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KEYS TO A DURABLE ENDOVASCULAR REPAIR

Experts share their views on managing aortic disease progression.

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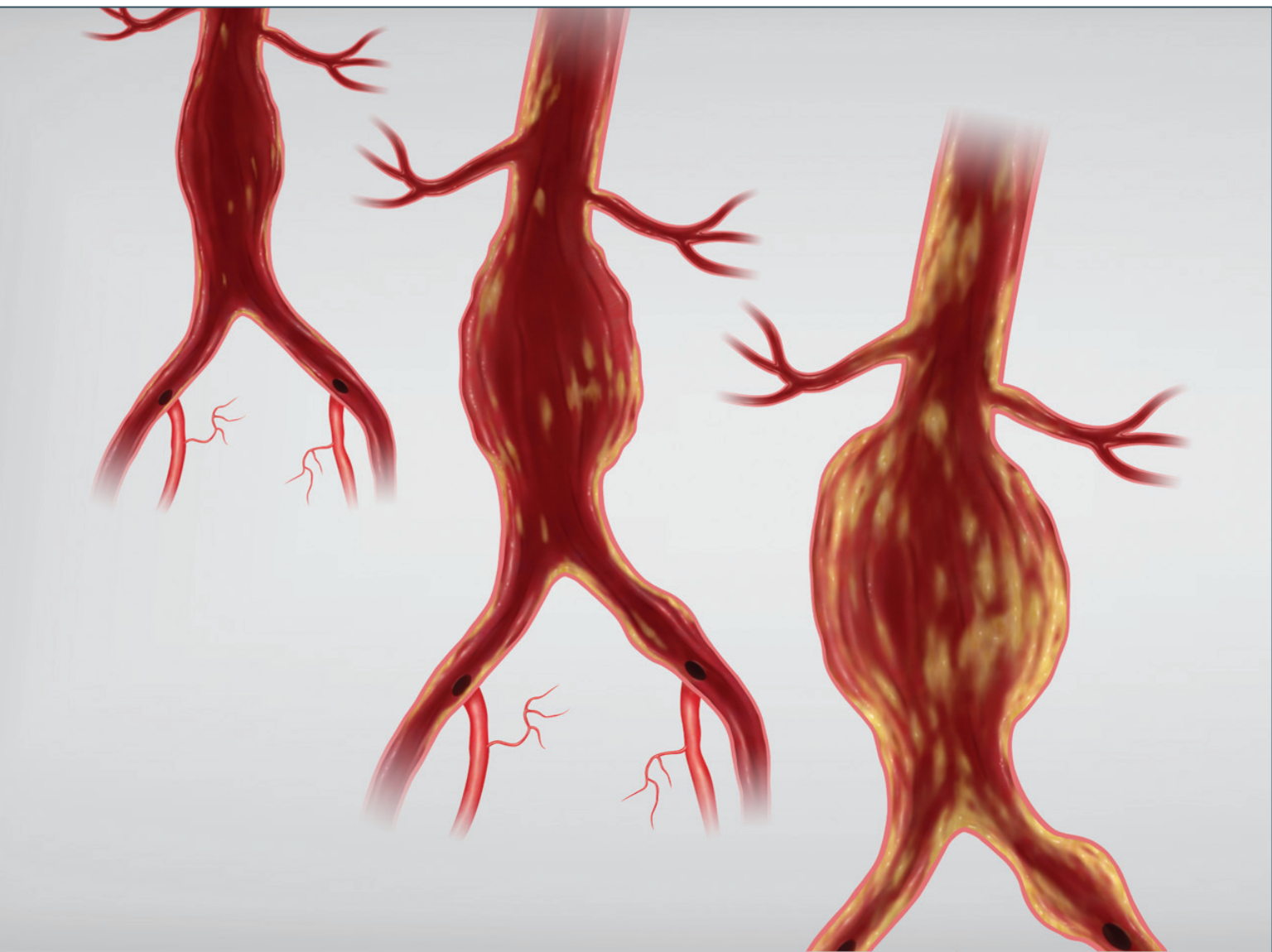

Awareness of Managing Aortic Disease Progression

An introduction by Phil Nowell and interview with Stephan Haulon, MD, PhD.

The understanding of the progressive nature of aortic disease is evolving; therefore, the approach to endovascular aneurysm repair (EVAR) must also evolve. As a chronic condition that requires long-term management, the ability to achieve a durable repair becomes the central consideration and objective. This is true as much for EVAR as it is has been for open surgical repair. The questions to be asked and answered, however, focus on the factors that need to be considered and the decisions that need to be made to provide the best possible durable repair for the patient at any age and with aortic disease at any stage of progression.

In pursuit of the answers, we have asked a group of experienced physicians to present papers in an attempt to further our understanding of the progressive nature of aortic disease. In "Aortic Aneurysm Sac Enlargement After EVAR," Andres Schanzer, MD, presents evidence that aneurysmal sac enlargement results from the progression of aortic disease post-EVAR. Nikolaos Tsilimparis, MD, and Tilo Kölbel, MD, PhD, explain how it is possible to achieve an acceptable seal zone from the aortic arch to the iliac bifurcation in "What Signs Indicate a Compromised Seal Zone?" Next, Martyn Knowles, MD; M. Shadman Baig, MD; and Carlos H. Timaran, MD, suggest an approach to device selection that can assist physicians in managing progressive aortic disease in "Beyond Standard EVAR."

To begin, we wanted to hear the perspectives of Professor Stephan Haulon, who has extensive experience with advanced aortic disease. In the following discussion, Professor Haulon shares his perspective on the principles he adopts to achieve a long-term durable repair.

Stephan Haulon, MD

What can you tell us about your practice?

I work at the University Hospital of Lille in Lille, France, which is a tertiary referral center offering medical services to more than 5 million people. I run an "aortic center" together with my colleagues—cardiothoracic and vascular surgeons, interventional radiologists, and cardiologists. We believe that this multidisciplinary approach is mandatory to provide the best medical treatment and the best surgical options (open and/or endovascular) to our patients. My practice specifically focuses on the endovascular treatment of complex aortic diseases such as thoracoabdominal aneurysms, aortic arch aneurysms, and aortic dissections. We perform approximately 250 aortic endovascular repairs per year.

What types of aortic cases do you see at your referral center?

Our intensive care unit and emergency departments accept all aortic emergencies. Acute type A dissections are treated by open surgery by our cardiothoracic surgeons, but early complications often require CT angiography (CTA) to plan for complementary endografting, stenting, or fenestration in the setting of persistent malperfusion. Endografting is usually the preferred treatment for complicated acute type B dissections with malperfusion or rupture and for ruptured abdominal aortic aneurysms (AAAs) with favorable anatomies. Thus, we have a CT scan and a hybrid room running 24/7.

There is a bias among the patients sent to my clinic because most of them have already been turned down for open surgery by a cardiothoracic or vascular surgeon colleague. These patients typically have complex aortic diseases. All cases are discussed during our weekly multidisciplinary meeting. In thoracic AAAs (TAAAs) or arch aneurysms with a compromised proximal sealing zone, we often offer a combined approach: proximal open ascending and arch repair with an elephant trunk and distal endovascular repair with branched or fenestrated endografts.

Whenever possible, we try to stage these procedures to decrease the surgical impact on patients. In patients

who are contraindicated for a (redo) sternotomy, we are currently evaluating a double-inner-branch (a-branch) endograft for arch repair. The a-branch device requires a proper landing zone in the ascending aorta (native or graft). We currently perform about 60 thoracic and 130 abdominal endograft procedures every year, including approximately 60 fenestrated and branched cases.

From the podium, you've spoken about the concept of aortic disease being progressive. Why is this an important factor?

We have learned from our early experience, including failures, that a "no compromise" strategy is integral when performing aortic endografting if favorable long-term results are to be expected. This strategy requires a thorough analysis of the preoperative CTA on a three-dimensional workstation to locate proper sealing zones, which are long segments of nondiseased aorta located above and below the aneurysm. A short sealing zone is usually diseased sealing zone that will enlarge during follow-up, potentially leading to a type I endoleak and/or endograft migration.

On top of that, especially in younger patients, we need to keep in mind that additional aortic endovascular repairs will probably be required in the future. The current repair needs to be compatible with a future repair; for example, when designing a four-fenestration endograft in the setting of a type IV TAAA, I would recommend positioning two sealing stents above the celiac trunk fenestration. If required during follow-up, placement of an additional proximal extension endograft will then be a straightforward procedure, with no risk of compromising flow to the celiac trunk and allows for a perfect seal between the endografts with a two-stent overlap.

