Intraoperative adverse events and early outcomes of custom-made fenestrated stent grafts and physician-modified stent grafts for complex aortic aneurysms

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ABSTRACT

Objective: Physician-modified fenestrated stent grafts (PMSGs) are a useful option for urgent or semiurgent treatment of complex abdominal aortic aneurysms (CAAAs). The aim of this study was to describe in-hospital outcomes of custom-made fenestrated stent grafts (CMSGs) and PMSGs for the treatment of CAAAs and thoracoabdominal aortic aneurysms (TAAAs).

Methods: In this single-center, retrospective study, all consecutives patients with CAAAs or TAAAs undergoing endovascular repair using Zenith CMSGs (Cook Medical, Bloomington, Ind) or PMSGs between January 2012 and November 2017 were included. End points were intraoperative adverse events, in-hospital mortality, postoperative complications, reinterventions, target vessel patency, and endoleaks.

Results: Ninety-seven patients were included (CMSGs, n = 69; PMSGs, n = 28). The PMSG group included more patients assigned to American Society of Anesthesiologists class 4 (n = 14 [50%] vs n = 16 [23%]; *P* = .006) and more TAAAs (n = 17 [61%] vs n = 10 [15%]; *P* < .0001). Intraoperative adverse events were recorded in eight (11%) patients in the CMSG group vs six (21%) patients in the PMSG group. No intraoperative death or open conversion occurred. In-hospital mortality rates were of 4% (n = 3) in the CMSG group and 14% in the PMSG group (n = 4). Chronic renal failure was an independent preoperative risk factor of postoperative death or complications (odds ratio, 4.88; 95% confidence interval, 1.65-14.43; *P* = .004). Rates of postoperative complications were 22% (n = 15) and 25% (n = 7) in the CMSG and PMSG groups. Spinal cord ischemia rates were 4% (n = 3) and 7% (n = 2) in the CMSG and PMSG groups. Reintervention rates were 16% (n = 11) in the CMSG group and 32% (n = 9) in the PMSG group. At discharge, target vessel patency rate in CMSGs was 98% (n = 207/210). All target vessels (n = 98) were patent in the PMSG group. Endoleaks at discharge were observed in 24% of the CMSG group (n = 16) vs 8% of the PMSG group (n = 2).

Conclusions: Our study showed clinically relevant differences of several important in-hospital outcomes in the CMSG and PMSG groups. Larger cohorts and longer follow-up are needed to allow direct comparison. PMSGs may offer acceptable in-hospital results in patients requiring urgent interventions when CMSGs are not available or possible. (J Vasc Surg 2020;71:1834-42.)

Keywords: Complex abdominal aortic aneurysm; Thoracoabdominal aortic aneurysm; Physician-modified stent graft; Custom-made stent graft; Early results

Manufactured custom-made fenestrated stent grafts (CMSGs) have gained widespread acceptance for the treatment of complex abdominal aortic aneurysms (CAAAs) and thoracoabdominal aortic aneurysms (TAAAs), especially for patients unfit for open repair. However, long manufacturing delays limit their use in patients with symptomatic or large aneurysms. Alternative endovascular techniques developed to deal with these cases include off-the-shelf branched devices,[1] parallel techniques,[2,3] and physician-modified stent grafts (PMSGs).[4-10] PMSGs consist of operator-customized fenestrations created on a back table; the stent graft is reconstrained into the delivery system, thus allowing deployment during the same operative course. Data on PMSGs remain limited. Retrospective studies have reported encouraging short-term and midterm results,[5,6,8,11] but concerns exist about the safety of the technique and long-term results. The objective of this report was to describe the intraoperative adverse events and early outcomes of CMSGs and PMSGs for CAAAs and TAAAs.

METHODS

Study population and technical features. This study is a single-center, nonrandomized, retrospective study. All consecutive patients with CAAAs or TAAAs undergoing endovascular repair with custom-made fenestrated Zenith devices (Cook Medical, Bloomington, Ind) or PMSGs between January 2012 and November 2017 were included. CAAAs included juxtarenal and suprarenal aneurysms. Because PMSGs were designed on a Cook platform and fenestrated Anaconda (Vascutek/Terumo Aortic, Inchinnan, Scotland, United Kingdom) and Ventana (Endologix, Irvine, Calif) devices were limited to juxtarenal and pararenal aneurysms, patients treated with the fenestrated Anaconda device (n = 9) or the Ventana (n = 9) during the study period were excluded. TAAAs were classified according to the modified Crawford classification. Patients were considered for open, hybrid, or endovascular repair in a multidisciplinary weekly meeting. Patients were precluded from open or hybrid repair following a series of criteria including the patient's performance status (American Society of Anesthesiologists [ASA] class and metabolic equivalent of task score) and medical history (cardiac, renal, and pulmonary status). Indications for a PMSG were painful aneurysms, rapidly enlarging >70-mm aneurysms, saccular aneurysms, type I endoleaks after previous endovascular aneurysm repair (EVAR) associated with >70-mm aneurysms, threatening intramural hematoma, and visceral patch false aneurysm after TAAA open repair. Rapidly enlarging aneurysms were defined as growth >5 mm within 6 months. All patients underwent computed tomography (CT) scan preoperatively and within 1 month after the operation. The study was in agreement with the principles of the Declaration of Helsinki, and informed consent was obtained from all patients. According to our center's local regulations and French prevailing legislation (article L1121-1, Code de Santé Publique), Institutional Review Board approval was not required for this retrospective study. In consenting of patients, potential risks and benefits of PMSGs and CMSGs were discussed in detail. The theoretical increased risk of infection associated with PMSGs, the lack of standardization, and the lack of midterm and long-term data were clearly explained.

