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Endovascular TODAY EUROPE

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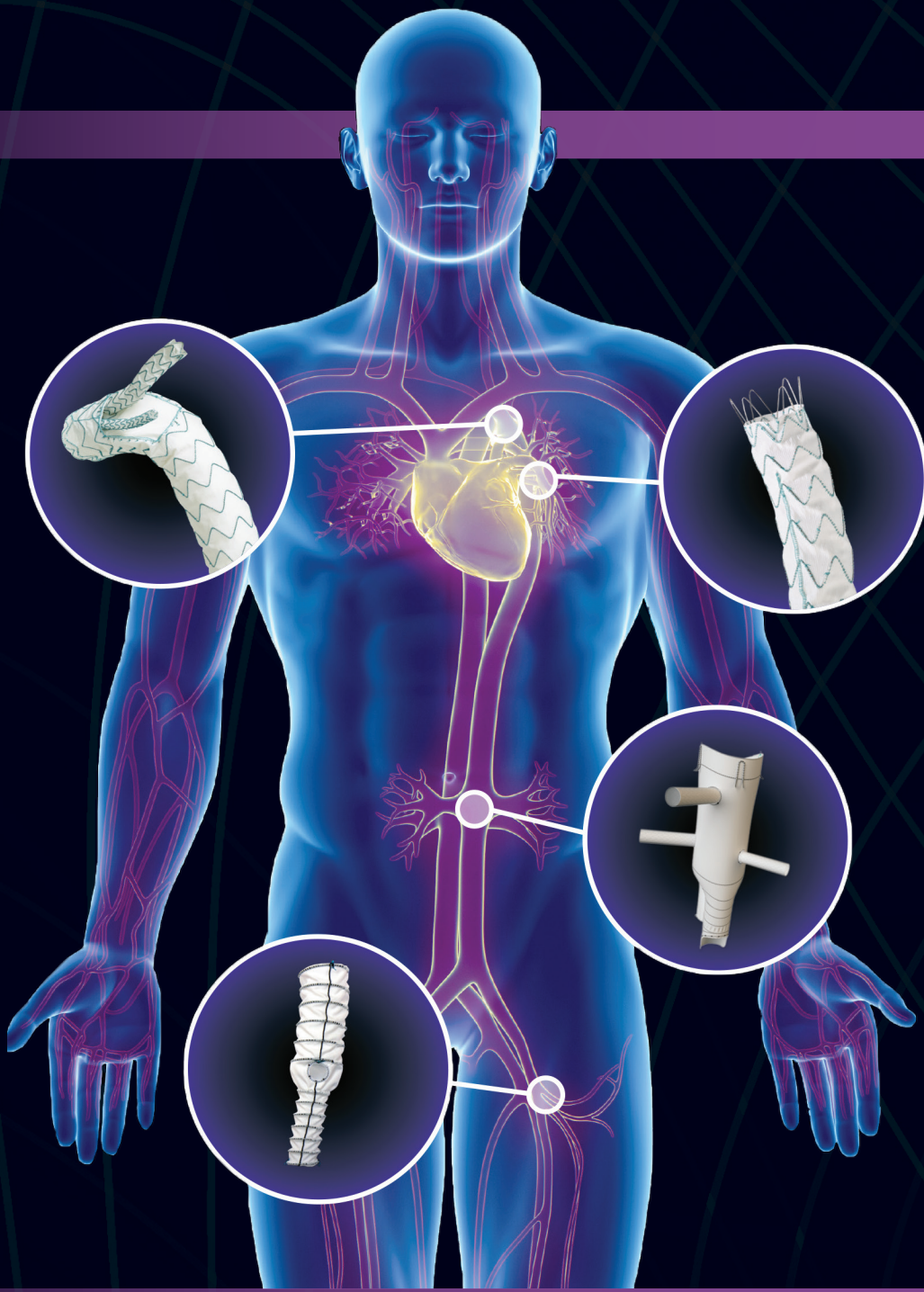
MORE OPTIONS & SOLUTIONS FOR TREATMENT OF COMPLEX AORTIC DISEASE



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The Fenestrated Anaconda™ for the Treatment of Complex Abdominal Aortic Aneurysms

An overview of the design, applicability, and clinical success of the Fenestrated Anaconda™ System for complex abdominal aortic aneurysm repair.

BY ARNE DE NIET, MD; MICHEL M.P.J. REIJNEN, MD, PHD; AND CLARK J. ZEEBREGTS, MD, PHD

Endovascular aneurysm repair (EVAR) for the treatment of abdominal aortic aneurysms (AAAs) has developed significantly since its introduction in the early 1990s.[1] Applicability of standard EVAR is restricted to anatomic configurations. Features such as a short neck (< 10 mm), a neck angle over 60°, neck thrombus or calcification, nonparallel neck configuration, or large neck diameter jeopardize an adequate sealing, consequently increasing the risk of migration, type Ia endoleak, and reinterventions. To treat patients with hostile neck anatomy, endografts were developed with fenestrations to the renal arteries, superior mesenteric artery (SMA), and/or celiac artery (CA).[2] Stenting of the fenestrations with balloon-expandable covered stents into the target vessel instead of bare-metal stents has improved apposition and prevented blockage of fenestrations by graft material and main device rotation and migration.[3-6] To support the target vessels' stents and prevent ripping of the fabric, fenestrations were reinforced with a nitinol ring.[7] The large variation in visceral artery configuration[8] requires customization of fenestrated endografts to the patients' anatomy. One of the current commercially available and extensively used customized endografts is the Fenestrated Anaconda™ (Vascutek Ltd.).[9]

THE FENESTRATED ANACONDA™

Design

Planning is done by preoperative computed tomography angiography (CTA) scanning of the total aorta and iliac arteries with a recommended maximum of 1-mm slides. Using dedicated software, clock positions and angles of the aorta, aortic side branches, and access vessels are measured. After preliminary design, an acrylic 3D model of the aneurysm is printed to test the custom-made endograft, allowing minor modifications to the final design (Figure 1).

The Fenestrated Anaconda™ consists of independent circular nitinol stents and woven polyester graft material. The proximal end of the main body consists of two lateral peaks and two valleys. The two proximal rings are specifically designed to deliver the appropriate radial force on each aortic diameter and can be oversized to achieve optimal sealing. The proximal rings can be parallel (Figure 2A and 2C) or augmented (Figure 2B) in case of planned sealing between the SMA or CA. To prevent migration, three or four pairs of hooks are attached to these proximal rings (Figure 2A–2C). The standard endograft requires a landing zone of at least 15 mm in length and an aortic diameter between 17.5 and 31 mm, and the design allows a landing zone angle up to 90°. With Fenestrated Anaconda™, however,

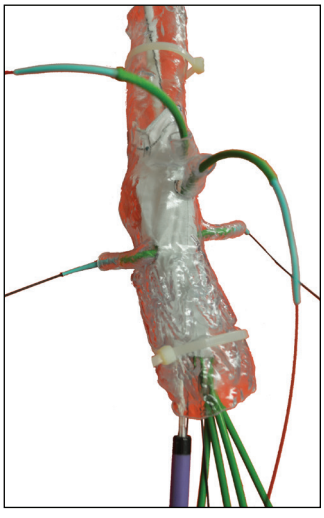

Figure 1. Three-dimensional model of a patient's aorta. The custom-made device remains connected to the delivery device (purple), while fenestrations and target vessels are cannulated with guidewire and catheter (green) to check for any mismatch. Permission for use granted by Vascutek Ltd.

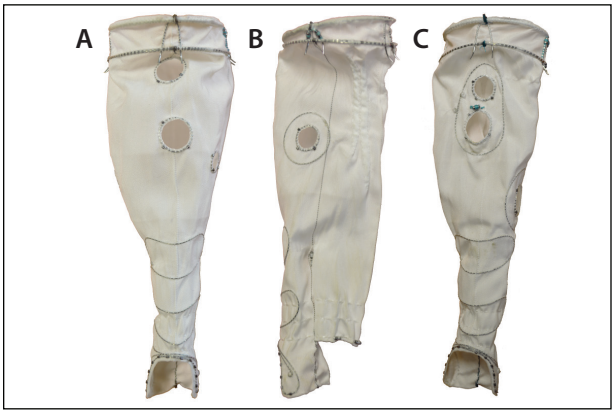

Figure 2. Three custom-made Fenestrated Anaconda™ endografts. Anterior view of the endograft showing the parallel proximal rings with attached hooks and the unsupported fabric with three standard nitinol-reinforced fenestrations for the CA, SMA, and left renal artery (A). Left-sided view of the endograft with the augmented proximal rings and the "halo" configuration of a left renal fenestration, which prevents shuttering of the fenestrations. Pleats are shown on posterior of the endograft for diameter reduction of the main body at the renal arteries (B). Anterior view of the endograft showing the "jelly bean" configuration for two proximate fenestrations (CA and SMA); a radiopaque marker is in between (C). Permission for use granted by Vascutek Ltd.

proximal sealing configurations with an augmented valley allow for a greatly reduced landing zone between visceral vessels; this is dependent on the geometry of the specific anatomy being treated. The unsupported region below the rings contains the nitinol-reinforced fenestrations (Figure 2A). The absence of stents in this area enables the potential for an unlimited number of fenestrations at any location but can also make it susceptible to folding of the graft. To prevent this, reinforcement rings can be placed around one (halo configuration, Figure 2B) or a combination of two proximate fenestrations (jelly bean configuration, Figure 2C). In addition, endografts can be pleated to remove excess fabric where deemed appropriate; the pleats also add an element of columnar stiffness and rigidity to the main body (Figure 2B). The endograft can be recollapsed after deployment or when required and can be repositioned at the desired location. The delivery system (ONE-LOK™) enables easy access in the contralateral limb by magnetically linking the guidewires, potentially reducing cannulation time.

