

# Proximal Abdominal Aortic Aneurysm Necks

The clinical issues and challenges that this anatomy poses for endovascular graft design.

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Endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) has revolutionized our approach to treating this disease. For more than a decade, this technology has undergone intense scrutiny, which has allowed for the rapid development and refinement of many generations of stent grafts—with careful attention applied to the mechanics of deliverability, profile, ease of use, and durability. These assessments have not only improved our understanding of the technology, but also caused the vascular community to begin to reevaluate our understanding of the pathobiology of aortic diseases.

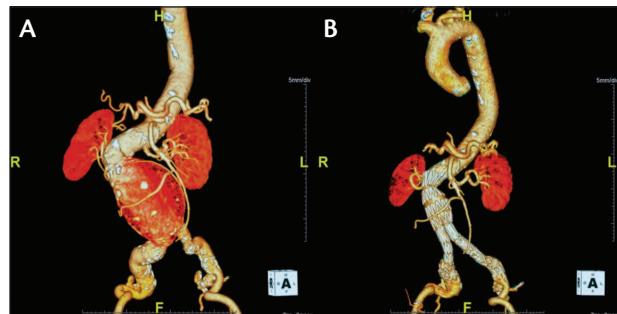


It has become clear that not only the technology but also disease progression plays an important role in the durability of endovascular aortic therapy. This is particularly important given the increasing longevity of the elderly population, even after aortic aneurysm repair.<sup>1</sup> One of the key features of EVAR that portends its success is addressing the proximal attachment site. In this article, we examine some of the clinical features that make the proximal neck of AAAs challenging to address, the evolution of EVAR device development that attempted to overcome these issues, and current device designs that may allow us to provide a durable repair in the face of progressive disease.



## CLINICAL CHALLENGES WITH THE PROXIMAL AORTIC NECK

The proximal aortic neck is the crux for long-term EVAR durability. Endografts must achieve a seal in this location to ensure exclusion of the aneurysm without developing type I endoleaks, and the device must achieve fixation to prevent migration. There are several morphologic features that can hinder the ability of an endograft to achieve adequate fixation and seal within the proximal aortic neck. These features include altera-



**Figure 1.** Three-dimensional reconstruction of a patient with an infrarenal AAA with significant angulation in the neck (A). Despite the angulation, the patient had successful placement of an endovascular graft that excluded the aneurysm (B).

tions in neck composition (such as the presence of thrombus or calcification), neck angulation, and undesirable neck length and diameter. Even as we improve the devices and push the boundaries of what may provide a durable repair, these unfavorable features remain the key challenges that must be overcome. Some of these features lead to mechanical issues that may be adequately addressed through device engineering, whereas others may be hallmarks of impending disease progression that is best managed through appropriate device or patient selection.

Assessment of these issues, however, is not new, as arguments for and against aggressive EVAR in unfavorable anatomy have been ongoing for well over a decade.<sup>2-5</sup> Instructions for use (IFUs) for EVAR have historically recommended more ideal aortic necks—those lacking thrombus/calcification, with longer ( $\geq 15$  mm), parallel, nondilated walls that are relatively free of angulation. With increased experience, however, these recommendations have been challenged. Outcomes of EVAR when used in more challenging necks (Figure 1) have been inconsistent, with reports highlighting the difficulties of EVAR in hostile necks<sup>6-8</sup> versus successful treatment of patients who are well outside the IFU.<sup>9,10</sup>

### Thrombus and Calcification

Most IFUs recommend against EVAR in the setting of significant neck thrombus and calcification. There have been few direct assessments of the durability of stent grafts in these settings. One difficulty in analyzing this morphologic feature is the lack of a universally agreed-upon method of quantifying the degree of calcification and thrombus within the proximal neck. Bastos and colleagues directly assessed outcomes related to the presence of neck thrombus and demonstrated that its presence (in ≥ 50% of neck circumference) was associated with endograft migration of > 10 mm (9.3% vs 2.3%) on univariate analysis.<sup>4</sup> Cox multivariate analysis, however, identified the lack of an active fixation system as the only significant factor for device migration, although nearly 20% of patients with neck thrombus in this series experienced device migration of at least 5 mm. This may become a significant factor, as shorter proximal necks are thought to be permissible.

