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Midterm outcomes of physician-modified endovascular stent grafts for the treatment of complex abdominal aortic aneurysms in Korea: a retrospective study

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Purpose: Physician-modified endovascular stent grafts (PMEG) are a good treatment option for complex abdominal aortic aneurysms (AAAs), especially in high-risk patients not amenable to open repair, and when commercial fenestrated devices are not available. We report our single-center experience with PMEG for the treatment of complex AAAs.
Methods: We retrospectively reviewed patients who underwent PMEG repair for AAA from November 2016 to September 2020 at our institution. Demographic data, anatomic characteristics, perioperative and postoperative outcomes, major adverse events, and 30-day mortality were analyzed.
Results: We identified 12 patients who underwent PMEG for complex AAA. The mean age was 74 years and the mean maximal AAA diameter was 58.1 mm. Indications for treatment included 4 impending or contained ruptures, 2 mycotic aneurysms, and 6 symptomatic cases. The technical success rate was 91.7%. Aneurysm sac regression was observed in 7 patients (58.3%), including 2 cases of complete regression. There was 1 aneurysm-related mortality at 3 months due to mycotic aneurysm. Also, there was 1 postoperative complication case of transient renal failure requiring temporary dialysis. At 1 year, there was 1 branch occlusion from the initial failed cannulation case and 2 type 1A endoleaks, and there was 1 case of open explantation.
Conclusion: PMEG showed a low technical failure rate and acceptable midterm stent durability and sac stability, comparable to conventional endovascular aneurysm repair. Despite the small number of cases, there was a tendency for a high sac regression rate, although longer follow-up is needed.
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Key Words: Abdominal, Aortic aneurysm, Endovascular aneurysm repair

INTRODUCTION

Open surgical repair has been traditionally considered the standard treatment option for complex abdominal aortic aneurysms (cAAA), but it is also related to increased perioperative mortality and morbidity due to the need for suprarenal or supraceliac aortic clamping [1,2]. Recently, fenestrated endovascular aneurysm repair (FEVAR) with commercially available custom-made devices (CMD) has gained popularity across the world due to its lower complication rates compared to open repair [3,4]. However, these devices often require an average of 6 to 12 weeks of planning and

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manufacturing time, which makes them unsuitable for symptomatic or ruptured aneurysms [5]. In Korea, regulatory issues and noncoverage by national healthcare insurance further hinder the use of such devices. To overcome these availability issues, we have adopted a physician-modified endovascular stent graft (PMEG) strategy as an alternative solution. PMEG refers to the modification of commercially available conventional stent grafts to fit the complex vascular anatomies of individual patients. Physicians can create necessary fenestrations to accommodate branch vessels before the operation. Although recent systematic reviews have shown comparable early clinical outcomes of PMEG with CMD, there are still very few reports on long-term outcomes [6]. The objective of this study is to report midterm outcomes of PMEG in high-risk patients with symptomatic or ruptured aneurysms with complex aortic pathology and to demonstrate the safety and efficacy of this technique.

METHODS

This study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (No. B-2201-734-101) and patient consent was waived due to the retrospective nature of the study.

Patient selection

We retrospectively reviewed consecutive patients who underwent PMEG repair for cAAA from November 2016 to September 2020 at Seoul National University Bundang Hospital. The indications for PMEG repair were as follows: symptomatic lesions, mycotic aneurysm, and aneurysm with contained or impending rupture. Also, patients with unsuitable aneurysm morphology for conventional endovascular aneurysm repair (EVAR) were included. One of the advantages of PMEG is the ability to increase the range of applicability compared to CMD. When constructing 3 or more fenestrations, it is important to select fenestration sites that are not to crossed by any stent struts. Unlike CMD, surgeons can obtain secure fenestration sites by modifying struts by tilting or compressing them. Therefore, PMEG was indicated broadly in complex aneurysm morphology.

The procedure was only performed for hemodynamically stable patients. All patients were informed that the stent graft modifications were made outside the instructions for use.

Device design and planning

For preoperative planning, three-dimensional CT angiography reconstructions with centerline reformatting were routinely performed with an imaging software (3mensio Vascular, Pie Medical Imaging). From the reconstructed image, fenestrations were planned, starting by setting the lower margin of celiac axis as a reference line, and the distances to the target vessels were measured. To determine the accurate orientation of the target vessels, clock positions were taken. At the level of the fenestrations, the inner vessel diameters were calculated to measure the circumferential distance of the fenestration from the 12 o'clock position as the reference point.

