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Treatment of Hostile Proximal Necks During Endovascular Aneurysm Repair

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Abstract

Endovascular aneurysm repair (EVAR) is a therapy that continues to evolve rapidly as advances in technology are incorporated into new generations of devices and surgical practice. Although EVAR has emerged as a safe and effective treatment for patients with favorable anatomy, treatment of patients with unfavorable anatomy remains controversial and is still an off-label indication for endovascular treatment with some current stent-grafts. The proximal neck of the aneurysm remains the most hostile anatomic barrier to successful endovascular repair with long-term durability. Open surgery for unfavorable necks is still considered the gold standard treatment in contemporary practice, despite the increased mortality and morbidity attributed to suprarenal cross-clamping, particularly in high-risk patients. Evolving technology may overcome the obstacles preventing endovascular treatment of unfavorable proximal neck anatomy; current approaches include purely endovascular as well as hybrid approaches, and generally include strategies that either extend the length of the short neck, move the proximal neck more proximally, or keep the short neck intact. These approaches include the use of debranching techniques, banding, chimneys, fenestrated and branched devices, filling the sac with endobags, endoanchors, and other novel devices. These newer-generation devices appear to have promising short- and midterm results. However, lack of good evidence of efficacy with long-term results for these newer approaches still precludes wide dissemination of endovascular solutions for the hostile proximal neck.

Key Words

Aneurysm · EVAR · Hostile neck · Angulated neck · Short neck

Introduction

One of the fundamental criteria for proper selection of patients who are good candidates for endovascular repair of an abdominal aortic aneurysm (AAA), to provide long-term success in prophylaxis of aneurysm rupture, is the anatomic characteristics of the aortoiliac arteries [1]. In particular, the most important area to consider is the proximal neck, e.g., the characteristics of the aorta below the lowest major renal artery and the beginning of the aneurysm. A short and/or angulated neck is considered hostile anatomy and can lead to complications after endovascular aneurysm repair (EVAR), such as loss of endograft fixation or seal, device migration, type 1 endoleak, sac enlargement, and, ultimately, aneurysm rupture and death [1,2].

The most common anatomic guidelines for successful EVAR, stated in most device manufacturers' instructions for use, are the presence of a proximal neck length of at least 1.5 cm with maximal angula-

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tion of the neck up to 60°. Therefore, the presence of a short (< 1.5 cm) and/or highly angulated proximal aortic neck (> 60°) portends reduced long-term efficacy of EVAR and is currently an off-label indication for repair with most commercially available devices [1]. Since traditional open surgical repair of aneurysms with short necks, e.g., juxtarenal aneurysms, is associated with increased mortality and impaired renal function in long-term, particularly high-risk patients [3], there remains impetus to improve the current approach to EVAR in patients with short necks. We review several of the current approaches to improving EVAR in patients with hostile proximal necks.

Extending the Length of the Short Proximal Neck

One approach to treat the short neck is to extend the neck length proximally so it is > 1.5 cm. Since this approach may cover renal or visceral vessels, alternative approaches to revascularization of these vessels is critical. Several approaches have been evaluated; revascularization of the excluded renal or visceral vessels was traditionally performed using open surgical techniques, although newer approaches use exclusively endovascular techniques.

(1) Extra-anatomic Bypass for Renal Debranching. In order to increase proximal neck length, the endograft is simply deployed more proximally into the pararenal aorta, covering the origins of the renal arteries. Revascularization of the covered vessels is performed in traditional fashion, typically with performance of a hepatic-renal bypass for the right renal artery and/or a spleno-renal bypass for the left renal artery. Alternatively, an ilio-renal bypass can be performed on either side. The endograft is placed conventionally, except for the exclusion of the debranched renal artery [4,5]. The extra-anatomic revascularization is typically performed prior to the endograft placement to avoid any renal ischemic time; in addition, this procedure may be staged, a potential advantage for some patients. This hybrid procedure requires a laparotomy, negating this potential advantage of EVAR.