Wyss et al demonstrated that the presence of neck thrombus may have a protective effect against the development of long-term complications following EVAR, whereas the presence of calcification, particularly when associated with neck angulation, was associated with the development of complications.<sup>5</sup> However, the adverse role of neck calcification has been disputed,<sup>11</sup> with aneurysm sac regression occurring in the presence of less severe aortic neck calcification.<sup>12</sup>

### Angulation

Proximal neck angulation has been extensively studied and found to be a significant factor affecting the success of EVAR. Grisafi et al demonstrated that the presence of an infrarenal neck angle > 45° was associated with a significantly increased risk of initial type IA endoleak.<sup>11</sup> Neck angulation can be lessened, however, with device placement. After successful EVAR, the degree of both suprarenal and infrarenal neck angulation decreases, with the angles continuing to “straighten” for up to 3 years postoperatively,<sup>13</sup> which may be independent of the type of device used.<sup>14</sup>

### Neck Length

Experimental modeling of proximal fixation strength in the aortic neck demonstrates that, among a variety of graft designs, pull-out forces significantly vary, and these pull-out forces can be lowered by shortening the length of the proximal seal, likely directly related to graft design.<sup>15</sup> Data from the EUROSTAR registry were used to assess outcomes for patients with short infrarenal necks.<sup>16</sup> Patients were categorized into one of three groups according to the neck length: > 15 mm, 11 to 15 mm,

and ≤ 10 mm. The rate of type IA endoleaks was significantly greater for patients with neck lengths ≤ 10 mm (11%). At follow-up, freedom from type I endoleak was 97% in those with > 15 mm necks, but only 90% in those with 11- to 15-mm necks, and 89% in those with ≤ 10-mm necks. No differences were observed with respect to device migration, late conversion, aneurysm rupture, or secondary intervention. Some of the current devices have adjusted their IFUs to include treatment of shorter-necked aneurysms.

### Neck Diameter and Dilation

Analysis of the EUROSTAR database by Leurs et al demonstrates that 32% of patients experience neck dilation following EVAR, with approximately 10% of these having migration associated with dilation.<sup>17</sup> In this analysis, risk factors for neck dilation included larger device main body diameter and graft oversizing by at least 20%, whereas less frequent neck dilation was observed with larger baseline neck diameters and the absence of a suprarenal bare stent. In contrast, Cao et al reported aortic neck dilation after EVAR was associated with neck circumferential thrombus, large preoperative aortic necks, and large AAA diameters.<sup>18</sup> Post-EVAR neck dilation has been observed at rates as high as 63% in patients who have thrombus-lined proximal necks.<sup>4</sup> Neck dilation, especially in cases of thrombus-lined or large necks, may be representative of underrecognized diseases and dilation secondary to disease progression. This process does not occur quickly, which may explain why problems with stent graft fixation and sealing may not become apparent for several years after the initial EVAR procedure.<sup>19,20</sup>

### Hostile Neck

Specific analysis of individual factors is difficult given that most patients without an ideal neck have multiple morphologic features that create a “hostile” neck. In a single-center series of 552 patients, Stather and colleagues demonstrated that the presence of hostile neck anatomy (defined as diameter > 28 mm, angulation > 60°, length < 15 mm, and neck flare and thrombus) was not associated with alterations in technical success, 30-day mortality, 30-day type IA endoleak development, or 30-day reintervention rates.<sup>21</sup> Outcomes after 30 days, however, demonstrate an increased rate of type I endoleaks (9.5% vs 4.5%;  $P = .02$ ) in those with hostile necks, but no differences with regard to device migration, sac expansion, aneurysm rupture, or 5-year mortality. Patients with hostile necks, however, required significantly more reinterventions (23% vs 11%;  $P < .01$ ), as a result of the need to treat type IA endoleaks.