After cannulation of the contralateral limb, the fenestrations and target vessels are cannulated and stented with balloon-expandable covered stents. The stents are flared to prevent type III endoleak. The system enables cannulation from femoral and/or brachial or

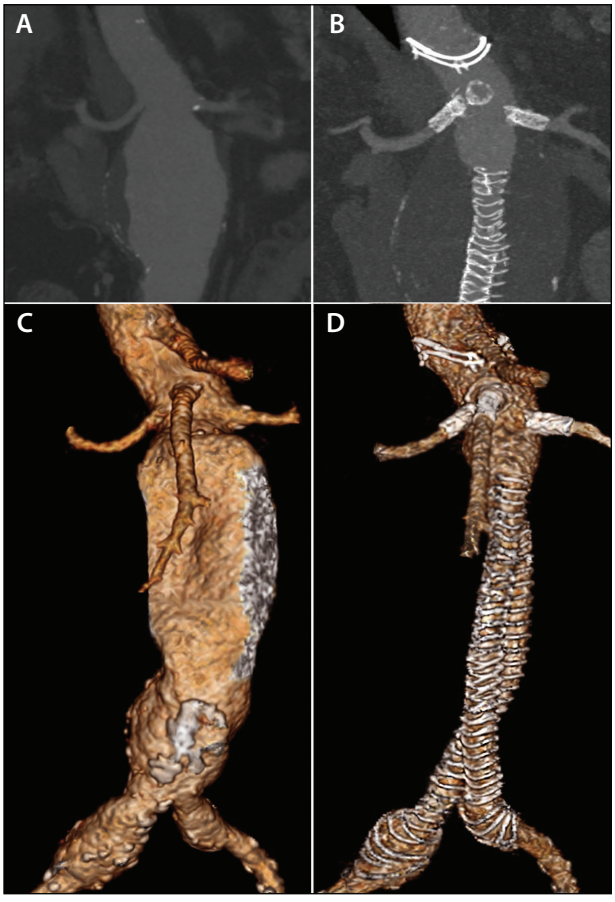

Figure 3. Preoperative CTA image of patient with a flared-neck AAA (A). Postoperative CTA image of a patient successfully treated with the Fenestrated Anaconda™; stents can be seen for both renal arteries and the SMA (B). Three-dimensional reconstructions of the same preoperative CTA (C). Three-dimensional reconstructions of the same postoperative CTA. Note the landing zone below the CA (D).

axillary access without releasing the main device. The endograft can be designed as a cuff, uni-iliac, or bi-iliac endograft. Limb extension(s) can be tapered, straight, or flared to be sized to the iliac diameter. These extensions consist of multiple independent circular nitinol rings, allowing them to be used in very tortuous iliac arteries.[10] Figure 3 shows a CTA and 3D reconstruction of a complex AAA before and after implantation of the Fenestrated Anaconda™. Fenestrated variants of the limb extensions have also been provided upon request as custom devices.

Study Results

Since the first report by Bungay et al in 2011,[11] a number of case series evaluating the Fenestrated Anaconda™ have been published (Table 1 and Table 2).[11-20] Although these studies include over

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TABLE 1. PREOPERATIVE PATIENT CHARACTERISTICS

First Author, Year	Number of Patients	Age (years)	Gender (M/F)	ASA Classification (mean)	Hypertension (%)	Hypercholesterolemia (%)	Diabetes Mellitus (%)	History of Cerebrovascular Disease (%)	Cardiac History (%)	Pulmonary History (%)	Renal Disease (%)	Estimated Glomerular Filtration Rate (ml/min/1.73m^2)	Peripheral Vascular Disease (%)
Bungay, 2011[11]	4	76.5	3/1	2.5	100	0	50	0	50	0	25	—	25
Dijkstra, 2014[12]	25	73	22/3	2.6	60	36	12	—	72	12	32	61	—
Rolls, 2014[13]	13	75	8/5	3.1	100	23.1	7.7	7.7	46.2	23.1	7.7	—	—
Gallitto, 2016[14]	5	78.4	-	3.2	100	20	20	20	40	80	20	88.4	20
Shahverdyan, 2016[15]	48	73	37/11	2.8	77.1	—	8.3	—	—	20.8	18.8	92	43.8
Kotelis, 2016[16]	39	74	36/3	3	87	—	13	—	61	17	41	—	20
Blankensteijn, 2017[17]*	60*	72	52/8	2.7	65	56.7	13.3	—	55	26.7	28.3	60	—
Falkensammer, 2017[18]	94	73	76/18	2.7	—	—	—	—	—	—	—	59.6	—
Colgan, 2017[19]	101	76	86/15	2.9	71	—	13	8	52	—	39	—	—
Midy, 2017[20]	86	73.4	82/4	2.8	76.7	68.6	22.1	4.7	60.5	41.3	15.1	—	41.9
Pooled results†	450	73.9	380/65	2.8	75.7	57.8	11.8	6.8	55.6	29.5	27.4	67.9	36.7

Abbreviations: —, not clearly stated; 30-day, within 30-day postoperative period; ASA, American Society of Anesthesiologists; EL, endoleak.
*Partially including the same patients from Dijkstra et al.[12]
†Pooled analysis excluding Dijkstra et al.[12] Number of patients, fenestrations, and gender are presented in totals.

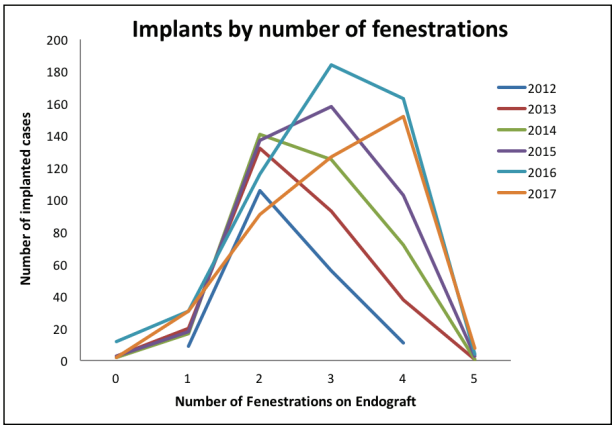

Figure 4. Graph showing the total number of endograft implants worldwide with a specific number of fenestrations for each fiscal year (April to April) from 2012 to 2017.* More implants have been performed each year up to 2016 (light blue line), and there is a trend toward more Fenestrated Anaconda™ endografts including more fenestrations. *2017 data does not include Q4 implants.

450 patients, the total number of implantations worldwide already exceeds 2,200 cases. All of these published studies include both results of primary AAA repair and redo after previous EVAR, either with a cuff, uni-iliac, or bi-iliac endograft. Pooled technical success was 89.3%, and successful target vessel cannulation was 96.7%. Despite the increasing number of fenestrations over time (Figure 4), the procedural time and contrast volume remained the same. The pooled percentage of accepted type Ia endoleaks at completion angiography can be observed in 8.6% of cases, but in only 1.5% of cases at 30 days postprocedure. At 30 days postprocedure, pooled mortality was 4.7% (Table 2).

Survival, reintervention-free survival, and target vessel patency were analyzed in four studies.[16,17,19,20] At 1 year, pooled patient survival, reintervention-free survival, and target vessel patency was 88.9%, 91.4%, and 97%, respectively (Table 2). Three of these studies also presented 3-year analysis for patient survival (pooled rate, 84.7%) and reintervention-free survival (pooled rate,

TABLE 2. RESULTS OF STUDIES EVALUATING THE FENESTRATED ANACONDA™

First Author, Year	Number of Patients	Number of Fenestrations (mean)	Technical Success (%)	Target Vessel Cannulation (%)	Procedural Time (min)	Contrast Volume (mL)	Accepted Procedural Type Ia Endoleak (%)	30-Day Patient Survival (%)	30-Day Reintervention-Free Survival (%)	30-Day Target Vessl Patency (%)	30-Day Type I Endoleak (%)	Mean Follow-Up (mo)	1-Year Patient Survival (%)	1-Year Reintervention-Free Survival (%)	1-Year Target Vessel Patency (%)	1-Year Type Ia Endoleak (%)	Reintervention for Type Ia Endoleak During Follow-Up (%)
Bungay, 2011[11]	4	8 (2)	100	100	261*	179*	0	100	75	100	0	1	—	—	—	—	—
Dijkstra, 2014[12]	25	56 (2.2)	84	94.6	240†	194†	12	96	96	98.1	0	11	92‡	96‡	98.1‡	0‡	0
Rolls, 2014[13]	20	35 (1.8)	100	100	—	—	0	100	90	100	—	7.6	—	—	97.2‡	0‡	0
Gallitto, 2016[14]	5	15 (3)	80	100	404*	240*	20	100	80	100	—	6	80‡	80‡	100‡	0‡	0
Shahverdyan, 2016[15]	48	129 (2.7)	93.8	97.7	201†	121†	—	95.8	85.4	98.4	—	24	93.5‡	—	98.4‡	0‡	2.2
Kotelis, 2016[16]	39	106 (2.7)	94.9	94.8	274†	170†	—	92	—	—	—	33	87.2	92	99	—	—
Blankensteijn, 2017[17§]	60§	140 (2.3)	85	97.1	262*	178†	11.7	96.7	—	99.3	—	16.4	91.4	96.5	95‡	0	0
Falkensammer, 2017[18]	94	282 (3)	90.2	91.4	267*	291†	—	94.7	97.9	100	—	10	88.3‡	88.3‡	100‡	—	—
Colgan, 2017[19]	101	255 (2.5)	88	98.8	—	—	9.9	97	95	98.4	1.6	12	91	91	97.6	0	0
Midy, 2017[20]	86	292 (3.4)	86	99.3	238†	186†	5.8	93	92.7	99.7	—	24	88.3	96.3	97.2	1.2	2.3
Pooled results[¶]	450	1,262 (2.8)	89.3	96.7	252	269	8.6	95.3	93.3	99.3	1.5	17.3	88.9	91.4	97	0.3	1

Note: Thirty-day means within the 30-day postoperative period.

