

From the New England Society for Vascular Surgery

Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

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Objective: Proximal attachment site complications continue to occur after endovascular repair of abdominal aortic aneurysms (EVAR), specifically type Ia endoleak and endograft migration. EndoAnchors (Aptus Endosystems, Sunnyvale, Calif) were designed to enhance endograft proximal fixation and sealing, and the current study was undertaken to evaluate the potential benefit of this treatment.

Methods: During the 23-month period ending in December 2013, 319 subjects were enrolled at 43 sites in the United States and Europe. EndoAnchors were implanted in 242 patients (75.9%) at the time of an initial EVAR procedure (primary arm) and in 77 patients with an existing endograft and proximal aortic neck complications (revision arm). Technical success was defined as deployment of the desired number of EndoAnchors, adequate penetration of the vessel wall, and absence of EndoAnchor fracture. Procedural success was defined as technical success without a type Ia endoleak at completion angiography. Values are expressed as mean \pm standard deviation and interquartile range.

Results: The 238 male (74.6%) and 81 female (25.4%) subjects had a mean age of 74.1 ± 8.2 years. Aneurysms averaged 58 ± 13 (51-63) mm in diameter at the time of EndoAnchor implantation (core laboratory measurements). The proximal aortic neck averaged 16 ± 13 (7-23) mm in length (42.7% <10 mm and 42.7% conical) and 27 ± 4 mm (25-30 mm) in diameter; infrarenal neck angulation was 24 ± 15 (13-34) degrees. The number of EndoAnchors deployed was 5.8 ± 2.1 (4-7). Technical success was achieved in 303 patients (95.0%) and procedural success in 279 patients (87.5%), 217 of 240 (89.7%) and 62 of 77 (80.5%) in the primary and revision arms, respectively. There were 29 residual type Ia endoleaks (9.1%) at the end of the procedure. During mean follow-up of 9.3 ± 4.7 months, 301 patients (94.4%) were free from secondary procedures. Among the 18 secondary procedures, eight were performed for residual type Ia endoleaks and the others were unrelated to EndoAnchors. There were no open surgical conversions, there were no aneurysm-related deaths, and no aneurysm ruptured during follow-up.

Conclusions: Use of EndoAnchors to treat existing and acute type Ia endoleaks and endograft migration was successful in most cases. Prophylactic use of EndoAnchors in patients with hostile aortic neck anatomy appears promising, but definitive conclusions must await longer term follow-up data. (J Vasc Surg 2014;60:885-92.)

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Endoleaks and endograft migration continue to occur after endovascular aortic aneurysm repair (EVAR), particularly in patients with hostile proximal aortic neck anatomy.¹⁻⁴ Imported devices and skills have prompted clinicians to treat more challenging cases, for instance, those with a short, conically shaped, large-diameter, or highly angulated aortic neck configuration.⁵ Improving the performance of devices in the setting of a challenging proximal aortic neck attains relevance with respect to two concerns. First, the presence of challenging proximal neck anatomy increases the risk of high-pressure endoleaks, endograft migration, secondary procedures, and potential for late aneurysm rupture. Second, hostile aortic neck anatomy remains a barrier to the widespread use of EVAR for infrarenal aneurysms. Even with current devices, many patients do not meet the proximal aortic neck eligibility criteria for such endografts.⁶

The Heli-FX EndoAnchor System (Aptus Endosystems, Sunnyvale, Calif) was designed to improve fixation and sealing of an endograft within the proximal aortic neck.⁷ Securing the endograft to the aortic wall with EndoAnchors mimics a surgically sutured anastomosis.⁸ Whereas the current data are anecdotal, EndoAnchors have the potential to diminish the risk of proximal aortic neck complications when challenging neck anatomy is encountered at the time of an initial endograft implantation.^{9,10} As well, EndoAnchors hold potential for treatment of endoleaks and migration when these complications are discovered in a previously placed endograft. The demonstration of clinical benefit after the prophylactic and therapeutic use of EndoAnchors will increase eligibility for EVAR to those with more complex aortic neck anatomy, improve the durability of endovascular repair through a more robust attachment between the endograft and the aorta, and facilitate an endovascular solution when type Ia endoleaks and migration are detected.

