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EndoAnchors: Endovascular Stitching During EVAR and TEVAR

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THE EVOLUTION OF ENDOVASCULAR REPAIR IS CHARACTERIZED BY INNOVATION

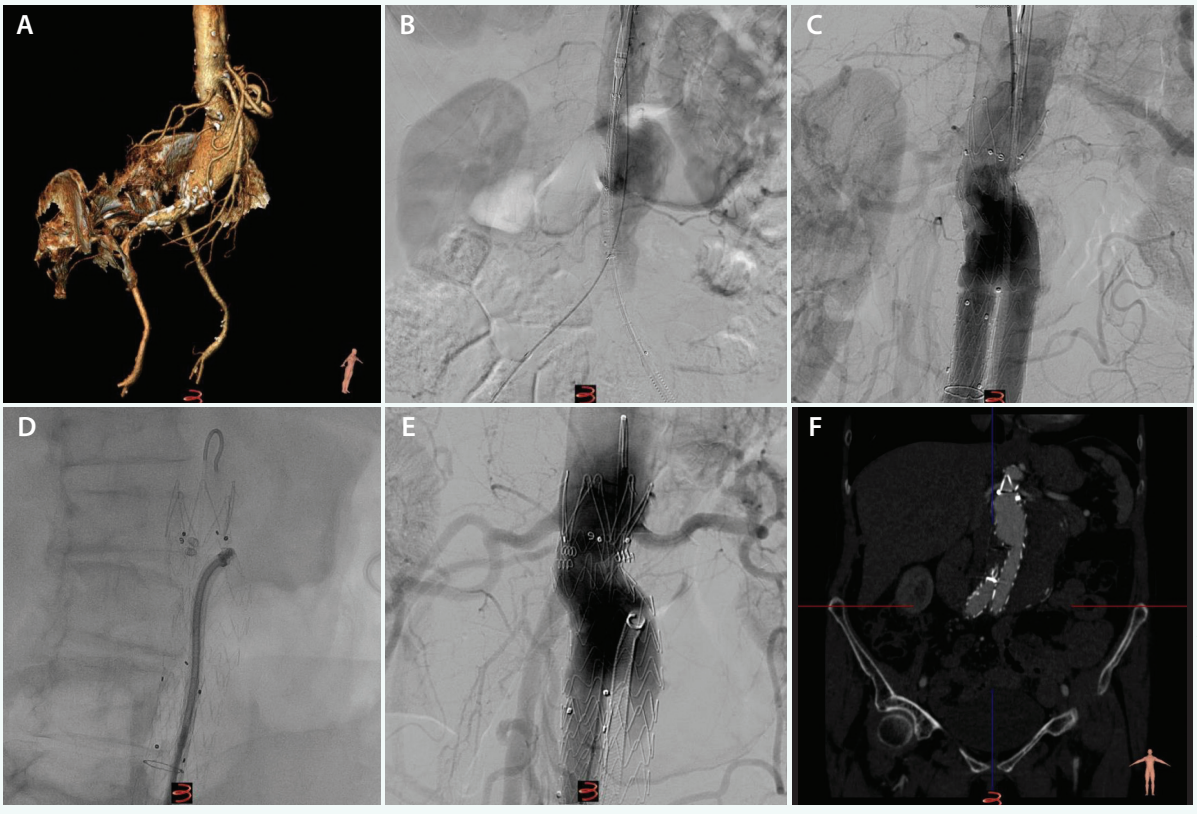
Endovascular aneurysm repair (EVAR) has evolved significantly since 1991 when Dr. Juan Parodi detailed in his pioneering report the treatment of five abdominal aortic aneurysm (AAA) patients with knitted Dacron tube endografts.[1] High failure rates of the first generation of endografts were due largely to stent migration and associated seal failure. Modern endografts are more advanced structurally to achieve greater fixation and sealing than their progenitor devices. A wide variety of aortic disease and anatomies can now be treated, but the envelope is continuously being pushed. Imaging techniques have also advanced significantly in the same time period. We now have high resolution multislice computed tomography angiograms (CTAs), contrast-enhanced ultrasound (CEUS), magnetic resonance (MR) technologies, and other advanced imaging methods for complex or straightforward EVAR.[2-6] Altogether, these have significantly aided physicians to identify the configuration of the AAA and to accurately visualize challenging aortic anatomies. Moreover, pre-EVAR planning and sizing has significantly improved. But challenges remain.

