The Evolution of Lower-Profile EVAR Delivery Systems

The impact of lower-profile systems on iliac and access-related complications and outcomes.

BY W. ANTHONY LEE, MD, FACS

More than 2 decades have passed since the introduction of endovascular therapy for the treatment of abdominal aortic aneurysms. Since then, significant advances in the endografts and their delivery systems have been made, both in terms of newer materials and design constructs. One aspect of these technological improvements has been in the so-called crossing profile of the delivery systems. This article outlines and highlights the impact that a lower-profile delivery system may have on the reduction of iliac and access-related complication rates during endovascular aneurysm repair (EVAR).

CURRENT STATUS

Early in the development of aortic endografts, unibody devices were introduced in an attempt to mimic the mechanical and anatomic features of a surgical bifurcated graft. Over the years, there has been a convergence of "form following function" where nearly all devices that are either presently available or in the regulatory pipeline are based on modular platforms. This fundamental modular design decreased the device profile, allowed customization of the repair to individual anatomy, and reduced the overall matrix of size offerings, which expedited the manufacturing process and reduced the overall volume of inventory by reducing the number of different parts needed to be made.

When considering these devices, one must approach them as an endovascular system instead of individual components, such as the main body, limb, or delivery system. Substantive design improvements in the delivery system must be linked to concomitant changes to the endograft itself. In the context of device profile, the design constraint that has challenged engineers has been how to make the system smaller without compromising the durability of the repair.

Broadly speaking in terms of profile, current and pipeline endograft systems can be categorized as standard, low, and ultra-low profile. Although, admittedly, this type of categorization has not been standardized, nor has the criteria for inclusion into one category versus another been clearly defined, there would be general consensus by most operators as to which endograft system might belong to one category versus another. Within any given endograft system, the largest and the smallest profiles may overlap with the profiles of another lower- or higher-profile system. Table 1 categorizes the endograft systems that are either currently available or undergoing the pivotal phase of their clinical trials with respect to their profiles (Figure 1). As the main bodies are larger than their respective limbs, the profile of the former is generally the rate-limiting factor when it comes to vascular access and serves as the principle criteria used for inclusion into one category versus another.

It should be noted that the profile designations by manufacturers do not follow any industry convention. Some reference the inner diameters of an integrated delivery sheath, whereas others refer to the profile of the bare constrained endograft, despite an obligatory use of an introducer sheath to safely deliver the device within the vasculature. Therefore, caveat emptor, as profile comparisons should be made using the proverbial "apples to apples."

ACCESS SITE COMPLICATIONS

In nearly every endograft clinical trial, access-related complications dominate the catalog of serious adverse events in the acute setting after EVAR.[1-3] These vascular complications range from localized dissections and bleeding to life-threatening, catastrophic iliac ruptures. Femoral artery injury at the site of insertion typically cannot be managed by endovascular techniques, even if the proce-

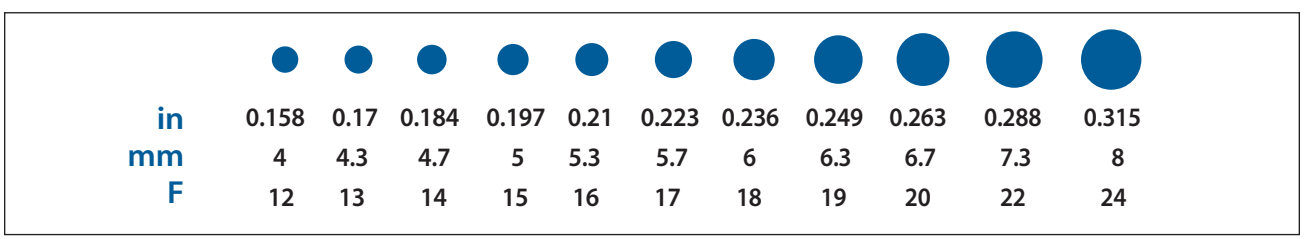

Figure 1. French sizes to scale.

TABLE 1. EVAR ENDOGRAFT SYSTEMS EITHER CURRENTLY AVAILABLE OR UNDERGOING CLINICAL TRIALS IN THE UNITED STATES

System	Main Body (OD, F)	Iliac Limb (OD, F)
Ultra-Low Profile		
Incraft (Cordis Corporation)*	14–16	12–13
Ovation (TriVascular, Inc.)	14–15	12–15
Low Profile		
Endurant II (Medtronic)	18–20	14–16
Evo (Medtronic)*	15–17	13–16
Nellix (Endologix, Inc.)*	17	N/A
Treovance (Bolton Medical)*	18–19	15–16
Zenith LP (Cook Medical)*	18	16–18
Standard Profile		
AFX (Endologix, Inc.)	19	11
Aorfix (Lombard Medical, Inc.)	22	20
Excluder C3 (Gore & Associates)	20	14–17
Zenith (Cook Medical)	21–23	16–18