Demographic, intraoperative, and postoperative data were prospectively recorded in a dedicated database. Procedure planning and device sizing were performed on a dedicated three-dimensional vascular imaging workstation (Aquarius NetStation; TeraRecon, San Mateo, Calif) with centerline luminal reconstructions. Procedures were performed either in an angiography suite (Philips FD 20; Philips Medical Systems, Inc, Shelton, Conn) or in an operating room equipped with a Philips Veradius C-arm. Juxtarenal, suprarenal, and type IV TAAAs were treated during a single-step

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective cohort study
- **Key Findings:** In-hospital results of 69 custom-made fenestrated stent grafts and 28 physician-modified stent grafts (PMSGs) for complex aortic aneurysm repair in high-risk patients are described. Rates of intraoperative adverse events, mortality, complications, and reinterventions are higher in the PMSG group but remain acceptable, given the patients' comorbidities.
- **Take Home Message:** The authors suggest that PMSGs may be an acceptable option for high-risk patients when custom-made stent grafts are not available or possible, although reinterventions were frequent. Long-term evaluations with larger series are necessary to assess the durability of stent graft modifications.

procedure. For extended TAAAs, our strategy was to stage repair whenever possible. All patients with types I, II, III, and V TAAAs underwent cerebrospinal fluid drainage.

In the PMSG group, fenestrations were created in our early experience in Zenith TX2 or Alpha Cook proximal components. More recently, the stent graft of choice was changed to Cook dissection endografts, which can be provided with an 8-mm tapering. A Valiant closed web device (Medtronic, Santa Rosa, Calif) was used in one case. Parallel grafts were used in combination with fenestrations in a few patients with difficult anatomies (ie, excessive aortic angulation at the visceral level, presence of a previous aortic stent graft with suprarenal bare-metal stents, or target vessel ostia too close together) for which successful target vessel cannulation through a fenestration was deemed unpredictable. Detailed planning and sizing steps, device preparation, and stent graft implantation were described in a previous publication from our group.[12] For target vessel stenting, Advanta V12 balloon-expandable covered stents (Maquet, Rastatt, Germany) were used in both groups as bridging stents from 2012 to early 2015. Each stent was flared using Mustang 10-mm × 2-cm or 12-mm × 2-cm balloons (Boston Scientific, Marlborough, Mass). After 2015, we began to use LifeStream (Bard, Tempe, Ariz) and BeGraft (Bentley Innomed GmbH, Hechingen, Germany) covered stents along with V12 as bridging stents.

In cases in which a thoracic fenestration was created to maintain temporary sac perfusion in the PMSG group, patients underwent endovascular reintervention under local anesthesia 2 to 4 weeks after PMSG implantation. An occlusion balloon was inflated in the fenestration through a femoral puncture. After 30 minutes of balloon occlusion with no neurologic deficit, the fenestration was

occluded. An Amplatzer device (St. Jude Medical, St. Paul, Minn) was deployed either directly through the fenestration or in a V12 Advanta stent inflated through the fenestration.

End points and statistics. End points included intraoperative adverse events, in-hospital and 30-day mortality or complications, short-term reinterventions, target vessel patency, and endoleaks. In addition, for multivariable analysis, we used a composite end point defined as major adverse events (MAEs) including in-hospital mortality and postoperative complications.

Complications were classified according to the Society for Vascular Surgery standards.[13] Postoperative renal failure was defined as a rise in creatinine concentration of >2 mg/dL from the preoperative value. Spinal cord ischemia was defined as occurrence of paraparesis or paraplegia. Intraoperative adverse events were defined as any intraoperative complication or technical issue (target vessel loss, cannulation failure, accidental coverage of hypogastric artery, or access complication) during stent graft implantation and included target vessel issues (such as dissections and perforations) that did not result in target vessel loss but were successfully treated intraoperatively. Usual guidelines were used to define endoleak type.[14]

Perioperative outcomes were analyzed by univariable and multivariable analysis. Quantitative variables were reported as means ± standard deviation and were compared using the Student test or Wilcoxon test when appropriate. Categorical variables were reported as number (percentage) and compared using the χ^2 or Fisher test when appropriate. A multivariable logistic regression model was developed (P.B.) to identify variables associated with MAEs. The model was built using variables with a $P < .20$ in univariable analysis. To account for potential confounding by indication, the model was adjusted on covariates that were significantly different between treatment groups. Preoperative fitness was evaluated by the Hosmer and Lemeshow test. Results were presented as odds ratios and 95% confidence intervals.

Statistical analysis was performed using SAS 9.4 software (SAS Institute, Cary, NC). We considered the test results significant at a P value <.05.

