Sponsored by Medtronic

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).

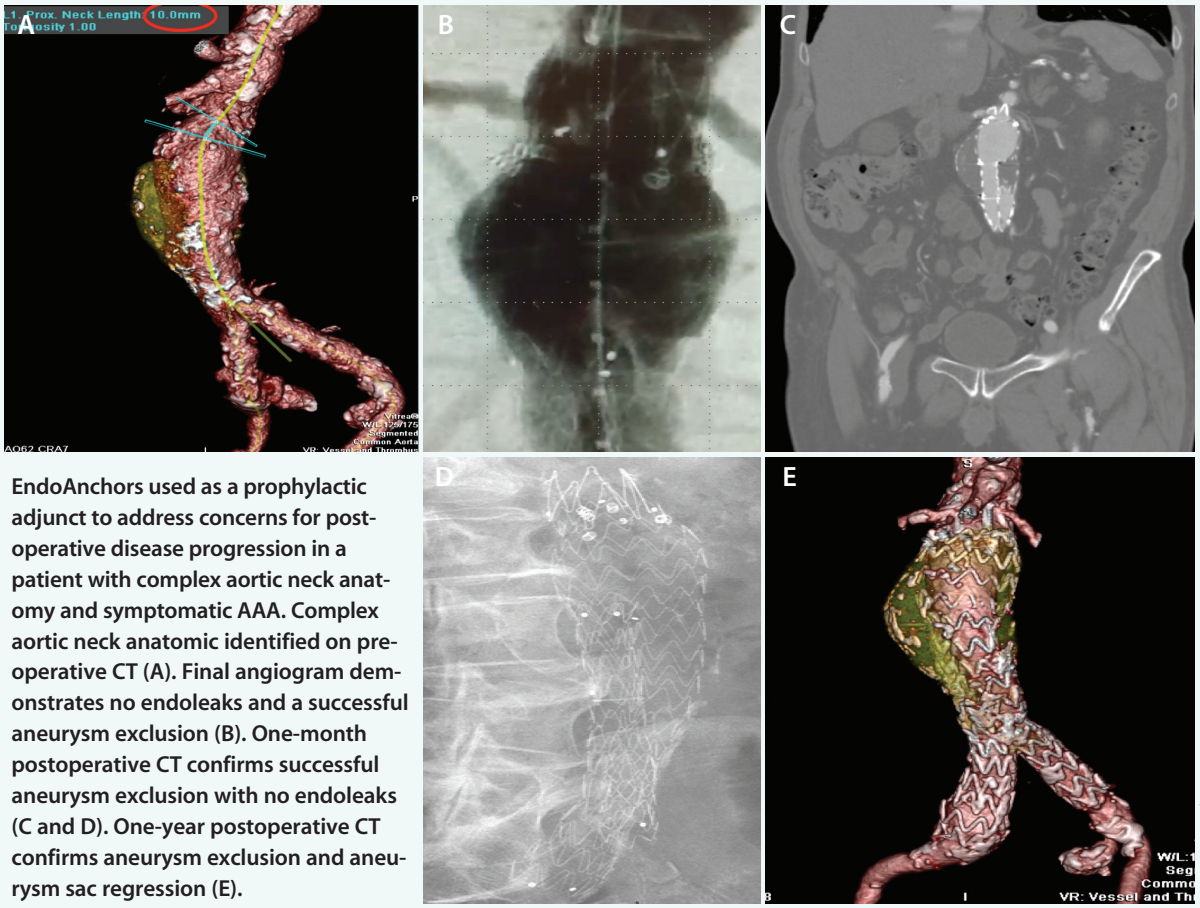
What is your history with EVAR treating complex anatomy?

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

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).

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.

