Midterm outcomes of the Zenith Renu AAA Ancillary Graft

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Objective: **The Zenith Renu abdominal aortic aneurysm (AAA) Ancillary Graft (Cook Medical Inc, Bloomington, Ind) provides active proximal fixation for treatment of pre-existing endografts with failed or failing proximal fixation or seal. The purpose of this study was to evaluate the midterm outcomes of treatment with this device.**

Methods: **From September 2005 to November 2006, a prospective, nonrandomized, multicenter, postmarket registry was utilized to collect physician experiences from 151 cases (89 converters and 62 main body extensions) at 95 institutions. Preoperative indications and procedural and postimplantation outcomes were collected and analyzed. Technical success and clinical success were determined as defined by the Society of Vascular Surgery reporting standards.**

Results: **Patients were predominantly male (87%) with a mean age of 77 years. The interval between the original endograft implantation to Renu treatment was 43.4 ± 18.7 months. The indications for treatment were endoleak (n = 111), migration (n = 136), or both (n = 94). Technical success was 98.0% with two cases of intraoperative conversion and one case of persistent type IA endoleak. The median follow-up for the cohort was 45.0 months (range, 0-56 months; interquartile range, 25.0 months). Overall, 32 cases had treatment failures that included at least one of the following: death (n = 5), type I/III endoleak (n = 18), graft infection (n = 1), thrombosis (n = 1), aneurysm enlargement >5 mm (n = 9), rupture (n = 4), conversion (n = 9, with 7 after 30 days), and migration (n = 1). Overall, the clinical success for the entire cohort during the follow-up period was 78.8% (119/151).**

Conclusions: **The postmarket registry data confirm that the Zenith Renu AAA Ancillary Graft can be used to treat endovascular repairs that failed due to proximal attachment failures. The salvage treatment with the Renu device had high technical success rate and resulted in clinical success in a majority of patients (78.8%). While failed endovascular repairs can be salvaged, a clinical failure in one of five patients still emphasizes the importance of patient and device selection during initial endovascular aneurysm repair to ensure durable success. (J Vasc Surg 2011;54:307-15.)**

Endovascular abdominal aortic aneurysm (AAA) repair (EVAR) was first introduced by Parodi and Volodos in 1991.[1,2] It has since gained wide acceptance as a safe and effective treatment modality for infrarenal AAAs. In the United States, over 50% of all AAAs are currently treated with EVAR,[3] and multiple clinical trials have confirmed its perioperative benefits.[4-6] However, the long-term survival benefits of EVAR compared with traditional open repair remain uncertain. Furthermore, EVAR has been associated with an increased rate of graft-related complications and secondary interventions.[4,7]

Successful aneurysm exclusion with EVAR depends upon anatomical suitability, appropriate device selection, and proper positioning of the endograft. A major complication of EVAR is the development of proximal attachment failure, which can lead to endograft migration with resultant type I endoleak, aneurysm growth, and possibly rupture. Migration is a potential complication with all commercially available endografts. When a graft is used within the guidelines of the manufacturer's instructions for use (IFU), excellent long-term results with low rates of migration can be obtained. However, as the use of EVAR is extended to patients with challenging anatomy beyond the scope of the IFU, there is a negative impact on late results.[8,9]

The Zenith Renu AAA Ancillary Graft (Cook Medical Inc, Bloomington, Ind) was approved by the United States Food and Drug Administration (FDA) in June 2005. It is an endovascular aortic ancillary device that acts as a "bailout" device for endovascular salvage by providing active proximal fixation for pre-existing endovascular aortic grafts with failed or failing proximal fixation or seal, especially in patients who are not candidates for open surgical repair. The graft is available in two configurations: a main body extension and a converter. The main body extension is an aortic cuff with transrenal fixation. The converter also has transrenal fixation, but extends distally into an iliac artery to achieve an aortouniiliac (AUI) repair. As such, the use of the converter requires concurrent femoro-femoral bypass and contralateral iliac ar-

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tery occlusion. The purpose of this study was to evaluate the midterm outcomes of treatment with the Zenith Renu AAA Ancillary Graft using data from a prospective, multicenter, postmarket registry.

