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THE PATENCY ISSUE

Leading EVAR experts highlight the latest technology and strategies to promote long-term limb patency in the most challenging anatomy.

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Maintaining Stent Graft Limb Patency

Daniel G. Clair, MD, discusses the risk factors leading to limb failure and device elements that can help diminish this complication.

The literature has shown that there are several risk factors that may lead to stent graft limb occlusions. What are the primary anatomical and procedural risk factors for limb complications?

The anatomic risk factors affecting limb thrombosis include angulation, tortuosity, and smaller-diameter iliac vessels, along with extensive calcification. These factors can affect not only limb thrombosis, but also delivery of the device to the treatment site. Additionally, the flow channel through the aneurysm can affect limb patency, as aneurysms with either extensive thrombus or some anatomic constriction within the flow channel can lead to compression of one or both limbs, which can reduce limb patency. In general, narrow or significantly angulated anatomy is a predisposition to limb thrombosis. An additional anatomic factor affecting limb patency is outflow anatomy. In most situations, the larger the vascular outflow bed, the better the patency of the limb, so restricted vascular outflow can negatively affect limb patency and increase the risk of thrombosis.

The primary procedural risk factors for limb thrombosis include some things that can be as simple as inadequate anticoagulation during the case. If thrombus is present, either in the graft itself or the outflow vessels, there is an increased risk of graft thrombosis. Significant angulation in the limb or graft itself can limit flow through the graft and lead to thrombosis, so these issues need to be addressed at the time of the procedure. Graft limbs ending in angulated anatomy need to be adequately assessed to ensure the limb is not ending directly into a severe angle that is restricting flow. These distal endpoint issues can often be addressed by either extending the graft limb or transitioning the graft limb into the native iliac anatomy with self-expanding stents. Injury or damage to the iliac vessels during insertion can lead to impaired patency rates, especially if the injury is flow-limiting and unrecognized. For example, this can happen when there is a dissection where the introducer sheath is located and the area of the sheath insertion is not imaged during completion imaging. Damage to the vessels at the point of insertion is particularly problematic, because this type of injury often cannot be assessed during completion imaging and may not occur until closure of the access point. Another critical factor is that the more distal in the anatomic bed the limb is placed, the higher the likelihood of occlusion. Therefore, graft limbs ending in the external iliac artery have lower patency rates than those placed in the common iliac artery.

How does stent graft design and material affect potential limb complications?

There is evidence that unsupported limbs have lower patency rates than fully supported limbs. Currently, there are really no devices in use with unsupported limbs. There is also at least some evidence that polytetrafluoroethylene (PTFE) is potentially associated with lower limb thrombosis rates, perhaps due to less inflammation, when compared with alternative fabrics (i.e., PET, also known as polyester/Dacron). In addition, there are some grafts with better flexibility, which will sit better in some anatomies and allow better accommodation of the graft and less limb kinking. It also is clear that larger limb diameters have better patency rates, although this needs to be taken in the context of assessing the vessel into which the device is being placed. Severely oversizing a limb into a small external iliac artery does not improve patency. In general, larger limbs provide better patency rates, but there is perhaps some evidence that shorter limbs improve patency as well.

Of all the previously discussed risk factors, which are responsible for the majority of limb occlusions?

Of these aforementioned factors, graft limb kinking and distal vessel disease appear to be the most common issues associated with graft limb thrombosis. More than the other causes, these two issues affect flow and can lead to thrombosis both early and late postprocedure.

Which endovascular aneurysm repair (EVAR) techniques may help reduce limb complications?

EVAR techniques to prevent this problem include utilizing a graft that will be the best fit for the patient and ensuring that outflow disease is treated adequately before completing the procedure. In choosing a graft, consider the iliac artery anatomy and ensure that the limbs are

flexible enough to accommodate the iliac flexibility. In patients with severe iliac disease, smaller device delivery systems should be chosen, and wire and device insertion should be carefully performed to avoid dissection. Completion imaging should include the iliac arteries below the point of graft insertion and may require removal of the device delivery sheath, as well as imaging of the vessels after the sheath has been removed to ensure that there is no vessel damage and there is good flow through the iliac artery below the stent graft limb. When the iliac artery is severely diseased or dissection of the vessel is noted, stenting should be part of the initial procedure.

Limb kinking can be addressed by additional supportive stenting within the limb as well. This is best assessed upon completion imaging with rigid wires removed, so the graft conforms to the position it will be in after all devices and equipment are removed. In patients with evidence of limb kinking, the treatment depends on the location and severity of the problem. In patients in whom the severe angulation is at the aortic bifurcation, the use of a "crossed-limb" technique can minimize the angulation at the proximal iliac arteries. For angulation at the distal end of the limb, accommodative, self-expanding stent placement will allow better positioning and flow through the limb distally. In patients with a narrow channel aortic lumen, dilating both limbs simultaneously with large-diameter balloons is often all that is required to adequately dilate the limbs and ensure adequate caliber of the limb flow channels. If this alone is inadequate, then stenting (performed simultaneously in the two limbs) can overcome the compressive force. It is important to remember that these stents need to be positioned at the same point in the limbs, as the placement of stents can lead to contralateral limb occlusion if the stent crushes the other limb lumen. Here again, completion imaging with adequate assessment, sometimes in two planes, is critical to ensuring the best outcomes.

If a limb thrombosis or occlusion does occur after an EVAR procedure, when does it typically present?

Generally, limb thrombosis tends to occur early on, with the vast majority presenting in the first year, and most of these occurring in the first 3 months. More than 50% of limb thrombosis occurs within 3 months of graft placement. These early failures are much more likely related to technical errors during the procedure, and in most instances, these should be considered avoidable.

What are the surgical and endovascular treatment options for limb occlusion?

