

Endovascular TODAY


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SFA Endoluminal Bypass

Optimizing clinical outcomes using
the GORE VIABAHN® Endoprosthesis for the
treatment of TASC C and D lesions in the SFA.





SFA Endoluminal Bypass

The peripheral vascular interventionist has a vast and expanding armamentarium of devices and techniques available to treat superficial femoral artery (SFA) disease.

The extent of SFA disease often dictates the choice of therapy. Based on clinical reports on the treatment of this vascular bed, there has been a trend to align these various therapies and devices with the appropriate “lesion-specific” diagnosis.

This supplement is focused on the use of an endoluminal bypass to treat the most challenging and diffuse (TASC C and D) SFA lesions. The articles are intended to offer insight to a clinical decision tree that leads to the use of a stent graft—specifically, the GORE VIABAHN® Endoprosthesis—to restore blood flow in the most difficult SFA lesions.

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Clinical images on cover courtesy of Mark W. Mewissen, MD.

REPORTED PRIMARY PATENCIES OF GORE VIABAHN® ENDOPROSTHESIS (6 MM TO 8 MM) IN THE SFA

| Author | Year | Journal Publication/Presentation | No. of Limbs | Lesion Length (cm) | Primary Patency (years) | | | | |
|-------------------------|------|---|--------------|--------------------|-------------------------|------------|------------|------------|------------|
| | | | | | 1 | 2 | 3 | 4 | 5 |
| Chopra ¹ | 2006 | AIM Symposium, Nov 13-16 | 70 | 20 | 93% | 87% | 72% | | |
| Kazemi ² | 2006 | TCT Meeting, October 23-27 | 65 | 12 | 90% | | | | |
| Coats ³ | 2006 | Endovasc Today, Sept | 83 | | 89% | | | | |
| Fischer ⁴ | 2006 | J Endovasc Ther, 13:281-290 | 48 | 10.7 | 80% | 73% | 71% | 64% | 62% |
| Kedora ⁵ | 2006 | SVS Annual Meeting, June 1-4 | 50 | 25.6 | 73% | | | | |
| Saxon ⁶ | 2006 | SIR Meeting, March 31 | 56 | 13.1 | 84% | 76% | 76% | 67% | |
| Zander ⁷ | 2006 | SIR Meeting, April 3 | 31 | 16.6 | 86% | 78% | 78% | 78% | |
| Panetta ⁸ | 2005 | Endovasc Today, August | 41 | 30.4 | 86% | 77% | | | |
| Hartung ⁹ | 2005 | Eur J Vasc Endovasc Surg, 30:300-206 | 34 | 10.8 | 85% | 85% | | | |
| Bleyn ¹⁰ | 2004 | Edizioni Minerva Medica, 14:87-91 | 67 | 14.3 | 82% | 73% | 68% | 54% | 47% |
| Jahnke ¹¹ | 2003 | J Vasc Interv Radiol, 14:41-51 | 52 | 8.5 | 78% | 74% | 62% | | |
| Turicchia ¹² | 2003 | Osp Ital Chir, 9:93-96 | 16 | 10 | 80% | 80% | | | |
| Railo ¹³ | 2001 | Annales Chirurgiae et Gynaecologiae, 90:15-18 | 15 | 8 | 93% | 84% | | | |
| Lammer ¹⁴ | 2000 | Radiology, 217:95-104 | 80 | 13.8 | 79% | | | | |
| Average/Total | | | 708 | 15 | 84% | 79% | 71% | 66% | 55% |

The authors of this supplement provide comprehensive insight into endoluminal SFA bypass. With this procedure, interventionists effectively re-line the SFA wall with a smooth expanded polytetrafluoroethylene (ePTFE) lumen supported by a highly flexible stent scaffold. In contrast to when a bare stent is used in the SFA, a stent graft, such as the GORE VIABAHN® Endoprosthesis, covers and seals off all the diseased and irregular tissue of the arterial wall.

More than 30 years ago, the first ePTFE surgical bypass was performed in the SFA. Since then, millions of above-the-knee femoropopliteal ePTFE bypasses have been used to restore blood flow to the lower limb with overall patency rates that rival vein bypass.

The advent of an ePTFE stent graft offers patients of peripheral vascular interventionists the option of a minimally invasive treatment that, similar to the surgical approach in the SFA, bypasses all the diseased tissue and plaque involved in long lesions. As with any new treatment option, the keys to successful outcomes are dependent on numerous factors, such as proper patient selection, technical considerations, the use of ancillary devices, and antiplatelet therapy.

As this chart of reported outcomes of the GORE VIABAHN® Endoprosthesis indicates, there has been broad interest over the last several years to determine the role of stent grafts to treat the SFA. ■

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Percutaneous Endovascular Treatment of SFA Disease Using the GORE VIABAHN® Endoprosthesis

Do the procedural success and 1-year follow-up data make this the treatment of choice?

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The prevalence and incidence of peripheral vascular disease (PVD) continue to increase with advancing age. In response to this increase, we must consider all options for management of PVD. Aggressive risk factor modification and a trial of an exercise program are recommended as the first line of therapy. Pharmacotherapy with cilostazol provides additional symptom relief.^{1,2} Patients who fail medical therapy and continue to have resting leg pain or nonhealing ulcers are candidates for invasive treatment strategy. The choice of vascular intervention as the next step in managing suprainguinal disease is clear-cut, but the same is not true for infrainguinal disease. Surgical revascularization may provide better long-term results, but it is associated with higher periprocedural morbidity and mortality, making the surgical option less desirable in elderly patients—a significant proportion of patients with PVD.

Dotter et al³ reported the first endovascular intervention in 1964. Although significant advances have been made in the endovascular treatment of PVD during the past 40 years (ie, percutaneous transluminal angioplasty [PTA], atherectomy, laser, stenting), long-term success has been hampered by a high rate of restenosis. PTA of the superficial femoral arteries (SFAs) has a high initial success rate (>90%), but the restenosis rate remains high (40%-60%).⁴⁻⁶ In longer lesions (>10 cm), the primary patency rate decreased to 20% at 1 year.⁷ PTA followed by stenting prevents the problems of elastic recoil and flow-limiting dissection. Although the initial success of SFA stenting is high, long-term patency is limited by increased rates of in-stent restenosis (ISR).⁸⁻¹¹ Managing ISR remains a challenge to this day despite all of the modalities now available for percutaneous intervention.

The self-expanding nitinol stents have shown better 1-year patency rates.¹² Mewissen et al¹³ and Kazemi et al¹² showed similar 1-year patency rates of 76%, whereas 18-month to 24-month primary patency rates decreased to 60% to 66%. Recently, Schillinger et al reported a 12-month primary patency rate of 63% in a self-expanding stent-treated group compared to 37% in an angioplasty-treated group.¹⁴ Studies in which different debulking devices were used yielded different results. A randomized trial of PTA versus atherectomy for 2-year patency showed worse results for atherectomy.¹⁵ Jahnke et al compared PTA with atherectomy, showing no additional benefit associated with atherectomy in 6-month patency.¹⁶ Laser-assisted angioplasty for patients with critical limb ischemia was tested in a single-center trial (LACI)¹⁷ with good results, but multiple other trials comparing laser angioplasty versus PTA showed no advantage of laser therapy.^{18,19}

Recently, endoprostheses have been used in treating long SFA lesions. The rationale for using a polytetrafluoroethylene (PTFE)-covered device is to prevent intimal hyperplasia, thus improving primary patency, especially in long lesions. However, the initial reports have been mixed for PTFE-covered endoprostheses. Primary patency rates of 29% to 87% have been reported in different studies.²⁰ Use of the Cragg EndoPro System endoprosthesis (Minimally Invasive Technologies SARL, La Ciotat, France), an expandable nitinol stent covered with woven polyester fabric, resulted in a low primary patency in the femoropopliteal vessels (59%) and a high rate of complications, including early and late thrombosis, graft misplacement, and distal embolization.²¹ In an international feasibility trial, the GORE HEMOBAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ) was assessed to have a 90%

patency at 6-month follow-up and 79% at 1-year.²²

The GORE VIABAHN® Endoprosthesis (Gore & Associates) is a flexible, self-expanding, endoluminal endoprosthesis constructed with an expandable, biocompatible

PTFE liner attached to the external nitinol stent structure. It is now FDA approved for treatment of SFA disease. We evaluated the potential of the GORE VIABAHN® Endoprosthesis to improve the long-term outcome of percutaneous intervention in complex SFA lesions.

