Final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms

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ABSTRACT

Purpose: To report 5-year results of the prospective, multicenter study designed to evaluate the Zenith Fenestrated AAA Endovascular Graft (William A. Cook Australia, Brisbane, Australia) for juxtarenal abdominal aortic aneurysms (AAAs).

Methods: Sixty-seven patients (54 male, mean age 74 ± 8 years) were prospectively enrolled at 14 U.S. centers from 2005 to 2012. Fenestrated stent grafts were used in patients with infrarenal aortic neck lengths of 4 to 14 mm to target 178 renal-mesenteric arteries with a mean of 2.7 vessels per patient. At 5 years, 42 of the 67 patients completed the final study follow-up, with clinical examination obtained in 41 and computed tomography imaging in 39. Outcomes adjudicated by a clinical events committee included all-cause and aneurysm-related mortality, major adverse events, renal stent occlusion/stenosis, renal function changes and renal infarcts, aneurysm sac enlargement (>5 mm), device migration (≥10 mm), type I/III endoleak, and secondary interventions.

Results: Median follow-up was 59.8 months (range, 0.1-67.5 months). There were seven deaths, including one (1.5%) within 30 days (procedure-related) and six beyond 30 days (not procedure-related in five, indeterminate in one). At 5 years, freedom from all-cause mortality was 88.8 ± 4.2% and freedom from aneurysm-related mortality was 96.8 ± 2.3%. There were no aneurysm ruptures or conversions to open surgery. Of the 129 renal arteries targeted by fenestrations, five (4%) occluded and 14 (11%) developed in-stent stenosis. Treatment included redo stenting/angioplasty in 13 vessels, renal artery bypass in 2 vessels, and failed thrombectomy in 1 vessel. Primary and secondary renal target patency was 82.7 ± 4.1% and 95.7 ± 2.1% at 5 years, respectively. Dialysis was required in one patient who had pre-existing chronic kidney disease. During the 5 years, there was 1 type IA endoleak (1.5%), 1 type IB endoleak (1.5%), 2 device migrations (3%), and 4 aneurysm sac enlargements (6%). Overall, 81% of patients had sac shrinkage at 5 years. Of 20 patients who underwent secondary interventions, 12 were for renal in-stent stenosis or occlusion, 7 were for endoleak, and 1 was for both indications. Freedom from secondary intervention was 63.5 ± 7.2% at 5 years.

Conclusions: These 5-year results confirm the safety and effectiveness of the Zenith Fenestrated AAA stent graft with no late graft- or aneurysm-related deaths. In-stent stenosis of bare metal renal stents was the most frequent indication for secondary intervention. The low rate of type IA endoleak, sac enlargement, and device migration support its use in patients with juxtarenal AAAs. (J Vasc Surg 2021;73:1128-38.)

Keywords: Fenestrated stent graft; Fenestrated endovascular aortic repair; Juxtarenal aortic aneurysm; Complex abdominal aortic aneurysm

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Fenestrated endovascular aortic aneurysm repair (FEVAR) applies fenestrations and/or scallops to incorporate the renal and mesenteric arteries into the proximal sealing zone for the treatment of abdominal aortic aneurysms (AAAs) with inadequate proximal aortic neck.[1] Since the first clinical case by John Anderson in 1998, the technique has gained widespread acceptance as an alternative to open surgical repair.[2-6] In the most recent practice guidelines published by the European Society for Vascular Surgery, FEVAR was recommended over open surgical repair as the treatment of choice in patients with juxtarenal aortic aneurysms with suitable anatomy (class IIa, level of evidence B).[7] This recommendation is based on multiple single-center reports, multicenter registries, and systematic reviews, indicating that endovascular repair with fenestrated stent grafts can be performed with high technical success, and lower morbidity and mortality as compared with open conventional repair.[7-9] Since the commercial approval of the Zenith Fenestrated AAA Endovascular Graft in the United States in 2012, the procedure has been widely adopted with approximately 2000 implants per year.[10] This report summarizes the final 5-year results of 67 patients enrolled in the Zenith Fenestrated (ZFEN) multicenter study designed to evaluate the safety and effectiveness of the Zenith Fenestrated AAA Endovascular Graft to treat juxtarenal AAAs.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective, nonrandomized pivotal study evaluating 5-year outcomes of the Zenith Fenestrated abdominal aortic aneurysm (AAA) stent graft for juxtarenal AAAs
- **Key Findings:** A total of 67 patients were enrolled in the study with 1.5% 30-day mortality. At 5 years, freedom from all-cause mortality was 88.8 ± 4.2%, freedom from aneurysm-related mortality was 96.8 ± 2.3%, primary and secondary renal target patency was 82.7 ± 4.1% and 95.7 ± 2.1%, respectively, and freedom from secondary intervention was 63.5 ± 7.2%. After a median follow-up of 59.8 months, there was 1 type IA endoleak (1.5%), 1 type IB endoleak (1.5%), 2 device migrations (3%), and 4 aneurysm sac enlargements (6%). There were no aneurysm ruptures or conversions to open surgery.
- **Take Home Message:** The study confirms the long-term safety and effectiveness of the Zenith Fenestrated stent graft with no late graft- or aneurysm-related deaths. The low rate of type IA endoleak, sac enlargement, and device migration support its use in patients with juxtarenal AAAs.

METHODS

Study overview. This was a prospective, multicenter, nonrandomized clinical study conducted under the U.S. Food and Drug Administration Investigational Device Exemption #G040063. The study consisted of a pivotal phase (NCT00875563) and a continued access phase (NCT0257756) preceding the U.S. Food and Drug Administration approval of the device in April 2012. Ethical approval was obtained from each institutional review board, and all patients provided informed consent.

The details of the study design, patient eligibility criteria, and mid-term results were published previously.[1,11] A total of 195 patients were reviewed for inclusion in the study, with 67 patients (42 pivotal, 25 continued access) enrolled at 14 academic U.S. centers between January 2005 and April 2012. One hundred twenty-eight patients (66%) were excluded because of inadequate anatomical criteria. All patients were treated for a juxtarenal abdominal aortic aneurysm with an infrarenal aortic neck of 4 to 14 mm in length. Study follow-up consisted of imaging and clinical examinations before discharge and at 1 month, 6 months, 12 months, and annually thereafter for 5 years. Follow-up imaging, including computed tomography angiography or computed tomography without contrast, duplex ultrasound of the renal and mesenteric arteries, and abdominal radiography were independently evaluated at investigative sites and by a core laboratory. All imaging data herein reported reflect the final core laboratory analysis. Prespecified adverse events, including all deaths, major adverse events (MAEs), and renal events were reviewed and adjudicated by an independent clinical events committee to assess whether each event was due to a pre-existing or unrelated condition, or was related to the procedure, technique, and/or device. The clinical trial was overseen by an independent data safety monitoring board according to an established safety monitoring plan.