The open surgical options can be directed to the occluded limb itself, performing open surgical limb thrombectomy from the groin or even from the iliac artery with or without iliofemoral bypass. Surgical thrombectomy is often performed with an over-the-wire balloon thrombectomy catheter to ensure access through the limb and even imaging of the limb after surgical thrombectomy is completed. Alternatively, revascularization can be achieved with extra-anatomic bypass grafting, either through femorofemoral bypass grafting or axillofemoral bypass grafting. An operator might choose one of these extra-anatomic techniques when thrombectomy or interventional therapies have failed to open the affected limb. One might also choose this option if the patient has had severe ischemia for an extended period, as this is often the fastest method of achieving blood flow restoration to the limb.

Endovascular options include mechanical thrombectomy, pharmacomechanical thrombus treatment, and standard thrombolytic therapy. Physician experience along with the acuity of the process may drive this decision. The more acute or significant the symptoms, the more a combined pharmacologic agent combined with a mechanical device will be helpful. In many instances, some combination of lytic therapy and mechanical device will be required, and it is imperative that an underlying cause be identified and treated. In most instances, this will involve angioplasty and stenting to resolve a kink, stenosis, or dissection.

Has the introduction of lower-profile systems increased or decreased the risk factors for limb complications? If so, why?

Although I know of no specific study relating the profile of an endograft delivery system to graft limb thrombosis, it is clearly evident that lower-profile devices now allow treatment of aortic aneurysm without the use of conduits that would have been required before. Additionally, a low-profile delivery system appears to induce fewer problems with vessel injury, including iliac artery perforation and dissection. Finally, the low-profile delivery system allows imaging of the outflow tract beyond the delivery sheath (as the delivery system is often much smaller than the iliac vessel) to assess runoff vessels, even with the sheath in place.

Recent EVAR investigational device exemption studies and peer-reviewed literature have reported limb occlusion rates ranging from 1% to 7%. How do the published data influence your choice of EVAR device?

Data on graft limb thrombosis rates show variations for differing devices, with lower rates for PTFE grafts when compared to others. In general, a number of features, including proximal neck anatomy (size, calcification, angulation, and length), iliac vessel tortuosity, and diameter, as well as other factors, drives decisions regarding endograft use specific to an individual patient's anatomic

issues. Although limb thrombosis rates do not directly drive graft choice, iliac artery angulation, calcification, and size do factor into the decision-making process. In general, the choice of endograft is based on an attempt to use the most appropriate device for each individual's specific anatomic needs. In those with limited anatomic issues, the choice is often dictated by physician familiarity and comfort, which should be an additional part of the decision-making process.

How would you describe the ideal stent graft and delivery system in regard to the aim of reducing the risk of limb complications?

The ideal stent graft and delivery system to limit stent graft limb thrombosis would be a low-profile delivery system with well-supported, flexible limbs that could adequately accommodate to tortuous anatomy and allow full expansion with placement in narrow aortic or iliac anatomy. The system would have adequate radial force to overcome stenosis and the ability to accommodate a variety of anatomies. The delivery system itself would not only be low-profile, but would also be flexible and hydrophilic to limit or diminish insertion forces and dissection. Ideally, this system would serve as a working sheath, so that multiple device insertions would not be required in situations where additional interventions are required, and orientation would be easily achieved in situ, so that significant manipulations would not be required to ensure precise positioning and orientation of the graft. ■

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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-

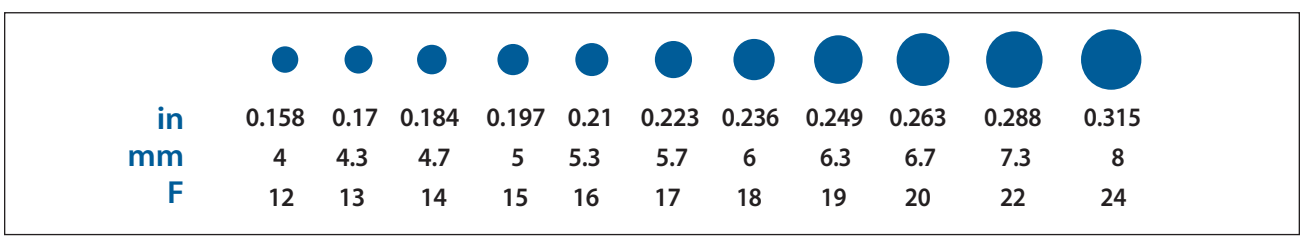

Figure 1. French sizes to scale.

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.

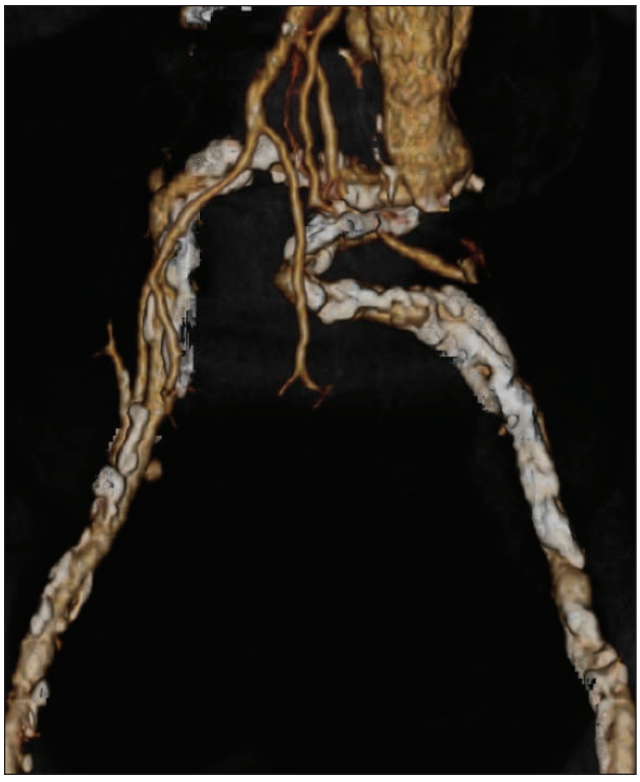

Figure 2. Severe iliofemoral calcific occlusive disease combined with tortuosity.