TABLE 1. PATIENT CHARACTERISTICS AND RESULTS IN PATIENTS WITH *DE NOVO* VIABAHN® USE

| Characteristics | n (%), Mean±SD |
|--------------------------------|---------------------|
| Patients | 81 |
| Legs | 98 |
| Age (y) | 69±9 |
| Male | 53% |
| Diabetes mellitus | 40 (49%) |
| Smokers | 24 (29.6%) |
| Fontaine class II or IIIa | 66 (67.3%) |
| Fontaine class III or IV | 15 (32.6%) |
| Average VIABAHN® diameter (mm) | 6 |
| Average VIABAHN® length (cm) | 15 (range, 5 to 20) |
| Average VIABAHN® per patient | 2 (range, 1 to 4) |
| Follow-up time (months) | 16±8 |
| 6-month primary patency | 98% |
| 12-month primary patency | 96% |
| Secondary patency | 100% |

METHODS

To assess the efficacy of the GORE VIABAHN® Endoprosthesis, we studied patients presenting with critical limb ischemia or lifestyle-limiting claudication. The GORE VIABAHN® Endoprosthesis was used for *de novo* native vessel disease in 98 patients. A second group of patients was randomized to placement of GORE VIABAHN® Endoprostheses or to atherectomy with the SilverHawk device (FoxHollow Technologies, Redwood City, CA). All patients were started on clopidogrel at 75 mg/d and aspirin 325 mg/d for at least 6 months. Restenosis was defined as ≥50% as determined by duplex ultrasound. The primary endpoint was target vessel revascularization during 12 months of follow-up. Secondary endpoints were clinical improvement of symptoms or progression to limb loss.

Procedural Details

Vascular access was achieved either from the contralateral common femoral artery or in an antegrade manner from the ipsilateral femoral artery using a modified Seldinger technique. In the contralateral approach, a 45-cm-long sheath was advanced over the aortic bifurcation over a

TABLE 2. BASELINE CLINICAL CHARACTERISTICS

| | VIABAHN® n (%), Mean±SD | SilverHawk Atherectomy n (%), Mean±SD | P Value |
|---------------------------------------|-------------------------|---------------------------------------|---------|
| Patients | 23 | 20 | |
| Legs | 29 | 23 | |
| Male | 12 (52%) | 9 (45%) | .767 |
| Age (y) | 70±10 | 70±10 | 1 |
| Diabetes mellitus | 15 (65%) | 10 (50%) | .365 |
| Smokers | 16 (69%) | 9 (45%) | .13 |
| Fontaine class III or IV | 90% | 90% | 1 |
| Average lesion length | 10 cm | 10 cm | 1 |
| Average distal runoff | 2 | 2 | 1 |
| Technical success | 100% | 100% | 1 |
| Complications (total) | 0 | 5 (21%) | .012 |
| dissection | 0 | 4 (17%) | .032 |
| perforation | 0 | 1 (4%) | .442 |
| Adjunctive therapy (balloon or stent) | | 48% | |
| Mean follow-up | 12 months | 12 months | 1 |
| Primary patency | 90% | 57% | .009 |

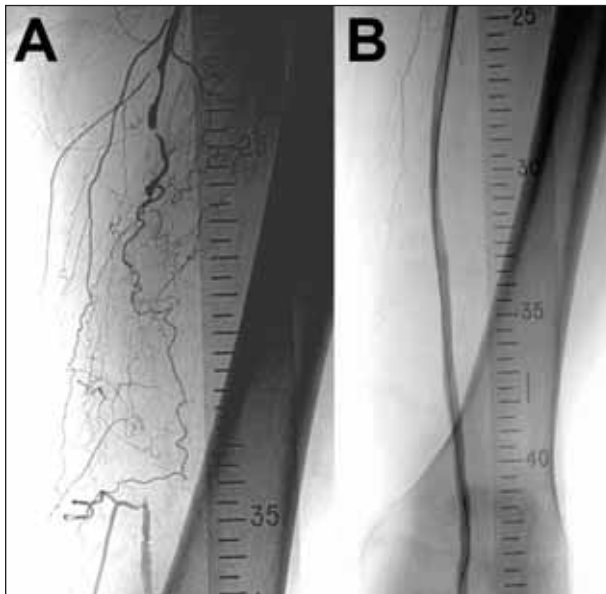


Figure 1. A 60-year-old man with claudication was treated with two GORE VIABAHN® Endoprostheses in the left SFA for a chronic total occlusion. Preprocedure image (A); postprocedure image (B).

.035-inch wire. Eight-French sheaths were used in all patients to deliver a 5-mm- or 6-mm-diameter GORE VIABAHN® Endoprosthesis. Patients were anticoagulated with either bivalirudin or heparin using a weight-based dose. Predilatation was performed in 80% of cases using an

undersized short balloon. The GORE VIABAHN® Endoprosthesis was then deployed over a stiff wire. Postdilatation was performed in all cases using a 1:1 sized balloon at high pressures. Care was taken to avoid any balloon dilatation outside the endoprosthesis edges using magnified fluoroscopic views. Patients randomized to atherectomy underwent plaque excision using the SilverHawk atherectomy device by experienced interventionists. PTA or stents were used as adjunctive therapy after atherectomy for suboptimal results.

Technical success was defined as reduction of stenosis to <20%, with restoration of brisk antegrade flow and without visible thrombus or dissection. Anticoagulation was discontinued at the end of the procedure.

Follow-Up

All patients were followed clinically and underwent ankle-brachial index with arterial duplex 1, 3, 6, and 12 months after the initial intervention. Patients with abnormal duplex studies underwent repeat angiography with reintervention when necessary.

RESULTS

De Novo Native Vessel Disease Group

Eighty-one patients received the GORE VIABAHN® Endoprosthesis for native vessel disease. A total of 167 GORE VIABAHN® Endoprostheses were deployed in 98 SFAs. More than 80% of interventions were performed

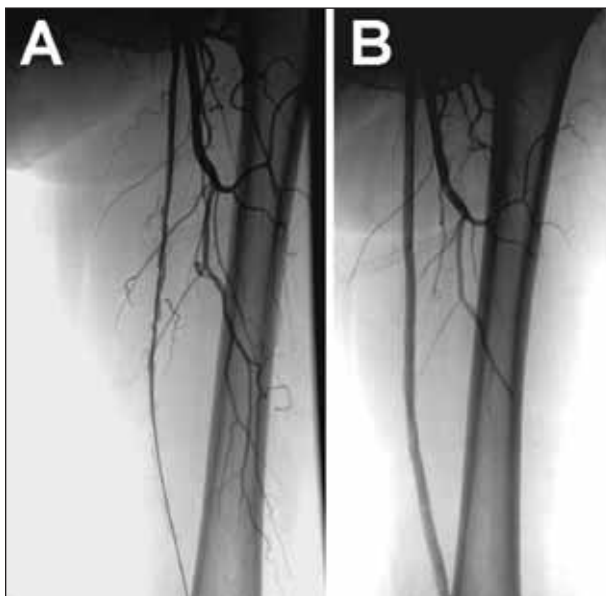


Figure 2. A 75-year-old woman presented with left lower-extremity, lifestyle-limiting claudication. Angiography revealed a chronic total occlusion. Two GORE VIABAHN® Endoprostheses (6 mm X 15 cm and 6 mm X 15 cm) were placed in the left SFA. Preprocedure image (A); postprocedure image (B).

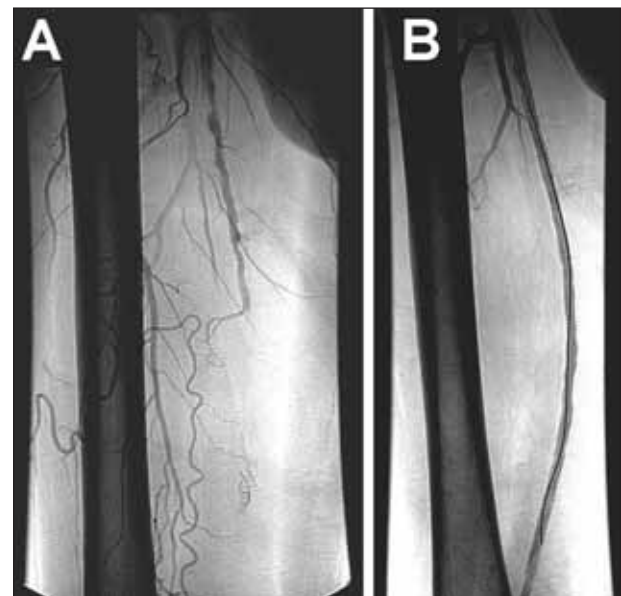


Figure 3. A 73-year-old man with claudication and abnormal arterial duplex ultrasound. Two GORE VIABAHN® Endoprostheses were placed covering the collaterals coming off the body of the SFA, with excellent angiographic and clinical results. Preprocedure image (A); postprocedure image (B).

