From the Western Vascular Society

Early report from an investigator-initiated investigational device exemption clinical trial on physician-modified endovascular grafts

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Objective: To determine whether a physician-modified endovascular graft (PMEG) is a safe and effective method for treating patients with juxtarenal aortic aneurysms who are deemed unsuitable for open repair.
Methods: A nonrandomized, prospective, consecutively enrolling investigational device exemption clinical trial was used. Data collected on patients treated with PMEG between April 2011 and August 2012 were analyzed. Subjects were followed with computed tomography, visceral duplex, and four-view X-ray at 30 days, 6 months, and 1 year. The protocol was designed to include follow-up to 5 years. The primary safety end point was the proportion of subjects who experienced a major adverse event (MAE) within 30 days of the procedure. The primary efficacy end point was the proportion of subjects experiencing treatment success.
Results: During the 16-month study period, 28 patients were consented and 26 underwent endovascular repair using PMEGs. Anatomic, operative details, and length of stay were recorded and included aneurysm diameter (mean, 62.5 mm), proximal neck length (mean, 4.4 mm), graft manufacture time (mean, 59.7 minutes), procedure time (mean, 169 minutes), fluoroscopy time (mean, 42.8 minutes), total contrast usage (mean, 63 mL), estimated blood loss (mean, 221 mL), and length of hospital stay (mean, 4.9 days). There were 63 fenestrations created for 48 renal arteries and 15 superior mesenteric arteries. Renal artery fenestrations were stented whenever possible (96%) and superior mesenteric artery fenestrations were all left unstented. There were no unanticipated adverse device events, no MAEs, and only a single minor adverse device event treated with a successful reintervention. At 30 days, there were no type I or III endoleaks and only four type II endoleaks (15.4%). Two patients died during the study period, one at day 23 from respiratory failure (in-hospital and 30-day mortality = 3.8%) and one at day 210 from urosepsis and congestive heart failure. MAEs occurred in 11.5% of patients at 30 days. The primary efficacy end point was achieved in 87.5% of patients (technical success 100%, freedom from migration, rupture or conversion, type I or III endoleaks, or sac enlargement = 100%, 100%, 87.5%, and 87.5%, respectively).
Conclusions: These preliminary data suggest that endovascular repair with PMEG is safe and effective for managing patients with juxtarenal aortic aneurysms. Endovascular repair with PMEG has acceptable early rates of morbidity, mortality, and endoleak. This endovascular aortic strategy is particularly appealing for those patients presenting with symptomatic or ruptured aortic aneurysms until reliable off-the-shelf solutions become widely available. (J Vasc Surg 2013;58:311-7.)

The management of patients presenting with juxtarenal abdominal aortic aneurysms continues to evolve. Pure endovascular strategies exist to manage these patients, but currently, no "off-the-shelf" solution is available outside of a clinical trial. On April 4, 2012, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health approved a customized fenestrated device (Zenith fenestrated abdominal aortic aneurysm endovascular graft with the adjunctive Zenith alignment stent; Cook, Incorporated, Bloomington, Ind) that requires 6 weeks to manufacture and deliver for each patient. Unfortunately, for patients presenting with symptoms or rupture, this option is mostly eliminated.

Our group recently reported our experience in managing 47 patients over a 3-year period with immediate physician-modified endovascular grafts (PMEGs) for the management of patients presenting with asymptomatic, symptomatic, or ruptured juxtarenal abdominal aortic aneurysms with limited options for repair.[1] Encouraged by our initial results, we sought an investigator-sponsored investigational device exemption (IDE) with the FDA to prospectively study this mode of therapy. Presented herein are early results of this IDE clinical trial.

METHODS

This clinical trial is in compliance with all FDA regulations, policies, and procedures governing IDEs and is registered with www.clinicaltrials.gov (Identifier # NCT015380 56). The FDA granted approval to commence this trial on January 26, 2011 with up to 150 subjects to enroll. This study is also approved by the Human Subjects Division at the University of Washington in Seattle. All patients underwent informed consent and agreed to participate in the

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trial. Anatomic inclusion criteria for those patients with a juxtarenal abdominal aortic aneurysm greater than 5.5 cm or with recent evidence of rapid growth are listed in Table I.

