001$) were seen in the LP group. Furthermore, the estimated 2-year branch-related endoleaks (type Ic, IIIc) were higher (hazard ratio, 1.65; $P = .014$) in the LP group.

Conclusions: The use of LP devices facilitated safe PMEG repair with a lesser need for access conduit. However, the higher rates of type I, type III, and branch-related endoleaks with LP devices raise concerns about their long-term durability; however, more study is required. Based on these data, the use of LP devices for PMEGs should be approached with caution. (J Vasc Surg 2025;■:1-12.)

Keywords: Complex abdominal aortic aneurysms; Fenestrated branched endovascular aortic repair; Physician modified endografting; Thoracoabdominal aortic aneurysms

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Fenestrated-branched endovascular aortic repair (FBEVAR) has emerged as a safe and effective treatment choice for patients with complex abdominal aortic aneurysms (AAAs) and thoracoabdominal aortic aneurysms (TAAAs).[1-5] Owing to the limited availability of custom-manufactured fenestrated-branched stent grafts, a growing number of physicians have embraced physician-modified endografts (PMEGs) as an alternative means to facilitate FBEVAR.[6,7] Although low-profile (LP) endografts decrease the risk of access complications,[8] recent data suggest that the material changes in the LP devices may result in higher risks of type III endoleaks and limb occlusions.[9-12] Although LP devices have been used successfully for PMEGs,[13] concerns about back-table modifications compromising durability remain untested. Therefore, this study aims to compare the outcomes of patients undergoing PMEG using standard-profile (SP) and LP devices for modification, leveraging the largest multicenter international data on PMEG to date.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective review
- **Key Findings:** Compared with the standard-profile (SP) physician-modified endograft (PMEG) group, older patients with higher comorbidity burden was treated with a low-profile (LP) PMEG. However, the overall endoleak rates were higher in the LP group (39% LP vs 21% SP; $P < .001$), primarily driven by higher rates of type I (11.3% LP vs 4% SP; $P < .001$) and type III endoleaks (18.3% LP vs 10.1% SP; $P < .001$). Specifically, these differences were driven by the higher type Ic (6.3% LP vs 1.3% SP; $P < .001$) and type IIIc (15.4% LP vs 6.2% SP; $P < .001$) endoleaks.
- **Take Home Message:** The use of LP devices with PMEGs for complex abdominal and thoracoabdominal aortic aneurysm carries a higher risk of branch-related endoleaks compared with SP PMEGs.

METHODS

Study population. A retrospective review was performed using an international multicenter PMEG database. The inclusion and exclusion criteria have been published previously.[6] Briefly, consecutive patients who underwent PMEG incorporating one or more visceral renal arteries for complex AAA and TAAA at the 19 participating centers between 2007 and 2022 were included. The institutional Ethics committee approval was obtained for the coordinating center (Ludwig Maximilian University Hospital, ref: 22-0155). In all participating centers, the study was approved or waived by the institutional review boards. All clinical presentations, including elective, symptomatic, and ruptured aneurysms, were included.

Device and modification details. LP devices were defined as those with fabric or wire constructions that enabled a reduced profile compared with their predecessors. All LP devices used nitinol frames and tighter woven polyethylene terephthalate (Dacron) graft material. A list of LP and SP devices used in the study is provided in Supplementary Table I (online only). Modification configurations included fenestrations, scallops, and directional antegrade/retrograde branches. Modification techniques including non-reinforced, reinforced fenestrations, placement of directional outer/inner branches on tubular thoracic endografts, or bifurcated abdominal endografts using thermal cautery or a scalpel.[14-16] Aortic arch PMEGs, modified iliac limbs, combination with parallel grafting, and in situ fenestrations were excluded. Patients were classified according to the base device used for modification into the SP or LP group. Use pattern of SP devices vs LP devices during the study period was noted.

Outcomes and definitions. Outcomes variables were defined according to the Society for Vascular Surgery (SVS) reporting standards for aortic aneurysms affecting visceral or renal segments.[17] Baseline patient characteristics included cardiovascular comorbidities, maximum aneurysm diameter, aneurysm extent, clinical presentation, history of aneurysm repair, aneurysm etiology, and family history of aneurysmal disease.

Procedural details included procedure and fluoroscopy times, radiation dose, contrast volume, and blood loss. Primary outcomes included technical success, 30-day mortality, type I or III endoleaks, and branch-related endoleaks (type Ic or IIIc). Secondary outcomes included major adverse events (MAEs), access site complications, all-cause and aneurysm-related mortality, and freedom from target vessel instability during follow-up. Technical success was defined as successful endovascular access and deployment of all devices, successful catheterization and stenting of all planned target vessels, absence of target vessel occlusion on completion angiography, and no persistent type I or III endoleak on computed tomography angiography within 30 days, according to the SVS reporting standards.[17] Target vessel instability was defined as any event related to a branch vessel that necessitates reintervention to maintain vessel patency or to address issues such as aneurysm rupture, death, occlusion, component separation, or endoleak associated with the branch vessel, according to the SVS reporting standards.[17]

MAEs were defined as a composite of all-cause mortality, myocardial infarction as reported by the sites, including non-ST elevation and ST elevation myocardial infarction, respiratory failure requiring prolonged (>24 hours beyond anticipated) mechanical ventilation or reintubation, renal function decline resulting in a >50% reduction in the

Table I. Baseline patient characteristics

Variable	No.	Total (n = 1220)	Low profile graft (n = 393)	Standard profile graft (n = 827)	*P* value
Age, years	1220	74 (68-79)	75 (69-80)	73.6 (67.1-79)	**.015**
Male sex	1220	921 (75.5)	284 (72.3)	637 (77.0)	.07
BMI	1085	26.3 (23.3-30)	26 (23-31)	26.7 (23.5-29.8)	.42
BMI >30	1085	270 (24.9)	111 (28.5)	159 (22.8)	**.038**
Coronary artery disease	1220	539 (44.2)	166 (42.2)	373 (45.1)	.35
CHF	1220	197 (16.1)	77 (19.6)	120 (14.5)	**.024**
Hypertension	1220	1074 (88.0)	353 (89.8)	721 (87.2)	.18
Hypercholesterolemia	996	633 (63.5)	210 (76.1)	423 (58.7)	**<.001**
Smoking	1212	853 (70.4)	306 (78.9)	547 (66.4)	**<.001**
COPD	1118	427 (38.2)	130 (34.8)	297 (39.9)	.10
Peripheral artery disease	1096	206 (18.8)	51 (18.4)	155 (18.9)	.85
Previous stroke	998	125 (12.5)	28 (10.8)	97 (13.1)	.35
Diabetes mellitus	1219	217 (17.8)	64 (16.3)	153 (18.5)	.34
Baseline creatinine, mg/dL	1095	1.1 (0.9-1.4)	1.0 (0.9-1.3)	1.1 (0.9-1.4)	.20
eGFR (CKD-EPI, presented in mL/min per 1.73 m^2)	1095	68.7 (51.7-87.9)	68.6 (53.7-87.3)	68.8 (49.6-87.9)	.85
Dialysis	974	30 (3.1)	10 (2.5)	20 (3.4)	.43
ASA risk score (≥3)	998	931 (93.3)	254 (98.4)	677 (91.5)	**<.001**