METHODS

Study design. Between September 9, 2005 and November 9, 2006, a prospective, nonrandomized, multicenter, postmarket registry was used to collect physician experiences with the Renu device. Data collection was prospectively planned for up to 5 years after device implantation. Information collected by the treating physicians included preoperative, procedural, and follow-up visit data from imaging and clinical evaluations. An independent Clinical Events Committee (CEC) and Data Safety Monitoring Board were established. All available imaging was independently evaluated by an angiographic core laboratory (Cleveland Clinic, Cleveland, Ohio). All registry data were collected, organized, stored, and statistically evaluated by MED Institute, Inc (West Lafayette, Ind). Authors of this study had complete access to the original registry data. The registry is ongoing, but for the purpose of this study, only data as reported through April 13, 2010 were utilized for the analyses.

Device. The Zenith Renu AAA Ancillary Graft is indicated for secondary endovascular intervention in patients who received prior endovascular repair of infrarenal abdominal aortic or aortoiliac aneurysms in which there is inadequate proximal fixation or seal. Additional details regarding the IFU as well as the device description have previously been reported (Appendix, online only).[10]

Implantation procedure. Before implantation, all cases were reviewed by a member of the physician review committee to ensure anatomic suitability and that patients met the IFU for the device. Options for treatment were then presented to the treating physician. The choice of final device configuration was ultimately left to the discretion of the implanting physician. Device delivery was performed in accordance with the IFU. Use of a converter device, in most patients, required a femoro-femoral bypass and occlusion of the contralateral iliac artery.

Definitions. In compliance with the reporting standards recommended by the Society of Vascular Surgery (SVS) and the American Association for Vascular Surgery, technical success was defined as successful introduction and deployment of the endograft without the need for conversion and without mortality, type I or III endoleak, or graft limb occlusion within the first 24 hours. Clinical success required successful deployment of the endovascular device without aneurysm-related death, type I or III endoleak, graft infection or thrombosis, aneurysm expansion, aneurysm rupture, or conversion to open repair. In the absence of aneurysm expansion, type II endoleaks were not considered clinical failures. All deaths that occurred within 30 days of the operative procedure were classified as procedure-related. Deaths that occurred after 30 days were considered late deaths. Aneurysm-related deaths were defined as all deaths due to aneurysm rupture, primary or secondary procedure, or surgical conversion.[11] Migration was defined as movement (antegrade or retrograde) >10 mm relative to anatomic landmarks identified on the first postoperative computed tomography scan. Endoleak was defined as persistent blood flow in the aneurysm sac outside of the endograft, which could be due to inadequate seal at either the proximal or distal ends of the graft or attachment zones (type I), retrograde perfusion via collateral vessels (type II), disconnection of device components or device fabric tear or disruption (type III), and high porosity graft material (type IV).

Statistical analysis. Statistical analysis was performed on the prospectively collected data using SAS 9.1 software (SAS Institute, Inc, Cary, NC). Descriptive data are presented as mean ± standard error. Fisher exact tests and Kaplan-Meier estimations were performed where appropriate, and a value of $P < .05$ was considered statistically significant.

RESULTS

A total of 151 cases at 95 institutions were enrolled into the registry. There were 131 (87%) males, and the mean age was 77 years for the entire cohort. The indications for treatment included migration in 136 cases (90.1%), endoleak(s) in 111 cases (73.5%), and presence of both migration and endoleak(s) in 94 cases (62.3%). Device integrity failure (eg, stent fracture or breakage, graft tear, component separation), kink, or occlusion were reported in conjunction with migration or endoleak in 15 cases. The AneuRx (Medtronic Vascular, Santa Rosa, Calif) device accounted for 83.4% of all pre-existing endovascular aortic grafts treated with the Renu device (Table I). The median time interval between implantation of the original devices and Renu implantation was 41.0 months (interquartile range, 28.0 months).

For Renu treatment outcomes, the median follow-up for the entire cohort was 45.0 months (range, 0-56 months; interquartile range, 25.0 months). Data were available for 100% of patients at 30 days, 97.8% of patients at 12 months, 84.3% of patients at 24 months, 69.7% of patients at 36 months, and 64.0% of patients at 48 months.