Abbreviations: —, not clearly stated.

*Presented as mean.

†Presented as median.

‡At last follow-up (no available survival analysis).

§Partially including the same patients from Dijkstra et al.[12]

¶Pooled analysis excluding the article from Dijkstra et al. [12] Number of patients and fenestrations are presented in totals.

84.2%).[16,17,20] In one study, 3-year target vessel patency was 96.3%.[20]

DISCUSSION

The current available data on the Fenestrated Anaconda™ demonstrate a satisfying technical success rate and high patient survival, reintervention-free survival, and target vessel patency rates during follow-up.

Technical success is described by Chaikof et al as successful access and planned deployment of the endograft without any type I or III endoleak.[21] The tendency for the Fenestrated Anaconda™ to have a

lower technical success rate[9] is due to higher prevalence of immediate type Ia endoleaks. As mentioned by Dijkstra et al and Blankensteijn et al, the Fenestrated Anaconda™ is designed with proximal nitinol rings, and it seems they need time to fully expand.[12,17] This overview supports this theory by demonstrating the high percentage of type Ia endoleaks at completion angiography and their spontaneous disappearance at early follow-up (Table 2).

A perioperative mortality rate around 4% seems inevitable, because patients are usually older and have multiple comorbidities (Table 1). Adequate case selection, both based on anatomical configuration and the patient's clinical state, is crucial. Open surgery should always be considered as an alternative for fit patients; consequently, patients treated with a fenestrated endograft have more preoperative comorbidities, and postoperative outcomes might be altered.

Katsargyris et al showed that more complex cases including three or more fenestrations did not influence perioperative outcomes for technical success (96.2% vs 98% in "standard" double-fenestrated endografts) and 30-day mortality (0.5% vs 0.5%, respectively).[22] Nor was there any statistically significant difference in 1-year patient survival (94% vs 95%, respectively), reintervention-free survival (95% vs 98%, respectively), or target vessel patency (99% vs 99%, respectively).[22] The presented data in this study support an increased experience over recent years, as reflected by the higher number of complex cases with more fenestrations, without an altered technical success rate, operating time, or contrast volume in the later and larger studies (Table 2).

Follow-up results from the literature are similar to the available custom-made Zenith® Fenestrated graft (Cook Medical). The 1-year pooled results with the Zenith® Fenestrated graft for patient survival, reintervention-free survival, and target vessel patency are 93%, 91%, and 98%, respectively.[9] The 1-year patient survival of 89% seems slightly lower with Fenestrated Anaconda™. Preoperative patient characteristics possibly influenced this difference, because it is not reflected by a difference in reintervention-free survival and target vessel patency (Table 1). This could also be due to case complexity; however, there are no available comparisons on number of device fenestrations used in each case.

Falkensammer et al separated reinterventions from primary cases but did not find any obvious difference, potentially related to the small sample size of the redo cases.[18] The other presented studies analyzed a mixed population of primary AAA repair and reinterventions after failed EVAR, leading to heterogenic groups and consequently influencing outcome, as revision cases are generally more challenging. An individual patient data analysis could tell us more about the results in primary cases.

One of the advantages of the Fenestrated Anaconda™ is the case rehearsal service offered for each fenestrated custom device request. This involved a prototype device being produced alongside an accurate 3D-printed model of the patient's anatomy and allows for testing and evaluation of the proposed design in the specific anatomy being treated. Evaluation is performed by engineers at Vascutek and subsequently by the requesting clinician. Following the evaluation, changes can be made to the design of the device prior to final manufacturing to ensure it is optimized for use in the specific anatomy being treated. Changing the custom design has been shown to lead to good results and might prevent unexpected misalignment by design.[23]

Although recent data show good results of the Fenestrated Anaconda™ system, the number of studies is still few and have limited follow-up compared to published data of the commercially available Zenith® Fenestrated AAA endovascular graft.[9] Larger studies are awaited, and recently a prospective study (the Global Fenestrated Anaconda™ Clinical Study [Global FACT]) has been initiated to evaluate global, multicenter outcomes.

CONCLUSION

The custom-made Fenestrated Anaconda™ is applicable in the treatment of complex AAAs with good surgical outcomes, technical success, and low postoperative reintervention rates, and high patient survival, reintervention-free survival, and target vessel patency rates at midterm follow-up. Longer follow-up that includes individual patient analysis should be performed to further support current results. ■

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A Single-Center Experience With the Fenestrated Anaconda™ Stent Graft

Patient demographics and procedural details, featuring a six-fenestration case report.

BY PAUL BACHOO, FRCS, AND DIANE HILDEBRAND, FRCS

Endovascular aneurysm repair (EVAR) is a well-established technique for repair of infrarenal abdominal aortic aneurysms (AAAs). The applicability of this technique depends on specific anatomical criteria as defined within the instructions for use. AAAs with a short (< 15 mm) or angulated (> 60°) proximal neck are generally considered unsuitable for EVAR. The continuing evolution of EVAR technology has seen the emergence of modern stent grafts capable of accommodating demanding neck angulation (up to 90° angulation). However, reduction in neck length remains a limitation for intermediate and long-term durability.

Open repair of these juxtarenal AAAs (JAAAs) carries the risk of significant morbidity as well as mortality.[1] The challenge of the short neck led early pioneers to move proximally to the visceral aorta for both fixation and seal while maintaining flow to essential organs through fenestrations. By redefining the site of active fixation and seal zone, this technology has greatly extended the remit of EVAR technology. Fenestrated EVAR (FEVAR) was first described in 1999[2] and has since been shown to be a safe and effective treatment intervention[3-5] with promising results from multiple centers.[6]

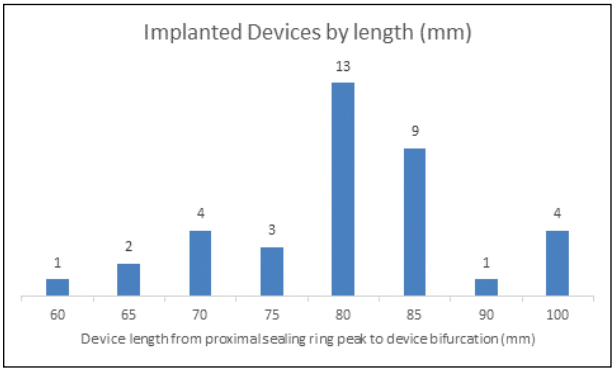

Figure 1. The first 37 subjects included a diverse set of body lengths.

The custom Fenestrated Anaconda™ AAA Stent Graft System (Vascutek Ltd.) was first successfully deployed in a human by Dr. Peter Bungay of Royal Derby Hospital in the United Kingdom in June 2010. To date, the company has successfully implanted more than 2,300 custom-made devices globally.

We present our single-center FEVAR series and provide our 21st procedure as a case report in which extreme anatomy was successfully managed with the use of the custom Fenestrated Anaconda™ AAA Stent Graft System. We believe this case to be the first in which a six-fenestration graft was successfully implanted to treat aneurysmal disease and include 12-month follow-up data.

SINGLE-CENTER EXPERIENCE

All patients who underwent FEVAR at our institution were entered into a prospectively maintained database. Of the 40 patients in the database awaiting implant, we present patient demographics, aortic morphology, stent graft details, procedural details, and outcome measures on the first 37 subjects, who presented with a diverse range of body lengths (Figure 1).

We have successfully implanted the custom Fenestrated Anaconda™ AAA Stent Graft System in a total of 37 subjects (84% men) with a mean age of 77 years (range, 66–85 years). The mean max dimension of the AAA was 62 mm (range, 59–80 mm); the majority (91%) were juxtarenal, with a mean neck length of 2.9 mm (range, 0–10 mm). There were six deaths during follow-up; none were aneurysm related. Survival by Kaplan-Meier analysis was 98% at 1 year and 82% at 2 years. Of the two target vessels that were lost, both were identified during CT surveillance. In neither case was there any clinical indication of end-organ ischemia (one was an occlusion of the proximal segment of a superior mesenteric artery [SMA] stent with retrograde filling of the vessel and remaining stent, and one was a renal artery [RA] stent). Secondary intervention (> 30 days) included extension of one SMA stent and

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TABLE 1. CLINICAL DETAILS OF ABERDEEN CASES

Number of Fenestrations	Frequency	
2 3 4 6	20% 57% 20% 3%	
Mean graft diameter, mm (Mean % oversize)	30 (19)	
Target Vessel	**Mean Diameter (mm)**	**Fenestration (mean angle)**
Celiac trunk Superior mesenteric artery Left renal artery Right renal artery	6.8 7 5.6 5.6	18° 5° 87° -63°
Renal Function (mean)	**Preoperative**	**Postoperative (last follow-up)**
Urea Creatinine eGFR	7.6 94 57	9 106 53
Graft Implant		
Technical success (%) Total number of visceral stents Intraoperative target vessel loss Target vessel loss at follow-up Target vessel patency at follow-up	98 109 0 2 98%	
Endoleak		
Type Ia/Ib Type II with sac size increase Type II with stable sac size Type III (target vessel junction) Type III (others)	0 0 4 1 0	
Mean operating time, min (range)	236 (146–360)	
Mean length of stay, days (range)	8 (3–30)	

Abbreviation: eGFR, estimated glomerular filtration rate.

one RA stent in separate patients. Further clinical details of the cases and outcomes are summarized in Table 1.