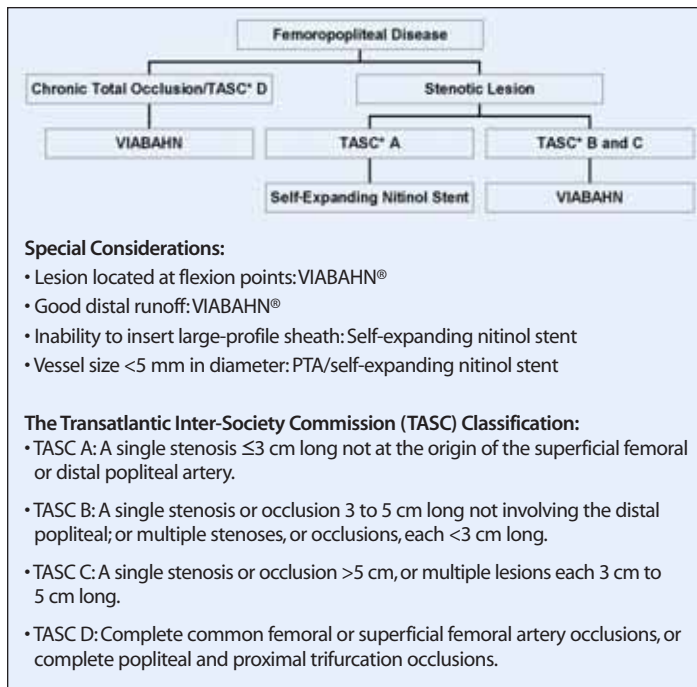


Figure 4. Algorithm tree used to determine management of femoropopliteal disease and TASC classification.

for Transatlantic Inter-Society Commission (TASC) class C and D lesions. Technical success was 100%, with a primary patency rate of 96% at 12-month follow-up. The baseline patient characteristics and results are shown in Table 1.

SilverHawk Atherectomy Subgroup

Forty-three consecutive patients were randomized in a GORE VIABAHN® Endoprosthesis versus SilverHawk atherectomy cohort. Twenty-three patients received GORE VIABAHN® Endoprostheses with intervention on 29 SFAs. The SilverHawk atherectomy group had 20 patients with interventions on 23 SFAs. There were no differences in age, gender, diabetes, or smoking between the two groups. The presenting symptoms and lesion length were similar between the two groups (Table 2).

During the initial procedure, the SilverHawk atherectomy group had significantly more complications than the GORE VIABAHN® group (21% vs 0%; $P=.012$). In the atherectomy group, four (17%) cases of flow-limiting dissection and one (4%) perforation were noticed. There were no procedure-related complications in the GORE VIABAHN® group. At the end of the initial procedure, technical success was achieved in all patients in both groups. There were no deaths in either of the groups. The mean follow-up was 12 months. The primary patency rate at 12 months was 90% in the GORE VIABAHN® group and 57% in the SilverHawk atherectomy group ($P=.009$).

DISCUSSION

In the past decade, many new technologies have emerged to deal with atherosclerotic SFA disease. Surgical revascularization carries significant morbidity and other comorbidities, especially in the elderly. The success of surgical intervention is hampered by the limited availability of autogenous venous conduits (which have a much better long-term patency compared to prosthetic conduits)²³ in these patients.

For percutaneous intervention, the incidence of restenosis remains the Achilles' heel of endovascular intervention. Self-expanding nitinol stents do provide excellent initial success, but long-term patency, especially for long stents, remains suboptimal. The anatomy of the SFA is partly to be blamed for this increased rate of in-stent restenosis. The SFA is unique in that it is the longest artery in the human body. The external forces that it has to bear are markedly influenced by its proximity to musculature, continuous mobility, and the location between two joints.

The use of sirolimus-eluting SMART stents (Cordis Corporation, a Johnson & Johnson company, Miami, FL) for the SFA was tested in the SIROCO I and II trials. Sirolimus-eluting nitinol stents were found to be safe and feasible, with a trend toward reducing late loss compared with uncoated stents. This apparent success was at a cost: an 18.2% incidence of stent fracture.²⁴ Stent fracture in the SFA is an important predictor of a need for repeat interventions.²⁵ Other endovascular techniques, including atherectomy or laser-assisted angioplasty, have shown no benefit over balloon angioplasty alone. In our experience, there were significantly more procedural complications and a reduced primary patency rate in patients who had atherectomy compared to those with GORE VIABAHN® Endoprostheses.²⁶

Although earlier studies with endoprostheses have been disappointing,²⁷ the results with PTFE-covered GORE VIABAHN® Endoprostheses are promising. Major advantages of the GORE VIABAHN® Endoprosthesis include excellent long-term patency and its stent fracture-resistant nature, making it the device of choice in long lesions of the SFA. For better long-term results, two-vessel runoff below the knee is preferred, although we have used this device in limb salvage situations with one-vessel-below-the-knee runoff with good results. Advances in implantation technique and dual antiplatelet therapy have improved immediate and long-term patency. We also determined that covering the diseased segment of the artery in its entirety (healthy to healthy), along with exerting extreme care to avoid balloon injury on the outside edges of the endoprosthesis (Figures 1 and 2), are crucial to reduce the chances of edge restenosis.

Although the GORE VIABAHN® Endoprosthesis device is safe, it does require large-profile sheaths (8 F or larger), making it difficult to use in elderly patients with calcified vessels and severe PVD. Another concern is that, due to its covered nature, the device cannot be used across the profunda femoral artery to prevent occlusion of an important source of collaterals. The same is not true for small collaterals originating from the body of the SFA. In our experience, we did not find any clinical or procedural adverse effects by covering these collaterals coming off the body of the SFA (Figure 3).

CONCLUSIONS

Based on our experience, with careful deployment technique, the GORE VIABAHN® Endoprosthesis had excellent long-term results for SFA disease. We believe that current endovascular intervention with the GORE VIABAHN® Endoprosthesis is the treatment of choice for patients with severe SFA disease (TASC class B, C, and D). Although management decisions may differ from case to case, we generally follow the algorithm tree shown in Figure 4. ■

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Tips for Using the GORE VIABAHN® Endoprosthesis in the SFA

The GORE VIABAHN® Endoprosthesis has excellent technical success rates and short-term durability when these techniques are followed.

BY JOHN G. ADAMS, JR, MD, FACS; RICHARD D. COATS, MD; PAUL W. HUMPHREY, MD, FACS;
KAREN ALTHAGE, CFA; AND MARY CHOTT, RESEARCH COORDINATOR

Recently, several novel techniques and products have been used in the percutaneous treatment of atherosclerotic occlusive disease of the lower extremity. Several investigators have described their experience using the GORE VIABAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ) for endoluminal bypass of the superficial femoral artery (SFA).¹⁻⁷ The GORE VIABAHN® Endoprosthesis is a flexible, self-expanding stent graft composed of an expanded polytetrafluoroethylene (ePTFE) tube inside an external nitinol support that extends along its entire length.

We began using the GORE VIABAHN® Endoprosthesis in July 2004 and have prospectively collected data since that time. As of August 2006, we have performed 100 procedures for occlusive disease in 79 patients. The indication for intervention was debilitating claudication in 59% and rest pain/tissue loss in 41%. The mean age of the patients was 71 years and ranged from 35 years to 88 years. Eighty-six procedures were limited solely to the SFA. Technical success was 100%. Mean contrast usage was 95 mL and ranged from 35 mL to 215 mL. The complication rate was 8% and consisted of five minor complications (three dissections, one target-vessel perforation, and one episode of access-vessel bleeding) and three major complications (three target-vessel thromboses). The 24-month primary and secondary patency rates were 72% and 81%, respectively. Figure 1 depicts a representative patient in our series treated for SFA disease.