ASA, American Society of Anesthesiologists; *BMI*, body mass index; *CHF*, congestive heart failure; *eGFR*, estimated glomerular filtration rate; *CKD-EPI*, Chronic Kidney Disease Epidemiology Collaboration; *COPD*, chronic obstructive pulmonary disease.
Values are median (interquartile range) or number (%).
Boldface entries indicate statistical significance.

baseline estimated glomerular filtration rate calculated by the Chronic Kidney Disease Epidemiology Collaboration formula or new-onset dialysis, bowel ischemia requiring surgical resection or unresponsive to medical therapy as defined by the SVS reporting standards, major stroke, and paraplegia (grade 3).

Statistical analysis. All statistical analyses were performed using STATA version 18 (Statistics/Data analysis, StataCorp). Continuous variables with normal distribution were expressed as mean and standard deviation, and the median, first and third quartiles (Q1-Q3) were used for non-normally distributed variables. Categorical variables are expressed in percentages. The pairwise deletion method was used for missing data. Comparative analyses were performed between the SP and LP groups, using univariate tests, including $\chi 2$ test, Fisher's exact test, Student *t* test, and Mann-Whitney *U* test when appropriate. Odds ratios (OR) with 95% confidence intervals (CIs) were reported. Time-to-event outcomes were analyzed using Kaplan-Meyer curves and life tables, univariate comparisons performed using the log-rank analysis. All analyses were considered statistically significant if a two-tailed *P* value of <.05 was observed.

Additionally, multivariable logistic regressions as well as Cox proportional hazard model were performed. Variables were selected based on clinical assessment based on prior knowledge in addition to significant baseline differences ($P < .05$) on univariable analysis. The proportional hazards assumption was assessed using Schoenfeld residuals. To mitigate confounding from the learning curve and evolving practice patterns, a subgroup analysis was performed, comparing SP and LP groups among patients who underwent repair in 2014 and on, when LP devices were introduced into PMEG practice. Additional subgroup analyses were performed for patients whose repair constructs included only fenestrations and those including at least one directional branch.

RESULTS

During the study period, 1220 patients received PMEGs at 19 centers (10 European, 9 US), with 827 (68%) treated with SP devices and 393 (32%) with LP PMEGs. The LP group was older compared with the SP group (75.0 years vs 73.6 years; $P = .015$). The majority of patients were male in both groups (72% vs 77%; $P = .07$). A history of coronary artery disease, hypertension, chronic obstructive pulmonary disease, peripheral artery disease, stroke, diabetes mellitus, dialysis dependency, and estimated glomerular filtration rate were similar between the groups. Obesity (body mass index of >30), congestive heart failure (CHF), hypercholesterolemia, smoking,

Table II. Aneurysm extent and anatomical characteristics

Variable	No.	Total (n = 1220)	LP graft (n = 393)	SP graft (n = 827)	*P* value
Aneurysm size, mm[a]	1181	65 (58-76)	64 (57-74)	66 (58-77)	**.033**
Clinical presentation	1220				**<.001**
Elective		787 (64.1)	302 (76.8)	485 (58.6)	
Symptomatic		310 (25.4)	73 (18.6)	237 (28.7)	
Rupture		123 (10.1)	18 (4.6)	105 (12.7)	
Aneurysm subtype	1220				**<.001**
Short neck/Juxtarenal AAA		229 (18.8)	102 (25.9)	127 (15.4)	
Pararenal AAA		351 (28.8)	89 (22.6)	262 (31.7)	
TAAA		640 (52.5)	202 (51.4)	438 (53.0)	
Subtype		495 TAAAs with subtype reported[a]			
Extent I		50 (10.1)	25 (12.4)	25 (8.5)	
Extent II		137 (27.7)	74 (36.8)	63 (21.4)	
Extent III		91 (18.4)	28 (13.9)	63 (21.4)	
Extent IV		190 (38.4)	65 (32.3)	125 (42.5)	
Extent V		27 (5.4)	9 (4.5)	18 (6.1)	
Previous aortic repair	1220	502 (41.1)	190 (48.3)	312 (37.7)	**<.001**
Open aortic repair		185 (15.1)	33 (8.4)	152 (18.4)	
Endovascular aortic repair		134 (34.1)	134 (34.1)	138 (16.7)	
Open and endovascular aortic repair		45 (3.7)	23 (5.8)	22 (2.7)	
Rescue of failed EVAR	1121	128 (11.4)	82 (21.9)	46 (6.2)	**<.001**
Postdissection aneurysm	1220	75 (6.1)	43 (10.9)	32 (3.9)	**<.001**
Connective tissue disease	1220	9 (0.7)	4 (1.0)	5 (0.6)	.62
Family history of aneurysmal disease	664	45 (6.8)	15 (5.9)	30 (7.3)	.48

AAA, abdominal aortic aneurysm; *EVAR*, endovascular aneurysm repair; *LP*, low-profile; *SP*, standard profile; *TAAA*, thoracoabdominal aortic aneurysm.
Values are median (interquartile range) or number (%).
Boldface entries indicate statistical significance.
[a]Aneurysm classification according to Crawford's classification modified by Safi.

American Society of Anesthesiologists (ASA) risk score of ≥3 were more frequent in the LP group (Table I).