Outcomes of EVAR vs Open Repair

EVAR is still not immune to late endograft failure, most often caused by disease progression that makes the anatomical conditions unconducive to maintaining seal and fixation, ultimately requiring endovascular reintervention or conversion to open surgical repair.[7] More late explants of endoprostheses are occurring as implanted second-generation and early third-generation devices begin to fail. Turney and colleagues at Cleveland Clinic in 2014 concluded that short-term failure is largely due to difficulty achieving initial adequate seal causing failure at less than 1 year. Failures occurring greater than 5 years are commonly thought to be attributable to the progression of aneurysmal disease.[8] Migration, major endoleaks, stent kinking, infolding, and limb thrombosis all loom as the Achilles' heel of EVAR, all causes of the need for reinterventions and even late open conversion, with endoleaks perhaps the most prominent threat.[2,9] Complex techniques have

Figure 1. The Aptus™ Heli-FX™ System Applier and Guide with EndoAnchor ready for deployment.

CASE ONE



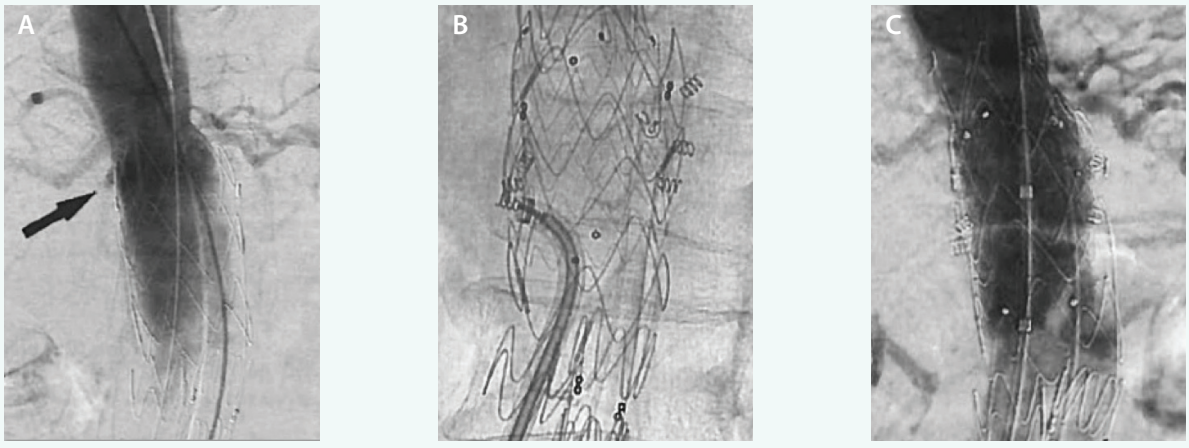
Courtesy of Dr. Jean-Paul P. M. de Vries

EndoAnchors used to treat an intra-operative type I endoleak and enhance durability to address concerns for future complications in a patient with complex aortic neck anatomy. Complex anatomy identified in preoperative CT brings concern for complications (A). Complex anatomy brings concern for complications (B). Intra-operative type Ia endoleak identified (C). EndoAnchors implanted to treat type I endoleak and enhance durability of proximal seal (D). Final angiogram demonstrates successful treatment of type Ia endoleak and aneurysm exclusion (E). One-month postoperative CT confirms exclusion of aneurysm and successful treatment of type I endoleak (F).

been developed to combat this issue with fenestrated and branched devices, but these expensive and labor-intensive endovascular devices and techniques are not immune to failure either. These techniques pose risks to the patient by increased radiographic contrast exposure and renal interference associated with greater risk of postoperative renal function decline and AAA related mortality, as well as increased radiation exposure for both the patient and treating physician.[10]