What is your treatment philosophy in approaching AAA patients who present with aortic necks that are short, angled, thrombus-laden, or nonparallel?

My philosophy is crystal clear: if analysis of the preoperative CT on the workstation has not depicted a long, relatively straight and parallel, and nondiseased neck, I will not implant a commercially available endograft. Schanzer et al[1] have clearly demonstrated that noncompliance with a device's instructions for use is associated with poor outcomes during follow-up. I don't understand why one would push the envelope in such circumstances.

The goal of endovascular treatment should not be restricted to a favorable completion angiogram or discharge CT angiogram; we should aim to achieve a durable exclusion of the aortic disease in the long-term. Therefore, I recommend the use of fenestrated and branched endografts if a proper sealing zone is not depicted in order to relocate the sealing zone more proximally. This is especially true now that systematic reviews and meta-analysis[2,3] have confirmed favorable outcomes with these endografts and the long-term follow-up is available.[4]

Is there a difference in considering a good seal zone for treating abdominal versus thoracic disease?

I believe so. I consider a 15-mm-long, healthy neck to be a good sealing zone in the abdominal aorta, but I usually look for a 25- to 30-mm-long neck in the thoracic aorta, especially when the sealing area is located in the arch. In this latter setting, it is mandatory to consider the landing zone in the horizontal portion of the arch, otherwise the endograft will not conform to the arch anatomy. The risk for type I endoleak arising from the lesser curvature is very high. Treatment for thoracic diseases frequently requires covering the origin of the left subclavian artery, which in my opinion, requires transposition or bypass of the left subclavian artery to the left common carotid artery.

After you've treated a patient for a challenging AAA or TAAA (with a short, angled, thrombus-laden, or nonparallel neck), what are your expectations for follow-up and the durability of the repair?

Because I would treat such a patient with a fenestrated or branched endograft to achieve stable sealing zones, I expect that durability will match that in patients treated with standard endovascular repair for AAAs with suitable anatomy.[5]

Thank you very much, Professor Haulon, for sharing insights on the way you and your colleagues approach aortic disease.

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In the articles that follow, I think you will find some commonalities with Professor Haulon's responses. In moving EVAR forward, we must challenge ourselves to uncover the critical issues that will allow us to achieve the best possible patient outcomes. As Professor Haulon states, in the face of aortic disease progression, this should include providing a multidisciplinary approach, looking beyond a favorable completion angiogram or discharge CTA, and offering no compromise in finding healthy aortic tissue for the seal zone.

The intent of this Endovascular Today *supplement is to engage and inform our physician readers and raise the EVAR conversation to a new level. We acknowledge the progressive nature of aortic disease and are working hard to find solutions that create long-term durable repairs. Cook Medical will always strive to ensure that we show the necessary rigor and discipline to be the responsible partner that physicians expect. We hope this supplement provides a new perspective and even some take-home points that physicians can use in the fight against aortic disease.*

Thank you,
Philip Nowell
Vice President, Cook Medical
Global Business Unit Leader, Aortic Intervention

Aortic Aneurysm Sac Enlargement After EVAR

Analyzing instructions-for-use compliance and its effect on patient outcomes.

BY ANDRES SCHANZER, MD

The most dramatic shift in the surgical management of abdominal aortic aneurysms (AAAs) occurred in 1991 when Juan Parodi reported the first endovascular aneurysm repair (EVAR).[1] This transformative moment paved the way for minimally invasive AAA repair as an alternative to open surgical repair. In 2006, only 15 years after the initial EVAR report, 21,725 EVAR procedures were performed in the United States, for the first time exceeding the number of open surgical AAA repairs.[2] Currently, more than 80% of elective AAA repairs in the United States are performed via EVAR.[3]

RECENT DATA

Results from the three largest prospective randomized trials (EVAR, DREAM, and OVER) that compared early and late outcomes after open and endovascular repair of AAAs were remarkably consistent in all major outcomes.[4-6] In aggregate, the findings can be summarized as follows: (1) perioperative morbidity and mortality are significantly lower after EVAR than after open repair; (2) the short-term survival advantage of EVAR diminishes during long-term follow-up such that if patients survive beyond approximately 2 years, the long-term survival of patients is similar for both groups; and (3) although the reintervention rate after EVAR is higher than after open repair, most of these reinterventions are performed with catheter-based techniques, albeit at overall higher costs.

Rates of AAA sac enlargement after EVAR are not negligible. In a large university series, the rate of aortic sac enlargement after EVAR was reported to be 21% at 5 years.[7] A more recent study that analyzed 478 patients who underwent EVAR demonstrated a 42% rate of aneurysm sac enlargement at 5 years.[8] In another study, in patients treated for type II endoleaks based on surveillance-detected AAA sac enlargement, 55% continued to show expansion > 5 mm 5 years after treatment.[9]

RETROSPECTIVE ANALYSIS OF POST-EVAR AAA SAC ENLARGEMENT

To better understand the predictors of AAA sac enlargement after EVAR, we conducted a study using data from a large, multicenter cohort CT scan database to determine the degree of compliance with anatomic guidelines in the instructions for use (IFU) for the EVAR device, examine changes in compliance with the IFU over the last decade, and determine the relationship between baseline aortic and iliac artery anatomic characteristics and the incidence of AAA sac enlargement after EVAR.[10]

Data from patients who underwent EVAR between January 1, 1999, and December 31, 2008, were obtained from a medical imaging repository at M2S (West Lebanon, NH). For the purposes of this study, M2S provided de-identified data on all patients in their prospectively acquired database who underwent a CT scan before EVAR and had at least one CT scan after EVAR. Using these criteria, 10,228 patients were identified. The primary limitation of this study was that the clinical characteristics of the patients were not available, and thus the generalizability of this population to those undergoing EVAR in the United States could not be established.[11] Similarly, no information was available regarding which interventions, if any, were performed in response to the findings of the CT scan.

This study demonstrated that the incidence of AAA sac enlargement after EVAR was 41% at 5 years in this cohort of patients—a rate that increased during the time period of the study. When all EVAR-treated patients were classified according to compliance with IFU criteria, 5,983 (58.5%) were found to be outside the most conservative IFU, and 3,178 (31.1%) were outside of the most liberal IFU available in the United States market. This indicates the presence of liberal interpretation of the anatomic characteristics deemed suitable for EVAR. Our analysis has shown that several of these factors, including aortic neck diameter, aortic neck angle, and common iliac artery diameter, were independently associated with

TABLE 1. SIGNIFICANT INDEPENDENT PREDICTORS FOR AAA SAC ENLARGEMENT AS IDENTIFIED VIA MULTIVARIABLE COX PROPORTIONAL HAZARDS ANALYSIS

Covariates	Hazard Ratio (95% Confidence Interval)	*P* Value
Age (y)		
< 60	Reference	–
60–69	0.8 (0.6–1.05)	.11
70–79	0.87 (0.67–1.14)	.31
≥ 80	1.32 (1.03–1.75)	.05
Female sex	0.96 (0.82–1.13)	.64
AAA diameter		
Maximum AAA diameter ≥ 55 mm	0.97 (0.86–1.13)	.62
Aortic neck length		
> 15 mm	Reference	–
10–15 mm	0.87 (0.71–1.07)	.19
< 10 mm	0.94 (0.77–1.15)	.53
Aortic neck diameter at lowest renal artery		
< 28 mm	Reference	–
28–32 mm	1.8 (1.44–2.23)	< .0001
> 32 mm	2.07 (1.46–2.92)	< .0001
Conical neck	1.17 (0.97–1.42)	.1
Aortic neck angle		
< 45°	Reference	–
45°–60°	1.04 (0.9–1.21)	.58
> 60°	1.96 (1.63–2.37)	< .0001
Iliac diameter		
Both common iliac arteries ≤ 20 mm	Reference	–
Only one common iliac artery > 20 mm	1.46 (1.21–1.76)	< .0001
Both common iliac arteries > 20 mm	1.31 (0.99–1.74)	.06
Endoleak during follow-up	2.7 (2.4–3.04)	< .0001

Undoubtedly, EVAR represents a tremendous advance in the treatment of AAA and has provided significant benefit to many patients.

AAA sac enlargement (Table 1). These observations raise the question as to whether such liberal selection of anatomic criteria is justified when using current endovascular device designs.

