

# Rethinking EVAR: Is Longer Seal Zone the Only Answer for Enhancing Durability?

Mimicking an interrupted anastomosis via an endovascular approach.

BY ROSS MILNER, MD, FACS

Endovascular aneurysm repair (EVAR) has continued to evolve since Dr. Juan Parodi treated the first patient in Buenos Aires, Argentina, almost 30 years ago with an intraluminal covered stent graft.<sup>1</sup> Since that time, industry-sponsored clinical trials and physician-led trials (eg, OVER, EVAR-1, DREAM) have shown the safety of EVAR in the early perioperative period compared to open surgical repair (OSR).<sup>2-4</sup> Longer-term follow-up, however, reveals concern that lifelong imaging surveillance of treated patients is necessary to identify endoleaks and/or device failure that can lead to aneurysm expansion and a recurrent risk of rupture.<sup>2-4</sup>

## DEVICES AND IMPROVEMENTS

The newer generation of devices used to treat abdominal aortic aneurysms has continued to improve since the first-generation devices gained FDA approval in the United States in the late 1990s. The device improvements have decreased the possibility of failure but have not completely eliminated the previously mentioned risks. Therefore, treating physicians and device manufacturers continue to investigate alternative mechanical solutions, such as chimneys and fenestrated repair (FEVAR), to solve complex patient problems of anatomy, biology, and physics. Chimney FEVAR and FEVAR, however, require more complex interventions with an associated inherent risk to the patient.

## OPEN SURGICAL REPAIR

OSR has an increased mortality risk to patients in the initial postoperative period (almost a 5% mortality rate in the randomized studies as compared to approximately 1.6% for EVAR).<sup>2-4</sup> Nevertheless, a sutured anastomosis used in OSR continues to be regarded as the gold standard for any vascular repair. Sutured anastomoses can fail over time, but this risk is relatively low. Treating physicians would like to incorporate the stability of an

open, sutured repair with the safety and technological advance of EVAR, combining the benefits of these two aneurysm repair techniques. Endovascular sutured aneurysm repair (ESAR) can combine the safety profile of EVAR with the possibility of gaining the durability of a sutured anastomosis seen in OSR.

## HELI-FX™ ENDOANCHOR™ IMPLANTS IN COMPLEX ANATOMY

I was previously skeptical about the use of Heli-FX™ EndoAnchor™ implants (Medtronic) in complex anatomy.<sup>5</sup> Strong proponents of FEVAR, too, remain skeptical of this short-neck approach. In contrast, EndoAnchor™ implants offer a treatment modality that does not involve cannulation and stenting of the renal arteries and creates an endovascular suture line that provides endograft and aortic neck stability. In addition, data are growing for the success of this approach. In this article, I review the current indications for the use of EndoAnchor™ implants and provide a brief summary of outcomes data to date.

## INDICATIONS (STANDARD AND HOSTILE NECK)

EndoAnchor™ implants can be used with many of the current FDA-approved EVAR devices. The Endurant™ II/III stent graft (Medtronic) is the only device in which EndoAnchor™ fixation expands its indications. For all other stent grafts with which EndoAnchor™ fixation is compatible, the use of EndoAnchor™ implants does not change the current instructions for use for any given device in terms of aortic neck characteristics or anatomic requirements for safe use of the device. EndoAnchor™ implants are contraindicated with the AFX stent graft (Endologix) due to the risk of fabric injury. EndoAnchor™ implants have not been evaluated with the Ovation device (Endologix); however, the engagement with the polymer ring brings concern for risk of injury.

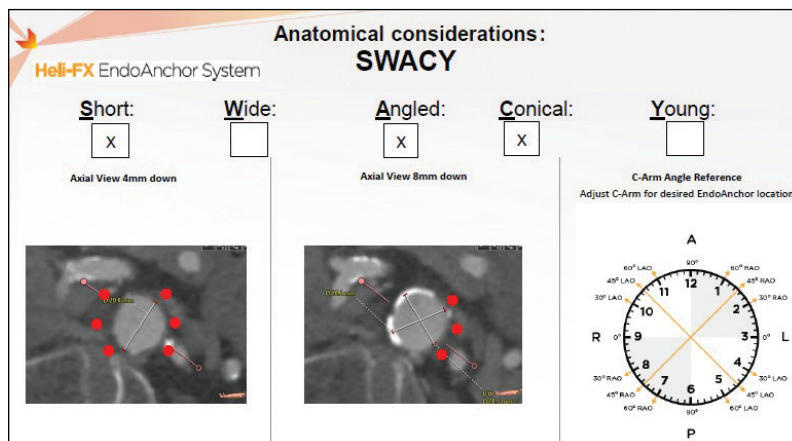


Figure 1. Illustration of SWACY and its use in decision-making for EndoAnchor™ implants.