METHODS

The Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry (ANCHOR) study is a single-arm, prospective, multicenter, multinational study of the real-world use of the currently available Heli-FX system with EndoAnchors in patients undergoing or who have undergone EVAR for infrarenal abdominal aortic aneurysms (AAAs). Participating investigators are listed in the [Appendix](#), online only.

Study design. The study was registered on [ClinicalTrials.gov](#) on February 9, 2012 (NCT01534819). Informed consent was obtained of every patient, and the study was conducted according to the Declaration of Helsinki, applicable sections of ISO 14155, MEDDEV 2.12-2, and the International Conference on Harmonization Good Clinical Practice guidelines. Eligible patients included those with asymptomatic, symptomatic, or ruptured AAA; adequate iliofemoral access for accommodation of a 16F sheath; life expectancy of 1 year or more; and no history of allergy to the metallic components of the device. Suitable endografts included the Zenith (Cook, Bloomington, Ind); the

Excluder (W. L. Gore, Flagstaff, Ariz); and the AneuRx, Talent, or Endurant devices (Medtronic Vascular, Santa Rosa, Calif). Exclusion criteria included prior EndoAnchor implantation, known bleeding diathesis, infection, and significant proximal aortic neck thrombus or calcium that would preclude adequate EndoAnchor penetration into the aortic wall. Consent could be obtained before EndoAnchor implantation or within 30 days after EndoAnchor implantation to include those patients with unplanned use of the device. To exclude selection bias, investigators were asked to enroll patients before the acquisition of the first postoperative imaging study (there were two protocol deviations from subjects enrolled beyond the 30-day window).

The primary arm comprised those patients with EndoAnchor implantation at the same procedure as the initial EVAR procedure. Patients in the primary arm were treated for prophylaxis of endoleak or migration when, in the opinion of the investigator, the anatomy put the patient at risk for future proximal aortic neck complications. Patients were also included in the primary arm when EndoAnchors were used to treat a type Ia endoleak evident at the time of an initial EVAR procedure. The revision arm included patients who had prior EVAR and presented with type Ia endoleak or endograft migration. Aortic extender cuffs were usually employed in this group when the original endograft was not adequately juxtaposed to the lowest renal artery, from either migration or misdeployment.

Study device. The Aptus Heli-FX EndoAnchor System consists of the Heli-FX Guide, EndoAnchors, and the Heli-FX Applier ([Fig 1](#)). The system is intended to provide fixation of an endograft to the aortic wall. The Heli-FX Applier is passed through the lumen of the Heli-FX Guide, and each EndoAnchor (4.5 mm in length, 3 mm in diameter) is implanted in a two-stage process to allow retraction of the EndoAnchor and repositioning before final deployment ([Fig 2](#)). The use of the device has been described in previous publications.⁷⁻¹³

End points and definitions. The index procedure was defined as the initial procedure in which EndoAnchors were implanted. Patients in the primary arm were those in whom the index procedure was concurrent with the initial endograft implantation. Patients in the revision arm were those in whom the index procedure was remote from prior EVAR. A proximal aortic neck was determined to be conical in configuration if its diameter increased more than 10% beyond the immediate infrarenal diameter within the first 10 mm of the lowest main renal artery. Significant mural thrombus or calcium was defined if its average thickness was >1 mm. Reporting of reinterventions and adverse events followed the Society for Vascular Surgery reporting standards for adverse events after medical device use and for endovascular aneurysm repair.^{14,15} Primary effectiveness and primary safety end points were prespecified in the Study Protocol. The primary efficacy end point required successful implantation of the minimum number of EndoAnchors as defined in the Instructions for Use (IFU) with respect to the diameter of the aortic neck and freedom