Elective repairs were performed more frequently in the LP group (76.8% LP vs 58.6% SP), whereas symptomatic (18.6% LP vs 28.7% SP) and rupture (4.6% LP vs 12.7% SP) presentations were more common in the SP group ($P <$ .001). Aneurysm extent differed between the groups, with juxtarenal TAAAs being more common in the LP group and pararenal AAAs more common in the SP group ($P <$ .001). Postdissection aneurysms were more common in the LP group (10.9% LP vs 3.9% SP; $P <$ .001). The maximum aortic diameter was slightly larger in the SP group (66 mm SP vs 64 mm LP; $P <$ .033). A history of prior aortic repair was more common in the LP group (48.3% LP vs 37.7% SP; $P <$ .001), with prior endovascular repair being the most common in the LP group and open repair in the SP group. Specifically, the use of a PMEG to rescue failed infrarenal EVAR was more common in the LP group (21.9% LP vs 6.2% SP; $P <$ .001). The low prevalence of connective tissue disease and a family history of aneurysm disease were seen in both groups (Table II).

Overall, fenestrations were the most common modification type. Directional branches were more frequently used in the LP group (BEVAR 5.3% vs 2.7%; FBEVAR 14.7% vs 12.7%; $P = .041$). The LP group also had a greater number of target vessels incorporated, with the majority having four or more (76.3% LP vs 59.9% SP; $P <$ .001). Additionally, preloaded wires were used more often in the LP group (33.9% LP vs 9.5% SP; $P <$ .001). (Supplementary Table II, online only).

Most LP cases were completed with percutaneous accesses only (89.3%), a significantly higher percentage compared with the SP group (60.9%; $P <$ .001). The LP group had a lower rate of access conduit use (5.9% LP vs 10.8% SP; $P <$ .013). Access complications were seen in 11.7% of SP patients compared with 8.1% of LP patients; however, this difference did not attain statistical significance ($P = .06$). Compared with men, women had higher use of access conduit (13.8% women vs 6.8% men; $P = .003$) and this difference was more marked in the SP group (20.0% women SP vs 8.5% men SP; $P = .002$), and not observed in the LP group (8.7% women LP vs 4.8% men LP; $P = .15$). Women also

Table III. Operative details

Variable	No.	Total (n = 1220)	LP graft (n = 393)	SP graft (n = 827)	*P* value
Percutaneous access	877	643 (73.3)	343 (89.3)	300 (60.85)	**<.001**
Unilateral		122 (13.9)	73 (19.0)	49 (9.9)	
Bilateral		521 (59.4)	270 (70.3)	251 (50.9)	
Upper arm access	876	493 (56.3)	202 (52.6)	291 (59.1)	.053
CSF drainage	1220	344 (28.2)	114 (29.0)	230 (27.8)	.66
Femoral/iliac conduit	789	67 (8.5)	22 (5.9)	45 (10.8)	**.013**
Fusion imaging	657	425 (64.7)	250 (68.7)	175 (69.7)	**.017**
Total procedure time, minutes	1132	264 (194-352)	256 (180-348.5)	266 (292-359)	.06
Endovascular procedure time, minutes	103	189 (138-260)	211 (135-250)	188 (142-265)	.83
Radiation dose, air kerma, mGy	532	1756 (974-3326)	1318 (776-2177)	2495 (1400-4600)	**<.001**
Fluoroscopy time, minutes	1064	73.6 (52-105)	69.1 (51-97.5)	76 (53-11)	**.005**
Contrast used, mL	996	125 (80-200)	120 (83.5-195.5)	129 (80-200)	.99
Blood loss, mL	963	300 (150-500)	200 (100-400)	300 (200-750)	**<.001**
Blood loss >1000 mL	1192	134 (11.2)	18 (4.4)	117 (14.6)	**<.001**

CSF, cerebrospinal fluid; *LP*, low-profile; *SP*, standard profile.
Values are number (%) or median (interquartile range).
Boldface entries indicate statistical significance.

experience higher rates of access complications compared with men (16.7% women vs 8.6% men; $P < .001$). This difference persisted in both the SP group (18.4% women SP vs 9.7% men SP; $P = .001$) and the LP group (13.8% women LP vs 6% men LP; $P = .012$) (Supplementary Table III, online only).

Although the preloaded wire technique was more common in the LP group, upper extremity access rates were similar between the groups (52.6% LP vs 59.1% SP; $P = .053$). Total procedure time, endovascular time, and contrast use were comparable. However, the LP group had shorter fluoroscopy time (69.1 minutes LP vs 76 minutes SP; $P < .005$) and lower estimated blood loss (200 mL LP vs 300 mL SP; $P < .001$) (Table III).

Technical success was high for both groups (92.5% LP vs 94.5% SP; $P = .19$). Thirty-day mortality was similar (4.1% LP vs 6.8% SP, $P = .06$), with nearly one-quarter of the patients in each group experiencing MAEs (23.1% LP vs 25.7% SP; $P = .38$). Acute kidney injury (13.7% LP vs 10.7% SP; $P = .18$) was the most common adverse events in both groups. Spinal cord ischemia was similar between the groups (6.4% LP vs 6.0% SP; $P = .83$), but stroke was higher in the SP group (2.3% LP vs 5.9% SP; $P = .005$).

Early reinterventions (within 30 days) were more common in the SP group (15.7% SP vs 11.6% LP; $P = .028$), with most of them related to the aorta or its side branches (Table IV).

At a median follow-up of 20 months (SP 28.2 months vs LP 12.0 months; $P < .001$), three patients in each group required open conversion (0.8% LP vs 0.6% SP; $P = .69$). The reasons for conversion included graft infection (1 SP, 2 LP), continued aneurysm growth owing to type II endoleak (1 LP, 1 SP), and rupture (1 SP). In addition to one patient who underwent open conversion for rupture, five other ruptures occurred (4 SP [0.9%] vs 1 LP [0.3%]; $P = .25$). The causes of rupture included a type IIIc endoleak from the superior mesenteric artery bridging stent and the aortic component (1 SP), rupture of the descending thoracic aneurysm proximal to the PMEG treatment zone (1 SP), type IIIa endoleaks between fenestrated and bifurcated components (1 SP, 1 LP), an aortoduodenal fistula (1 SP), and endograft infection (1 SP). Of the six patients with rupture, four declined further intervention and died. One patient underwent bridging TEVAR for a type IIIa endoleak and died 1 month later from an unknown cause.