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. ■

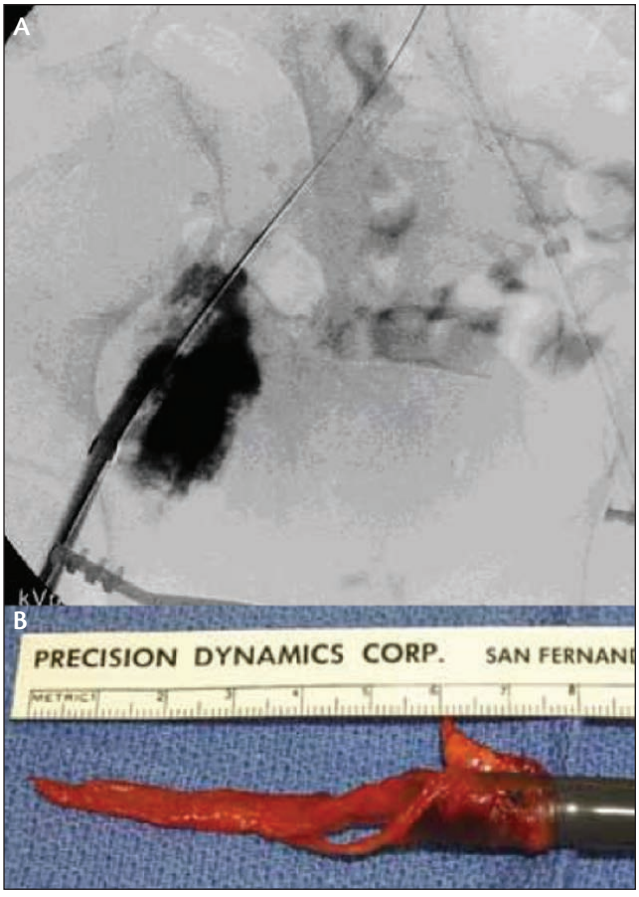

Figure 3. Iliac rupture with extravasation (A); avulsed external iliac artery attached to the delivery system (B).

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Stent Graft Material Factors That Impact Limb Complication Rates

Optimizing limb design to address EVAR-specific challenges.

BY DAVID MINION, MD

Iliac limb occlusion after endovascular aneurysm repair (EVAR) can result in acute ischemic symptoms and subsequent major morbidity or mortality. In contemporary investigational device exemption (IDE) trials, the incidence of limb occlusion at 12 months has ranged from approximately 1% to 8%. Despite the fact that these rates far and away surpassed that of type I endoleaks in these same trials, the importance of improving limb patency has received comparatively little focus.

In order to optimize graft design for improved limb patency, it is important to first understand the factors that contribute to limb occlusion. It is only after recognizing failure patterns that improvements can be made to overcome them. In broad terms, two factors have consistently been implicated to negatively affect limb patency: disadvantaged outflow (e.g., extension into the external iliac artery or small iliac arteries) and tortuosity (which is also often increased in the external iliac artery).[1-4]

Disadvantaged outflow affects patency and is common to all vascular interventions. However, tortuosity leading to kinking and limb occlusion has emerged as a concern, primarily because of the unique challenges of EVAR. The prostheses utilized for EVAR face strong conformational forces as they course, essentially free-floating, through an aneurysm sac until they reach the confines of an iliac landing zone that

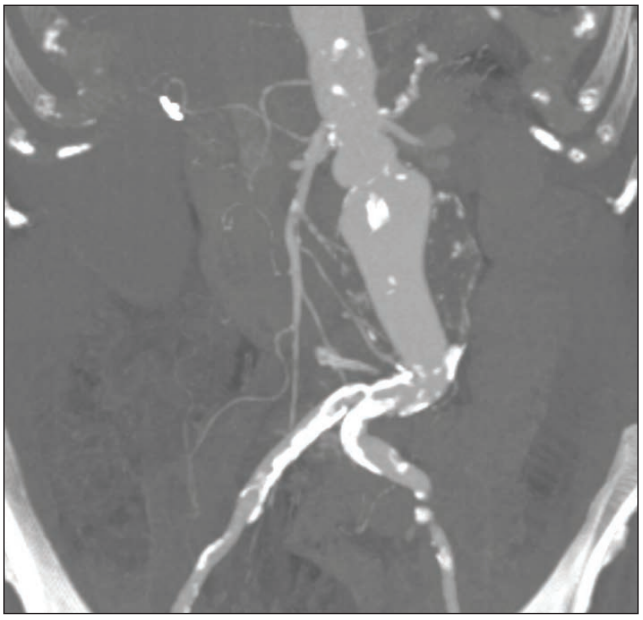

Figure 1. Most EVAR limbs originate in the essentially free-floating, pulsating conditions of the aneurysm sac and then must abruptly transition to the confines of the iliac arteries. These conformational challenges are intensified in small, diseased, or tortuous iliac vessels.