### Aortic Neck and Patient Characteristics

The term SWACY is commonly used to describe aortic neck and patient characteristics that may benefit from the addition of EndoAnchor™ implants to the approved devices. SWACY is an acronym for short (S), wide (W), angulated (A), conical (C), and young (Y) (Figure 1). SWACY represents the anatomic characteristics that make EVAR prone to fail and can lead to a type Ia endoleak. Young patients need as durable a repair as possible, and this is a reasonable indication to utilize the device. In my current practice, I have been using the technology for patients with wide necks. I select an aortic device that is < 30 mm in diameter due to the risk of late type Ia endoleak, as demonstrated in the literature, for larger diameter aortic necks (Figure 2).

### Number of Implants

The suggested minimum number of EndoAnchor™ implants is based on the aortic diameter, which has demonstrated optimal outcomes when they “gain purchase” into adventitia. A minimum of four EndoAnchor™ implants

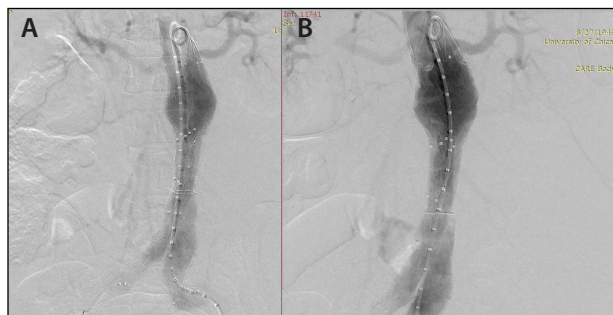


Figure 2. Patient who presented with a ruptured aneurysm and required a 32-mm Endurant™ II/IIIs stent graft (A). EndoAnchor™ implants were used due to the challenging neck anatomy and larger-diameter device (B).

are recommended for a native aortic diameter ≤ 29 mm. A minimum of six EndoAnchor™ implants are suggested for an aortic diameter > 29 mm. A treating physician can place as many EndoAnchor™ implants as they would like for a given case, as each cassette contains 10 EndoAnchor™ implants.

### Implant Placement

The goal of EndoAnchor™ placement is to gain circumferential EndoAnchor™ implants, penetrate the aortic endograft, and “gain purchase” into the adventitia of the aorta and mimic OSR. The use of the deflectable sheath in combination with different oblique

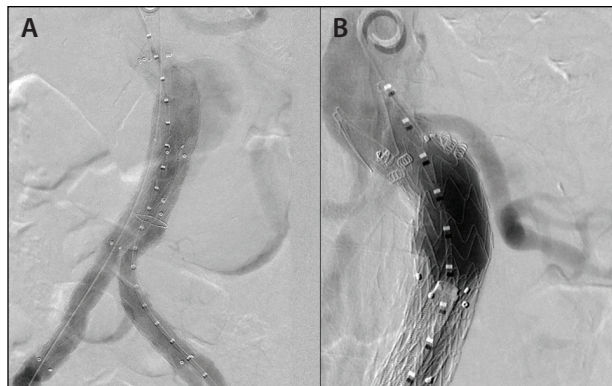
imaging techniques allows this circumferential placement. The EndoAnchor™ is 4.5 mm in length and will easily penetrate this distance without injuring surrounding structures.

The deployment system has excellent feedback for safe placement of the EndoAnchor™ implants with the two-stage system; however, it is unable to provide feedback on the penetration to the level of the adventitia. The best mechanism to make this assessment is using intraoperative intravascular ultrasound or on the initial postoperative CT scan. I would highly recommend critical assessment of the EndoAnchor™ implants on CT scan imaging as the interventionalist gains experience to confirm that he or she is accomplishing the goal of additional fixation and seal that mimics open repair.

### Expanded Indication

In addition to the standard indication, Endurant™ II/IIIs stent graft has been approved for a short neck indication with EndoAnchor™ implants (Figure 3). The ANCHOR registry has collected data on both primary cases and revision cases using EndoAnchor™ implants with multiple different stent graft devices. As part of the ANCHOR registry, a cohort of 70 patients were critically analyzed that combined the Endurant™ II/IIIs stent graft and Heli-FX™ system. This group of complex patients had aortic necks < 10 mm and down to 4 mm in length. The results were excellent in terms of 1-year outcomes related to type Ia endoleak (1.9%, 1/53 patients) and device migration (0%, 0/41 patients).<sup>\*</sup> Based upon these results and the full data set, the FDA approved this short neck therapy utilizing the combination of the Endurant™ II/IIIs stent graft and EndoAnchor™ implants.