Recent large studies have compared EVAR to open surgical repair and confirm that EVAR may be more vulnerable to these complications over time than open repair, particularly in regard to endograft seal at the proximal aortic neck. In their 2010 randomized trial of 351 patients between EVAR and open surgery, De Bruin and colleagues reported that survival was similar between procedures, but there were higher rates of EVAR-related complications and reinterventions, with a persistent risk for ruptured AAAs (rAAAs) in the EVAR group.[11] The ACE study in 2011 compared 316 patients with AAA randomized to EVAR or open repair. The study concluded that open repair was just as safe as EVAR but more durable because of the higher rate of EVAR-related complications. There was also noted a persistent risk for late rAAAs that necessitated significantly more reinterventions in the EVAR group versus open repair (16% vs 2.4% at 3 years median follow-up).[12] A 2010 study reported data from 37 hospitals in the United Kingdom (UK), randomizing 1,252 patients with AAAs to either EVAR or open repair. The investigators found that endograft-related complications and reinterventions were more prevalent than open surgery, although the two interventions showed similar mortality rates.[13] The same UK EndoVascular Aneurysm Repair (EVAR) trials

CASE TWO



Courtesy of Dr. Jean-Paul P. M. de Vries

In a patient with a late type Ia endoleak, EndoAnchors were used to treat the endoleak and enhance durability to address concerns for redeveloping future complications. Late type Ia endoleak identified (A). Cuff and EndoAnchors implanted (B). Final angiogram demonstrates successful aneurysm exclusion with no endoleaks (C).

group reported in 2012 that EVAR has definite early benefits in survival compared to open repair, but again they could not show a long-term survival advantage.[14] More recent evidence, though in a smaller sample of patients, was reported in a 2016 study of 57 moderate to high-risk AAA patients (28 received EVAR; 29 open surgery). There were notable short-term survival benefits with EVAR, but this benefit could not be sustained, and open surgical repair was concluded to have a better long-term outcomes in these higher-risk patients.[15] These studies highlight the need for surveillance post-EVAR to safeguard patients against risk for late complications.

Some evidence suggests reinterventions and surveillance post-EVAR have an impact on increased lifetime costs. European studies have reported that there was no cost benefit of EVAR versus open repair for AAAs.[16] When costs were assessed acutely in the OVER trial conducted in the US, EVAR was found to be less costly and more effective than open repair, necessitating less time in the operating room and shorter length of hospital stay.[17] Similarly, a 2014 study reported cost-effectiveness of EVAR and open repair in the short- and mid-term time horizons (30 days and from 2 to 5 years follow-up). It showed that rAAAs treated with EVAR was as cost effective as open repair and had no significant difference in reintervention rates.[18] However, an examination of the longer-term resource use reported that EVAR is costlier than open repair, which results in higher lifetime costs for aneurysm-related events.[13] This suggests that while there may be early and mid-term cost benefits of EVAR, these advantages cannot be maintained in the long-term, ultimately dwindling over time. Another 2014 study by Kapma and colleagues reported that costs were higher for EVAR versus open repair for rAAA patients, although EVAR showed a slight survival benefit.[19] In fact, total costs at up to 6 months post-index procedure were notably raised in eight EVAR patients who necessitated open repair, three of whom had access failure and five who had a persistent type I endoleak. The authors commented that EVAR cost performance could likely be improved if these types of conversions can be avoided by better patient selection.[19] Zhang and colleagues also reported in 2016 that EVAR costs were significantly higher than open repair costs in moderate to high-risk AAA patients.[15] There are likely significant opportunities to achieve reductions in EVAR-related complications and reinterventions, as well as to more efficiently employ judicious surveillance and cost reductions. Advancements in refining existing procedures to be more simple and uncomplicated is the essence for extending acute cost advantages of EVAR into the long-term.

Anatomic Variations of the Aorta Requires Adaptive, Innovative Solutions

While the newer generation of endografts has steadily improved over their progenitor devices, there remains a wide complexity of anatomic variations, rendering each patient truly unique. Addressing the anatomy of the proximal neck typically involves customized case planning. Some necks may have severe suprarenal or infrarenal angulation (or both). Necks may be tapered, conical (reverse tapered), and may have

TABLE 1. COMPATIBLE ENDOGRAFT SYSTEMS PER THE OUS INSTRUCTIONS FOR USE (IFU).[28] THE APTUS™ HELI-FX™ AND HELI-FX™ THORACIC ENDOANCHOR™ SYSTEMS HAVE BEEN EVALUATED AND DETERMINED TO BE COMPATIBLE WITH THE FOLLOWING ENDOGRAFTS

Cook Medical	Gore & Associates	Jotec GmbH	Medtronic
Zenith®	Excluder®	Jotec E-vita	Endurant™
			Valiant™
Zenith® TX2®	TAG®		AneuRx™
			Talent™