Device overview. The Zenith Fenestrated AAA Endovascular Graft (William A. Cook Australia, Brisbane, Australia) is a modular system consisting of a fenestrated proximal body graft, a distal bifurcated body graft, and an iliac leg. Detailed device descriptions were published previously.[11]

Data analysis. Study data were managed by a centralized data-coordinating center, Cook Research Incorporated (West Lafayette, Ind). Results were analyzed for all 67 enrolled patients with final study dataset as of February 13, 2018. Statistical analyses were performed using SAS (9.1 or higher). Continuous variables are reported as means and standard deviations unless otherwise noted, and categorical variables are reported as percentages and ratios. The Kaplan-Meier method was used to estimate freedom from mortality, MAEs, renal function deterioration, target renal artery patency, and secondary interventions. P values $<.05$ were considered statistically significant.

Specific end point definitions have been previously reported.[1,11] Briefly, prespecified renal events include dialysis in patients with normal preoperative renal function, renal insufficiency (defined as creatinine rise to >2 mg/dL and by >30% from baseline on two or more follow-up tests), renal infarct (reported by sites as an adverse event, regardless of whether confirmed by core lab), and occlusion of a fenestrated renal vessel. Other end points including freedom from renal function deterioration, primary and secondary target vessel patency, aneurysm sac changes, endoleak, migration, and device integrity have been previously defined.[1,11,12] The diameters at the levels of celiac axis, superior mesenteric artery (SMA), and the lowest renal artery were measured at each follow-up time and compared with pre-discharge values to evaluate neck enlargement.

RESULTS

There were 67 patients enrolled in the pre-approval phase of the Zenith Fenestrated multicenter study. The final study results herein reported reflect a median follow-up of 59.8 months (range, 0.1-67.5 months). At 5 years, 42 of the 67 patients completed the final study follow up, with clinical examination obtained in 41 and computed tomography imaging in 39. Reasons for incomplete 5-year follow up in 25 patients were as follows: no consent provided for follow-up longer than 2 years in 6 patients, death in 7 patients, and withdrawal or loss to follow up in 12 patients.

MAEs and mortality

A total of 22 patients experienced 27 MAEs during follow-up (Table I). There was one 30-day death (1.5%), which was due to bowel ischemia and was adjudicated as procedure-related. There were six deaths beyond 30 days, which were considered not procedure-related in five patients and indeterminate in one patient. At 1 year and 5 years, freedom from all-cause mortality was 97.0 ± 2.3% and 88.8 ± 4.2% (Fig 1), respectively. Freedom from AAA-related mortality was 98.5 ± 1.5% at 1 year and 96.8 ± 2.3% (including the patient with indeterminate cause) at 5 years. There were no aneurysm ruptures or conversions to open surgical repair. The most frequent MAEs were cardiovascular in origin (21%) and attributed to pre-existing comorbidities and not to the procedure. Three patients (4%) had procedure-related MAEs, all due to bowel ischemia within 30 days. All three patients had patent SMAs. Of these, one patient died and two recovered. At 1 year and 5 years, freedom from MAEs was 89.6 ± 3.7% and 62.0 ± 7.2%, respectively (Fig 2).

Renal outcomes

Infarct, stenosis, and occlusion. Eight patients had renal infarcts noted on 30-day imaging, including seven patients with asymptomatic infarcts and patent renal arteries. One patient developed renal infarct due to occlusion of an accessory renal artery incorporated by fenestration at 6 months, which was not associated with change in renal function or a need for dialysis.

A total of 129 renal arteries were targeted by 118 small fenestrations (all stented) and 11 scallops (8 stented, 3 not stented). Of these, 11 patients (16%) experienced stenosis in 14 (11%) targeted renal arteries (8 unilateral, 3 bilateral, Supplementary Table I, online only). Among these 11 patients, secondary interventions were performed in all, including successful angioplasty or stenting in 10 patients and one unsuccessful attempt due to inability to successfully catheterize the vessel. In addition, one patient developed stenosis of an untargeted and unstented right renal artery, which was successfully treated by angioplasty and stent placement. Five patients experienced occlusion of one fenestrated renal artery (4% [5 of 129]), which occurred between 31 days and 1 year in two patients, 1 and 2 years in two patients, and 3 and 4 years in one patient. Of these, three patients were not treated, and two patients had successful renal artery bypasses after failure of attempted endovascular revascularization. Among eight renal arteries targeted by scallops and stented, one renal artery had stenosis. There was no renal occlusion in this subgroup.

Patency of targeted renal arteries. At 1 year and 5 years, primary patency was 95.2 ± 1.9% and 82.7 ± 4.1%, respectively (Fig 3). Loss of primary patency was due to 5 renal target occlusions and 14 renal target stenoses requiring reinterventions, as described above. Among the 19 renal arteries with loss of primary patency, 18 had bare metal stents and 1 had a covered stent at the index procedure. The secondary patency was 98.4 ± 1.1% at 1 year and 95.7 ± 2.1% at 5 years. Of the 129 renal arteries, 107 received bare metal stents, 19 received covered stents, and the remaining 3 were not stented. Primary patency for bare metal renal stents was 95.2 ± 2.1% at 1 year and 80.3 ± 4.7% at 5 years; for covered renal stents, the primary patency was 94.4 ± 5.4% at both 1 year and 5 years. The events leading to the loss of secondary patency were the five target renal artery occlusions described above.