The short neck indication has only been evaluated and approved with the Medtronic Endurant™ II/IIIs stent graft system and is not approved for other commercial stent grafts. The short neck approach with the Endurant™ II/IIIs



**Figure 3.** Short-neck EVAR in an 82-year-old patient who is a poor surgical risk. EndoAnchor™ implants were planned due to her SWACY evaluation (6-mm neck). A type Ia endoleak (A) resolved with placement of EndoAnchor™ implants (B).

stent graft and EndoAnchor™ implants is a valuable option for patients with small renal arteries or difficult renal artery anatomy. In addition, the lower profile of this approach (compared to FEVAR) may be a better option in patients with challenging iliac artery access.

### CLINICAL DATA: THE ANCHOR REGISTRY

The majority of valuable data concerning the efficacy of EndoAnchor™ implants comes from the original ANCHOR registry that was initiated by Aptus Endosystems and continued by Medtronic after their acquisition of the technology. The registry included patients treated in the United States and Europe. The registry is led by Dr. William Jordan (Emory University Hospital, Atlanta, GA) and Dr. Jean Paul de Vries (Groningen University Hospital, Groningen, the Netherlands).<sup>5,6</sup>

Two important concepts that have resonated with me have been published based on data from the primary treatment arm of the ANCHOR registry. These concepts demonstrate part of the efficacy of an endovascular repair: (1) the residual aneurysm sac regression and (2) aortic neck dilation seem to be favorable when EndoAnchor™ implants are included as part of the treatment algorithm. The aortic endograft and aortic neck typically function as two separate entities that have competing forces.

The desired goal of the endograft and aortic neck seal zone is for them to function as one unit to prevent the aneurysm sac from becoming pressurized and placing the patient at risk of aneurysm rupture. The device typically wants to expand to its nominal diameter, however, and a diagnosis of an aneurysm in a patient already means that he or she has a dilating disease. Thus, the aortic neck wants to dilate over time in many patients.

The device is only able to dilate to its manufactured diameter. The aortic neck can continue to dilate. These

competing forces have potential to lead to treatment failure and the development of a type Ia endoleak.

EndoAnchor™ implants cause the two components, the endograft and aortic neck seal zone, to function as one unit and the desired therapeutic endpoint. In other words, the device is fixed to the aorta, and the aorta is fixed to the device when the EndoAnchor™ implants are used appropriately.

### Preliminary Data

This fixation and one-unit concept can potentially lead to complete depressurization of the aneurysm sac and prevent aortic neck dilation. The interface of the device and the aortic neck has not been well studied. At our institution, we have initiated studies using computer simulation models and finite element analysis to study the interfacial relationship between the endograft and the aortic neck seal zone.

Preliminary data have demonstrated that higher simulated blood pressures can lead to interfacial separation of the endograft and aortic neck seal zone. This finding is true even in an excluded aneurysm sac and appears to expose the residual aneurysm sac to systemic pressure for a period of time. This short-lived pressure exposure can lead to aneurysm sac expansion, although imaging studies may not show an obvious endoleak.

We need to complete more work to confirm this finding and apply our model to patients with EndoAnchor™ implants. This work will hopefully allow a comparison of the interfacial dynamics in patients with and without the one-unit concept.

### PUBLISHED STUDIES

Muhs et al recently published in the *Journal of Vascular Surgery* their cohort-matched analysis of patients treated with an endovascular repair and their outcomes related to residual aneurysm sac behavior at 2 years.<sup>7</sup> The study included a group of patients treated in the ANCHOR registry compared to a second group of patients treated without EndoAnchor™ implants over the same time frame. The two groups included patients treated with several different devices without a significant difference between device selections for the groups. There was no difference in the low type Ia endoleak rate between both groups in a challenging anatomy cohort. Despite these similarities, there was a significant difference in the residual aneurysm sac behavior. At 2 years, patients with EndoAnchor™ implants had an 81% reduction in aneurysm sac size as compared to only 49% in the non-EndoAnchor™ cohort ( $P = .01$ ). I believe these data are a clinical demonstration of the one-unit concept and the improved efficacy of aneurysm sac exclusion.



In addition, a recent publication shows increased patient mortality with a lack of aneurysm sac regression.<sup>8</sup> Longer-term follow-up will be important to confirm a sustained difference in outcome.

