Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms

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Objective: **This article reports the intermediate-term (24-month) outcomes of a prospective multicenter trial designed to evaluate the Zenith Fenestrated AAA Endovascular Graft (Cook Medical, Bloomington, Ind) for treating juxtarenal abdominal aortic aneurysms with short proximal necks. The study goals were to evaluate the safety and preliminary effectiveness of the device and refine patient selection criteria.**

Methods: **Five centers in the United States enrolled 30 patients with juxtarenal aortic aneurysms with ≥50-mm diameter and short proximal necks. Devices were custom-designed for each patient based on measurements from reconstructed computed tomography (CT) data. Follow-up studies included physical examinations, laboratory studies, CT imaging, mesenteric-renal duplex ultrasound imaging, and abdominal flat plate radiographs at hospital discharge, at 1, 6, and 12 months, and yearly thereafter up to 5 years.**

Results: **During a 1-year period, 30 patients (80% men; mean age, 75 years) with a mean aneurysm size of 61.4 mm were enrolled. In these 30 patients, 77 visceral vessels were accommodated by fenestrations located within the sealing segment of the grafts. The most common design accommodated two renal arteries and the superior mesenteric artery (66.7%). All prostheses were implanted successfully. No visceral arteries were lost. Of the 30 patients treated, 27 were available for 12-month follow-up and 23 were available for 24-month follow-up. No aneurysm-related deaths, aneurysm ruptures, or conversions were observed through 24 months of follow-up. No type I or type III endoleaks were observed. Type II endoleaks were noted in six (26.1%) at 12 months and four (20.0%) at 24 months. No patients had aneurysm growth >5 mm. Aneurysm size decreased in 16 of 23 (69.6%) and was stable in the remaining patients at 24 months. Eight patients experienced a renal event (4 renal artery stenoses, 2 renal artery occlusions, and 2 renal infarcts). Five underwent secondary interventions. No renal failure developed requiring dialysis.**

Conclusions: **The intermediate-term (24-month) results of the 30 patients in this multicenter study are concordant with previous single-center studies and support the concept that placement of fenestrated endovascular grafts is safe and effective at centers with experience in endovascular repair and renal/mesenteric stent placement. (J Vasc Surg 2009;50:730-7.)**

Unfavorable anatomy of the proximal aortic neck of an infrarenal abdominal aortic aneurysm (AAA) is the most common factor (up to 40% of patients) precluding patients from an endovascular treatment option.[1,2] Multiple studies of conventional commercial aortic endografts[3-5] have demonstrated that short or compromised proximal aortic necks can lead to inadequate proximal seal by the graft and are associated with higher incidences of proximal endoleak, device migration, and aneurysm rupture. These results have led to a well-accepted anatomic requirement for a proximal neck length of ≥15 mm for most commercially available endografts in the United States.

If such exclusion criteria could be addressed by a modified endovascular approach, up to 80% of infrarenal aneurysms could be managed in a minimally invasive fashion.[2] Endovascular grafts with fenestrations, which are openings within the graft fabric to accommodate visceral arteries, have been developed to improve the proximal seal by incorporating segments of the visceral arteries into the proximal sealing zone.

Initial reports have demonstrated the technical feasibility of using fenestrated devices and documented short-term to intermediate-term safety and effectiveness.[6-12] However, the absence of multicenter trial data has often raised the question whether these devices can be made more widely available. This article reports the results of first prospective multicenter trial intended to assess the safety and effectiveness of the Zenith fenestrated device (Cook Medical, Bloomington, Ind).

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Competition of interest: Drs Greenberg and Chuter disclose they have intellectual property licensed to Cook Inc and have received travel expenses.

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

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Table I. Participating centers in the Cook Zenith Fenestrated AAA Endovascular Graft trial

Institution	*Location*	*Principal investigator*	*Patients enrolled, No.*
Cleveland Clinic Foundation	Cleveland, Ohio	Sean Lyden, MD	8
Massachusetts General Hospital	Boston, Ma	Christopher J. Kwolek, MD	6
Ochsner Clinic	New Orleans, La	W. Charles Sternbergh III, MD	0[a]
University of California, San Francisco/VA	San Francisco, Calif	Darren Schneider, MD	7
University of Pittsburgh Medical Center	Pittsburgh, Pa	Michel Makaroun, MD	6
Hospital of the University of Pennsylvania	Philadelphia, Pa	Ronald Fairman, MD	3
Total			30

[a]This center enrolled one patient who later transferred to Massachusetts General Hospital as a result of Hurricane Katrina in 2005.