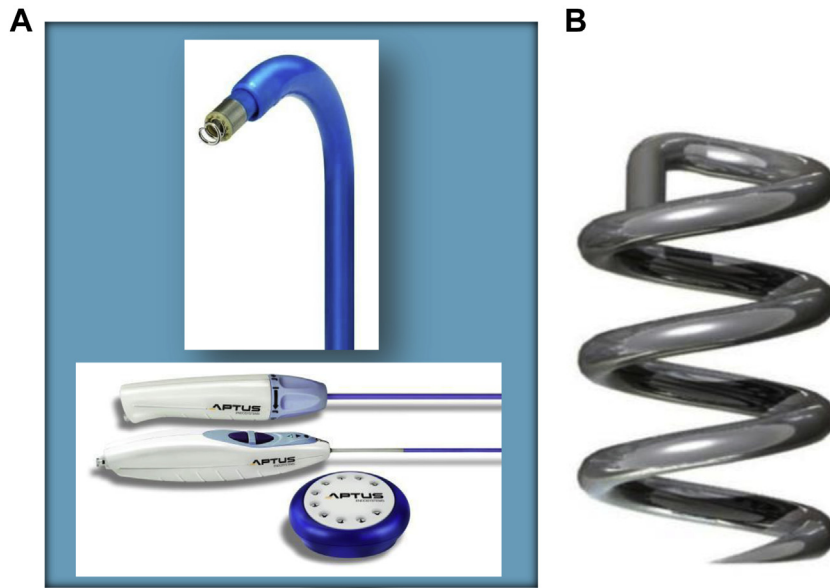


Fig 1. The Aptus Heli-FX device. **A**, Delivery system. **B**, EndoAnchor. (Image from Aptus Endosystems with permission.)

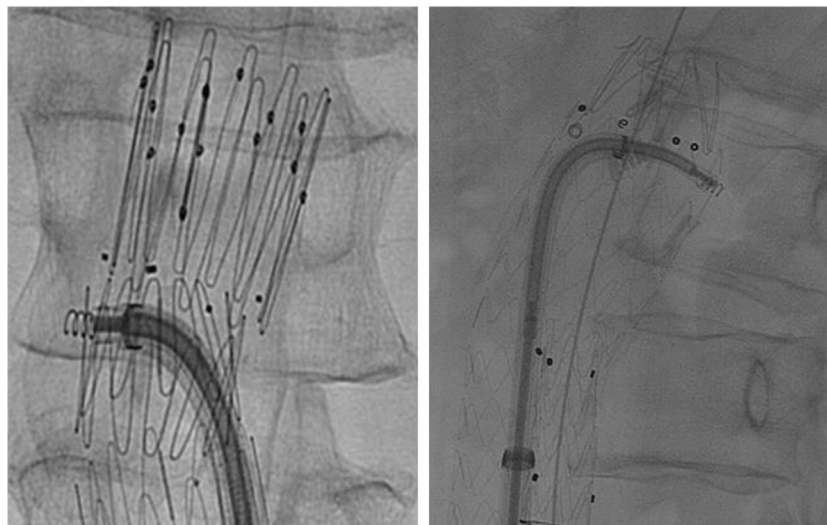


Fig 2. Deployment of EndoAnchors through endograft and into aortic wall. (Image from Aptus Endosystems with permission.)

from endograft migration or type Ia endoleak at 12 months. The primary safety end point was a composite defined as freedom from serious adverse device-related events or procedure-related adverse events during 12-months, excluding those events solely attributable to the endograft or the endograft implantation procedure but including aneurysm-related mortality. Technical success was defined as deployment of the desired number of EndoAnchors with adequate penetration of the vessel wall and without EndoAnchor fracture and with uneventful removal of the Heli-FX Guide. Procedural success was defined as technical

success without a type Ia endoleak at completion angiography. Details of the procedure and the hospitalization were recorded; these included total procedure time, time to implant EndoAnchors, duration of fluoroscopy, and length of intensive care unit stay and hospital stay. Secondary end points were not prespecified but included the frequency of endoleak (all types), migration (>10 mm), all-cause mortality, and secondary procedures.

Imaging studies. Follow-up was not protocol driven but was performed according to each investigator's standard of care. Societal guidelines were recommended for computed tomography (CT) imaging with and without