Overall endoleak rates were higher in the LP group (39% LP vs 21% SP; $P < .001$), primarily driven by higher rates of type I endoleaks (11.3% LP vs 4.0% SP; $P < .001$) and III endoleaks (18.3% LP vs 10.1% SP; $P < .001$). Specifically, these differences were driven by the higher type Ic endoleaks (6.3% LP vs 1.3% SP; $P < .001$), and type IIIc endoleaks (15.4% LP vs 6.2% SP; $P < .001$). The overall branch-related endoleaks (type Ic or IIIc) were more frequent in the LP group (16.9% LP vs 7% SP; $P < .001$). Device migration was rare in both groups (1.4% LP vs 0.3% SP; $P = .1$), and rates of aneurysm sac regression were similar (Table V).

Kaplan-Meier estimates showed similar overall survival at 2 years between groups (66.3% LP vs 60.5% SP; hazard ratio [HR], 0.77; $P = .054$) (Fig 1). Freedom from reintervention was also similar (50.2% LP vs 57.1% SP; HR, 1.09; $P = .48$) (Fig 2), as was freedom from the composite outcome of branch occlusion and branch-related reintervention (65.2% LP vs 73.7% SP; HR, 0.90; $P = .63$).

Table IV. Thirty-day outcomes

Variable	No.	Total (n = 1220)	LP graft (n = 393)	SP graft (n = 827)	*P* value
Technical success	1121	1052 (93.8)	346 (92.5)	706 (94.5)	.19
30-Day mortality	1220	72 (5.9)	16 (4.1)	56 (6.8)	.06
Elective	787	32 (4.1)	12 (4.0)	20 (4.1)	
Symptomatic	310	24 (7.7)	3 (4.1)	21 (8.9)	
Ruptured	123	16 (13.0)	1 (5.6)	15 (14.3)	
MAEs at 30 days	1097	275 (25.1)	64 (23.1)	211 (25.7)	.38
Any adverse events at 30 days	1103	351 (31.8)	88 (31.2)	263 (32.0)	.80
Myocardial infarction	1220	43 (3.5)	8 (2.0)	35 (4.2)	.052
Respiratory failure	1220	89 (7.3)	21 (5.3)	68 (8.2)	.071
Stroke	1220	58 (4.7)	9 (2.3)	49 (5.9)	**.005**
Spinal cord ischemia (any grade)	1220	75 (6.1)	25 (6.4)	50 (6.0)	.83
Grade 1		22 (1.8)	13 (3.3)	9 (1.1)	
Grade 2		25 (2.0)	2 (0.5)	23 (2.8)	
Grade 3		28 (2.3)	10 (2.5)	18 (2.2)	
Acute kidney injury (any)	1097	126 (11.5)	38 (13.7)	88 (10.7)	.18
Increase in creatinine ×2 (no dialysis)		81 (7.4)	24 (8.7)	57 (7.0)	
Temporary dialysis		22 (2.0)	6 (2.2)	16 (1.9)	
Permanent dialysis		23 (2.1)	8 (2.9)	15 (1.8)	
Bowel ischemia	1220	71 (5.8)	21 (5.3)	50 (6.0)	.62
Access-related complications	1220	129 (10.6)	32 (8.1)	97 (11.7)	.06
Early reintervention (30-day)	989	140 (14.1)	46 (11.6)	94 (15.7)	**.028**
Aortic/branch related		101 (10.2)	28 (7.1)	73 (12.2)	
Nonaortic/branch related		39 (3.9)	18 (4.5)	21 (3.5)	

LP, Low-profile; *MAE*, major adverse event; *SP*, standard-profile.
Values are number (%).
Boldface entries indicate statistical significance.

However, the higher rate of branch-related endoleaks in the LP group remained significant on log-rank analysis (freedom from branch-related endoleak: 70.9% LP vs 81.2% SP; HR, 1.65; $P = .014$) (Fig 3).

Multivariable logistic regression models were constructed for type I or type III endoleaks, as well as branch-related endoleaks. Covariates included in the models were age, sex, use of LP graft, obesity, hypercholesterolemia, smoking, ASA score of ≥3, urgency of repair, aneurysm diameter, post-dissection, aneurysm extent, previous aortic repair, device design incorporating directional branches, and incorporation of three or more target vessels. On multivariable logistic regression analysis for type I or III endoleaks, the use of LP devices was the strongest independent risk factor (OR, 2.34; 95% CI, 1.33-4.13; $P = .003$). Other independent risk factors included urgency of repair (elective, symptomatic, or ruptured) (OR, 2.23; 95% CI, 1.24-4.33; $P = .008$), thoracoabdominal aneurysm extent (OR, 1.67; 95% CI, 1.06-2.61; $P = .026$), three or more target vessels (OR, 1.98; 95% CI, 1.03-3.80; $P = .04$), and modifications incorporating directional branches (OR, 1.86; 95% CI, 1.19-2.90; $P = .006$). Age, ASA score of ≥3, postdissection aneurysm, and aneurysm diameter were not associated with the risk of type I or III endoleaks.

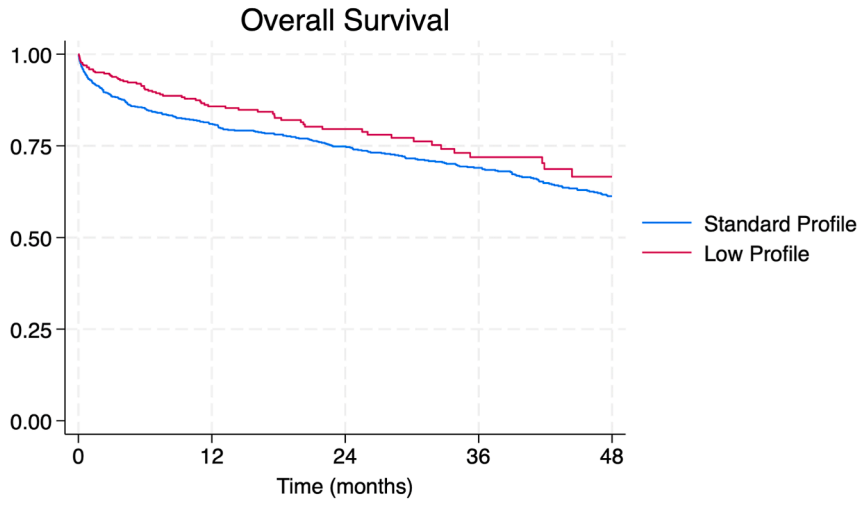
On multivariable logistic regression analysis for branch-related endoleaks, use of LP (OR, 2.23; 95% CI, 1.18-4.21; $P = .013$), incorporation of three or more target vessels (OR, 3.59; 95% CI, 1.26-10.2; $P = .017$), and history of previous open or endovascular aortic repairs (OR, 1.69; 95% CI, 1.04-2.76; $P = .034$) were independent risk factors. Thoracoabdominal aneurysm extent, design incorporating directional branches, age, ASA score of ≥3, postdissection aneurysm, and aneurysm diameter were not independent risk factors for increased branch-related endoleaks.