Sample size justification. We considered that a difference of 5% between the CMSG and PMSG groups regarding end points was clinically relevant. For a 5% difference with a power of 0.80 and a one-sided α of .05, the sample size required 343 patients/group. Given that we do not have 343 patients per group available for analysis, this study does not allow direct comparison of CMSG and PMSG outcomes. However, the detailed description of initial outcomes of both techniques may be useful to generate data that could be used in a later meta-analysis if one is done in the future.

RESULTS

Baseline characteristics. A total of 97 patients were included during the study period (CMSG group, n = 69; PMSG group, n = 28). During the study period, 32 patients underwent open repair for TAAAs and 43 for CAAAs, and 5 underwent hybrid repair. Demographic data and preoperative risk factors are summarized in Table I. Proportions of ASA class 4 patients (23% vs 50%; $P = .006$) and patients with a history of peripheral artery disease (7% vs 25%; $P = .03$) were significantly higher in the PMSG group. Aneurysm characteristics are detailed in Table II. Symptomatic aneurysms (0% vs 46%; $P < .0001$) and TAAAs (15% vs 61%; $P < .0001$) were more frequent in the PMSG group. Aneurysms were significantly larger in the PMSG group (mean diameter, 59 ± 8 mm in the CMSG group vs 74 ± 19 mm in the PMSG group; $P < .0001$). Mean time to treatment from initial evaluation was 3.7 months in the CMSG group and 27 days in the PMSG group.

Indications for PMSG implantation were painful aneurysms (n = 12), >70-mm or rapidly enlarging aneurysms (n = 10), type I endoleak after previous EVAR (n = 2), saccular aneurysms (n = 2), rapidly expanding aortic intramural hematoma (n = 1; Fig), and false aneurysm after previous type IV TAAA open repair (n = 1; Table II). The patients presenting with type I endoleak after EVAR had large aneurysms (respectively, 70 mm and 85 mm) and were considered to have a high risk of rupture. Another 77-year-old patient was admitted for an intramural hematoma of the thoracoabdominal aorta that was first treated medically. Persistent pain, presence of left pleural effusion, and onset of multiple ulcer-like projections on a control CT scan performed 3 days later led to emergent cervical debranching and thoracic graft stenting (Fig, A). One week after the operation, the patient had persisting abdominal pain. Another control CT scan showed growing ulcer-like projections at the abdominal level (Fig, B and C), which led to an emergent PMSG procedure (Fig, D-F). The patient with the visceral patch false aneurysm after open repair of a type IV TAAA performed 5 years earlier presented with a contained rupture that we considered emergent to treat. In the PMSG group, five patients presenting with large and asymptomatic TAAAs underwent a staged procedure. In four cases, an additional thoracic fenestration was created for temporary sac perfusion, which was successfully closed 2 to 4 weeks after PMSG implantation. No neurologic event was recorded during these planned reinterventions. One elderly patient with a painful TAAA involving the distal segment of the arch underwent a two-stage procedure. During the first stage, she underwent cervical debranching and stent grafting of the arch and thoracic aorta (with, respectively, Relay NBS [Vascutek/Terumo Aortic] and Cook Alpha). During the second stage 7 days later, the PMSG was deployed. Although she had thoracic pain, we thought she was too frail to cope with a long one-stage procedure.

Table I. Demographics and comorbidities

	CMSG (n = 69)	PMSG (n = 28)	*P* value	Overall (N = 97)
Age, years	73 ± 5	73 ± 11	.55	73 ± 11
Men	56 (81)	24 (86)	1	80 (82)
Comorbidities				
Diabetes mellitus	14 (20)	4 (14)	.58	18 (18)
Smoking history	48 (69)	16 (57)	.25	64 (66)
Hypertension	59 (85)	24 (86)	1	83 (85)
Coronary artery disease	32 (46)	10 (35)	.37	42 (43)
Congestive heart failure	22 (32)	11 (39)	.49	33 (34)
History of myocardial infarction	19 (27)	5 (18)	.44	24 (25)
History of stroke	12 (18)	3 (11)	.54	15 (15)
Chronic renal insufficiency	17 (25)	7 (25)	1	24 (25)
COPD	24 (35)	14 (50)	.18	38 (39)
Obesity	7 (10)	4 (14)	.72	11 (11)
History of cancer	10 (14)	4 (14)	1	14 (14)
Peripheral artery disease	5 (7)	7 (25)	.03	12 (12)
History of aortic surgery	9 (13)	7 (25)	.22	16 (16)
ASA class				
2	15 (22)	0 (0)	.004	15 (15)
3	37 (54)	14 (50)	.82	51 (52)
4	16 (23)	14 (50)	.006	30 (31)
SVS comorbidities score	7 ± 3.7	7.6 ± 5	.86	7 ± 4

ASA, American Society of Anesthesiologists; *CMSG*, custom-made stent graft; *COPD*, chronic obstructive pulmonary disease; *PMSG*, physician-modified stent graft; *SVS*, Society for Vascular Surgery.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