Technical success. Of 151 cases, 89 (59%) were treated with a Renu converter and 62 (41%) with a Renu main body extension. Deployment of the Renu device was successful in all cases. There were two cases of intraoperative conversion to open repair. One patient with a proximal type I endoleak with associated migration of an AneuRx device was treated with a Renu converter, iliac occluder, and a Palmaz stent (Johnson & Johnson Corp, New Brunswick, NJ). The patient required emergent conversion to open repair due to rupture of the aortic wall proximal to the Renu device. The patient did not survive the conversion. A second patient was treated with a Renu converter for a proximal type I endoleak with associated migration of an AneuRx device. On completion angiography, a persistent type I endoleak was detected. No further endovascular treatments were attempted; as the patient was considered a candidate for surgery, the treating physician chose to con-

Table I. Pre-existing endovascular grafts treated with the Zenith Renu AAA Ancillary Graft

Device treated	*Number (%)*	*Implantation time prior to Renu (month)*[a]		
		Median	*Quartile range*	*n*
AneuRx (Medtronic Vascular, Santa Rosa, Calif)	126 (83.4)	40.0	25.5	116
Ancure (Abbot Vascular, Abbot Park, Ill)	9 (6.0)	59.0	13.5	8
Excluder (W. L. Gore, Flagstaff, Ariz)	6 (4.0)	36.5	34.0	6
Talent (Medtronic Vascular, Santa Rosa, Calif)	3 (2.0)	38.5	1.0	2
Vanguard (Boston Scientific, Natick, Mass)	2 (1.3)	96.0	0	2
Other[b]	2 (1.3)	75.0	20.0	2
Fortron (Cordis Endovascular, Warren, NJ)	1 (0.7)	44.0	0	1
Lifepath (Baxter, Morton Grove, Ill)	1 (0.7)	38.0	0	1
Zenith (Cook Inc, Bloomington, Ind)	1 (0.7)	15.0	0	1

[a]The implantation times for 10 AneuRx grafts, one Ancure graft, and one Talent graft were not provided.
[b]Handmade graft (one aortouni-iliac, one bifurcated).

vert the procedure to open repair. In addition, there was one instance of a persistent type I endoleak. This patient was treated with a Renu converter for proximal type I endoleak, migration, and kink of an AneuRx device. A proximal type I endoleak was identified at the end of the procedure, but was not treated intraoperatively. The endoleak did not resolve with time and the patient was successfully treated via conversion to open repair at 3 months post-Renu implantation. In all, the technical success rate for the Renu devices was 98.0% (148 of 151 patients).

Aneurysm rupture. There were four aneurysm ruptures after Renu implantation. Three patients were treated with Renu main body extensions for migrated AneuRx devices. Preoperatively, physician peer reviewers suggested that a Renu converter may be a better treatment option for all three patients due to anatomic reasons. These included severe angulation of the pre-existing endograft, infrarenal aortic angulation, and significant infrarenal diameter change. However, all ultimately had implantation of a main body extension at the discretion of the treating physician. These three ruptures were due to type III endoleaks/separation between devices, and the patients were treated with emergent open surgical repair. One patient was treated at 12 months and survived. The other two were treated at 12 months and 16 months, respectively, and did not survive the conversion procedures. The fourth aneurysm rupture occurred in a patient treated with a Renu main body extension for migration and proximal type I endoleak. At the 12-month follow-up, the patient was found to have aneurysm expansion associated with a type II endoleak. The patient declined further intervention, the aneurysm subsequently ruptured, and the patient expired 30 months after Renu implantation. The Kaplan-Meier analysis estimated that 55-month freedom from aneurysm rupture is 97.3% (Fig 1).

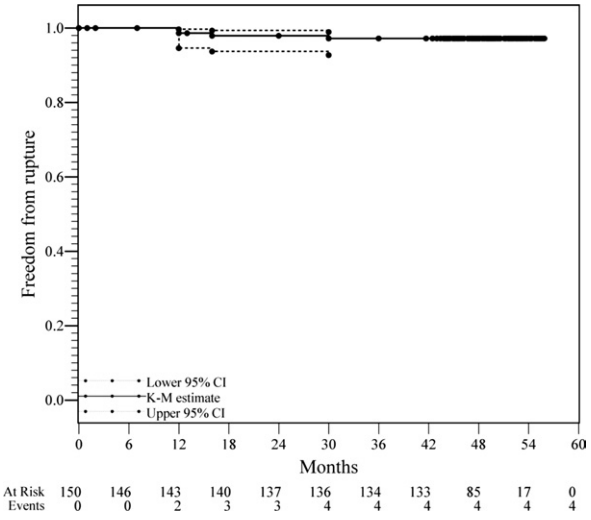

Fig 1. Kaplan-Meier curve of freedom from rupture in patients treated with a Zenith Renu AAA Ancillary Graft.

