Endograft Treatment in the SFA

Current SFA stent graft technology has overcome early shortcomings and carries the potential to become the standard of care in selected patients.

BY MARK W. MEWISSEN, MD

The standard of care for treating long superficial femoral artery (SFA) occlusive disease continues to be above-knee femoropopliteal surgical bypass using either vein or synthetic grafts. Although vein bypass likely yields a more durable result, the difference between above-knee vein and synthetic bypass is small, and synthetic grafts (ePTFE or Dacron) are most commonly used.[1-3] With the advent of catheter-based technology, clinicians began turning to percutaneous transluminal angioplasty (PTA) and stenting to maintain vessel patency in selected patients rather than bypassing a vessel entirely. Early results with PTA alone and balloon-expandable stents in the SFA were dismal.[4-7] Use of nitinol self-expanding stents have improved outcomes, although issues of in-stent stenosis, stent fractures, and overall stent durability remain.[8-11]

During the past decade, the concept of percutaneously deploying a bypass graft was pursued, and as early as 1996, studies were published reporting on the use of stent grafts in the SFA to bypass diseased vessel segments.[5,12,13] Many of these early reports dealt with home-made devices consisting of ePTFE or Dacron grafts grossly sewn to balloon-expandable stents and then delivered percutaneously. The outcomes from use of these early devices were largely disappointing. However, current SFA stent graft technology has overcome early shortcomings and carries the potential to become the standard of care for the treatment of long, diffuse SFA occlusive lesions in selected patients.

Today, there are four small-diameter stent grafts that are commercially available in the US (Table 1). Of these four stent grafts, the Gore Viabahn Endoprosthesis (Gore & Associates, Flagstaff, AZ) is the only device approved for use in the SFA, and it is the only device used for this application (Figure 1).

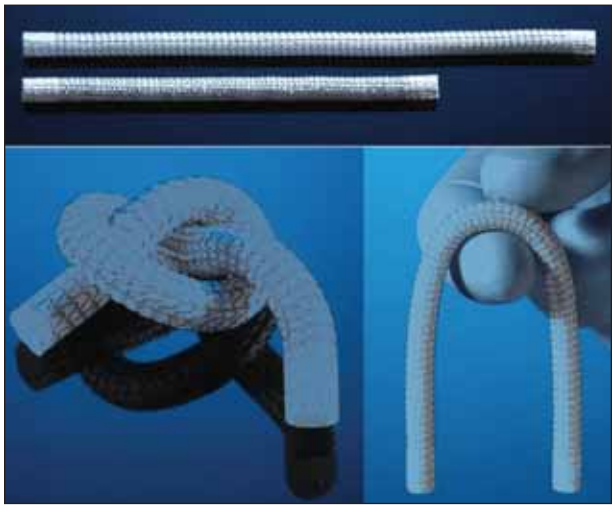

Figure 1. Images of the Viabahn Endoprosthesis demonstrating its flexibility and longitudinal compression.

BENEFITS OF ENDOGRAFTS IN THE SFA

The concept of endograft treatment in the SFA is to bypass the diseased vessel entirely, creating a new flow channel. This differs from traditional metallic bare stents, engineered to prop open existing diseased vessels. The

TABLE 1. SMALL-DIAMETER STENT GRAFTS AVAILABLE IN THE US		
Device Name	**Materials**	**FDA Indication**
Gore Viabahn Endoprosthesis (Gore & Associates)	ePTFE/nitinol self-expanding	SFA occlusive disease; tracheobronchial strictures
Fluency Plus Tracheobronchial Stent Graft (Bard Peripheral Vascular, Tempe, AZ)	ePTFE/nitinol self-expanding	Tracheobronchial strictures
Atrium iCast Covered Stent (Atrium Medical Corporation, Hudson, NH)	ePTFE/stainless steel balloon-expandable	Tracheobronchial strictures
Wallgraft Tracheobronchial Endoprosthesis (Boston Scientific Corporation, Natick, MA)	PET/Elgiloy self-expanding	Tracheobronchial strictures

potential benefit of bypassing the diseased arterial segment entirely is the elimination of in-stent stenosis, the most common cause of bare-stent failure in this application. In-stent stenosis in ePTFE stent grafts in the SFA is reportedly rare.

