How to Select a Proper Sealing Zone

A review of anatomical criteria for a good sealing, characteristics and impact of a bad sealing, and how to rescue a failed stent graft repair.

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Over the past 2 decades, endovascular aneurysm repair (EVAR) has gained popularity as a treatment option over conventional open surgical repair. Two randomized trials have demonstrated lower morbidity and mortality rates after EVAR compared with open surgical repair. However, late follow-up of these trials and other large cohorts has demonstrated that the early survival advantage diminishes over time, and a proportion of late deaths after EVAR are due to aneurysm rupture.[1,2]

EVAR aims to prevent aortic rupture by excluding blood flow and depressurization of the aneurysm wall. This requires a sealing zone to fix and seal the device in the proximal aortic neck and distal iliac arteries. In case of leakage, the repressurization of the aneurysm sac is related to sac enlargement and rupture.[3] Specific anatomic factors are recommended to guide patient selection for EVAR. Even if there is no agreement on the instructions for use (IFU)—specified anatomic characteristics required to achieve durable endovascular repair—studies suggest that the use of EVAR devices outside of the IFU is associated with worse outcomes.[4]

This article reviews the anatomical criteria and methods required to achieve good sealing, the consequences of a bad sealing, and how to rescue a failed stent graft repair.

CRITERIA TO SELECT A PROPER SEALING ZONE

Instructions for Use

Preoperative anatomical evaluation is crucial for the durability of EVAR in cases of adverse anatomy, especially for the sealing zones. In the literature, hostile neck anatomy is usually defined as neck length < 15 mm, neck diameter > 28 mm, or angulation > 60°, alone or in any combination; however, the main anatomical characteristics and indications may vary according to graft model.[5] Minimal requirements from three manufacturers are listed in Table 1. In addition to proper length and diameter, it is generally agreed that thrombus and calcifications must not exceed 50% of the sealing zone circumference, and together with aortic neck calcification, aortic curvature appears to be strongly correlated with bad sealing.[6] Conical neck with a change in diameter that exceeds 3 mm of dilatation within 10 mm of the most caudal renal artery is considered hostile.[7] Figure 1 shows examples of poor proximal sealing zones.

Using the M2S, Inc. imaging database (1999–2008), Schanzer et al reported the imaging analysis of 10,228 patients undergoing EVAR. Only 42% of patients had anatomy that met the most conservative IFU criteria, and 69% had anatomy that met the most liberal IFU. The 5-year post-EVAR rate of aneurysm sac enlargement was 41%.[4]

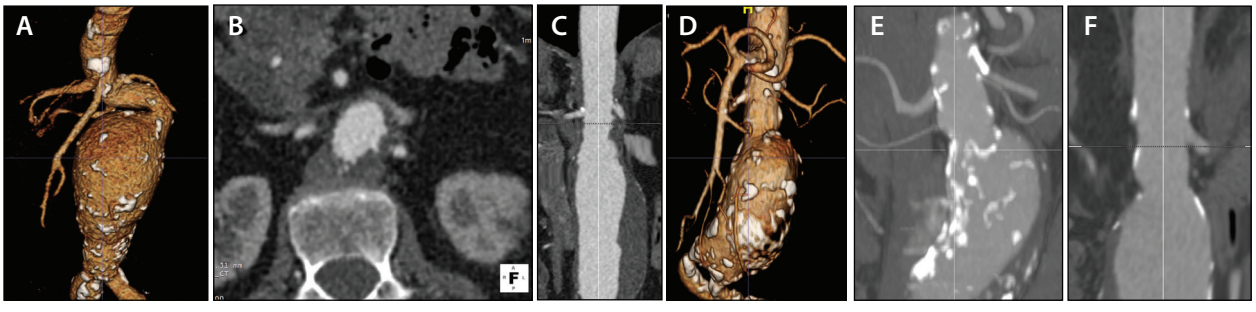

Figure 1. Preoperative CTA of patients presenting with an unsuitable proximal sealing zone for an infrarenal endovascular repair. Three-dimensional (3D) reconstruction of a 90° angulated neck (A); frontal and centerline view of a neck with circumferential thrombus (B, C); 3D reconstruction (D), maximum intensity projection (MIP) (E), and centerline view (F) of a conical neck.