(2) VORTEC (Viabahn Open Revascularization Technique). This is a variant of the above hybrid debranching procedure, with the distal anastomosis of the debranching procedure performed using a covered stent, avoiding a sutured distal anastomosis in the target visceral vessel [6]. A self-expanding covered stent or stent-graft, such as a Viabahn or Hybrid graft (W. L. Gore & Associates, Flagstaff, AZ) is placed via Seldinger technique into the target renal or visceral artery; the proximal end of the covered stent or graft that remains outside the artery is directly sutured to the proximal native artery or main endograft to complete the extra-anatomic revascularization (Fig. 1). The advantage of this technique is that it preserves the target vessels that are difficult to dissect and control, or are otherwise encased in scar tissue. However, the experience with this type of procedure is limited and still requires laparotomy to be performed in a hybrid fashion.

(3) Proximal Aortic Neck Banding. In order to extend the short aortic proximal neck, the neck is extended distally onto the proximal aspect of the aneurysm through a banding procedure to reinforce the strength of the neck. Typically the banding is performed via a small supraumbilical mini-laparotomy, or it can be performed laparoscopically by surgeons with these skills. After dissection of the infrarenal aortic neck, potentially including a small amount of the proximal aneurysm, a strip of Dacron felt is passed circumferentially around it and tightened firmly [7]. EVAR is then performed in the usual fashion, anchoring the device proximally within the banded zone (Fig. 1). The advantage of this procedure is that it avoids moving the neck proximally and does not require revascularization of the visceral branches. A potential disadvantage of this technique is the limited experience and the inclusion of a small area of aneurysm within the landing zone, although this technique has often been used in open aneurysm repair as well.

(4) The Chimney or Snorkel Technique. This technique is an endovascular extension of the proximal neck. A stent is placed with its distal end into the renal or visceral artery, and with its proximal aspect placed parallel to and within the proximal aorta; the EVAR is then performed, with the proximal end of the main body of the stent-graft placed alongside the newly placed stent (Fig. 1). The newly placed stent acts as a "chimney" or "snorkel" around the stent-graft, creating a "double barrel" or dual-channel flow path, perfusing the target vessel alongside the aortic endograft. The stent-graft and the chimney graft are sealed together in the new proximal neck, avoiding a proximal type 1