MATERIALS AND METHODS

Six centers (Table I) with experience in conventional endovascular grafting and familiarity with the interventional treatment of renal and mesenteric occlusive disease participated in patient enrollment of this study. Five centers enrolled 30 patients between January 2005 and January 2006. Informed consent, approved by the respective institutions' Institutional Review Boards, was obtained for all individuals treated.

Preoperative assessment and device sizing. Preoperative high-resolution computed tomography (CT) scans for all patients, and angiography obtained at the physician's discretion, were used to determine if the aneurysm morphology was unsuitable for traditional infrarenal endovascular grafts yet within the anatomic guidelines (Table II) for repair with the Zenith fenestrated device.

Customized devices for each patient (Fig 1) were designed according to multiplanar reconstruction and centerline of flow calculations derived from CT scans. Diameters and lengths of the aorta and iliac arteries, and visceral vessel morphology were used to denote the relative positions of visceral vessels intended to be incorporated within the sealing zone of the fenestrated device in a manner similar to prior publications.[1] Small, large, or scalloped fenestrations were included as options for the device design. Device designs proposed by the implanting physicians were reviewed by at least one of two centers with prior experience with device planning (William A. Cook Australia and Cleveland Clinic). The following guidelines were used for device design:

- Adequate seal must be achieved after placement of the proximal sealing stent within a segment of aorta that radiographically appears relatively healthy; for example, parallel walls, consistent diameter, and free of luminal debris.
- The target vessel to be stented must have adequate length without aneurysmal involvement.
- The proximal fenestrated component must terminate approximately 20 to 30 mm above the aortic bifurcation.
- The modular distal bifurcated component must have a minimum of two stents (50-mm) of overlap with the

Table II. Inclusion and exclusion criteria for the Zenith Fenestrated AAA Endovascular Graft trial

Inclusion criteria
- Aortic or aortoiliac aneurysm with diameter >5 cm
- Aortic or aortoiliac aneurysm with a history of growth >0.5 cm/y, or clinical indication for AAA repair

Exclusion criteria

General exclusion criteria
- Age <18 years
- Life expectancy <2 years
- Pregnant or breastfeeding
- Unwilling to comply with the follow-up schedule
- Inability or refusal to give informed consent

Medical exclusion criteria
- Baseline creatinine >2.0 mg/dL
- Cultural objection to receipt of blood or blood products
- Allergic to stainless steel or polyester
- Anaphylactic reaction to contrast material
- Leaking/ruptured or symptomatic aneurysm
- Uncorrectable coagulopathy
- Previous stent in any renal or visceral artery to be accommodated with a small fenestration

Anatomic exclusion criteria
- Significant occlusive disease, tortuosity, or calcification
- Proximal neck <4 mm, or >15 mm in length unless otherwise compromised to preclude seal
- Proximal neck, measured outer wall to outer wall on a sectional CT image >31 mm or <19 mm in diameter
- Proximal neck angulated >45° relative to the long axis of the aneurysm
- Immediate suprarenal neck angulated >45° relative to the immediate infrarenal neck
- Proximal neck diameter change over the length of the proximal seal zone >4 mm
- Proximal seal site with circumferential thrombus/atheroma above the renal arteries
- Iliac artery diameter, measured inner wall to inner wall on a sectional CT image <7.5 mm at any point along access length (before deployment)
- Ipsilateral iliac artery fixation site diameter, measured inner wall to inner wall on a sectional CT image <9.0 mm before deployment
- Iliac artery diameter, measured outer wall to outer wall on a sectional CT image >21 mm at distal fixation site
- Iliac artery distal fixation site <30 mm in length
- Inability to maintain at least one patent hypogastric artery
- Renal artery stenosis >50%
- Nonbifurcated segment of any artery to be stented <15 mm in length
- Unsuitable arterial anatomy

AAA, Abdominal aortic aneurysm; *CT,* computed tomography.