Technical success and short-term patency rates of the GORE VIABAHN® Endoprosthesis for use in the SFA have been excellent. We describe what we consider to be several of the important technical aspects of using the GORE VIABAHN® Endoprosthesis.



Figure 1. This patient is representative of patients we have treated using the GORE VIABAHN® Endoprosthesis. The SFA is occluded near the origin and reconstitutes distally (A). The SFA is widely patent without residual stenosis after insertion of two GORE VIABAHN® Endoprostheses, measuring 6 mm X 15 cm (B).

PATIENT SELECTION

Traditionally, open revascularization of the lower extremity was reserved for patients in jeopardy of limb loss and those presenting with rest pain or tissue loss. With rare exception, patients with claudication were not believed to be candidates for intervention because of the low risk of limb loss (approximately 1% to 2% per year).^{8,9} Because the risks of revascularization have dramatically decreased with percutaneous techniques and because we have learned that patients who cannot



Figure 2. The tip of the sheath (arrow) is positioned in the distal external iliac artery.

exercise can do little to promote cardiovascular fitness, patients with claudication refractory to conservative measures are being considered for revascularization to improve their overall cardiovascular health.

The gold standard for infrainguinal revascularization for occlusive disease continues to be autologous vein bypass, which yields long-term patency rates superior to any currently available percutaneous technique.¹⁰⁻¹²

Although vein bypass remains the most durable procedure in our armamentarium, it is associated with a major morbidity of 5% to 10% and a mortality of 1% to 5%.¹⁰⁻¹³ We continue to use vein bypass procedures for our low-risk patients who have a life expectancy >5 years. For patients who are moderate-to-high risk and/or have limited life expectancy, we consider percutaneous revascularization as our initial approach in management.

APPROACH/SHEATH POSITIONING

We typically use a contralateral rather than an ipsilateral approach when treating lesions in the SFA. There are numerous advantages to a contralateral, retrograde approach, including more working room for lesions that involve the proximal SFA, smaller-caliber working devices placed across the common femoral artery (CFA) and SFA resulting in less risk of decreasing flow and subsequent target-vessel thrombosis, and decreased risk of thrombosis that can occur with postprocedure compression after ipsilateral sheath removal. Instances in which ipsilateral, antegrade access is preferable include patients who have undergone previous placement of an aortoiliac or aortofemoral bifurcated graft, previous placement of a bifurcated endograft, and in those patients who require an adjunctive below-the-knee percutaneous intervention. Below-the-knee percutaneous interventions are difficult to perform from a contralateral approach because of “trackability” and “steerability” issues.

We believe that the three major complications that

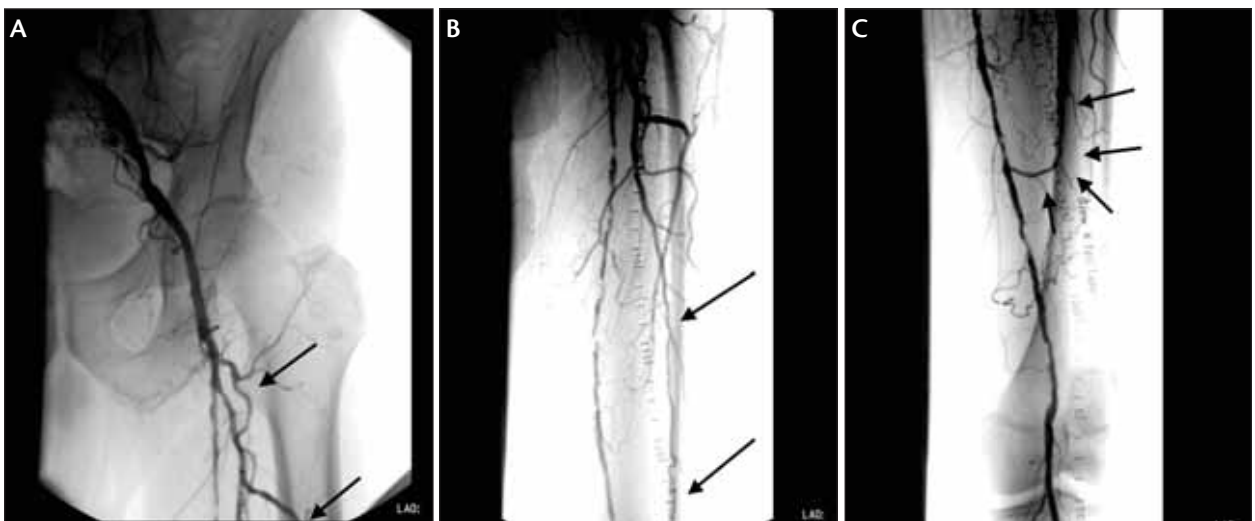


Figure 3. Branches of the profunda femoris artery (arrows) provide critical distal perfusion in this patient with severe disease of the SFA (A). A branch of the profunda femoris artery (arrows) is visualized as it courses distally to establish a collateral route to the distal SFA (B). The distal profunda femoris artery branch provides flow to the superior, lateral genicular artery establishing the collateral network (arrows), which reconstitutes the distal SFA (C).

we have encountered in our series were the direct result of obstructing flow through the CFA and SFA with a large sheath, which resulted in perisheath thrombosis within the target artery. We take special care to place the working sheath no further distally than the external iliac artery to avoid obstruction of flow through the CFA and SFA (Figure 2). In those instances when we need a rigid platform extending into the SFA for pushability/trackability, we limit placement of the sheath in the SFA for 2 to 3 minutes at a time.

COLLATERAL FLOW PRESERVATION

In patients with chronic disease of the SFA, multiple collaterals are often present and are critical for distal perfusion (Figure 3). Whereas placing bare stents across branch vessels often results in patency of those vessels, placing covered stents across branch vessels results in vessel occlusion. The profunda femoris artery is an extremely valuable collateral pathway that usually reconstitutes the distal SFA or popliteal artery via one of the genicular arteries. Every attempt must be made to preserve the profunda femoris artery and genicular artery collateral pathway when using covered stents in the SFA. We do not treat the proximal 2 cm of the SFA with covered stents for fear of jeopardizing the profunda femoris artery. We preserve all major collateral genicular arteries in the distal SFA (Figure 4). We use a variety of other techniques, such as cryoplasty or atherectomy, for treating these areas when required. While we make every attempt to preserve collateral vessels, we liberally cover muscular branches in the SFA that do not contribute to distal perfusion.

TARGET ARTERY PREPARATION/EQUIPMENT/DEPLOYMENT

As with any percutaneous intervention in the SFA, anatomical considerations for treatment include proximal and distal extent of disease, location of collateral vessels, stenosis versus occlusion, and status of the runoff vessels. The primary technical goal is to place the GORE VIABAHN® Endoprosthesis across the diseased artery with the proximal and distal ends of the endoprosthesis positioned within arterial segments relatively

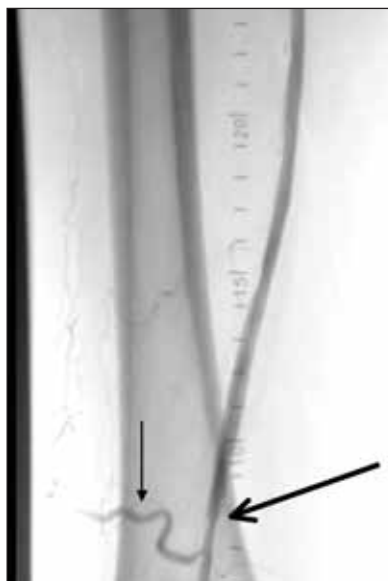


Figure 4. The large superior, lateral genicular artery, which provides critical collateral flow to the distal extremity, has been preserved (small arrow) by careful placement of the GORE VIABAHN® Endoprosthesis proximal to its origin (large arrow).

free of disease while preserving major collateral vessels. Most of the patients in our series had chronic occlusion of the SFA with reconstitution in the distal SFA or the proximal popliteal artery. Flush occlusions of the SFA are technically more demanding. Disease that involves the SFA proximally within 2 cm of its origin or extends distally into the popliteal artery often requires additional, adjunctive percutaneous techniques. We make every effort to achieve adequate runoff by aggressively treating any associated popliteal and tibial artery disease that is hemodynamically significant with cryoplasty and/or atherectomy when encountered.

