Supplement to

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Endovascular TODAY

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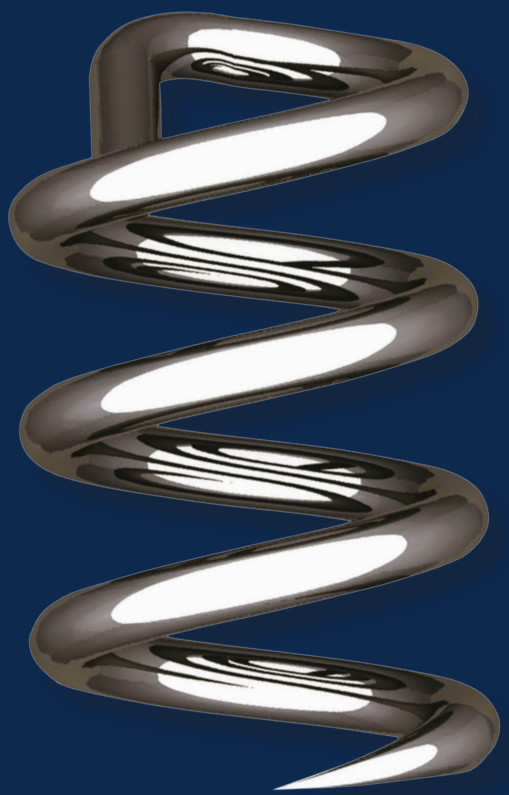
UNCOMPLICATING EVAR



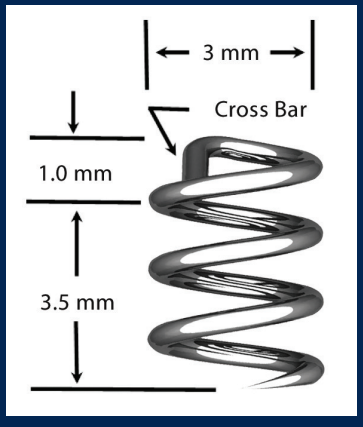
Experts share how EndoAnchors are empowering physicians and aortic centers with unparalleled capabilities in the treatment of patients with aortic disease.

UNCOMPLICATING EVAR

The Aptus™ Heli-FX™ and Heli-FX™ Thoracic EndoAnchor™ Systems

WHAT IS AN ENDOANCHOR?

Delivered endovascularly, the EndoAnchor implant provides independent transmural fixation of compatible endografts to the aortic wall, which enhances inherent sealing and fixation. It is designed to bring the stability of the surgical anastomosis to EVAR and TEVAR.



WHAT IS THE CLINICAL HISTORY OF THE DEVICE?

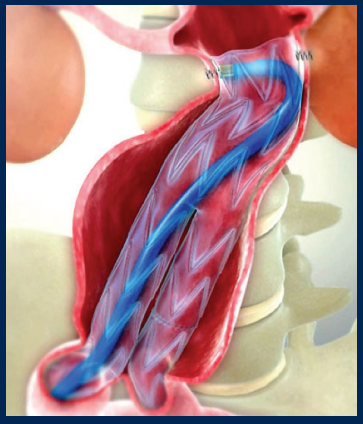
Since the first case in 2005, more than 30,000 EndoAnchors have been implanted in over 5,000 patients treated to date worldwide. Over 800 patients have been studied in IDE and post-market registry studies.

WHAT ARE THE MAJOR APPLICATIONS FOR THE DEVICE?

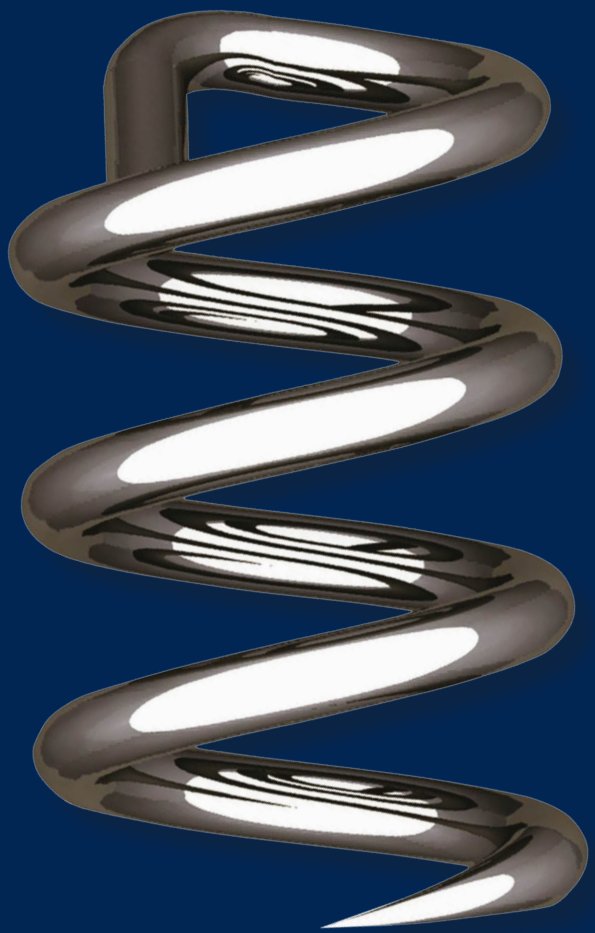
Major applications are for use as a prophylactic adjunct in patients with complex anatomy or mitigating risk factors and for targeted sealing of intraoperative and late type I endoleaks.

WHAT ARE THE FDA AND CE MARK INDICATIONS FOR USE?

To provide **fixation and sealing** between an endovascular aortic graft(s) and the native artery. The Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited **migration or endoleak**, or who are **at risk of such complications**, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.



This therapy is not for everyone. Please consult your physician. A prescription is required. For further information, please call Medtronic at +1.888.283.7868.



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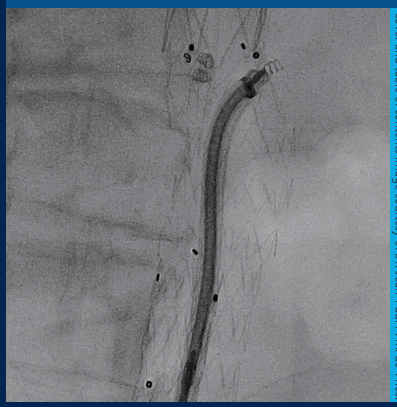

Cover and table of contents image courtesy of Dr. Jean-Paul P. M. de Vries

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EndoAnchors: Endovascular Stitching During EVAR and TEVAR