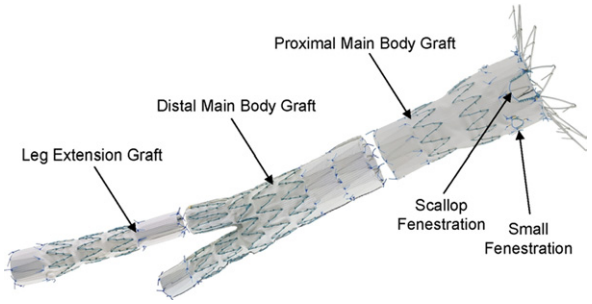

Fig 1. This photograph of the Zenith Fenestrated AAA Endovascular Graft shows the components of the endograft, as well as the scallop and small fenestrations.

proximal tubular fenestrated component, with greater overlap recommended.

Device implantation. A proctor physician who had experience with the fenestrated endograft was present for all cases in this study. Fundamental aspects of the deployment technique will be summarized subsequently and are described in detail in previously published reports.[9,10] In brief, patients were given anticoagulation therapy and bilateral femoral access was obtained. A stiff guidewire was introduced on the side intended for delivery of the proximal fenestrated component, and a large diameter, valved sheath (20F to 22F Check-Flo, Cook Medical) was inserted from the contralateral side for access to fenestrations. The proximal fenestrated component was introduced and oriented by visualizing the radiopaque gold markers on the anterior and posterior aspects of the graft component and around each fenestration.

The proximal component was partially deployed, and the fenestrations were aligned with the corresponding visceral vessels. Sheaths or guiding catheters were then inserted through the contralateral access sheath into all fenestrations and the respective vessels that were to be stented. The constraining wire was removed to fully expand the graft, and the top cap was deployed to release the uncovered barbed fixation stent.

The study protocol required stent placement in all visceral vessels accommodated by small fenestrations, whereas stent placement through large fenestrations or scallops was performed at the discretion of the implanting physician. Stents were deployed such that most of the stent was anchored within the visceral artery and approximately 2 to 4 mm of the stent extended into the aorta. Flaring of the proximal (aortic) end of the stents was achieved with a 10-mm-diameter balloon.

The distal bifurcated component was deployed, ensuring adequate overlap with the proximal fenestrated component. The leg component was then deployed in a manner similar to conventional Zenith AAA endovascular grafts. A large diameter balloon (eg, CODA Balloon, Cook Medical) was inflated at the overlap joints and distal sealing regions of the device to assure optimal sealing between the graft and the aorta. An angiogram was recorded after the procedure to assess for endoleak and graft patency.

Table IV. Pre-existing risk factors[a] and smoking status

Factor	*No. (%) N = 30*
Cardiovascular	
Prior myocardial infarction	8 (26.7)
Prior diagnosis of CHF	3 (10.0)
Prior diagnosis of CAD	15 (50.0)
Prior diagnosis of arrhythmia	14 (46.7)
Hypertension	26 (86.7)
Vascular	
Thromboembolic event	5 (16.7)
Peripheral vascular disease	7 (23.3)
Family history of aneurysmal disease	4 (13.3)
Pulmonary	
COPD	9 (30.0)
Renal	
Failure requiring dialysis	0 (0)
Insufficiency	2 (6.7)
Diabetes	7 (23.3)
Neurologic	
Prior diagnosis of CVD	5 (16.7)
Previous endarterectomy	1 (3.3)
Smoking	
Current	8 (26.7)
Quit	19 (63.3)
Never	3 (10.0)

CAD, Coronary artery disease; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CVD,* cerebrovascular disease.
[a]Patients may have presented with more than one comorbid condition.

Patient follow-up. CT scans, visceral duplex ultrasound imaging, abdominal radiographs, physical examinations, and laboratory studies were obtained before discharge, at 1, 6, and 12 months, and yearly thereafter up to 5 years. Imaging studies were evaluated by the investigative sites and the core laboratory. Data presented here reflect only the results from the core laboratory analysis.