Table I. Baseline characteristics

	Primary arm (n = 242)	Revision arm (n = 77)	All (N = 319)
Age, years	73.8 ± 8.3	77.4 ± 7.1	74.1 ± 8.2
Male/female	74.4%/25.6%	75%/25%	74.6%/25.4%
Height, cm	172.8 ± 15.3	171.4 ± 15.5	172.5 ± 15.3
Weight, kg	83.3 ± 19.2	84.1 ± 19.5	83.5 ± 19.3
Comorbidities, n/N (%)			
Hypertension	197/242 (81.4)	66/77 (85.7)	263/319 (82.4)
Hyperlipidemia	169/242 (69.8)	58/77 (75.3)	227/319 (71.2)
Diabetes	46/241 (19.1)	15/77 (19.5)	61/318 (19.2)
Cardiac	144/241 (59.8)	44/77 (57.1)	188/318 (59.1)
Pulmonary	77/241 (32.0)	23/77 (29.9)	100/318 (31.4)
Renal	50/241 (20.7)	17/76 (22.4)	67/317 (21.1)
Cerebrovascular/neurologic	36/242 (14.9)	10/75 (13.3)	46/317 (14.5)
Bleeding disorder	3/241 (1.2)	1/77 (1.3)	4/318 (1.3)
Gastrointestinal	79/241 (32.8)	18/77 (23.4)	97/318 (30.5)
Genitourinary	58/241 (24.1)	12/77 (15.6)	70/318 (22.0)
Vascular	112/241 (46.5)	26/77 (33.8)	138/318 (43.4)
Thoracic aneurysm	16/241 (6.6)	2/77 (2.6)	18/318 (5.7)

Denominators are smaller than group size because of missing values.

contrast material or without contrast material but with duplex ultrasonography at 30 days and 12 months and annually thereafter. Independent core laboratory analyses (Syntactx, New York, NY) were performed on non-contrast-enhanced and contrast-enhanced CT imaging studies that were available at the time of data lock on December 13, 2013. Centerline reformatting and segmentation of CT data sets were performed with iNtuition imaging software (TeraRecon, Foster City, Calif). The proximal aortic neck length was calculated as the length at which the aortic diameter remained no more than 10% greater than the immediate infrarenal diameter. Infrarenal aortic neck angulation was defined by three centerline points: 20 mm proximal to the lowest renal artery, at the lowest renal artery, and 40 mm distal to the lowest renal artery. Aortic neck calcium and thrombus content was measured and expressed in degrees of circumference where the involvement exceeded 1.0 mm.

Data management and statistics. An electronic data capture system was used (iMedNet, Minnetonka, Minn). Each electronic case report form was verified and electronically signed by the investigators. All elements of each case report form were remotely monitored by independent reviewers (Syntactx). All safety end points were evaluated by an independent Medical Monitor in both individual listings and summary table format. The Medical Monitor identified any unanticipated adverse device effects that by virtue of severity or incidence, individually or in the aggregate, were not previously expected.¹⁵

No sample size calculation was performed because of the observational study design that was not hypothesis driven. Continuous variables are expressed as mean and standard deviation, median and interquartile range (IQR). Dichotomous end points were calculated as a numerator, defined as the number of subjects triggering the end point, divided by a denominator, defined as the number of subjects available for analysis. Imputation of missing data was not performed, nor was any interim analysis planned except for publication

or safety and regulatory purposes. *P* values were considered to be significant when the two-tailed α was less than .05.

RESULTS

During the period between February 2012 and December 2013, 319 patients from 43 sites in the United States, The Netherlands, Germany, Italy, and the United Kingdom were enrolled in ANCHOR. Among these, 242 patients (75.8%) were primary cases and 77 (24.1%) were revisions. The number of subjects enrolled per site ranged from 1 to 59 (average, 7.4 ± 10.5).

Baseline patient characteristics. Patient demographics and risk factors are listed in Table I. Aneurysms were asymptomatic in 87.8% and symptomatic in 12.2%. Aneurysms were intact in 99.0% and ruptured in 1.0%. The American Society of Anesthesiologists physical status was 1 in three patients (0.9%), 2 in 29 patients (8.9%), 3 in 228 patients (71.5%), and 4 in 59 patients (18.5%). Core laboratory analysis of baseline anatomic characteristics is summarized in Table II.

Index procedure. Details of the index procedure are displayed in Table III. The principal indications for EndoAnchor use in the primary arm were concern for future type Ia endoleak or migration in 186 cases with hostile proximal aortic neck anatomy (76.9%), treatment of a type Ia endoleak after endograft deployment in 52 cases (21.5%), and treatment of misdeployed endografts in four cases (1.7%). The principal indications for EndoAnchor use in the revision arm were treatment of a type Ia endoleak in 45 cases (58%), treatment of endograft migration with type Ia endoleak in 21 cases (27%), and treatment of migration without type Ia endoleak in 11 cases (14%). The endografts in the primary and revision arms are displayed in Table IV.