Table II. Aneurysm features

	CMSG (n = 69)	PMSG (n = 28)	*P* value	Overall (N = 97)
Symptomatic	0 (0)	13 (46)	<.0001	13 (13)
Aortic diameter, mm	59 ± 8	74 ± 19	<.0001	63 ± 13
Type of aneurysm				
CAAAs	59 (85)	8 (29)	<.0001	67 (69)
Juxtarenal	40 (58)	4 (14)		44 (45)
Suprarenal	19 (27)	4 (14)		23 (24)
TAAAs	10 (15)	17 (61)	<.0001	27 (28)
Type I	1 (1)	6 (21)		7 (7)
Type II	2 (3)	1 (3)		3 (3)
Type III	2 (3)	5 (18)		7 (7)
Type IV	3 (4)	4 (14)		7 (7)
Type V	2 (3)	1 (3)		3 (3)
Intramural hematoma	0 (0)	1 (3)	.29	1 (1)
Type I endoleak	0 (0)	2 (7)	.08	2 (2)

CAAAs, Complex abdominal aortic aneurysms; *CMSG*, custom-made stent graft; *PMSG*, physician-modified stent graft; *TAAAs*, thoracoabdominal aortic aneurysms.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

Operative details. In the CMSG group, all endografts were custom-made fenestrated Cook devices. In the PMSG group, all patients but one had a modified Cook thoracic stent graft implanted. One patient presented with a type IA endoleak after previous EVAR using an aortouni-iliac Endurant (Medtronic) device and an occluded celiac artery. Because this patient had a single iliac access available and we were concerned about successful renal cannulation through fenestrations and previously placed bare-metal stent in an angulated visceral aorta, we decided to treat him using a modified closed web Valiant device with one fenestration for
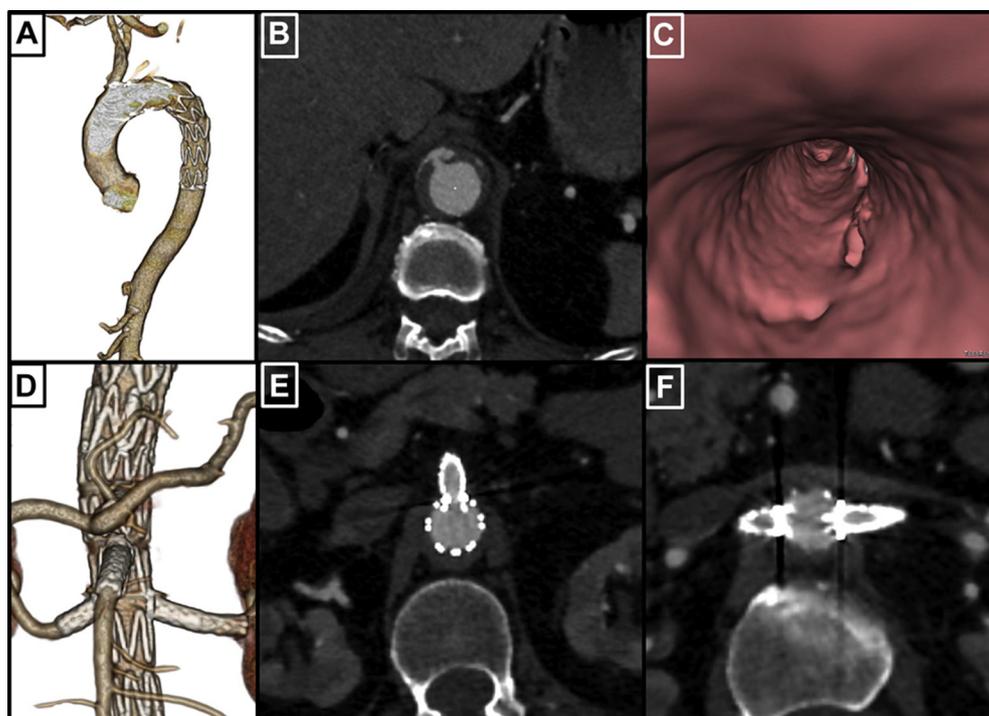
Fig. A-C, Computed tomography (CT) angiography scan performed 8 days after cervical debranching and thoracic stent grafting for an intramural hematoma with persisting thoracic pain despite medical therapy. Postoperatively, the patient presented with persisting thoracic and abdominal pain. Three-dimensional reconstructions and axial view showed new onset of ulcer-like projections that we decided to treat with a four-fenestration physician-modified stent graft (PMSG). **D-F,** CT angiography scan performed after PMSG implantation showed satisfactory exclusion of the aortic disease and target vessel patency.

the superior mesenteric artery that was cannulated from an axillary access and two chimney grafts for renal arteries.

In the CMSG group, 210 target vessels were revascularized. One patient with a juxtarenal aneurysm and four renal arteries was treated using a fenestrated stent graft with two renal fenestrations and two chimney grafts for accessory renal arteries.

In the PMSG group, 98 target vessels (3.5 per patient vs 3 per patient in the CMSG group) were revascularized through fenestrations (n = 87) or parallel grafts (n = 11). Parallel grafts were used in combination with fenestrations in six patients. Indications for this combined technique and outcomes have already been published.[15]

Intraoperative results. No intraoperative death occurred in this series. Intraoperative adverse events occurred in eight (11%) CMSG patients and six (21%) PMSG patients. Details of intraoperative adverse events are given in Table III.

Postoperative outcome. Overall, three (4%) patients died in the CMSG group vs four (14%) in the PMSG group during the postoperative course. Causes of in-hospital deaths and details of postoperative complications are given in Table IV.