Once the CFA has been accessed from a contralateral approach using a crossover Tempo catheter (Cordis Corporation, a Johnson & Johnson company, Miami, FL) and an angled-tip Glidewire (Terumo Medical Corporation, Somerset, NJ), a .035-inch stiff wire, such as a Jindo (Cordis) or Amplatz Super Stiff EX (Boston Scientific Corporation, Natick, MA), is exchanged for the Glidewire. All wires must be 260 cm or longer to ensure adequate working length. A Raabe sheath (5-F, 55-cm-long, Cook Medical, Bloomington, IN) is placed across the aortic bifurcation and positioned in the distal external iliac artery.

Guidewire positioning across chronic occlusions of the SFA can be a technically challenging exercise. We use a subintimal dissection technique that has been well described.¹⁴⁻¹⁶ We use an MP A1 catheter (Cordis) and a steerable angled-tip Glidewire as our initial approach to crossing a chronic occlusion. Other catheters that we have found to be useful in difficult cases of crossing chronic occlusions are the 4-F and 5-F Glidecaths (Terumo), the Micro Guide Catheter XP (Cordis), and the Frontrunner XP CTO Catheter (Cordis), which creates a channel for wire access using blunt dissection to fracture the plaque. The Jindo wire is also helpful when a stiffer platform is needed. Occasionally, re-entrance into the true lumen distally is a problem with the subintimal technique. We have employed the Outback LTD Re-Entry Catheter (Cordis) in such situations. The Outback catheter is a 6-F, single-lumen catheter fitted with a coaxial cannula, designed

to track over a .014-inch guidewire. The distal curved-tip cannula consists of a nitinol sharp needle, activated via the proximal end of the catheter and used to puncture the true lumen of the vessel under fluoroscopic guidance. Once the true lumen has been entered with the needle, the .014-inch guidewire is advanced through the cannula to gain intraluminal access. Once a guidewire has been successfully positioned across the SFA, the 5-F sheath is exchanged for a 65-cm, 8-F Super Arrow-Flex PSI set sheath (Arrow International, Inc., Reading, PA) for insertion of a 6-mm GORE VIABAHN® Endoprosthesis. If a 7-mm GORE VIABAHN® Endoprosthesis is required, a 45-cm, 9-F Brite-tip Sheath Introducer (Cordis) is used. Again, the tip of the sheath is positioned in the distal external iliac artery.

Aggressive treatment of the target vessel with angioplasty in the subintimal plane is required to place the GORE VIABAHN® Endoprosthesis. The endoprosthesis is uncovered and as such can be damaged if the subintimal channel is not well developed (we have had no device failures in our series). There are also theoretical benefits to aggressive preparation of the artery prior to placing the endoprosthesis—the less rigorous the dilatation that is performed within the endoprosthesis, the less the theoretical risk of stent fatigue and fracture. We begin with a low-profile, 3-mm or 4-mm Ultra-Thin Diamond balloon (Boston Scientific Corporation) and perform graduated dilatation of the subintimal plane until the appropriately sized channel has been developed. For areas of heavy calcification and high elastic recoil, a high-pressure, noncompliant balloon such as a Conquest (Bard Peripheral Vascular, Tempe, AZ) is employed. If areas proximal or distal to the site of planned endoprosthesis placement require intervention, those areas are treated prior to placement of the GORE VIABAHN® Endoprosthesis.

The GORE VIABAHN® Endoprosthesis is oversized by 5% to 20% in the target vessel. After the endoprosthesis has been placed, postdeployment dilatation is performed with a 1:1 noncompliant balloon. Great care must be used to ensure that the balloon does not extend outside the endoprosthesis for fear of dissection. When treating long segments of the SFA, we have found it helpful to use 8-cm-long balloons (Ultra-Thin SDS, Boston Scientific Corporation) for postdeployment dilatation to decrease procedure times.

ANTICOAGULATION

All patients who are scheduled for angiography with or without a planned intervention are placed on aspirin therapy (81 mg/d) unless a specific contraindication exists. This is continued up to, and includes

administration the morning of the intervention. All patients are given 2,000 units of heparin intravenously at the time of access sheath placement. In patients undergoing an intervention, therapeutic anticoagulation is achieved by administering an additional 2,000 to 4,000 units of heparin based on patient weight (50-75 U/kg). Additional doses of 1,000 units of heparin are given each hour thereafter to maintain therapeutic anticoagulation. The heparin is not reversed at the conclusion of the procedure unless a bleeding problem is encountered.

In patients in whom an intervention is planned, clopidogrel (300 mg) is administered orally the morning of the procedure. In patients who do not receive preoperative clopidogrel and undergo an intervention, 300 mg is given orally in the recovery area. Clopidogrel (75 mg) is empirically continued on a daily basis for 30 days. Data are lacking for the optimal dosage and timing of clopidogrel therapy in peripheral vascular interventions, but there does appear to be a distinct advantage to clopidogrel plus aspirin versus aspirin alone in reducing overall ischemic events.¹⁷

CLOSURE DEVICES

Currently, insertion of the 6-mm GORE VIABAHN® Endoprosthesis requires an 8-F sheath, and the 7-mm endoprosthesis requires a 9-F sheath. Early in our series, we employed manual compression of the access site after removal of the sheath with selective use of closure devices. Even though our access site bleeding rate was low, manual compression often took 30 to 45 minutes. We now use closure devices in virtually all patients in whom a 7-F or larger access is required. We use the AngioSeal Vascular Closure Device (St. Jude Medical, St. Paul, MN). We have almost completely obviated the need for manual compression with the use of closure devices, with an access complication rate of <1%. Closure devices have allowed us to liberally anticoagulate our patients before, during, and after interventions.

CONCLUSION

The GORE VIABAHN® Endoprosthesis has been shown to have excellent technical success rates and short-term durability in treating SFA occlusive disease. There are, however, several technical points that need to be emphasized. We believe that with adherence to these technical recommendations, the GORE VIABAHN® Endoprosthesis can be used with acceptably low complication rates. ■

John G. Adams, Jr, MD, FACS, is from Columbia Surgical Associates, Columbia, Missouri. He has disclosed that he is a
(Continued on page 23)

Debunking the Myth of Failed Lower-Extremity Endoprostheses

Increased long-term patency and reduced morbidity rates support use of the GORE VIABAHN® Endoprosthesis to treat lifestyle-limiting claudication.

BY CHRISTOPHER L. WIXON, MD

The prevalence of peripheral arterial disease (PAD), as defined by a resting ankle brachial index ≤ 0.9 , is estimated to range between 3% and 10% of individuals in their 6th decade of life and may approach 20% of individuals who are older than 70 years of age.¹ Approximately 75% of affected individuals are either asymptomatic or unaware of the disease process.

The presence of PAD has been noted to be associated with an increased risk of coronary artery disease, cerebrovascular disease, and premature death. Progression of the disease is largely dependent on the activity level of the individual and the proper management of identifiable cardiovascular risk factors. While the progression of unrecognized PAD may not be as disabling as other vascular beds, the progression to critical limb ischemia (CLI) eventuates in amputation in approximately 2% of individuals.

Moreover, as a consequence of limited exercise performance and walking ability, individuals who have symptoms of intermittent claudication experience a significantly negative impact on quality of life, which produces functional impairment similar to that of NYHA class II and III congestive heart failure. Remarkably, of the individuals with PAD who manifest symptoms of intermittent claudication, only 10% to 50% are noted to have consulted a physician regarding their symptoms.

Despite these factors, the diagnosis of PAD has largely been underrecognized and underreported by the medical profession. While most vascular specialists would not advocate treating individuals who are asymptomatic, many clinicians maintain a decidedly conservative stance in both asymptomatic and symptomatic patients. This generalized reluctance to recommend intervention is likely based upon the marginal results associated with the limited technologies that have previously existed.

AVAILABLE TECHNOLOGY

Because greater than 50% of individuals with lower extremity claudication have atherosclerotic disease confined to the superficial femoral artery (SFA), a flurry of endovascular techniques has recently emerged to treat this arterial segment. Many of these techniques offer minimally invasive therapies to individuals who were not previously believed to be endovascular candidates, including Trans-Atlantic Inter-Society Consensus Document (TASC) B, C, and D lesions. Unfortunately, the enthusiasm for new technology often eclipses the clinical benefit, and a critical review of technologies is presently warranted.