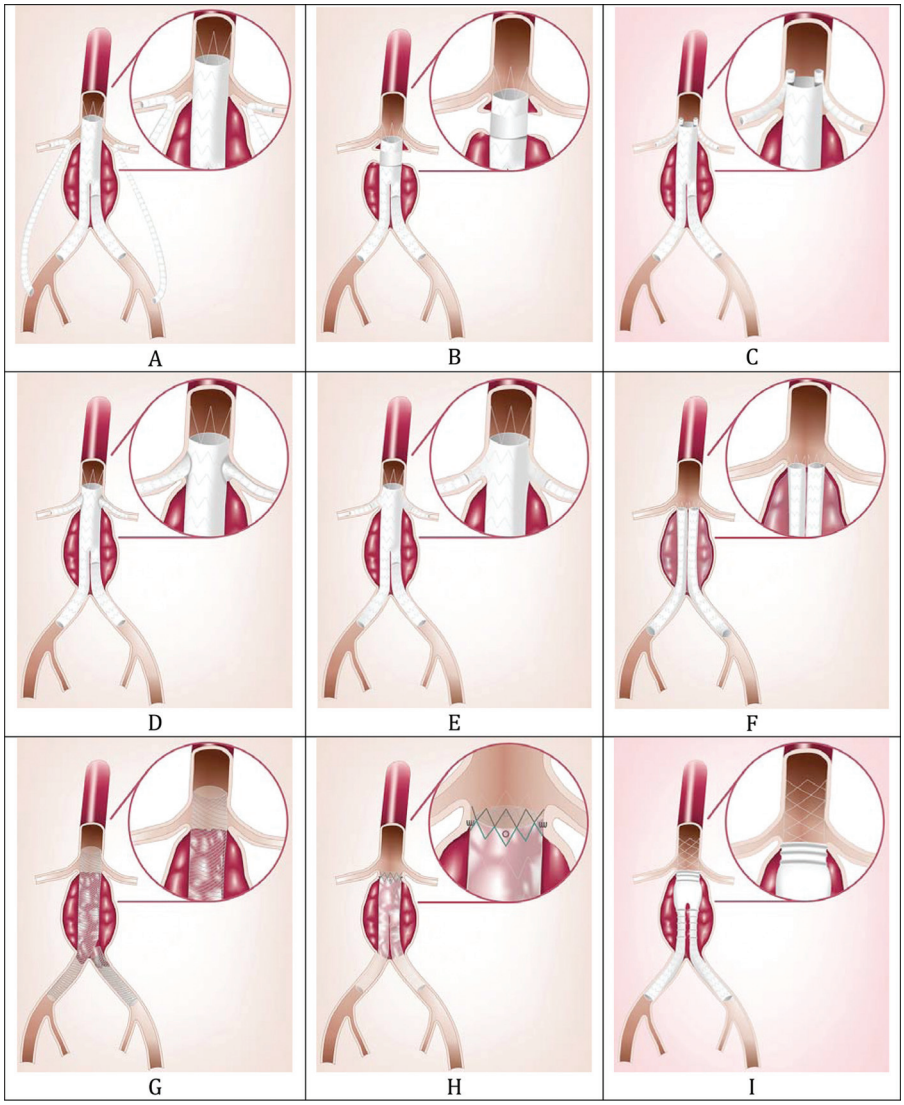

Figure 1. Different types of techniques for AAA repair in cases of a hostile proximal neck. (A) VORTEC, (B) neck banding, (C) chimney, (D) fenestrated, (E) branched, (F) Nellix, (G) Multilayer, (H) endostapling, and (I) Ovation.

endoleak. This technique is simpler and cheaper compared to using fenestrated and/or branched devices (discussed below), and is readily available ("off-the-shelf"), particularly in the emergency setting [8,9].

Long-term durability of chimney grafts will likely be related to the degree to which the two parallel stent-grafts are apposed to each other; incomplete apposition may compromise the aortic seal zone and even lead to deformation of one or both stent-grafts, ultimately leading to kinks, fractures, or leaks.

Antoniou et al. [10] reviewed 21 studies treating the juxtarenal or suprarenal aorta with this technique. In 102 patients, there was a technical success rate of 91%, and perioperative mortality was 5% and major morbidity was 17%; there was type 1 endoleak in 13%. The authors concluded that this technique may serve as a complementary technique in high-risk patients.

Moulakakis et al. [11] reviewed the use of the chimney graft technique in the visceral vessels of 93 patients, 77.4% of whom had abdominal aortic aneurysms. A total of 134 stents were placed with primary technical success in 100%. However, type 1 endoleak occurred in 13 patients (14%). Three of these 13 were diagnosed intraoperatively, and two of these were

treated with an aortic stent-graft, while the third was corrected with an Amplatzer occluder device. Of the 10 cases that were detected during follow-up, only 4 needed reintervention whereas in 6 cases the endoleak sealed spontaneously. The 30-day in-hospital mortality was 4.3%; 12% of patients suffered renal function impairment. During a mean follow-up of 9 months, 97.8% of the stents remained patent.

Early results with the chimney technique suggest safe and effective treatment of the patient's aneurysm, considering the traditional limitations of a hostile proximal aortic neck. However, long-term endograft durability and proximal fixation will remain a significant concern until these results are reported. In the absence of long-term data, there has been a reasonable hesitation to adopt this technique.

Moving The Proximal Neck More Proximally

Another approach to treating aneurysms with hostile proximal necks is to abandon the site and move the proximal sealing zone entirely more proximally to a more appropriate site. This approach is more suitable for an entirely endovascular approach; however, the need to revascularize the visceral segment makes this approach more technically complicated. The current approach generally uses fenestrated and/or branched grafts.

Fenestrations and branches are two approaches to revascularization of the visceral arteries. Fenestrations or scallops are complete or partial holes in the stent-graft fabric that provide direct access to a branch artery; after the main body is placed, these arteries are typically accessed, a balloon-expandable covered stent is placed, and the proximal end of the covered stent is then flared against the inside of the stent-graft, providing a seal around the branch artery (Fig. 1). Although branched aortic stent-grafts can be used to revascularize visceral arteries in thoracoabdominal aortic aneurysms [12–14], application to treat AAA with a hostile neck is not currently popular. The main limitation of the use of this technique in AAA with a hostile neck is the anatomy. Branched aortic stent-grafts require deployment in an aneurysmal area in order to have sufficient working room to facilitate manipulating the branches. This condition is rarely met in AAA with a hostile neck. Branched endografts have prefabricated branches for the visceral arteries that are integral to the main device. In general, in fenestrated systems, the covered stents for the branches are oriented perpendicularly away from the main body, through the fenestration and into the branch artery. Branched systems often allow the covered stents to curve at other angles away from the main body (Fig. 1) [15]. The fenestrated and branched approach allows extension of the proximal seal zone or moving it entirely more proximally, depending on the number of fenestrations and branches.