Data analysis. Data were managed by MED Institute Inc. All statistical analyses were performed using SAS 9.1 software (SAS Institute, Cary, NC). Specific endovascular outcomes, including technical success, clinical success, aneurysm size change, endoleaks, migration, device integrity, and death were analyzed in accordance with the reporting standards for endovascular aortic aneurysm repair.[13] Adverse events were defined and analyzed in a manner similar to previous Zenith AAA studies,[14,15] and the Kaplan-Meier method was used to assess freedom from major adverse events. Renal events were defined as a serum creatinine rise by >30% from baseline and to >2 mg/dL on two or more follow-up tests, or detection of new renal pathology (stenosis, occlusion, dissection, or infarct) involving renal arteries accommodated by the fenestrations.

RESULTS

Preprocedural patient characteristics. The stringent anatomic exclusion criteria resulted in the rejection of 19 screened candidates from this study after detailed film review. Causes of the rejections are presented in Table III (online only). This study included 30 patients (24 men and 6 women), with a mean age of 75 years (range, 59-86

Table V. Configuration of the proximal fenestrated component

Configuration	*No. (%) (N = 30)*
1 SMA scallop + 2 RA small fenestrations	20 (66.7)
2 RA small fenestrations	1 (3.3)
1 main RA scallop + 1 main RA small fenestration	5 (16.7)
1 main RA artery scallop	3 (10.0)
2 main RA artery scallops	1 (3.3)

RA, Renal artery; *SMA,* superior mesenteric artery.

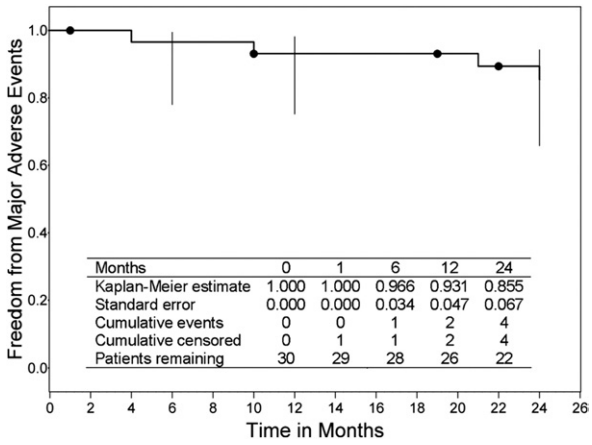

Fig 2. Kaplan-Meier analysis of freedom from major adverse events, defined as Q-wave myocardial infarction, congestive heart failure, cardiac ischemia requiring intervention, renal failure requiring permanent dialysis, bowel obstruction, ischemia or fistula, stroke, paralysis, conversion to open surgery, aneurysm rupture, or death. The *circles* represent time points when any patient is censored from the analysis. The *vertical bars* represent 95% confidence intervals.

years). A history of cardiovascular and pulmonary disease was common (Table IV). Only two patients (6.7%) had documented pre-existing renal insufficiency.

The mean maximum aneurysm diameter was 61.4 mm (SD, 9.7 mm; range, 48.8-88.0 mm). All patients had short (<15 mm) proximal necks (9.2 [SD, 2.9]; range, 2.4-14.4 mm). The shape of the sealing zone was considered parallel in 63.3%, funnel in 16.7%, inverted funnel in 6.7%, or irregular in 13.3%. The mean angle between the suprarenal and perirenal aorta was 15.8° (SD, 9.3°; range, 2°-40°), and the mean angle between the perirenal and infrarenal aorta was 32.4° (SD, 13.8°; range, 7°-57°).

Device design. In this study, 77 visceral vessels were accommodated by fenestrations (Table V), including 47 renal arteries accommodated by small fenestrations, and 10 renal arteries and 20 superior mesenteric arteries (SMAs) accommodated by scallop fenestrations. None of the devices incorporated the celiac artery or an accessory renal artery into the repair; however, accessory renal arteries were covered at the discretion of the implanting physician, provided the primary renal arteries carried most of the renal flow. The most common proximal fenestrated design included a scallop for the SMA and two small fenestrations for the main renal arteries (66.7%).