Another benefit of endografts compared to traditional bare stents is that the graft material provides additional flexibility in design. In the Viabahn design, the presence of the graft material allows the elimination of longitudinally connecting stent struts present in most devices. This design change allows the device to conform to the SFA with little or no residual stress on the stent frame (or vessel) as it responds to biomechanical stresses such as flexion and longitudinal compression. The high degree of vessel conformance may substantially contribute to the fracture resistance of this device. To date, no fractures in the SFA associated with this device have been reported, even with overlapping devices in long-segment disease.

ENDOGRAFT FAILURE MODES

Acute Thrombosis

One major concern many clinicians have regarding the use of endografts in the SFA is acute (within 30 days) thrombosis. Some early stent graft reports were indeed plagued with high acute thrombosis rates. In part, this has been attributed to poor patient selection and poor device deployment techniques, such as spot stenting and stent-edge dilatation, responsible for the development of edge stenoses and resulting stent failure. Currently, better endograft design and better techniques of deployment, combined with the use of more effective antiplatelet agents, such as clopidogrel, have resulted in patencies historically superior to balloon angioplasty and metallic stenting. The rate of acute thrombosis in endografts implanted in the SFA has been reported to vary between 2% to 5%,[14-18] not substantially higher than recently reported acute thrombosis rates of 2% to 3.5% for bare metal stents.[11,19] The use of more aggressive antiplatelet therapy may be an important adjunct to reduce acute thrombotic rates for Viabahn. In a 1996 study by Lammer et al, patients were administered heparin for 48 hours after the procedure followed by aspirin only, and the resulting acute thrombotic rates were reported at 3.8% (3/80 limbs).[17] In a later study by Janke et al, patients were on a more aggressive antiplatelet therapy (clopidogrel and aspirin), reducing acute thrombotic events to 1.9% (1/52 limbs).[15]

Late Thrombosis

Late thrombosis is a failure mode also associated with stent grafts. Although in-stent stenosis is generally absent, disease progression or edge stenosis can compromise graft flow and result in late thrombosis. Similar to acute thrombotic events, these occlusions can usually be treated by means of mechanical or pharmacologic lysis, followed by treatment of the flow obstruction, a strategy widely used for the salvage of failed surgical grafts. Successful treatment of late thrombosis is reflected in secondary patency rates reported for the Viabahn device as high as 86% at 6 years in an appropriately selected patient population.[20] Careful and dedicated graft surveillance strategies will also likely decrease the rate of late thrombosis.

Collateral Vessels

In addition to thrombosis, concern has been voiced over covering collateral vessels when using a stent graft in the SFA. Clinical outcomes, however, do not seem to support this concern. It is the opinion of the author that some collateral vessels must at times be covered if the edges of the graft are to be delivered in relatively disease-free arterial margins. The benefits of this technique likely outweigh the risks of alternative spot stenting strategies,

a reported mechanism of early stent failure. Furthermore, it is important to flare the stent edges at sites free of plaque. This latter concept also aids in selecting the appropriate stent length to ensure complete exclusion of the diseased segment (no plaque left behind).

Clinical Study

We are currently participating in the VIBRANT trial, which is prospectively randomizing the Viabahn device to nitinol stents in long lesions. This study will provide valuable information about patency and failure modes of these SFA treatment options.

REVIEW OF THE LITERATURE

Viabahn is the only currently marketed stent graft that has been reported in the literature with respect to the treatment of SFA disease. Currently, 17 studies have reported 1-year primary patency for Viabahn use in the SFA,[14-17,20-32] with some reported results out to 6 years. This experience represents 830 limbs with an average lesion length of 16 cm and primary patency of 82% and 79% at 1 and 2 years, respectively. Of particular interest, a recently published prospective randomized study comparing above-knee surgical bypass to the Viabahn device showed no difference between the two study arms.[16]

CONCLUSION

Currently, the Viabahn device is the only percutaneous covered stent graft to possess an indication for the treatment of SFA disease. Recent data suggest improved patencies compared to PTA and metallic stenting. Appropriate patient and lesion selection are of paramount importance to ensure durable early and late results. The VIBRANT trial, currently enrolling patients in the US, will undoubtedly provide an opportunity to better understand the natural hemodynamic history of this potentially revolutionizing endovascular device. ■

Mark W. Mewissen, MD, is Director, Vascular Center at St Luke's Medical Center in Milwaukee, Wisconsin. He has disclosed that he has received an honorarium for speaking engagements from Gore & Associates. Dr. Mewissen may be reached at (414) 385-2429; mark.mewissen@aurora.org.

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