In patients treated for CAAA, three (5%) died in the CMSG group vs one (12%) in the PMSG group. In patients treated for a TAAA, there was no early death in the CMSG group vs three (17%) in the PMSG group.

MAEs occurred in 18 (26%) patients in the CMSG group vs 11 (42%) in the PMSG group. Multivariable analysis (Supplementary Table, online only) showed a trend toward more MAEs in the PMSG group without reaching statistical significance (odds ratio, 3.76; 95% confidence interval, 0.92-15.41; $P = .07$). Univariable and multivariable analysis showed that preoperative chronic renal impairment was significantly associated with postoperative MAEs.

Early reinterventions. Early reintervention rates were 16% (n = 11) in the CMSG group and 32% (n = 9) in the PMSG group. Details of reinterventions are given in Table V. One postoperative aneurysm rupture occurred in a patient in the PMSG group. This ASA class 4 patient presented with a rapidly enlarging 74-mm type II TAAA and a type IA endoleak after previous EVAR with an AFX (Endologix) device. The right renal artery was occluded. He was treated using two proximal thoracic components and a PMSG with three fenestrations. The postoperative course was uneventful. Postoperative CT scan showed a mild opacification of the aneurysm sac that was considered a type II endoleak. One week after discharge, the patient presented with a ruptured infrarenal aneurysm. A CT scan revealed a type III endoleak related to disconnection between the tubular and bifurcated

Table III. Intraoperative details

	CMSG (n = 69)	PMSG (n = 28)	Overall (N = 97)
Patients presenting with intraoperative adverse events	8 (11)	6 (21)	14 (8)
Intraoperative death	0 (0)	0 (0)	0 (0)
Open conversion	0 (0)	0 (0)	0 (0)
Target vessel loss	3 (1.4)	0 (0)	3 (3)
Renal artery injury	1 (1)	0	1 (1)
Celiac artery injury	0 (0)	1 (3.5)	1 (1)
Cannulation failure	2 (3)	2 (7)	4 (4)
Requiring bailout procedure	1	1 (3.5)	
Requiring reintervention	1	1 (3.5)	
Accidental coverage of hypogastric artery	1 (1)	1 (3.5)	2 (2)
Iliac or femoral access complication	5 (7)	5 (18)	10 (10)

CMSG, Custom-made stent graft; *PMSG*, physician-modified stent graft.
Values are reported as number (%).

Table IV. Postoperative outcomes

	CMSG (n = 69)	PMSG (n = 28)	Overall (N = 97)
30-Day mortality	3 (4)	4 (14)	7 (7)
In-hospital mortality	3 (4)	4 (14)	7 (7)
Cause of death			
Myocardial infarction	0 (0)	1 (3.5)	1 (1)
Stroke	0 (0)	1 (3.5)	1 (1)
Bowel or colonic ischemia	2 (3)	1 (3.5)	3 (3)
Pulmonary infection	0 (0)	1 (3.5)	1 (1)
Access infection	1 (1)	0 (0)	1 (1)
Patients presenting with ≥1 nonfatal complication	15 (22)	7 (25)	22 (23)
Total of nonfatal postoperative complications	16	8	24
Stroke	1 (1)	0 (0)	1 (1)
Spinal cord ischemia	3 (4)	2 (7)	5 (5)
Definitive	1 (1)	0 (0)	1 (1)
Partially regressive	0 (0)	1 (3.5)	1 (1)
Totally regressive	2 (3)	1 (3.5)	3 (3)
Renal failure requiring hemodialysis	1 (1)	0 (0)	1 (1)
Bowel or colonic ischemia	3 (4)	0 (0)	3 (3)
Severe acute respiratory syndrome	2 (3)	0 (0)	2 (2)
Transient renal failure	4 (6)	4 (14)	8 (8)
Hemorrhage	1 (1)	2 (7)	3 (3)
Access site infection	1 (1)	0 (0)	1 (1)

CMSG, Custom-made stent graft; *PMSG*, physician-modified stent graft.
Values are reported as number (%).

components of the AFX device. Emergent open repair was performed, but the patient died of multiorgan failure.

Target vessel patency and endoleaks. All postoperative CT scans were available. At discharge, target vessel patency rate of CMSGs was 98% (207/210). All target vessels (n = 98) were patent in the PMSG group.

On postoperative CT scans, 19 (29%) patients in the CMSG group presented with endoleak vs 7 (25%) in the PMSG group. Postoperative type I and type III endoleak rates were recorded in 0% and 4% (n = 3) of cases, respectively, in the CMSG group and 7% (n = 2) and 11% (n = 3) of cases in the PMSG group.