Study description and objectives. This is a prospective, consecutively enrolling, nonrandomized single-institution clinical evaluation of the safety and efficacy of physician modification of a currently FDA-approved off-the-shelf aortic stent graft (Cook Zenith Flex-TFFB) to preserve branch vessels when used in the treatment of patients with asymptomatic, symptomatic, or ruptured juxtarenal aortic aneurysms with no other options for repair.

The safety of PMEGs will be determined by evaluating the proportion of patients that experience a rate of major adverse events (MAEs). The MAE rate was compared with a performance goal.

The efficacy of PMEGs will be determined by evaluating the proportion of patients that achieve treatment success at 12 months postprocedure. The treatment success rate was compared with a performance goal.

Study primary end points. The primary safety end point is defined as the proportion of subjects who experience an MAE within 30 days of the initial procedure. The primary efficacy end point is the proportion of subjects that achieve treatment success. Treatment success is a composite end point assessed at 12 months that requires the following criteria to be met: technical success, defined as successful delivery and deployment of the PMEG with preservation of those branch vessels intended to be preserved, freedom from type I and III endoleaks at 12 months, freedom from stent graft migration >10 mm at 12 months, freedom from aortic aneurysm sac enlargement >5 mm at 12 months, and freedom from aortic aneurysm rupture and conversion to open repair through 12 months.

Study secondary end points. The following secondary safety end points were evaluated through 12 months: mortality rates at 30 days and 12 months, aneurysm-related mortality at 30 days and 12 months, MAE through 12 months, conversion to open repair and aneurysm rupture. The secondary clinical utility end points evaluated were procedural blood loss, duration of procedure, intensive care unit stay, and length of hospital stay.

Follow-up intervals and events. Follow-up intervals were 1, 6, and 12 months following the initial implant procedure, then planned annually through 5 years. The follow-up events are as follows: physical examination, ankle brachial index at hospital discharge if history of peripheral artery disease, contrast-enhanced spiral abdominal/pelvic computed tomography, abdominal X-ray (KUB), including anterior-posterior, lateral, left oblique, and right oblique projections, device/aneurysm assessment based on imaging analysis, laboratory assessment, and assessment of adverse events.

MAEs. MAEs included death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, and procedural blood loss of greater than 1 liter. All MAEs were adjudicated by a clinical events committee composed of three academic faculties from various medical and surgical specialties at the University of Washington.

Table I. Anatomic inclusion criteria

Anatomic criterion	Parameter
Proximal neck diameter, mm	20-32 (OD)
Proximal neck length, mm	≥2
Juxtarenal aortic angle, °	<60
Iliac diameter, mm	8-20 (OD)
Iliac length (distal seal zone), mm	≥15

OD, Outer diameter.

Procedural details. Procedural details have been previously reported.[1] Three-dimensional reconstruction imaging software (Aquarius; Tera-Recon, Foster City, Calif) was used routinely for preoperative planning to ensure precise placement of aortic fenestrations in "clock-face" positions for branch vessel preservation. As the study evolved, planning modifications were made to include arc length measurements (Fig 1) and centerline correction for angulated aortic anatomy (Fig 2).

Statistical analysis. This study is designed to estimate the rate of MAEs following juxtarenal abdominal aortic aneurysm repair with PMEG. The proportion of patients receiving PMEG who experience one or more MAEs within 30 days of the procedure is the rate of interest. A target performance goal of 56% is based on the rate of MAEs at 30 days reported for open surgical control patients from the Society for Vascular Surgery Lifeline Registry of Endovascular Repair.[2]

Treatment success is the primary efficacy end point for the study. The proportion of patients who are a treatment success at 12 months is the rate of interest. PMEG is considered to be effective if this study's result verifies that the lower limit of the one-sided 95% confidence interval is above 80%. All data are presented as percentages, means ± standard deviation and range.