Procedural data. Median procedure time was 234 minutes (range, 170-554 minutes). Average blood loss was 601 mL (range, 50-2400 mL), and seven patients required replacement blood products. The mean stay in the intensive care unit was 0.8 days (range, 0-6 days), and overall length of hospital stay averaged 3.7 days (range, 1-8 days). Patients required an average of 1.4 days (range, 0-5 days) from the procedure to resume a regular diet and 1.4 days (range, 0-7 days) to ambulation.

During the procedure, uncovered metal stents were placed in 54 renal arteries (47 small fenestrations, 7 scallops). No stents were placed in SMAs. Adjunctive procedures included placement of an iliac conduit in 1 patient, iliac angioplasty for device passage in 1, iliac stent placement in 2, angioplasty within a kinked iliac limb in 1, femoral endarterectomy in 1, and thromboendarterectomy in 1.

Procedural angiography resulted in 12 patients being diagnosed with endoleaks: 3 with type Ia, 1 with combined type Ia and type III, 4 with type III between the proximal fenestrated component and distal bifurcated component, and 4 with type II. Two of the 3 proximal type Ia leaks were treated with repeated ballooning, and one was treated with the addition of a Palmaz stent (Cordis Endovascular, Warren, New Jersey). The patient with a combined type Ia and III endoleak was treated with repeated ballooning proximally and at the contralateral leg joint. One of the three patients with isolated type III endoleaks underwent additional balloon angioplasty, and two patients underwent placement of a Palmaz stent. The type III endoleak in one patient resolved before discharge without any treatment.

Patient follow-up. Two patients were lost to follow-up at 1 month and 10 months, and two deaths occurred. Among the patients eligible for follow-up, 27 of 28 (96.4%) and 23 of 27 (85.2%) underwent follow-up evaluations at 12 and 24 months, respectively.

Death, rupture, conversion, and adverse events. No deaths occurred ≤30 days of the procedure. Two late deaths occurred at 677 and 754 days. One death was a result of several pre-existing comorbidities and the other was attributed to atherosclerotic cardiovascular disease, and an independent Clinical Events Committee (CEC) adjudicated both deaths as not related to the AAA repair.

No aneurysm rupture or conversion to open repair occurred in the study patients through 24 months of follow-up, and no AAA-related major adverse events were observed. Other major adverse events included three episodes of congestive heart failure in three patients; none were related to the device or the procedure, as adjudicated by the CEC. Freedom from major adverse events is depicted in Fig 2. The rates of all adverse events are presented by organ systems in Table VI.

Renal events. Early renal events occurred in two patients as a result of renal infarcts noted on the predischarge

Table VI. Number of patients experiencing events by category

Category	*No. (%)*	*Comments*
Cardiac		
0-30 days	2 (6.7)	2 arrhythmia
31-365 days	3 (10.0)	2 CHF, 1 arrhythmia
≥366 days	1 (3.3)	1 CHF
Renal		
0-30 days	2 (6.7)	2 renal infarct
31-365 days	3 (10.0)	1 occlusion, 2 stenosis
≥366 days	3 (10.0)	1 occlusion, 2 stenosis
Vascular		
0-30 days	7 (23.3)	7 transfusions, 1 LE embolus[a]
31-365 days	0 (0)	
≥366 days	0 (0)	
Pulmonary		
0-30 days	1 (3.3)	1 supplemental O_2 at discharge
31-365 days	1 (3.3)	1 pneumonia requiring antibiotics
≥366 days	0 (0)	
Gastrointestinal		
0-30 days	1 (3.3)	1 paralytic ileus >4 days
31-365 days	0 (0)	
≥366 days	0 (0)	
Neurologic		
0-30 days	0 (0)	
31-365 days	0 (0)	
≥366 days	0 (0)	
Wound		
0-30 days	1 (3.3)	1 infection requiring antibiotics
31-365 days	2 (6.7)	2 incisional hernia
≥366 days	0 (0)	
Other		
0-30 days	9 (30.0)	
31-365 days	9 (30.0)	
≥366 days	4 (13.3)	

CHF, Congestive heart failure; *LE*, lower extremity.
[a]Treated with embolectomy. This patient also required transfusion.