Binary logistic regression showed that reinterventions, technical failure, and late type I endoleak development

were significantly increased in patients with increased neck diameters ( $> 28$  mm). Similar outcomes showing early technical success have been demonstrated in other single-center series,<sup>7</sup> with favorable outcomes in hostile neck anatomy being attributed to the use of suprarenal fixation.<sup>22</sup> Outcomes for more recently available stent graft systems have shown similar early outcomes in patients with hostile neck anatomy, but long-term assessment of their durability is not yet available.<sup>23-25</sup>

Stather et al performed a meta-analysis of EVAR in patients with hostile necks (defined as length  $< 15$  mm, diameter  $> 28$  mm, and angulation  $> 60^\circ$ ) ( $n = 3,039$ ) compared to those with a favorable neck anatomy ( $n = 8,920$ ).<sup>26</sup> In contrast to the single-center series, this analysis demonstrated that the presence of a hostile neck was associated with an increase in 30-day mortality (2.4% vs 3.5%;  $P < .01$ ), intraoperative adjuncts (8.8% vs 15.4%;  $P = .01$ ), and 30-day migration (0.9% vs 1.6%;  $P < .01$ ). When all three hostile neck criteria were present, primary technical success was reduced to 94%. Although those with a hostile neck had a significantly increased risk for early and late type IA endoleaks and required more secondary procedures, there were no differences in long-term aneurysm-related mortality, all-cause mortality, migration, or aortic expansion.

### ENDOVASCULAR GRAFT DESIGN FOR A DURABLE PROXIMAL SEAL

Overcoming the aforementioned challenges of the AAA proximal neck has been the primary goal in endovascular graft design since the first placement of an endovascular graft in a human to treat AAA in 1990.<sup>27</sup> For such a novel treatment modality, the baseline that had to be matched was the known performance of the open operation, in which a surgical graft is attached to the vessel wall with sutures. In the open operation, it was recognized that for a satisfactory seal and reliable attachment, it was necessary to suture the proximal anastomosis to a healthy vessel.

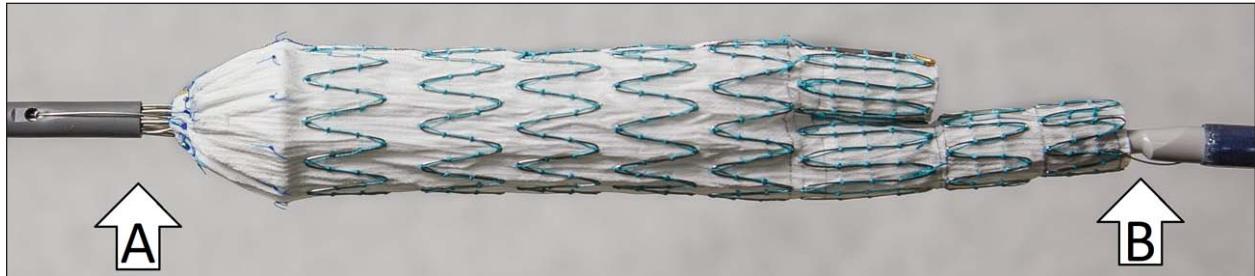
Twenty-five years of endovascular graft design has focused on meeting this requirement, with designs evolving from devices built by the implanting physicians for their specific patients in the operating room to highly engineered and extensively tested devices available today from several manufacturers. The methods of seal and attachment have varied, and include balloon-expanded stainless steel stents (the giant Palmaz [Cordis Corporation, Bridgewater, NJ]), self-expanding stents with infrarenal active fixation, self-expanding infrarenal stents with column strength but no active fixation, self-expanding stents with a suprarenal bare stent without active fixation, and steel self-expanding stents with a bare suprarenal stent with active fixation (Figure 2).



**Figure 2.** Proximal design of an endovascular graft including a self-expanding stent with suprarenal fixation and an internal self-expanding stent for sealing.

Until the analysis by Liffman et al,<sup>28</sup> originally presented in 1999, there had been little appreciation for the nature of the forces being applied to the proximal attachment stents. There was even less appreciation for the extent by which the relentless pulsation forces could bring about fatigue failure of the metallic and fiber components on the most proximal aspect of the endovascular graft, which can cause migration, with and without component failure. Some of the robust designs of this early phase, enhanced by detailed improvements, have survived to the present day and have been the platform for further development of specialized devices to address the hostile infrarenal neck.