MOVING FORWARD

This analysis of M2S data was meant to be a starting point for a critical conversation in the evolving field of EVAR, rather than a conclusion. It has now been unambiguously established that the risk of late rupture after EVAR is higher than initially believed.[12] A consensus exists that the primary anatomic determinant of late AAA rupture after EVAR is aortic sac enlargement.[12,13] It is likely that the rate of aortic sac enlargement after EVAR will be dependent on the specific patient population and endovascular device studied. Based on this analysis of patients undergoing EVAR in the M2S database, EVAR is frequently performed in patients outside of industry-recommended anatomic guidelines, and this practice increases the risk of late aortic sac enlargement.

Undoubtedly, EVAR represents a tremendous advance in the treatment of AAA and has provided significant benefit to many patients. However, if the widespread application of this technique continues to grow in patients with unfavorable anatomy, the benefits of EVAR may be offset by increased rates of treatment failure, costly reinterventions, and the potential for late aneurysm rupture. Endovascular technologies must continue to evolve so that patients with anatomy that is not optimal for currently available devices can be treated more effectively.

Next-generation fenestrated and branched EVAR devices appear to offer a repair option that is more durable than standard EVAR devices in patients with compromised sealing zones. However, these devices are only available at select sites through clinical trials or early postapproval rollout programs.[14-19] Furthermore, it is important to note that these devices are typically more complex and require larger doses of radiation and prolonged procedure times.

In summary, within the last 2 decades, countless patients have benefitted from a minimally invasive approach to the treatment of AAAs. In an exceptionally brief span of time, vascular surgeons have developed and implemented the necessary skill set required to safely provide EVAR to patients, with extremely low perioperative mortality. Continued device development with a focus on durability in treating patients with more complex anatomy and in preventing late AAA sac enlargement and rupture is an imperative. Next-generation EVAR devices, such as the highly promising branched and fenestrated solutions, will expand the suitable anatomic criteria for successful EVAR; however, with standard EVAR technology, careful patient selection is critical for successful long-term patient outcomes. ■

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What Signs Indicate a Compromised Seal Zone?

How to achieve an adequate seal zone from the aortic arch to the iliac bifurcation.

BY NIKOLAOS TSILIMPARIS, MD, AND TILO KÖLBEL, MD, PHD

"You can compromise on a lot of things, but you cannot compromise on surgical exposure."
— Prof. Cambria, Past President of the Society for Vascular Surgery, Chair of Vascular Surgery at Massachusetts General Hospital

The respective dogma in endovascular surgery should read, "You can compromise on a lot of things, but you cannot compromise on seal zones!"

Placing any stent graft in a healthy, nondissected, thrombus-free, parallel aortic segment should be a nonnegotiable condition for endovascular aortic interventions. All of the currently available devices for endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) have received CE Mark approval for use within the manufacturers' instructions for use (IFU). Deviation from this practice could lead to devastating results, as demonstrated in the article by Schanzer et al, reporting enlargement of the aortic sac in 40% of overall patients at 5 years and a higher growth rate in patients treated outside the IFU for infrarenal abdominal aortic aneurysms (AAAs).[1] Interestingly, of all patients who experienced sac enlargement, 30% manifested at 3 years or later after the index procedure, suggesting that late endoleaks are not that infrequent.

Currently, a number of publications suggest that technical success can be achieved by EVAR in patients with short-neck aneurysms,[2-4] but long-term results from these reports are lacking. A recent meta-analysis clearly demonstrated a higher risk of intraoperative type IA endoleaks requiring adjunctive procedures, as well as higher 30-day postoperative morbidity in patients with hostile neck anatomy that were not consistent with the IFU or at least meeting the criteria of neck length < 15 mm and neck angulation > 60°.[5] Although EVAR can be performed in patients with short aortic necks, it is associated with a significantly higher rate of early and late type I endoleaks, resulting in an increased use of proximal aortic cuffs for endoleak sealing.

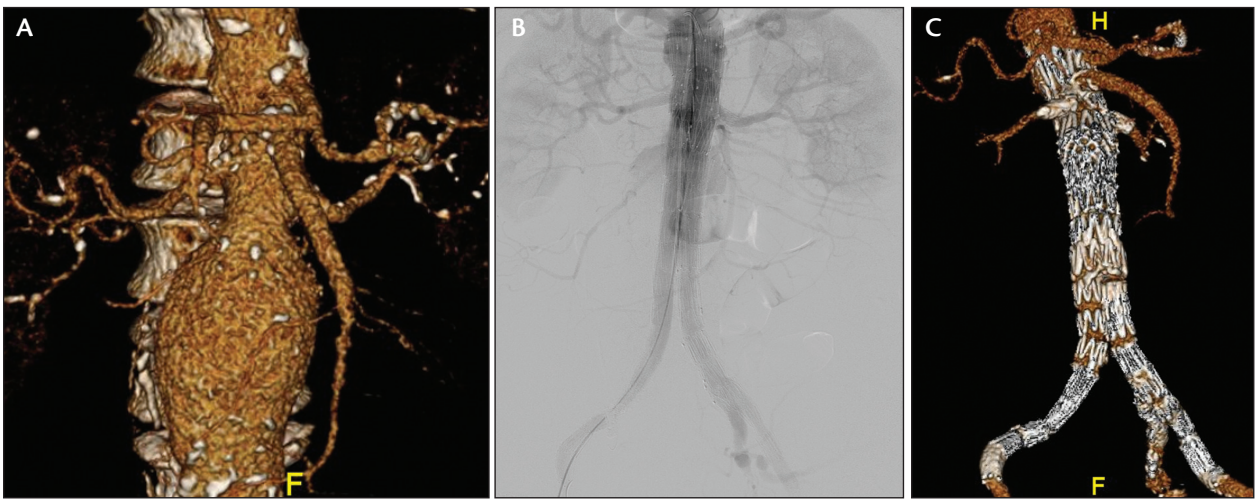

Figure 1. A patient with a short-neck aortic aneurysm that is unsuitable for treatment with a standard infrarenal stent graft (A) was successfully treated with a Zenith fenestrated EVAR device (Cook Medical, Bloomington, IN) for the short aortic neck and a Zenith branch iliac device (Cook Medical) for a left common iliac artery aneurysm, as shown on intraoperative angiography (B) and the follow-up CT scan (C).

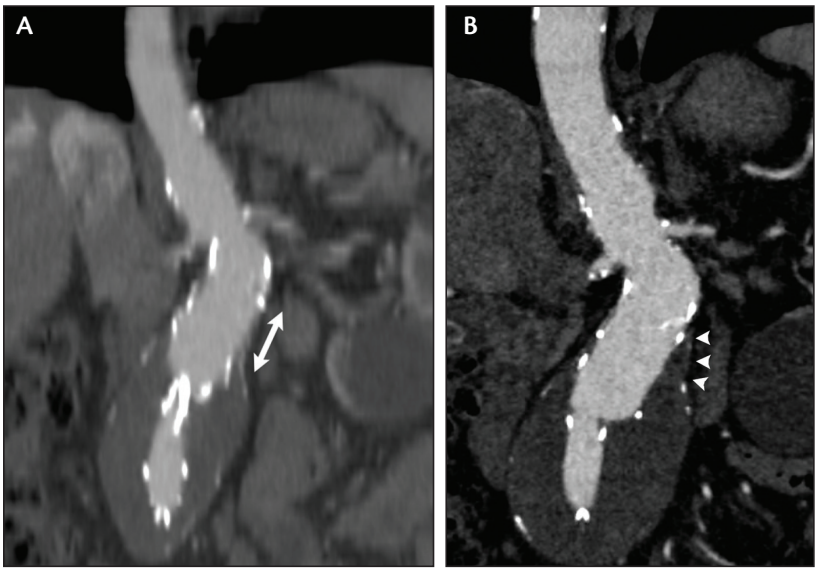

Figure 2. Follow-up CT scans at 6 months (A) and 2 years after EVAR (B) in a patient with a type II endoleak, demonstrating progression of the aortic neck diameter and shortening of the proximal seal zone. The double arrow demonstrates the initial length of the landing zone, and the multiple arrowheads demonstrate the lost sealing zone after aneurysm neck expansion.