BY JEAN-PAUL P. M. DE VRIES, MD, PHD

THE EVOLUTION OF ENDOVASCULAR REPAIR IS CHARACTERIZED BY INNOVATION

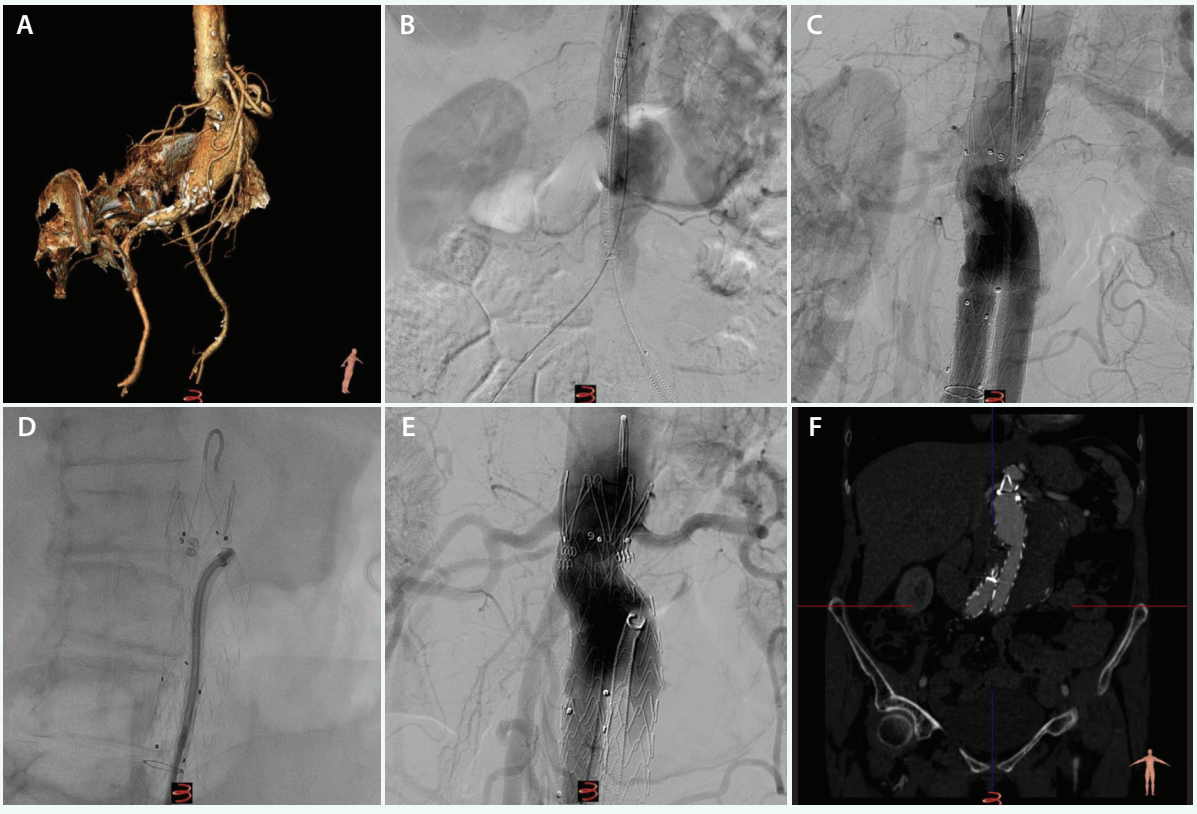
Endovascular aneurysm repair (EVAR) has evolved significantly since 1991 when Dr. Juan Parodi detailed in his pioneering report the treatment of five abdominal aortic aneurysm (AAA) patients with knitted Dacron tube endografts.[1] High failure rates of the first generation of endografts were due largely 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



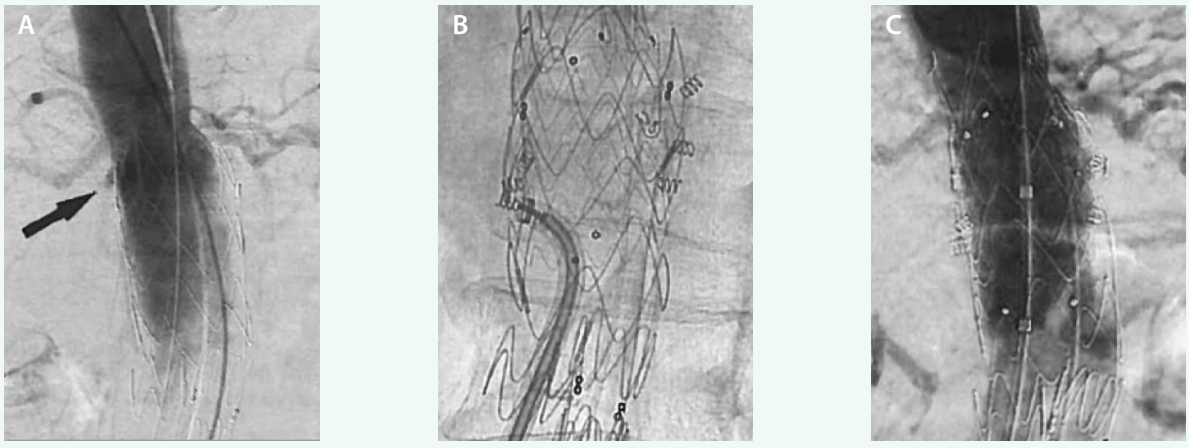
Courtesy of Dr. Jean-Paul P. M. de Vries

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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Considerations Beyond Anatomy to Best Manage Aortic Disease: The Benefits of EndoAnchors

WITH FRANK R. ARKO III, MD

How did you begin using EndoAnchors?

I began using the EndoAnchor as part of the ANCHOR registry in early 2012. I then realized early on that EndoAnchors had the ability to secure the endograft in a similar fashion to a standard open surgical repair. I felt that this could be beneficial in those with normal anatomy, and younger presentation, as well as older patients with severely angulated and short necks. In the younger patients with normal anatomy my hope and belief is that this will prevent or limit the risk of late disease progression. In the older population, my hope is that I can limit the repair to an EVAR with EndoAnchors and minimize my need for extending further into the aorta with either ChEVAR (chimney endovascular aneurysm repair) or FEVAR (fenestrated endovascular aneurysm repair).

What is your history with EVAR treating complex anatomy?

My aortic practice, for the most part, comprises of patients with complex anatomies. When I started practicing in 2001, endografts at that time required a neck length of 10 mm to 15 mm or greater. At that point I had a physician-sponsored IDE for a graft that allowed us to treat a 5-mm-long neck. While we were successful putting in the graft, a 5-mm-long neck is actually very short and finding that neck during a case can be challenging. I could actually put the graft in this length neck, but the graft was at risk of migrating peri-procedurally or over the long-term. These patients were often very sick, could not tolerate open surgical repair and had large aneurysms at a high risk of rupture. Clearly, if these individuals are young and healthy with this short of a proximal neck, then open surgical repair is the way to proceed. However, most of what is referred to me are those who cannot undergo an open repair. What I do find interesting, though, is that when we do those open cases, while we clamp above the renal arteries, we often still sew the graft to the aorta just below the renal orifices. I've found now that the use of an endograft, in which I can be very accurate in its placement just below the renal arteries, can simulate this open operation with the EndoAnchors simulating the sutures. To date, I've found this to be very successful.

Describe your general approach to treating patients and how EndoAnchors fit in your treatment algorithm.

There is obviously more to every patient beyond anatomy alone, and I try to consider this before approaching any intervention. When I approach a case, I try to individualize, personalize to a degree, in terms of a physician-patient relationship. Communication and education is essential because it not only helps the patient, but also helps the physician provide the patient with what they need. Ultimately, you want the patient to survive and thrive. So it's important to look at all potential risk factors before presenting options. When I evaluate a patient for repair, I would say that nearly 60% to 70% of patients that I treat have already been seen and referred by another vascular surgeon. Thus, this often already excludes them from an open repair. Often, they may be a candidate for open repair; however, they themselves are not willing to undergo an open surgical repair and are seeking something less invasive. I tend to think that if they are healthy but with a short neck, I like to extend that neck to healthy aorta with either ChEVAR or FEVAR. However, if they are of advanced age with a short neck and physiologic state in which I believe provides them a life expectancy