CAUTION: The EndoAnchor system has undergone in vitro evaluations for compatibility and durability with the endograft devices listed in the Warnings and Precautions section of the instructions for use (section 4). The transferability of these data to other endograft designs is not known and therefore use with other endografts is not recommended.

focal aneurysmal degeneration (bulging) or may be short (such as those less than 15 mm in length), all variations that may be demanding for standard endoprostheses. A 2013 study by Antoniou et al was a meta-analysis of seven EVAR studies and compared outcomes in hostile necks versus so-called "friendly" neck anatomies (N = 1,559).[20] Type I endoleaks were 4.5 times more likely to occur in hostile necks at 1-year follow-up versus friendly necks (P = 0.010). In addition, aneurysm-related mortality in hostile necks was nine times greater than that of friendly necks (P = 0.013). Another similar meta-analysis by Stather et al of 16 major studies (N = 11,959 patients) confirms higher risks in hostile necks in addition to greater intra-operative challenges, suggesting EVAR still faces significant challenges in hostile proximal neck anatomy.[21] And in 2014, Speziale and colleagues added further detail to the scope of the problem. They reported that the presence of more than one hostile neck factor predicted the increase of major adverse events, intra-operative endoleaks and adjunctive procedures, and a heightened risk of mortality.[22]

The proximal neck remains an area that is difficult to adequately seal in the presence of hostile neck factors. There is a need to better predict where we need improved diagnostic, prognostic, and treatment solutions to prevent EVAR-related complications. For instance, one potential measurement was proposed this year by Schuurmann and colleagues regarding aortic curvature. This measurement reportedly quantifies degree of bending and tortuosity. Aortic curvature may provide a more useful predictive value for neck complications to define patients at risk for early complications following EVAR.[23] There are also significant challenges to follow-up imaging, such as the cumulative deleterious effect on kidney function in the elderly, cost issues, as well as the pervasive issue of non-compliance to follow-up. A 2015 study by Schanzer et al reported 50% of post-EVAR patients were lost to annual imaging at 5-year follow-up in a US population-based study of 19,962 Medicare beneficiaries, a concerning result because complications in patients not compliant to surveillance presents a greater risk for rupture and mortality.[24]

HELI-FX ENDOANCHORS ARE DESIGNED FOR DURABILITY TO REINFORCE AND PRESERVE ENDOGRAFT SEAL

EndoAnchors were designed to take the proven concept of surgical anastomosis achieved in open repair and adapting for the endovascular realm: essentially taking the best practices of the past to advance current endovascular techniques. The concept of suturing the graft to the aorta was intended to meet many challenges surrounding EVAR and TEVAR by empowering clinicians to directly address intra-operative complications in establishing or reestablishing endograft seal in diverse and highly challenging anatomies. They can secure with even more confidence an endograft's seal and fixation to mitigate the risk of future complications, especially in patients with hostile neck pathologies. In 2011, my colleagues and I published the first report of EndoAnchor use, describing two revision EVAR cases in which EndoAnchors secured primary endografts that had migrated: a Talent and an AneurRx (both devices manufactured by Medtronic, Inc., Minneapolis, MN, USA).[25] EndoAnchors were deployed successfully in both cases and found they were both safe and feasible. The following year, we expanded to using EndoAnchors prophylactically in patients receiving primary EVAR with hostile neck anatomy. In 13 subjects, our early results were both feasible, promising, and relatively quick: the median time to deploy EndoAnchors in that case series was 12 minutes.[26] Another 2012 study by Melas et al tested EndoAnchors left in situ in nine human cadaveric aortas.[27] Since EndoAnchors were designed to provide adjunctive radial support to the native endograft and to resist neck dilatation, the study tested caudal displacement force and reported that EndoAnchors successfully create the stability of a sur-

TABLE 2. SIZES AND OTHER TECHNICAL SPECIFICATIONS OF THE APTUS™ HELI-FX™ AND HELI-FX™ THORACIC ENDOANCHOR™ AORTIC SECUREMENT SYSTEMS