The index procedure was performed in an operating room setting in 246 patients (77.1%), in an endovascular suite in 42 patients (13.2%), and in a catheterization laboratory in 31 patients (9.7%). The procedure was performed under general anesthesia in 283 patients (88.7%), regional

Table II. Anatomic characteristics (core laboratory analysis)

	Primary arm	Revision arm	All
Maximum aneurysm diameter, mm	56 ± 11 (50-60)	65 ± 13 (58-75)	58 ± 13 (51-63)
Aortic neck length, mm	17 ± 13 (7-24)	15 ± 12 (6-20)	16 ± 13 (7-23)
5 mm or less	14.1%	23.3%	16.7%
10 mm or less	41.7%	46.5%	42.7%
15 mm or less	58.3%	60.5%	58.8%
Aortic neck diameter, mm	26 ± 4 (23-28)	29 ± 5 (26-32)	27 ± 4 (25-30)
Suprarenal angulation, degrees	16 ± 12 (8-21)	12 ± 10 (6-17)	15 ± 11 (7-20)
Infrarenal angulation, degrees	25 ± 15 (13-35)	24 ± 16 (12-32)	24 ± 15 (13-34)
Thrombus in neck, % patients	36.6%	21.4%	33.2%
>90 degrees of circumference	12.7%	23.2%	10.0%
61-90 degrees of circumference	1.2%	2.4%	0.9%
31-60 degrees of circumference	0.7%	2.3%	0.5%
Calcium in neck, % patients	48.1%	11.6%	40.2%
>90 degrees of circumference	1.3%	0%	1.0%
61-90 degrees of circumference	2.5%	0%	2.0%
31-60 degrees of circumference	5.1%	4.7%	5.0%
Conical proximal aortic neck	41.7%	46.5%	42.7%

Data are presented as frequencies or mean ± standard deviation (interquartile range).

Table III. Index procedure data

	Primary (n = 242)	Revisions (n = 77)	All (N = 319)
Percutaneous access	22.9%	27.0%	23.9%
Anesthesia			
General	88.8%	88.3%	88.7%
Epidural	1.7%	1.3%	1.6%
Spinal	1.9%	2.1%	1.3%
Local	9.1%	7.4%	7.8%
Number of EndoAnchors ^a	5.5 ± 1.8 (4-6)	6.8 ± 2.6 (5-9)	5.8 ± 2.1 (4-7)
Duration of procedure, ^a minutes	138 ± 71 (90-172)	143 ± 89 (90-162)	138 ± 76 (90-170)
Duration of EndoAnchor implantation, ^a minutes	18 ± 21 (7-20)	21 ± 22 (6-26)	19 ± 21 (7-24)
Technical success ^b	96.3%	90.9%	95.0%
Procedural success ^b	89.7%	80.5%	87.5%

^aMean ± standard deviation (interquartile range).

^bTechnical success is defined as deployment of the desired number of EndoAnchors with adequate penetration of the vessel wall and without EndoAnchor fracture. Procedural success is defined as technical success without a type Ia endoleak at completion angiography.

anesthesia in 11 patients (3.5%), and local anesthesia in 25 patients (7.8%). Access was percutaneous in 23.9% and by cutdown in 76.1%. The total duration of the procedures was 139 ± 76 minutes, of which 19 ± 17 minutes was devoted to introduction and deployment of EndoAnchors. The mean total fluoroscopic time was 30 ± 14 minutes. Admission to an intensive care unit was required in 32.8% of patients, and the mean intensive care unit stay was 1.9 ± 1.5 days in those who were admitted. The mean hospital stay was 3.5 ± 6.0 days (median, 2 days; IRQ, 1-4 days).