Since the first implantation of a fenestrated graft in 1996, there has been tremendous advancement in the technology driving these devices [16]. The fenestrated endovascular aneurysm repair consensus working group of the British Society of Endovascular Therapy concluded that the current role of fenestrated devices remains unclear [17]. Literature review showed heterogeneous case series without clear indications for use of fenestrated devices. A survey of current practice in the United Kingdom showed wide variations in practice. Consensus agreement on the role of fenestrated devices was present, at most, in only 68%, with more consensus present on the risk associated with open repair and suprarenal cross-clamping, and less consensus for age over 85 years, 5.5-6 cm aneurysms, and short-necked infrarenal aortic aneurysms.

Cross et al. [18] reported a meta-analysis of 660 fenestrated procedures. Definitions of aneurysm morphology were variable, and clear inclusion and exclusion criteria were not always clearly documented. Target vessel perfusion rates ranged from 90.5 to 100%. The 30-day mortality was 2.0%. Morbidity was poorly reported. The authors concluded that fenestrated repair for juxtarenal and suprarenal aneurysms is a viable alternative to open repair; however, there is currently no level 1 evidence supporting its efficacy, with current evidence being weak and leaving many unanswered questions.

Tambyraja et al. [19] reported midterm results of 29 patients who were treated with fenestrated devices. No procedures required conversion to open surgery, but one procedure was abandoned. A total of 79 visceral vessels were treated and documented as patent at completion angiography. No patient died within 30 days of surgery. Follow-up was for a median of 17 months during which there was 14% mortality that was not aneurysm related. However, 62% of patients had graft-related complications and 38% required reintervention. The authors concluded that fenestrated devices are a safe option to treat juxtarenal aneurysms in patients at high risk for open surgery;

however, the high rate of graft-related complications and reinterventions, even during medium-term follow-up, is concerning.

Currently there are three classes of fenestrated devices:

- Customized devices, such as the Zenith (Cook Medical Inc., Bloomington, IN), Jotec, or Anaconda (Terumo, Ann Arbor, MI) devices, typically require a 6- to 8-week period for custom manufacturing for patient-specific anatomy. This is a good option for elective patients, but it is not widely available or for patients in need of urgent or emergent repair [20].
- Surgeon-modified devices are immediately available, formed as needed from off-the-shelf devices available to the surgeon, and overcome the long manufacturing time required for custom devices. However, these modified devices often require considerable time and effort to create and use, and in many instances, these devices cannot be tested prior to deployment; in addition, the legal ramifications of using these devices in elective patients is not clear [16,20].
- Standard devices that can treat patients with particular anatomic specifications can be stocked and ready for emergent use. The Ventana system is designed with two renal fenestrations, a superior mesenteric artery fenestration, and a scallop for the celiac artery. Interestingly, it is possible to access a wide range of renal artery anatomies, as the device has a dome with an outer 15 mm diameter and an inner 6 mm diameter fenestration [21]. Initial experience in 7 patients showed 100% success in target vessel catheterization and one renal artery occlusion at 2 months [21].

Keeping The Short Proximal Neck

A third approach to treating aneurysms that have a hostile proximal neck is to use a device that treats the aneurysm using an entirely different paradigm.

(1) The NELLIX System. The Nellix (Endologix, Irvine, CA) endoprosthesis consists of dual, balloon-expandable endoframes, surrounded by polymer-filled endobags, which obliterate the aneurysm sac and maintain endograft position. Its use is intended for both favorable and adverse anatomy, including neck length < 10 mm, neck angle $> 60°$, and iliac diameter > 23 mm (Fig. 1) [22]. Initial experience with 34 patients reported no change in aneurysm size or endograft position and no new endoleaks in follow-up up to 2 years, without any differences in outcome between patients with favorable and adverse anatomy [18].

(2) The Multilayer System. The Cardiatis (Isnes, Belgium) 3D multilayer braided stent is fabricated in several interlocking layers (Fig. 1); this configuration reduces the trans-stent flow up to 90%, reducing sac pressure and risk of rupture, but apparently preserves flow in branches [23–25]. However, aortic rupture after stent placement has been reported [26].