RESULTS

The first patient (subject 001) was enrolled on March 11, 2011 and underwent successful PMEG on April 12, 2011. Data lock for this report occurred on September 1, 2012. The time from presentation to treatment averaged 19 days and ranged from 0 days (rupture) to 32 days. During the 16-month study period, the author performed 92 subdiaphragmatic aortic aneurysm repairs; 62 (67%) were performed using endovascular methods, 26 (28%) were performed using traditional open surgery, and four (4%) were hybrid procedures. Endovascular procedures comprised 24 standard endovascular aneurysm repairs (EVARs), four fenestrated EVARs in the context of a clinical trial, eight ruptured EVARs, and 26 PMEGs. Open procedures comprised seven open infrarenal aneurysm repairs, one open ruptured aneurysm repair, nine type IV thoracoabdominal repairs, six pararenal aneurysm repairs, and three juxtarenal aneurysm repairs.

Fig 3 depicts a summary and flow chart of subject enrollment to date. During the 16-month study period, 28 patients were consented and 26 underwent the PMEG procedure (one patient had denial of insurance

$$Arc\ Length = \frac{D \times \pi \times \alpha}{360}$$

$$Arc\ Length = \frac{22.6 \times \pi \times 85}{360} = 16.75\ mm$$
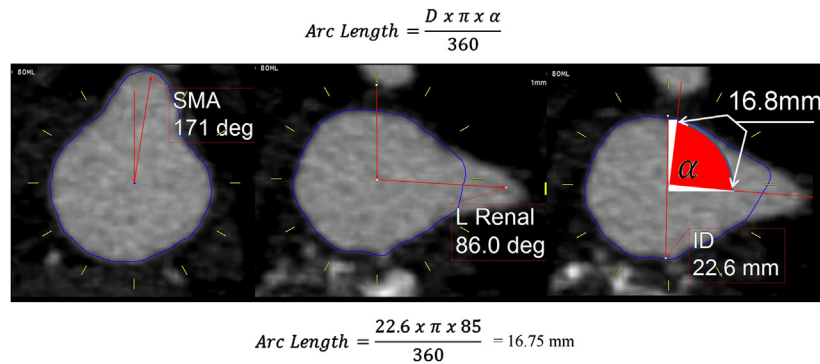
Fig 1. Arc length example. The length measurement is between the superior mesenteric artery (*SMA*) and the left renal artery.
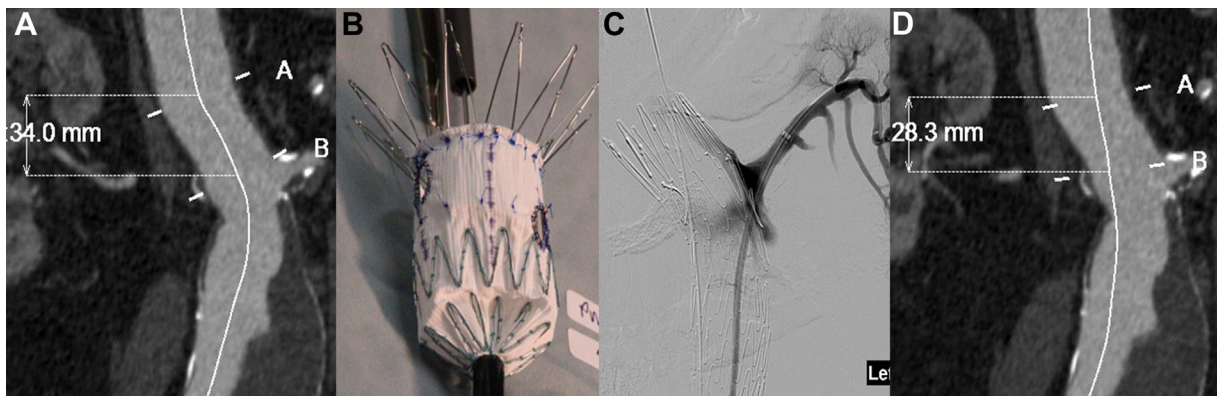
Fig 2. Example of centerline adjustment for enhanced measurement precision in angulated anatomy. **A,** Automatically generated centerline showing length measurement from proximal graft and top of left renal to be 34 mm. **B,** Actual photograph of physician-modified endovascular graft (PMEG) device for this subject. **C,** Angiogram demonstrating right renal already stented and left renal fenestration positioned too low for proper alignment. **D,** Centerline adjustment to mimic path of stiff wire in **(C)** showing a different length measurement of only 28.3 vs 34 representing a measurement error of 6 mm. Notice the path of the wire in **(C)** vs the centerline automatically generated in **(A)**.