TABLE 1. INSTRUCTIONS FOR USE FOR THREE ENDOVASCULAR GRAFT MANUFACTURERS			
	Gore Excluder*	**Zenith Flex†**	**Endurant II‡**
Aortic sealing zone diameter	19–29 mm	18–32 mm	19–32 mm
Aortic sealing zone length	≥ 15 mm	≥ 15 mm	≥ 10 mm
Angle from suprarenal aorta to neck	Not stated	≤ 45°	Not stated
Angle from neck to aneurysm	≤ 60°	≤ 60°	≤ 60°
Iliac sealing zone diameter	8–18.5 mm	7.5–20 mm	8–25 mm
Iliac sealing zone length	≥ 10 mm	≥ 10 mm	≥ 15 mm

*Gore & Associates; †Cook Medical; ‡Medtronic, Inc.

Routine Use of Three-Dimensional Workstations

For an accurate assessment of the aortic anatomy, high-quality (≤ 1 mm thickness) CT angiography (CTA) is required to be analyzed in endograft sizing software that provides three-dimensional (3D) reconstructions and a semiautomated centerline generated from the thoracic aorta to the iliac arteries. The stretched view generated by the centerline allows an accurate measurement of the vessel lengths and diameters. The image can be rotated on its centerline axis to identify the optimal view of the renal arteries as well as the beginning of the aneurysm, providing an accurate assessment of the proximal sealing zone. Sobocinski et al evaluated the impact of routine EVAR planning with a 3D workstation on early and midterm outcomes as compared to their previous experience using CTA axial images. Over 295 patients were included, and they reported a significant reduction in type I endoleak (8.7% vs 1.4% without and with the use of the 3D workstation, respectively) and secondary interventions related to type I endoleak (5.4% vs 0%). They concluded that access to 3D workstations is mandatory to properly assess the sealing zones and to enhance durability after EVAR.[8]

Short Neck AAA

Short neck (< 15 mm) aneurysms treated with EVAR may achieve initial proximal sealing, but a recent review reports increased operative mortality and morbidity, proximal endoleak, and migration compared with EVAR used with longer proximal neck length.[9] Another meta-analysis combining length, diameter, and angulation to define an unfavorable neck anatomy reported an increase for intraoperative adjuncts, a decrease in primary technical success, and poor 30-day outcomes with regard to proximal endoleaks, migration, and mortality. Late outcomes also revealed an increased risk of type I endoleak and secondary intervention.[5]

In short neck anatomy, fenestrated endovascular aneurysm repair (FEVAR) is currently the most reliable

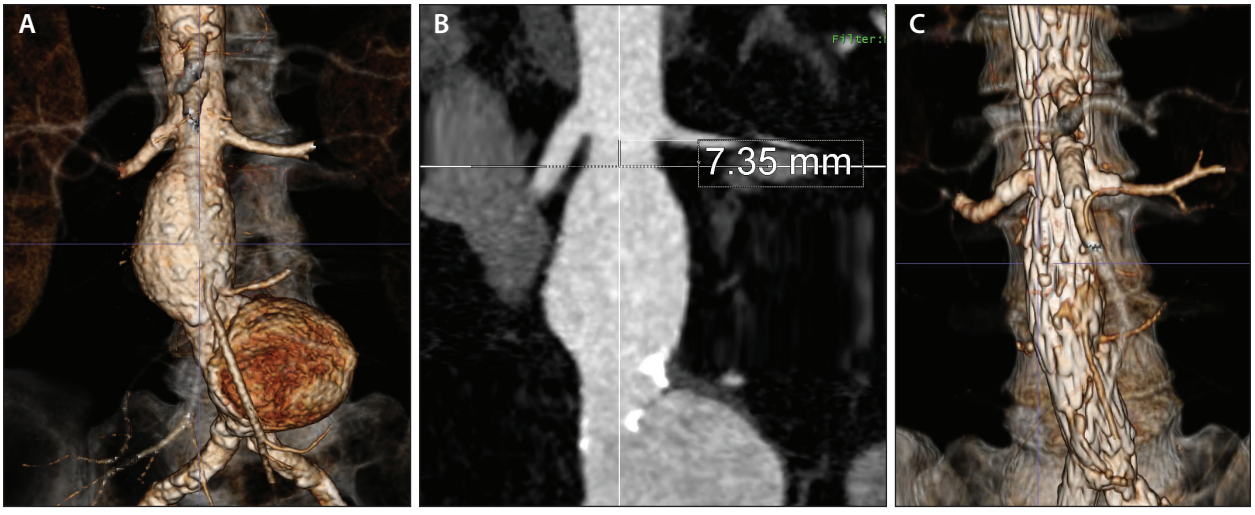

Figure 2. CTA 3D reconstruction and centerline analysis of an infrarenal aneurysm with a short neck (A, B). Postoperative CTA 3D reconstruction showing successful treatment with a fenestrated stent graft (C).