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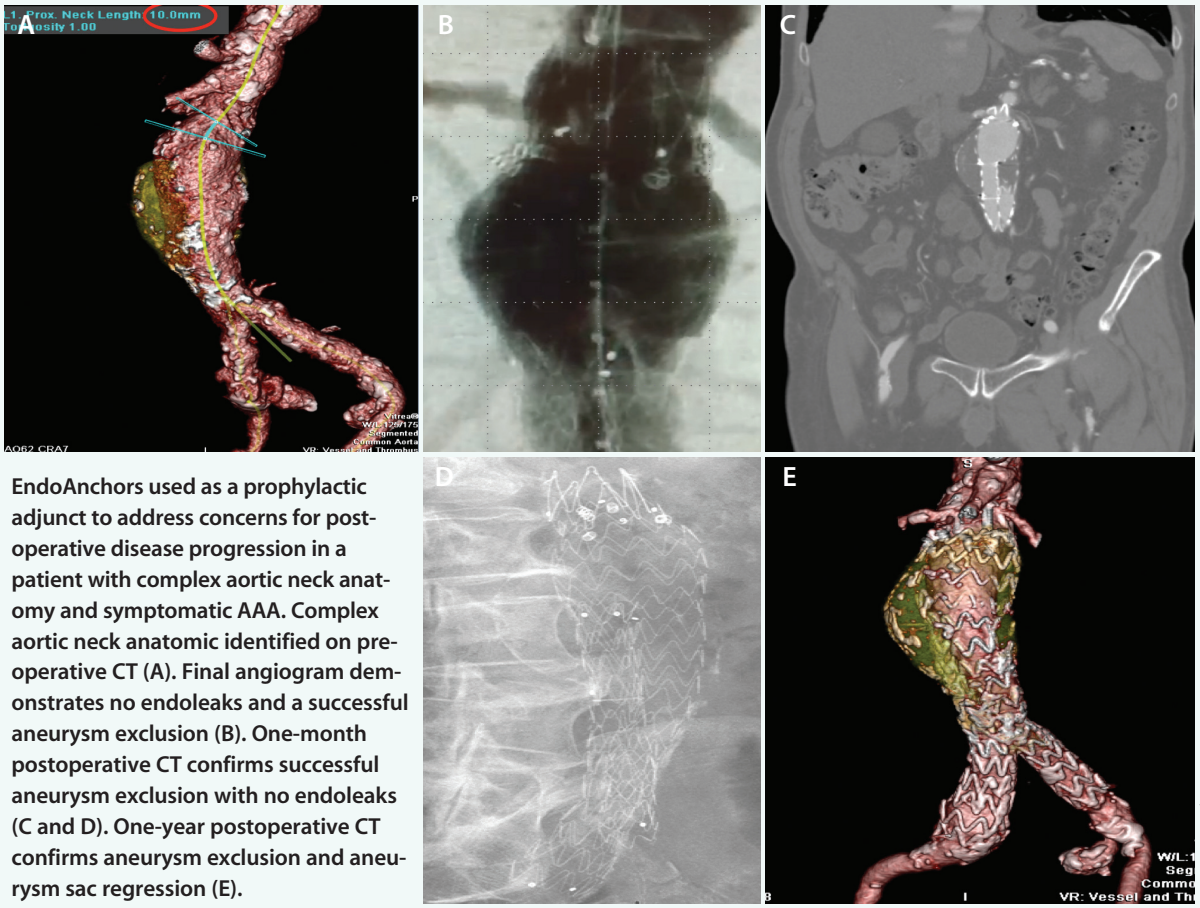
CASE ONE



EndoAnchors used as a prophylactic adjunct to address concerns for post-operative disease progression in a patient with complex aortic neck anatomy and symptomatic AAA. Complex aortic neck anatomic identified on pre-operative CT (A). Final angiogram demonstrates no endoleaks and a successful aneurysm exclusion (B). One-month postoperative CT confirms successful aneurysm exclusion with no endoleaks (C and D). One-year postoperative CT confirms aneurysm exclusion and aneurysm sac regression (E).

Courtesy of Dr. Frank Arko

of less than 10 years, I don't think it's unreasonable to proceed with standard EVAR with the addition of EndoAnchors. This is based off the ANCHOR registry and experiences in combining these two technologies.

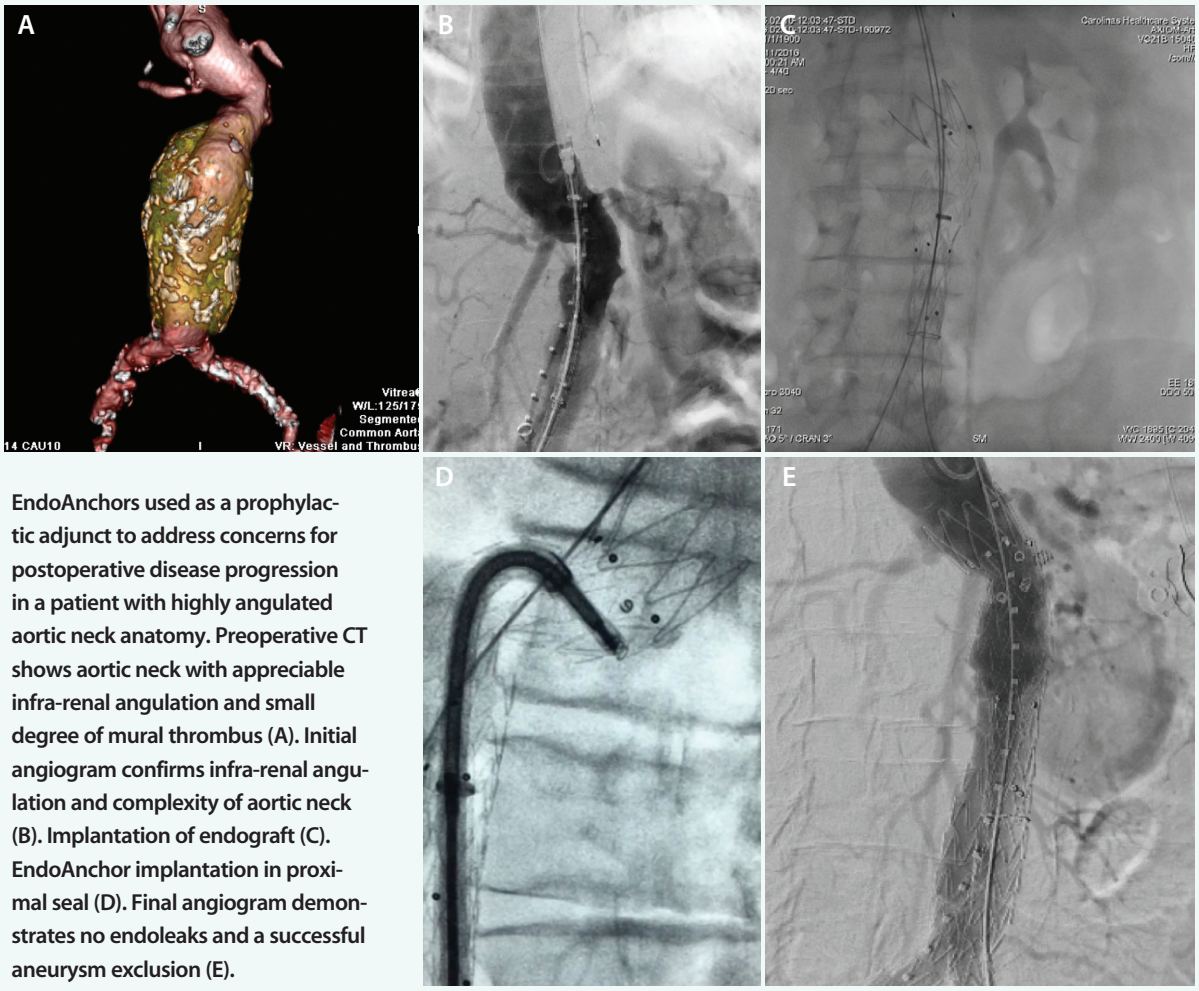
The intervention must last for the length of the patient's life. Since the overall goal is long-term survival, you need a durable procedure to achieve good outcomes both acutely and midterm to 5 years. If someone is of advanced age (let's say older than 90 years) and has a short neck, I'm going to avoid open surgery or any complex endovascular repair. I typically repair with Endurant II or Endurant IIs, though I have used others, and then use EndoAnchors to ensure a seal I know won't give the patient or me problems down the road. It's not strictly about anatomy. It's about the patients, their entire picture, their comorbidities, renal function, and their age. I may get referrals for complex ChEVAR and FEVAR with the patient being told that they need stents in the SMA (superior mesenteric artery) and the renal arteries. However, when I evaluate the patient comprehensively, including their age and other comorbid conditions, I may feel as though they are poor candidates for a complex EVAR and instead proceed with EVAR plus EndoAnchors. Let's take someone with chronic kidney disease with a baseline creatinine of 3.2 mg/dL. If I have to proceed with a complex repair with stents in their renal arteries, they have a high likelihood of accelerating their need for dialysis. What I'm trying to do for asymptomatic aneurysms is to get them back to their normal self as quickly as possible and minimizing their risk for a quality long-term repair.