Today, alternative infrarenal stent graft designs with unique means of excluding the aneurysm and achieving proximal seal and attachment are also being conceived and evaluated in clinical trials.<sup>29,30</sup> The surgical practice, in the absence of a satisfactory infrarenal neck, was to suture the graft to the healthy suprarenal aorta (and provide flow to the renal and any visceral vessels other-



**Figure 3.** Multistage, controlled delivery of an endovascular graft is accomplished with multiple constraints. Retraction of the delivery sheath demonstrates proximal constraints (bare stent inside cap) (A) and a distal constraining wire (B).

wise occluded) by implantation or bypass procedures. As such, the alternative endovascular strategy is also to move more proximal into the visceral aorta for better seal and attachment in healthy vessels. Again mimicking the surgical approach, endovascular devices were developed, beginning as early as 1997, with the intent to place the sealing component above the renal arteries and supply flow to the renal and the mesenteric vessels with fenestrations and/or side branches.<sup>31</sup> Continued development of devices targeted toward a more proximal seal continues today.<sup>32-34</sup>

Similar to open repair, the primary design objective of AAA endovascular grafts is simply to prevent aneurysm rupture and subsequent patient death. However, durable exclusion of the aneurysm sac from hemodynamic pressure requires that several interrelated design functions and specific performance goals be achieved to meet this primary design objective. First, the endovascular graft delivery system must have the ability to accurately deploy the graft in its intended location. Once placed in its intended landing site, the endovascular graft must provide a proximal seal and prevent its migration. Most importantly, the graft must provide these functions for the life of the patient; structural durability of the device is paramount. Herein is a discussion of these fundamental design features and the performance criteria required to achieve these design functions.

#### Deployment Accuracy

Achieving reliable and accurate deployment is critical to the long-term success of the repair. Failure of the endovascular graft to deploy and subsequent need for conversion to open repair puts the patient at high risk. Butch et al reported a perioperative mortality rate of 22% for patients who were converted to open repair in the EUROSTAR study.<sup>35</sup> Although the majority of the deployment failures in this study were related to early device designs, they underscore the importance of deployment reliability. In addition to reliability, deploy-

ment accuracy of the endovascular graft system has a significant effect on the success of the repair, specifically the ability to attain adequate proximal seal. Consider the AAA with a 15-mm-long proximal neck. If deployment accuracy can only be expected to be within 5 mm, the resulting seal zone may only be 10 mm in length, or worse yet, a renal artery may be covered.

Deployment accuracy is most critical when the neck available for seal is complicated with a short length, angulation, calcification, and/or thrombus. Multistaged, controlled delivery facilitates accurate placement of the endograft,<sup>36,37</sup> which in turn can maximize the amount of healthy aorta available for seal (Figure 3). However, it is important to note that specific aortic features (eg, a short neck, angulation, calcification, and/or thrombus) that require a precise landing zone may also make accurate endograft placement more difficult and result in an increased number of procedural complications.<sup>38</sup>

#### Radial Force and Proximal Seal

Once placed in a stable position, the endovascular graft must inhibit blood from leaking around the proximal seal (type IA endoleaks). Stents at the proximal end of the graft must exert adequate radial force, or sealing pressure, to keep the graft against the aortic wall throughout the cardiac cycle and potentially other biomechanical motions to prevent type I endoleaks. The radial force produced by stents varies based on the extent of oversizing, and thus proper oversizing is critical in maintaining a seal in the short- and long-term. Endovascular grafts are designed and tested to maintain adequate radial pressure over a specified range of oversizing. These oversizing recommendations are explicitly defined in the IFU, and oversizing outside these bounds risks complications such as endoleaks,<sup>39</sup> continued aneurysm growth and/or migration,<sup>40</sup> or endovascular graft collapse.<sup>41</sup>

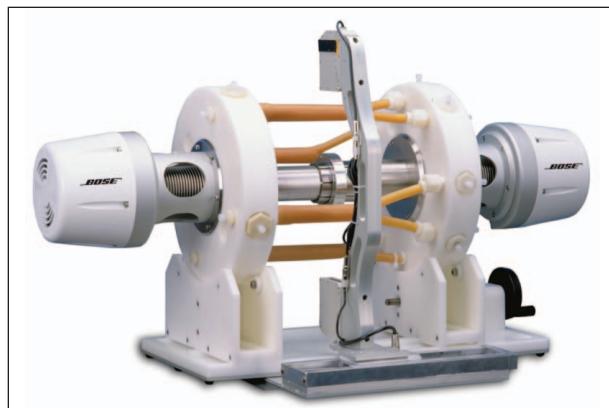
The mechanical properties and long-term stability of the aorta in the seal zone must also be considered in selecting an appropriate seal, so that the proximal endo-