Whether in the aortic arch, the visceral segment, or the iliac bifurcation, adequate preoperative imaging and careful preoperative planning are of paramount importance to identify potential failure modes in the sealing zones. CT scans with 1-mm slice thickness, as well as centerline measurements, are crucial in planning cases with challenging aortic anatomies. Knowing the particular anatomy of the patient cannot be overemphasized. We strongly advocate planning in workstations with three-dimensional reconstruction and centerline-of-flow measurements to reduce the risk of false measurements of the aortic neck (eg, in elliptical or highly angulated necks). A number of obvious or masked signs may contraindicate a standard endovascular approach and require more advanced endovascular techniques or open surgery. Customized, as well as off-the-shelf devices, for complex aortic diseases are widely available, and the early advantages of fenestrated or branched EVAR compared to open repair are well documented.[6-8]

PATTERNS OF SEAL FAILURE IN EVAR

Landing zones with at least 20 mm of straight, parallel, healthy aorta at the infrarenal level is the optimal condition for successful implantation of an aortic endograft, thus avoiding reinterventions. However, favorable proximal and distal neck anatomy are encountered in approximately only 50% of the elective[9] and 54% of the emergent AAA cases.[10] In such cases, extension of the sealing zone proximal to the renal arteries with fenestrated or branched EVAR could substantially reduce the need for reintervention.[11]

The length of the proximal landing zone is often understood to be the primary factor in early type I endoleak and procedural success. Technical success in EVAR procedures can be assumed if the final intraoperative angiography is free of type IA endoleaks. However, this may not guarantee durable repair in the long-term.[2-4,12] A few groups have suggested that hostile neck

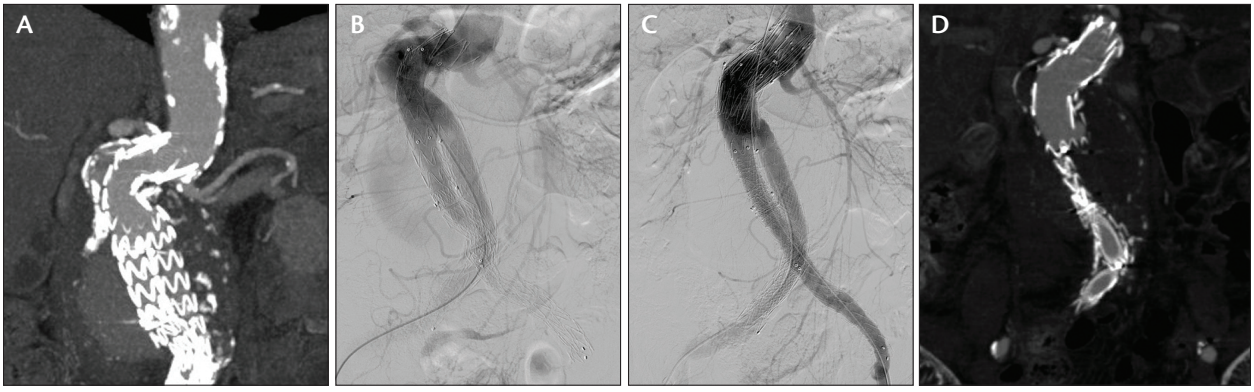

Figure 3. An 81-year-old woman was treated at another institution with aortobi-iliac EVAR for an inflammatory, 8-cm, infrarenal AAA and severe neck angulation (> 90°). CT angiography before proximal cuff extension demonstrates a lack of adequate apposition (A), and intraoperative angiography shows a type IA endoleak (B). Final angiography after extending proximal with a proximal cuff (C) and the postoperative CT scan demonstrate successful exclusion of the endoleak (D).

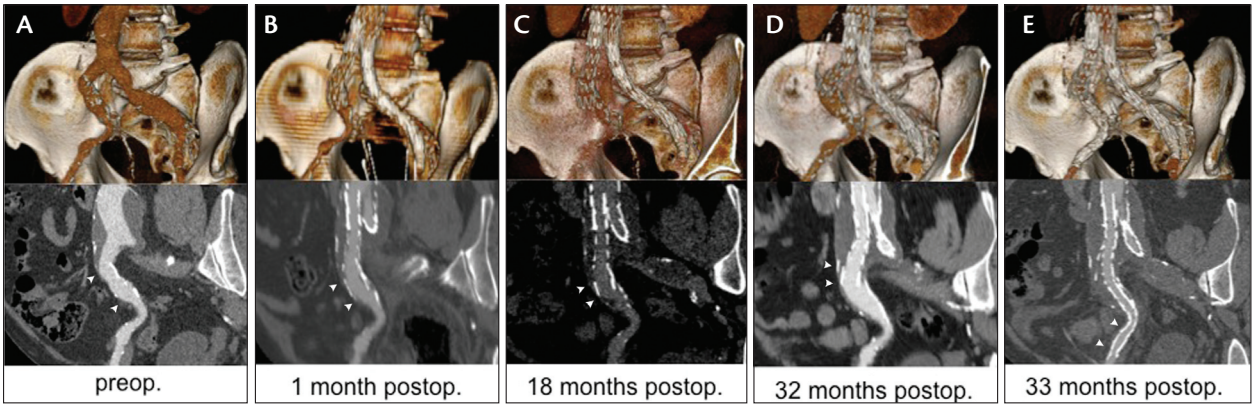

Figure 4. CT scans (three-dimensional and multiplanar reconstruction) of a patient with an aortoiliac aneurysm extending to the right iliac artery (A) who underwent EVAR extending to an aneurysmal common iliac artery (B). Progression of the diameter of the common iliac artery resulted in further reduction of the seal zone at 18 months (C) and a type IB endoleak at 32 months of follow-up (D). The patient was successfully treated with distal extension of the seal zone in the external iliac artery (E).

anatomy is related to stent migration, thus increasing the risk of late type IA endoleaks.[13,14] Furthermore, we have previously shown that aortic neck diameter significantly changes during a time frame of 24 to 36 months postoperatively.[12] Fenestrated or branched EVAR provides adequate proximal seal and achieves complete exclusion of short-neck aneurysms with a durable result (Figure 1).[15]

A tapered aortic neck should always warrant caution when planning an EVAR procedure. Reversed conical necks are also frequently associated with a relevant thrombus burden, thus reducing the actual seal zone to significantly less than the desired 20 mm. One group recently suggested that stent graft oversizing of 40% could reduce endoleak rates in patients with reversed-tapered aortic necks undergoing EVAR, but the data were retrospective and from a single center.[16]

Recommendations to accept hostile neck anatomy outside the IFU for elective EVAR cases are weak and should be handled with caution.

A shaggy aorta loaded with thrombus at the pararenal level is another potential indicator of severe disease in the landing zone area. Apart from the potential catastrophic embolic complications that may occur in both the mesenteric and renal branches,[17,18] the risk of further degeneration and aneurysmal dilatation is substantial.

Exclusion of a short-neck AAA with the absence of an intraoperative type IA endoleak but the presence of a type II endoleak should induce awareness of the possible effect of persistent aneurysm sac pressure causing disease progression and early expansion of the short aortic neck, which may subsequently result in type IA endoleaks or even stent graft migration (Figure 2).

A dilated suprarenal or visceral segment, as well as a primary large aortic neck (30–36 mm), is known to be associated with a higher risk of migration on follow-up, potentially compromising the proximal seal, especially in patients with short necks.[19] Stather et al[20] demonstrated that an initial larger aortic diameter (> 28 mm) was independently associated with a higher risk for secondary intervention (P = .009), technical failure (P = .02), and late type I endoleaks (P = .002).

Recommendations to accept hostile neck anatomy outside the IFU for elective EVAR cases are weak and should be handled with caution.

Penetrating aortic ulcers (PAUs) are also signs of a severely diseased aorta. In cases of AAA with a PAU in the landing zone, we recommend extending the seal zone 20 mm above the upper border of the PAU into the visceral segment using a fenestrated or branched stent graft. Management of such a PAU with adjunctive methods such as coils, liquid embolic agents (eg, Onyx, Covidien, Mansfield, MA), and deployment of the stent graft below the PAU have been reported[21] but obviously yield a high risk of reintervention and proximal seal failure.