Overall, the number of patients I'm willing to treat is increasing. Preventing dilatation and migration are different uses I've found with EndoAnchors. Physicians have to be cognizant of what their technical skill set is and intimately aware of what their hospital equipment will allow them to do. I believe imaging is often the biggest driver for referring these patients.

What anatomies do you view as candidates for EndoAnchor therapy?

The key anatomic consideration is about the neck, although there are other factors to consider such as angulation. If I have no plans on doing either ChEVAR or

CASE TWO



EndoAnchors used as a prophylactic adjunct to address concerns for postoperative disease progression in a patient with highly angulated aortic neck anatomy. Preoperative CT shows aortic neck with appreciable infra-renal angulation and small degree of mural thrombus (A). Initial angiogram confirms infra-renal angulation and complexity of aortic neck (B). Implantation of endograft (C). EndoAnchor implantation in proximal seal (D). Final angiogram demonstrates no endoleaks and a successful aneurysm exclusion (E).

Courtesy of Dr. Frank Arko

FEVAR, then I utilize EndoAnchors when my neck length is short. I will also use EndoAnchors when my neck length is short and there is high angulation of the infrarenal neck. I've used EndoAnchors both prophylactically and for endoleak. But I want to emphasize that it's all about the neck. I've used EndoAnchors in complex anatomy in combination with a 3-vessel ChEVAR and have been able to accurately place EndoAnchors to resolve a gutter leak. When you're confident in what EndoAnchors will do (which physicians will recognize very quickly after using them for the first time) and you have them in your inventory, you'll think about how EndoAnchors can be used in high-risk necks.

With EndoAnchors, it's not all about complex anatomies. The types of patients I believe it's actually counterintuitive for most physicians to use EndoAnchors are those with relatively simple anatomies, patients who are healthy, young, and resilient. They'll live a long period of time, decades longer perhaps, and are at risk for developing complications over time as they age and their aorta remodels. If I can prevent complications before they start, I'll do that. And I see an opportunity to use EndoAnchors to anticipate problems down the road in a more durable way.

What are the economic considerations of EndoAnchor therapy?

If you look at the overall economics to endovascular repair, you know there's a significant cost to the procedure. If you can prophylactically, if you will, secure your proximal neck with EndoAnchors, I believe you're offering a durable, quality outcome for the patient, the health system and the US economy as a whole. If reimbursement for a diagnosis-related group (DRG) is the same regardless if I do 3-vessel parallel endografting or EVAR with EndoAnchors, then EndoAnchors suddenly become not only economically feasible, but more efficient because they're easier and quicker

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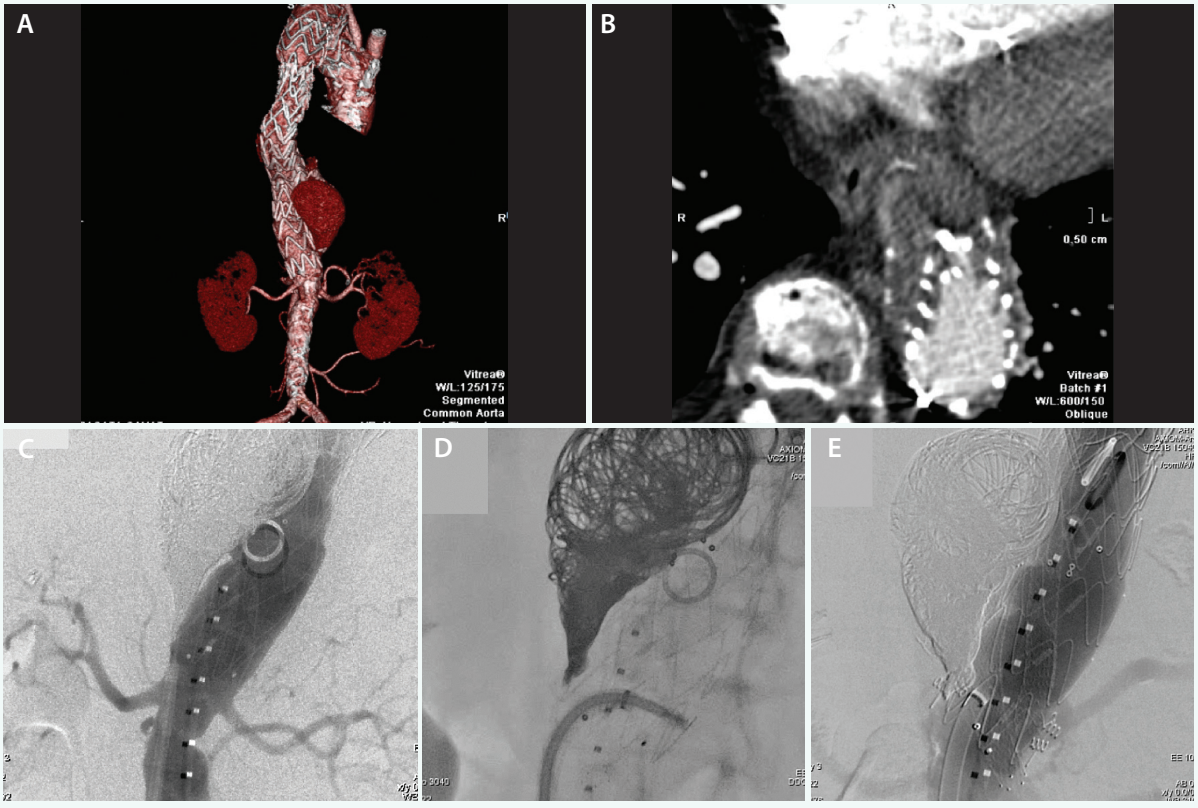
CASE THREE



Courtesy of Dr. Frank Arko

EndoAnchor used to enhance durability and prevent recurring complications in a patient with type Ib endoleak. Follow-up CT confirms late type Ib endoleak, short distal landing zone and inability to place distal extension without covering renal arteries or parallel endografting approach (A and B). Coiling and Onyx® used to treat type I endoleak (C). EndoAnchors implanted to enhance durability of distal seal and prevent future complications (D). Final angiogram shows the successful sealing of type Ib endoleak and re-established aneurysm exclusion (E).

to deploy, thereby shortening the procedure. This probably makes the procedure safer than placing a stent in the renal arteries and adding a largely unneeded dimension of complexity to the repair. I do believe in giving the highest-quality repair at the outset to minimize complications both early and late and eliminate, if possible, the need for any secondary interventions.

What stent grafts are most conducive for EndoAnchor therapy?

I know many endografts have the ability to use EndoAnchors that are compatible, whether you're using grafts from Medtronic, Cook Medical, or Gore & Associates. If you considering using EndoAnchors for any other stent graft, they may not be compatible. You have to look at the IFU (instructions for use). This is, for the most part, a technology that can be used with the majority of stent grafts. For me, I rely on Endurant II and IIs. I've utilized EndoAnchors with both Cook Medical and Gore & Associates, and in my experience they work equally as well with both of those. The Aptus Heli-FX EndoAnchor system gives you that tactile, haptic feedback you need as an operator to be precise. If you utilize an endograft that is on-label with EndoAnchors, then I do believe that you'll find the added benefit of their use in certain cases to achieve a better outcome.

What training is necessary? How do you train fellows and physicians new to using EndoAnchors?

Aptus is now with the Medtronic family and they have great staff dedicated to help with training for novel use. They can do a physical device demonstration, which is actually easier to do than a computer simulation. The technology is that simple. One advan-

tage, especially in a cost-conscious world, is that it doesn't take a lot of time to deliver and implant EndoAnchors. We know from the ANCHOR registry EndoAnchors take about 15 minutes to deploy.

The nice thing about this device system is how intuitive it is to use. It's actually very, very easy. You don't have to be a technical genius. The Heli-FX system's radiopaque markers are highly visible on fluoroscopy and implants smoothly with motorized controls. You'll find it's highly trackable even through tortuous vessels. Positioning and repositioning can be very precise. The guide has a very articulate adjustable tip capable of a high degree range of motion so you can get to pretty much anything. Once the desired deflection angle is achieved, it can keep that angle. Once you get in place, it's a simple two-stage deployment for the EndoAnchor itself.