Conversion. There were a total of nine instances of conversion to open repair in the entire cohort (Table II). As noted, two patients underwent intraoperative conversion at the time of the Renu graft implantation, and one patient underwent elective conversion at 3 months due to a persistent proximal type I endoleak. As described above, three patients who presented with ruptured aneurysms underwent emergent conversion. Three additional instances of conversion to open repair occurred more than 12 months after implantation of the Renu device. One conversion was performed at 19 months post Renu implantation due to a suspected graft infection and resulted in successful open repair with endograft explantation. The site reported that the graft infection was related to the original endograft. Furthermore, core laboratory analysis of the preprocedure imaging (prior to Renu implantation) indicated that stranding within the aneurysm sac was a possible indication of infection of the pre-existing endograft. The second conversion was performed at 30 months, following identification of a proximal type I endoleak during the 24-month follow-up time period. The patient underwent coil embolization at 25 months and additional stenting at the graft neck at 29 months. Both endovascular attempts to resolve the endoleak were unsuccessful. The proximal type I endoleak was ultimately successfully treated with open repair. The final conversion to open repair was performed at 45

Table II. Conversion to open repair in patients treated with the Zenith Renu AAA Ancillary Graft

Months	*Reason for conversion*	*Rupture*	*Death*
0[a]	Rupture of aortic wall proximal to Renu device	—	X
0[a]	Persistent proximal type I endoleak	—	—
3	Persistent proximal type I endoleak	—	—
12	Type III endoleak	X	—
12	Type III endoleak	X	X
16	Type III endoleak	X	X
19	Suspected graft infection	—	—
30	Proximal type I endoleak	—	—
45	Iliac artery rupture during reintervention for distal type I endoleak	—	X

[a]Conversion occurred intraoperatively.

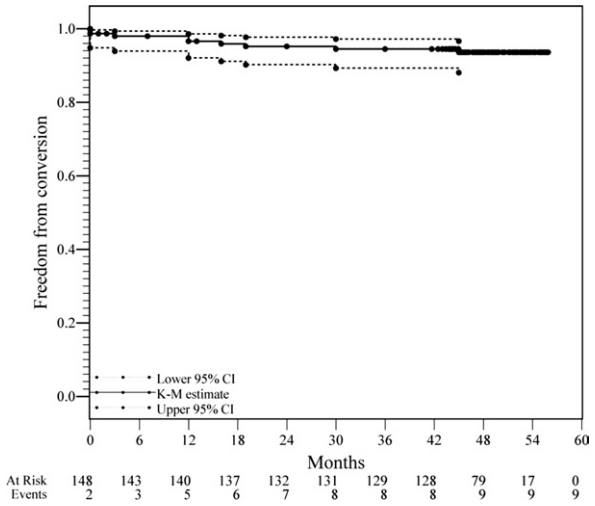

Fig 2. Kaplan-Meier curve of freedom from conversion in patients treated with a Zenith Renu AAA Ancillary Graft.

months during a secondary endovascular intervention to treat a distal type I endoleak (distal to the Renu main body extension). Rupture of the external iliac artery occurred during advancement of iliac limbs through difficult access anatomy. The patient died following the emergent conversion to open repair. The Kaplan-Meier 55-month estimated freedom from conversion is 93.8% (Fig 2).

Death. A total of 44 deaths have been reported in the registry cohort. These included one intraoperative death, one early (≤30 days) death, and 42 late (>30 days) deaths. All deaths were reviewed by the CEC, and three have been adjudicated as procedure-related and two as Renu-related (Table III).

Among the three procedure-related deaths, one occurred intraoperatively when the patient failed to recover after conversion to open repair following rupture of the aorta proximal to the Renu device. In the second procedure-related death, hematologic complications occurred approximately 2 weeks after Renu implantation. This patient was treated with a Renu graft on an emergent basis after being hospitalized due to aneurysm rupture and low platelet count. The third procedure-related death occurred 10 months after Renu implantation. The cause of death was cardiorespiratory arrest secondary to hypotension and sepsis. In this patient, a pulmonary embolism and a suspected graft infection (although blood cultures were negative) were identified at 4 months. The patient was hospitalized at 7 months to drain an abdominal abscess. The treating institution noted that the death was probably related to an undiagnosed infection that was present prior to implantation of the Renu device.

Two Renu-related deaths occurred in patients who required emergent conversion to open repair because of aneurysm rupture due to type III endoleak. The Kaplan-Meier estimate of freedom from aneurysm-related death is 96.6% at 55 months (Fig 3).