**Figure 4.** An endovascular graft incorporating fenestrations and scallops to accommodate visceral vessels and allow sealing in the suprarenal aorta (A). Alternative designs incorporate features such as pivoting fenestrations to allow for variability in visceral vessel location (B).

vascular graft design can take advantage of that sealing zone. As previously stated, short-length seal zones, large neck diameters, significant angulation, the presence of thrombus, and calcification may increase the risks for type I endoleaks and sac expansion. These increased risks may not be a result of limitations in endograft design, but rather limitations in the durability of aortic seal zones with these features.

Architects and civil engineers have understood for thousands of years that there are specific requirements for designing foundations so that a structure is stable and durable for centuries to come. These requirements have less to do with the structural design capabilities of concrete, steel, or wood, but the ability of the earth to be stable under the weight of a building. We are only just beginning to understand these tradeoffs for endovascular grafts, especially in terms of how the seal zone of an endovascular graft interacts with a hostile neck. Rather than pushing the limits of infrarenal EVAR into a less-than-adequate seal zone, branched and fenestrated endovascular grafts were developed to take advantage of the additional suprarenal aortic segment, effectively increasing the amount of sealing zone available (Figure 4).<sup>31</sup>



**Figure 5.** Test setup used to evaluate fatigue durability of a bifurcated endovascular graft to treat AAAs. Devices sit inside the bifurcated tubes as the tubes are subjected to physiologic motion. Laser measurement tools are used to measure the motion of the tubes.

#### Migration Resistance

In order to maintain a durable seal and exclude the aneurysm for the life of the patient, the endovascular graft must maintain its position relative to the aorta. Endograft migration can lead to late failure of the repair, specifically, type I endoleak, aneurysm rupture, and death. Endovascular grafts are subject to a hemodynamically challenging environment in which they must resist the physiologic forces associated with blood flow. Fluid mechanics analyses show that bifurcated aortic endovascular grafts are subject to cyclic forces on the order of 10 N, acting to displace the graft in a caudal direction for the life of the patient.<sup>28</sup> As previously described, many means of fixation have been utilized in commercially available endovascular grafts, including columnar strength, iliac fixation, bare stents, and active fixation (eg, hooks or barbs) (Figure 2). Nonclinical studies comparing grafts with and without active fixation have demonstrated that endovascular grafts with active fixation have higher migration resistance (ie, force required to displace them from the aorta) than those without active fixation.<sup>42-44</sup> These findings have been supported by lower migration rates of devices with active suprarenal fixation in clinical use.<sup>40,45-48</sup>

#### Fatigue Durability

Finally, the endovascular graft must be durable in order to maintain its function for the life of the patient. Endovascular grafts must be evaluated in all modes where cyclic (fatigue) loads are expected. Primary cyclic loads are a result of pulsatile blood flow. However, the mechanical loads and arterial motions from other sources, such as respiration or other bodily motions, also need to be considered. The aggregate effects of these loads on all

components of the endovascular graft (eg, stents, graft, sutures, etc.) need to be thoroughly evaluated. Clinical use of early endovascular grafts has elucidated many potential failure modes. These failures provided the opportunity to develop new graft designs and, in parallel, new test methods to evaluate for potential failure modes. The result is mature testing equipment (Figure 5) and standards for endovascular testing.<sup>49</sup> Standards typically require testing to be completed for a 10-year equivalent of 400 million cycles.

## SUMMARY

The key challenges in achieving a stable and durable proximal seal in EVAR include inadequate length of healthy aorta for sealing, large neck diameters, and the presence of thrombus or calcification. These challenges have become increasingly critical as EVAR is disseminated to more patients, especially those whose proximal neck anatomy challenges IFU recommendations. These complex anatomies present key challenges to endovascular graft design. Engineering requirements for device deployment, proximal sealing, migration resistance, and durability were reviewed relative to these key challenges. Although advancements in endovascular graft design continue to push the indications for EVAR, it remains clear that healthy aorta is required for adequate fixation of the endograft to prevent migration and to maintain a durable seal without endoleaks. ■

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