The median number of EndoAnchors deployed was five in the primary arm (IQR, 4-6) and seven in the revision group (IQR, 5-8). EndoAnchor deployment was technically successful in 304 patients (95.3%). EndoAnchor penetration of the aortic wall was deemed inadequate by the investigator in 15 cases (4.7%), as assessed at the index procedure. Among these, inadequate penetration resulted from EndoAnchor fracture in two patients (0.6%), intentional deployment between two endograft components distal to the proximal neck in two patients (0.6%), and inability to position the guide in one patient (0.3%). Each

Table IV. Endografts in the primary and revision arms

	Primary arm (n = 242), No. (%)	Revision arm (n = 77), No. (%)	All (N = 319), No. (%)
Gore Excluder	86 (35.5)	16 (20.8)	102 (32.0)
Cook Zenith	40 (16.5)	11 (14.3)	51 (16.0)
Medtronic Endurant	112 (46.3)	10 (13.0)	122 (38.2)
Medtronic AneuRx	0	18 (23.4)	18 (5.6)
Medtronic Talent	0	14 (18.2)	14 (4.4)
Other	4 (1.7)	8 (10.4)	12 (3.8)

of the EndoAnchor fractures was thought to be a result of torquing of the guide before complete EndoAnchor release.

Aortic extension cuffs were used in 24 patients in the primary arm, four of which were placed after unsatisfactory endograft deployment distally in the aortic neck. Bare metal aortic stents (all Palmaz) were deployed in four patients in the primary arm, each for residual type Ia

Table V. Early outcome by indication for EndoAnchor use in all patients and in the primary and revision arms

	<i>Patients, No.</i>	<i>Technical success,^a No. (%)</i>	<i>Procedural success,^b No. (%)</i>	<i>No evidence of type Ia leak at completion angiography, No. (%)</i>
All	319	303 (95.0)	279 (87.5)	290 (90.9)
Primary arm	242	233 (96.3)	217 (89.7)	223 (92.1)
Prophylaxis for hostile neck	186	180 (96.8)	172 (92.5)	177 (95.2)
Treatment of type Ia endoleak	52	51 (98.1)	43 (82.7)	43 (82.7)
Treatment of distal deployment	4	2 (50.0)	2 (50)	3 (75.0)
Revision arm	79	70 (90.9)	62 (80.5)	67 (87.0)
Treatment of type Ia endoleak	45	43 (95.6)	35 (77.8)	36 (80.0)
Treatment of migration	11	8 (72.7)	8 (72.7)	11 (100)
Treatment of endoleak and migration	21	19 (90.5)	19 (90.5)	20 (95.2)

^aTechnical success is defined as deployment of the desired number of EndoAnchors with adequate penetration of the vessel wall and without EndoAnchor fracture.

^bProcedural success is defined as technical success without a type Ia endoleak at completion angiography.

Table VI. Secondary procedures

<i>Secondary procedure</i>	<i>Primary arm (n = 242), No. (%)</i>	<i>Revision arm (n = 77), No. (%)</i>	<i>All (N = 319), No. (%)</i>
Open surgical conversion	0	0	0
Repair of type Ia endoleak	1 (0.4)	7 (9.1)	8 (2.5)
Treatment of type II endoleak	1 (0.4)	4 (5.2)	5 (1.6)
Treatment of migration	0	0	0
Treatment of graft limb kinking	1 (0.4)	1 (1.3)	2 (0.6)
Treatment of graft limb occlusion	2 (0.8)	1 (1.3)	3 (0.9)
Treatment of access vessel injury	1 (0.4)	0	1 (0.3)
Lower extremity revascularization	2 (0.8)	1 (1.3)	3 (0.9)
Total secondary procedures ^a	7 (2.9)	11 (14.3)	18 (5.6)
Total patients with secondary procedures	7 (2.9)	7 (9.1)	14 (4.4)

^aSome secondary procedures addressed more than one indication.

endoleaks after EndoAnchor deployment, and three of these remained after stent placement. Aortic extender cuffs were used in 50 patients in the revision arm: nine in patients with endograft migration, 17 in patients with type Ia endoleak and migration, and 24 in patients with type Ia endoleak alone. Bare metal aortic stents were placed in three patients in the revision arm to treat residual type Ia endoleaks after EndoAnchor deployment. Among these, two were Palmaz stents (Cordis Endovascular, Warren, NJ), and one was an AndraStent (Andramed, Reutlingen, Germany). Endoleaks remained in two of these three cases.