CASE REPORT

A 72-year-old man (body mass index, 26.9 kg/m^2) was found to have an AAA on ultrasound imaging carried out during investigation for hematuria, the cause of which was identified as benign prostatic hypertrophy. His comorbidities included hypertension (1998), hyperlipidemia (1996), and diabetes mellitus type 2 (2010). Initial CT imaging identified a JAAA, 77-mm anteroposterior diameter, with three right RAs and two left RAs.

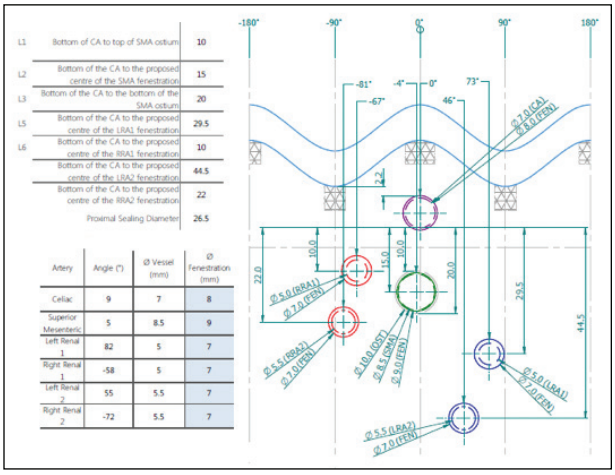

Figure 2. Six-fenestration Anaconda™ device scheme.

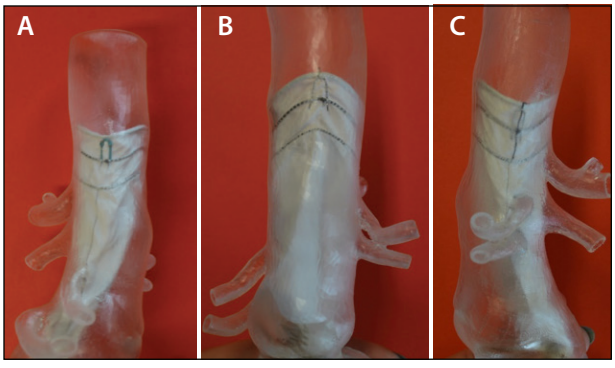

Figure 3. Six-fenestration prototype device in plastic anatomy model.

Following multidisciplinary discussion, a decision was made to proceed with FEVAR. The plan involved selective sacrifice of a small lower pole right RA and stenting of the celiac axis, SMA, and two RAs on each side. Case plan device scheme and prototype testing images for this six-vessel fenestration Anaconda™ AAA Stent Graft are shown in Figures 2 and 3, respectively. This is, to our knowledge, the first case of a six-fenestration graft to be successfully implanted that reported 12-month follow-up with no complications.

Procedural Details

The procedure was performed with renal cover using preoperative oral 600 mg N-acetyl cysteine and 3 mL/kg/hour intravenous infusion of 1.26% sodium bicarbonate preprocedure, which was infused at 1 mL/kg/hour throughout the procedure and for 6 hours postoperatively. A further 600 mg of oral N-acetylcysteine was given for 6 hours postoperatively. In addition, the patient was given 4,000 units of intravenous heparin as a loading bolus and then maintained on a heparin infusion throughout the procedure,

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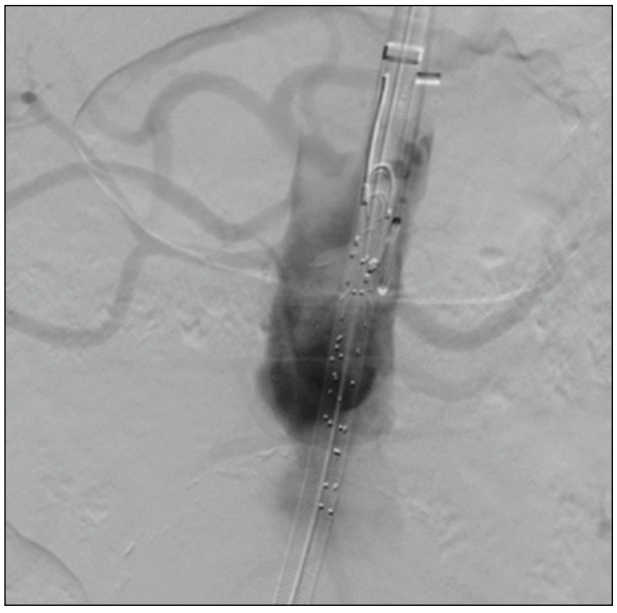

Figure 4. Introduction of the device.

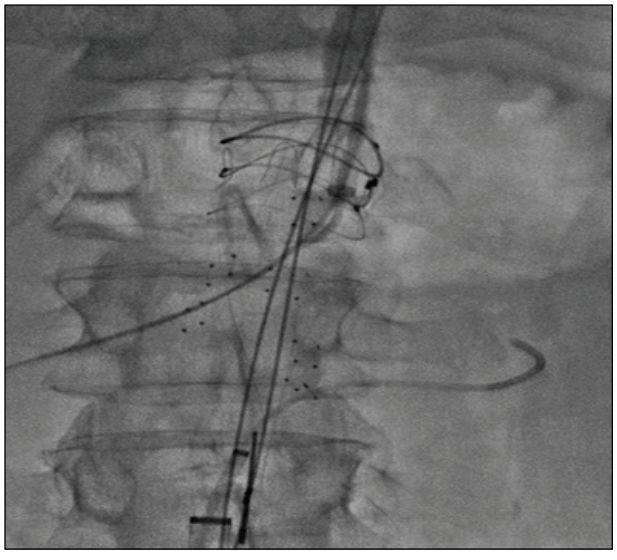

Figure 5. Cannulation from above.

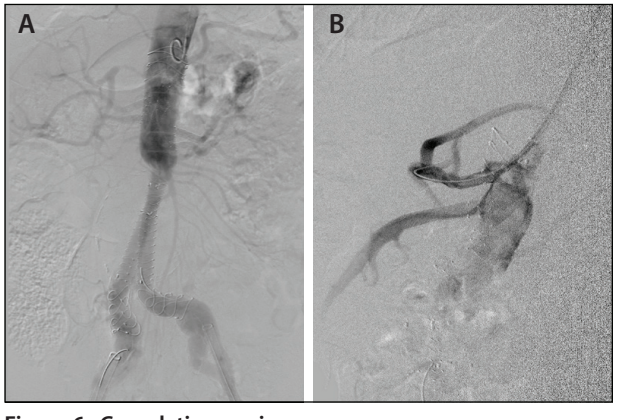

Figure 6. Completion angiogram.

TABLE 2. PERIOPERATIVE DETAILS OF A SIX-FENESTRATION FEVAR	
Duration	240 min
Dose area product	35,960 cGy-cm^2
Skin dose	2,534 mGy
Screening time	87.3 min
Contrast volume	105 mL iodixanol, 320 mg concentration

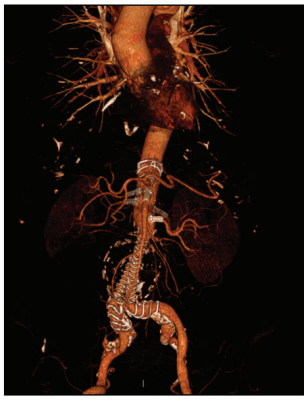

Figure 7. One-month CT follow-up.

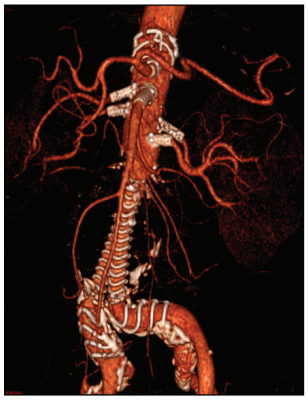

Figure 8. Six-month CT follow-up.

aiming to achieve an activated partial thromboplastin time that was three times that of normal.

An Anaconda™ Stent Graft (30 mm, 15% oversize) was introduced though the right common femoral artery (Figure 4). Atrium Advanta covered stents (Getinge) were used in the celiac trunk (7 X 22 mm), the SMA (9 X 38 mm), the upper pole RAs (5 X 22 mm), and the lower pole RAs (6 X 22 mm). The lowest right RA was covered as planned.

The visceral vessels and upper pole RAs were cannulated from the axillary access (Figure 5). The lower pole RAs were cannulated from the groin access. The iliac limbs of the main body were then extended bilaterally, in the standard fashion, into the common iliac arteries. Retrieval of the nose cone was uncomplicated despite the presence of multiple flared Atrium Advanta stents.

The completion angiogram demonstrated no endoleak with patency of all the stented vessels (Figure 6).

The common femoral arteries were repaired with 5–0 Prolene sutures. The procedural details are summarized in Table 2.

Postoperatively, the patient recovered without complications and was discharged home on the third postoperative day. Serum creatinine was 104 and 115 µmol/L pre- and postoperatively, respectively. The serum creatinine level at 3 and 6 months was 95 and 104 µmol/L, respectively.

CT follow-up at 1 month (Figure 7) and 6 months (Figure 8) confirmed no evidence of endoleak and patency of all six stented vessels. The aortic sac size remained unchanged at 12 months on ultrasound surveillance.