Renal function deterioration. Seven patients (10%) experienced renal insufficiency as defined per protocol, all occurring after 1 year from the index operation. Of these, five patients had pre-existing chronic kidney disease (CKD) stage II, and the reported renal insufficiency was adjudicated as neither procedure- or device-related. In one patient, renal insufficiency was considered procedure-related. In the remaining patient, renal insufficiency was considered procedure- and device-related (Supplementary Table II, online only). One patient (1.5%) with pre-existing CKD required dialysis at 3 years. None of the patients with normal renal function, defined as baseline CKD stage I or II, required dialysis. Freedom from protocol-defined renal insufficiency was 100% at 1 year and 85.4 ± 5.3% at 5 years. When analyzed according to a more stringent definition, freedom from

Table I. Summary of major adverse events (MAEs), including mortality

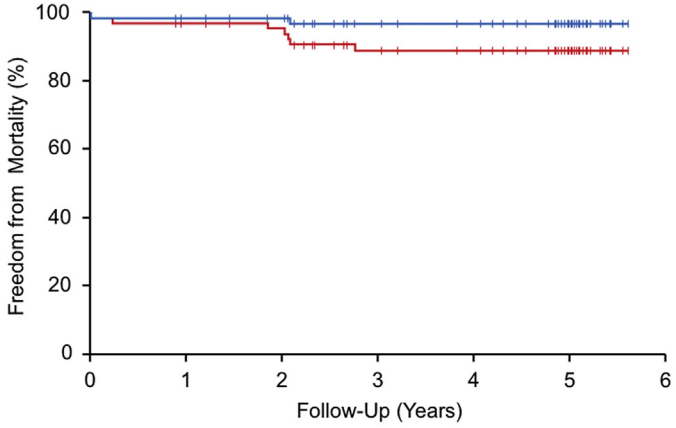
Category	Days to event	Event description	Clinical event committee adjudication
Death	2	Bowel ischemia	Procedure-related
	85	Septic shock, acute myocardial infarction, and multisystem organ failure	Not related
	677	Unknown[a]	Not related
	740	Complications from metastatic lung cancer	Not related
	754	Atherosclerotic cardiovascular disease and hypertension	Not related
	761	Unknown[b]	Unable to determine
	1010	Exacerbation of CML	Not related
Cardiovascular	76	Anterior septal MI	Not related
	140	Congestive heart failure	Not related
	245	Cardiac ischemia requiring intervention	Not related
	314	Congestive heart failure	Not related
	625	Congestive heart failure	Not related
	808	Cardiac ischemia requiring intervention	Not related
	854	Cardiac ischemia requiring intervention	Not related
	1360	Congestive heart failure	Not related
	1362	Cardiac ischemia requiring intervention	Not related
	1463	Congestive heart failure	Not related
	1555	Congestive heart failure	Not related
	1656	Congestive heart failure	Not related
	1666	Cardiac ischemia requiring intervention	Not related
	1716	Congestive heart failure	Not related
Gastrointestinal	0	Bowel ischemia	Procedure-related
	8	Bowel ischemia	Procedure-related
	25	Bowel ischemia	Procedure-related
	383	Bowel obstruction	Not related
Neurologic	992	Stroke	Not related
Renal	1189	Renal failure requiring permanent dialysis[c]	Not related

CML, Chronic myeloid leukemia; *MI*, myocardial infarction.
[a]This patient had been hospitalized several times in the preceding months for various reasons including urinary tract infection, endovascular graft infection and sepsis, congestive heart failure, pleural effusions and anemia, chronic renal failure, and hoarseness.
[b]This patient was lost to follow-up at 37 days. Limited death information was obtained from social security death index by the site.
[c]This patient had preoperative pre-existing renal dysfunction.

renal function deterioration (>30% decrease from baseline in estimated glomerular filtration rate at two or more follow-up tests) was 98.5 ± 1.5% at 1 year and 68.5 ± 7.7% at 5 years (Fig 4).

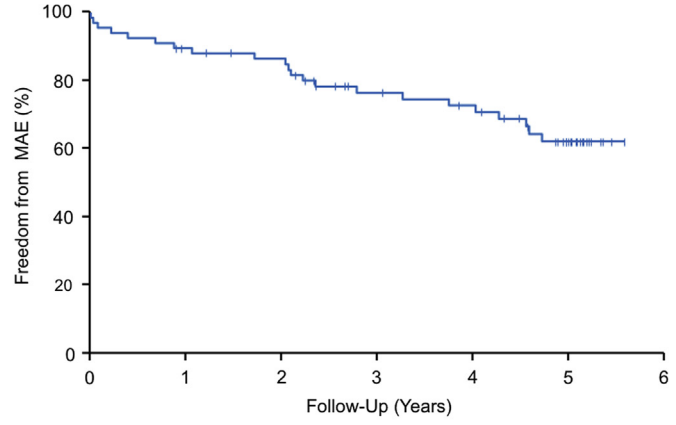
Device performance

Endoleaks and aneurysm sac changes. According to core laboratory analysis, all endoleaks detected on standard follow-up imaging exams were either type II (in 24 patients total) or indeterminate (in 5 patients total; Table II). In addition, the core laboratory detected one type IA and one type IB endoleak on unscheduled imaging. The patient with type IA endoleak was initially diagnosed with indeterminate endoleak by the core lab on standard follow-up imaging from 6 months to 3 years. At 3 years, the patient underwent multiple secondary interventions including a diagnostic angiography, which confirmed a type IA endoleak, originating at the SMA scallop due to progression of aneurysmal disease with degeneration of the sealing zone. This type IA endoleak was successfully treated by coil embolization, and no endoleak was detected at 4-year and 5-year follow-up examinations. The aneurysm sac remains stable. The patient with type IB endoleak was found to have enlargement of the right common iliac artery sealing zone with endoleak on an unscheduled exam between the fourth- and fifth-year follow-up because of aneurysm growth. The patient later underwent a successful secondary intervention (coil embolization of the right internal iliac artery and extension into the right external iliac artery) to treat this type IB endoleak, which was no longer present on the 5-year follow-up examination.



All-cause mortality	No. at Risk	67	63	60	49	46	28
	Cumulative events	0	2	3	7	7	7
	Cumulative censored	0	2	4	11	14	32
	Kaplan-Meier estimate (%)	100	97.0	95.4	88.8	88.8	88.8
	Standard error	–	2.1	2.6	4.2	4.2	4.2
AAA-related mortality	No. at Risk	67	63	60	49	46	28
	Cumulative events	0	1	1	2	2	2
	Cumulative censored	0	3	6	16	19	37
	Kaplan-Meier estimate (%)	100	98.5	98.5	96.8	96.8	96.8
	Standard error	–	1.5	1.5	2.3	2.3	2.3

Fig 1. Kaplan-Meier analysis of freedom from all-cause and abdominal aortic aneurysm (*AAA*)-related mortality. *Vertical bars* represent time points when any patient is censored from the analysis.