Technical success was achieved in 303 patients (95.0%), 233 (96.3%) of the patients in the primary arm and 70 (90.9%) of the patients in the revision arm. Procedural success was accomplished in 279 patients (87.5%) overall, 217 of 242 in primary cases (89.7%) and 62 of 77 in revisions (80.5%). Results by indication for EndoAnchor use are listed in Table V. There were 29 residual type Ia endoleaks (9.1%) at the end of the procedure, four of which occurred in the 15 patients with technically unsuccessful EndoAnchor deployment. There were no instances of EndoAnchors causing an endoleak. In one patient in whom EndoAnchor implantation was attempted before completion of endograft deployment, an EndoAnchor entrapped the proximal release wire of an Excluder C3 delivery system (W. L. Gore) and resulted in the inability to remove the endograft

delivery device. Additional maneuvers were required to remove the delivery device, but open surgical conversion was not necessary.

Follow-up. During a mean follow-up period of 9.3 ± 4.7 months, no patient developed a new type Ia endoleak or endograft migration after the index procedure. A total of 18 secondary procedures were necessary in 14 patients (4.4%), seven (2.9%) in the primary arm and 11 (14.3%) in the revision arm (Table VI). Secondary procedures were aneurysm related in four of the primary cases (1.7%) and in 10 of the revisions (13%). Secondary procedures were performed for residual type Ia endoleaks in one patient (0.4%) in the primary arm and in seven patients (9.1%) in the revision arm. The frequency of secondary procedures was greatest in the early postprocedure period; 8 (44.4%) occurred within 30 days, 5 (29.4%) between 31 and 90 days, and the remaining 5 (29.4%) more than 180 days after the index procedure. Secondary procedures performed within the 30 days of the index procedure were done to treat residual type Ia endoleaks (4) or leg ischemia (4), whereas procedures beyond 90 days were most commonly performed to treat type II endoleaks (4).

The primary safety end point was achieved in 294 patients (92.2%) overall and in 226 patients (93.4%) in the primary arm and in 68 patients (88%) in the revision arm. No patient experienced an unanticipated adverse device effect. There

were nine deaths that occurred during follow-up (2.8%), none of which was aneurysm related or device related.

DISCUSSION

The proximal aortic neck remains an important area of failure after endovascular treatment of AAAs, particularly when the aortic neck is short, highly angulated, or conical. Even with currently available endografts, a large number of patients with AAA will fall outside the device IFU,⁶ and approximately one fifth are entirely unsuitable for standard endovascular repair because of neck anatomy requiring the endograft to cross the renal ostia to achieve sealing.¹⁶ The IFU of most currently marketed endografts limit the intended use of the devices to those patients with a proximal aortic neck of at least 10 mm and in most cases 15 mm in length. Even the Cook Zenith fenestrated endograft IFU suggest that the proximal neck length be at least 4 mm in length. Further, most current endografts are limited to proximal aortic neck angulation of less than 60 degrees.

The term *hostile neck* has been applied to a short, angulated, or conically shaped proximal aortic neck or when the neck contains abundant thrombus or calcium, and the results of EVAR are inferior when it is employed in such cases.^{1,17-21} A meta-analysis of seven studies by Antoniou et al²² compared early and late outcomes of EVAR performed in patients with hostile vs friendly aortic neck anatomy. The requirement for adjunctive procedures was more frequent in the presence of a challenging proximal aortic neck anatomy. Type I endoleaks were almost five times more likely at 1 year after endograft implantation in patients with hostile proximal aortic neck anatomy ($P = .010$). As well, the risk of aneurysm-related mortality was ninefold higher in patients with hostile neck anatomy ($P = .013$).

Recognizing these limitations, EndoAnchors were designed as an adjunct to endovascular aneurysm repair to enhance fixation and sealing at the attachment site between an endograft and the aortic wall. An in vitro study documented an increase in the force required to displace an endograft from silicone tubes and human cadaveric aortas when EndoAnchors were used.⁸ EndoAnchors do not address a thrombus- or calcium-laden aortic neck and are contraindicated when mural thrombus or calcium would prohibit the penetration of the EndoAnchor into the aortic wall at the site of intended deployment. Fixation and sealing, however, can be improved in short, angulated, or conical aortic necks.^{7,9,23} The ANCHOR trial was designed to evaluate the performance of the Heli-FX System in two groups of patients with AAA, those undergoing initial implantation of an endograft (primary arm) and those in whom a previously placed endograft developed proximal neck complications (revision arm). The primary arm comprised those patients undergoing primary repair with a commercially available endograft. EndoAnchors were used in this group in two different clinical scenarios: prophylactically, when the treating physician believed that long-term endograft fixation and sealing would be compromised by challenging proximal aortic neck anatomy; and therapeutically, when completion angiography revealed a

type Ia endoleak. The revision arm was more homogeneous, comprising patients who underwent EVAR in the past and presented with type Ia endoleak or endograft migration remote from the initial endograft implantation procedure. At times, EndoAnchors were used outside of the device IFU, but these patients were still included in the overall data analysis, albeit identified as protocol deviations.