It has become increasingly clear that no single technology is suitable for the full spectrum of lesions that present themselves to the vagaries of peripheral vascular disease, and the modern endovascular specialist must be familiar with multiple techniques to select properly the most favorable technology for the patient's anatomy.

The GORE VIABAHN® Endoprosthesis

One of the most significant methods to arise utilizes a vascular prosthesis delivered in a less-invasive, endovascular manner to bridge an area of chronic occlusion between two healthy segments of artery. The only currently FDA-approved device for this purpose is the GORE VIABAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ). Theoretical benefits include reduction of neointimal hyperplasia, the potential to expand the blood vessel beyond the normal limits of the adventitial diameter, and reduced risk of periprocedure atheroembolization (Table 1).

Challengers of this technology, however, cite the requirement to cover collateral blood vessels that are believed to be critical in the subsequent prevention of

TABLE 1. THEORETICAL ADVANTAGES OF THE GORE VIABAHN® ENDOPROSTHESIS

- Reduction of neointimal hyperplasia
- The potential to expand the blood vessel beyond the normal limits of the adventitial diameter
- Reduced risk of atheroembolization

ischemia should the intervention fail, thereby potentially converting a lifestyle-limiting problem to one of CLI.

The purpose of this article is to explore the manner by which failed SFA GORE VIABAHN® Endoprostheses have produced progression of lower-extremity ischemic symptoms.

CLINICAL METHODS

Records were examined in a retrospective manner. Patients were eligible for inclusion based on previous symptomatic, chronic lower-extremity ischemia; existence of focal occlusive disease (TASC B, C, and D) of the SFA; and previous placement of an endovascular stent graft (Table 2). During the 4.4-year interval, 69 consecutive extremities in 62 patients were treated.

The decision to proceed with intervention was based on refractory claudication symptoms, ischemic rest pain, or lower-extremity ulceration. Preprocedure imaging was performed using physiologic testing, duplex ultrasound, computed tomography angiography, or mechanical resonance angiography. Based on contrast angiography, mean lesion length was 12 cm. Individuals with concomitant inflow or outflow disease were not excluded from treatment. Deployment of the GORE VIABAHN® Endoprosthesis was confined to chronic total occlusions of SFA at or above the adductor canal, as indicated by the product's instructions for use. Potential future sites of surgical bypass were not covered with stent-graft endoprostheses. A mean of 1.8 GORE VIABAHN® Endoprostheses were used per individual. Concomitant adjunctive inflow and outflow procedures were required in 17% of patients. Technical success in treating the target lesion was achieved in 94% of individuals.

Of the 69 extremities that were treated, objective, duplex ultrasound follow-up data were available for 66 patients during a mean follow-up period of 14 months (30 days to 4.4 years). Unless specific contraindication existed, individuals were treated with an antiplatelet regimen consisting of either aspirin and/or clopidogrel. After implantation, patients were observed using duplex ultrasound, and reintervention was performed for duplex-identified stenosis as defined by peak systolic velocity >350 cm/s or a velocity ratio of 4:1.²

TABLE 2. DEGREE OF OCCLUSIVE DISEASE

| |
|--------------|
| TASC A – 0% |
| TASC B – 7% |
| TASC C – 68% |
| TASC D – 25% |

RESULTS

Since initiating this treatment methodology, eight extremities experienced stent-graft thrombosis at a mean interval of 13 months after implantation. In

each case, failure was documented by either duplex ultrasound or contrast angiography. Cases of stent graft thrombosis did not correlate with the length of the lesion treated (mean length thrombosis group, 12.8 cm vs mean length nonthrombosis group, 11.8 cm). After intervention, four individuals failed early within the postintervention period (<3 months after intervention) and four patients failed late (>3 months after intervention). In the cases of stent thrombosis, patients did not present with acute limb-threatening ischemia, but rather, patients were noted to re-present with their preprocedure degree of ischemia as documented by Rutherford Classification (Tables 3 and 4). There were no amputations performed in any individuals during the follow-up period.

To determine the etiology of the failure, angiograms and postoperative duplex ultrasounds were examined (Figure 1). Of the four individuals who experienced early endoprosthesis failure, a review of the procedure angiogram demonstrated significant disease distal to the GORE VIABAHN® Endoprosthesis. In retrospect, two individuals were believed to be poor endovascular candidates, and they underwent subsequent bypass to the infrageniculate popliteal artery without complication. The other two early failures occurred in patients in whom the importance of covering all hemodynamically significant segments (rather than just treating only the occluded segment) was poorly recognized. Both of these individuals reverted to their previous Rutherford category of leg ischemia. One individual elected to

TABLE 3. RUTHERFORD CLASSIFICATION OF LOWER-EXTREMITY PERIPHERAL VASCULAR DISEASE

| Class | Symptoms |
|-------|---|
| 0 | Asymptomatic |
| 1 | Mild claudication |
| 2 | Moderate claudication |
| 3 | Severe claudication |
| 4 | Ischemic rest pain |
| 5 | Mild tissue loss, nonhealing ulcer, salvageable |
| 6 | Major tissue loss, unsalvageable |

TABLE 4. CASES OF STENT GRAFT FAILURE

| Patient No. | Length of Lesion (cm) | Preprocedure Rutherford Class | Interval to Failure (mo) | Postthrombosis Rutherford Class | Acute Limb Threat? | Secondary Intervention |
|-------------|-----------------------|-------------------------------|--------------------------|---------------------------------|--------------------|------------------------|
| 1 | 5 | 3 | 18 | 3 | No | Endovascular salvage |
| 2 | 22 | 2 | 3 d | 2 | No | None |
| 3 | 10 | 4 | 27 | 4 | No | Endovascular salvage |
| 4 | 4 | 5 | 1 | 5 | No | Infrageniculate bypass |
| 5 | 14 | 2 | 25 | 2 | No | None |
| 6 | 26 | 3 | 3 | 3 | No | Infrageniculate bypass |
| 7 | 4 | 1 | 17 | 1 | No | Endovascular salvage |
| 8 | 18 | 5 | 1 | 4 | No | Endovascular salvage |

undergo reintervention with an extension of the endovascular prosthesis to cover properly all segments of diseased artery.

Of the four cases of late failure, one case had demonstrated clear duplex ultrasound evidence of stenosis at the distal aspect of the stent, which was electively not treated due to reluctance of the physician. The other three cases of stent graft thrombosis were not predictable through either retrospective questioning of the patient for recurrent claudication symptoms before the event or through prospective ultrasound evaluation of the involved artery. None of these individuals experienced acute limb, threatening symptoms. Three of the four patients underwent repeat endovascular intervention successfully. One individual elected not to receive any further intervention.

DISCUSSION

The GORE VIABAHN® Endoprosthesis became commercially available in the US in January 2002 for tracheo-

bronchial applications. The indication was extended to use in the SFA in June 2005. The GORE VIABAHN® Endoprosthesis is the only endoluminal prosthetic device approved by the FDA for applications in the SFA.

Given the variety of treatment modalities available for the treatment of the SFA, recent data suggest that the GORE VIABAHN® Endoprosthesis is emerging as the preferred method of treating complex TASC C and D lesions.³⁻⁵

However, several unsettled issues raise uncertainty among many clinicians. The most significant issue concerns the widely accepted perception that if the endoprosthesis fails, the individual's lifestyle-limiting problem may be transformed from that of lifestyle-limiting claudication to that of acute limb threat. This perception is based on previously reported data in which thrombosed prosthetic femoropopliteal bypass grafts resulted in significant progression of limb ischemia beyond that which was previously experienced.^{6,7} Moreover, many of these studies indicated that the risk of major amputation was quite significant in individuals who experienced bypass failure.⁸

More recently, Dr. Frans Moll reported that the risk of acute limb ischemia was significantly reduced in cases of failed intervention after employment of the remote endarterectomy technique to recanalize the SFA.⁹ Remote endarterectomy of the SFA has the theoretical benefit of preserving arterial collateral vessels, and it is from this potential benefit that we concluded ameliorates the risk of future ischemia should the intervention fail.