Patients with severely angulated (≥ 60°) aortic necks (Figure 3) appear to have a 70% risk for adverse events despite an adequate length of proximal aortic neck.[22] Thus, great caution should be given to avoid early and

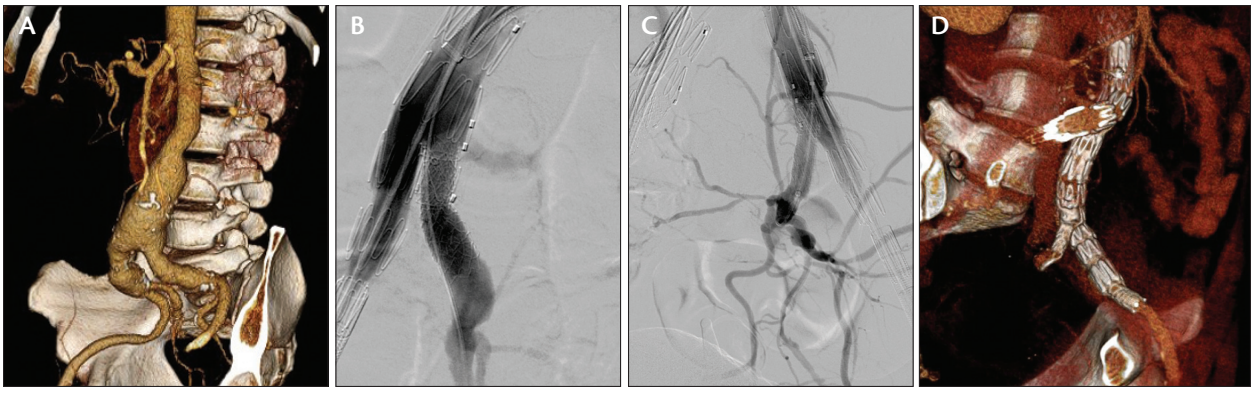

Figure 5. CT scan (A) and intraoperative angiography (B) of a AAA with aneurysmal dilatation of both common iliac arteries. The patient underwent repair with a Zenith bifurcated device and bilateral implantation of Zenith branch iliac devices, as demonstrated in the intraoperative angiography (C) and follow-up CT scan (D).

late complications in patients with such hostile neck anatomy.

Patients with aortoiliac aneurysms frequently have inadequate landing zones in the common iliac artery. Currently, iliac limb stents offer a range of diameters up to 28 mm. Although a 28-mm iliac limb can be a useful device in unusual situations, it is not recommended for treatment of standard elective AAAs. Assuming 20% oversizing, this would suggest anchoring the iliac limb in an aneurysmal 22-mm iliac artery.

The combined experience of a Dutch group and an American group with 154 endografts implanted at both centers demonstrated that, in addition to the risk of distal type IB endoleaks, patients with short seal zone lengths in the iliac arteries are at significantly higher risk of endograft main body migration.[19] This is of great importance, especially because we know that at long-term follow-up, there is a trend toward dilatation of the aortic neck and iliac arteries, even in patients whose aneurysm sac has regressed.[12,23] In patients with aneurysmal iliac sealing zones, distal extension of the sealing area into the external iliac artery using occlusion techniques of the hypogastric artery (Figure 4) or using branched iliac stent grafts (Figure 5) is recommended to achieve durable long-term outcomes.

SEAL ZONES IN THE THORACIC AORTA

Although TEVAR is routinely performed with good technical success (93%–98%), the incidence of type I and II endoleaks is reported to occur in approximately 8% to 29% of treated patients.[24-26]

A critical point during TEVAR is to avoid deploying the stent graft in a segment of the thoracic aorta with extreme proximal angulation, which would result in "bird-beaking" and thereby a compromised proximal seal. Bird-beaking has become less of a problem over the years with the introduction of conformable stent grafts that offer staged proximal deployment.[27] In a comparison of the conformable Zenith TX2 with Pro-

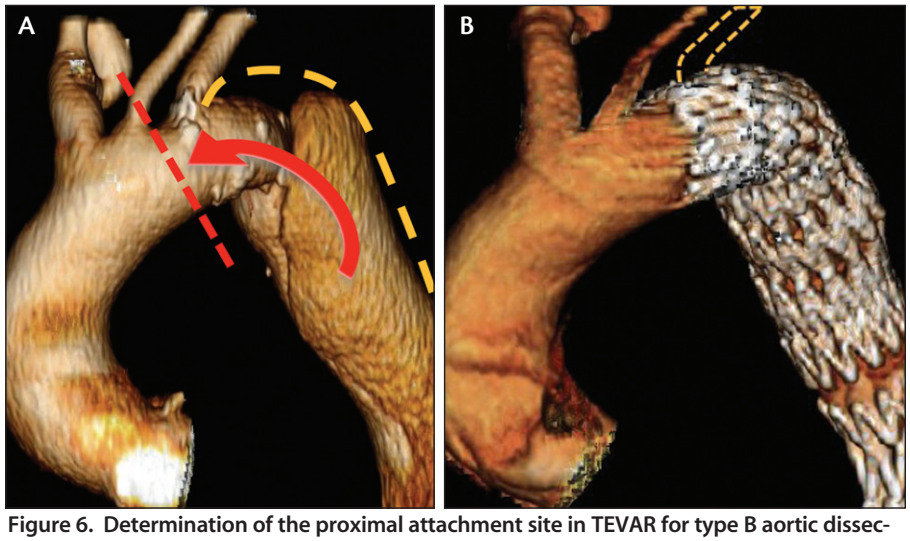

Figure 6. Determination of the proximal attachment site in TEVAR for type B aortic dissections: volume rendering of pre- and postoperative CT angiography in a patient with a type B aortic dissection. Preoperative: although contrast in the false lumen does not stretch to the ostium of the LSA, the aortic wall is dissected up to the LSA (dotted yellow line) so that the edge of the stent graft should land at the distal edge of the left common carotid artery (dotted red line) (A). Postoperative: the stent graft is placed as planned, covering the ostium of the LSA (dotted yellow line) (B).

Form thoracic delivery system (Cook Medical) with other nonconformable devices, Lee et al[28] demonstrated better apposition of the Zenith device in the landing zone of the thoracic aorta.

SEAL ZONES IN AORTIC DISSECTIONS

A major issue in endograft repair of Stanford type B aortic dissections is overstenting of the left subclavian artery (LSA), with the stent graft landing in a dissected aortic segment. In our experience and as recently verified by the International Registry of Acute Aortic Dissection data presented at the European Society for Vascular Surgery 2013 annual meeting, a significant portion of type B aortic dissections (17%) extend in a retrograde fashion to involve the aortic arch. These patients are at high risk of developing a retrograde type A dissection when a stent graft is deployed in the area of retrograde intramural hematoma. Manning et al[29] demonstrated that landing a stent graft distal to the LSA within a dissected segment of the aorta in a type B aortic dissection carries a high risk of subsequent dilatation and rupture due to the increased wall stress in the outer curvature. Therefore, our institution recommends intentional coverage of the LSA in all cases, with entry of the dissection close to the LSA (Figure 6).

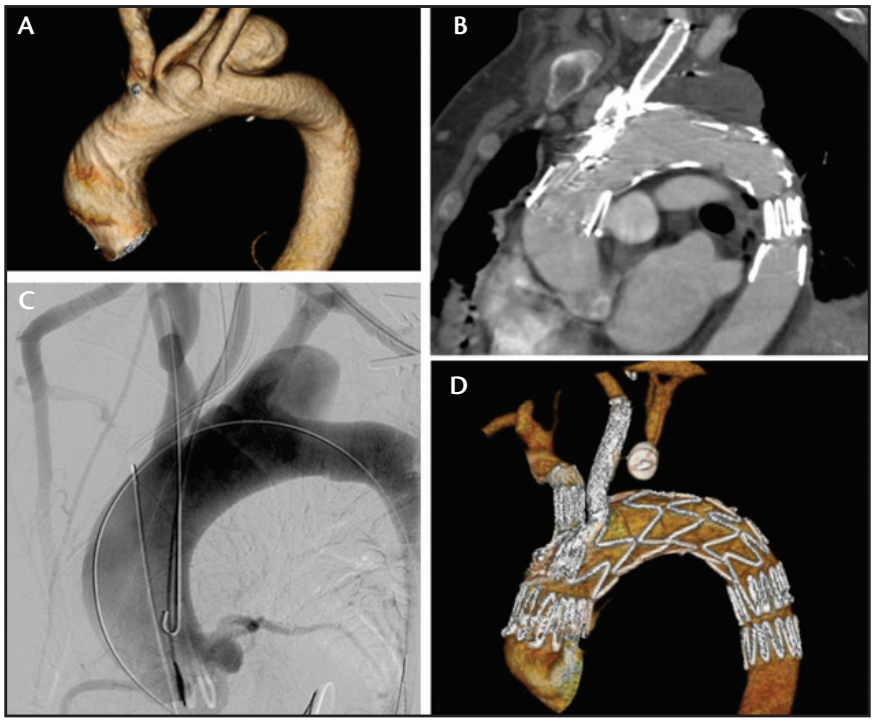

Figure 7. An aneurysm of the aortic arch in a patient who is unfit for open repair (A) was treated with a fenestrated branched endograft in the aortic arch with branches for the left carotid artery and the brachiocephalic trunk (B, C) to achieve an adequate proximal sealing zone and aneurysm exclusion, as seen in the postoperative CT scan (D).