Technique

Specific techniques for preparing physician-modified endovascular grafts have been described in previous studies [7,8]. Modification of the stent graft was performed before the operation under sterile conditions at the back table of the operating room. Commercially available Zenith Flex AAA endovascular graft (Cook Medical) was mainly used, in which scallops and fenestrations were made according to the patient's anatomy and aneurysmal characteristics. To create fenestrations, an electrocautery device was used and reinforced with radiopaque wires secured around the fenestrations using continuous running sutures (Fig. 1B). After modifications were finished, the stent graft was reloaded into the original delivery system.

Implantation of the modified stent graft was performed in a hybrid operation room with an angiography device. Both femoral arteries were used for the access. The right femoral artery was primarily used for the introduction of the main graft, while the left femoral artery was used for visceral artery catheterization. In some cases, the brachial artery was used for additional access.

After obtaining the proper orientation of the stent graft, the modified main body was carefully deployed. Then, individual target vessel selection was performed using 7- or 8-French sheaths through the contralateral limb. After deploying the ipsilateral part of the main body, a CODA balloon (Cook Medical) was used to stabilize the proximal portion of the graft. Flexor Shuttle or Ansel Sheaths (Cook Medical) were then used to introduce the bridging-covered stents. The LifeStream balloon-expendable covered stent (Bard Peripheral Vascular) was used as a bridging stent, and selective reinforcement with self-expandable stents was performed in patients with tortuous renal arteries. Before the LifeStream stent was available, a balloon-expandable bare stent was used as a renal bridging stent. If no endoleak was identified, both iliac limb stent grafts were deployed and the whole system was molded with a CODA balloon. Completion aortogram was obtained at the end of each procedure.

Definitions

Outcome measurements included technical success, 30-day mortality, major adverse events (MAEs), branch instability, endoleaks, reintervention, and sac regression or expansion. MAEs were reported using the Society for Vascular Surgery