In the CMSG group, endoleaks resulted in three reinterventions, including stenting of one additional celiac

Table V. Early reinterventions

	CMSG (n = 69)	PMSG (n = 28)	Overall (N = 97)
Patients requiring reinterventions	11 (16)	9 (32)	20 (21)
Total reinterventions	12	13	25
Open conversion for AAA rupture	0 (0)	1 (3.5)	1 (1)
Branch-related instability			
Gastroduodenal embolization	0 (0)	1 (3.5)	1 (1)
Renal stenting secondary to dissection	1 (1)	0 (0)	1 (1)
Additional celiac artery stenting[a]	1 (1)	1 (3.5)	2 (2)
Celiac artery stenting for type III endoleak	0 (0)	1 (3.5)	1 (1)
Renal artery stenting for type III endoleak	2 (3)	2 (7)	4 (4)
Colectomy for colonic ischemia	1 (1)	1 (3.5)	2 (2)
Endoleak unrelated to target vessels			
Proximal extension	0 (0)	1 (3.5)	1 (1)
Distal extension	0 (0)	1 (3.5)	1 (1)
Iliac ligation for type II endoleak	0 (0)	1 (3.5)	1 (1)
Access			
Iliofemoral bypass	2 (3)	1 (4)	3 (3)
Femorofemoral bypass	1 (1)	0 (0)	1 (1)
Lower limb embolectomy	3 (4)	0 (0)	3 (3)
Lower limb amputation	0 (0)	1 (4)	1 (1)
Iliac stenting for retroperitoneal hemorrhage	0 (0)	1 (4)	1 (1)
Groin wound debridement for sepsis	1 (1)	0 (0)	1 (1)

AAA, Abdominal aortic aneurysm; *CMSG,* custom-made stent graft; *PMSG,* physician-modified stent graft.
Values are reported as number (%).
[a]Celiac artery stenting performed through a brachial access during a secondary procedure because of cannulation failure through a femoral access.

artery and two additional renal arteries. These endoleaks resolved after reintervention (Table V). At discharge, the remaining endoleaks in the CMSG group were type II endoleaks (n = 16 [24%]).

In the PMSG group, five patients underwent endovascular reinterventions for treatment of type I or type III endoleaks. As mentioned before, one patient presenting with aneurysm rupture related to a type III endoleak underwent surgical conversion. In the PMSG group, one patient with a type IA endoleak through the gutters of chimney grafts dedicated to the superior mesenteric artery and celiac artery died during the postoperative course before any reintervention could be performed. For the three remaining patients, reinterventions are detailed in Table V. At discharge, no patient in the PMSG group had persisting type I or type III endoleak, and the remaining endoleaks were type II (n = 2 [8%]).

DISCUSSION

In this study, neither propensity score matching nor stratification was possible because of the limited number of patients in the PMSG group and the important presurgical differences between the CMSG and PMSG groups. This resulted in the inability to perform a statistically based comparison of initial outcomes of CMSG and PMSG techniques. However, the descriptive analysis is of interest, given the paucity of data reported for PMSGs.

Besides, such data may be used in the future if a meta-analysis were to be performed.

Although no direct comparison should be made, rates of intraoperative adverse events, mortality, complications, and reinterventions in the PMSG group were two to three times those of the CMSG group. More than being related to the type of technique, this result may be explained by the fact that patients in the PMSG group were more fragile, with more extended aneurysms. Deaths and severe complications in the PMSG group occurred in compassionate cases, mostly ASA class 4 patients with emergent aneurysms and complex anatomy. Multivariable analysis showed a trend to an increased rate of MAEs in the CMSG group but without reaching statistical significance, limited by the small number of events and patients. In looking at technical outcomes such as target vessel cannulation failures, rates of target vessel loss, and persistent endoleaks at discharge, PMSGs seem to be an acceptable option for high-risk patients needing rapid treatment of emergent CAAAs or TAAAs.

In our PMSG group, the 14% mortality rate does not compare favorably with previous studies of PMSGs.[5,7,10] Heterogeneity in selection of patients may explain this difference. Previous series reporting more favorable outcomes mainly included elective repair of juxtarenal aneurysms. Starnes et al[11] have reported a 5.1% 30-day mortality rate in 59 patients treated for juxtarenal aneurysms. In

the current series, most patients were high-risk patients with extensive or symptomatic aneurysms requiring rapid treatment. Tsilimparis et al[16] reported a series of PMSGs in high-risk patients with CAAAs or TAAAs with a 14% mortality rate, with results similar to those of our series. However, excellent results for the treatment of CAAAs and TAAAs in high-risk patients were recently reported by the teams of the Mayo Clinic and the University of Massachusetts with 30-day mortality rates, respectively, of 5.5% and 4.9%,[17,18] reflecting the experience of high-volume centers. Indeed, the latter studies included a considerably larger number of patients compared with our series of physician-modified devices, and their experience began, respectively, in 2007 and 2010, whereas we began in 2012, highlighting a possible learning curve effect.

We reported high rates of reinterventions in the PMSG group in our study (32%), similar to those recently reported by Oderich et al[17] and Dossabhoy et al[18] (41% and 37%, respectively) but much higher than the 4.5% reported in the meta-analysis by Georgiadis et al.[19] Reinterventions seem more and more to appear in the literature as the Achilles heel of the physician-modified technique. This may be explained by high rates of endoleaks, requiring close and patient-specific follow-up.

It is also likely that poor results of stent graft modifications are under-reported in the literature because of negative bias of publication. We reported one fatal case of postoperative aortic rupture after PMSG implantation secondary to a disconnection between the physician-modified device and the previously placed bifurcated component. As described by others, the use of cone beam CT at the end of the procedure might have allowed early diagnosis and treatment of such an event.[20] This case obviously does not compromise the use of physician-modified devices but should be kept in mind when physician-modified devices are used.