Once they've completed Medtronic's training, I can have fellows and other physicians I've brought in who want the experience to deploy EndoAnchors during an actual case. It's easy to train fellows and physicians new to this and to get the staff efficient at loading the Applier to be ready at a moment's notice. The learning curve isn't steep at all. You become very accurate to guiding the EndoAnchors exactly where you want up the right or left side. Using both the right and left groins in a highly angulated neck with very tortuous iliac vessels can give you a more ergonomically comfortable position to feel the Guide on your hand for EndoAnchoring the graft to the aorta. I like to call it just suturing. It gives me the opportunity to extend my hand and place the sutures with my hand.

How do you see the role of aortic centers, and in what applications is EndoAnchor therapy a must? Rupture cases? Can efficiencies be gained with EndoAnchors if used across disciplines?

This is a technology I believe should be on the shelf in most facilities. The need is there, and given the track record of EndoAnchors in ruptures, having them on-hand for physicians who know how to use them can be a real help in urban regionalized centers of excellence and urban or rural community centers. You don't need a hybrid suite to deploy them. Again, they really don't take much time at all to get up to speed on because they're so easy to use. Certainly, any interventionist who treats aneurysms will have the technical skill set to deploy EndoAnchors.

I think if you're going to be a comprehensive center of excellence for aortic disease, yes, you need to have these devices on-hand. I am often asked what percentage of cases I use EndoAnchors in. At present, I would say about 15% to 20% is a conservative answer. However, I do believe that this may increase in the future. I use them both for abdominal and thoracic cases. We typically know when we're going to use them beforehand. But if you don't have the time or ability to do a fenestrated 3-vessel repair, then yes, you want these on the shelf. Do you have to have 20 of them? Not necessarily. Par levels should be high for high-volume centers. But for lower-volume centers, just observe how often you utilize them. I wouldn't say they have to be used in every single case. What's the appropriate number? It depends. I've been using them for more than 5 years and I would venture to say that you can expect to use them in 25% to 40% of your complex cases if you're not doing ChEVAR or FEVAR.

What is the potential for EndoAnchors in solving late-term problems like type Ia or Ib endoleaks?

I have been successful in treating proximal type I endoleaks in EVAR with EndoAnchors. When I do utilize them in this circumstance, I combine it with IVUS. IVUS gives me the ability to see where there is no apposition of the stent graft to the vessel wall. Then I can place the EndoAnchors in this area to achieve the seal that the patient requires. I've also utilized this same technique to repair a type Ib in TEVAR. This has been very successful, and I believe is an important tool. I find that the distal neck of thoracic aortic aneurysms has the greatest risk of further dilatation, increasing tortuosity, and loss of a distal seal. I've been using EndoAnchors more frequently to prevent this problem in the future. ■

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EndoAnchors Advance Treatment of Aortic Aneurysms: Experience in a Community Hospital

BY MAZIN FOTEH, MD

CONFRONTING THE COMPLEX ANATOMY OF AAAs AND THE LIMITATIONS OF EVAR

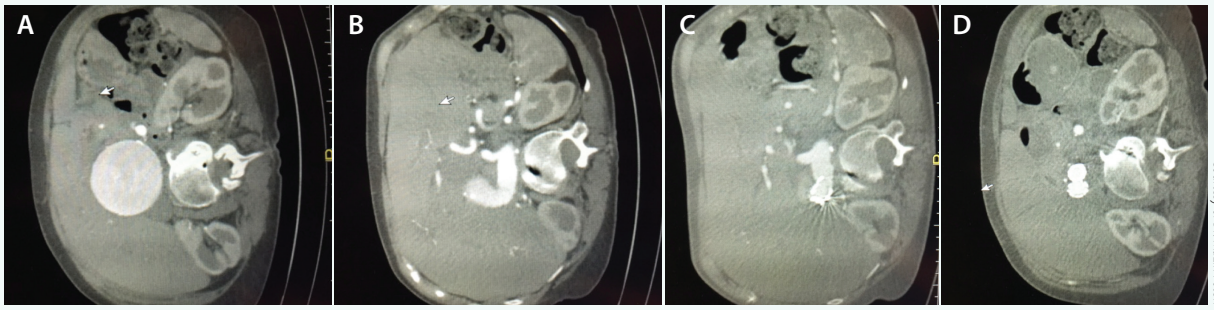
Even though endovascular aortic aneurysm repair (EVAR) has been embraced and widely adopted for being minimally invasive compared to open surgery, it has a number of shortcomings, as does open surgery. Both of these imperfect solutions may be appropriate to treat select abdominal aortic aneurysms (AAAs) and thoracic aortic aneurysms (TAAs). Evidence suggests open surgery may be a more durable long-term option compared to EVAR,[1-3] although reinterventions for open repair also carry a risk of mortality reported as high as 23%.[4] Yet, late complications are a persistent problem for EVAR, with a higher risk for rupture and reinterventions. Type Ia endoleak in hostile necks are too common both acutely and over time and must be managed, ultimately with either endovascular reintervention or conversion to open repair, possibly even explantation of the failed endograft. Despite technologic improvement in third-generation endograft design and decreased rates of type I and type III endoleaks, these problems continue in hostile neck anatomy. The crux of the problem is endograft sealing in challenging proximal aortic necks and maintaining that seal post-repair, even as aortic disease progresses.

In 2009, it was posited that no single approved endograft device would likely perform well in angulated necks.[5] At present, this may still be the case. For highly complex anatomies, there is a lack of durable, on-label, endograft-only solutions that can significantly ameliorate the problem of late complications with any graft generation.

Within the realm of infrarenal graft enhancements, active fixation appears to have had the greatest impact on long-term durability.[5-7] Data from the EUROSTAR registry, although reported in 2005, are still relevant to contemporary devices: active fixation using barbs in the infrarenal or suprarenal positions is associated with lower migration risk compared to devices without barbs.[8] While there are certainly applications for fenestrated and branched endograft systems, these devices carry an added dimension of complexity, not only in the number and types of components and their spatial endovascular deployment, but also in the time needed to deploy them. Procedure times are longer, which heightens risk for complications with greater doses of contrast, radiation exposure to the patient and physician, and their associated economic implications. After more than 2 decades, we are still faced with significant difficulty in resolving both early and late complications for hostile neck anatomy. For instance, the 2011 study by Schanzer and colleagues reported a large data set of 10,228 EVAR patients with sufficient preoperative and postoperative CT scans, of which 41% showed sac enlargement after 5 years. Of these, the rate of sac growth was significantly higher in patients treated outside the instructions for use (IFU). The authors concluded the use of endografts outside their respective IFUs was rampant, resulting in a high rate of sac enlargement and elevating concern for aneurysm rupture.[9]

EndoAnchor therapy has been reported as safe, feasible and effective in treating early and late type I endoleaks and augmenting the seal and fixation of stent grafts, as a prophylaxis for future seal complications.[10] This capability led to the approval of the Aptus™ Heli-FX™ EndoAnchor™ System to be used in approved endografts in both the United States and

CASE ONE



Courtesy of Dr. Mazin Foteh

EndoAnchors used as a prophylactic adjunct to address concerns for postoperative disease progression in a patient with complex aortic neck anatomy and large AAA with high-rupture risk. Preoperative CT demonstrates large AAA and high infra-renal neck angulation (A and B). One-year postoperative CT demonstrates aneurysm exclusion and significant sac regression (C and D).

Europe (listed previously in this supplement). Data from ANCHOR (Heli-FX Aortic Securement System Global Registry), the prospective, multicenter registry of patients undergoing EVAR adjunctively treated with EndoAnchor therapy, showed ANCHOR patients had notably more challenging neck anatomy than the general EVAR population.[11] When compared to EVAR patients described in the aforementioned 2011 paper by Schanzer and colleagues, ANCHOR patients had, on average, notably larger proximal aortic neck diameters and shorter neck lengths.[11] Speziale et al confirmed in a 2014 study that the presence of more than one proximal neck risk feature is associated with higher rates of complications and reinterventions.