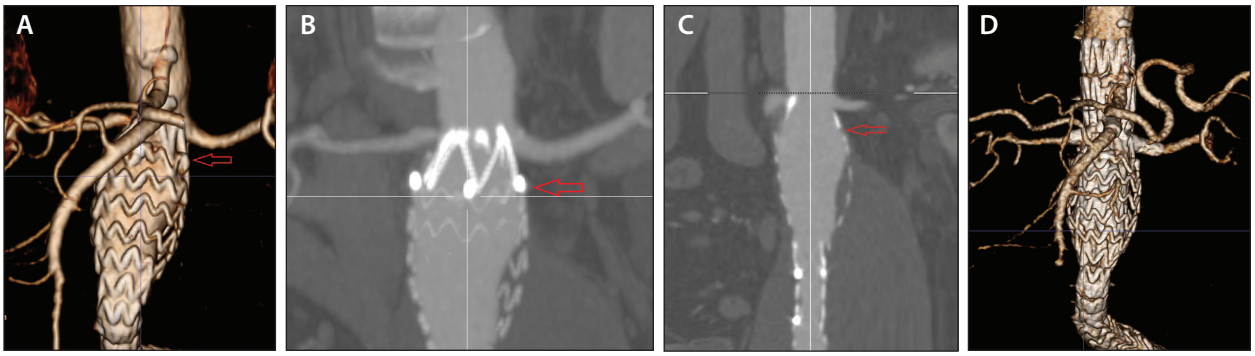

Figure 3. Postoperative CTA 3D reconstruction (A), MIP sagittal view (B), and centerline analysis (C) showing a low graft positioning; the arrow illustrates the top of the first covered stent. Postoperative CTA 3D reconstruction after a fenestrated cuff was added to rescue the failed infrarenal stent graft (D).

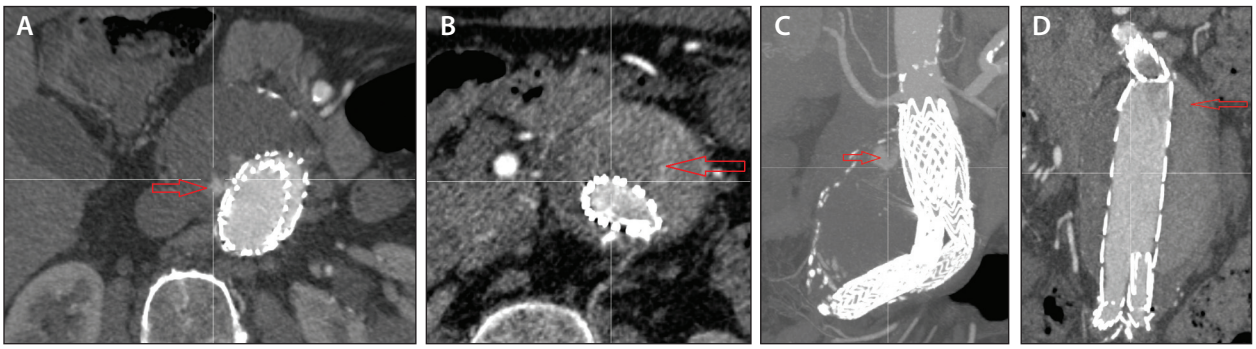

Figure 4. Frontal (A, B) and MIP sagittal views (C, D) of a CTA of two patients diagnosed with a proximal endoleak (arrows).

endovascular option (Figure 2), and using standard EVAR is not recommended if the desired outcome is a durable repair. FEVAR is likely effective because it removes the artificial boundary of the renal arteries and allows a vascular surgeon to "treat to normal aorta." Chimney EVAR is also feasible but is associated with a high rate of postoperative stroke, increased proximal type I endoleak, and lacks long-term data.[10] Newer technologies that include endovascular sealing have proposed repair without need for a neck, but the durability of this option is untested.[10] Certainly, more long-term data that adequately assess both perioperative medical status as well as the true anatomic conditions are needed to help refine the indications for different technologies in challenging necks.