Subgroup analysis for contemporary SP and LP PMEG performed in 2014 and after. The distribution of cases over the study period is shown in Fig 4. LP devices were introduced in 2012, became the dominant device of choice for modification in 2019 and 2020, and then declined thereafter (Fig 4). To account for the learning curve and evolving practice patterns, a subgroup analysis was performed on SP and LP PMEG cases from 2014 onward as the midpoint of the study period. This strategy resulted in a balanced sample size between the SP

Table V. Follow-up outcomes

Variable	No.	Total (n = 1220)	LP graft (n = 393)	SP graft (n = 827)	*P* value
Follow-up, months	1220	20 (5-48.7)	12 (4.6-26)	28.2 (5.4-64.1)	**<.001**
Patients who survived hospital stay and have follow-up >30 days	1220	1149 (94.2)	377 (95.9)	772 (93.3)	.07
Overall death rate	1097	275 (25.1)	64 (23.1)	211 (25.7)	.38
Overall reintervention rate	989	302 (30.5)	116 (29.6)	186 (31.2)	.60
Endoleak	1078	288 (26.7)	133 (39.1)	155 (21.0)	**<.001**
Rate of type I or III endoleaks	1078	178 (16.4)	79 (23.0)	99 (13.4)	**<.001**
Rate of type I endoleaks	1086	69 (6.3)	38 (11.3)	30 (4.0)	**<.001**
Ic		32 (2.9)	22 (6.3)	10 (1.3)	
Rate of type III endoleaks	1087	138 (12.7)	63 (18.3)	75 (10.1)	**<.001**
IIIc		99 (9.1)	53 (15.4)	46 (6.2)	
Rate of any branch-related endoleak	1084	110 (10.1)	58 (16.9)	52 (7.0)	**<.001**
Rate of open conversion	871	6 (0.7)	3 (0.8)	3 (0.6)	.69
Rate of secondary rupture	965	6 (0.6)	1 (0.3)	5 (0.9)	.25
Aneurysm sac changes:	883				
Regression		377 (42.7)	138 (39.4)	239 (44.8)	.09
Stable		380 (43.0)	152 (43.4)	228 (42.8)	
Expansion		126 (14.3)	60 (17.1)	66 (12.4)	
Main device migration	712	6 (0.8)	5 (1.4)	1 (0.3)	.10

BEVAR, Branched endovascular aneurysm repair; *fEVAR*, fenestrated endovascular aortic repair; *LP*, low-profile; *SP*, standard-profile; *TV*, target vessel.
Values are median (interquartile range) or number (%).
Boldface entries indicate statistical significance.

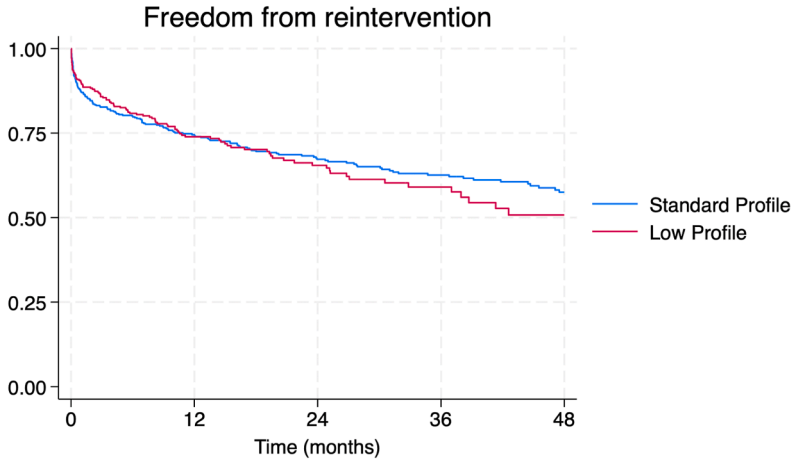


Follow-up (months)	0	12	24	36	48
LP at risk	391	198	112	61	25
SP at risk	826	546	446	364	287

Fig 1. Overall survival. *LP*, low profile; *SP*, standard profile.

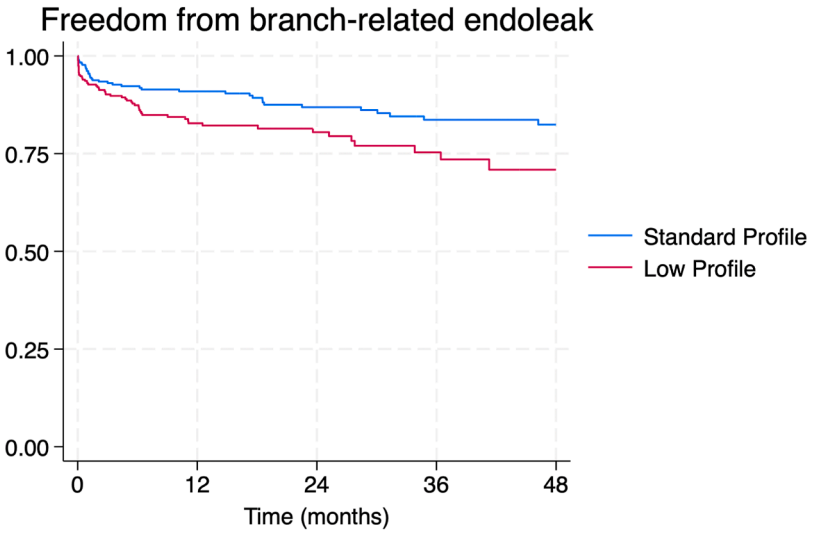
(n = 342) and LP (n = 369) groups for this subgroup analysis.