and underwent open repair and one patient did not meet inclusion criteria upon re-review of images). Twenty-five patients had 30-day follow-up, 17 patients had 6-month follow-up, and eight patients had 1-year follow-up. Mean follow-up for the entire cohort was 11.9 months; 73% of the subjects were male. Demographics and patient characteristics are listed in Table II, PMEG procedure details are listed in Table III, and anatomic details of the treatment group are listed in Table IV.

There were 63 fenestrations created for 48 renal arteries and 15 superior mesenteric arteries (SMAs). Renal artery fenestrations were stented whenever possible (96%) and SMA fenestrations were all left unstented. Two renal stents were unable to be placed at the initial procedure, but perfusion to the respective kidneys was maintained. One patient underwent successful renal stenting the day following the index procedure and successful aneurysm exclusion and endograft seal was achieved in each of these patients.

At 30 days, there were no type I or III endoleaks and only four type II endoleaks (15.4%). Two patients died during the study period, one at day 23 from respiratory failure (in-hospital and 30-day mortality = 3.8%) (Table V) and one at day 210 from urosepsis and congestive heart failure. MAEs occurred in 11.5% of patients at 30 days and included two myocardial infarctions and one patient experiencing respiratory failure leading to death (Table VI).

There were no unanticipated adverse device events, no major adverse device events, and only a single minor adverse device event at 12 months treated with a successful reintervention. This subject (003) developed a type III endoleak because of component separation involving a left renal stent (Fig 4) and underwent successful reintervention (Fig 5).

The primary efficacy end point was achieved in 87.5% of patients (technical success 100%, freedoms from migration, rupture or conversion, type I or III endoleaks, or
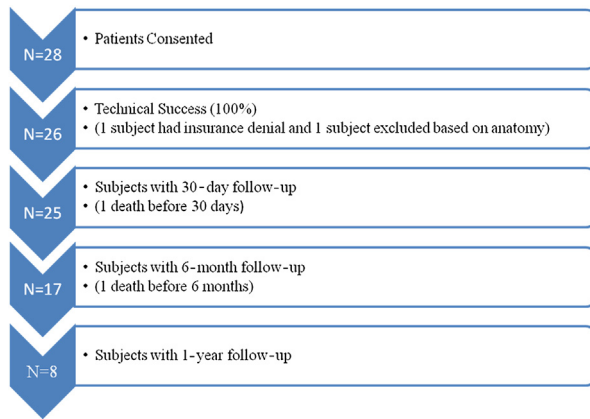
Fig 3. Summary and flow chart of subject enrollment to date.

Table II. Demographics and patient characteristics

Demographics	No. (%) or mean ± SD (range)
Age, years	76 ± 7.7 (64-90)
Male	19 (73.1)
Coronary artery disease	14 (53.8)
Congestive heart failure	5 (19.2)
Hypertension	25 (96.2)
COPD	10 (38.5)
Diabetes mellitus	8 (30.8)
Hyperlipidemia	21 (80.8)
ASA ≥ 3	26 (100)
ASA = 4	2 (7.7)
(including one rupture- 4E)	

ASA, American Society of Anesthesiologists; *COPD,* chronic obstructive pulmonary disease; *SD,* standard deviation.