Migration, component separation, limb occlusion, and device integrity. Migration, patency, and integrity of Renu components were based upon core laboratory analysis. To date, there has been a single case of migration. In a 69-year-old patient, the original 28 mm AneuRx device was found to have a >10 mm migration and a proximal type I endoleak at 36 months. Core laboratory analysis of the preprocedure computed tomography demonstrated an inverted funnel-shaped neck measuring 30 mm just below the lowest renal artery and 34 mm at 15 mm below the lowest renal artery. The patient was treated with a 32 mm diameter Renu converter. No endoleaks were identified following the procedure, but migration of the Renu converter >10 mm was identified at the 12-month follow-up. No secondary interventions were performed, and the patient ultimately died of lung cancer 30 months following Renu implantation. One patient with a Renu main body extension underwent conversion to open repair due to component separation. At the 24-month follow-up, one case of device occlusion was identified in a patient treated with a Renu converter. The site reported that an axillofemoral bypass was performed when the endograft became occluded. In addition, one case of kinking (Renu converter) and one case of endograft infolding (Renu main body extension) have been identified. No proximal type I or III endoleaks or occlusions have been reported for either of these cases.

Endoleak, aneurysm enlargement, and secondary endovascular intervention. Prior to Renu treatment, 111 (73.5%) patients were found to have endoleaks. Of the 136 endoleaks noted in these 111 patients, 96 (63.6%) were proximal type I endoleaks, nine (6.0%) were distal type I

Table III. Procedure- and Renu-related deaths in patients treated with the Zenith Renu AAA Ancillary Graft

Months	*Age*	*Cause of death*	*CEC adjudication*
0[a]	82	Rupture of aorta proximal to Renu device	Procedure-related
<1[b]	90	Low platelet count/hematologic complications	Procedure-related
10	73	Arrest from hypotension/sepsis	Procedure-related
12	81	Multisystem organ failure following rupture	Renu-related
16	76	Cardiac arrest following rupture	Renu-related

[a]Death occurred intraoperatively.
[b]Death occurred 2 weeks after Renu implantation.

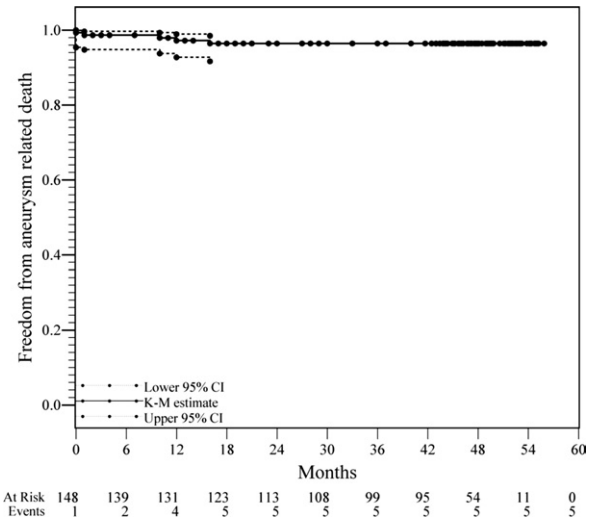

Fig 3. Kaplan-Meier curve of freedom from aneurysm-related death in patients treated with a Zenith Renu AAA Ancillary Graft.

endoleaks, 17 (11.3%) were type II endoleaks, 10 (6.6%) were type III endoleaks, and four (2.6%) were of unspecified or unknown type. At 1 month after Renu implantation, 95 of 96 (99.0%) proximal type I endoleaks had resolved. The patient who had the one persistent proximal type I endoleak underwent conversion to open repair as noted previously. All 10 type III endoleaks resolved by the 1-month follow-up. During the follow-up period, 17 (11.3%) new type I or III endoleaks were identified. These included four proximal type I endoleaks, three distal type I endoleaks in patients treated with a Renu converter, one distal type I endoleak in a patient treated with a Renu main body extension, and nine type III endoleaks. Of note, all new type III endoleaks occurred in patients treated with a Renu main body extension. Of the four patients with new proximal type I endoleaks, one had an inverted funnel shaped aortic neck, one had an inverted funnel shaped neck and a short (2.9 mm) sealing zone between the lowest renal artery and the proximal edge of the pre-existing graft, and a third had a short (3.6 mm) sealing zone. The fourth case did not have any particular high risk aortic neck characteristic identified.