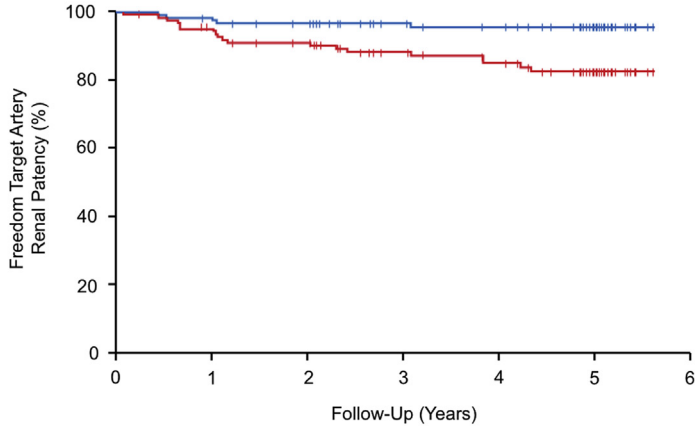


MAE	No. at Risk	66	58	54	41	37	20
	Cumulative events	1	7	9	15	17	22
	Cumulative censored	0	2	4	11	13	25
	Kaplan-Meier estimate (%)	98.5	89.6	86.4	76.4	72.6	62.0
	Standard error	1.5	3.7	4.3	5.8	6.2	7.2

Fig 2. Kaplan-Meier analysis of freedom from major adverse events (*MAEs*). *Vertical bars* represent time points when any patient is censored from the analysis.

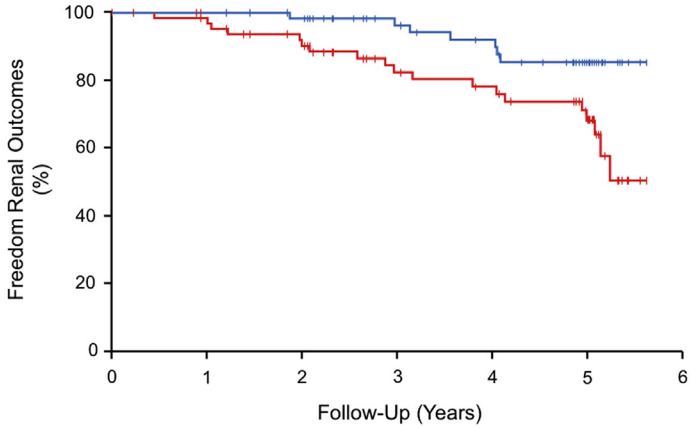
Most aneurysms decreased >5 mm in diameter during follow-up, including 53.2% of patients (33 of 62) at 6 months and 80.6% (29 of 36) at 5 years. Four patients (6%) experienced aneurysm sac expansion during follow-up, first detected at 3 years in three patients and at 4 years in one patient. All four patients underwent a secondary intervention, for type II endoleak in three patients and for distal type IB endoleak in one patient.

Migration and integrity. Radiographic migration, defined as movement of the stent graft ≥10 mm detected by the core laboratory and confirmed by the clinical events committee, was noted in two patients (3%). Both patients



Primary renal patency	No. at Risk	129	117	106	85	76	49
	Cumulative events	0	6	11	14	14	19
	Cumulative censored	0	6	12	30	36	61
	Kaplan-Meier estimate (%)	100	95.2	91.1	88.4	85.1	82.7
	Standard error	–	1.9	2.6	3.1	3.7	4.1
Secondary renal patency	No. at Risk	129	121	113	92	85	53
	Cumulative events	0	2	4	4	5	5
	Cumulative censored	0	6	12	33	39	71
	Kaplan-Meier estimate (%)	100	98.4	96.8	96.8	95.7	95.7
	Standard error	–	1.1	1.6	1.6	2.1	2.1

Fig 3. Kaplan-Meier analysis of primary and secondary renal artery patency. *Vertical bars* represent time points when any patient is censored from the analysis.



Renal insufficiency	No. at Risk	67	63	59	47	42	26
	Cumulative events	0	0	1	2	4	7
	Cumulative censored	0	4	7	18	21	34
	Kaplan-Meier estimate (%)	100	100	98.3	96.3	92.1	85.4
	Standard error	–	–	1.7	2.7	4.0	5.3
Renal function deterioration	No. at Risk	67	62	55	40	36	25
	Cumulative events	0	1	5	10	12	16
	Cumulative censored	0	4	7	17	19	26
	Kaplan-Meier estimate (%)	100	98.5	92.0	82.5	78.3	68.5
	Standard error	–	1.5	3.5	5.5	6.0	7.7

Fig 4. Kaplan-Meier analysis of freedom from renal insufficiency and renal function deterioration. *Vertical bars* represent time points when any patient is censored from the analysis.

had caudal movement of the proximal fenestrated component detected at 24 months and at 60 months, respectively. In the first patient, device migration resulted in mild deformation and stenosis of the right renal stent, which required reintervention with additional renal stent placement at postoperative day 883. No secondary

Table II. Endoleak, changes in the aneurysm sac size, and in the proximal neck size from core lab analysis of regular follow-up imaging examinations