Table III. PMEG procedure details

Procedural details	Mean (range) or %
Graft manufacture time,[a] minutes	59.7 (31-78)
Operative time, minutes	169 (96-378)
Fluoroscopy time, minutes	42.8 (19.7-164)
Contrast usage, mL	63 (30-120)
Estimated blood loss, mL	221 (20-1000)
General anesthesia, %	96.2

PMEG, Physician-modified endovascular graft.
[a]Data not available or recorded on four initial patients.

Table IV. Anatomic details of treatment group

Measurement	Mean (range)
Maximum aneurysm diameter, mm	62.5 (54-91)
Proximal aortic neck length, mm	4.4 (2-11.7)

Table V. Mortality and lengths of stay

	No. (%) or mean ± SD (range)
30-day mortality	1 (3.8)
ICU length of stay, days	2.8 ± 4.4 (0.8-19.7)
Hospital length of stay, days	4.9 ± 5.4 (1.3-23.7)

ICU, Intensive care unit.

sac enlargement = 100% , 100%, 87.5%, and 87.5%, respectively) (Table VII). Of the eight patients with 1-year follow-up, seven (87.5%) had evidence of sac shrinkage, and one patient had sac enlargement.

DISCUSSION

To the layperson, it must seem amazing that even though fenestrated stent graft technology has existed worldwide for over a decade, in the United States, we still do not have an "off-the-shelf" endovascular solution for patients presenting with juxtarenal aortic aneurysms. The reasons for this are quite evident, however. Carefully conducted clinical trials to prove safety and efficacy of a medical device take time and considerable resources. Rushing devices to public market before proof of safety and efficacy is both reckless and hazardous.[3] Although it is exciting that we have a customizable device that is now FDA approved for commercial use, this is technology that was innovated 10 years ago and newer devices and better technologies currently exist in the "commercial pipeline."

Faced every day with patients who have limited options, a few physicians have pushed the limits of current

technologies by hearkening back to their surgical roots and customizing aortic stent grafts using back table modifications to fit the anatomic needs of the patient.[1,4,5] This raises concerns of quality, product liability, and most of all, durability. For all of these reasons, we decided to study this methodology in a carefully controlled prospective clinical trial overseen by the U.S. FDA.

Based on our institutional experience and the results described in this article, we believe PMEG to be a safe and durable option for this challenging patient population. We have learned several valuable lessons along the way.

First, these procedures require advanced imaging, precise and detailed planning, and technical expertise in visceral artery intervention. Our procedures typically require about an hour to manufacture the device, about 2 one-half hours of operative time with roughly 40 minutes of fluoroscopy time, and on average only 60 mL of contrast. The concept of reaching higher in the aorta above the visceral vessels into a normal and healthy-appearing segment is counterintuitive at first, as it theoretically increases the risk associated with the procedure. To the contrary, we have learned that this effort is associated with better fixation and seal and lessens the risk for graft-related complications such as migration and/or type I endoleak.

The consistent use of arc length measurements and centerline adjustments for angulated aortic anatomy represented significant improvements in our operative planning strategies and subsequent successful conduct of the procedures. Stent grafts do not always conform to angulated

Table VI. Primary safety end point; MAEs

	Procedure, No. (%)	Postprocedure, No. (%)	1 month, No. (%)	6 months, No. (%)	12 months, No. (%)
Number of subjects	26	26	25	17	8
Death	0 (0)	0 (0)	1 (4)[a]	1 (5.9)	0 (0)
Myocardial infarction	0 (0)	2 (11.1)	0 (0)	0 (0)	1 (13)[b]
Stroke (excludes TIA)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal failure (excludes renal insufficiency)	0 (0)	0 (0)	0 (0)	1 (4)	0 (0)
Respiratory failure (excludes COPD)	0 (0)	0 (0)	1 (4)[a]	0 (0)	0 (0)
Paralysis (excludes paraparesis)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bowel ischemia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Procedural blood loss (≥1000 mL)	1 (5.5)	0 (0)	0 (0)	0 (0)	0 (0)