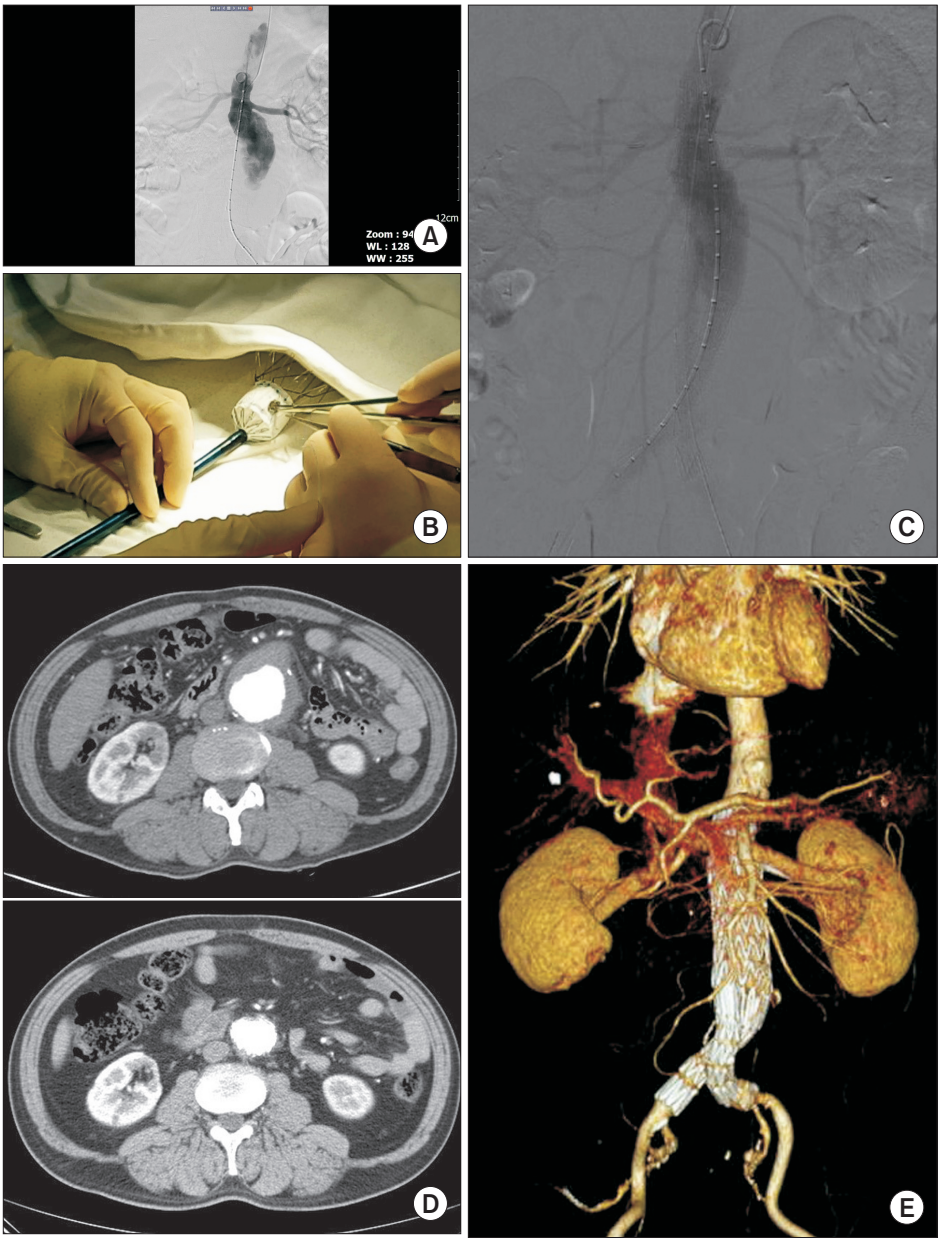

Fig. 1. (A) A case of physician-modified endovascular stent graft for a patient with a 73.0-mm impending rupture abdominal aortic aneurysm with a short neck. The distance between the right renal artery (RRA) and left renal artery was 15 mm. (B) A single left renal fenestration was created. (C) Final angiogram showed patent flow through both renal arteries without endoleak. (D) Comparison of preoperative and postoperative CT scans (77.4 months after operation) shows complete resolution of the aneurysmal sac. (E) Follow-up CT reconstruction demonstrates patent endograft with flow through RRA.

guidelines. Technical success was defined as an intent-to-treat basis and required the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type 1 or 3 endoleak, and graft limb obstruction ≤24 hours postoperative period [9]. The data are demonstrated as percentages and ranges.

RESULTS

From November 2016 to September 2020, 12 patients underwent PMEG repair for cAAA at our institution. The mean age of the patients was 74 years (range, 53–85 years) and 11 patients were male. The most common medical comorbidities were hypertension, history of smoking, and diabetes mellitus. Six patients presented with symptomatic AAA, mostly flank or abdominal pain, and 1 patient with hematochezia. Two patients presented with ruptured aneurysm, and 1 patient presented with impending rupture. In 1 patient, the distance from the lowest renal artery to the aortic bifurcation was short, which made it unsuitable to use a conventional EVAR stent graft. All patients were hemodynamically stable enough to undergo meticulous planning and back-table modification of the stent graft. Detailed baseline characteristics of the patients are demonstrated in Table 1.

All patients were put under general anesthesia. Mean operation time was 258.3 minutes (range, 135.0–405.0 minutes). There were 10 juxtarenal AAAs, 1 infrarenal AAA, and 1 thoracoabdominal aneurysm which extended from the T10 to

L1 level of the spine. A bifurcated Zenith Flex stent graft was used in 11 cases. For the thoracoabdominal aneurysm case, a Zenith TX2 TAA endovascular graft (Cook Medical) was used. Successful target vessel revascularization was achieved in 11 cases. A total of 25 vessels were targeted with 17 fenestrations, 6 scallops, and 1 side arm branch constructed with a VIABAHN covered stent (W.L. Gore & Associates). The characteristics of the PMEG stent grafts are further illustrated in Table 2.

Technical success was achieved in 11 out of 12 patients (91.7%). One technical failure was seen in a patient with a 52-mm juxtarenal AAA with a short neck, measuring less than 10 mm from the lowest left renal artery (LRA). A single 8 mm-sized fenestration for the LRA was created. However, cannulation for the LRA constantly failed due to severe stenosis of the renal artery ostium. On final angiography, there was no flow in the LRA and flow was identified only for the right renal artery (RRA).