	Pre-discharge	1 month	6 months	1 year	2 years	3 years	4 years	5 years
Endoleak								
Type II[a]	31.0% (18/58)	23.3% (14/60)	21.1% (12/57)	21.2% (11/52)	18.2% (8/44)	18.9% (7/37)	13.3% (4/30)	7.7% (2/26)
Type unknown[b]	1.7% (1/58)	0% (0/60)	1.8% (1/57)	5.8% (3/52)	6.8% (3/44)	2.7% (1/37)	0% (0/30)	0% (0/26)
Aneurysm sac size change								
Increase >5 mm[c]	n/a	0% (0/61)	0% (0/62)	0% (0/57)	0.0% (0/54)	6.8% (3/44)	7.3% (3/41)	2.8% (1/36)
Decrease >5 mm	n/a	1.6% (1/61)	53.2% (33/62)	70.2% (40/57)	75.9% (41/54)	77.3% (34/44)	80.5% (33/41)	80.6% (29/36)
Change ≤5 mm	n/a	98.4% (60/61)	46.8% (29/62)	29.8% (17/57)	24.1% (13/54)	15.9% (7/44)	12.2% (5/41)	16.7% (6/36)
Proximal neck size change								
Diameter at celiac artery								
Increase >5 mm	–	0% (0/65)	0% (0/61)	0% (0/58)	3.8% (2/53)	4.4% (2/45)	10.0% (4/40)	8.6% (3/35)
Average change, mm (mean ± SD)	–	0.26 ± 1.26	0.81 ± 1.38	1.07 ± 1.60	1.15 ± 1.74	1.62 ± 2.27	1.88 ± 2.52	1.91 ± 2.12
Diameter at superior mesenteric artery								
Increase >5 mm	–	0% (0/65)	0% (0/61)	6.9% (4/58)	11.1% (6/54)	15.6% (7/45)	20.0% (8/40)	17.1% (6/35)
Average change, mm (mean ± SD)	–	0.19 ± 1.23	1.12 ± 1.52	1.65 ± 1.97	2.02 ± 2.37	2.37 ± 2.76	2.77 ± 2.79	2.60 ± 2.55
Diameter at lowest renal artery								
Increase >5 mm	–	0% (0/65)	9.7% (6/62)	15.5% (9/58)	32.7% (18/55)	39.1% (18/46)	53.7% (22/41)	66.7% (24/36)
Average change, mm (mean ± SD)	–	0.70 ± 1.62	2.65 ± 2.68	2.99 ± 2.13	4.04 ± 2.28	4.89 ± 2.03	5.08 ± 2.11	5.96 ± 2.51

SD, Standard deviation.
The same imaging finding (eg, endoleak or aneurysm size change) can occur in a patient at multiple time points.
[a]Type II endoleak was detected in 24 patients total.
[b]Type unknown endoleak was detected in 5 patients total.
[c]Aneurysm sac size increase (>5 mm) occurred in 4 patients total.

intervention was needed in the second patient. Device integrity observations through 5 years include five patients who had barb separation, two patients with single stent fractures in the endograft (none with clinical sequelae) and four patients with fractures in the fenestration stent, associated with stent occlusion in two. In addition, four patients had deformation or compression of a fenestration stent, which were not associated with any loss of device integrity.

Secondary interventions. A total of 20 patients underwent secondary interventions. Indications for reinterventions included renal in-stent stenosis or occlusion in 12 patients, endoleaks in 8 patients, and both indications in 1 patient. All renal events that required a secondary intervention had a bare metal stent (14 renal stenoses, two renal occlusions) except for one patient who developed stenosis of an untargeted and unstented right renal artery, which was successfully treated by angioplasty and stent placement. There was no secondary intervention for renal arteries that had a covered stent (15% [16 of 91] vs 0%, $P = .13$). Table III summarizes the indications and types of secondary interventions. At 1 year and 5 years, freedom from secondary intervention was 90.8 ± 3.6% and 63.5 ± 7.2%, respectively (Fig 5).

Aortic neck remodeling. An increase in the proximal aortic sealing zone diameter >5 mm was evaluated on follow-up imaging at the levels of the lowest renal artery, the SMA, and the celiac artery, respectively. At 5 years, the diameter increase >5 mm was more prominent at the level of the renal arteries, occurring in 24 of 36 patients (66.7%), compared with 6 of 35 patients (17.1%) at the level of the SMA and 3 of 35 patients (8.6%) at the celiac artery. The average 5-year aortic diameter increase at the level of the lowest renal artery, SMA, and celiac artery was 5.96 ± 2.51 mm, 2.60 ± 2.55 mm, and 1.91 ± 2.12 mm, respectively.

Table III. Secondary interventions

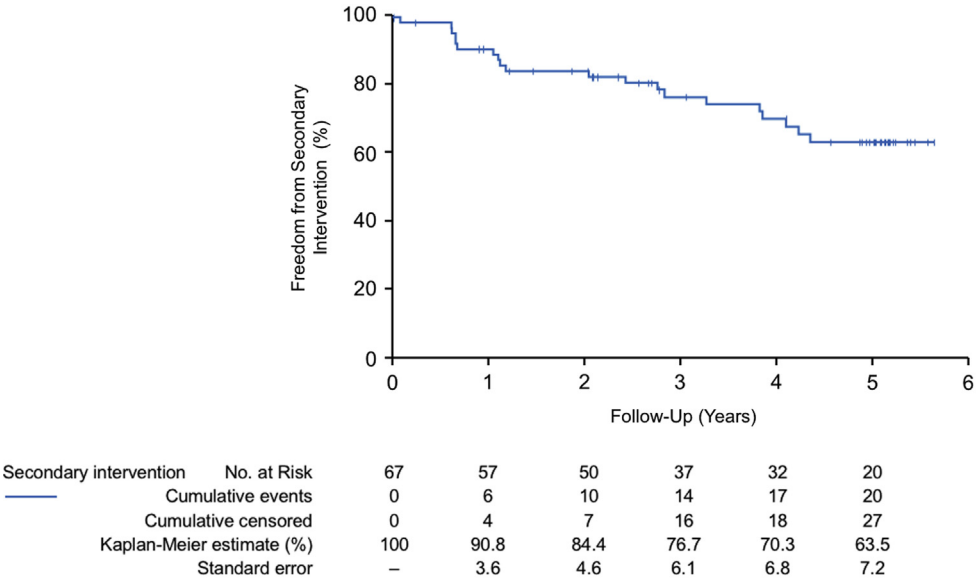
Patient	Reason for reintervention	Days to reintervention	Type of reintervention
For renal artery occlusion			
1	Renal artery occlusion (left)	222	Renal artery bypass (iliorenal)
2	Worsening renal function	398	Renal artery cannulation attempted (unsuccessful)
	Renal artery occlusion (right)	435	Renal artery bypass (common hepatic-renal
For renal stent stenosis			
3	Renal stent stenosis (right)	30	Thrombectomy attempted (unsuccessful)
4	Renal stent stenosis (right)	238	Stent placement
5	Renal stent stenosis (bilateral)	245	Stent placement
6	Renal stent stenosis (left)	382	Angioplasty, stent placement
7	Renal stent stenosis (right)	406	Angioplasty, stent placement
8	Renal stent stenosis (right)	427	Stent placement
	Renal stent stenosis (left); device migration	840	Stent placement
9	Renal stent stenosis (right)	743	Angioplasty, stent placement
10	Renal stent partially crushed (right)	883	Stent placement
11	Renal stent stenosis (bilateral)	1400	Angioplasty, stent placement
12	Renal stent stenosis (left)	1539	Angioplasty, stent placement
13	Renal stent stenosis (right)	1582	Angioplasty
For endoleak or aneurysm growth			
14	Endoleak, type II	224	Coil and glue embolization
15	Endoleak, type II	239	Coil embolization
16	Endoleak, type I proximal	1003	Stent placement
		1100	Coil embolization attempted (unsuccessful)
		1142	Coil embolization
17	Aneurysm rupture,[a] endoleak unknown type	1031	Ancillary components placement in iliac arteries
18	Endoleak, type III[b]	1188	Angioplasty, stent placement
19	Endoleak, type II; aneurysm growth	1393	Suture ligation of the IMA
20	Endoleak, type II	1490	Coil embolization
21[c]	Endoleak, type I distal	1746	Coil embolization and ancillary component placement