(3) Endostapling and Endoanchoring Systems. There are two current systems available to improve the device fixation to the hostile proximal neck, endostapling systems [27] and endoanchoring systems (Aptus, Sunnyvale, CA) (Fig. 1) [28]. The endostapling systems were developed to improve sealing at the proximal neck and prevent migration. However, a systematic review of the literature was not conclusive, as no randomized controlled trials have been published [29]. Use of these systems is associated with reduced rates of type 1a endoleak and migration, suggesting reduced future need for reintervention.

(4) Reinforcement With a Palmaz Stent. Farley et al. [30] reviewed 18 cases in which Palmaz stents were placed as an adjunct to EVAR in patients with a hostile aortic neck after a type 1 endoleak was detected. The authors concluded that this approach was effective. Chung et al. [31] reviewed midterm outcomes and reported that this strategy does not appear to compromise durability of this procedure. However, patients requiring adjunctive Palmaz stent placement are likely to be at high risk for subsequent graft-related events.

(5) Use of Thoracic Endografts. To treat severe aortic neck angulation, Silingardi et al [32] reported placement of the EVAR main body stent graft within a thoracic stent graft placed just below the most distal renal artery, a clever but expensive adjunct to achieve a proximal seal.

(6) The Ovation Abdominal Stent Graft System. The Ovation Abdominal Stent Graft System (TriVascular Inc. Santa Rosa, CA) consists of a device with a main body with polymer-filled rings on its top that can seal the aortic neck, a

suprarenal stent with anchors for suprarenal fixation, and polytetrafluoroethylene (PTFE)-covered nitinol stents for the iliac limbs (Fig. 1).

Mehta et al. [33] published the 1-year results of a multicenter trial using the Ovation stent graft. The authors included patients with the following characteristics of the proximal neck length. (1) Proximal neck length should be ≥ 7 mm and inner diameter from 16 to 30 mm. (2) If the proximal neck length is < 10 mm, then the neck angulation should be $\leq 45°$. (3) If the proximal neck length is ≥ 10 mm, then the neck angulation should be $\leq 60°$. The device implantation succeeded in 161 patients (100%). There was one major adverse event (death) at 30 days (0.6%); in this patient the polymer-filled rings became disconnected and the polymer was injected intravascularly, which resulted in anaphylaxis and culminated in a fatal outcome. After 1 year, AAA-related mortality was the same (0.6%) and all-cause mortality was 2.5%. There was no stent-graft migration and the only type of endoleak observed was type II (34% of patients). There was sac enlargement in only one patient, which did not rupture. The authors suggested that the Ovation stent graft was safe and effective in the treatment of AAA with a hostile neck. However, longer follow-up is needed.

The Angulated Neck

One important cause of a hostile proximal neck, in addition to the short neck, is the angulated neck. In this situation, the use of EVAR may be difficult and unsafe. Most aortic stent-grafts are not recommended for use in those aortas with a neck having $> 60°$ of angulation. However, new grafts have been designed to be used in extremely angulated aortic necks.

(1) Aorfix. A new device that has been approved by the FDA is the Aorfix from Lombard (Oxfordshire, UK). Weale et al. [34] studied the safety and early outcome of 30 patients with severe proximal neck angulation (mean 81.2°) treated with the Aorfix endovascular stent-graft. Three patients had type 1 endoleaks noted intraoperatively and treated immediately by balloon angioplasty. Clinical success at 30 days was 96.7% with no type 1 or type 3 endoleaks, and no graft thrombosis or migration. At 6 months, two patients developed type 1 endoleaks that did not require intervention; no patient died due to aneurysm rupture or required removal of the endograft. The authors concluded that the Aorfix graft was a reasonable option to treat patients with aneurysms that have highly angulated necks. However, no mid- or long-term results are available.

(2) Endurant. One of the Endurant (Medtronic, Minneapolis, MN) stent-graft's design features is to expand applicability of EVAR. Verhagen et al. [35] reported the first-in-human European trial and concluded that it can be delivered and deployed safely even in the presence of severe angulation. Bastos Gonçalves et al. [36] compared treatment of patients with hostile proximal necks (mean 80.8° angulation) to patients with favorable necks and concluded that the Endurant device has satisfactory outcomes in both angulated and nonangulated anatomies. However, long-term results are needed to verify its durability.