The mean preoperative serum creatinine level was 1.1 mg/dL (range, 0.5–2.8 mg/dL) and predischarge serum creatinine level was 1.1 mg/dL (range, 0.4–3.1 mg/dL). The mean stay at the intensive care unit was 2.3 days (range, 0–8 days) and mean hospital stay was 14.9 days (range, 5–40 days). There was no mortality within 30 days. For MAEs within 30 days, there was a single acute renal failure case that did not require hemodialysis and a single case for intraoperative blood loss over 1,000 mL. Major blood loss occurred in 2 ruptured aneurysm cases, 1,200 and 900 mL each. Early postoperative outcomes are shown in Table 3.

The mean follow-up was 32.3 months (range, 6.7–77.4 months) in 11 patients. One patient did not visit the outpatient clinic after the operation. Ten patients underwent a CT scan as a follow-up imaging modality and 1 patient underwent duplex ultrasonography. In the follow-up CT scans and ultrasonography, all target vessels were patent. The time to the most recent follow-up CT scan was 25.8 months (range, 1.9–77.2 months). The mean maximal aneurysm sac diameter on the latest CT scan was 49.9 mm (range, 29.0–70.0 mm). Compared with the preoperative sac size, 7 patients demonstrated a noticeable regression in size. Among them, complete resolution

Table 1. Baseline characteristics of patients

Characteristic	Data
No. of patients	12
Age (yr)	74 (53–85)
Male sex	11 (91.7)
Body mass index (kg/m^2)	21.8 (17.5–27.6)
Medical comorbidities	
History of smoking	7 (58.3)
Hypertension	9 (75.0)
Dyslipidemia	4 (33.3)
Coronary artery disease	4 (33.3)
COPD	2 (16.7)
Chronic kidney disease	3 (25.0)
Diabetes mellitus	5 (41.7)
Stroke/TIA	1 (8.3)
ASA PS classification	
III	8 (66.7)
IV	3 (25.0)
Aneurysm characteristics	
Infrarenal	1 (8.3)
Juxtarenal	10 (83.3)
Suprarenal/thoracoabdominal	1 (8.3)
Symptomatic	6 (50.0)
Impending rupture or ruptured aneurysm	3 (25.0)
Mycotic aneurysm	2 (16.7)
Maximal AAA diameter (mm)	58.1 (39.0–73.0)
Preoperative sCr (mg/dL)	1.1 (0.5–2.8)

Values are presented as number only, mean (range), or number (%).
COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack; ASA, American Society of Anesthesiologists; PS, physical status; AAA, abdominal aortic aneurysms; sCr, serum creatinine.

Table 2. The characteristics of physician-modified endovascular stent grafts

Variable	No. of patients
Branch vessels revascularized	25
Celiac artery	2
Superior mesenteric artery	5
Right renal artery	7
Left renal artery	11
Fenestrations	17
Scallops	8

Table 3. Early outcomes (postoperative <30 days) (n = 12)

Variable	Data
Operation time (min)	258.3 (135.0–405.0)
Contrast volume (mL)	182.9 (110.0–370.0)
Estimated blood loss (mL)	471.7 (10.0–1,200.0)
Endoleaks on completion of angiography	6 (50.0)
Technical success (%)	11 (91.7)
ICU stay (day)	2.3 (0–8)
Hospital day (day)	14.9 (5–40)
Reintervention, <30 days	1 (8.3)
Predischarge sCr (mg/dL)	1.1 (0.4–3.1)
Mortality, <30 days	0 (0)
MAE, <30 days	
Myocardial infarction	0 (0)
Stroke	0 (0)
Renal failure	1 (8.3)
Respiratory failure	0 (0)
Paraplegia	0 (0)
Bowel ischemia requiring resection	0 (0)
Procedural blood loss, >1,000 mL	1 (8.3)

Values are presented as mean (range) or number (%).
ICU, intensive care unit; sCr, serum creatinine; MAE, major adverse effect