How to Recognize a Bad Sealing

Inadequate proximal sealing may result from misguided planning (eg, short neck, undersizing), a technical issue leading to low positioning of the stent graft during the procedure (Figures 3A–C), migration or extension of the aneurysmal disease, or lack of availability of complex devices at the time the patient needs treatment.

An inadequate proximal sealing is usually detected on postoperative imaging surveillance and classified as a type Ia endoleak (Figure 4), defined as an incomplete aneurysm sac exclusion due to the persistence of high-pressure blood flow outside the lumen of the graft but within the aneurysm sac, which can lead to rupture (Figure 5). In some patients, progressive enlargement of the aneurysm sac is observed despite the absence of a detectable endoleak. This can either be interpreted as "endotension," which appears to be associated with residual high pressure within the aneurysmal sac, or an endoleak undetected on CT because of timing of contrast.[11]

In the literature, abdominal aortic aneurysm (AAA) sac enlargement, defined as a maximum diameter growth ≥ 5 mm, provides the most direct evidence of EVAR failure due to bad sealing and is the most common indication for stent graft explantation (73% of indications for explant in a large report).[3,12,13] Lifelong surveillance is mandatory for early detection and characterization of endoleaks and sac expansion. Most surveillance protocols include either CTA or alternative imaging techniques such as color duplex ultrasound or contrast-enhanced ultrasonography.[7]

Connective Tissue Disease

In 2008, The Society of Thoracic Surgeons Endovascular Surgery Task Force stated that "stent grafting in patients

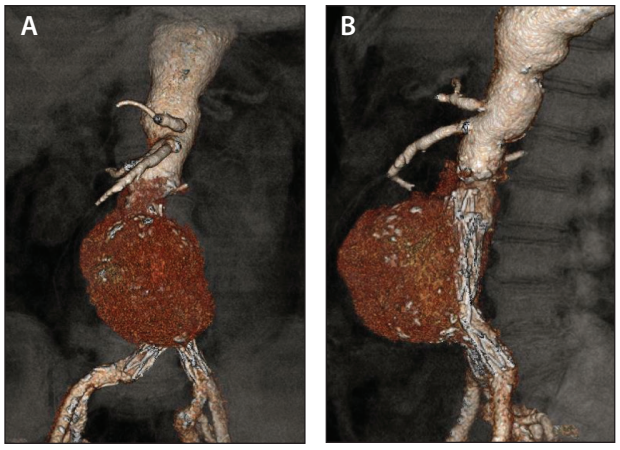

Figure 5. Anterior (A) and lateral (B) view of CTA 3D reconstruction showing a failed EVAR with type Ia endoleak associated with an aneurysm rupture.

with Marfan syndrome or any other known connective tissue disorder is not recommended, [as] there is limited information regarding the impact of persistent radial forces of a stent graft in the abnormal and weak aorta."[14] Despite this, the University of Florida has reported 16 patients with Marfan syndrome who underwent 19 aortic stent graft procedures. Seven patients (44%) experienced primary treatment failure, including three patients found to have a proximal endoleak. The authors suggest that considering the high rate of failure, endovascular therapy can provide a therapeutic adjunct only to patients who have poor or no open options or those who would not survive an open repair.[15]

PREDICTORS ASSOCIATED WITH POST-EVAR ANEURYSM RUPTURE

A meta-analysis published in 2009 reported 270 aneurysm ruptures after EVAR; 38 occurred within 30 postoperative days and 164 occurred during follow-up (mean time to rupture, 24 ± 18 months). In 129 of the 270 cases, the cause of the rupture was related to the sealing zone and included 57 proximal endoleaks, 31 distal endoleaks, and 41 graft migrations.[16]

In a large retrospective analysis of 1,736 patients who underwent EVAR at 17 medical centers from 2000 to 2010, Candell et al identified 20 post-EVAR ruptures, including five early ruptures related to endoleak. Among the 15 remaining patients (median time to rupture, 31.1 months), 10 presented with aneurysm sac increases and nine had documented nonproximal sealing.[17]

METHODS FOR RESCUE OF A BAD SEALING

As discussed previously, bad sealing leading to a proximal endoleak is the most feared complication after EVAR, as it is associated with an increased risk for aneurysm rupture and needs to be corrected. To rescue a bad proximal sealing, several methods are available.