TABLE 1. COMPARISON OF PTFE AND PET[5]

	PTFE	PET
Chemical name	Polytetrafluoroethylene	Polyethylene terephthalate (polyester/Dacron)
Biocompatibility	Excellent	Good
Chemical resistance	Excellent	Good
Friction	Exceptionally low	Low
Compliance	Very compliant	Very rigid plastic
Architecture	Can be formed into complex three-dimensional shapes	Must be woven/knitted to create flexible grafts
Porosity	Contains blood (if porosity is low enough)	Not liquid tight; must be preclotted or coated to contain blood
Ingrowth	Permeability can be controlled to enhance or inhibit ingrowth	Yes

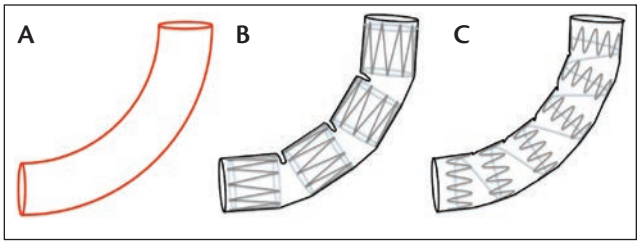

Figure 2. A 10-mm-diameter tube shaped as a 90° arc with a centerline length of 5 cm has an outermost curve length of 5.8 cm and an innermost curve length of 4.2 cm—a 27% difference (A). When an iliac limb is engineered as a series of discrete stent segments, any length discrepancy due to tortuous anatomy must be compensated for entirely in the intervening unsupported segments, leading to infolding orthogonal to the stents and luminal encroachment (B). In contrast, when an iliac limb is engineered with helical stent architecture, all points are at least partially supported in cross-section, and excess material is distributed evenly along the length of the stent (C). Further, any infolding occurs along the lines of flow at approximately the angle of the helix, limiting any luminal encroachment.

often extends at an acute angle relative to the aortic flow channel (Figure 1). These forces not only begin immediately after implantation and are compounded by the cardiorespiratory cycle, but additional conformational forces may result as the sac remodels and contracts. Engineering considerations to overcome these challenges include choices in graft material, stent material, and stent configuration.

GRAFT MATERIALS

Similar to open bypass technology, EVAR graft material options (Table 1)[5] have primarily been polytetrafluoroethylene (PTFE) or polyethylene terephthalate (PET, also known as polyester/Dacron). PTFE has many unique qualities that appear to be advantageous for use in EVAR. Biochemically, it consists of a polymer chain of carbon-fluorine bonds. The compound was accidentally discovered by DuPont's Roy Plunkett in 1938 and was patented in 1941. The fluorine creates a virtually impenetrable shield around the carbon polymer backbone, resulting in extreme thermal stability and chemical resistance. It has the third lowest friction known for a solid material, and there is no known solvent.[6] The material is very compliant and can be formed into complex three-dimensional shapes. Its porosity can be manipulated to contain blood or other liquids while allowing air to escape.

PET, although considered to have both good biocompatibility and chemical resistance, differs from PTFE in that it is a very rigid plastic that must be woven or knitted to create flexible grafts. As such, it requires preclotting or coating to contain blood.

Although early studies suggested that PTFE grafts might have better patency than PET grafts when used for open aortoiliac reconstruction in challenging anatomy,[7]

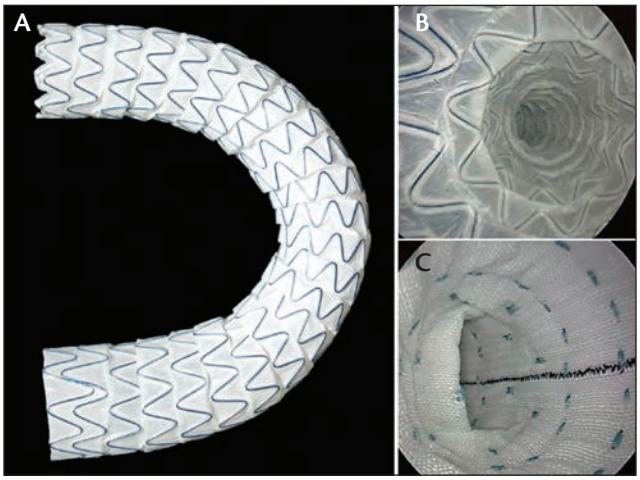

Figure 3. The Ovation® system's iliac limbs are engineered using PTFE and a helical architecture for the supporting nitinol framework, allowing for exceptional flexibility (A). Endoscopic view of a flexed Ovation limb, illustrating the internal creases distributed along the helical architecture with minimal luminal encroachment (B). Endoscopic view of a flexed iliac limb engineered with PET and discrete stent segments, illustrating focal infolding that results in significant luminal encroachment (C).

subsequent studies have not necessarily corroborated these findings. In fact, PET appears to achieve superior patency in open femoral-to-above-knee bypass procedures.[8] However, it is important to recognize that an open femoral-to-above-knee bypass is a much different procedure than an EVAR. In the former, PET's rigidity and increased tissue ingrowth may play to its advantage in the straight anatomy configuration. PET has enough rigidity to obviate the need for external supporting rings that are commonly found in PTFE bypass grafts, and the woven design's propensity for external tissue ingrowth may further add to its long-term anatomic stability in above-knee bypasses.

However, this rigidity can be a detriment in the situation of EVAR, where at least some tortuosity is the norm, and the only external tissue available for ingrowth are the endothelial cells of the iliac artery. This lesson was learned early in EVAR device design. The first EVAR device approved by the US Food and Drug Administration, the EVT/Ancure endoprosthesis (formerly Guidant Corporation), had unsupported PET limbs complicated by thrombosis in 7% and flow limitation in 31% of the patients in its phase II trial,[9] leading many to recommend pre-emptive adjuvant stenting to improve patency.[10] Not surprisingly, subsequent grafts have incorporated supported limbs in their design.

STENT MATERIALS

Similar to occlusive disease, the options for self-expanding stent material to provide support in EVAR limbs have focused on stainless steel, cobalt chromium,

and nitinol. Given the superiority of nitinol stents in lower extremity occlusive disease[11-13] (and that one of the key tasks of supporting stent framework is to improve patency in disadvantaged outflow), it is not surprising that the majority of graft designs have utilized (or are moving to) nitinol as the alloy of choice for their supporting framework.