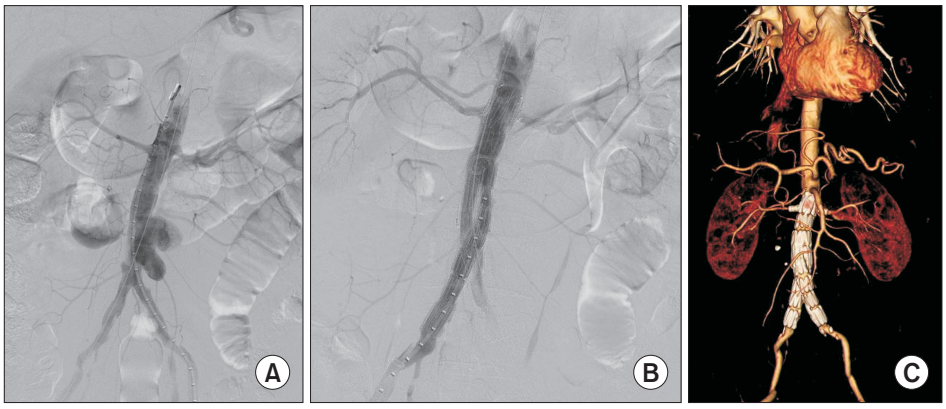

Fig. 2. (A) A case of ruptured 51-mm mycotic infrarenal abdominal aortic aneurysm. (B) The patient was treated with 2 renal fenestrations for both renal arteries. (C) Follow-up CT reconstruction demonstrates patent endograft with flow through both renal arteries.

of the aneurysmal sac was observed in 2 cases, including the patient who was treated with a single fenestration on the LRA for juxtarenal AAA (Fig. 1).

On completion of angiography, 1 type 2 endoleak was identified. Three type 1A endoleaks were observed at the short-term follow-up CT scan. In 1 patient, the type 1A endoleak persisted and the aneurysm sac eventually increased on the most recent CT scan. This patient is currently under close observation without any further intervention. For the other 2 patients with type 1A endoleak, the amount of the endoleak decreased without intervention, with 1 patient showing no change in sac size and the other showing a decreased sac size. For 1 patient with type 2 endoleak, resolution of the endoleak was seen at 1 month without evidence of aneurysm sac growth. Additionally, 1 patient who was treated with a single fenestration for the RRA developed postoperative abdominal compartment syndrome due to the type 2 endoleak that was not identified at the final angiogram, which required stent graft explantation and corrective repair.

During the follow-up period, there were 2 mortalities, including 1 case due to biliary sepsis caused by acute cholecystitis. In another mortality case, the patient was originally treated with 2 fenestrations on both renal arteries for ruptured mycotic aneurysm. Although the procedure was technically successful (Fig. 2), continued active inflammatory changes in the aneurysm were observed which eventually led to an increase in sac size. The patient underwent stent graft removal and aortobiiliac replacement with composite graft at 3 months postoperatively but died due to postoperative pneumonia. The summary of the 12 patients is demonstrated in Table 4.

DISCUSSION

Endovascular treatment has become the current trend for the treatment of aortic aneurysms. Especially for cAAA in patients with multiple comorbidities under emergent setting, the mortality of open repair is reported to be up to 48%–50% [10,11]. Previous studies have shown that for cAAA, repair with fenestrated and branched stent grafts has shown low perioperative morbidity and mortality in high-risk patients [4,5,12]. However, these CMD devices take 4–6 weeks to be manufactured and delivered, which makes it hard to be used in the emergent setting. Additionally, these customized fenestrated stent grafts are not approved for use in Korea and thus not covered by the current insurance system. Therefore, the only possible endovascular treatment option in such situations for patients with difficult aneurysmal morphology would be for the physicians to make the modifications themselves. PMEG in this respect has the potential to fulfill the unmet needs, not only for emergency use but also for elective cases of AAA with unfavorable anatomies such as short proximal neck or severe angulation, when commercial FEVAR devices are not available.