SEAL ZONES IN THE AORTIC ARCH

Whether in type B aortic dissections with retrograde involvement of the aortic arch or in aneurysmal disease of the proximal descending thoracic aorta or even of the aortic arch, patients who are unfit for open repair could benefit from a totally endovascular repair. Fenestrated and branched stent grafts in the aortic arch could achieve better sealing zones in this very challenging vascular territory, thereby reducing endoleaks and reinterventions (Figure 7).

DISTAL SEALING ZONE ABOVE THE CELIAC TRUNK FOR TEVAR

Accurate deployment of thoracic stent grafts just above the origin of the celiac trunk is of paramount importance to ensure an adequate distal seal zone and to avoid the possibly catastrophic complications of a celiac trunk occlusion. The distal component of the Zenith TX2 stent graft facilitates precise deployment without the risk of uncontrolled "jumping" of the stent graft during deployment. If distal thoracic sealing zones are compromised in length, diameter, thrombus load, or shape, extending the stent graft repair to the infrarenal aorta using fenestrated or branched devices should be considered. Distal landing in a thrombosed segment of a distal descending thoracic aortic aneurysm is not considered safe, as pressure is transferred through thrombus even in cases that do not show residual sac perfusion.

CONCLUSION

Endovascular surgery is beyond the "teenager phase" in which the role of adequate sealing zones has been unclear and indications have partly been liberalized.The fenestrated branched endografts now available for the entire thoracoabdominal aortic tree, including the aortic arch and hypogastric arteries, represent the future of interventional vascular medicine. ■

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Beyond Standard EVAR

With the progressive nature of aortic disease, fenestrated EVAR might be the best option for treating infrarenal AAAs with marginal short necks.

BY MARTYN KNOWLES, MD; M. SHADMAN BAIG, MD; AND CARLOS H. TIMARAN, MD

The fundamental tenet of successful long-term endovascular aortic aneurysm repair (EVAR) is adequate proximal and distal fixation and seal. Because aortic aneurysmal disease is progressive in nature, compromising the initial repair in patients with a marginal neck can lead to secondary interventions and eventual failure. Fenestrated EVAR is a less-invasive alternative to open repair that improves proximal fixation by raising the proximal neck to the normal suprarenal and paravisceral aorta.

BACKGROUND

To understand the benefits of fenestrated EVAR, it is key to identify patients at risk of failure after standard EVAR. With infrarenal abdominal aortic aneurysms (AAAs), the proximal neck is the most common site of endovascular repair failure. The length, diameter, and angulation of the proximal neck, as well as the presence of a reverse taper, all influence proximal fixation.[1] An inadequate proximal neck hinders EVAR in up to 40% of patients with infrarenal AAAs.[2] Advances in device designs and techniques have not improved the outcomes of EVAR for marginal necks. In a study by Moise et al, anatomical barriers to EVAR were investigated during two time periods, before and after the year 2000. Interestingly, even with the progress in EVAR technology and some progress in dealing with anatomical factors such as arterial access, an inadequate proximal neck remained the main exclusion criterion for EVAR during both time periods.[3]

Many adjuncts have been introduced to improve fixation in unfavorable necks. Active fixation prevents migration and is available in the majority of the currently approved devices. Suprarenal fixation extends the site of actual fixation to an area above the renal arteries where the aorta may be healthier. Sealing, however, still occurs in the infrarenal aorta. Although intuitive, suprarenal fixation has not consistently been effective in limiting migration compared to infrarenal devices.[4]

Appropriate positioning of the C-arm with cranio-caudal and lateral projections may remove parallax and allows deployment of the covered portion of the device just below the renal arteries. This, in theory, may optimize fixation and seal throughout the entire length of a marginal neck. The use of repositionable endografts may allow a few attempts to optimize deployment and utilize all of the available neck below the renal vessels. Although these adjuncts may temporarily aid in achieving proximal fixation, they cannot prevent future aortic degenerative changes, which are frequently seen after aneurysm repair where there are unfavorable aortic necks.

EVAR AND THE INSTRUCTIONS FOR USE

In an attempt to identify and standardize guidelines for patients at risk for EVAR failure, the Ad Hoc Committee of Standardized Reporting Practices for the Society for Vascular Surgery defined a marginal neck as having a length < 15 mm, diameter > 28 mm, angle > 60°, and presence of significant calcification or thrombus.[5] These guidelines predominantly coincide with the instructions for use (IFU) for the majority of EVAR devices. The Zenith Flex device (Cook Medical, Bloomington, IN) requires a neck size of 18 to 32 mm with a length ≥ 15 mm, ≤ 60° neck angle, and iliac diameter of 10 to 20 mm for a length ≥ 15 mm.

The Endurant stent graft (Medtronic, Inc., Minneapolis, MN) requires a neck size of 19 to 32 mm and is the only device that requires a length ≥ 10 mm, ≤ 60° neck angle, and iliac diameter of 8 to 25 mm for a length ≥ 10 mm. The Excluder device (Gore & Associates, Flagstaff, AZ) requires a proximal neck of 19 to 32 mm in neck size with a length ≥ 15 mm, ≤ 60° neck angle, and iliac diameter of 10 to 27 mm for a length ≥ 15 mm. The Ovation (TriVascular, Inc., Santa Rosa, CA) and Powerlink (Endologix, Inc., Irvine, CA) devices have similar requirements in their IFUs. The Aorfix device (Lombard Medical Technologies, Oxfordshire, UK) was recently approved by the US Food and Drug Administration (FDA) and allows treatment of angulated necks up to 60°; in Europe, angulated necks up to 90° can be treated.

If devices are used according to IFU criteria, results are generally excellent and comparable between devices, with < 1% type IA endoleaks. However, a large number of patients that undergo standard EVAR have anatomies that are outside the IFU. Schanzer et al[6] demonstrated the