Aneurysm enlargement was defined as an increase in the maximum aortic diameter by >5 mm based upon imaging evaluated by the core laboratory. Aneurysm enlargement was identified in six patients at the 12-month follow-up and in an additional three patients at the 24-month follow-up. Of these nine cases of aneurysm enlargement, seven were associated with an identified endoleak. These included one patient with a distal type I and type II endoleak, four patients with type II endoleaks, and two patients with type III endoleaks.

As all patients in this registry had undergone previous endograft placement, there were instances of secondary endovascular interventions to treat complications related to the original endograft. As such, there were six procedures considered unrelated to the Renu component (Table IV). However, seven other interventions in five patients were considered Renu-related (Table V). One patient was successfully treated with angioplasty and Palmaz stent placement for a proximal type I endoleak of the Renu device that was identified during routine 24-month follow-up. The endoleak recurred and was successfully remedied at 34 months. Another patient had two failed endovascular treatments (coil embolization at 25 months and stent placement at 29 months) for a proximal type I endoleak of the Renu device and subsequently underwent successful conversion to open repair. A patient developed migration of the previous endograft with development of a type III endoleak between the previous endograft and the Renu main body extension. This was successfully treated with a Renu converter at 30 months. One patient had a persistent proximal type I endoleak of the Renu converter and was treated successfully with placement of a Renu main body extension 38 months after placement of the Renu converter. In the final patient who underwent Renu-related secondary intervention, dilatation of the distal iliac attachment site was treated with a branched iliac endograft 44 months after implantation of the Renu device.

Adverse events (excluding endoleak, rupture, conversion, and death). Adverse event information was requested intraoperatively, at the 1-month time period, and annually thereafter. All events underwent medical review and, if necessary, were adjudicated by the CEC to determine whether the events were related to the endovascular intervention. If related to the endovascular intervention, the CEC further determined whether the event was procedure-related, technique-related, or device-related (Renu or pre-existing graft). In total, 12 early (≤30 days) adverse events were reported in 11 patients, and 14 late

Table IV. Secondary endovascular interventions unrelated to the Zenith Renu AAA Ancillary Graft

Month	*Intervention*	*Reason*
1	Placement of additional stent	Graft limb occlusion on opposite side used for Renu main body extension implantation
10	Placement of iliac component	Distal type I endoleak in an iliac limb distal to Renu main body extension
12	Coil embolization	Type II endoleak
22	Placement of Zenith iliac limb graft	Type III endoleak in limb of pre-existing endograft
38	Placement of Zenith graft within original graft	Type III endoleak
45	Failed endovascular attempt[a]	Distal type I endoleak in an iliac limb distal to Renu main body extension

[a]This patient suffered from external iliac artery rupture leading to emergent conversion and subsequent death.

Table V. Secondary endovascular interventions related to the Zenith Renu AAA Ancillary Graft

Month	*Intervention*	*Reason*
24[a]	Angioplasty, Palmaz stent placement	Proximal type I endoleak
25[b]	Coil embolization	Proximal type I endoleak
29[b]	Placement of additional stent	Persistent proximal type I endoleak
30	Renu converter, zenith leg extension, occluder plug, and femoro-femoral bypass	Migration of pre-existing graft with type III endoleak
34[a]	Percutaneous angioplasty	Recurrent proximal type I endoleak
38	Proximal cuff placement	Proximal type I endoleak
44	Implantation of branched iliac endograft	Iliac artery dilatation at distal iliac attachment site

[a]The same patient underwent interventions at 24 months and 34 months.
[b]The same patient underwent interventions at 25 months and 29 months. Both interventions failed to resolve the endoleak and the patient underwent successful conversion to open repair at 30 months.

Table VI. Procedure-related adverse events

Month	*Category*	*Specific adverse event*
Day 1	Vascular	Right groin exploration with revision of femoro-femoral bypass graft
Day 2	Vascular	Brachial artery pseudoaneurysm repair
Day 3	Renal[a]	Serum creatinine rise >30% above baseline resulting in persistent value >2.0 mg/dL
1	Vascular[a]	Contralateral limb occlusion requiring implantation of stents
1	Wound	Persistent drainage at the groin incision requiring surgical intervention
1	Other[a]	Spontaneous retroperitoneal hematoma
	Renal[a]	Renal failure requiring temporary dialysis (baseline creatinine 4.0 mg/dL)
1	Wound	Groin seroma requiring operative debridement and closure
4	Other[a]	Suspected graft infection with negative cultures was reported at day 124; patient admitted for computed tomography-guided drainage of an abdominal abscess at 7 months, and died at 10 months

All events underwent medical review by the treating physician. Those events marked with ([a]) underwent adjudication by the independent Clinical Events Committee.