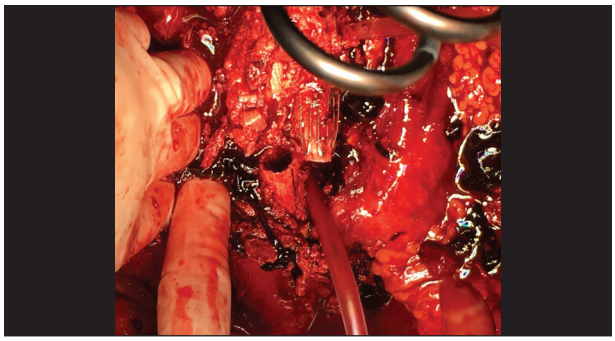

Figure 6. Operative view of an open conversion after failed endovascular repair illustrating the complexity of the surgical exposure due to the failed graft.

Rescue in a Suitable Infrarenal Neck

During the completion angiogram, if a type I endoleak is detected due to a malaposition of the stent graft, another compliant balloon angioplasty (with a Coda balloon [Cook Medical]) may resolve the leak. In the case of a low deployment, an additional proximal endovascular stent graft (either an aortic cuff or another stent graft in case of aorto-uni-iliac device) can be used with a good result.

Open Conversion

Conversion from endovascular to open repair may be required either at the original operation (primary conversion) or on a subsequent occasion (secondary conversion) also classified as urgent or elective.[13] Late surgical conversion is invasive and technically challenging because the presence of the stent graft complicates the surgical exposure (Figure 6). Kelso et al reported 41 late stent graft explantations with an overall hospital mortality rate of 19% and a higher mortality in patients with ruptures as compared with nonruptures (67% vs 9%). After excluding ruptures and infected grafts, the mortality rate was 3.3%.[13] To reduce morbidity and mortality, recent reports have suggested that total stent graft removal may not be necessary and that preserving functional parts of the stent graft may improve results.[18]

Fenestrated Cuff

FEVAR is a well-established technique for treatment of short-necked and pararenal aneurysms, with excellent early and mid- and long-term outcomes.[19] In addition, fenestrated cuffs can be designed to rescue failed infrarenal repair with slightly increased morbidity and mortality than if used in the index procedure (Figure 3D).

Martin et al recently reported the largest series of 52 patients rescued from a failed EVAR with FEVAR (mean

time from primary repair, 5.1 years). The risk of failure was higher in younger patients and those with chronic renal impairment at the time of the implantation. The technical success rate was 85%, and 92% of target vessels were stented. The 30-day mortality was 3.8%, and late death occurred in 38.5% of patients, including two aneurysm-related deaths. The rate of reintervention after the rescue procedure was 10% early in the postoperative course and 17% later, mainly for persistent endoleaks. They concluded that FEVAR performed to rescue failed EVAR is more complex than repair in the native aorta, and more research is required to identify patients with high risk of failure after EVAR.[20]

Other

Chimney/periscope. The use of chimney and periscope grafts has been recently described with a high technical success rate (96%) at high-volume centers, as well as estimated survival and chimney graft patency of 83% and 94% at 36 months, respectively, in the largest series of 24 patients. The main advantage is the use of off-the-shelf devices that allow for immediate treatment. However, this technique needs standardization and further assessment, especially with regard to the ideal number of grafts, and close imaging follow-up is warranted to rule out recurrent or de novo endoleaks.[21]

Palmaz stent. Although it was once thought that an additional Palmaz stent (Cordis/Cardinal Health) in the graft could provide a better apposition if the neck is moderately angulated or conical, this technique has become less popular in modern times.

Endoanchors. Deployment of small helical anchors to affix a stent graft to the aortic wall has been described to treat proximal endoleak.[22] Although this technique may immediately resolve an intraoperative endoleak, it does not alter the natural history of the disease and thus does not prevent progression of neck degeneration over time.

Distal endoleak. Management of distal type I endoleak is simpler than for proximal endoleak and in most cases requires an extension of the stent graft limbs into the distal common or external iliac artery. When extending into the external iliac artery, back bleeding should be prevented with either internal iliac embolization or use of an iliac branch device.

CONCLUSION

Multiple trials have shown excellent short-term outcomes after EVAR compared with traditional open AAA repair, but the long-term durability is mostly related to the sealing of the graft. The choice of a suitable sealing zone, with respect to the IFU of each stent graft, is the key point for long-term durability. In the presence of a short neck, the use of a fenestrated stent graft is currently the most validated and reliable endovascular option. If any proximal endoleak or sac expansion is detected during the lifelong follow-up, it has to be taken very seriously and the underlying problem needs to be corrected; otherwise, aneurysm rupture might occur. ■

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