CT scans with no clinical sequelae (no alteration in their serum creatinine levels or other therapy required). Late renal artery stenosis or occlusion occurred in six of the 57 renal arteries accommodated by fenestrations. Secondary interventions were performed in five patients with late renal events.

Late renal artery stenosis was reported in four patients. One patient was diagnosed with in-stent stenosis of the right renal artery at 6 months. Review of the predischarge imaging study revealed suboptimal alignment of the fenestration, possibly due to uneven stent graft expansion as a result of pre-existing heavy calcifications. This patient was successfully treated with angioplasty and placement of an additional 6- × 17-mm Express stent (Boston Scientific, Natick, Mass).

The second patient was diagnosed with bilateral renal artery in-stent stenoses at 6 months. This patient received angioplasty of both renal arteries and placement of a covered iCast stent (Atrium Medical, Hudson, NH) in the left renal artery to treat residual stenosis and dissection. Follow-up examinations at 12 months demonstrated patent and stenosis-free bilateral renal arteries.

In-stent stenosis of the right renal artery was observed at 12 months in the third patient. The patient was successfully treated with angioplasty and additional stent placement (Palmaz Corinthian stent, Cordis Endovascular, Warren, NJ). Follow-up evaluation demonstrated a patent, stenosis-free right renal artery.

In the fourth patient, in-stent stenosis of the right renal artery was noted at 24 months. The metallic component of the 7- × 20-mm Paramount stent (eV3, Plymouth, Minn) was visibly deformed, an event likely resulting from caudal movement (<10 mm) of the proximal fenestrated component. The stenosis was successfully treated with the implantation of two additional 7- × 17-mm Express stents.

An additional stenosis of a right renal artery in the bare stent fixation zone was observed in a patient at 40 months and was treated by angioplasty and stent placement. This artery was not included in the calculation of renal events because it was not incorporated by a fenestration.

Renal artery occlusion developed in two patients. The size of the left kidney had markedly diminished at 6 months in one patient, and angiography demonstrated an occluded left renal artery with proximal compression of the left renal stent. The patient underwent a left iliac-renal bypass that successfully restored on of blood flow to the left kidney. In the other patient, the size of the left kidney was slightly decreased at 6 months, but a renal occlusion was not noted until the 12-month follow-up. The patient did not receive any secondary intervention and has maintained a stable serum creatinine level of 1.3 mg/dL through 24 months of follow-up.

Endoleak and aneurysm growth. No type I or type III endoleaks developed through 24 months. Type II endoleak was observed in eight of 26 patients (30.8%) before discharge, in six of 23 (26.1%) at 12 months, and in four of 20 (20.0%) at 24 months. One patient with a persistent type II endoleak was treated with coil embolization of the inferior mesenteric artery (IMA) at 8 months, with no type II endoleak noted on subsequent follow-up evaluations.

No aneurysm enlargement >5 mm was documented. At 24 months, aneurysm shrinkage >5 mm was observed in 16 of 23 patients (69.6%), with shrinkage >10 mm observed in 14 (60.9%; Table VII).

Migration and device integrity. One patient required reintervention for clinically significant graft migration. Caudal movement (approximately 6 mm) of the proximal fenestrated component was likely responsible for deformation of the right renal stent, with subsequent renal stenosis that required a secondary intervention (previously described). No proximal type I endoleak was identified, and the aneurysm has decreased in diameter by approximately 15 mm since the implantation of the fenestrated device.