(3) C3 Excluder. The C3 Excluder (Gore, Flagstaff, AZ) stent-graft claims to have increased accuracy with controlled deployment at the proximal landing zone due to the ability to constrain the graft after initial deployment, allowing repositioning [37]. An early experience with this system demonstrated good function of the deployment system, allowing repositioning as needed. Additional cuffs were not required in the 25 patients of this study, with no mortality and no type 1 endoleaks at early follow-up; no long-term data are available [37].

Perspective on Development of New Technology

Many EVARs are performed in cases that do not meet the manufacturers' instructions for use due to hostile anatomy [1,2,38,39]. This practice is likely a reflection of the need to treat increasing numbers of high-risk patients, especially as the population ages and lives with a greater number of comorbid conditions. The literature suggests that it is reasonable to expect satisfactory rates of aneurysm palliation in the midterm and possibly even the long term for these patients, as long as type 1 endoleaks are detected and treated [2,38,39]. However, treatment of persistent type 1a endoleaks in this group of patients is challenging and remains a persistent criticism of EVAR in patients with hostile neck anatomy [40].

In specialized and tertiary centers, traditional open surgery still remains the gold standard to treat stan-

dard-risk patients with anatomy that is poorly suited for EVAR. Chisci et al. [41] compared outcome of open repair and EVAR, using both standard and fenestrated stent-grafts, and concluded that despite increased numbers of reinterventions after EVAR in patients with hostile necks, the results of open surgery and EVAR were similar. Greenberg et al. [42] questioned, "Should patients with challenging anatomy be offered endovascular aneurysm repair?" Comparing outcomes in patients at high and low anatomic risk, the authors reported similar perioperative mortality (0.7% versus 1%) and increased frequency of endoleak in patients with high-risk anatomy (25% versus 11%), but this increase was not statistically significant ($P > 0.05$). Despite acceptable short-term technical results, reduced long-term survival (largely unrelated to the procedure) and slightly higher frequency of endoleak may temper enthusiasm for EVAR in patients with hostile necks with current generation devices.

These conflicting results reflect the continuing evolution of the endovascular devices and their reception in the general vascular surgical community. The promise of new technology to treat an ever-shrinking number of patients with challenging anatomy is both exciting and threatening. However, given manufacturers' incentives to treat as many patients as possible, patients may benefit with continuing refinements and less invasive procedures.

Some intraoperative maneuvers help achieve effective and durable fixation and sealing of stent-grafts in patients with hostile proximal neck anatomy: use of high-pressure balloons to reinforce the seal, deployment of a proximal cuff, controlled slow deployment of the main body of the stent-graft, use of the bending-the-wire technique to realign the axis of the aneurysm with the neck, and use of appropriate C-arm angulation to adequately visualize the landing zone [44]. As endovascular technology continues to evolve, it is likely that additional maneuvers will evolve, enhancing the surgeon's skill in dealing with hostile anatomy.

Conclusions

An issue that will need attention in the future is the observation that we and others have made, that neck angulation after EVAR can change during follow-up [45]. As such, endografts must be durable to changing seal zone anatomy and forces as the aneurysm continues to remodel, a challenge to the long-term durability of these devices. However, recent improvements in technology have allowed current generation devices to better deal with difficult anatomy [46]. As technology evolves, treatment will expand to additional patients and will prevent complications inherent in older devices [46].

Unfavorable anatomy, and, in particular, a hostile neck, represents a major limitation to performing EVAR. Despite a number of devices and techniques that have been developed to treat short and/or highly angulated necks, the results of EVAR in this setting remain suboptimal, limited in length of follow-up time, and supported by insufficient numbers of large series. Perhaps the major barrier to successful aneurysm treatment is the lack of understanding of the biology of aneurysms, in particular, the long-term natural history of aneurysms, especially with a stent-graft in place. It is imperative to understand the magnitude and types of forces that the aneurysm continues to exert on the stent-graft so the durability of EVAR as a treatment can be effective in the long-term, both for individual patients and as a cost-effective treatment for society and payers. Until we understand aneurysm biology more completely, long-term durability will continue to rely on appropriate patient selection, outstanding operator training, and continued improvements in technology [46].

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

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