FRAMEWORK ARCHITECTURE

The architectural design of the supporting framework may have as big or bigger impact on limb patency as the alloy itself. To understand why these architectural considerations are so important, it is first necessary to understand the underlying geometric principals behind conforming an inherently straight tube to a curved shape (e.g., an arc).

Because a tube has a diameter, the length of any arc will vary depending on its position within the cross-sectional area of the tube. In other words, the length of the inner curve of the arc will be less than that of the centerline, which in turn will be less than that of the outer curve of the arc. Unfortunately, because EVAR limbs start out straight, there is the same length of material that must conform to the inner curve as there is to the outer curve. Therefore, the material along the inner curve must be compacted in order for the limb to conform (Figure 2).

Conceptually, PTFE appears better suited to be compacted than PET. The conformability of PTFE should allow the material to collapse or "accordion" very easily, whereas the rigidity of PET would likely make it more prone to kinking and flow disturbances.

Perhaps even more important, as previously alluded to, is the configuration of the stent. Stent configuration design options include a continuous (e.g., diamond) pattern, interrupted rings, or a helical shape. A continuous pattern has limited flexibility and must often rely on forcing the artery to conform to its shape. Interrupted rings and helical stents can more easily conform to a curved shape, but in two very different patterns. Limbs with an interrupted ring design do not bend so much as they reticulate. In other words, there is minimal flexibility in the discrete segments where the individual stents are attached, with virtually all of the flexibility occurring in the intervening segments of unsupported fabric. Therefore, in order to conform to an arc, the endoprosthesis must make up the entirety of the discrepancy between the outer and inner curve arc lengths in the segments of unsupported fabric. Thus, all of the conformational forces are concentrated on the segments that have no external support, which can result in excessive kinking and flow disturbances. In addition, the infolding from the kinking will likely occur orthogonal to the line of flow, accentuating the narrowing to the lumen.

In contrast, a helical architecture will uniformly distribute the length discrepancy throughout its course and avoid the convergence of multiple stent struts at the same longitudinal position. Further, any internal creases from fabric infolding will be angled relative to the flow direction (by approximately the helix angle), which should reduce the incidence of flow stagnation and thrombus formation (Figure 3). These same advantages of a helical architecture apply not only to tortuous anatomy, but also to any longitudinal foreshortening performed acutely during deployment or that occur later due to aneurysm remodeling.

Given these considerations, it is easy to understand how the Ovation® platform (TriVascular, Inc.) has been able to achieve such laudable limb patency outcomes, reporting a 1.2% incidence of limb occlusions through 1 year in their IDE trial, despite the fact that approximately one-third of the patients had iliac access vessels < 6 mm in diameter (i.e., disadvantaged outflow), with the smallest vessel diameter treated being a mere 3.2 mm.

CONCLUSION

In summary, limb occlusions that occur after EVAR remain a significant source of morbidity. The main contributors to occlusions are disadvantaged outflow and tortuosity. As devices decrease in profile, they will continue to expand the applicability of EVAR to patients with small or diseased access vessels with disadvantaged outflow, making optimization of limb design paramount for continued success. The design features that conceptually appear to be most suited to overcome these challenges are the combination of PTFE and nitinol in a helical architecture. The Ovation Abdominal Stent Graft platform has utilized these principals in their limb design and reported one of the lowest limb occlusion rates in an IDE trial, despite involving, arguably, the most challenging cohort. ■

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Limb Patency Outcomes in Contemporary Data

A review of peer-reviewed publications on real-world limb patency rates.

BY GEORGE N. KOUVELOS, MD; ATHANASIOS KATSARGYRIS, MD; AND ERIC VERHOEVEN, MD, PHD

During the last decade, endovascular aneurysm repair (EVAR) has gained wide acceptance as the preferred method of treating suitable patients with abdominal aortic aneurysms.[1] EVAR is associated with lower 30-day mortality and morbidity rates, faster discharge, and fewer complications than with surgery, but seems to be associated with higher secondary intervention rates.[2] Graft limb stenosis or thrombosis are important causes of secondary interventions after EVAR.

Graft limb patency in the major randomized controlled EVAR trials has not been extensively reported. In the OVER and ACE trials, no separate data on outcomes of graft limbs are available.[3,4] The DREAM study reported a 6.9% rate of thromboembolic events, but did not provide detailed data on these graft limb complications.[5] In the EVAR 1 trial, limb graft stenosis and thrombosis were found in 0.6% and 3.2% of patients, respectively, during a mean follow-up of 6 years.[6] In the EUROSTAR registry, the limb occlusion rate was 5% at 2 years, but first-generation stent grafts were mainly used.[7] Mehta et al retrospectively evaluated 1,768 EVAR patients and reported a 1.4% limb occlusion rate during a mean follow-up of 34 months. Furthermore, 7.4% of the secondary procedures were performed for graft limb occlusion.[8]

GRAFT-SPECIFIC REPORTS

Modern commercially available stent grafts each have important variations, both in graft material (polyester or polytetrafluoroethylene [PTFE]), stent material (stainless steel or nitinol), and stent configuration ("Z-M" or helical shaped). These variations may result in different adaptations of the graft limb to the iliac artery anatomy, especially in cases of severe angulation or nonuniform-diameter landing zones.