COPD, Chronic obstructive pulmonary disease; *MAE,* major adverse event; *MI,* myocardial infarction; *TIA,* transient ischemic attack.
[a]This is the same patient.
[b]MI 329 days postoperatively.
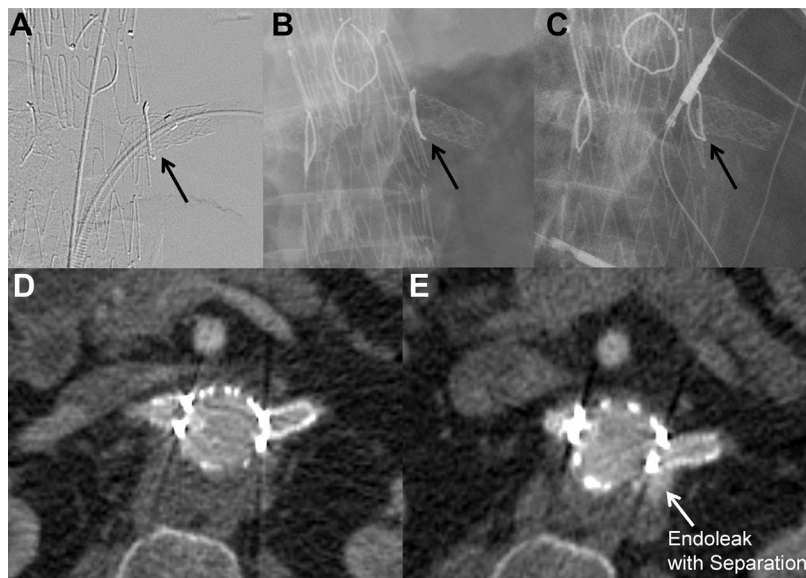
Fig 4. Subject 003 X-ray at **(A)** index procedure (July 11, 2011), **(B)** 1 day postprocedure (July 12, 2011), and **(C)** 6-month follow-up (December 12, 2011). It is unclear on **(C)** if there is stent separation. **D,** Depicts axial computed tomographic angiogram (CTA) image on August 19, 2011 for 30-day follow-up (no stent separation), and **(E)** depicts axial CTA image on December 12, 2011 clearly demonstrating stent separation and type III endoleak (*arrow*).

anatomy and when deployed, tend to "straighten out" the aorta (Fig 2). It may be that this endovascular approach may not be suitable for patients with severe aortic angulation and may be associated with less favorable outcomes. We believe that a thoughtfully and carefully planned PMEG procedure equates with a technically efficient and well-executed operative procedure which in turn, translates into better outcomes for the patient. This can be in the form of less time under general anesthesia, less contrast usage, and less ischemic time to the lower extremities.

As reported previously, our results compare favorably with contemporary results of fenestrated endografting in the current medical literature.[6-10] In this early series, PMEG was associated with a 3.8% 30-day mortality rate in

a single patient who died of respiratory failure on postoperative day 23. In our initial report on PMEG, our average number of fenestrations per patient was 1.75 compared with two to three in other studies.[6,9,11] In the current series, the average number of fenestrations per case was 2.5. This is probably reflective of our learning curve over a 5-year period and the realization that "higher was better."