(>30 days) adverse events were reported in 10 patients. No adverse events have been adjudicated as technique-related or device-related; however, nine events (in eight patients) have been adjudicated as procedure-related (Table VI).

Clinical success. In accordance with the standards recommended by the SVS, there were a total of 49 events contributing to clinical failure in 32 patients. These included the following: five deaths, 18 type I or type III endoleaks, one graft infection, one thrombosis, nine aneurysm expansions (>5 mm), four ruptures, nine conversions, and one migration. The clinical success for this cohort at a median follow-up of 45.0 months was 78.8% (119 of 151 patients). However, it merits emphasis that some of the included events were related solely to the pre-existing endograft and were not directly related to the Renu implant. Therefore, the calculated clinical success rate likely represents an underestimation of the real clinical outcomes related to the Renu graft. A summary of the clinical outcomes of this registry cohort can be found in Table VII.

DISCUSSION

Since the introduction of EVAR almost two decades ago, this technique has been rapidly adopted as a viable and often preferred method of treating infrarenal AAAs. In addition to low perioperative mortality rates, data from clinical trials have also demonstrated excellent long-term

Table VII. Clinical outcomes of the Zenith Renu AAA Ancillary Graft

Category	*Outcome*
Deployment success	100%
Technical success	98.0%
Freedom from aneurysm-related mortality[a]	96.6%
Freedom from conversion[a]	93.8%
Freedom from rupture[a]	97.3%
Clinical success[b]	78.8%

[a]Kaplan-Meier estimates at 55 months.
[b]At a median follow-up of 45.0 months.

outcomes with >95% freedom from aneurysm-related mortality, conversion, rupture, and migration.[12-15] However, recent evidence has demonstrated the lack of long-term survival benefits of EVAR compared with traditional open repair.[4-7] Furthermore, despite initial technical success, the long-term durability of EVAR continues to be a concern. Outside of the clinical trial setting, secondary interventions to treat failing endovascular repair are common and can be seen in 9% to 14% of patients during follow-up.[16-18]

A critical complication unique to endovascular repair is the development of proximal attachment failure with subsequent development of migration and/or endoleak.[19] Migration has been shown to be a potential complication of all commercially available endografts. However, the AneuRx stent graft has typically been associated with higher migration rates than other devices. In earlier series, migration rates of 27% to 42% at 3 years were reported.[20,21] Data from the multicenter AneuRx clinical trial showed a Kaplan-Meier estimate of migration of 19% at 3 years.[22] While the endograft itself may be responsible for the high migration rates, subsequent literature suggested that migration may also be related to suboptimal aortic anatomy. In patients who met the criteria in the IFU for the AneuRx device, the migration rate at 4 years was only 6.1%, compared with 42.1% for patients with unfavorable neck anatomy.[23]

Proximal attachment failure can develop several years after initial device implantation. When attachment failures occur, the patients are older and often present with additional medical comorbidities not present during the initial endovascular treatment. Because migration and proximal endoleak can ultimately lead to aneurysm expansion, secondary interventions should be performed to prevent aneurysm rupture and patient death. As many of the patients who initially underwent EVAR were considered unfit for traditional open repair, any means of salvaging the failed EVAR in an endovascular fashion may be the best option for these patients. The use of proximal aortic cuffs has been reported for the treatment of proximal attachment failures; however, the technical and clinical success rates of cuff placement remain in question.[24-27]

The Zenith Renu AAA Ancillary Graft, which received FDA approval in 2005, was designed as a "bailout" device for endovascular salvage of endografts with failed or failing proximal fixation. In this study, data obtained from a postmarket registry were used to evaluate clinical outcomes of the Renu graft. The vast majority (>80%) of patients treated for proximal fixation failure had previous implantation of the AneuRx device. Furthermore, reinforcing the concern about long-term failure of endovascular repair, the patients who had proximal graft failures necessitating treatment had a median interval of 41.0 months between the original graft placement and the Renu graft placement.