Discussion

In this case, the complex arrangements of multiple vital RAs would have significantly increased the open operative challenge and increased risk of significant morbidity as well as mortality.[1] By redefining the site of active fixation and seal zone, fenestrated technology has greatly extended the remit of EVAR with challenging neck anatomy and has been shown to be a safe and effective treatment methodology[3-5] with promising results from multiple centers.[6] Available grafts are usually limited to four fenestrations in their instructions for use. With the inherent design and manufacturing flexibility of this graft, we could plan not only a bespoke graft but one with six separate fenestrations to maintain flow in critical end arteries and maximally preserve renal function. The Fenestrated Anaconda™ AAA Stent Graft System successfully managed an extreme anatomical case, which we understand to be unique and previously unreported. Although early follow-up is encouraging, ongoing surveillance is imperative to ensure longevity and avoid harm in this novel case.

CONCLUSION

FEVAR is an exciting technology, and our clinical outcomes using the Anaconda™ Stent Graft System are encouraging. On the back of our EVAR program in Aberdeen, as a team, we have been able to rapidly transcend the FEVAR learning curve without significant adverse clinical events. The team has managed to consider a unique anatomical challenge and use the versatility and capability of the stent graft system to maximize benefit and acquire a good patient-centered clinical outcome. Careful and robust evaluation is ongoing. ■

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State-of-the-Art Treatment of Proximal Endograft Failure After EVAR

Feasibility of Fenestrated Anaconda™ implantation for the treatment of existing or impending type Ia endoleak after EVAR.

BY JÜRGEN FALKENSAMMER, MD, FEBVS; MIRIAM UHLMANN, MD; FADI TAHER, MD; AND AFSHIN ASSADIAN, MD, FEBVS

Over the last 2 decades, endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs) has gained broad acceptance. Endovascular aneurysm repair (EVAR) offers reduced perioperative morbidity and mortality, and the ongoing improvements in graft design have reduced reintervention rates and improved long-term results.[1-5] However, recent studies suggest that an increased risk for late failure remains after EVAR.[6] Failure of the proximal seal is among the most critical concerns and can result in a secondary type I endoleak (Figure 1), aneurysm progression, and rupture. Although this can be the consequence of disease progression and stent graft fatigue, it may also be related to poor preoperative planning (short neck, undersized graft diameter) or incorrect intraoperative graft deployment.[7,8] Regardless of the mode of failure, a loss of proximal seal represents a significant complication, and salvage of a failed EVAR procedure can be especially demanding in cases with a short or no infrarenal neck.

ENDOVASCULAR TREATMENT OPTIONS

Improvement of Proximal Anchoring

Devices designed for improving graft alignment to the aortic wall include the uncovered Palmaz stent (Cordis, a Cardinal Health company) and Heli-FX EndoAnchors (Medtronic). The use of an uncovered Palmaz stent to extend the proximal anchoring and increase the radial force of the endograft has been described for the treatment of primary type I endoleaks as well as for secondary procedures.[9-11] Although 95% to 100% primary technical success rates have been reported, long-term results were disappointing. Arthurs et al reported a loss of proximal sealing zone in 35% and sac enlargement in 45% of cases upon a median follow-up of 53 months in 31 patients.[9] According to the authors, continued aortic degeneration accounted for the loss of proximal seal zone, which the balloon-expandable Palmaz stent is not designed to address. Also, the use of bare-metal stents is limited to cases without significant endograft migration.

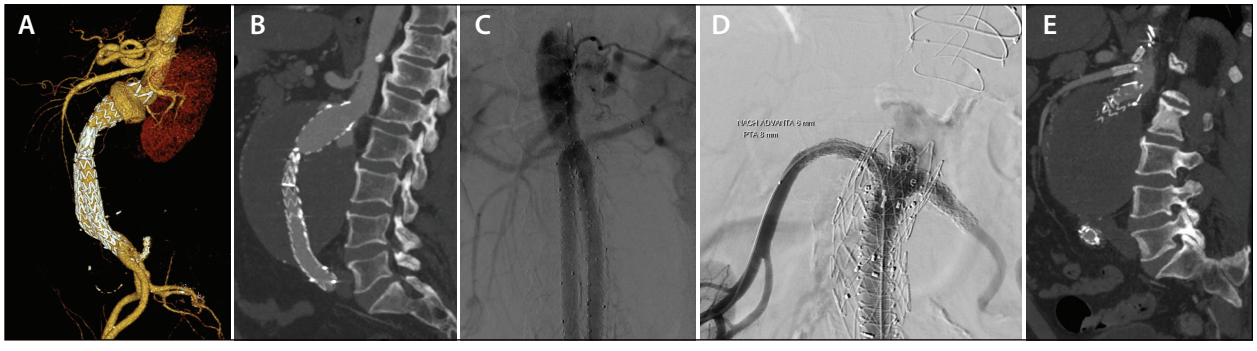

Figure 1. One year after EVAR for symptomatic AAA with an infrarenal neck of 14 mm, a type Ia endoleak was diagnosed by CTA (A, B). The patient was scheduled for FEVAR with four fenestrations, and completion angiography showed good perfusion of the renal and visceral arteries with no endoleak (C, D). Postoperative CTA was performed on postoperative day 6 and confirmed complete resolution of the endoleak and optimal perfusion of all four target vessels (E).

EndoAnchors have also been used to improve graft alignment to the aortic wall.[12,13] For secondary interventions to treat a type I endoleak, a procedural failure rate of up to 20% has been reported despite the use of an additional aortic cuff in 65% of cases.[12] After a relatively short follow-up interval of 9 months, 9% of patients had to undergo a secondary procedure for the same endoleak.

Extension of the Proximal Landing Zone

Cranial extension of the sealing zone may be the more sensible approach to improving endograft alignment, especially in cases in which proximal failure is associated with a diseased juxtarenal aortic neck. Greenberg et al first described the use of renal or visceral artery stents parallel to the aortic endograft,[14] a technique that was originally intended to preserve aortic branch vessels in aortic anatomies with a short or nonexistent infrarenal sealing zone. This technique allows an extension of the aortic seal zone into the paravisceral segment, using covered self-expanding or balloon-expandable stent grafts.[14,15] Although initial results demonstrated the technical feasibility of this technique, recent publications have reported 30-day procedure-related major complication rates of 25% to 40%.[16-20] Data on the use of the chimney technique for redo cases are very limited. Donas et al reported on 18 interventions for the treatment of proximal seal failure, with a reintervention rate of 22% (n = 4) within 17 months.[21]

Fenestrated endografts can be specifically designed to extend the proximal sealing zone of an abdominal aortic endograft into the pararenal and paravisceral segment. In contrast to the parallel graft technique, these devices allow for an anatomic reconstruction of this critical aortic segment, and existing results demonstrate an improved patency rate for visceral target vessels. Data on the use of fenestrated endografts for the treatment of proximal sealing failure after standard EVAR are limited. Katsargyris et al reported a technical success rate of 92% and a target vessel perfusion rate of 94% in 26 patients using the fenestrated Zenith device (Cook Medical).[22] At an average follow-up of 26 months, reinterventions were necessary in four (15%) patients, and target vessel patency was 100%. Martin et al compared patients undergoing redo EVAR cases with patients undergoing primary fenestrated or branched interventions.[23] Unfortunately, the authors did not differentiate between branched and/or fenestrated Zenith devices. For 52 patients undergoing rescue procedures, the technical success rate was 85%, and the target vessel perfusion rate was 92%. Although a follow-up interval and target vessel patency were not reported, the total reintervention rate was 27%.

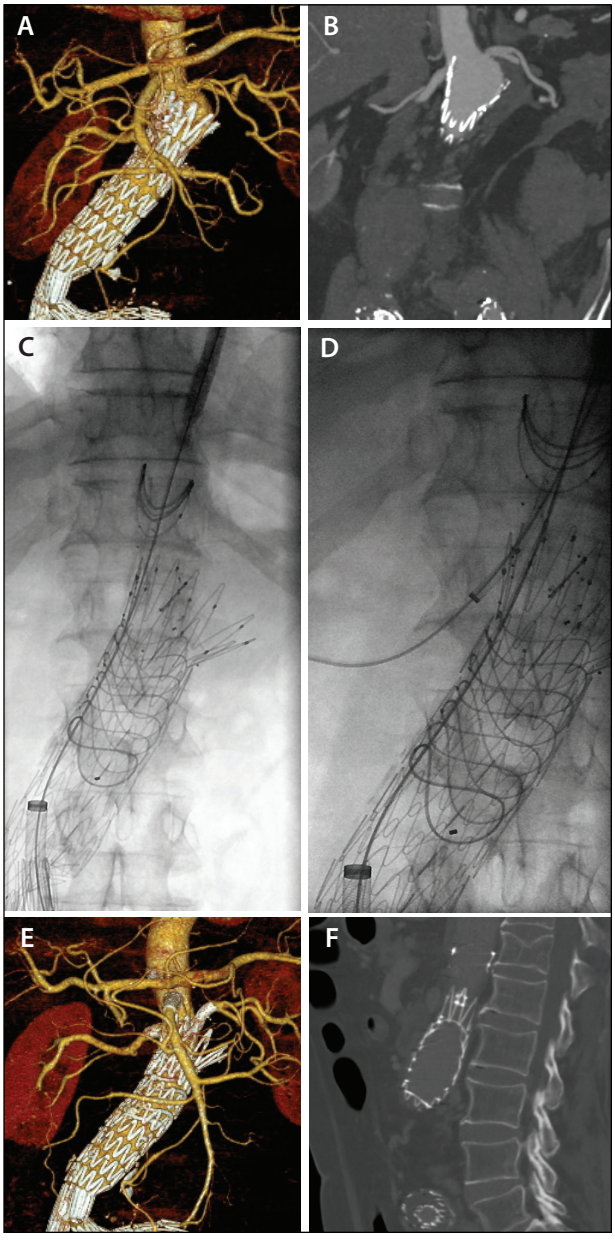

Figure 2. Four years after EVAR, follow-up CT showed stent graft migration with no evidence of an endoleak (A, B). FEVAR with four fenestrations was indicated. During deployment, identifying fenestration markers that partially overlap with stent material in situ can be challenging (C). The right renal artery was cannulated successfully via a subclavian access (D). Postoperative CTA showed ideal positioning of the proximal ring stents and optimal perfusion of the four target vessels (E). A detailed image of the postoperative CTA showed the confined space caused by crossing bare-metal stents of the original conventional endograft (F).