Others have criticized our strategy of routinely leaving the SMA unstented. This is a valid criticism but must be explained. The reason for this strategy is related to current device constraints and nothing else. Our goal is to leave the renal fenestrations completely strut free and to use a large (~12 mm) fenestration for the SMA. This typically involves struts spanning the SMA fenestration because of
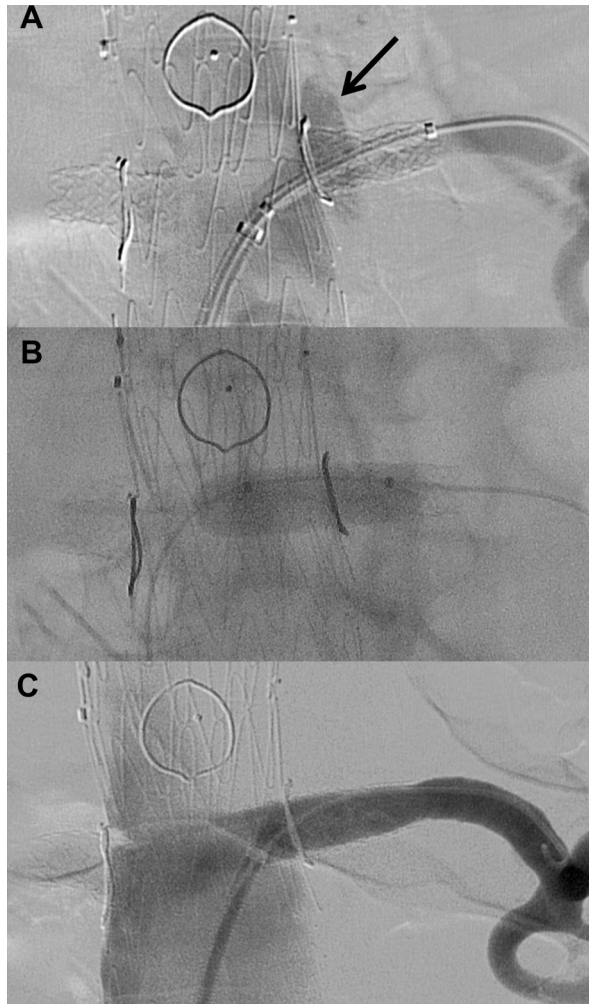
Fig 5. Subject 003 underwent secondary intervention on February 21, 2012. **A,** Depicts component separation and type III endoleak (*arrow*). This subject underwent successful placement of a second covered stent (**B**) and had resolution of endoleak (**C**).

the stent design inherent to the Cook device. The addition of a stent into this fenestration would potentially lead to stent failure because of the interaction between the stent and struts.

There was a single minor adverse device event in this series. Interestingly, it involved stent separation of a left-sided renal artery stent. Renal artery deformation with respiration has been previously reported, but the impact of this phenomenon on renal artery stent durability is ill defined.[12,13] Left renal artery stent fractures are thought to be more common that right-sided fractures.[12] Future stent designs may demand specific characteristics to overcome these challenges, as it seems that in this region of the aorta, the Achilles' heel of any branched or fenestrated stent graft technology is the renal artery.

With recent FDA approval of the Z-Fen device (Cook, Incorporated), we have observed that many patients

Table VII. Primary effectiveness end point; treatment success

Criteria	No. (%)
Technical success	26/26 (100)
Freedom from migration at 12 months	8/8 (100)
Freedom from rupture or conversion at 12 months	8/8 (100)
Freedom from type I or III endoleak at 12 months	7/8 (87.5)[a]
Freedom from sac enlargement at 12 months	7/8 (87.5)[a]

[a]The same patient (subject 003) had sac enlargement from a type III endoleak successfully treated with secondary intervention.

currently managed with PMEG can undergo treatment with this commercially available system. There will, however, continue to be a need for a truly off-the-shelf device applicable to most patients or a customizable device, like PMEG, for those patients requiring urgent or semi-urgent repair. It should be clearly emphasized that the PMEG fenestrated procedure as described in this article should only be used for juxtarenal and not pararenal aneurysms. Physician-modified endografts can be used to treat suprarenal aneurysms as well, but this is not within the scope of this report.

CONCLUSIONS

This early report on PMEGs is encouraging and suggests that the technique is valid, safe, and effective, at least in the short term. This endovascular aortic strategy is particularly appealing for those patients presenting with symptomatic or ruptured aortic aneurysms until reliable off-the-shelf solutions become widely available. Durability issues have not been proven and will be determined by mid- and long-term results.

