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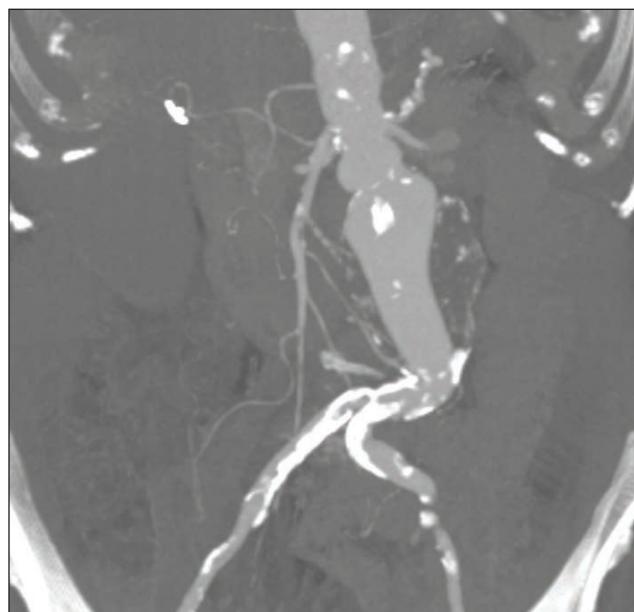
Figure 1. Most EVAR limbs originate in the essentially free-floating, pulsating conditions of the aneurysm sac and then must abruptly transition to the confines of the iliac arteries. These conformational challenges are intensified in small, diseased, or tortuous iliac vessels.

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
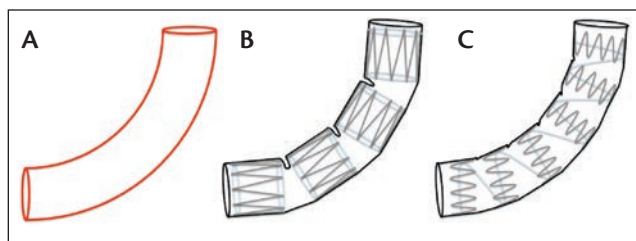
Figure 2. A 10-mm-diameter tube shaped as a 90° arc with a centerline length of 5 cm has an outermost curve length of 5.8 cm and an innermost curve length of 4.2 cm—a 27% difference (A). When an iliac limb is engineered as a series of discrete stent segments, any length discrepancy due to tortuous anatomy 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.

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).
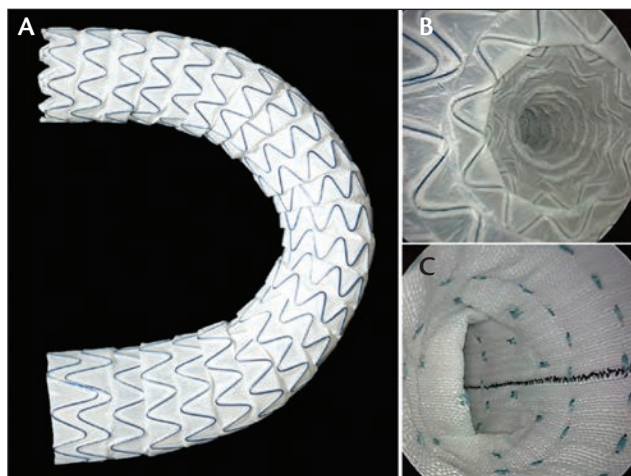
often extends at an acute angle relative to the aortic flow channel (Figure 1). These forces not only begin immediately after implantation and are compounded by the cardiorespiratory cycle, but additional conformational forces may result as the sac remodels and contracts. Engineering considerations to 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]

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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