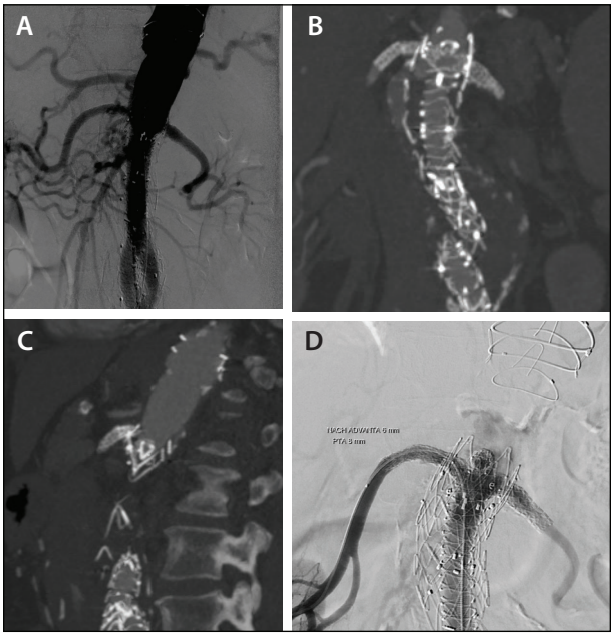

Figure 3. Completion angiogram after FEVAR with three fenestrations for type Ia endoleak after EVAR showed good perfusion of all target vessels with no evidence of an endoleak (A); however, postoperative CTA revealed a type III endoleak emerging from the right renal artery connecting stent (B). A detailed image of the postoperative CTA demonstrated the confined space and partial compression of the connecting stent by crossing bare-metal stents of the original conventional endograft (C). The patient was scheduled for early reintervention and treated by relining the right renal artery connecting stent, which resolved the endoleak (D).

Results Using the Fenestrated Anaconda™ Device

The Fenestrated Anaconda™ (Vascutek Ltd.) is a custom-made device based on the Anaconda™ AAA Stent Graft System (Vascutek Ltd.) that allows treatment of juxtarenal, pararenal, and suprarenal AAAs. Proximal sealing is achieved by two ring stents. Proximal fixation is achieved by nitinol hooks attached at the peaks and valleys of the ring stents. Depending on the configuration of the visceral segment, the anterior valley hook can be omitted or reduced in size, and the ring stents can be configured with an augmented valley to allow for sealing between closer visceral vessels. The deployment system allows precise positioning as well as repositioning of the endograft even after complete unsheathing. Cannulation of the fenestrations and respective target vessels can be achieved via inguinal, subclavian, or axillary access. The manufacturing process of this custom-made graft includes the production of a three-dimensional model of the aorta, as well as a nonsterile prototype that allows a test implantation by the treating physician so that changes can be requested for the production of the final sterile device, if necessary.

Although some have reported on the application of the Fenestrated Anaconda™ device for treating the proximal seal after EVAR in individual cases,[24,25] our recent report on the technical results of rescue fenestrated EVAR (FEVAR) after failed EVAR compared to primary FEVAR was the first to systematically address this issue.[26]

Among 94 patients treated with the Fenestrated Anaconda™ device, 12 patients with prior EVAR were treated for a pathology of the proximal neck, including type I endoleak in seven cases (Figure 1), stent migration with no apparent endoleak in two cases (Figure 2), and progressive aortic disease immediately cranial to the proximal sealing zone including the visceral segment in three cases. Previous EVAR devices included the Excluder AAA endoprosthesis (Gore & Associates; n = 4), Talent Occluder (Medtronic; n =1), Endurant AAA stent graft system (Medtronic; n = 4), Powerlink system (Endologix, Inc.; n = 2), and the Zenith graft (n = 1). One patient had already undergone a temporarily successful treatment with proximal cuff extension plus EndoAnchors. Deployment of fenestrated endografts in redo cases proved to be challenging—increased friction between the Fenestrated Anaconda™ graft and the old graft in situ hindered accurate graft deployment, and cannulation of visceral arteries was complicated by bare-metal stents placed with previously implanted stent grafts crossing the ostium (Figure 3). This was reflected by reduced primary technical success rates when compared to primary interventions (58.3% vs 87.8%; *P* = .02). However, functional success rates, defined as successful exclusion of the aneurysm without type I or type III endoleak or loss of organ function, were comparable between the two groups (91.7% in redo and 95.1% in primary cases, respectively).

Intraoperative mortality was 0% and there was no conversion to open surgery. Thirty-day mortality was 0% in redo cases and 6.1% in patients with primary FEVAR (*P* = .5). Major systemic complications including perioperative stroke, myocardial infarction, spinal cord ischemia, and renal insufficiency were comparable between redo cases, and primary FEVARs (8.3% vs 8.5%). Postoperative imaging was performed by CTA (n = 89) or, in cases of renal insufficiency, contrast-enhanced ultrasound (n = 5). After an average follow-up of 10 months, two cases of iliac limb occlusion were observed, but imaging did not reveal any cases of visceral connecting stent occlusions. The reintervention rate was 16.7% in redo cases compared to 11% after primary FEVAR (*P* = .57).

CONCLUSION

Treatment of patients after failed EVAR procedures and with no or insufficient infrarenal aortic neck is demanding. Due to limited midterm success rates, secondary anchoring of a failed infrarenal EVAR should be reserved for selected cases. The primary aim should be to extend the proximal sealing zone into a healthy aortic segment to prevent early failure of these complex redo cases. Fenestrated endografts allow for an anatomic reconstruction of juxtarenal, pararenal, and suprarenal aneurysmal aortic disease. Although redo procedures using fenestrated devices are associated with an increased risk of failure to cannulate the visceral target vessels compared with primary FEVAR interventions, secondary technical and functional success rates are satisfactory at > 90%. Increased primary failure rates seemed to be commonly attributable to space restrictions inside the old endografts and especially to difficulties accessing target vessels as a result of bare-metal stents crossing the ostium of a target vessel. Importantly, these difficulties did not result in increased perioperative complication rates or impaired short-term results. Whether there is a negative impact on long-term reintervention rates or patient morbidity and mortality remains to be evaluated. ■

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Relay®Branch: A Review of the Technology and Early Results

The endovascular approach to aortic arch pathologies using the RelayBranch Thoracic Stent Graft System.

BY BARTOSZ RYLSKI, MD, AND MARTIN CZERNY, MD

When John Gibbon first carried out a successful open heart procedure on a human using the heart-lung machine in 1953 in Philadelphia,[1] cardiac surgeons did not even dream about heart transplantation. Then, in 1967 in Cape Town, South Africa, Christiaan Barnard performed the world's first human-to-human heart transplant.[2] The aortic endovascular era started exactly 30 years ago in 1987 when Nikolai Volodos implanted the first thoracic stent graft in a patient with thoracic aortic false aneurysm.[3] At that time, nobody even thought about endovascular treatment of the aortic arch. Today, endovascular aortic arch repair has become reality. This article reviews our algorithm for treatment of aortic arch pathologies based on the patient's specific aortic anatomy and condition and describes the RelayBranch Thoracic Arch System (Bolton Medical; Figure 1), including prosthesis design, anatomic requirements, and recently published results.

TREATMENT DEFINED BY AORTIC PATHOLOGY

The treatment approach is defined by aortic pathology and the patient's condition, not the technology available at a hospital or the physician's expertise. The decision-making process starts with a CTA of the entire aorta. Thoracic endovascular aortic repair (TEVAR) is chosen if the aortic arch pathology is more distal and subclavian-to-carotid or if a double transposition provides a sufficient proximal landing zone at least 2.5-cm long measured along the lesser curvature and the diameter is < 4 cm. In case of more proximal pathologies without an adequate landing zone in the aortic arch, we consider total aortic arch replacement with the frozen elephant trunk procedure, or we use the RelayBranch System in patients at increased risk for open surgery.

RelayBranch DESIGN

The RelayBranch System consists of three components: (1) the Main Body Graft, which is intended to be placed in the arch and spans from zones 0 to 4 and includes a large covered window with two internal tunnels designed to extend into the innominate and left carotid arteries; (2) the first branch graft that connects the posterior tunnel with the innominate artery; and (3) the second branch graft that connects the anterior tunnel with the left carotid artery (Figure 1). All three components are composed of self-expanding nitinol stents sutured to a polyester vascular graft fabric. The main body's proximal end consists of sinusoidal nitinol stents and crown-shaped nitinol stents with no uncovered portions or bare springs, similar to the Relay non–bare stent (NBS) thoracic stent graft (Bolton Medical). The main body has two standard total length offerings: the 270 mm with an ascending section of 60 mm and the 255 mm with an ascending section of 45 mm. The main body's proximal diameter ranges between 32 to 48 mm in 2-mm increments, and the distal diameter ranges between 22 and 48 mm in 2-mm increments. Multiple tapering configurations are available (eg, 48-mm proximal and 32-mm distal diameters in the same endoprosthesis).