IMA, Inferior mesenteric artery.
[a]The clinical events committee adjudicated this as related to component failure and noted that they did not consider this event to be an aneurysm rupture, but rather an endoleak due to the leak of contrast into the aneurysm sac.
[b]This was according to site assessment; the endoleak was type II according the core laboratory analysis of the follow-up imaging before the secondary intervention.
[c]This is the same patient who had an earlier reintervention for a right renal stent stenosis on postoperative day 30.

DISCUSSION

The primary goal of endovascular aortic aneurysm repair is prevention of aortic-related death from aneurysm rupture. The U.S. Zenith Fenestrated multicenter study is the first industry-sponsored prospective nonrandomized pivotal trial to document the safety and efficacy of fenestrated stent grafts for patients with juxtarenal aortic aneurysms up to 5 years of follow-up. The low rates of procedure-related mortality, aortic-related death, target vessel occlusion, type IA endoleak, and dialysis through 5 years attest to the safety, efficacy, and durability of this fenestrated repair strategy using the ZFEN device.

In the absence of prospective randomized trials, results of this study should be analyzed in the context of the historical outcomes obtained with alternative techniques. Gupta et al[13] reported a retrospective analysis of 1742 patients treated by open surgical repair or FEVAR using the American College of Surgeons National Surgical Quality Improvement Program database. In that study, open surgical repair was associated with a twofold increase in 30-day mortality (4.7% vs 2.4%) and significantly higher rates of early pulmonary complications, cardiac events, new onset dialysis, stroke, return to the operating room, and transfusion requirements, as well as longer length of stay.[13] O'Donnell et al[14] analyzed data from the Society



Secondary intervention	No. at Risk	67	57	50	37	32	20
	Cumulative events	0	6	10	14	17	20
	Cumulative censored	0	4	7	16	18	27
	Kaplan-Meier estimate (%)	100	90.8	84.4	76.7	70.3	63.5
	Standard error	–	3.6	4.6	6.1	6.8	7.2

Fig 5. Kaplan-Meier analysis of secondary intervention. *Vertical bars* represent time points when any patient is censored from the analysis.

for Vascular Surgery Vascular Quality Initiative and reported that mortality of open juxtarenal aortic repair was significantly higher in centers with low compared with high surgical volume (9% vs 3%).

Despite the early advantages of the endovascular approach, secondary reinterventions remain high with FEVAR, averaging 22% to 37% at 5 years in recent reports.[15-19] Tinelli et al[20] reported a retrospective propensity matched comparison of FEVAR with open surgical repair. In that study, open surgical repair had higher rates of acute kidney injury (52% vs 20%), similar freedom from renal function deterioration, but higher freedom from reinterventions at 6 years (93.4% vs 63.9%). Nonetheless, a criticism to that study is the underreporting of laparotomy-related reinterventions (hernia and bowel obstructions) in retrospective reviews of open surgical reports.

Parallel stent grafts and standard EVAR with or without the use of endo-anchors have also been increasingly applied to treat patients with juxtarenal and short neck aneurysms. The Protagoras Study used a standardized approach with the Endurant stent graft (Medtronic, Santa Rosa, Calif) and parallel grafts to the renal arteries using iCAST covered stents (Maquet, Hudson, NH).[21] In that study, 128 patients and 187 parallel stent grafts (1.5 per patient) were evaluated. Technical success was achieved in all patients with one operative mortality (0.8%). After a mean follow-up of 25 months, there was one rupture, two type IA endoleaks, and eight (5%) target vessel occlusions. The PERICLES registry included 517 patients with more liberal use of parallel grafts (1.7 vessels per patient) and wider variation of aortic devices. In that study, elective 30-day mortality was 3.7% and stroke occurred in 1.7%. During a mean imaging follow-up of 17.1 months, the rate of type IA endoleak was 3.7%, although only two patients were reported to have persistent endoleaks.[22] The use of endo-anchors with short neck indication is also based on limited studies, which indicate low rate of type IA endoleak at 9 months' follow-up.[23] Although the technical success is high in these studies, the use of short sealing zones can be easily compromised by any progressive aortic neck enlargement, thereby calling durability of these strategies into question. Kouvelos et al[24] reported a systematic review including 9721 patients who underwent EVAR for AAAs in 26 studies and found dilatation of the aortic neck (with various definitions) at the level of the renal arteries in 80% of patients at 2 years. Moreover, several investigators reported the high failure rates of EVAR when applied in patients with wide aortic necks (>28 or 30 mm).[24,25] Therefore, disease progression may pose excessive risk of proximal endoleaks and neck failure in the long term. On the basis of these concerns, the European practice guidelines do not recommend parallel grafts for elective repair and state that they should be reserved as a bail-out alternative or to patients who are not anatomical candidates for FEVAR and open surgical repair.[7]

The concern with progression of aortic disease has led several investigators to apply more complex designs based on supraceliac sealing zones when planning FEVAR. Mastracci et al[15] reported one of the first studies to document that three to four fenestrations were associated with lower rates of type IA endoleaks after FEVAR compared with one to two fenestrations. In that study, type I endoleak occurred in 3% of patients with four

fenestrations and in 10% in those with two or fewer fenestrations after a mean follow-up of 8 years.[15] Oderich et al[26] reported a prospective study of 127 patients (3.9 ± 0.5 vessels per patient) treated with supraceliac sealing zones and three or four fenestrations. In that study, there was no mortality, dialysis, rupture, or type I endoleak. The rate of paraplegia was 1%, occurring only in a patient with a thoracoabdominal aneurysm.[26] Katsargyris et al[17] reported on 384 patients treated with 2- vs 3- to 4-vessel FEVAR. The overall mortality was 0.5% with no difference between groups.[17]