Two device integrity issues were observed. In one patient, fracture of the left renal artery stent (Express Biliary LD, Boston Scientific) was observed on 12- and 24-month CT evaluations. The renal artery has remained patent through 24 months, with no clinical sequelae. In the other

Table VII. Change in the aneurysm size from predischarge values

Change over time	*Total*	*No. (%)*
1-month	27	
Shrinkage ≥10 mm		0 (0)
Shrinkage >5 to <10 mm		1 (3.7)
No change[a]		26 (96.3)
Growth >5 mm		0 (0)
6-month	26	
Shrinkage ≥10 mm		4 (15.4)
Shrinkage >5 to <10 mm		8 (30.8)
No change		14 (53.8)
Growth >5 mm		0 (0)
12-month	24	
Shrinkage ≥10 mm		10 (41.7)
Shrinkage >5 to <10 mm		6 (25.0)
No change		8 (33.3)
Growth >5 mm		0 (0)
24-month	23	
Shrinkage ≥10 mm		14 (60.9)
Shrinkage >5 to <10 mm		2 (8.7)
No change		7 (30.4)
Growth >5 mm		0 (0)

[a]No change was defined as an increase or decrease in aneurysm size of ≤5 mm.

patient, separation of a single fixation barb of the fenestrated graft was observed on the 6-month CT evaluation. Follow-up evaluations at 12 months revealed a patent graft and bilateral renal arteries in this patient, with no clinical sequelae.

DISCUSSION

The mortality benefit ascribed to endovascular aortic repair vs open surgical repair[16] has the potential to be more significant for aneurysms encroaching upon the renal and visceral branches due to a higher risk of complications associated with open repair of such aneurysms.[16-18] Endovascular grafts with fenestrations can improve proximal sealing in patients with juxtarenal aneurysms and short infrarenal aortic necks. However, impediments to the use of fenestrated devices include technical challenges of device design and deployment, implant integrity, and the ability of regional centers to support this technology with adequate training and resources.

Single-center reports of fenestrated devices[9-12,19,20] have demonstrated successful intermediate-term outcomes that resemble those from large studies of the Zenith infrarenal device.[14,15] In the current multicenter study with stringent patient selection criteria, no ruptures, conversions, or aneurysm-related deaths occurred through 24 months of follow-up.

The planning and sizing of the Zenith fenestrated graft is more involved than that of a standard Zenith AAA graft. It is critical that implanting physicians understand the requisite imaging and anatomic criteria for the design of fenestrated devices. Adequate CT imaging studies with sufficient *z*-plane (longitudinal) resolution are required to obtain accurate anatomic measurements. In addition, the configuration of the renal and other visceral vessels must be reviewed and determined to be amenable to fenestration alignment. For example, if the vessels are very close together (roughly <5 mm longitudinal distance and ≤45° radially), the design may require fenestrations to overlap or struts may cross the visceral artery orifice. The main renal trunk should also be long enough to allow proper placement of a renal stent with the uniform-diameter portion lying within the renal artery and the flared portion extending into the aorta.

Procedural techniques did not markedly differ between sites in this study. The methods to obtain renal access before complete deployment of the proximal fenestrated component and the choice of mating stents constituted most of the differences. We anticipate that the procedural parameters will improve as each investigator gains more experience with the fenestrated device.

The presence of aneurysmal disease close to the renal arteries results in a higher incidence of deleterious renal outcomes after open surgical repair, where periprocedural renal events have been largely attributed to ischemia or emboli created by the requisite proximal dissection and suprarenal clamping.[17] Endovascular repair avoids these risks of surgical repair, but the manipulation required may also dislodge atheroma, with resultant renal infarcts. The required manipulation is more significant in patients with concomitant renal stenosis.

In addition, endovascular procedures require the use of potentially nephrotoxic contrast agents. When these are superimposed on preoperative renal insufficiency, the ability of the kidneys to recover from the procedure is hampered. These observations have been reported previously[21] and resulted in the exclusion of patients with significant renal stenoses (>50%) or with serum creatinine levels >2 mg/dL. Renal infarcts were noted on the predischarge CT scans (both reperfused during follow-up) in two patients, and both had atheroma within the proximal neck. Therefore, investigators are strongly encouraged to assess all available preprocedural imaging for the presence of atheroma at the orifice of the renal arteries.

Late renal events are perhaps more concerning than early events. Events occurring after 1 month are largely related to stenosis or occlusion of the renal vasculature. A study by Haddad et al[21] found renal obstructions in 15 of 142 renal arteries accommodated by fenestrations, irrespective of preoperative renal stenosis. In the current study, late renal events occurred in six of 57 renal arteries accommodated by fenestrations (54 of them stented). Of these, two cases exemplify possible causes for renal artery stenosis or occlusion.