Component	Specification	Aptus Heli-FX EndoAnchor System	Aptus Heli-FX Thoracic EndoAnchor System
Heli-FX Guide	French Size (OD)	16 F	18 F
	Working Length	62 cm	90 cm
	Deflecting Tip Length	2 options: 22 mm, 28 mm	3 options: 22 mm, 32 mm, 42 mm
	Recommended aortic neck	18–28 mm, 28–32 mm	18–28 mm, 28–38 mm, 38–42 mm
Heli-FX Applier	French Size (OD)	12 F	
	Working Length	86 cm	114 cm
	Deployment Sequence	2 stage	
	EndoAnchor Size and Quantity	10/Cassette 3 X 4.5 mm (w X l)	
Ancillary EndoAnchor Cassette	EndoAnchor Size and Quantity	5/Cassette 3 X 4.5 mm (w X l)	

gical anastomosis between the aorta and compatible endografts. EndoAnchors should be used with a compatible endograft system, a list of which is shown in Table 1.[28] The Heli-FX™ Applier and Guide is depicted in Figure 1, and the technical specifications of the Aptus™ Heli-FX™ and Heli-FX™ Thoracic EndoAnchor™ systems shown in Table 2.

KEY ANATOMICAL CONSIDERATIONS FOR ENDOANCHORS

Similar to surgical anastomoses performed in open repair, EndoAnchors also require adventitial purchase to provide the intended strength. As a result, they are not recommended in proximal neck thrombus, calcification and/or plaque > 2 mm in thickness and > 50% (180°) continuous coverage of the vessel circumference in the sealing zone, nor in irregular or eccentric thrombus. Significant calcification, thrombus load, and/or plaque may compromise EndoAnchor penetration into the aortic wall, which is key for success. Attempts to deploy into areas of excessive calcification can lead to EndoAnchor misdeployment, deformation, and/or fracture. EndoAnchors are indicated for use to provide fixation and augment sealing of an endograft to the native vessel wall and are not indicated for attaching multiple components and/or layers of endografts, bridging an endoleak path, or if the native aorta has dilated beyond the maximum diameter of the endograft. Indications and contraindications for use are shown in Table 3.[28]

In What Endovascular Cases Should EndoAnchors Be Used?

The long-term design objectives of EndoAnchors in EVAR and TEVAR are, quite simply, to replicate surgical anastomosis, capable of withstanding significant displacement force, as was reported to be achieved or exceeded in the human cadaveric aorta study by Melas et al in 2012.[27] EndoAnchors are primarily useful treating existing seal complications, in highly challenging anatomies. In existing EVAR seal complications, EndoAnchors have demonstrated success in resolving both acute and late type Ia endoleaks,[29] as well as treating acute type Ia endoleaks in urgent or ruptured EVAR. They may also augment stability in migrated grafts.[30] In my professional opinion, EndoAnchors have also proven useful in treating highly challenging anatomies, particularly for irregularly shaped aortic necks (short, wide, highly angulated, and conical necks)[30] and securing grafts in difficult proximal landing zones.[31]

The clinical vision for the EndoAnchor technology include:

- Treat seal complications and prevent recurrence
- Mitigate risk of late-term seal complications and reinterventions, especially in complex anatomies
- Improve surveillance intervals by demonstrating substantial risk mitigation of type I endoleaks and sac enlargement.

ENDOANCHORS HAVE ESTABLISHED SAFETY AND PERFORMANCE

Between the IDE trials and post-market registry studies, more than 800 patients have been enrolled. The

TABLE 3. INDICATIONS AND CONTRAINDICATIONS FOR USE (BASED ON THE OUS IFU)[28]

INDICATIONS	CONTRAINDICATIONS
The Heli-FX and Heli-FX Thoracic EndoAnchor systems are intended for use to provide the following:	Treatment with the Heli-FX and Heli-FX Thoracic EndoAnchor systems are contraindicated for use in the following circumstances:
Fixation and seal • Intended to provide fixation and sealing between endovascular aortic grafts and the infrarenal aortic neck • In patients augmented where radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion **Migration or endoleak** in primary cases, at-risk (prophylactic) cases, or during an endovascular reintervention. • Indicated for use in patients whose endovascular grafts have exhibited migration or endoleak or are at risk of such complications • May be implanted at the time of the initial endograft placement, or during a secondary (ie, repair) procedure	**Allergies** • In patients with known allergies to the EndoAnchor Implant material (MP35NLT) **Other** • In conjunction with the Endologix AFX™ endograft • In patients with a condition that threatens to infect the endograft • In patients with a bleeding diathesis