In 2017, Starnes et al. [13] reported midterm results of PMEG for the treatment of juxtarenal aortic aneurysm. They reported 50-month follow-up data of patients who underwent PMEG and compared them with elective open repair and Zenith fenestrated stent graft cases. They demonstrated that PMEG had acceptable midterm rates in terms of morbidity, mortality, and endoleak, and appeared to be durable. They also reported the freedom from sac enlargement at 12 months to be 97.7%. In our study, we presented a case series of patients with high-risk comorbidities who were treated with PMEG for complex aortic pathologies. In most of our cases, the operation was indicated for infrarenal cAAA with a short neck. However, we also performed PMEG for patients who had a short lowest renal artery to iliac bifurcation distance (<80 mm). There was no 30-day mortality, and MAE was observed in only 1 patient who had blood loss greater than 1,000 mL with the development

Table 4. Summary of 12 patients

Patient No.	Sex	Age (yr)	Type of AAA	Stent graft configuration	Technical success	Follow-up (mo)	Complications/reinterventions during follow-ups
1	Male	53	73-mm juxtarenal AAA, impending rupture	1 Fen (LRA)	Yes	77.4	None
2	Male	85	49-mm ruptured juxtarenal AAA	1 Fen (RRA)	Yes	27.8	Abdominal compartment syndrome due to type 2 endoleak Open AAA repair performed
3	Male	79	40-mm mycotic aneurysm (saccular), juxtarenal AAA	1 Scallop (RRA), 1 Fen (LRA)	Yes	21.0	None
4	Male	72	51-mm ruptured mycotic aneurysm (saccular), infrarenal AAA	2 Fen (LRA, RRA)	Yes	6.8	Continued active inflammatory change of mycotic aneurysm Graft removal and aortobiiliac replacement performed
5	Male	77	51-mm juxtarenal AAA	1 Scallop (SMA), 2 Fen (LRA, RRA)	Yes	27.5	None
6	Male	78	61-mm juxtarenal AAA	3 Fen (1 large Fen for CA, SMA and 2 Fen for LRA, RRA)	Yes	45.8	None
7	Male	77	72-mm juxtarenal AAA	3 Fen (SMA, RRA, LRA)	Yes	48.4	None
8	Male	81	52-mm juxtarenal AAA	1 Fen (LRA)	No	17.1	Transient AKI due to LRA stenosis
9	Male	74	64-mm juxtarenal AAA	1 Scallop (RRA, SMA), 1 Fen (LRA)	Yes	17.5	Biliary sepsis due to acute cholecystitis
10	Male	71	52-mm juxtarenal AAA	1 Scallop (LRA)	Yes	39.8	None
11	Male	66	61-mm thoracoabdominal aneurysm	1 Branch (CA), 1 Fen (SMA), 2 Scallop (LRA. RRA)	Yes	29.7	None
12	Female	75	66-mm juxtarenal AAA with severe proximal angulation	1 Fen (LRA)	Yes	28.3	LRA perfusion decrease

AAA, abdominal aortic aneurysm; Fen, fenestration; LRA, left renal artery; RRA, right renal artery; CA, celiac artery; SMA, superior mesenteric artery; AKI, acute kidney injury.

of acute renal failure, which eventually resolved with vigorous hydration without the need for hemodialysis.

In a recent systematic review by Canonge et al. [6], a total of 340 patients treated with abdominal PMEGs were analyzed. Of these patients, 91.8% underwent the procedure for emergent cases. They reported a 30-day all-cause mortality of 7.7% for abdominal PMEG, while aneurysm-related mortality was about 1.1%. In the follow-up data, aneurysm-related mortality occurred in 17 patients (5.0%). In our study, there was no postoperative mortality within 30 days, but there was 1 aneurysm-related death during the overall follow-up period. As previously stated, the patient was treated with 2 renal fenestrations for a ruptured mycotic aneurysm. Inflammation persisted after the procedure and did not resolve even after graft removal. This case suggests that although endovascular treatment for mycotic aneurysm has been shown to be a viable treatment option, PMEG is related to more prosthetic parts and requires more manipulation, which may be more prone to failed infection control. Therefore, although PMEG has a role in treating cAAA in emergency cases, it should be used with more caution for mycotic aneurysms, and possibly considered a bridging therapy, since procedures in this setting are usually performed before the virulence of the causing organism is known.