Consistent with the overall comparisons, patients in the LP subgroup were older and more likely to be obese, have CHF, hypertension, hypercholesterolemia, a history of smoking, and an ASA score of ≥3. The maximum aortic diameter was similar between groups. However, the LP group had a higher prevalence of extent I, II,



Follow-up (months)	0	12	24	36	48
LP at risk	387	159	86	42	18
SP at risk	539	274	195	138	89

Fig 2. Freedom from reintervention. *LP*, low profile; *SP*, standard profile.



Follow-up (months)	0	12	24	36	48
LP at risk	354	148	85	42	14
SP at risk	366	182	130	94	64

Fig 3. Freedom from branch-related endoleaks (type Ic, IIIc). *LP*, low profile; *SP*, standard profile.

and III TAAAs; chronic dissections; and prior aortic repairs, including EVAR.

Femoral access was more frequently percutaneous, and upper extremity access more common in the LP subgroup. Although the total operative and fluoroscopy times were similar, radiation dose was significantly lower in the LP subgroup (1317 mGy LP vs 2207 mGy SP; $P < .001$), as was the estimated blood loss (200 mL LP vs 300 mL SP; $P < .001$). Technical success rates were high in both groups (92.4% LP vs 94.1% SP; $P = .35$). Although 30-day mortality and MAEs were also similar, unadjusted rates of spinal cord ischemia (6.2% LP vs 3% SP; $P = .034$) and acute kidney injury (13.9% LP vs 8.6% SP; $P = .027$) were higher in the LP subgroup. Rates of postoperative myocardial infarction, respiratory failure, stroke, gastrointestinal complications, and access-related complications were similar between the subgroups.

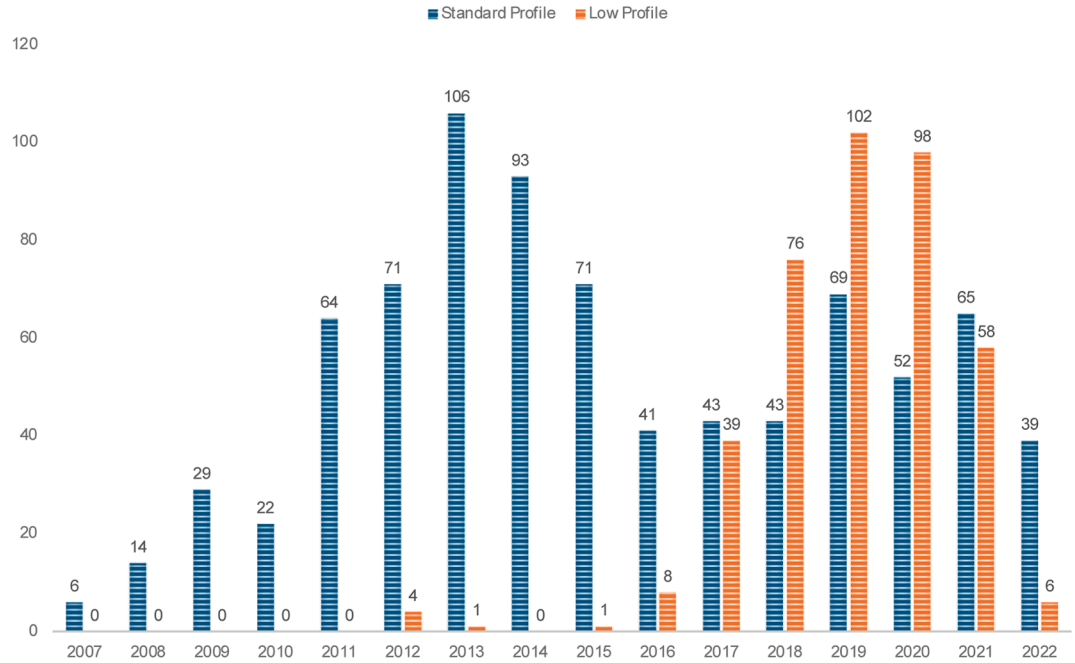


Fig 4. Annual case distribution between low-profile (LP) and standard-profile (SP) physician-modified endografts (PMEGs).

At a median follow-up of 13 months, open conversion, device migration, and aortic rupture were rare in both subgroups. Aneurysm sac remodeling was similar, with most patients exhibiting regression or stability.

Kaplan-Meier analysis showed similar overall 2-year mortality rates in both subgroups. Although univariate log-rank analysis suggested lower 2-year aortic-related mortality rates in the LP subgroup, this difference was not significant on multivariate Cox proportional hazards analysis (HR, 0.66; 95% CI, 0.29-1.54; $P = .34$). Freedom from reintervention and target vessel instability were also similar between the subgroups. Endoleak rates remained significantly higher in the LP subgroup (38.7% vs 19.3%; $P < .001$), again driven primarily by increased rates of type Ic endoleaks (6.4% LP vs 1.6% SP; $P = .01$) and type IIIc endoleaks (15.23 LP vs 5.8% SP; $P < .001$).

Subgroup analysis for fenestrated PMEG vs fenestrated branched PMEG. Patients with PMEGs incorporating directional branches were more likely to have type I endoleaks (13.6% FBEVAR vs 6.2% FEVAR; $P < .001$), specifically type Ia endoleaks (5.3% FBEVAR vs 1.9% FEVAR; $P = .01$), type Ic endoleaks (7.7% FBEVAR vs 2.3% FEVAR; $P < .001$), as well as type III endoleaks (22.3% FBEVAR vs 11% FEVAR; $P < .001$), specifically type IIIc endoleaks (17.1% FBEVAR vs 7.7% FEVAR; $P < .001$).

Excluding the patients who had at least one directional branch in their PMEG design, patients who had fenestrated PMEG using LP had higher rate of type Ic endoleaks (4.7% LP FEVAR vs 1.2% SP FEVAR; $P = .002$) and IIIc endoleaks (11.7% LP FEVAR vs 5.9% SP FEVAR; $P = .003$), compared with the SP. Type Ia, Ib, and IIIa or IIIb endoleaks were similar between the LP and SP fenestrated cohorts.

Comparing patients who received a PMEG with one or more directional branches, the LP subgroup had more type Ic endoleaks (14.1% LP FBEVAR vs 3.1% SP FBEVAR; $P = .008$), and type IIIc endoleaks (30% LP FBEVAR vs 7.1% SP FBEVAR; $P < .001$), but similar type Ia, Ib, and type IIIa/b endoleaks compared with the SP subgroup (Supplementary Table IV, online only).