**Currently in a pivotal phase clinical trial.*
Abbreviations: F, French; N/A, not applicable; OD, outer diameter.

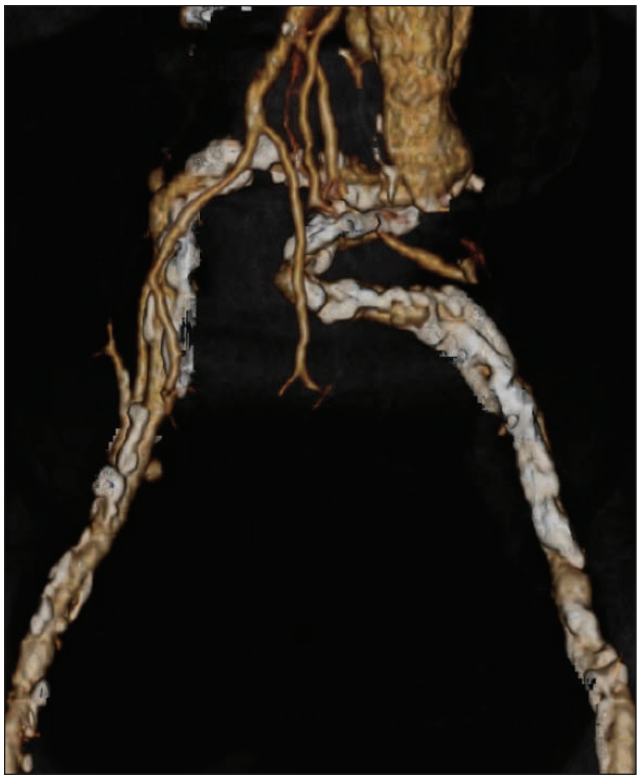

Figure 2. Severe iliofemoral calcific occlusive disease combined with tortuosity.

dure was attempted percutaneously, due to the location of the injury in the common femoral artery, the proximity to the femoral bifurcation, and the inability to access the site of injury from the contralateral artery once the bifurcated repair is completed. Arterial repair often requires endarterectomy and patch closure of the arteriotomy.

Consequences of these complications include increased procedure times, duration of anesthesia, and risk of wound infection. Failure to promptly recognize access site injury can lead to limb thrombosis and leg ischemia, either as related or independent events. Interestingly, endograft limb thrombosis does not often lead to critical limb ischemia, as does a femoral occlusion. Provided that the limb has been properly deployed proximal to the hypogastric artery, collateral perfusion to the leg from the hypogastric artery is sufficient to maintain viability of the leg, and patients often present with proximal claudication. Perioperative thrombosis of the femoral artery is a more serious matter, as it threatens the patency of the endograft limb itself (especially in the setting of a diseased or occluded ipsilateral hypogastric artery) and severely compromises the distal perfusion to the leg. In these situations, patients often present in the first few postoperative hours with a severely painful, cool, and pulseless leg that is consistent with critical limb ischemia.

ILIAC VESSELS

Endograft profile can have an impact on vascular complications remote from the access site itself, namely the iliac vessels. The presence of occlusive disease, with or without tortuosity, can significantly affect one's ability to deliver the endograft safely to the intended target (Figure 2). Despite the use of superstiff guidewires to straighten most cases of tortuosity, the iliac arteries become extremely rigid when combined with significant calcific disease, and even the stiffest guidewires are forced to conform along compound curvatures. Although there are many mechanical factors that contribute to the trackability of a particular device, profile is clearly a dominant factor, and in this instance, smaller is better. Vigorous attempts to advance an endograft through a calcified, atherosclerotic, tortuous iliac artery can result in iliac dissection and, in the worst case, iliac rupture (Figure 3). Acute hypotension is often seen, and bailout techniques have been described to manage this life-threatening complication. However, localized iliac dissection is more insidious and may be more difficult to diagnose acutely. The reason is that during completion angiography, the external iliac arteries are frequently incompletely visualized due to presence of the delivery sheaths. Even after the delivery system is removed, the femoral artery is repaired, and a normal pulse is palpated, a flap may acutely occlude the iliac artery in a delayed manner.

Although the causes of endograft limb occlusion may be varied, one of the most common reasons is compromised outflow. Typical limbs are large in diameter, and occlusion from compression or kinking results in significant luminal reduction. On the other hand, this same attribute of endograft limbs requires a robust outflow in order to

maintain patency, and iliac occlusion from an unrecognized dissection can rapidly result in limb thrombosis.