Revision cases have become increasingly common in modern-day practices. As the general population ages, more time has passed from initial repair, allowing for greater aortic disease progression.[12] To say this more simply, patients are outliving their disease and repairs. Lastly, early graft failure with open conversion is not a benign risk. Ferrero et al reported in their single-center experience that early graft explanation carried a mortality risk of 50% and approximately 20% for late conversions.[13]

Lifestyle factors play a large role in the progression of aortic disease and aneurysm development, since it is well-known that persistent hypertension and smoking contribute to late changes in aortic disease progression.[14] High-risk anatomical factors are a marker for aortic disease progression and ultimate EVAR failure.[15] Likewise, multiple factors portend a risk of intraoperative type Ia endoleak. A recent study in 2016 showed that type Ia endoleaks were predicted with confidence by a lesser-known measure of aortic curvature along with the more well-known risk of significant aortic neck calcification. In fact, aortic curvature appears to be a better predictor of intraoperative type Ia endoleak than neck angulation.[16] Any improvements to bolster current EVAR techniques are clearly welcome and may mitigate late complications while improving outcomes.

Importance of Active Fixation

Just as the advent and adoption of active fixation found success in newer-generation stent grafts, EndoAnchor therapy presents a unique active fixation adjunct to endovascular endografting. In fact, the success of the open surgical anastomosis rests in the buttressed nature of hand-sewing the sutures to reach to the external layer of the aorta: the adventitia. In a similar fashion, EndoAnchors were designed to securely fix the endograft to the aorta's adventitial layer from within by penetrating the intima and media layers,[17] thus creating a series of functional anchors that provide both radial and axial support just as with sutures. As demonstrated in a human cadaver study in 2012, EndoAnchors provide the strength and stability equivalent to or exceeding that of a surgical anastomosis for withstanding large blunt hemodynamic and anatomically imposed forces.[18] The clinical experience of EndoAnchor therapy is approaching a decade of use and is broadly available in both the United States and Europe. Published reports show the rationale for EndoAnchor use, which includes improving proximal fixation of an endograft,[19] obtaining more complete graft apposition,[19,20] and overcoming graft nonalignment issues in TAAs to facilitate seal.[21]

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The Role of EndoAnchors in EVAR Practice for AAAs

Where might EndoAnchors fit in practice? Figure 1 illustrates one approach to treating complex AAAs. The most obvious situations where EndoAnchor therapy could augment and improve outcomes are in complex aortic neck anatomies. Hostile neck features run the gamut of short, highly angulated, and/or tapered configurations. However, less subtle findings, including thrombus and dense calcium deposition, are also predictors of early failure and ultimate rupture.[15] Prior to the advent of EndoAnchor therapy, more complex treatment options have included open surgical repair, fenestrated repair, or parallel endografting. Now, EndoAnchors in concert with a compatible stent graft are a viable option and promise a simpler procedure to consider for patients needing elective or emergency repair.[10,22-25]

Less obvious situations may include young patients who are not candidates for open repair and who need a permanent fix. If a patient is young, relatively healthy, and has a long-term life expectancy, but the patient has factors that preclude open repair or the patient refuses open repair, EndoAnchors with a standard EVAR approach may be an appropriate option. Furthermore, if the patient is of advanced age, has a short-term life expectancy, has numerous comorbidities, and is not a strong candidate for fenestrated endovascular repair (FEVAR), EndoAnchors with a standard EVAR approach may be an appropriate intervention.

After any aortic procedure, then the challenge of patient compliance to imaging surveillance protocols begins. A 2016 study by AbuRahma and colleagues reported that of 565 patients, 57% were noncompliant, a disconcerting result. It was notable that subgroups of patients were created to compare compliance between patients with hostile neck anatomy (neck angle exceeding 60°, n = 251 [48%]) compared to patients with favorable neck anatomy (275 [52%]). Noncompliance of patients with hostile neck anatomy was significantly higher compared to those with favorable neck anatomy (64% vs 50% noncompliance; $P = 0.0007$).[26]

There are several potential reasons for noncompliance in addition to patients residing in remote geographies relative to their aortic center. Patients may have ambulatory challenges, advanced age, cognitive decline and comorbid disease. There may be insufficient family and/or caregiver support. For patients identified to be potentially noncompliant to surveillance, EndoAnchor therapy applied in the primary repair may perhaps increase physician confidence in the durability of the procedure.

It must also be noted that there are also inherent risks with standard follow-up imaging surveillance, such as cumulative radiation exposure posing a risk for malignancy and the cumulative impact on renal function from contrast, particularly in the elderly and patients with renal insufficiency. A 2016 study reported risk factors associated with renal decline in 135 EVAR patients, of which 25 (19%) were recognized to have a

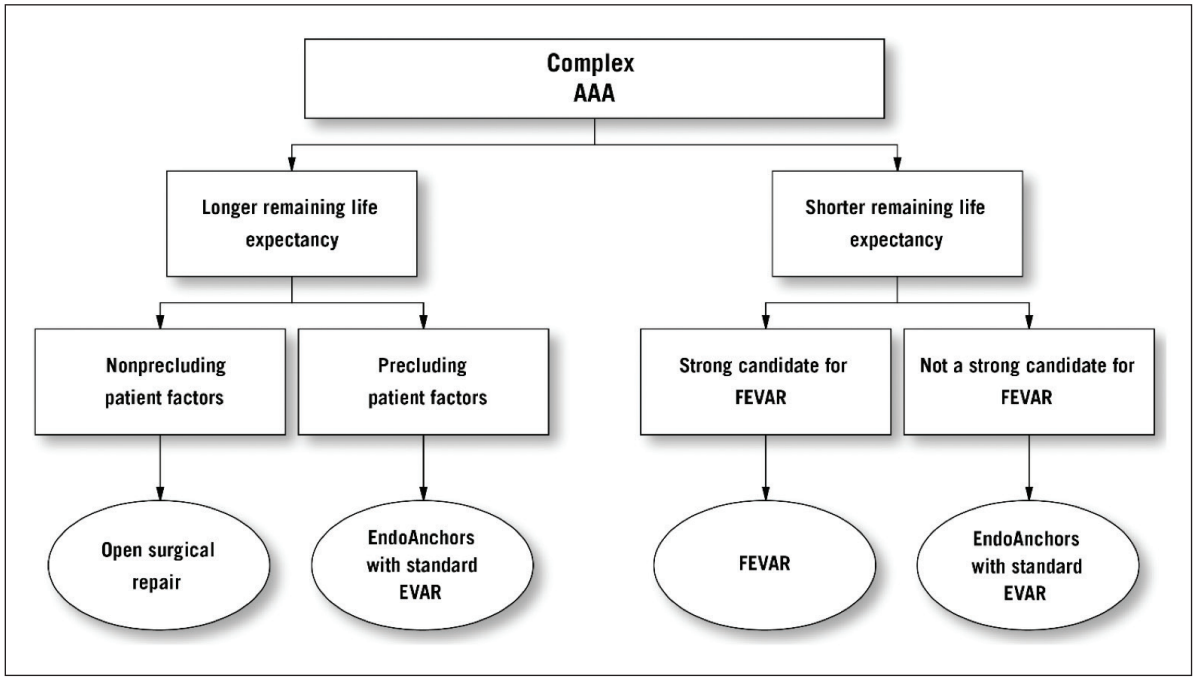
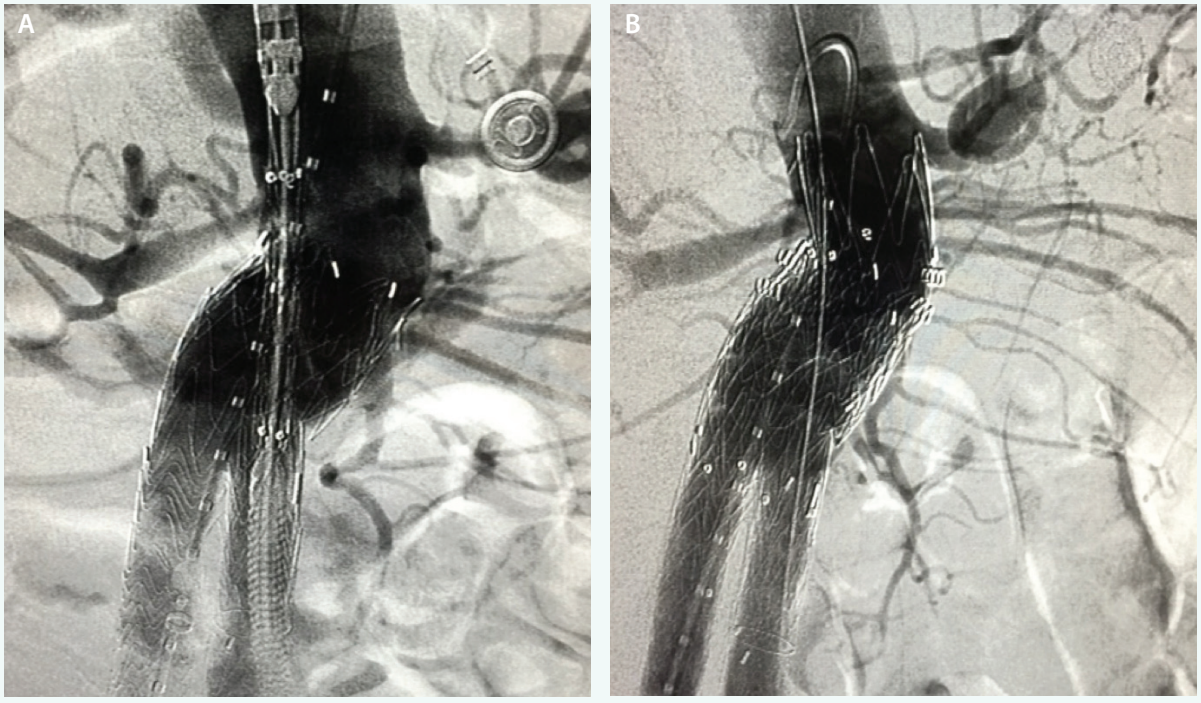