DISCUSSION

Our data support the procedural safety of PMEG using LP devices, with similarly high technical success and low 30-day mortality compared with SP devices. This finding was observed despite the LP group comprising older patients with a higher comorbidity burden, including increased rates of CHF, obesity, and patients with an ASA grade of ≥3. Furthermore, patients in the LP group had more extensive aortic disease, including a greater prevalence of TAAA and postdissection aneurysms, a greater number of target vessels incorporated, and greater use of directional branches in the repair. These trends persisted in our subgroup analysis of contemporary cases performed in 2014 and after, indicating that the pattern of LP device use remained consistent over the study period. This finding aligns well with the notion that LP PMEG has expanded treatment options for older,

higher-risk patients with more complex aortic aneurysms.

As expected, percutaneous femoral access was more common, and iliac conduit use lower, in the LP group. However, access site complication rates were comparable between the groups. Additionally, there appears to be a gender influence on the access conduit usage stratified by the LP vs SP devices. A prior study by Ramanan et al[8] on off-the-shelf Cook Zenith t-Branch device (Cook Medical) reported similar intraoperative and postoperative outcomes with fewer access site complications and less iliac conduit use in women receiving LP devices. Although we did not reproduce this exact finding, women in our study had significantly greater access complication rates than men, regardless of the device profile used. Overall, our study showed more selective use of iliac conduits compared with the study by Ramanan et al, with lower rates in both LP and SP groups. In our study, women were more likely to require an access conduit than men, and this factor was primarily driven by its use in the SP group. As expected, the use of an LP appears to reduce the need for access conduits in women. However, this benefit did not translate to a decrease in access complications in women.

One of our key observations was that LP device was independently associated with an increased risk of type I and III endoleaks, predominantly branch-related endoleaks (type Ic and type IIIc). This trend remained significant in the subgroup analysis of cases performed in 2014 and on. The rationale for the composite outcome of type I and III endoleaks was based on their definitions as clinically significant events, representing a failure of the device seal. Notably, the individual rates of type I and III endoleaks were higher in the LP group. A prior study by Dias-Neto et al[18] on LP custom-manufactured FBEVAR devices reported a greater frequency of type IIIb endoleaks in LP devices, attributed to fabric failure (1.7% LP vs 0.4% SP). Although our study raises similar concern for LP PMEGs, a more granular analysis remains unavailable with our current dataset, because we relied on individual center reports for differentiation between type IIIa from IIIb endoleaks, resulting in a significant amount of missing data. Fortunately, branch-related endoleaks, specifically type IIIc, were captured in most cases. Nevertheless, it is noteworthy that type IIIc endoleaks comprised the majority of type III endoleaks in our study (99/138 [71%]). This finding suggests that the mechanisms for these endoleaks we observed in PMEG using LP devices may differ from those seen in company-manufactured LP FBEVAR devices.

Intuitively, modification of LP devices may introduce structural weaknesses at the interface between bridging stents and aortic components, increasing the risk of type IIIc endoleaks. However, the association between the type Ic endoleaks and the LP device is more difficult to explain. Prior studies have demonstrated that a greater gap distance between the aortic component and the target vessel origin can contribute to branch instability, particularly in the development of type Ic and IIIc endoleaks.[19] Although our study did not measure the gap distance directly, we found that extensive aortic disease (TAAA vs pararenal AAA) was a predictor of type I or III endoleaks (OR, 1.66; $P = .026$), but not specifically branch-related endoleaks (OR, 1.5; $P = .139$). However, even after adjusting for aneurysm extent, LP device use remained a significant independent predictor of both type I and III endoleaks, specifically type Ic and type IIIc endoleaks, suggesting that this association may be due to factors beyond gap distance. Patients who received LP devices in repair constructs—whether incorporating only fenestrations or including directional branches—had higher rates of type Ic and type IIIc endoleaks. Notably, 30.5 % of patients (22/72) who received LP PMEGs with one or more directional branches developed type IIIc endoleaks. Despite the small sample size, this raises serious concern that the modification to add directional branches to the LP devices is suboptimal.

Branch performance including endoleak is influenced by complex interactions of multiple factors, including the aortic main body, modification techniques, bridging stents, and target vessel characteristics. Unfortunately, detailed data on bridging stents and target vessel characteristics were unavailable for a substantial portion of our cohort, precluding analysis to further elucidate potential mechanisms for our observation. However, our subgroup analysis of contemporary PMEGs provides an indirect adjustment for confounders such as the evolution of bridging stent technology and practice pattern change during the study period, spanning more than a decade. Finally, participating centers have been high-volume regional centers of excellence, and the perioperative outcomes observed may not be fully generalizable to lower-volume centers with less experience in FBEVAR or with PMEGs.

Limitations. In addition to missing data on the bridging stents used, the exact location and branch(es) involved in endoleaks were not recorded, limiting a more granular branch-level analysis to further elucidate the mechanisms of these failures. Additionally, key details regarding modification techniques, such as materials used for fenestration reinforcement, suture types, directional branches, diameter reduction strategies, and removal of proximal fixation barbs, were missing in a substantial portion of the database. Owing to the lack of branch-specific endoleak location data, we were unable to determine whether directional branches, rather than fenestrations in patients who underwent FBEVAR constructs, were the sites of the higher observed type Ic/IIIc endoleaks.

Type Ic endoleaks may be more attributable to the branch stent rather than device modifications. Despite

multiple indirect adjustments—including directional branches, aneurysm extent, and implant period—this association persisted. However, any mechanical explanation remains speculative at this time.

Additionally, repeated events in the same patient were not reported consistently in all patients, which prohibited our ability to perform accurate cluster adjustments with the current dataset.

Despite the higher incidence of type I/III and branch-related endoleaks in the LP group, there was no observed difference in aortic-related mortality, rupture rates, or reintervention. However, a time lag between endoleak development and rupture may have influenced these findings. Additionally, the retrospective nature of this study precluded the use of a predefined, standardized follow-up protocol, and the decision to pursue reintervention was left to the discretion of the treating physicians in conjunction with shared decision-making with their patients.