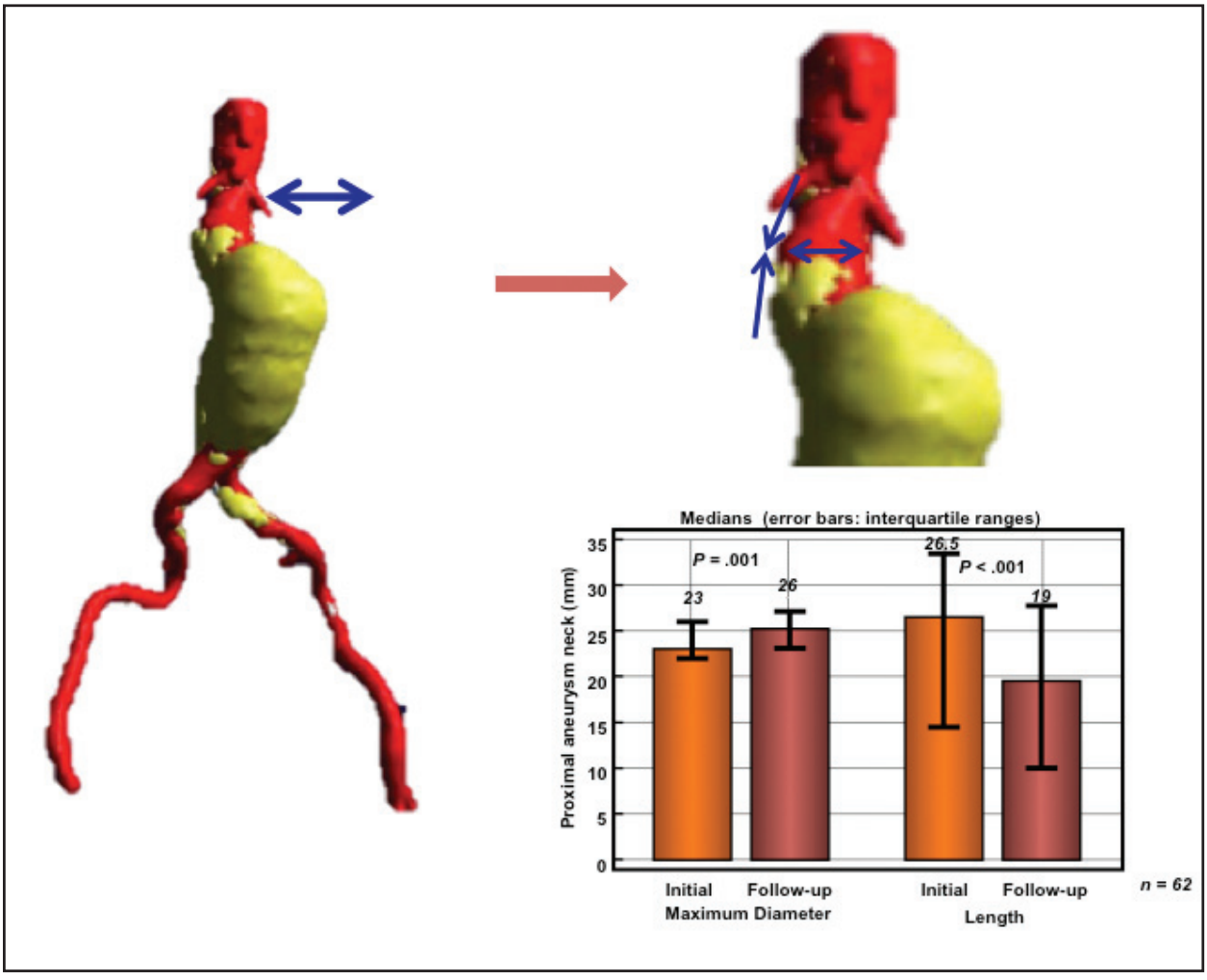

Figure 1. Significant neck changes were observed during surveillance in aortic neck length and diameter during mid- and long-term follow-up.

frequent use of EVAR outside the IFU in 10,228 patients undergoing EVAR. Patients were separated into either a conservative (neck length > 15 mm, neck size < 28 mm, and angle < 45°) or liberal (neck length > 10 mm, neck size < 32 mm, and angle < 60°) group. Interestingly, in the entire cohort, 58.5% of all patients were outside the conservative group requirements, and 31.1% were additionally outside the liberal group requirements.

The primary outcome was measured as sac enlargement > 5 mm within 5 years, and for the entire cohort, that rate was a staggering 40.9%. Significant sac enlargement was observed in 39% of patients in the conservative group, 40.9% in the liberal group, and 43% in those outside both groups ($P < .001$). Of note, 60% of the AAAs were smaller than 55 mm preoperatively. Predictors of sac enlargement included endoleak, age 80 years or older, aortic neck diameter ≥ 28 mm, aortic neck angle > 60°, and common iliac diameter > 20 mm.[6] These findings are echoed in multiple studies that reveal increased rates of type I endoleak, reinterventions, and decreased freedom from graft-related adverse events in those with proximal neck criteria outside the IFU.[7-11]

As experience with EVAR has increased, surgeons are treating increasingly complex aneurysms with devices that were never tested nor designed for such adverse anatomy. In addition to marginal neck characteristics, the progressive nature of aortic disease leaves these patients at high risk for failure.

CHANGES IN THE AORTIC NECK AS EVIDENCE OF PROXIMAL DISEASE PROGRESSION

Aortic aneurysmal disease is a truly progressive disease. Prior to intervention, there is evidence of changes in the

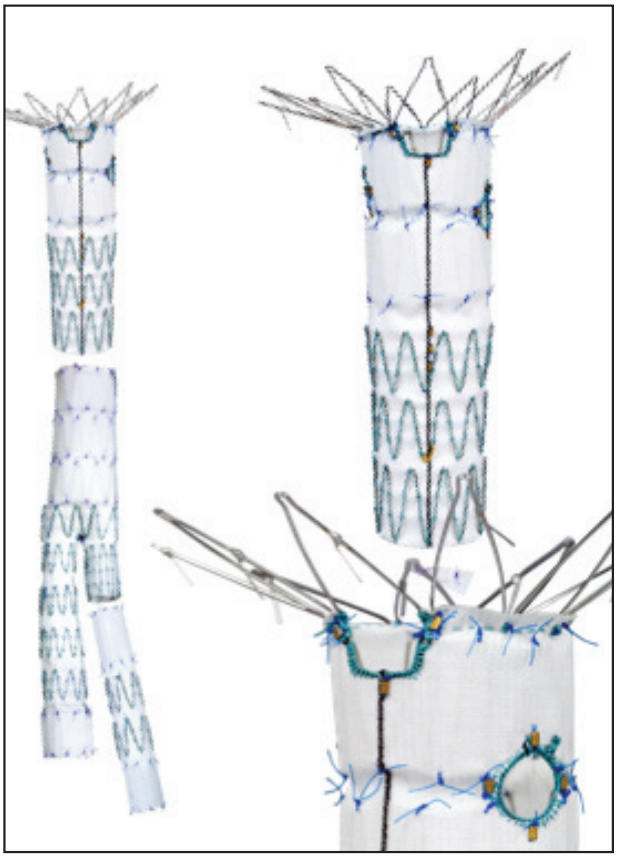

Figure 2. The Zenith Fenestrated endovascular AAA graft (Cook Medical) was approved for use in the US by the FDA in April 2012.

Figure 3. The Zenith p-Branch device (Cook Medical) is an off-the-shelf fenestrated device that is under investigation for endovascular repair of juxtarenal AAAs.

proximal aortic neck with aneurysm growth. Wellborn et al found that the increasing diameter of an aneurysm is associated with a loss of suitability for EVAR. More than 80% of patients with 3- to 4-cm aneurysms were EVAR candidates, which dropped to 60% to 62% for 4- to 6-cm aneurysms, 46% for 6- to 7-cm aneurysms, and 21% of those larger than 7 cm.[12] In a follow-up study in patients with aneurysms from 4 to 5.4 cm, a significant increase in median neck diameter and decrease in median neck length were observed during 2 years of follow-up, although there was no major loss of suitability for EVAR.[13] This study, however, did not focus on those with marginal neck characteristics (length < 15 mm and diameter > 28 mm) and only followed patients for 2 years. A later study with longer follow-up of patients with marginal neck characteristics revealed a significant decrease in median neck length, increase in median neck size, and a loss of suitability for EVAR (Figure 1).[14]

Changes in the aortic neck do not only occur prior to repair. It is well documented that the aortic neck dilates after endograft placement, which is thought to be in part related to the oversizing often associated with repair. Besides preoperative marginal neck characteristics, disease progression is another likely cause and contributes to the failure of endograft repairs. Ouriel et al compared outcomes of EVAR for smaller (< 5.5 cm) versus larger aneurysms (> 5.5 cm). A higher rate of type I endoleak, migration, conversion to open procedures, and lower patient survival was evident in the larger aneurysm group.[15] In a substudy of the EVAR trial cohorts, an increase in the aortic neck diameter was greater after EVAR compared to open repair at 2 years.[16] Additionally, that progression of disease and neck enlargement has been seen after EVAR with both infrarenal and suprarenal fixation.[17] Given the evidence of progression of aortic disease, patients with marginal neck characteristics are at particularly high risk for loss of fixation and likely require a treatment that avoids sealing and fixation in the diseased neck altogether.

CURRENT STATUS OF FENESTRATED ENDOGRAFTS IN THE US

In April 2012, approval for the Zenith Fenestrated device was received from the FDA (Figure 2). Outside

of the initial clinical trial[18] and investigational device exemptions, experience with fenestrated endografts originated outside the US. In fact, the Zenith Fenestrated endograft has been used extensively worldwide, with excellent midterm results.[19-21] In three large European studies, a total of 552 patients underwent fenestrated EVAR, the vast majority for short-necked and juxtarenal aneurysms. All cases were elective in asymptomatic patients. Cumulative technical success was 99%, between the three studies, for 986 of 996 fenestrations. Intraoperative conversion to open repair was needed in two patients (0.4%) due to an inability to remove the top cap and distal aortic occlusion. Thirty-day mortality was 2.9%. No deaths were noted in patient follow-up to be aneurysm related. The UK GLOBALSTAR registry showed survival rates of 94%, 91%, and 89% at 1, 2, and 3 years, respectively.[20] Verhoeven et al reported survival rates of 90.3%, 84.4%, and 58.5% at 1, 2, and 5 years, respectively, and visceral vessel patency of 93.3% at 5 years.[21]

In the data reported from the US Multicenter trial with the Zenith Fenestrated endograft, 30 patients were followed for 24 months. Seventy-seven visceral vessels were fenestrated, with 100% technical success. During the 2-year follow-up, no aneurysm-related deaths, aneurysm ruptures, or conversions were noted. Additionally, no type I or III endoleaks were observed. Aneurysm size decreased in 16 of 23 patients who were followed to 24 months (69.6%), was stable in seven patients (30.4%), and there were no patients who underwent aneurysm growth > 5 mm. Eight patients were identified to have renal events, five requiring reintervention; however, none required dialysis.[18]

Based on European and early US experience with fenestrated EVAR, it is clear that improved outcomes are achieved in patients with marginal short necks. The Zenith Fenestrated device is currently approved by the FDA for juxtarenal aneurysms with proximal neck lengths between 4 to 14 mm. Fenestrated EVAR, therefore, allows endovascular repair for many AAAs that do not meet standard EVAR criteria according to the IFU. As with standard EVAR, optimal fixation and seal is mandatory in normal proximal aorta, which, in fenestrated EVAR, can extend well above the level of the renal arteries.