total experience of commercial and clinical EndoAnchor use to date has been more than 30,000 EndoAnchors implanted in more than 5,000 patients. The phase 1 investigational device exemption (IDE) study, STAPLE-1,[32] employed EndoAnchors as part of an investigational endograft system evaluated in 21 AAA patients and demonstrated excellent 6-month and 1-year results, establishing safety and feasibility of the concept of EndoAnchor use. The pivotal phase 2 IDE trial STAPLE-2 enrolled 155 patients across 25 sites, with a total of 810 EndoAnchors (median of 5 per patient, range 2 to 14) were implanted in 154 subjects.[33] The STAPLE-2 pivotal trial demonstrated that no subjects experienced endograft migration. One subject had a secondary intervention to address a type Ia endoleak (0.8%, 1/119). Furthermore, EndoAnchors did not exhibit any unanticipated adverse device effects. One-year follow-up showed no EndoAnchor fractures or migration of EndoAnchors from their original implanted positions as observed by the core lab.[33]

The Heli-FX Aortic Securement System Global Registry (ANCHOR)[34] is a prospective, observational, international, multi-center (40 US sites and 17 European sites) postmarket registry designed to evaluate the real-world use and outcomes of the Heli-FX EndoAnchor System with independent core lab adjudication. The two treatment arms consist of a primary arm and a revision arm. Enrollment goals for each arm are 1,000 patients to be followed for 5 years. As of November 2015, more than 600 patients have been enrolled.

Highlights of Prophylactic Use of EndoAnchors in ANCHOR

One of the indications ANCHOR is evaluating is prophylactic use of EndoAnchors in a primary EVAR setting. In the most recent report that included 269 prophylactic use patients, 77.6% (159/205 available CT scans) met the criteria for a hostile aortic neck, as defined by having any one or more of the following parameters: diameter > 28 mm, length < 10 mm, infra-renal angulation > 60°, conicity > 10% over 10 mm, neck thrombus or calcium average thickness > 2 mm, thrombus or calcium of > 1-mm thickness covering > 50% (180°) of neck circumference. There were 11.2% of subjects (30/269) classified as having a rupture or a symptomatic aneurysm. In a mean clinical follow-up of 21.3 months, there were no EndoAnchor-related severe adverse events (SAEs). Per core lab adjudication, 1.7% of patients (3/177 available CT scans) had a type I endoleak at a mean follow-up of 8.2 months. In patients with 1-year CT, sac regression was observed in 64.1% of patients (25/39 available CT scans), and no cases of sac enlargement were reported. These results promise EndoAnchors are a useful adjunct as prophylaxis against proximal seal complications, especially given this subset of patients with hostile aortic neck anatomy.

Highlights of Therapeutic Use of EndoAnchors in ANCHOR

ANCHOR is also evaluating therapeutic use, which includes treatment of intraoperative and late type Ia endoleaks, with or without endograft migration.

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ANCHOR's most recent report of 263 patients showed 74.5% of patients (120/161 available CT scans) had aortic necks meeting the analysis criteria for hostile neck anatomy. Technical success was reported in 95.7% of patients (249/263). Freedom from EndoAnchor-related SAEs was 99.3% (261/263 subjects). Freedom from rupture was 99.6% (262/263 subjects) and freedom from reintervention for type Ia endoleak was 97.7% (257/263 subjects). These results confirm safety and deployment success in challenging cases, with freedom from reinterventions that exceed expectations.

EndoAnchors have been extensively studied since 2007, a proven history of safety with demonstrated benefits for patient groups previously considered problematic for interventionalists. Published data and our experience continue to confirm its unique value in EVAR and TEVAR, particularly in patients with complex aortic pathologies. In patients with persistent or challenging type I endoleaks, the ability for EndoAnchors to readily treat these endoleaks and potentially avoid the need for more complex treatment or conversion to open repair is welcome. In patients with complex anatomies who have traditionally been problematic for EVAR, we are finding relative ease in treating these patients in the primary repair with EndoAnchors and also maintaining strong outcomes in follow-up. We look forward to report on maturing data as it becomes available, which will provide us greater insight into the long term value of EndoAnchor therapy. ■

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