CONCLUSIONS

LP devices enable the use of PMEGs in older patients with more comorbidities and more extensive aortic disease while reducing the need for access conduits in women. Short-term outcomes were excellent for both LP and SP PMEGs. Although the aortic-related mortality and freedom from reintervention rates were similar at the midterm follow-up, the use of LP devices was associated with a higher risk of type I, type III, and branch-related endoleaks, even when adjusting for aneurysm extent. Given these findings, LP device use for PMEGs should be approached with caution, and closer surveillance should be considered for patients who received LP PMEGs. Further analysis, including bridging stent performance and long-term outcomes, is warranted.

Additional collaborators to the International Multicenter PMEG Study Group include the following investigators and their institutions: Salvatore Scali (University of Florida), Gregory Magee, Alyssa Pyun (University of Southern California), Nicholas Swerdlow (Beth Israel Deaconess Medical Center), Maciej Juszczak (University Hospitals Birmingham NHS Foundation Trust), Mahmoud Malas (University of California, San Diego), Giuseppe Panuccio (German Aortic Center Hamburg), Sara Zetterval (University of Washington), George Josph (Christain Medical College Vellore), Daniela Branzan (University Hospital Leipzig), Frederic Chochennec, Jean Pierre Becquemin, Jennifer Cannonge (Henri Mondor University Hospital), Carlos Timaran (University of Texas Southwestern Medical Center), Emanuel R Tenorio (University of Texas, Houston), Luca Bertoglio (Vita Salute San Raffaele University), Enrico Cieri, Antonino Giordano (Santa Maria della Misericordia University Hospital), Fabio Verzini (University of Turin), Luis Mendes Pedro (Centro Hospitalar Universitário Lisboa Norte).

AUTHOR CONTRIBUTIONS

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Analysis and interpretation: SH, RM, ABe, MSc, TK, MSw, ABa, MF, DA, BM, GO, NT
Data collection: SH, RM, ABe, MSc, TK, MSw, ABa, MF, DA, BM, GO, NT
Writing the article: SH
Critical revision of the article: SH, RM, ABe, MSc, TK, MSw, ABa, MF, DA, BM, GO, NT
Final approval of the article: SH, RM, ABe, MSc, TK, MSw, ABa, MF, DA, BM, GO, NT
Statistical analysis: RM
Obtained funding: Not applicable
Overall responsibility: SH

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

Supplementary Table I (online only). List of low-profile (*LP*) and standard-profile (*SP*) devices used for physician-modified endografts (PMEG)

SP devices	LP devices
Cook TX2 Dissection (ZDEG)	Cook Zenith Alpha Thoracic
Cook TX2 Aneurysm (ZTEG)	Cook Zenith Alpha Abdominal
Cook Zenith Flex Abdominal	Medtronic Navion
Cook RENU	Medtronic Endurant
Cook Zenth Fenestrated	
Cook T-Branch	
Cook ESBE	
Medronic Valiant	
Gore C3 Excluder	
Terumo Relay	

Supplementary Table II (online only). Device modification design

Variable	No.	Total (n = 1220)	LP graft (n = 393)	SP graft (n = 827)	*P* value
Type of repair	1121				
fEVAR		931 (83.0)	299 (79.9)	632 (84.6)	**.041**
BEVAR		40 (3.6)	20 (5.3)	20 (2.7)	
FBEVAR		150 (13.4)	55 (14.7)	95 (12.7)	
Three or more TV included	1219	1047 (85.9)	367 (93.4)	680 (82.3)	**<.001**
Four or more TV included	1219	795 (65.2)	300 (76.3)	495 (59.9)	**<.001**
Used straight graft for main modification	1062	1013 (95.4)	375 (97.4)	638 (94.2)	**.018**
Included a distal component	1059	629 (59.4)	272 (70.8)	357 (52.9)	**<.001**
Straight		111 (10.5)	61 (15.9)	50 (7.4)	
Bifurcated		518 (48.9)	211 (54.9)	307 (45.5)	
Removed barbs from distal bifurcated component	471 with distal bifurcated component	93 (19.7)	29 (15.5)	64 (22.5)	.06
Included preloaded catheter or wires	783	145 (18.5)	98 (33.9)	47 (9.5)	**<.001**

BEVAR, Branched endovascular aneurysm repair; *FBEVAR,* fenestrated-branched endovascular aortic repair; *fEVAR,* fenestrated endovascular aortic repair; *LP,* low-profile; *SP,* standard-profile; *TV,* target vessel.
Values are number (%).
Boldface entries indicate statistical significance.

Supplementary Table III (online only). Gender differences in conduit use and access complications in low-profile (*LP*) vs standard-profile (*SP*) groups

	Overall			LP			SP		
	Male	Female	*P* value	Male	Female	*P* value	Male	Female	*P* value
Conduit	41 (6.8)	26 (13.8)	**.003**	13 (4.8)	9 (8.7)	.15	28 (8.5)	17 (20.0)	**.002**
Access complications	79 (8.6)	50 (16.7)	**<.001**	17 (6.0)	15 (13.8)	**.012**	62 (9.7)	35 (18.4)	**.001**

Values are number (%).
Boldface entries indicate statistical significance.

Supplementary Table IV (online only). Endoleaks for physician-modified endografts (PMEGs) including directional branches vs those with only fenestrations

Variable	N	Total (n = 1121)	Devices without branches (fEVAR) (n = 931)	Devices with branches (FBEVAR + BEVAR) (n = 190)	*P* value
EL type I	1003	66 (6.6)	43 (6.2)	23 (13.6)	**<.001**
EL type Ia	1003	25 (2.5)	16 (1.9)	9 (5.3)	**.010**
EL type Ib	1003	15 (1.5)	13 (1.6)	2 (1.2)	.71
EL type Ic	1003	32 (3.2)	13 (7.7)	19 (2.3)	**<.001**
EL type III	1004	130 (12.9)	92 (11.0)	38 (22.3)	**<.001**
EL type IIIa or IIIb	1004	45 (4.5)	34 (4.1)	11 (6.5)	.17
EL type IIIc	1004	93 (9.3)	64 (7.7)	29 (17.1)	**<.001**

BEVAR, Branched endovascular aneurysm repair; *EL,* endoleak; *FBEVAR,* fenestrated-branched endovascular aortic repair; *fEVAR,* fenestrated endovascular aortic repair.
Values are number (%).
Boldface entries indicate statistical significance.