The rate of reinterventions in the ZFEN study was mostly driven by renal in-stent restenosis. It is important to highlight that bare metal stents were used in 115 of the renal targets, and 18 of the 19 cases of renal occlusion or stenosis occurred with bare metal stents in the current study. This practice has been replaced by covered stents because of their resistance to neointimal hyperplasia following stent flare, which may explain improved primary patency in recent reports. The primary renal patency in the ZFEN trial was 91% and 83% at 2 and 5 years, respectively. In most contemporary FEVAR series, primary patency ranges from 88% to 97% with covered stents at 3 years.[26,27] Aside from renal reinterventions, type II endoleaks remain a cause of sac enlargement and have been linked to late deaths and cardiovascular events in recent reports.[25,28,29] Finally, in the ZFEN study, 67% of patients had enlargement of the aortic neck at the level of the renal arteries, though the dilatation at suprarenal levels was much less in extent and frequency. Progression of aortic disease led to one type IA endoleak, and it is possible that with persistent enlargement of the aortic neck, more patients may experience this problem beyond the first 5 years.

The applicability of the ZFEN stent graft was limited by the design constraints that were predefined in instructions for use, which allowed a maximum of three fenestrations and the extension of the stent-graft fabric up to the lower edge of the celiac axis. Although designs with up to three fenestrations represent a viable option in most patients with short neck or juxtarenal aneurysms, 128 of 195 patients (66%) were excluded from the current study due to inadequate anatomy, most often because of proximal aneurysm extension beyond the constraints of the device design.[11] Mendes et al[30] analyzed 390 patients with complex aortic aneurysms for suitability of fenestrated repair using the Zenith p-Branch device, which has three fenestrations and a scallop for the celiac axis, thereby providing a higher level of sealing zone in the supraceliac aorta compared with the Zenith Fenestrated stent graft. Based on that analysis, it was estimated that 237 patients (61%) would not fit a minimum sealing zone criterion even with three fenestrations and a scallop, indicating that suitability to the ZFEN design is even lower. Future designs built off the current ZFEN platform to include four to five fenestrations aim to address these areas of clinical need, in addition to providing other adjuncts to facilitate the procedure, such as preloaded catheters and lower profile fabric.

There are limitations inherent to this study design. Although the study has several strengths including prospective enrollment, use of independent core lab, and data adjudication, the study population is relatively small and 36% of patients did not complete the initial planned 5-year follow-up due to earlier death, withdrawal, or loss to follow-up. The excellent results should not be generalized without consideration of the strict anatomical criteria used in the trial.

CONCLUSIONS

The 5-year results of the Zenith Fenestrated AAA stent-graft study confirm the long-term safety and effectiveness for treatment of short neck infrarenal or juxtarenal AAAs with no graft- or aneurysm-related late deaths. In-stent stenosis of bare metal renal stents was the most frequent indication for secondary intervention. The low rate of type IA endoleak, sac enlargement, and device migration support the use of ZFEN in patients with short neck infrarenal or juxtarenal AAAs. Future designs will focus on use of supraceliac sealing zones to address clinical need for treatment of more complex AAAs and to mitigate risk of late failure from progression of aortic disease.

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AUTHOR CONTRIBUTIONS

Conception and design: GS
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REFERENCES

1. Greenberg RK, Sternbergh WC III, Makaroun M, Ohki T, Chuter T, Bharadwaj P, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. J Vasc Surg 2009;50:730-7.e1.
2. Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. J Endovasc Ther 2001;8:3-15.
3. Verhoeven E, Katsargyris A, Oikonomou K, Kouvelos G, Renner H, Ritter W. Fenestrated endovascular aortic aneurysm repair as a first line treatment option to treat short