Finally, although women comprise only 20% of the demographics treated by this therapy, they bear the brunt of the vascular access–related complications due to the relatively smaller size of iliofemoral vessels.[4] Before the availability of low-profile devices, alternative access techniques had been devised to overcome compromised access cases. Over the years, these have included conventional endovascular techniques of balloon and/or so-called "Dotter" angioplasties to "crack and pave" where the iliac artery was lined with a covered stent and purposely dilated (and ruptured), as well as creation of a temporary retroperitoneal iliac conduit. The need for these types of adjunctive techniques ranged from 10% to 13% in the early years of EVAR.[4] However, with the introduction of lower-profile devices, the need for these techniques has become exceedingly rare. This is fortunate, as these procedures significantly contributed to the early morbidity and outcomes of the therapy itself, delayed recovery, and obviously detracted from the overall benefits of endovascular repair, especially in those who had the most to gain from the less-invasive nature of the procedure.[5]

PERCUTANEOUS EVAR

Although percutaneous closure of access sites (i.e., the "preclose" technique) without the need for any direct surgical exposure of the femoral arteries had been described and routinely practiced by some operators for over a decade, its adoption has been gradually gaining momentum over the past 5 years.[6] Informal surveys among vascular surgeons show that the practice of this technique has gone from < 5% in the last decade to > 30% at the present time. This can be attributed to multiple factors, including improvements in suture-mediated closure devices, increased operator exposure to the technique during vascular training, and certainly the decreased profile of endograft systems. When properly performed in appropriately selected patients, percutaneous EVAR has led to a decrease in: procedure times, pain and discomfort from bilateral groin incisions, and most importantly, the wound complication rates that have plagued EVAR procedures.

Although, historically, suture-mediated closure has been associated with infrequent but limb-threatening necrotizing femoral arteries and mycotic pseudoaneurysms, the introduction of the monofilament suture, stricter adherence to sterile technique, and performance of most EVARs in the operating room environment (versus a cath lab) have significantly reduced the incidence of these serious adverse events. The result has been the ability to perform select cases using local anesthetic on an ambulatory basis with return to the patient's baseline activities in 24 to 48 hours.

CONCLUSION

EVAR has seen many technological improvements since its introduction nearly a quarter century ago. One of these has been the progressive reduction in the profile of the delivery systems. At the present time, the Ovation® System (TriVascular, Inc.) represents the smallest-profile endograft system currently available in the United States. Profile reduction has led to significant benefits for the patient, including safer and shorter procedures, decreased pain and discomfort, and faster recovery, all without compromising the durability and long-term effectiveness of the repair. ■

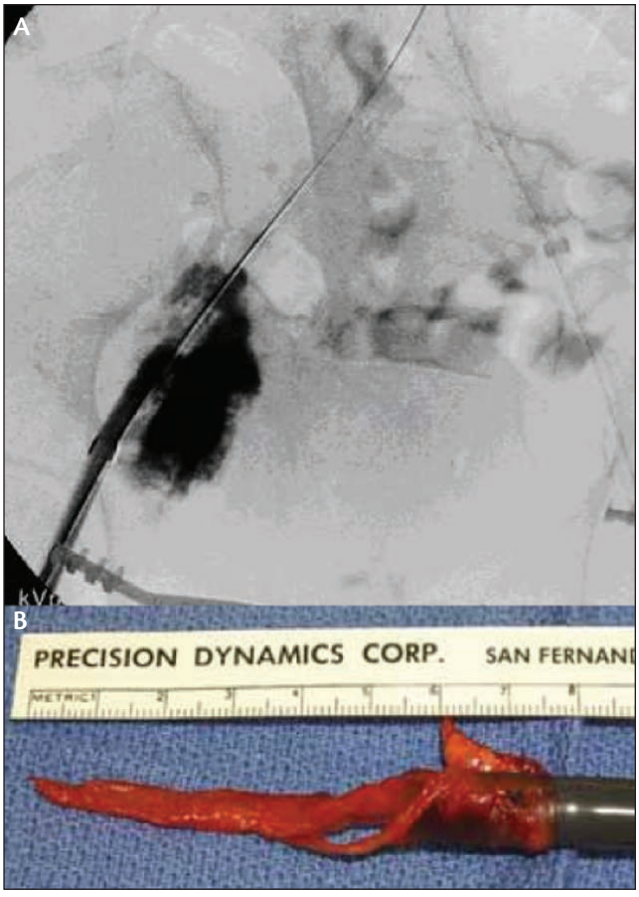

Figure 3. Iliac rupture with extravasation (A); avulsed external iliac artery attached to the delivery system (B).

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