The Renu device has two configurations that allow the physician to treat patients depending on patient-specific anatomic factors. Both configurations have a stable transrenal attachment with active fixation along with a proximal sealing stent designed to seal type I endoleaks. This feature distinguishes the main body extension device from other proximal aortic cuffs. The converter device has an additional distal component which extends into the iliac artery to create an AUI repair. While the use of this configuration is more labor intensive, the femoro-femoral bypass associated with AUI repair has been shown to be durable with excellent long-term patency rates.[28,29] While the IFUs for both configurations are similar, there are certain anatomic features that favor the use of the converter device. When a main body extension is utilized, aneurysm exclusion is still reliant upon proper functioning of the pre-existing endograft. As demonstrated in the three patients that developed aneurysm rupture from a type III endoleak, a cuff placed in an angulated neck can separate from the pre-existing endograft from the forces pushing on the components.

The literature on the use of aortic cuffs to treat migrated endografts remains limited. In a single-center retrospective series of 20 patients with proximal attachment failure from an AneuRx device, 14 of 16 were successfully treated at 1-year follow-up with an aortic cuff.[25] However, a later series of 23 patients from two institutions showed that 26% had failed secondary reconstruction at 14 months of follow-up.[26] In a series of 42 patients that underwent endovascular revision of their failed EVAR, proximal cuffs were successful in only 45% of the patients, while the use of an AUI device allowed for successful repair in 86% of cases.[27] A previous report of the short-term data from this registry suggested that the converter configuration was the better reconstructive option compared with the main body extension.[10] While the comparison between the two configurations was not repeated during this study, further analyzes are pending to evaluate this variable, as well as other factors, as follow-up for patients in this registry is ongoing.

Limitations. The Zenith Renu AAA Ancillary Graft is used to treat failing or failed pre-existing endovascular repairs. As such, the operative as well as imaging details of the prior endograft implantation may provide valuable insight into patient outcomes. As this registry was intended only to focus on the outcomes of treatment with the Renu device, details regarding the prior endograft treatment were not always available. Although every case in this registry underwent evaluation by a member of the physician review

committee, the choice of final device configuration was left to the discretion of the treating physician. There were multiple instances in which the implanted device was different from the recommendation of the committee. In cases of adverse events, it remains unclear whether the use of the recommended device configuration would have led to different clinical outcomes. Furthermore, there is no control group available, as comparison to alternative treatments is not an aim of this registry.

CONCLUSION

The Zenith Renu AAA Ancillary Graft registry data demonstrate that the Renu device was easy to use with successful deployment in all cases. The technical success rate was high (98.0%) with only two cases of intraoperative conversion and one persistent endoleak. In midterm follow-up of over 3 years, the clinical outcomes also suggest that the Renu device is a safe and viable endovascular reconstruction option for patients with proximal failure and/or graft migration. The Renu graft has shown good midterm device integrity with only one instance of device occlusion and no other clinically significant events. The Kaplan-Meier estimates at 55 months for freedom from rupture, conversion, and aneurysm-related mortality were 97.3%, 93.8%, and 96.6%, respectively. These outcomes are comparable to those seen in other multicenter device trials of original endovascular treatments.[12-15] In fact, these results become even more impressive when it is understood that patients in this registry clearly represent a cohort with challenging anatomy in which endovascular repair has already failed. While endovascular salvage is possible in almost four out of five patients at midterm follow-up as reported in this study, these results emphasize the importance of proper patient selection, accurate device deployment, and the need for diligent postimplantation surveillance after initial endovascular aneurysm repair.

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AUTHOR CONTRIBUTIONS

Conception and design: JJ, LS
Analysis and interpretation: JJ, BR, PG, LS
Data collection: JJ, SM, LS
Writing the article: JJ, LS
Critical revision of the article: JJ, BR, PG, SM, LS
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Appendix (online only). Selected anatomic criteria within the instruction for use of the Zenith Renu AAA Ancillary Graft.

Indication	*Main body extension*	*Converter*
Length	>43 mm from the lowest renal artery to bifurcation of pre-existing endograft	>37 mm from the lowest renal artery to bifurcation of pre-existing endograft
Distal fixation	Within a graft segment ≤34 mm diameter and ≥17 mm (1 Cook Z-stent) in length, with more overlap length being preferred	If used without an iliac leg, within a graft segment <12 mm diameter and ≥17 mm in length, with more overlap length being preferred If used in combination with the iliac leg, 7.5-20 mm in diameter (measured outer wall to outer wall) and >10 mm in length, with 20-30 mm being preferred
Both configurations require the following: aortic fixation site diameter to be between 18 and 32 mm (measured outer wall to outer wall); angle <60 degrees relative to the long axis of the aneurysm; angle <45 degrees relative to the axis of the suprarenal aorta; adequate femoral/iliac access compatible with the required introduction systems		