Tassiopoulos et al also published their work in the *Journal of Vascular Surgery*.<sup>9</sup> Using the ANCHOR registry, this group has performed an analysis of aortic neck dilation at 1 year after EVAR. Their work allows for the expected enlargement seen after the initial device implantation. They compare changes in neck diameter at the 1-month imaging and the 1-year imaging time points in patients treated with EndoAnchor™ implants. They are able to assess both positive and negative factors that affect aortic neck enlargement. One of the most important factors to prevent aortic neck dilation at 1 year is the number of EndoAnchor™ implants placed. I believe these data further reinforce the one-unit concept.

## CONCLUSION

EVAR technology has continued to improve since the original devices were FDA approved in the late 20th century. However, 21st century treatment requires durability and cost effectiveness. EndoAnchor™ implants allow EVAR to mimic the durability of OSR and provide the perioperative safety of the less invasive approach. Although skeptics have debated that greater seal zone is required for EVAR durability and that chronic neck dilatation is a concern, EndoAnchor™ implants provide a means to change the requirements for durability to one that mimics the inter-

rupted anastomosis. I believe the one-unit concept of the endograft and aortic neck will be valuable over the long term. Computer simulation modeling and longer-term follow-up of the ANCHOR registry data will provide the necessary knowledge to prove this concept. ■

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#### Endurant™ II/Endurant™ IIs Stent Graft System

**Indications:** The Endurant™ II/Endurant™ IIs bifurcated stent grafts are indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms. They may be utilized in conjunction with the Heli-FX™ EndoAnchor™ system when augmented radial fixation and/or sealing is required; in particular, in the treatment of abdominal aortic aneurysms with short ( $\geq 4$  mm and  $< 10$  mm) infrarenal necks (see Neck length definition below). The Endurant II stent graft system aorto-uni-iliac (AUI) stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients whose anatomy does not allow the use of a bifurcated stent graft. The Endurant II/IIs stent graft system is indicated for use in patients with the following characteristics:

- Adequate iliac or femoral access that is compatible with vascular access techniques, devices, or accessories
- Proximal neck length of
  - $\geq 10$  mm; or
  - $\geq 4$  mm and  $< 10$  mm when used in conjunction with the Heli-FX EndoAnchor system (bifurcated stent graft only)

**Note:** Neck length is defined as the length over which the aortic diameter remains within 10% of the infrarenal diameter.

- Infrarenal neck angulation of  $\leq 60^\circ$
- Aortic neck diameters with a range of 19 to 32 mm
- Distal fixation length(s) of  $\geq 15$  mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

**Contraindications:** The Endurant II/Endurant IIs stent graft system is contraindicated in:

- patients who have a condition that threatens to infect the graft.
  - patients with known sensitivities or allergies to the device materials.
- When used with the Heli-FX EndoAnchor system, the Endurant II/IIs stent graft system is also contraindicated in:
- patients with known sensitivities to the EndoAnchor implant materials.
- For contraindications regarding ancillary devices used with the Endurant II/Endurant IIs stent graft system, refer to the *Instructions for Use* provided with the device.

#### Warnings and Precautions

- The long-term safety and effectiveness of the Endurant II/Endurant IIs stent graft system has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and the performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or less than the recommended number of EndoAnchor system when used in short ( $\geq 4$  mm and  $< 10$  mm) proximal necks) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleaks may be required to undergo secondary interventions or surgical procedures.
- The Endurant II/Endurant IIs stent graft system is not recommended in patients unable to

undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use*.

- Renal complications may occur: 1) From an excess use of contrast agents. 2) As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.

- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.

- The safety and effectiveness of the Endurant II/Endurant IIs stent graft system has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

**MRI Safety and Compatibility:** Non-clinical testing has demonstrated that the Endurant II/Endurant IIs stent graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

**Adverse Events:** Potential adverse events include (arranged in alphabetical order): amputation; anesthetic complications and subsequent attendant problems (e.g., aspiration), aneurysm enlargement; aneurysm rupture and death; aortic damage, including perforation, dissection, bleeding, rupture and death; arterial or venous thrombosis and/or pseudoaneurysm; arteriovenous fistula; bleeding, hematoma or coagulopathy; bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); claudication (e.g., buttock, lower limb); death; edema; EndoAnchor system (for infrarenal EVAR procedures using the Heli-FX EndoAnchor system): partial deployment, inaccurate deployment, fracture, dislodgement, embolization, stent graft damage, modelling balloon damage; embolization (micro and macro) with transient or permanent ischemia or infarction; endoleak; fever and localized inflammation; genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection); hepatic failure; impotence; infection of the aneurysm, device access site, including abscess formation, transient fever and pain; lymphatic complications and subsequent attendant problems (e.g., lymph fistula); neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); occlusion of device or native vessel; pulmonary complications and subsequent attendant problems; renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting and/or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow; surgical conversion to open repair; vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection; vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death); vessel damage; wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

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

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.