The customizable graft may actually allow seal up to the level of the superior mesenteric artery (SMA) with either a scallop or fenestration. Customization usually requires planning and manufacturing of devices specific for each patient's anatomy, which takes several weeks. Such a delay may not be acceptable in patients with symptomatic or very large aneurysms. The need for off-the-shelf fenestrated devices is self-evident. The Zenith p-Branch is an off-the-shelf device that is currently under investigation (Figure 3).[22] This device allows endovascular repair of an aneurysm that extends to the level of the SMA, providing pivot fenestrations for the renal vessels, a fenestration for the SMA, and a scallop for the celiac artery.

An alternative to fenestrated EVAR in patients with an inadequate neck is the use of chimneys and snorkels (ie, visceral stents that are placed alongside the aortic graft to allow proximal extension of the aortic graft while preserving flow to the visceral vessel). Good immediate success has been reported.[23-25] Unfortunately, no long-term data exist to support their use. A higher rate of type IA endoleak has been reported, given the lack of complete graft apposition to the aortic wall due to the visceral stents alongside the aortic graft and the complexity in using more than two visceral vessels.[25] Bilateral and multiple upper extremity accesses are also required, which has been associated with an increased risk of stroke in the range of 3% to 9.5%.[23-25] The progressive nature of aortic aneurysmal disease suggests that chimney and snorkel grafts are prone to failure due to inadequate sealing when several grafts are placed alongside each other, the added radial force associated with each endograft, the limitation to extend proximal fixation above the SMA, and the ongoing neck dilatation after suboptimal fixation.

FENESTRATED EVAR FOR FAILED STANDARD EVAR REPAIRS

In addition to primary repair of short-neck and juxtarenal aneurysms, fenestrated EVAR has been used for endovascular salvage of failed EVAR. These patients usually present with type IA endoleaks, migration, sac enlargement, or dilation of the proximal aortic neck. They typically don't respond to reballooning, cuff placement, or other adjunct measures. Such failures occur in patients with progressive disease and those who did not meet IFU criteria and therefore didn't have an adequate initial repair, or a combination of both. Typically, fenestrated cuff placement with a combination of fenestrations and/or scallop allows extension into normal aorta without compromising the visceral vessels.

Previous repair with an infrarenal device allows easier endovascular salvage. The bare suprarenal stents may create difficulties in cannulating the renal and visceral vessels through the bare stent, although several failed EVARs with suprarenal fixation have been successfully repaired with fenestrated cuffs. In our experience, six patients presented with proximal type IA endoleaks and aneurysm enlargement, and one developed a pseudoaneurysm with a suprarenal stent fracture. There was a 100% technical success rate for retreatment and no

reduction in renal function. An important addition is the use of staging angiography and intravascular ultrasound with possible renal angioplasty/stenting to aid in cannulation during the subsequent fenestrated repair.

Recently, Katsargyris et al published their experience with 26 patients who underwent fenestrated EVAR for complications after standard EVAR. Of the 26 patients (21 had previously been repaired with suprarenal fixation), 23% were repaired for disease extension, and 19% were repaired for a < 10-mm neck. Other indications for treatment included low initial stent graft placement (27%) and migration (23%). Almost 90% were repaired with a fenestrated proximal cuff. Catheterization difficulties due to the previous stent were reported in 42% of cases, although the target vessel perfusion success rate was 95%. There was no patient mortality; however, one conversion was required due to an inability to retrieve a top cap. There were no type IA endoleaks after repair.[26] In comparison, open conversion and explantation is associated with a significant mortality risk of 20%.[27,28] These results favorably support the use of fenestrated EVAR for the repair of failed initial EVAR.

CONCLUSION

EVAR continues to be the primary technique used for treating infrarenal aneurysms, although it is rampantly being performed outside the IFU. A significant risk of failure after standard EVAR for aneurysms with an inadequate neck exists, which may manifest as endoleak, migration, sac enlargement, and possibly rupture. Such failures impose further interventions, morbidity, and mortality. Additionally, the progressive nature of aortic disease renders initial treatments inadequate, as they are prone to failure in the long-term. Among patients with marginal necks and juxtarenal AAAs, fenestrated EVAR offers excellent results when adequate proximal fixation and seal are achieved and should be the first-line treatment in patients with neck characteristics outside the IFU for standard devices. ■

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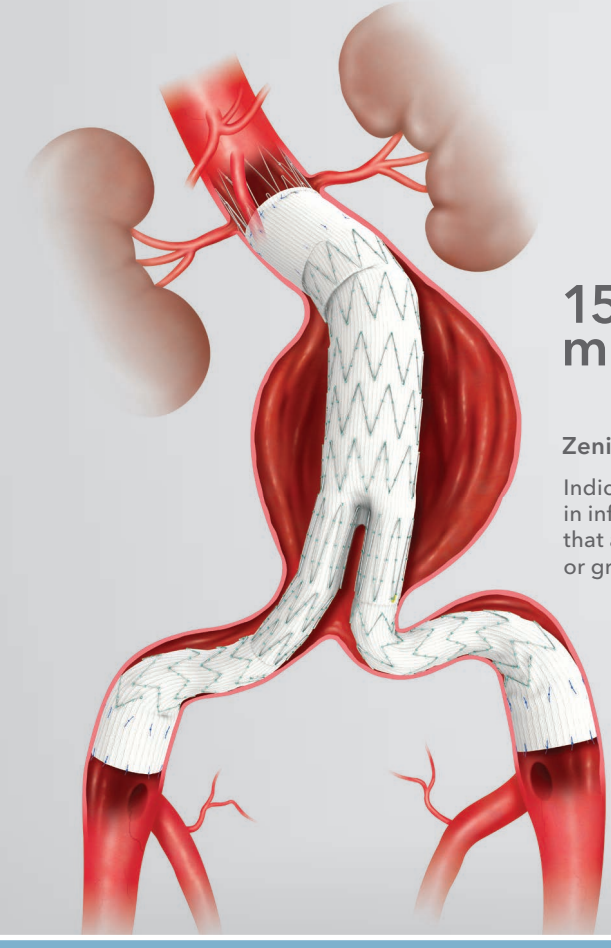

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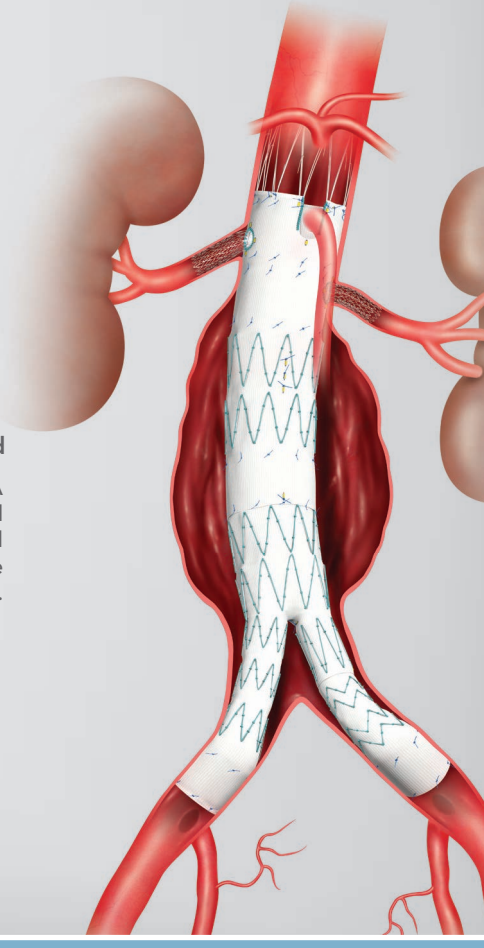

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