Figure 1. EndoAnchor therapy in the EVAR treatment algorithm.

CASE TWO



Courtesy of Dr. Mazin Foteh

EndoAnchors used to treat a late type Ia endoleak and enhance the durability to address concerns for further complications. Initial angiogram shows type Ia endoleak (A). Final angiogram demonstrates successful sealing of type I endoleak after implantation of cuff and EndoAnchors (B).

significant progression in chronic kidney disease. Independent risk factors for this decline included a diseased-thrombus laden aorta, lack of oral ß-blocker administration, renal insufficiency, and an elevated creatinine > 1.4 mg/dL.[27] A 2014 study of late rescue of proximal endografts reported that chronic renal impairment at the time of the procedure was an independent risk factor for late failure.[28] Less frequent imaging follow-up could likely be of benefit in these patients at risk for nephropathy.

ENDOANCHOR EXPERIENCE AT A COMMUNITY AORTIC CENTER

Cardiothoracic and Vascular Surgeons (CTVS), Austin, Texas

EndoAnchors are being used in the many cases at CTVS, a growing community aortic center in Austin, Texas. Because of their widespread use, our center was interested in tracking EndoAnchor cases and evaluating outcomes over time. Therefore, our institution initiated a site-based series of EVAR use with EndoAnchors independent of the ANCHOR registry. Imaging surveillance was site-reviewed by the author as primary investigator and a radiologist.

A total of 37 patients were treated with the Aptus HeliFX EndoAnchor Systems during abdominal or thoracic endovascular repair (EVAR/TEVAR) from April 2013 to March 2016. Of those 37 patients, 36 underwent EVAR for an AAA and 1 TEVAR case was performed for a TAA. An average of 5.6 ± 1.1 EndoAnchors were deployed for each case (range, 4–9). In 6 patients (16.2%), EndoAnchors were not initially planned but were used at the discretion of the operator. Our treatment algorithm has evolved over time. As our comfort with the device increased, its utility became more apparent. Now, our practice has evolved to include EndoAnchors in the planning phases for EVAR, particularly when we are treating patients with hostile neck anatomies.

Three revision cases were performed (8.1%). The first, a ruptured AAA with observed graft migration on May 1, 2013. The other two patients both presented with a type I endoleak and graft migration (August 1, 2013 and November 14, 2014). The mean age was 76.3 ± 7.9 years (range, 62–92; median, 77 years). The vast majority of patients had a history of coronary artery

disease (64.9%) and hypertension (97.3%); 27% had documented diabetes mellitus (27%). Mean creatinine values were 1.46 ± 0.44 mg/dL (range, 0.8–2.5 mg/dL).

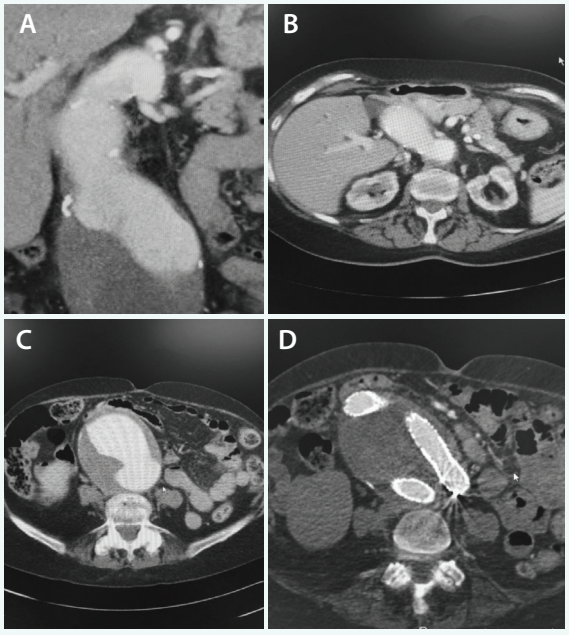
Among the entire cohort, notable anatomic characteristics were significant aortic calcification observed in more than half of patients (51.4%), ranging from 25% calcification to circumferential calcified aortas. A high-risk aortic neck was identified in 31 patients (83.7%), one case of which included a ruptured aneurysm. The most frequent indications for EndoAnchor use included a short neck in 10 patients (27.0%), high neck angulation in five patients (13.5%), and an intraoperative type I endoleak in four patients (10.8%). Average aortic neck diameter was 27.3 ± 5.5 mm (range, 18–38 mm).

We observed excellent early outcomes and over a mean follow-up of 6.5 months (N = 37). Technical success was achieved in all patients with no notable intraoperative complications and no endoleaks viewed intraoperatively or postoperatively over follow-up. All patients have had at least 1 month of follow-up and 24 patients have been followed for 6 months or more (maximum of 23 months). Over follow-up, there were no reinterventions or conversions to open surgical repair. Among all 37 patients observed over follow-up, there were no cases of aneurysm sac growth reported. Notable sac regression was observed in the majority of patients (56.8%), and sac size remained stable in the other 43.2% of patients. Overall, our experience with EndoAnchor use during EVAR has been overwhelmingly positive and corroborates with the overall findings from the ANCHOR registry. Long-term durability needs to be proven over time, and we plan to report follow-up of these patients and the addition of future primary and revision cases to document EndoAnchor use as an adjunct for EVAR and TEVAR.

EXPANDING THE CAPABILITIES OF COMMUNITY AORTIC CENTERS

The benefits in building a comprehensive aortic center include serving a greater number of patients who otherwise might not be treated at the community level, obviating the need for referrals to high-volume centers and potentially reducing the number of type I endoleaks and revision cases. Community centers are also closer to the majority of patients than regionalized centers, to which patients must travel longer distances for care. Bolstering the capabilities of community aortic centers, including adding EndoAnchors as part of the interventional armamentarium, can thereby provide local care to patients who would have otherwise been referred.