The presence of endoleaks must be addressed since it is well-known that some types of endoleaks are related to high reintervention and mortality rates [14]. Previous studies have shown that the presence of an endoleak on any postoperative CT imaging was the most important factor for increased sac size which could lead to rupture [15]. In the most recent treatment recommendations, type 1 and 3 endoleaks should be considered for treatment [16]. According to a previous study, type 1 endoleaks were observed in 0%–14.3%, and type 3 endoleaks were observed in 0%–14% of abdominal PMEG cases [6]. In our study, 1 type 2 endoleak was identified at the initial completion angiogram. Additionally, 3 type 1A endoleaks were identified at the short-term follow-up CT scan after the patient was discharged. Although 2 patients showed resolution of endoleaks during follow-up, the other 1 patient had consequence related to persistent endoleaks. One patient with ruptured AAA showed a minor type 1A endoleak on a CT scan, which we decided to closely observe. The patient with type 2 endoleak, which was not identified at the final angiogram, presented with abdominal compartment syndrome due to suspected ongoing bleeding and underwent explorative laparotomy the next day. Therefore, endoleaks must be addressed more aggressively, and the clinician should have a low threshold for additional treatment. Type 3 endoleaks were not identified in our case series, and there was 1 type 2 endoleak case that was not treated because it was minor and did not affect the size of the aneurysm.

Besides aneurysmal sac growth caused by endoleaks, sac enlargement without any detectable endoleak is often reported in conventional EVAR cases, which is commonly referred to as "endotension." According to Schlösser et al. [17], endotension played a role in 9 of 270 cases of a ruptured AAA after EVAR [17,18]. However, FEVAR allows the physicians to obtain a sufficient length of healthy aortic segment for sealing zone. Teter et al. [19] hypothesized that since FEVAR enables physicians to obtain a better sealing zone, there will be decreased endotension, which would lead to a higher rate of sac regression (>5 mm) compared to conventional EVAR (63.33% *vs.* 42.22%). In another case-series study performed by Tran et al. [20], >70% of FEVAR patients demonstrated sac regression at the midterm follow-up. In our study, sac regression was observed in 58.3% of the cases. Although it is not possible to draw definitive conclusions due to the small number of cases, we also observed a higher sac regression rate after PMEG compared to our previously reported regression rates for conventional EVAR [21].

Acute kidney injury (AKI) is one of the most common complications after fenestrated and branched endovascular aneurysm repair (F/BEVAR), which is reported to be in the range of 5% to 29% [22-24]. Although AKI resolved within 30 days in 17% of the cases, persistent renal insufficiency after F/BEVAR was associated with decreased short and long-term survival [25]. For patients who underwent PMEG procedure, a previous study showed that 13% of the patients developed deterioration in renal function and 4% of patients experienced progression of chronic renal insufficiency to require dialysis [26]. One of the causes of AKI in the previous studies was failure to cannulate the renal arteries due to preexisting renal artery stenosis, severe angulation, or malposition of the fenestrations. In our study, we failed to cannulate an LRA in 1 patient. Although the patient did not experience acute renal failure until discharge, he eventually developed left kidney failure after 12 months. His level of creatinine was elevated up to 4.37 mg/dL, and abdominal CT showed atrophy of the left kidney and compensatory hypertrophy of the right kidney. Additionally, in our most recent case of a 66-mm juxtarenal AAA with severe proximal angulation which was treated with a single fenestration for the LRA, there was a decrease in LRA perfusion after 2 years. These experiences suggest that PMEG is more prone to renal function deterioration, and early intervention may be warranted.

The limitation of the current study is that the number of cases is small, and it is a retrospective study from a single institution. Also, there are patients who were lost during the follow-up period and the mean follow-up period was not enough to show the long-term outcomes. Randomized controlled trials with open repair or FEVAR with commercially available devices may be warranted in the future. Yet, to our knowledge, this is the first study to report midterm outcomes of PMEG in Korea. PMEG showed low technical failure rates, and stent durability as well as sac stability were comparable to

conventional EVAR. We also observed a tendency for a higher sac regression rate compared to conventional EVAR, although limited by the small number of cases and the retrospective nature of the study.

In summary, PMEG is a viable option for the treatment of cAAA in high-risk patients, either in the emergent setting or in elective cases when commercial devices are not available. To achieve satisfactory outcomes, the procedure should be performed on selective patients by a dedicated team with sufficient experience and technical support.

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Conflict of Interest
Sukgu Han is a member of the scientific advisory board of W.L. Gore & Associates, Cook Medical, and Vestek. Sukgu Han is also a consultant for W.L. Gore & Associates, Cook Medical, Vestek, and Terumo Aortic.

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