The ANCHOR cohort comprised patients with more challenging aortic anatomy than is characteristically encountered in the overall population of patients undergoing EVAR. In comparison to a large data set of preoperative anatomic baseline characteristics in EVAR patients reported by Schanzer et al,²⁴ the ANCHOR primary arm had, on average, shorter length (17 vs 21 mm) and larger diameter (26 vs 23 mm) proximal aortic necks. As well, aortic neck length of less than 10 mm was more common in the ANCHOR primary patients (42% vs 24%), and necks were more often conical in configuration (42% vs 32%). The anatomic variance between the ANCHOR revision arm and the Schanzer series is even more striking, a not unexpected finding in view of the selection differences between the two study populations.

Despite the challenging proximal aortic neck anatomy in the ANCHOR patients, midterm outcome was excellent. Prophylactic EndoAnchor implantation was associated with procedural success in approximately 90% and 80% of the primary and revision arms, respectively, and no patient developed new type Ia endoleaks or endograft migration in follow-up. This observation, however, must be taken in the context of the limited follow-up currently available, the limited number of cases performed at some of the investigational sites, and the nonhomogeneity of treatment paradigms from center to center. The frequency of such complications increases with longer length of follow-up. Perhaps more compelling are the results in therapeutically treated patients who presented with proximal aortic neck complications either at the time of endograft implantation or remote from the initial procedure. EndoAnchor use was associated with resolution of type Ia endoleaks in approximately 80% of patients treated, and once resolved, no endoleak reappeared on follow-up imaging studies. It is axiomatic that patients presenting with endograft migration will require the use of an aortic extension endoprostheses in addition to EndoAnchors. The outcome of patients who received both EndoAnchors and aortic extensions cannot be parsed between the effects of the two devices. However, each investigator makes the decision about using both modalities, considering that the primary endograft has already exhibited failure because of proximal aortic neck problems. In other patients in whom the endograft was deployed well below the level of the renal arteries, an aortic extension cuff might be used alone, and the patient would not be included in the registry. These examples illustrate the principle that the management of proximal neck complications often requires the use of multiple modalities, each of which should be in the armamentarium of the endovascular surgeon.²⁵ Even with multiple modalities, however, failures may occur. Although an

analysis of failures was not the focus of this study, potential causes include deployment of an inadequate number of EndoAnchors or deployment nonuniformly over the circumstances of the aortic neck; incomplete penetration of EndoAnchors into the aortic wall due to thrombus, calcium, or misdeployment; and failure from severe luminal irregularities within the neck that preclude endograft apposition.

CONCLUSIONS

The results of the ANCHOR study suggest that EndoAnchors are of utility to secure an endograft in patients with challenging proximal aortic neck anatomy. Considering that there have been no unanticipated serious device events, we conclude that the device is safe to use in this population. Clinical benefits unambiguously accrue to the group of patients with frank type Ia endoleak or migration, with resolution of the problem in the majority of cases. ANCHOR also enrolled patients with prophylactic implantation of EndoAnchors at the time of initial EVAR in patients with unfavorable proximal neck anatomy. Whereas the confirmation of clinical benefit in prophylactically treated patients can be conclusively established only with a randomized comparison of patients treated with and without EndoAnchors, the midterm observations of ANCHOR appear encouraging.

AUTHOR CONTRIBUTIONS

Conception and design: WJ, KO, JV

Analysis and interpretation: WJ, KO

Data collection: WJ, MM, DV, WM, FA, JJ, KO, JV

Writing the article: WJ, KO

Critical revision of the article: WJ, MM, DV, WM, FA, JJ, KO, JV

Final approval of the article: WJ, MM, DV, WM, FA, JJ, KO, JV

Statistical analysis: KO

Obtained funding: Not applicable

Overall responsibility: WJ

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