Anaconda

The Anaconda graft limbs (Vascutek, a Terumo Company) are made of independent nitinol circular stents with no interconnection struts, which are combined with woven polyester graft material. This configuration is specifically designed for tortuous iliac anatomy; however, the lack of columnar support may result in a higher risk of proximal limb retraction.[9] In the largest single-center clinical experience using this stent graft, Freyrie et al reported a 5.1% secondary intervention rate for limb thrombosis/stenosis in 177 patients during a mean follow-up period of 33 months.[10] Similar results have also been described in a smaller recent study, which reported a 1.4% graft limb occlusion rate during a 29-month period.[9]

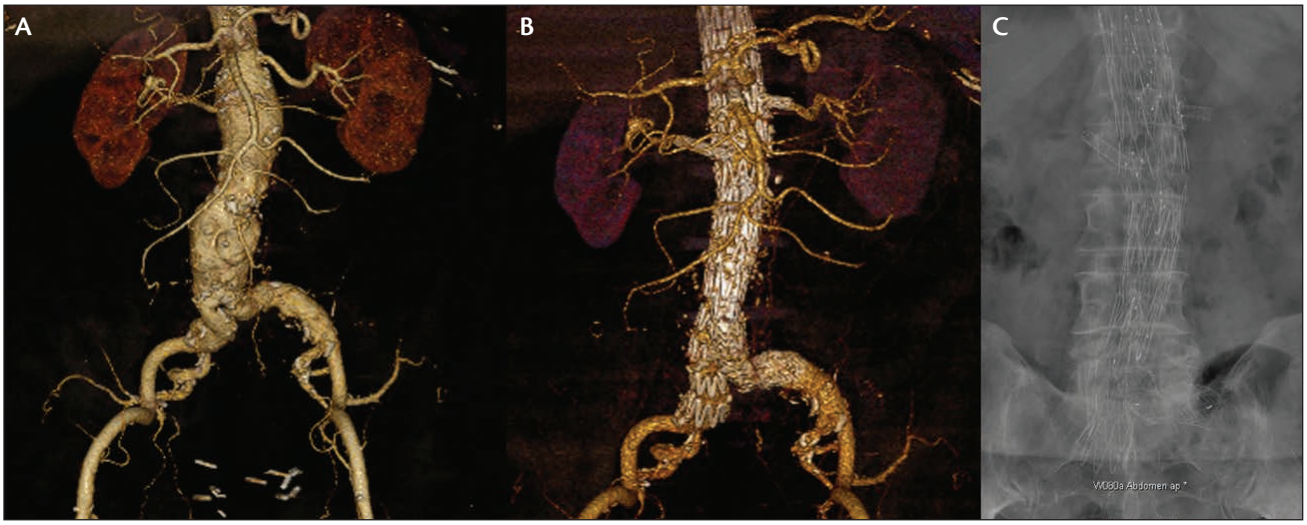

Figure 1. Three-dimensional volume-rendered CT reconstruction of a patient with severe left iliac angulation treated with a combination of a Zenith stent graft body (Cook Medical) and an Excluder (Gore & Associates) iliac limb (A). CTA (B) and x-ray (C) 2 years postoperatively, showing good patency of the graft limb.

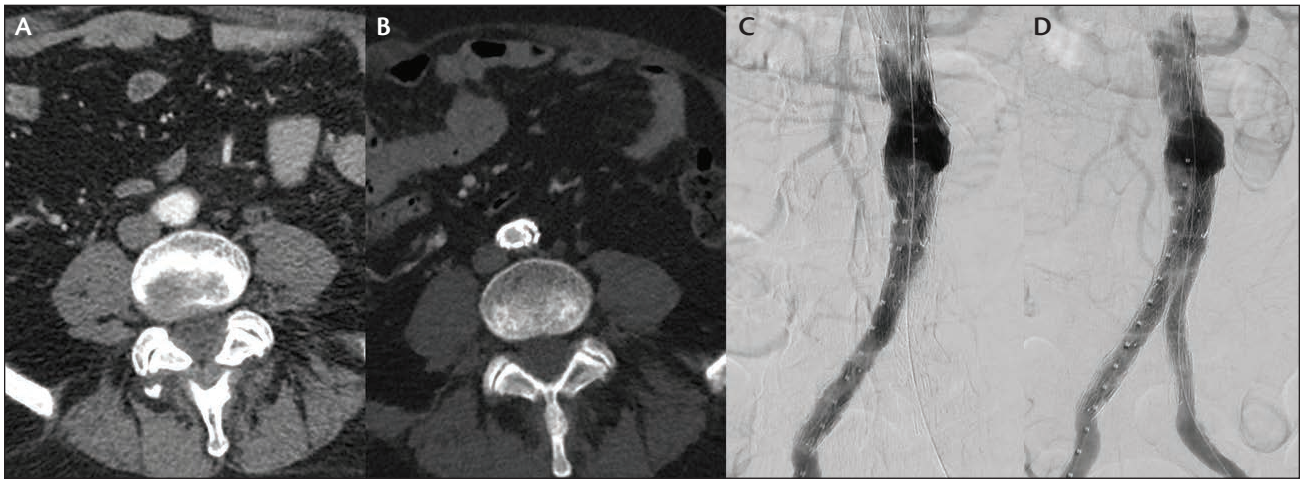

Figure 2. Preoperative CTA showing a narrow (18 mm) aortic bifurcation (A). CTA 4 hours postoperatively depicting acute thrombosis of a Zenith (Cook Medical) left limb due to collapse (B). Intraoperative digital subtraction angiography showing left limb thrombosis (C). Completion angiography after thrombectomy and relining of an Express left limb (Boston Scientific Corporation) (D).