The RelayBranch Main Body is delivered in two stages. First, the introducer with hydrophilic

Figure 1. The RelayBranch design. The RelayBranch System consists of three components: the Main Body Graft and two branch stent grafts.

coating is inserted over a stiff wire via transfemoral access into the thoracoabdominal aortic segment. Next, the primary sheath (the hydrophilic coated introducer) remains on the thoracoabdominal level and the arch graft, compressed in a very flexible secondary sheath, and is advanced into the aortic arch. The flexibility of stage two allows the most atraumatic access possible into the aortic arch. Correct orientation of the arch graft, with both internal tunnels oriented toward the larger curvature, is ensured by the outer primary sheath's preformed tip and by radiopaque markers assisting orientation of the arch graft. To avoid the bird-beak phenomenon and guarantee optimal apposition of the proximal arch graft end in the curved ascending aorta, two heart-shaped nitinol wires (support wires) attached to the delivery system catheter actively guide the inferior portion of the graft toward the inner curvature.

The RelayBranch branch graft components are modified iliac branches of the TREO® device (Bolton Medical) with proximal clasping to the delivery system. The proximal apexes of the branch grafts are uncovered. Because the internal tunnels of the main body always measure 12 mm in diameter, the proximal diameter of both branch grafts is 13 mm. The distal diameter ranges between 8 and 24 mm, and the length spans from 70 to 140 mm.

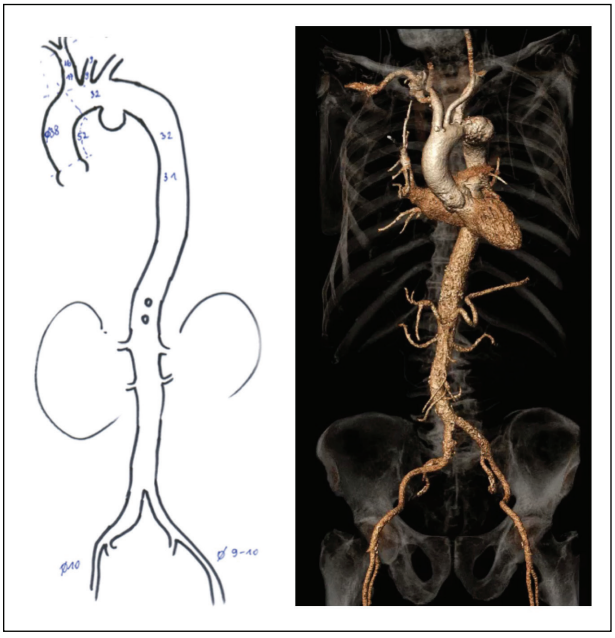

Figure 2. CT and draft of aortic anatomy of a patient with a penetrating aortic ulcer in the distal aortic arch in which the proximal landing zone with carotid-subclavian bypass would have been 7 mm and only 13 mm in the case of double transposition. Due to severe comorbidities, open aortic arch surgery was too risky, and the patient underwent successful implantation of the RelayBranch with carotid-subclavian bypass on the left side.

Anatomic Requirements

The success of any aortic endovascular procedure is defined by accessing the appropriate landing zones. The main body of the RelayBranch requires a proximal landing zone at least 30-mm long with a diameter up to 43 mm. The anatomic prerequisites for the distal landing zone are the same as in standard TEVAR cases. Because the shorter ascending portion of the arch graft measures 45 mm in length and has an additional 10- to 15-mm distance to the coronary arteries, and because 10 mm between the arch graft window and innominate artery are necessary, the distance between the sinotubular junction and innominate artery should be at least 65 mm. Due to the main body window size, the distance between the proximal and distal edges of the innominate and left carotid arteries should not exceed 45 mm. The diameters of the innominate and left carotid arteries should range between 7 and 20 mm, and the landing zone lengths should measure at least 25 and 30 mm, respectively. In patients with a remaining dissection in the supra-aortic vessels after type A dissection repair, use of the RelayBranch System is inadvisable. The reasons for this are usually a very small true lumen in a chronically dissected aortic arch, dissected supra-aortic vessels with a compromised true lumen, and a short ascending graft[4] or previous ascending replacement with two grafts anastomosed under a sharp angle. Figure 2 illustrates a penetrating aortic ulcer in the distal aortic arch in a patient with anatomy suitable for RelayBranch implantation.

RESULTS

The first published series on the RelayBranch includes 15 treated patients, 12 of whom underwent revascularization of the left subclavian artery.[5] There was one in-hospital mortality due to myocardial infarction 2 weeks after the procedure. One patient had a disabling stroke due to a heavily calcified ascending aorta and supra-aortic vessels. No patients had symptomatic spinal cord ischemia.[5] There were no type Ia or type III endoleaks, and there was a single type Ib endoleak that resolved spontaneously.[5] During a median follow-up of 263 days, one patient developed an endoleak via the left subclavian artery, which was successfully treated by embolization. Aortic-related survival was 100%, and four patients died during follow-up of nonaortic-related causes.[5] Figure 3 shows a postoperative 3D reconstructed CTA obtained after RelayBranch implantation in one patient in this study.

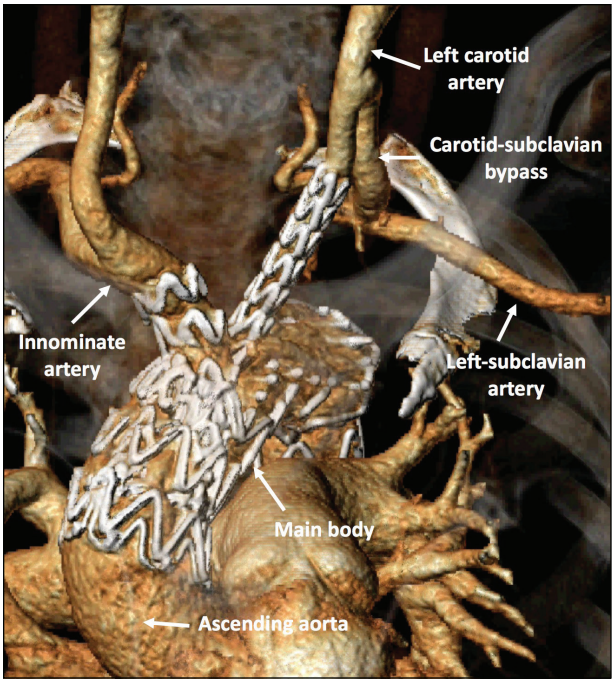

Figure 3. Three-dimensional reconstructed CTA of the aortic arch after implantation of the RelayBranch.

SUMMARY

The RelayBranch System enables the effective treatment of aortic arch pathologies with very low mortality and excellent aortic-related survival in patients anatomically suitable for TEVAR. The number of patients in the published report is quite low, and larger studies with longer follow-up are necessary to compare the RelayBranch with other endovascular and open approaches to aortic arch pathologies. The risk of neurologic injuries is omnipresent and should be carefully evaluated before planning treatment with the RelayBranch. A high degree of calcification in the ascending aorta, aortic arch, and supra-aortic vessels is a reason to favor open arch repair, because endovascular manipulation in this milieu can quickly lead to serious neurologic complications. Careful deairing of the delivery device, clamping the carotid arteries during branch graft implantation, and flushing the carotid arteries before declamping may reduce the risk of cerebral embolization. Frequently, aortic arch pathologies extend downward into the thoracic descending aorta, requiring distal extension with TEVAR. Preserving the flow via the left subclavian artery via transposition or carotid-subclavian bypass is necessary to keep the risks for spinal cord ischemia as low as possible.[6] We prefer the carotid-subclavian bypass to transposition, because the anastomosis on the carotid artery may be placed more distally, eliminating the risk of covering the bypass offspring with a branch graft and avoiding passing the anastomosis with the branch graft's delivery device.

Aortic arch repair requires careful assessment—first of the aortic anatomy and then choosing the treatment option according to the patient's anatomy and condition, not the other way around. The RelayBranch System is a safe and feasible device, enriching our armamentarium and giving us another option to repair the aortic arch without sternotomy. ■

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Relay®Plus Subset Analysis From the United States FDA Phase 2 Clinical Trial

Midterm results of the Bolton Relay® Thoracic Stent Graft with an emphasis on improvements to the delivery system.

BY MARVIN D. ATKINS, MD; PRASHANTH VALLABHAJOSYULA, MD, MS; AND WILSON Y. SZETO, MD

Thoracic endovascular aortic repair (TEVAR) has supplanted open surgical repair for all of the various pathologies of the descending thoracic aorta, including thoracic aneurysms, transections, dissections, and penetrating aortic ulcers (PAUs). The perioperative and 30-day morbidity, mortality, and rates of paraplegia all compare favorably to historical series of open surgical repair. The mid- and long-term durability of TEVAR devices must be examined rigorously and compared to the historical gold standard of open repair to ensure that patients undergo the treatment not only with the lowest perioperative risk, but also with the greatest long-term durability and benefit. We know from the endovascular treatment of abdominal aortic aneurysms that the long-term durability of endografts has been called into question 3 to 5 years after device implantation due to issues of migration, untreated endoleaks, and subsequent aneurysm sac expansion and delayed rupture.[1]

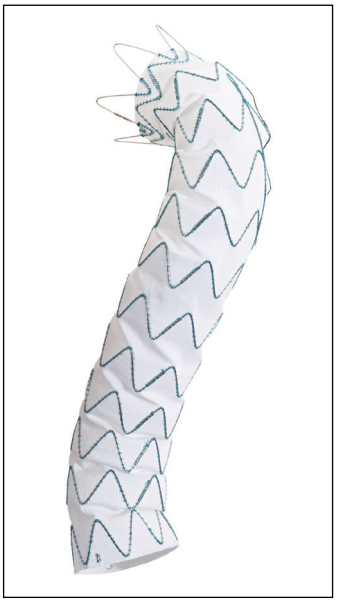

Figure 1. The Relay Thoracic Stent Graft.