CASE THREE



Courtesy of Dr. Mazin Foteh

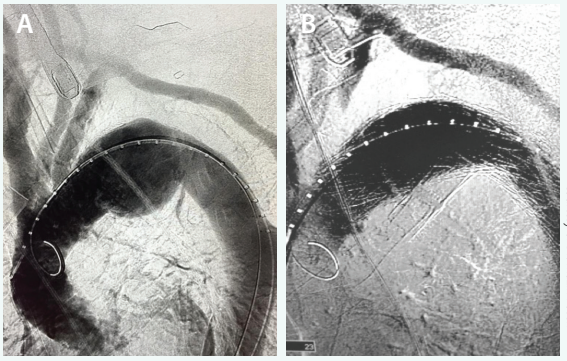
EndoAnchors used as a bailout for an intra operative type Ia endoleak in an emergency EVAR for ruptured AAA. Preoperative CT demonstrates ruptured AAA with large 9-cm aneurysm and complex aortic neck (A–C). EndoAnchors successfully treat type I endoleak, as demonstrated in postoperative CT (D).

There are many tools required in building a comprehensive aortic center, of which being EndoAnchor therapy-ready is but one consideration. It is a significant task with a large investment in time, expertise, and resources. At our institution, we are dedicated to institutional growth and expanding our aortic center services. We are currently pursuing expanding our services in the three following areas:

(1) Investments in infrastructure,
(2) Streamlining protocols, and
(3) Selectively expanding endovascular inventory.

On the infrastructure front, we are undertaking a hybrid suite retrofit to include a new Philips image fusion C-arm, which can fuse CT angiography with on-table fluoroscopy to allow us to treat more complex cases on the table while reducing radiation exposure to the patient and team. It will also allow us to do on-table three-dimensional CT scans for the diagnosis of acute type A and B dissections and ruptures. This advanced imaging will expedite care and improve outcomes. The patient can be moved directly from the emergency department to the hybrid operating

CASE FOUR



Courtesy of Dr. Mazin Foteh

EndoAnchors used as a prophylactic adjunct in complex TEVAR to enhance durability and address concerns for future complications. Initial angiogram shows complex proximal neck (A). Final angiogram confirms successful exclusion of TAA postdeployment of graft and EndoAnchors in proximal seal (B).

room suite to have CT scans performed expeditiously, which translates into faster "door-to-repair" times. It must be noted that a hybrid suite is not required to deploy EndoAnchor therapy (the topic for discussion of this issue) or a number of other endovascular techniques. There has been debate whether hybrid suites are a luxury or necessity.[29] As an institution, we have elected to invest in a hybrid suite retrofit of existing our OR space with guidance from the literature.[30,31] An updated hybrid suite will help advance our community hospital's capabilities at treating more complex anatomy, harness our multidisciplinary expertise, and be in a better position to improve patient and health worker safety.

With this infrastructure in place, CTVS is also streamlining structured protocols for acute aortic pathologies, including rupture. Adoption of such rupture protocols has been recognized to improve outcomes.[32,33] We have found EndoAnchor therapy is an important on-hand treatment option for emergent cases and bailout to prevent conversion to open repair.

We have also selectively increased our on the shelf inventory of endografts, not only increasing supply to match a greater demand, but also to allow us to perform more complex anatomic cases without needing a manufacturer representative to be present. Inventory management is necessary to maintain capabilities for effective elective and emergency aortic aneurysm repair. The Aptus Heli-FX and Heli-FX Thoracic EndoAnchor systems occupy an important place in our inventory since they are used in many cases with compatible endografts. Unlike most endograft components, Heli-FX is a single-platform technology designed to accommodate a large range of anatomies, making it conducive to judicious inventory management.

Expanding the capabilities of a community center can help treat more patients who may be otherwise referred to regionalized aortic centers of excellence. There is a tendency nationally for physicians to seek opportunities that keep patients for the obvious benefit of geographic proximity for the patient and ability for community practices to manage their patients locally. In my view, EndoAnchors can enable more physicians to treat not only simple, straightforward EVAR cases with a confident, potentially improved long-term result but also more complex cases.

Any community aortic centers can likely benefit from integrating EndoAnchor therapy into their interventional armament to improve their patients' health outcomes. Its ease of use and proven outcomes has generated confidence that this unique intervention can improve the durability of standard EVAR. The learning curve is low. It may take up to five cases to reach one's most comfortable familiarity and efficiency in deploying EndoAnchors. In the ANCHOR registry, average total deployment time has been reported at roughly 16 minutes, which includes a mean of five EndoAnchors implanted as a prophylactic adjunct to primary EVAR.[11] This is comparable to our center's experience. In training other physicians in EndoAnchor deployment, I've found physicians new to the therapy tend to want to use them first on a tough case, say a revision case, to rapidly gain experience similar to how surgeons new to pedal access may opt for tough cases first. Contrary to current adoption trends, I recommend finding the opportunity to use them in a relatively simple, straightforward case first to become accustomed to the device delivery system and deployment, and only then tackling a tougher case.

In our community center experience, EndoAnchors offer a simple option with ease of deployment that does not appreciably extend procedure time and improves results. EndoAnchor therapy can effectively enhance durability of a standard EVAR approach for complex cases that may have previously called for observation, open surgery, or more complex interventions. Overall, EndoAnchor therapy will complement and bolster a community aortic center's capabilities in providing more comprehensive care for patients, especially those with complex anatomies, and avoid the need for costly referrals. ■

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INDICATIONS FOR USE:

The Aptus Heli-FX™ EndoAnchor™ System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Aptus Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion. The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e. repair) procedure.

Contraindications

Treatment with the Aptus Heli-FX EndoAnchor System is contraindicated for use in the following circumstances:

- In patients with known allergies to the EndoAnchor Implant material (MP35N-LT)
- In conjunction with the Endologix Powerlink® endograft

Warnings

- The long term performance of the EndoAnchor has not been established. All patients should be advised endovascular aneurysm treatment requires long-term, regular follow-up to assess the patient's health status and endograft performance, and the EndoAnchor does not reduce this requirement.
- The EndoAnchor implant and the Aptus Heli-FX EndoAnchor System have been evaluated via in vitro testing and determined to be compatible with the Cook Zenith®, Cook Zenith TX2®, Gore Excluder®, Gore TAG®, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™, and Medtronic Valiant™ endografts. Use with endografts other than those listed above has not been evaluated.
- The performance of the EndoAnchor has not been evaluated for securing multiple endograft components to one another. Without EndoAnchor securement into aortic tissue, this could result in graft fabric damage, component separation, and resultant Type III endoleaks.
- The performance of the EndoAnchor has not been evaluated in vessels other than the aorta. Use of the EndoAnchor to secure endografts to other vessels may result in adverse patient consequences such as vascular perforation, bleeding, or damage to adjacent structures.
- The Aptus EndoAnchor has not been evaluated for securing multiple anatomical structures together. Such use could result in adverse patient consequences such as vascular perforation, bleeding, or embolic events.

MRI Safety and Compatibility

- The EndoAnchors have been determined to be MR Conditional at 3T or less when the scanner is in Normal Operating Mode with whole body averaged SAR of 2 W/kg, or in First Level Controlled Mode with a maximum whole body averaged SAR of 4 W/kg.
- Please refer to documentation provided by the endograft system manufacturer for MR safety status of the endograft system with which the EndoAnchors are being used.

Potential Adverse Events

Possible adverse events associated with the use of Aptus Heli-FX EndoAnchor include, but are not limited to:

- Aneurysm rupture
- Death
- EndoAnchor embolization
- Endoleaks (Type III)
- Enteric fistula
- Failure to correct/prevent Type I endoleak
- Failure to prevent endograft migration
- Infection
- Renal complications (renal artery occlusion/dissection or contrast-induced AKI)
- Stroke
- Surgical conversion to open repair
- Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage, including dissection, perforation, and spasm

Please reference product Instructions for Use for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner. See package inserts for full product information. EndoAnchor implant locations should be based upon a detailed examination of the preoperative CT imaging in cases involving irregular or eccentric plaque in the intended sealing zone(s). EndoAnchors should be implanted only into areas of aortic tissue free of calcified plaque or thrombus, or where such pathology is diffuse and less than 2mm in thickness. Attempting to place EndoAnchors into more severe plaque or thrombus may be associated with implantation difficulty and suboptimal endograft fixation and/or sealing.

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