Aorfix

The Aorfix limbs (Lombard Medical, Inc.) are made of woven polyester material and a continuous nitinol wire following a ring stent configuration that allows the device to be flexed axially without kinking.[11] The initial results were promising, as no iliac thromboses occurred in 30 patients with angulated proximal necks and/or tortuous iliac arteries during a mean follow-up of 27 months.[11] In a retrospective 12-year study, Weale et al reported great results when using Aorfix in complex iliac anatomy. After 2007, patients with highly angulated iliac anatomy were treated with the Aorfix stent graft, or when a Zenith main body (Cook Medical) was chosen, the Aorfix iliac limbs were used. A substantial reduction in limb thrombosis rates was noted after the adoption of this policy, and Aorfix iliac limbs were implanted in highly angulated iliac anatomy (6.2% vs 0%).[12]

Endurant

The Endurant graft limb (Medtronic) is made of M-shaped nitinol stents surrounded by polyester material. The ENGAGE registry prospectively included 1,143 patients treated with bifurcated devices who were followed for up to 2 years.[13] The rate of graft limb occlusion was 3.4%. Out of the 42 diagnosed occlusions, 13 (31%) were observed within 30 days, and 30 (71%) were seen within 6 months.[13] Bisdas et al reported a graft limb occlusion rate of 3.7% during a mean follow-up period of 42 months in a total of 273 patients who were treated with the Endurant stent graft.[14]

Excluder

The Excluder limbs (Gore & Associates) are fabricated from ePTFE with an outer self-expanding nitinol support structure. These limbs are thin and very flexible, adapting well to complex iliac anatomy. Clinical reports have demonstrated promising results in clinical performance. ITER (Italian Excluder Registry) included 872 patients and reported nine (1.1%) graft limb thromboses at a mean follow-up of 20.6 months. Interestingly, five of these occurred in the first 12 months.[15] In the GREAT registry, reintervention for graft limb occlusion was low (2%) during a mean follow-up period of 16 months, confirming the excellent performance of Excluder graft limbs.[16]

Ovation

The Ovation iX™ Iliac Stent Graft Limbs (TriVascular, Inc.) consist of highly flexible nitinol stents encapsulated in a low-permeability PTFE and are delivered through a 10- to 13-F integrated sheath, reducing the risk of iatrogenic vessel injury. The overall device characteristics allow access in iliac arteries as small as 4.7 mm. The iliac limbs feature one continuous piece of nitinol wire that resists kinking and twisting, even in hostile iliac anatomy. This wire is precisely manufactured to lie on the PTFE to reduce kinking of the material between the stents. The stents are embedded between layers of PTFE and are not sutured onto the graft material, creating a smooth luminal surface. Clinical reports confirm low limb occlusion rates. In a prospective multicenter study of 161 patients treated with the Ovation Iliac Stent Graft (TriVascular, Inc.), Mehta et al reported three (1.8%) reinterventions for graft limb stenoses or occlusions during the first year.[17] In a smaller multicenter study of 36 patients treated with the Ovation iliac stent graft, no limb occlusions were reported during a 2-year follow-up period.[18] The Ovation iliac stent graft seems to behave well in challenging iliac access anatomies, as no iliac occlusions occurred in a report of 42 patients with hostile iliac configuration, irrespective of iliac diameter or angulation.[19]

Zenith

The Zenith stent graft is constructed with individual Gianturco Z-stents surrounded by polyester material.

Greenberg et al reported the 5-year results of the Zenith United States multicenter trial in 2008 and found a cumulative risk of 2.6% for graft limb occlusion.[20] Furthermore, Mertens et al reported a graft limb stenosis in 2.1% and occlusion in 5.6%.[21] Most graft limb occlusions occurred during the first 3 months after the procedure. Initially, the interrupted stent design of the first-generation Zenith stent graft was considered to be associated with a higher risk of iliac limb kinking and occlusion. The manufacturer therefore increased the spacing between the Z-stents to enhance compatibility with hostile iliac anatomy. Recently, Cook released a new graft limb that is constructed of two self-expanding stainless steel Z-stents at the ends and a continuous nitinol spiral stent in between. The initial results for this device are promising, as no limb occlusions and only one graft limb stenosis out of 100 graft limbs were reported during a 6-month period.[22]

COMPARATIVE STUDIES

Large, prospective, randomized studies comparing limb patency rates among different endografts are lacking. In a device-specific analysis of the effect of three different first-generation endografts (Zenith, Excluder, and AneuRx [Medtronic]) on EVAR outcomes, Excluder had the lowest graft limb thrombosis rate, despite being implanted more frequently in women and outside the indications for use.[23] In contrast, Mantas et al found no significant differences in the incidence of graft limb thrombosis between the different types of second- and third-generation endografts, although the small sample size should be acknowledged.[24] Nevertheless, it seems that some graft limbs are behaving better in hostile iliac anatomies, although this does not seem to play an important role toward an overall clinical benefit. Although, perhaps, it has not been studied enough.

In an experimental study, Demanget et al investigated the mechanical performance of eight different graft limbs. The authors concluded that spiral and circular stents may provide greater flexibility, as well as lower stress values, compared to Z-stents. They further associated this with potentially better durability.[25] These findings have been confirmed in the clinical setting in a retrospective study investigating the impact of stent grafting on aortoiliac tortuosity. The reduction of the iliac tortuosity index was greatest with Zenith compared with Endurant, and the least change was seen after Excluder implantation, probably as a result of better adaptation to the iliac anatomy.[26] Interestingly, no significant differences in graft limb complication rates between the three stent grafts were found.[26] Bos et al showed that there is a preferential strategy in using flexible graft limbs (e.g., Excluder) in complex iliac artery anatomy and even used them in combination with a stent graft body of a different type (e.g., Zenith with a suprarenal fixation) (Figure 1). This hybrid endograft solution proved feasible, with no adverse events at the midterm follow-up.[27]

We reviewed the contemporary limb patency data, including data from all commercially approved, investigational device exemption (IDE) studies (Table 1), as well as peer-reviewed publication studies with at least 100 patients and 1-year follow-up published since 2012 (Table 2). Overall, loss of limb patency ranged from 0.4% to 7.7%, with the lowest rates reported for the Excluder and Ovation systems (Table 1). Considering that > 90% of limb complications required secondary intervention in these studies, selection of a suitable stent graft and identification of patient-related risk factors for limb occlusion are crucial to reduce limb-related morbidity.