A retrospective review in one patient with renal artery occlusion revealed suboptimal deployment of the renal stent into the middle/upper portion of the fenestration. Even slight distal migration of the fenestrated graft in this situation can cause proximal compression of the renal stent. We therefore recommend that after sheath access into the renal vessels but before removal of the constraining wire, the device be advanced, if necessary, to ensure deployment

of the renal stent into the lower portion of the fenestration. In one patient with renal artery stenosis, a proximal neck dilation of approximately 4 mm was observed, which may have contributed to the slight caudal migration of the graft, thus causing compression and even deformation of the renal stent. Additional stenting was performed in this case, but we remain concerned that migration may persist.

As previously reported, this situation may be avoided by placing the graft more proximally into a healthy aortic segment.[21] This may require the incorporation of both the SMA and celiac vessels, however, thus further complicating the procedure. Accurate planning and sizing of the device and optimized device deployment are important for minimizing the risk of late renal events. In addition, this study emphasizes the importance of continued and careful assessment of renal artery flow to detect and treat adverse renal events in a timely manner.

The stability of the proximal component is paramount to long-term success of the fenestrated device, because even slight graft movement (less than the migration standard of 10 mm) can be catastrophic to the visceral arteries accommodated by fenestrations. The Zenith fenestrated device uses the same barb fixation that has adequately stabilized the conventional infrarenal Zenith device through 5 years of follow-up.[22] The fenestrated device has a modular design that allows for relative movement of the proximal fenestrated component and distal bifurcated component.[23] Thus, forces causing migration are not directly transmitted from one component to the other. In addition, the two components can adjust independently to morphologic changes by relative movement, thus diminishing the risk of aneurysm repressurization. To maintain complete seal when such relative movement occurs, we recommend that the two components overlap by at least two stents. Long proximal components are ideal, terminating approximately 20 mm above the aortic bifurcation; the distal component is intended to be deployed with the distal end of the contralateral limb approximately 5 to 10 mm above the aortic bifurcation. As for other device integrity issues, the current study only noted a renal stent fracture and a single barb separation; both were free of any clinical sequelae.

CONCLUSIONS

This article presents the intermediate results of a prospective multicenter study designed to evaluate the preliminary safety and effectiveness of the Zenith Fenestrated Endovascular Graft. The results through 2 years of follow-up resemble those of single-center reports on fenestrated devices. The results of this study are also similar to those of the parent infrarenal Zenith endograft with respect to protection from rupture, freedom from migration, and other endovascular end points. Continued emphasis must be placed on training the implanting centers on patient selection, device design, and the evolution of implantation techniques.

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AUTHOR CONTRIBUTIONS

Conception and design: RG, TC
Analysis and interpretation: RG, TC, PB
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Writing the article: RG, WS, MM, TO, TC, PB
Critical revision of the article: RG, WS, MM, TO, TC, PB
Final approval of the article: RG, WS, MM, TO, TC, PB
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Table III (online only). Reasons for not including 19 patients who passed the initial enrollment screening in the study

Reasons	*No. (%)*
Aneurysm diameter <5.0 mm	1 (5.3)
Proximal neck length <4 mm	4 (21.1)
Proximal neck length ≥15 mm	2 (10.5)
Proximal neck angulation relative to long axis of aneurysm >45° and/or immediate suprarenal neck angulation relative to immediate infrarenal neck >45°	2 (10.5)
Nonbifurcated segment of any artery to be stented <15 mm in length	1 (5.3)
Unsuitable arterial anatomy[a]	8 (42.1)
Baseline creatinine >2.0 mg/dL	1 (5.3)

[a]Unsuitable arterial anatomy included significant tortuosity and/or calcification of the iliac arteries, presence of two main renal arteries on the same side, presence of excessive thrombus in the perirenal aorta, or presence of a hepatic artery next to the superior mesenteric artery that needed to be accommodated with a fenestration.