Regarding the treatment of CAAAs by CMSGs, our 4% in-hospital mortality rate is in line with previous reports from high-volume centers.[21-25] Compared with our initial results,[26] short-term outcomes improved significantly with larger experience. Of the three deaths in the CMSG group, two occurred in our early experience in patients with shaggy aortas, which are currently considered strict contraindications to fenestrated stent grafts. In-hospital mortality and complication rates reported in the CMSG group for the treatment of TAAAs were also comparable to those previously reported in the literature.[22,27-30]

With growing experience, technical adjustments for graft modifications were done to reduce the risks of cannulation problems and endoleak. For asymptomatic large aneurysms, fenestrations are created in custom-made devices, which can be provided within 5 days with specific proximal and distal diameters, with a specific level of tapering, and without proximal barbs. When a proximal thoracic component is needed, distances are calculated to obtain a minimum of three stents of overlap with the fenestrated device (60-80 mm). For symptomatic aneurysms, we now use Zenith dissection stent grafts, which can be delivered within 24 hours with straight, 4-mm tapering, or 8-mm tapering designs. Devices with 8-mm tapering were particularly useful in painful juxtarenal and suprarenal aneurysms. The two proximal stents ensured good proximal sealing, whereas the tapering on the third stent allowed adequate fenestration positioning in the visceral aorta. However, because we did not use scallops, juxtarenal aneurysms were mainly treated with four-fenestration stent grafts, which could be considered unnecessary with custom-made fenestrated devices. Graft modifications for four fenestrations took us approximately 2 hours, which is too long in the setting of ruptured unstable aneurysms. Clearly, PMSG was not a good technique for ruptures. We also found that fenestration positioning and adequate graft deployment were difficult to predict in case of posterior takeoff of renal arteries, especially in small aortic diameters, where reducing ties have the effect of pulling fenestrations even more posteriorly. We now tend to avoid fenestrations when the left and right renal ostia are positioned between 4:30 and 6:00 and between 6:00 and 7:30, respectively.

Our results suggest that the PMSG represents an option for emergent CAAAs or TAAAs in high-risk patients when a custom-made device is not possible or available. It remains a complex procedure with a substantial learning curve. Well-trained and dedicated physicians in the planning and customization of the grafts and fenestrations are of paramount importance. Finally, off-label modifications induce legitimate concerns about durability, which needs a longer term evaluation.

CONCLUSIONS

PMSGs offer acceptable short-term results in terms of mortality and complications for high-risk patients needing rapid treatment. The need for endovascular reinterventions was frequent in our early experience. Long-term evaluations with larger series are necessary to assess the fate of fenestrations and bridging stents and the durability of grafts.

AUTHOR CONTRIBUTIONS

Conception and design: JS, JB, FC
Analysis and interpretation: JS, IBA, PB, JT, HK, PD, JB, FC
Data collection: JS, IBA
Writing the article: JS, IBA, PB, JT, JB, FC
Critical revision of the article: HK, PD, JB, FC
Final approval of the article: JS, IBA, PB, JT, HK, PD, JB, FC
Statistical analysis: JS, PB
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Overall responsibility: FC

REFERENCES

1. Bisdas T, Donas KP, Bosiers MJ, Torsello G, Austermann M. Custom-made versus off-the-shelf multibranched endografts for endovascular repair of thoracoabdominal aortic aneurysms. J Vasc Surg 2014;60:1186-95.

2. Donas KP, Lee JT, Lachat M, Torsello G, Veith FJ; PERICLES investigators. Collected world experience about the performance of the snorkel/chimney endovascular technique in the treatment of complex aortic pathologies: the PERICLES registry. Ann Surg 2015;262:546-53.

3. Lobato AC, Camacho-Lobato L. A new technique to enhance endovascular thoracoabdominal aortic aneurysm therapy—the sandwich procedure. Semin Vasc Surg 2012;25:153-60.

4. Pisimisis GT, Kougias P, Barshes NR, Bechara CF. Surgeon-modified fenestrated endograft to treat ruptured juxtarenal aneurysm. JAMA Surg 2014;149:447-9.

5. Starnes BW, Tatum B. Early report from an investigator-initiated investigational device exemption clinical trial on physician-modified endovascular grafts. J Vasc Surg 2013;58: 311-7.

6. Ricotta JJ 2nd, Tsilimparis N. Surgeon-modified fenestrated-branched stent grafts to treat emergently ruptured and symptomatic complex aortic aneurysms in high-risk patients. J Vasc Surg 2012;56:1535-42.

7. Starnes BW. Physician-modified endovascular grafts for the treatment of elective, symptomatic, or ruptured juxtarenal aortic aneurysms. J Vasc Surg 2012;56:601-7.

8. Oderich GS, Farber MA, Sanchez LA. Urgent endovascular treatment of symptomatic or contained ruptured aneurysms with modified stent grafts. Perspect Vasc Surg Endovasc Ther 2011;23:186-94.

9. Oderich GS, Fatima J, Gloviczki P. Stent graft modification with mini-cuff reinforced fenestrations for urgent repair of thoracoabdominal aortic aneurysms. J Vasc Surg 2011;54:1522-6.

10. Oderich GS, Ricotta JJ 2nd. Modified fenestrated stent grafts: device design, modifications, implantation, and current applications. Perspect Vasc Surg Endovasc Ther 2009;21:157-67.