In this series, we note that in all eight cases of failed intervention, the patient did not present with acute, limb-threatening ischemia beyond that which was previously

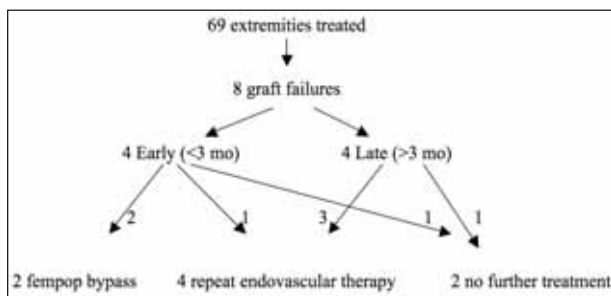


Figure 1. Four-year experience with the GORE VIABAHN® Endoprosthesis.

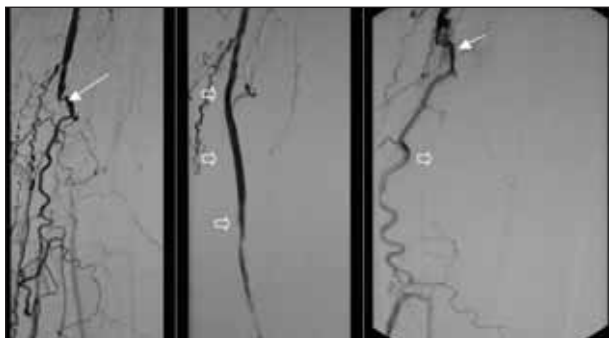


Figure 2. The preprocedure angiogram demonstrates an 8-cm, heavily calcified, chronic total occlusion of the SFA (A). Note the location and appearance of the large collateral proximal to the occlusion (arrow) and the 6-mm X 10-cm GORE VIABAHN® Endoprosthesis (open arrow). Proper endovascular treatment of the chronic occlusion necessitated covering the large, proximal collateral (open arrows) (B). Three years later, the patient re-presented with an occlusion of the previously placed GORE VIABAHN® Endoprosthesis (open arrow). Despite the origin of the collateral being covered by the stent graft, re-recruitment of the collateral is noted upon thrombosis of the GORE VIABAHN® Endoprosthesis (arrow) (C).

experienced. To explore this observation more carefully, we reviewed the status of the collateral blood vessels in individuals who had experienced stent graft thrombosis (Figure 2). In many cases, it was interesting to note that, in spite of the origin of the collateral vessel being covered by the stent graft, re-recruitment of the collateral is noted upon thrombosis of the stent graft. The continued availability of the collateral as a network through which blood may be shunted to the more distal circulation is one potential hypothesis why the individuals in this series did not develop CLI upon stent-graft thrombosis. It should be noted, however, that in this series, the mean length of diseased segment was approximately 13 cm. It is possible that applications in which significantly longer segments are treated may not benefit from the re-recruitment of collateral blood vessels to the same degree.

CONCLUSION

The disparate concepts of properly treating all hemodynamically significant disease while trying to preserve collateral circulation creates opposing objectives when treating complex peripheral arterial disease of the SFA with an endoprosthesis. When weighing the risks and benefits against each of these contrasting concerns, it is the author's opinion that one should plan for long-term procedure success rather than failure. Failure to treat a lesion wholly with a sufficient-length endoprosthesis, for the

theoretical benefit of preserved collateral blood flow, will compromise the patency of the procedure and therefore cannot be justified.

From an economic standpoint, performing the most durable procedure possible at the initial operation will be the most cost-effective method in the long term. However, many physicians are sensitive to the shrinking remuneration under CMS Ambulatory Payment Classification (APC) and reserve the application of the endoluminal prostheses for situations in which a lesser-cost intervention has previously failed. However, from a health economics standpoint, the procedures that tend to be the most expensive are those that must be repeated.¹⁰ Good judgment would indicate that if a particular modality has a high rate of failure when applied to a particular disease pattern, the increased durability of a more costly alternative procedure would be justified.

In properly selected patient populations, patency rates comparable to that of prosthetic femoropopliteal bypass should be achievable.³ It must be emphasized, however, that continued favorable outcomes for such procedures will continue to rely on proper patient selection.

The combined benefit of increased long-term patency, the reduced procedure morbidity rate associated with an endovascular approach, and the seemingly limited risk of long-term complications (should the intervention fail) will provide increased assurance to individuals with lifestyle-limiting claudication wishing to pursue intervention. ■

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Endovascular Femoropopliteal Bypass in a Complete Occlusion

Use of the GORE VIABAHN® Endoprosthesis to treat an SFA lesion.

BY PARAMJIT “ROMI” CHOPRA, MD, AND SWARNAM CHIRAMEL, MS

Peripheral vascular disease commonly affects the arteries supplying the leg and is mostly caused by atherosclerosis, a primarily systemic inflammatory process.¹⁻³ Intermittent claudication alone is often a symptom of severe atherosclerotic or occlusive arterial disease of the peripheral vascular system. Even though many patients with claudication remain stable, about 150 to 200 per million of the population progress to critical limb ischemia each year.⁴ It is established that without revascularization, critical limb ischemia appears as a significant risk of limb loss.⁵

Our earlier study has reported hemodynamic patency rates of 97%, 93%, 89%, and 87% at 6, 12, 18, and 24 months, respectively, in 60 patients in whom a GORE VIABAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ) was used to treat limb ischemia.⁶ This article depicts a case report of an endovascular technique for treating a TASC D superficial femoral artery (SFA) lesion using the GORE VIABAHN® Endoprosthesis.

CASE STUDY

A 75-year-old woman presented with a severe, lifestyle-limiting (half-block) claudication of the left calf. She had a known history of coronary artery disease and hypertension. Her ankle-brachial indexes (ABIs) obtained at the time were 0.8 on the right and 0.6 on the left with abnormal waveforms. She underwent aortography and runoff arteriography that showed a normal aorta and iliac vessels.

Left lower-extremity arteriography showed a mild narrowing of the proximal 2 cm to 3 cm of the left SFA followed by complete occlusion of the remainder of the SFA. The distal SFA was reconstituted near the adductor canal by collaterals from the profunda femoris artery. The popliteal artery showed mild but insignificant stenosis. The posterior tibial artery occluded in the mid portion of the leg. The main runoff vessel to the foot was the anterior tibial artery and the peroneal artery (Figure 1).

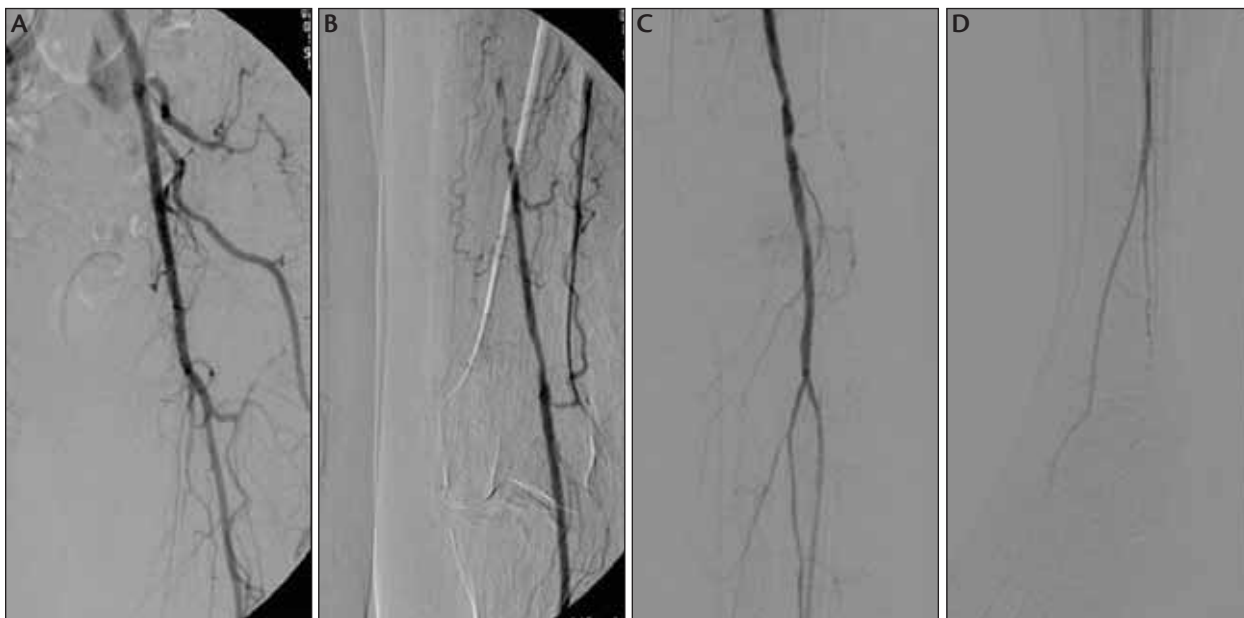


Figure 1. Left leg arteriogram depicting complete occlusion of the SFA (A, B). Patent popliteal artery and two-vessel runoff. Note the large collateral from the profunda femoris artery reconstituting the popliteal artery (C). Patent dorsalis pedis artery (D).