necked, juxtarenal, and suprarenal aneurysms. Eur J Vasc Endovasc Surg 2016;51:775-81.
4. Farber MA, Oderich GS, Timaran C, Sanchez LA, Dawson Z, Investigators Zp-BFS. Results from a prospective multicenter feasibility study of Zenith p-Branch stent graft. J Vasc Surg 2019;70:1409-18.e3.
5. Ambler G, Boyle J, Cousins C, Hayes P, Metha T, See T, et al. Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. Circulation 2012;125:2707-15.
6. O'Donnell TF, Boitano LT, Deery SE, Schermerhorn ML, Schanzer A, Beck AW, et al. Open versus fenestrated endovascular repair of complex abdominal aortic aneurysms. Ann Surg 2020;271:969-77.
7. Wanhainen A, Verzini F, Van Herzeele I, Allaire E, Bown M, Cohnert T, et al. Editor's choice—European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines on the management of abdominal aorto-iliac artery aneurysms. Eur J Vasc Endovasc Surg 2019;57:8-93.
8. Rao R, Lane TR, Franklin IJ, Davies AH. Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms. J Vasc Surg 2015;61:242-55.e5.
9. Orr NT, Davenport DL, Minion DJ, Xenos ES. Comparison of perioperative outcomes in endovascular versus open repair for juxtarenal and pararenal aortic aneurysms: a propensity-matched analysis. Vascular 2017;25:339-45.
10. Simons JP, Shue B, Flahive JM, Aiello FA, Steppacher RC, Eaton EA, et al. Trends in use of the only Food and Drug Administration-approved commercially available fenestrated endovascular aneurysm repair device in the United States. J Vasc Surg 2017;65:1260-9.
11. 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.
12. 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.
13. Gupta PK, Brahmbhatt R, Kempe K, Stickley SM, Rohrer MJ. Thirty-day outcomes after fenestrated endovascular repair are superior to open repair of abdominal aortic aneurysms involving visceral vessels. J Vasc Surg 2017;66:1653-8.e1.
14. O'Donnell TF, Boitano LT, Deery SE, Lancaster RT, Siracuse JJ, Schermerhorn ML, et al. Hospital volume matters: the volume-outcome relationship in open juxtarenal AAA repair. Ann Surg 2020;271:184-90.
15. Mastracci TM, Eagleton MJ, Kuramochi Y, Bathurst S, Wolski KJ. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg 2015;61:355-64.
16. Roy I, Millen A, Jones S, Vallabhaneni S, Scurr J, McWilliams R, et al. Long-term follow-up of fenestrated endovascular repair for juxtarenal aortic aneurysm. Br J Surg 2017;104:1020-7.
17. Katsargyris A, Oikonomou K, Kouvelos G, Mufty H, Ritter W, Verhoeven ELG. Comparison of outcomes for double fenestrated endovascular aneurysm repair versus triple or quadruple fenestrated endovascular aneurysm repair in the treatment of complex abdominal aortic aneurysms. J Vasc Surg 2017;66:29-36.
18. Blankensteijn LL, Dijkstra ML, Tielliu IF, Reijnen MM, Zeebregts CJ, Geelkerken RH, et al. Midterm results of the fenestrated anaconda endograft for short-neck infrarenal and juxtarenal abdominal aortic aneurysm repair. J Vasc Surg 2017;65:303-10.
19. Patel SD, Constantinou J, Simring D, Ramirez M, Agu O, Hamilton H, et al. Results of complex aortic stent grafting of abdominal aortic aneurysms stratified according to the proximal landing zone using the Society for Vascular Surgery classification. J Vasc Surg 2015;62:319-25.e2.
20. Tinelli G, Crea MA, de Waure C, Di Tanna GL, Becquemin J-P, Sobocinski J, et al. A propensity-matched comparison of fenestrated endovascular aneurysm repair and open surgical repair of pararenal and paravisceral aortic aneurysms. J Vasc Surg 2018;68:659-68.
21. Donas KP, Torsello GB, Piccoli G, Pitoulias GA, Torsello GF, Bisdas T, et al. The PROTAGORAS study to evaluate the performance of the Endurant stent graft for patients with pararenal pathologic processes treated by the chimney/snorkel endovascular technique. J Vasc Surg 2016;63:1-7.
22. 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.
23. Jordan WD Jr, Mehta M, Varnagy D, Moore WM Jr, Arko FR, Joye J, et al. Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy. J Vasc Surg 2014;60:885-92.e2.
24. Kouvelos GN, Oikonomou K, Antoniou GA, Verhoeven EL, Katsargyris A. A systematic review of proximal neck dilatation after endovascular repair for abdominal aortic aneurysm. J Endovasc Ther 2017;24:59-67.
25. Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-55.
26. 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.
27. Schneider DB, Oderich GS, Farber MA, Schanzer A, Beck AW, Timaran CH, et al. SS03. target artery outcomes after branched and fenestrated endovascular repair of pararenal and thoracoabdominal aortic aneurysms in the US investigational device exemption experience. J Vasc Surg 2018;67:e83.
28. O'Donnell TF, Deery SE, Boitano LT, Siracuse JJ, Schermerhorn ML, Scali ST, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. J Vasc Surg 2019;69:414-22.
29. Deery SE, Ergul EA, Schermerhorn ML, Siracuse JJ, Schanzer A, Goodney PP, et al. Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair. J Vasc Surg 2018;67:157-64.
30. Mendes BC, Oderich GS, Macedo TA, Pereira AA, Cha S, Duncan AA, et al. Anatomic feasibility of off-the-shelf fenestrated stent grafts to treat juxtarenal and pararenal abdominal aortic aneurysms. J Vasc Surg 2014;60:839-48.e2.

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Supplemental Table I (online only). Summary of patients with stenosis or occlusion of targeted renal vessels

Patient	Event	Target vessel	Days to event	Corresponding bridging stents placed in index procedure	Reintervention	CEC adjudication
Stenosis						
1	Stenosis	Right	25	Cook Zenith Alignment	POD 30 (unsuccessful)	Aneurysm-related[a]
2	Stenosis	Right	188	eV3 IntraStent	POD 238	Device-related
3	Stenosis	Bilateral	245	Left—eV3 Primus GPS Right—eV3 Primus	POD 245	Device-related
4	Stenosis	Left	355	Cook Zenith Alignment	POD 382	Procedure-related
5	Stenosis	Right	370	Cook Zenith Alignment	POD 743	Procedure-related
6	Stenosis	Right	373	Boston Scientific Express Biliary SD Monorail	POD 406	Device-related
7	Stenosis	Right	427	Cook Zenith Alignment	POD 427	Procedure-related
	Stenosis	Left	840	Cook Zenith Alignment	POD 840	Procedure-related
8	Stenosis	Right	883	eV3 ParaMount XS	POD 883	Device-related
9	Stenosis	Bilateral	1400	Left and right—eV3 Primus GPS	POD 1400	Procedure-related
10	Stenosis	Left	1539	eV3 ParaMount XS	POD 1539[b]	Procedure- and device-related
11	Stenosis	Right	1582	Cook Zenith Alignment	POD 1582	Procedure-related
Occlusion						
12	Occlusion	Right accessory	162	Atrium iCAST	Untreated	Procedure-related
13	Occlusion	Left	196	Boston Scientific Express Biliary SD Monorail	POD 222	Procedure-, technique-, and device-related
14	Occlusion	Left	373	Boston Scientific Express Biliary LD	Untreated	Device-related
15	Occlusion	Right	386	Cook Zenith Alignment	POD 435	Device-related
11[c]	Occlusion	Left	1124	Cook Zenith Alignment	Untreated	Procedure- and device-related

CEC, Clinical events committee; *POD*, postoperative day.
[a]CEC was unable to determine if procedure-, device-, or technique-related.
[b]Re-stenosis of the left renal vessel was observed at the 5-year visit (POD 1844) and was treated later with angioplasty on POD 1876 (not reported as a secondary intervention because it was beyond the 5-year follow-up).
[c]This is the same patient who had right renal stent stenosis on POD 1582.

Supplemental Table II (online only). Summary of patients with renal insufficiency, defined as creatinine rise to >2 mg/dL and by >30% from baseline on two or more follow-up tests

Patient	Days to event	Occlusion or stenosis of a target renal vessel?	Treatment	CEC adjudication
1	683	No	Untreated	Procedure-related
2	1089	No	Dialysis on POD 1189	Not related
3	1144	No—but stenosis of a nontargeted, nonstented right renal artery (POD 1144)	Angioplasty and stent placement on POD 1221 (for the nontargeted, nonstented right renal artery)	Not related
4	1301	No	Unresolved, still treating. Patient underwent medication adjustment	Not related
5	1476	No	Treating with antihypertensive medication	Not related
6	1481	No	Untreated	Not related
7	1493	Yes—occlusion of the left renal artery (POD 1124) and mild stenosis of the right renal artery stent (POD 1582)	Left renal occlusion untreated. Angioplasty for the right renal stent on POD 1582	Procedure- and device-related

CEC, Clinical events committee; *POD*, postoperative day.