AUTHOR CONTRIBUTIONS

Conception and design: BS
Analysis and interpretation: BS, BT
Data collection: BS, BT
Writing the article: BS
Critical revision of the article: BS, BT
Final approval of the article: BS
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: BS

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DISCUSSION

Dr Stephen Cheng (*Hong Kong, China*). Dr Starnes presented his early results from the IDE clinical trial on PMEGs in a series of 26 patients with juxtarenal aortic aneurysms. He is to be congratulated in achieving excellent early outcomes with limited tools on the back table.

In a custom-made device, it is possible to place the fenestrations in the optimum position to match the patient's anatomy and adjust the stents to fit around them, but when fenestrations are made on an already-sterile graft, it may be necessary to place the fenestrations in a perhaps less-than-optimum position to fit in between the stent struts. The fact that Dr Starnes can achieve a 100% technical success rate is testimony to his planning skills and technical expertise.

Devices modified in this manner were by all accounts similar to the early fenestrated grafts that were made and implanted in other patients outside the United States. Although the follow-up period of this present series is a mere 11 months, there is no reason to suspect that longer-term outcomes would not be as good, if not better, than those published by the same group in this month's *Journal of Vascular Surgery*. In the inevitable comparison between the two series, it is evident that a larger number of fenestrations were used in the later IDE trial, in particular for the SMA. The authors attributed this to a need to maximize proximal seal.

I have the following questions for Ben:

You addressed the issue of not stenting the SMA due to limitations of the stent struts crossing the large fenestration. In this manner, the SMA fenestration essentially functions as a large scallop and cannot add much to extending the proximal seal. In your opinion, would that limit the PMEGs to treating juxtarenal aneurysms, but not true suprarenal aneurysms? Have you used this graft to treat aneurysms with less than the 2-mm neck length?

On a technical note, when you used nitinol snares around the fenestrations, do these function only as a radiopaque marker? In standard fenestrated grafts, the nitinol reinforcing rings help to lock the stents onto the fenestration and allow for better flaring. Unreinforced fenestrations may stretch and expand in size to the diameter of virtually any balloon that was used, and the origin of the target vessel could be expanded to more than would be considered safe. Do you see these as concerns for long-term failure?

Finally, in light of the competing fenestrated systems such as the Ventana and the Anaconda, or the newer-generation Zenith p-branch off-the-shelf devices, how do you see the role of physician-modified grafts in the future?

I thank the society for the opportunity to discuss this paper.

Dr Benjamin Ware Starnes. Thank you, Stephen, for those insightful comments. Regarding the SMA fenestration remaining unstented, I do not believe that this fenestration serves merely as a scallop. In fact, with PMEG, I have found that the creation of a scallop using these techniques actually disrupts the integrity of the proximal graft fabric and makes the device more difficult to reload into the sheath. Also, there is actually quite good seal in and around the unstented SMA fenestration in these cases. Remember that we are confined by the standard Cook device design and try at all costs to leave the renal fenestrations strut-free. This then, in the majority of situations, leaves struts spanning the SMA fenestration. Stenting the SMA in this situation, I believe is fraught with hazard to include stent kinking and crushing with greater radial strength of the existing struts over the renal stents. This leads to the second part of your first question which is— PMEG is really only for true juxtarenal aneurysms with at least 2 mm of neck below the renal arteries, not for para- or suprarenal aneurysms. All of these patients had at least 2 mm of neck with a range of between 2 and 11 mm.

The gold markers are hand sewn into place using 4-0 prolene in a 720° circumferential fashion, so while not being a true reinforced fenestration, with good aortic wall apposition and parallel walls, I believe this is a durable alternative. One of the benefits of this IDE is going to be the ability to assess the durability of this approach over the long term.

Finally, even with off-the-shelf solutions in the industrial pipeline, I still believe that there will be a role for PMEG in specific anatomic situations. These grafts are truly customized to each and every patient, and time will tell if they are even *more* durable than an off-the-shelf solution to manage more than just 70% of patients with juxtarenal aortic aneurysms, which is what these new grafts tout.