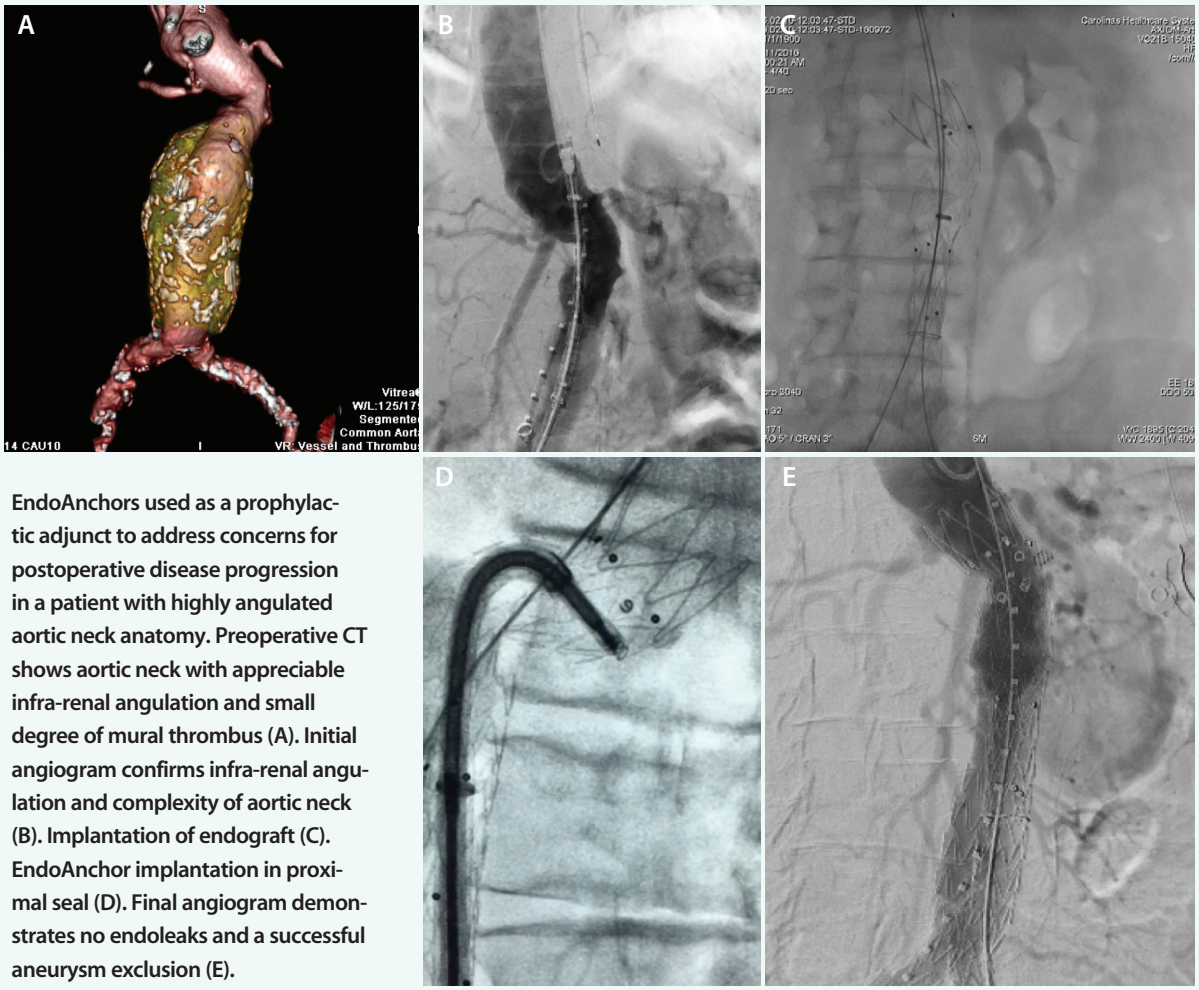
The intervention must last for the length of the patient's life. Since the overall goal is long-term survival, you need a durable procedure to achieve good outcomes both acutely and midterm to 5 years. If someone is of advanced age (let's say older than 90 years) and has a short neck, I'm going to avoid 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 infra-renal 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.

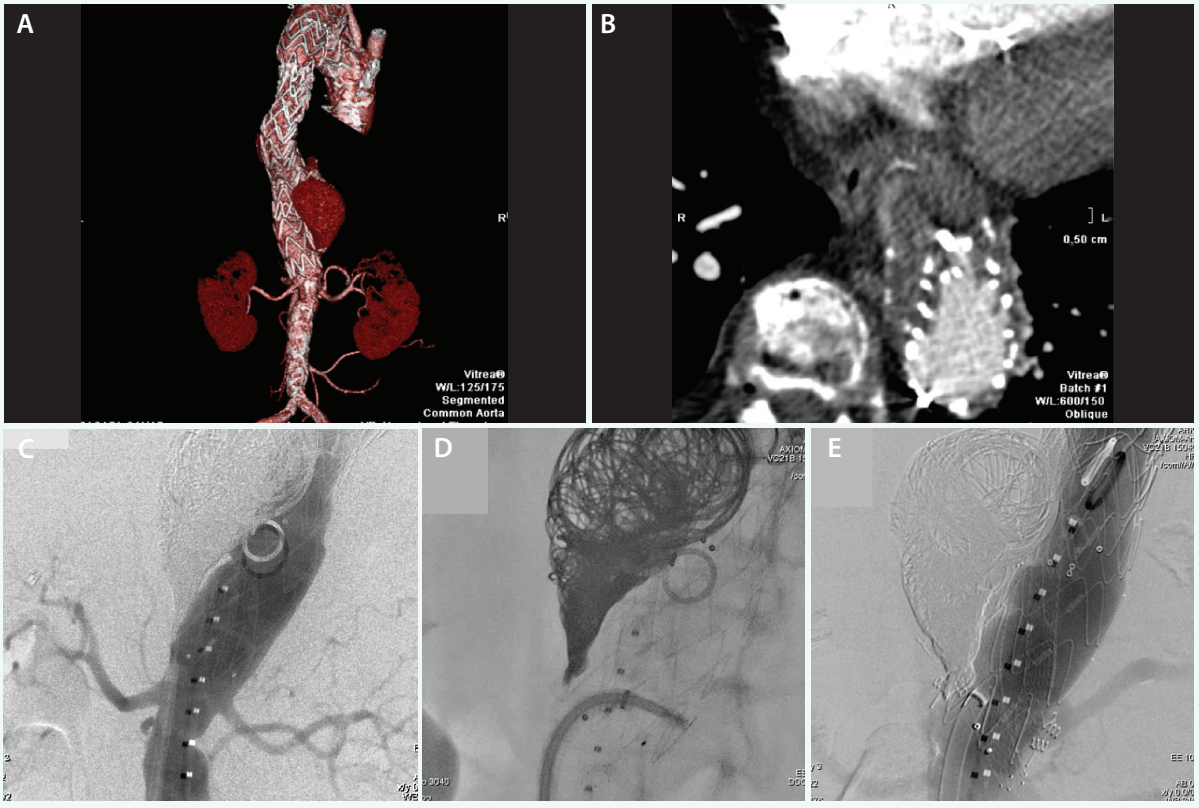
With EndoAnchors, it's not all about complex anatomies. The types of patients I believe it's actually counterintuitive for most physicians to use EndoAnchors are those with relatively simple anatomies, patients who are healthy, young, and resilient. They'll live a long period of time, decades longer 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

Sponsored by Medtronic

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. ■

Frank R. Arko III, MD
Director
Endovascular Surgery
Co-Director
Aortic Institute, Carolinas Medical Center
Sanger Heart and Vascular Institute
Charlotte, North Carolina