Multiple thoracic aortic stent graft technologies have emerged to treat the various pathologies of the descending thoracic aorta. Continued refinements of the stent grafts themselves, as well as their delivery systems, have shown improved results over earlier device iterations. As surgeons continue to gain experience with TEVAR techniques, the risks associated with such therapy have decreased. The Relay Thoracic Stent Graft with Plus Delivery System (Bolton Medical) (Figures 1 and 2) is one such device that has undergone refinement of its original delivery system. The midterm (5-year) results of the United States Pivotal Trial were recently reported, showing favorable outcomes compared to historical surgical controls. The device delivery system was redesigned during this period, and a subset analysis was performed to analyze differences between the two cohorts. This article presents the results of this subcohort of patients, highlighting the clinical and technical benefits of device delivery improvements.

PIVOTAL TRIAL RESULTS

The Relay Thoracic Stent Graft with Plus Delivery System received US Food and Drug Administration approval in September 2012, but it has been used in Europe and other international markets since 2005. The Bolton Relay Thoracic Aortic Endovascular Pivotal Trial was a prospective, nonrandomized, multicenter, United States investigational device exemption study conducted at 27 United States sites. Between January 2007 and May 2010, 120 TEVAR patients were treated with the Relay device. Thirteen additional patients were enrolled during the continued access phase of the study through September 2012. Ninety-five patients were treated with the original Relay transport delivery system, and 38 patients were treated with the RelayPlus delivery system. The initial and midterm results of the device were recently published.[2] TEVAR outcomes were compared to a retrospectively and prospectively captured cohort of 60 open surgical controls. Patients were followed clinically and underwent imaging yearly for 5 years after TEVAR.

Stent grafts were successfully delivered in 129 of 133 (97%) patients. Access failures were noted early in the

study and were associated with the use of the original transport delivery system. Perioperative outcomes revealed a lower mortality rate with TEVAR compared to open surgical controls (5.3% vs 10%; *P* = .23). TEVAR was associated with a significantly lower rate of major adverse events (MAEs), defined as stroke, paralysis/paraplegia, myocardial infarction, procedural bleeding, respiratory failure, renal failure, wound healing complications, and aneurysm-related mortality. (20.3% vs 48.3%; *P* < .001). This was mostly due to a lower frequency of adverse respiratory complications (5.5% vs 21.6%; *P* = .007), and periprocedural bleeding (transfusion was required in 10 [7.5%] vs 50 [84.7%] patients; *P* < .001). Midterm (5-year) outcomes of freedom from aneurysm-related mortality were similar between groups (91.3% for TEVAR vs 89.4% for open surgery; *P* = .406). Freedom from MAEs at 5 years favored the TEVAR cohort (65.7% vs 44.7%; *P* = .001). Ten (7.5%) patients required secondary procedures after TEVAR. Aneurysm sac size decreased or remained stable in 113 (85%) patients through 5-year follow-up. Endograft migration occurred in three (2.3%) patients, and wireform fractures were seen in two (1.5%) patients. There were no instances of aneurysm rupture or endograft occlusion in the TEVAR cohort.

SUBSET ANALYSIS

In September 2009, two major changes were implemented concurrently to the study design confounding the aforementioned results. The first major change to the study design was the introduction of the Plus delivery system. Of the 133 patients enrolled in the pivotal study, 38 were treated with the newer RelayPlus device.

The following modifications were made to the original transport delivery system with the new Plus delivery system: (1) hydrophilic coating was placed on the sheath tip as well as higher radiopacity, (2) the delivery sheath was lengthened, and (3) the inner stainless steel catheter was replaced with a precurved nitinol inner catheter to improve tracking to the natural curvature of the aorta; the precurved design self-aligns the S-bar. The S-bar is a curved nitinol torsion bar that provides longitudinal support to the Stent Graft and is ideally placed on the outer curvature of the distal aortic arch. The Plus delivery system uses a two-stage device deployment technique, consisting of an outer delivery sheath followed by an inner sheath containing the device. The outer sheath provides support during delivery and protects access vessels by acting as a conduit for the inner sheath. The flexible inner sheath allows for atraumatic advancement and staged graft expansion for precise deployment. The new design not only improves the steerability and trackability of the device, but also the precision of deployment in tough angulated arches.

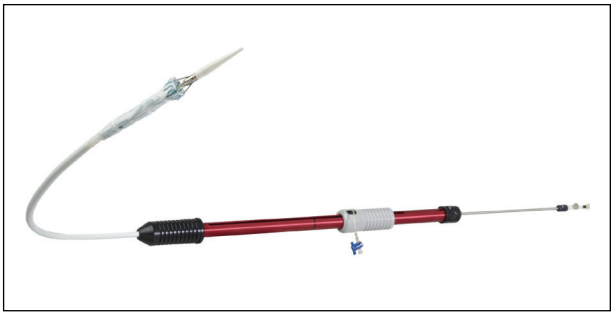

Figure 2. The Relay Thoracic Stent Graft with Plus Delivery System.

The second major change to the study design was the inclusion of patients with PAUs. Saccular aneurysms and PAUs accounted for 41 of 133 (30.8%) patients in the study. PAUs are an ideal pathology to treat with TEVAR, as the pathology is typically isolated with relatively normal seal zones proximally and distally. PAU is defined as an ulceration of an aortic atherosclerotic plaque penetrating the internal elastic lamina into the media, often associated with a variable degree of intramural hematoma formation. PAUs are often multiple and vary greatly in size and can be up to 5 mm in diameter and 4 to 30 mm in depth. They can occur at any point throughout the aorta, most commonly in the middle and lower descending aorta, less frequently in the aortic arch and abdominal aorta, and rarely in the ascending aorta.

In a recent literature review and meta-analysis by D'Annoville et al of TEVAR in patients presenting with PAUs, > 80% of patients were treated with a single device, there was a very low stroke rate of 2.4% (7 of 287), and the paraplegia rate was low at 2.9% (9 of 308).[3] Only one patient had permanent paraplegia, and neurologic deficits completely resolved in the other eight patients.[3] Based on the pivotal trials of the other commercially available TEVAR devices used solely in the setting of aneurysmal disease, patients typically have an average 5% risk of stroke and 5% risk of paraplegia/paraparesis.

Although confounded by selection bias in the published literature, the risk of stroke and paraplegia associated with TEVAR in the setting of PAU appears lower compared to pivotal device trials of TEVAR involving aneurysmal disease alone. The lower risks associated with PAUs may be related to the use of single, short-piece thoracic endografts involving less aortic coverage. Quicker procedures are also likely associated with less wire manipulation and catheter exchanges. The pathology is also most likely in the mid to lower portions of the descending thoracic aorta, and as such, the risk of stroke is lower. The addition

of patients presenting with PAU to the study design confounds the results of the Bolton Relay Thoracic Aortic Endovascular Pivotal Trial when making direct comparisons to the results of studies evaluating other available thoracic endografts.

Outcomes

A subset analysis of outcomes was performed comparing patients treated with the original transport delivery system with those treated with the updated Plus delivery system. The RelayPlus group had 100% device delivery and no device alignment issues, as the precurved nitinol inner cannula allowed for self-alignment of the S-bar to the greater curvature. There were no type I or III endoleaks, device migrations, or stent strut fractures. Follow-up was similar between the two groups (3.2 years for the RelayTransport device vs 3 years for RelayPlus). In the original RelayTransport device cohort, there were five type I endoleaks (5.1%) and one type III endoleak (1.1%). Migration was seen in three patients (3.2%), and there was evidence of two wireform fractures of the stent struts (2.1%). In terms of MAEs, there was a significant difference between the two cohorts, with six (15.8%) MAEs seen in the RelayPlus group versus 34 (35%) MAEs in the original RelayTransport group.

There are several factors that could explain the improved results associated with the RelayPlus system other than device delivery design improvements alone. As the trial progressed, the investigators gained greater experience with the delivery and deployment of the device, as well as improved patient selection. In the RelayTransport system, 24 of 95 (25.3%) patients required an iliac conduit versus two of 38 (5.3%) using the RelayPlus delivery system (P = .017).

There was a noticeable improvement in the rate of stroke in RelayPlus group. One (1 of 38, 2.6%) patient experienced a stroke in the RelayPlus cohort versus 12 (12 of 95, 12.6%) patients in the original RelayTransport cohort (P = .108). This single patient had a stroke beyond the 30-day perioperative period but was noted at a 6-month evaluation. The lower stroke rate could be attributed to design improvement vis à vis self-alignment of the S-bar and less torque and manipulation required to position the device. An addition of patients with PAUs later in the trial could also have affected stroke rates. Less wire manipulation as well as catheter and device exchanges could explain the lower stroke rate seen in the RelayPlus cohort. Because the RelayPlus cohort was small, it may be impossible to perform further subset analyses to assess for other meaningful significant differences.

CONCLUSION

The Bolton Relay Thoracic Aortic Pivotal Trial supports the use of the Relay Thoracic Stent Graft with Plus Delivery System as an effective, safe, durable treatment option for patients with descending thoracic aortic aneurysms and PAUs. The RelayPlus delivery system appears to confer improved results over the first-generation delivery system design, making the procedure even safer for patients. Results from Bolton Relay Thoracic Aortic Pivotal Trial compare favorably to the midterm results of studies evaluating other commercially available thoracic stent grafts. Further follow-up of the patients enrolled in the pivotal trial, as well as those enrolled postapproval, is needed to ensure long-term durability of the device. ■

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