FACTORS POTENTIALLY AFFECTING ILIAC OUTCOMES

Graft-related factors providing resistance to limb occlusion have not been adequately studied. Although a reduced inflammatory response after implantation of an ePTFE stent graft compared to those of polyester is known, there is no evidence depicting the effect of graft material on limb thrombosis.[28] Several anatomical risk factors that predispose to graft limb thrombosis have been reported. Faure et al investigated the patients of the ENGAGE registry and found that the strongest independent predictors for graft limb thrombosis were (1) distal landing zone on the external iliac artery, (2) an external iliac diameter < 10 mm, and (3) kinking.[19]

TABLE 1. COMPARISON OF 1-YEAR LIMB OCCLUSION RATES FROM IDE STUDIES*

	Ovation IDE (TriVascular, Inc.)	Zenith Flex IDE† (Cook Medical)	PowerLink IDE (Endologix, Inc.)	Excluder Combined IDE (Gore & Associates)	Aorfix IDE (Lombard Medical, Inc.)	Endurant IDE (Medtronic)
Number of patients enrolled	161	200/100	192	565	218	150
Limb occlusions‡	1.2%	0.5%/3%	3.1%	0.4%	3.7%	2.7%

**Data adapted from instructions for use and annual clinical updates.*
†Values are for Zenith standard-risk/high-risk patient cohorts, respectively.
‡Based on investigator-reported events. Includes reinterventions on day 0, defined as reintervention to treat a limb occlusion.

TABLE 2. LOSS OF LIMB PATENCY RATES FROM LITERATURE*

Peer-Reviewed Articles	Stent Graft	Limb Occlusion		Secondary Intervention for Limb Occlusion	
		n/N	%	n/N	%
Kalteis et al,[29] 2012	Various†	[5/106]	[4.7%]	[5/106]	[4.7%]
Conway et al,[30] 2012	Various‡	31/661	4.7%	31/661	4.7%
van Zeggeren et al,[31] 2013	Endurant	20/496	4%	20/496	4%
Verhoeven et al,[16] 2014	Excluder	8/400	2%	8/400	2%
Mehta et al,[32] 2014	Aptus (Aptus Endosystems, Inc.)	12/155	7.7%	12/155	7.7%
Bisdas et al,[14] 2014	Endurant	[10/273]	[3.7%]	[10/273]	[3.7%]
Taudorf et al,[33] 2014	Zenith	18/504	3.6%	18/504	3%
Freyrie et al,[10] 2014	Anaconda	9/177	5.1%	9/177	5.1%
Ishibashi et al,[34] 2014	Various‡	5/175	2.9%	3/175	1.7%
Mantas et al,[24] 2014	Various§	18/439	4.1%	18/439	4.1%
Pratesi et al,[15] 2014	Excluder	9/872	1.1%	9/872	1.1%
Donas et al,[35] 2015	Endurant	15/712	2.1%	15/712	2.1%
Böckler et al,[36] 2015	Endurant	8/171	4.7%	5/171	2.9%
Faure et al,[13] 2015	Endurant	42/1143	3.4%	[42/1143]	[3.4%]

**All studies were published in the last 3 years, include at least 100 patients, and have reported at least 1-year follow-up data. Brackets represent estimates, assuming that all limb occlusions were treated with secondary intervention.*
†Primarily the Zenith device.
‡Primarily the Zenith and Excluder devices.
§Primarily the Zenith, Excluder, and Anaconda devices.

These findings have recently been partially confirmed in a case-control–designed study reporting the presence of significant angulation and calcification of the iliac arteries, as well as excessive limb oversizing as important predisposing factors.[24] Carroccio et al also suggested that graft limb occlusion is associated with a limb diameter < 14 mm, whereas Abbruzzese et al reported a higher incidence of graft limb stenosis when deployment was performed at least outside one instruction for use.[37,38] The wide range of anatomic factors associated with graft limb occlusion demonstrates the importance of meticulous preoperative sizing and planning for assessing the thrombosis risk. In the ENGAGE registry, almost all occlusions (90.5%) occurred in high-risk iliac arteries.[9] Recognizing high-risk patients may help define specific strategies to prevent graft limb occlusion and improve overall outcomes.

LIMB STENOSIS: NEED FOR RELINING

Angioplasty of iliac stenosis after stent graft deployment seems to potentially reduce the risk of extrinsic compression or kinking (Figure 2). Selective preoperatively planned relining of the graft limbs with a bare-metal stent may offer supplementary radial force to amplify limb diameter and prevent thrombosis or to prevent kinking in between two Z-stents. Whereas the first reason may apply to all types of graft limbs, the second may be redundant when choosing a graft limb that is less prone to kinking. Oshin et al found a significantly lower limb occlusion rate in EVAR patients treated with a more liberal use of adjunctive stenting based on preoperative imaging.[39] Meticulous focus on the preoperative CT angiography (CTA) followed by scrutinization of the completion angiogram to identify limbs at risk is of importance.

In our practice, we tend to liberally reline iliac limbs that seem to be at a higher risk for kinking and occlusion based on the preoperative CT. In our opinion, a completion angiogram that looks good should not be the reason to change one's mind about relining, when the preoperative CTA showed severe kinking. Indeed, in the beginning, the graft limb will win over the artery, but with time, the artery will force the graft limb to go back into the original angulated path. We advocate the use of self-expandable stents to avoid kinking in a graft limb and the use of kissing-balloon–expandable stents in case of a small distal aortic diameter (< 20 mm) to keep the lumen open.

CONCLUSION

Graft limb patency clearly affects the long-term durability of EVAR. Different stent grafts provide different graft limb properties, which may eventually affect the clinical outcome. It seems that spiral and circular stents provide better flexibility and less risk of kinking, especially in hostile iliac anatomy. It needs to be taken into account, however, that the amount of available evidence is low. Prophylactic relining of high-risk limbs should be considered in order to reduce graft limb–related complications and secondary interventions. ■

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