11. Starnes BW, Heneghan RE, Tatum B. Midterm results from a physician-sponsored investigational device exemption clinical trial evaluating physician-modified endovascular grafts for the treatment of juxtarenal aortic aneurysms. J Vasc Surg 2017;65:294-302.

12. Cochennec F, Kobeiter H, Gohel M, Leopardi M, Raux M, Majewski M, et al. Early results of physician modified fenestrated stent grafts for the treatment of thoraco-abdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2015;50:583-92.

13. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg 2002;35:1048-60.

14. Fillinger MF, Greenberg RK, McKinsey JF, Chaikof EL. Society for Vascular Surgery Ad Hoc Committee on TEVAR Reporting Standards. Reporting standards for thoracic endovascular aortic repair (TEVAR). J Vasc Surg 2010;52:1022-33.e15.

15. Touma J, Verscheure D, Majewski M, Desgranges P, Cochennec F. Parallel grafts used in combination with physician-modified fenestrate d stent grafts for complex aortic aneurysms in high-risk patients with hostile anatomies. Ann Vasc Surg 2018;46:265-73.

16. Tsilimparis N, Heidemann F, Rohlffs F, Diener H, Wipper S, Debus ES, et al. Outcome of surgeon-modified fenestrated/branched stent-grafts for symptomatic complex aortic pathologies or contained rupture. J Endovasc Ther 2017;24:825-32.

17. Oderich GS, Ribeiro MS, Sandri GA, Tenorio ER, Hofer JM, Mendes BC, et al. Evolution from physician-modified to company-manufactured fenestrated-branched endografts to treat pararenal and thoracoabdominal aortic aneurysms. J Vasc Surg 2019;70:31-42.e7.

18. Dossabhoy SS, Simons JP, Flahive JM, Aiello FA, Sheth P, Arous EJ, et al. Fenestrated endovascular aortic aneurysm repair using physician-modified endovascular grafts versus company-manufactured devices. J Vasc Surg 2018;67:1673-83.

19. Georgiadis GS, van Herwaarden JA, Antoniou GA, Hazenberg CE, Giannoukas AD, Lazarides MK, et al. Systematic review of off-the-shelf or physician-modified fenestrated and branched endografts. J Endovasc Ther 2016;23: 98-109.

20. Dijkstra ML, Eagleton MJ, Greenberg RK, Mastracci T, Hernandez A. Intraoperative C-arm cone-beam computed tomography in fenestrated/branched aortic endografting. J Vasc Surg 2011;53:583-90.

21. Roy IN, Millen AM, Jones SM, Vallabhaneni SR, Scurr JRH, McWilliams RG, et al. Long-term follow-up of fenestrated endovascular repair for juxtarenal aortic aneurysm. Br J Surg 2017;104:1020-7.

22. Oderich GS, Ribeiro M, Hofer J, Wigham J, Cha S, Chini J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones. J Vasc Surg 2017;65:1249-59.e10.

23. British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry. Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. Circulation 2012;125:2707-15.

24. Verhoeven EL, Vourliotakis G, Bos WT, Tielliu IF, Zeebregts CJ, Prins TR, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. Eur J Vasc Endovasc Surg 2010;39:529-36.

25. Oderich GS, Greenberg RK, Farber M, Lyden S, Sanchez L, Fairman R, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg 2014;60:1420-8.e1-5.

26. Raux M, Patel VI, Cochennec F, Mukhopadhyay S, Desgranges P, Cambria RP, et al. A propensity-matched comparison of outcomes for fenestrated endovascular aneurysm repair and open surgical repair of complex abdominal aortic aneurysms. J Vasc Surg 2014;60:858-63; discussion: 863-4.

27. Chuter TA, Rapp JH, Hiramoto JS, Schneider DB, Howell B, Reilly LM. Endovascular treatment of thoracoabdominal aortic aneurysms. J Vasc Surg 2008;47:6-16.

28. Haulon S, D'Elia P, O'Brien N, Sobocinski J, Perrot C, Lerussi G, et al. Endovascular repair of thoracoabdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2010;39:171-8.

29. Greenberg RK, Lu Q, Roselli EE, Svensson LG, Moon MC, Hernandez AV, et al. Contemporary analysis of descending thoracic and thoracoabdominal aneurysm repair: a comparison of endovascular and open techniques. Circulation 2008;118:808-17.

30. Verhoeven EL, Katsargyris A, Bekkema F, Oikonomou K, Zeebregts CJ, Ritter W, et al. Ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms: results from 166 consecutive patients. Eur J Vasc Endovasc Surg 2015;49:524-31.

Supplementary Table (online only). Statistical analysis

	Univariable analysis	Multivariable analysis	
	P	OR (95% CI)	*P*
MAEs			
PMSG group vs CMSG group	.20	3.76 (0.92-15.41)	.07
Chronic renal impairment	.004	4.88 (1.65-14.43)	.004
TAAA vs CAAA	.64	0.34 (0.09-1.28)	.11

CAAA, Complex abdominal aortic aneurysm; *CI,* confidence interval; *CMSG,* custom-made stent graft; *MAEs,* major adverse events; *OR,* odds ratio; *PMSG,* physician-modified stent graft; *TAAA,* thoracoabdominal aortic aneurysm.