Figure 2. Recanalization of the left SFA complete occlusion with a hydrophilic catheter and guidewire. Contrast is injected to ensure that the catheter is in the true lumen within the popliteal artery.

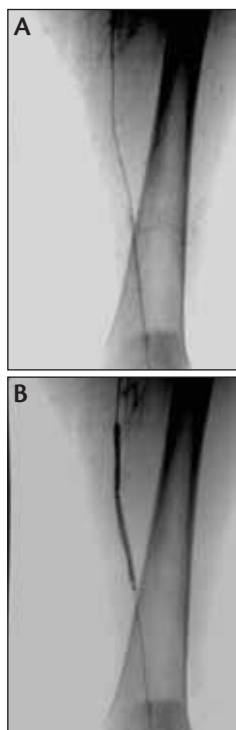


Figure 3. Angioplasty of the occluded segment was performed with a 6-mm X 10-cm high-pressure angioplasty balloon. Note that the collateral from the profunda is spared.



Figure 4. Angiogram after completion of the endoluminal femoropopliteal bypass with the GORE VIABAHN® Endoprosthesis. Note excellent straightline flow through the SFA.



Figure 5. Note the tight stenosis at the origin of the SFA in the few millimeters at the proximal portion of the GORE VIABAHN® Endoprosthesis.

Procedural Considerations

The patient refused a surgical bypass and, after discussing the various options with her, she opted for revascularization of the left lower limb by placement of a percutaneous endograft in the left SFA.

The right common femoral artery was accessed percutaneously, and an 8-F sheath was placed over the aortic bifurcation. The occluded SFA was recanalized with a straight 4-F glide catheter and a 0.035-inch Glidewire (Terumo Medical Systems, Somerset, New Jersey). The 4-F glide catheter was then positioned within the true lumen of the patent popliteal artery. Contrast arteriography confirmed that the catheter was within the true lumen of the popliteal artery (Figure 2). Every effort was made to prevent injury to the intima of the popliteal artery. The Glidewire was then exchanged for a soft-tip wire.

Angioplasty of the occluded SFA was performed. Every effort was made to prevent injury or occlusion of the large collateral channel that reconstituted the distal SFA at the adductor canal (Figure 3). Angioplasty

beyond this point was not performed to prevent injury to the popliteal artery intima and to avoid future intimal hyperplasia and restenosis.

The SFA, although patent after angioplasty, had irregular margins and sluggish flow thorough it. Six-millimeter GORE VIABAHN® Endoprostheses were deployed covering the entire SFA from its origin to the point where the SFA reconstituted via collateral at the level of the adductor canal. Importantly, the GORE VIABAHN® Endoprostheses were deployed carefully to avoid covering the large collateral into the SFA. Thirty-one centimeters of the SFA were covered with GORE VIABAHN® Endoprostheses (two 6 mm X 15 cm and one 6 mm X 5 cm). Follow-up, postprocedure arteriograms (Figure 4) showed a widely patent SFA and popliteal artery with excellent flow down into the foot. A 2+ dorsalis pedis arterial pulse was palpable.

After-Treatment Evaluation

The patient's symptoms completely resolved. Non-invasive arterial evaluation of the lower extremities by

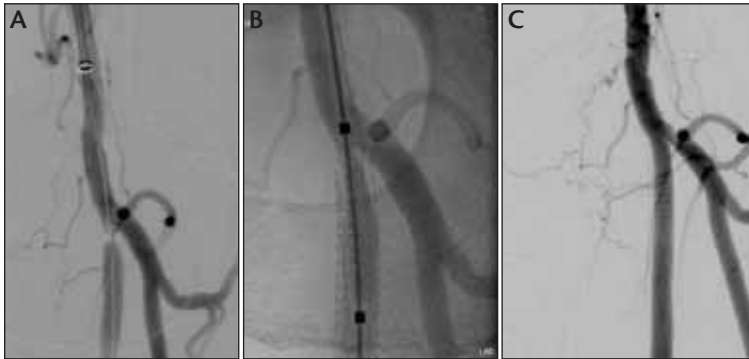


Figure 6. An 8-F sheath is noted in the common femoral artery (A). A wire has been placed across the stenosis (B). A 6-mm X 2.5-cm GORE VIABAHN® Endoprosthesis was placed in the proximal stenosis and reangioplastied to obtain an excellent result with a patent endograft (C).

analysis of the Doppler analog signal and segmental limb pressure was done 2 weeks after the procedure, and the ABI on the left leg had improved from 0.6 to 1.01. She was prescribed clopidogrel bisulphate and returned for clinical and noninvasive follow-up every 3 months.

One-Year Follow-Up

At 1-year follow-up, the patient was noted to have a stenosis at the origin and the first few millimeters of the SFA proximal to the GORE VIABAHN® Endoprosthesis. The ABI on the left lower extremity was reduced from 1.0 to 0.84. A 90% stenosis of the origin (3 mm to 4 mm) of the left SFA, proximal to the endograft, was noted above the previously placed GORE VIABAHN® Endoprosthesis (Figure 5). The entire GORE VIABAHN® Endoprosthesis and the remainder of the SFA and the popliteal artery were widely patent with good runoff vessels.

The stenosis was treated by angioplasty with a 6-mm balloon and placement of a 6-mm X 2.5-cm GORE VIABAHN® Endoprosthesis.

Arteriography after deployment showed a widely patent profunda with good coverage of the origin of SFA stenosis (Figure 6) with excellent flow to the foot. The patient's ABI 2 weeks after the procedure had increased from 0.84 to 1.0. Bilateral lower-extremity and Doppler imaging of the arterial tree showed a widely patent left SFA and popliteal artery.

DISCUSSION

Over the past few years, use of the GORE VIABAHN® Endoprosthesis for the treatment of femoropopliteal disease has been well documented.⁷⁻¹⁰ Previous reports have shown that polytetrafluoroethylene-coated stents placed in the intraluminal location may reduce intimal hyperplasia in the peripheral vascular system.^{11,12} Our earlier studies have also provided promising patency results with all grades of

TASC A to D lesions. However, the device's capability in maintaining the long-term patency is yet to be evaluated.

In the present case study, a TASC D lesion is successfully treated using a GORE VIABAHN® Endoprosthesis, thus demonstrating its efficacy in treating long-segment occlusive disease of the SFA. Durable treatment of such long-segment occlusive disease is not feasible with bare metallic stents. GORE VIABAHN® Endoprostheses permit the placement of a percutaneous femoropopliteal artery bypass graft safely and effectively. However, aggressive follow-up and prophylactic measures are crucial for achieving continued patency.

CONCLUSION

Endovascular treatment with the GORE VIABAHN® Endoprosthesis can be regarded as an effective option for treating long-segment occlusive disease of the SFA with high patency rates. ■

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Treating Significant Stenosis in the SFA With Covered Self-Expanding Stent Grafts

Use of the GORE VIABAHN® Endoprosthesis in significant stenosis complicated by a significant aneurysm in the SFA.

BY JAMES B. PARK, MD, FACC

Endovascular therapy has gained widespread acceptance for treating peripheral artery disease (PAD) in several anatomical locations. The iliac arteries are one such area, particularly in the common iliacs and proximal external iliac areas, especially if the length of lesion is less diffuse. Greater acceptance is also being garnered for endovascular therapy in the superficial femoral artery (SFA), especially for nitinol self-expanding stents when used in relatively short lengths.

Among several concerns related to SFA intervention are the diffuse nature of some SFA disease and the frequent need to use relatively long stent lengths, at times requiring the treating physician to overlap multiple stents. Further complicating the treatment of SFA disease is the recent controversy surrounding the possibility of stent fractures and subsequent restenosis related to this event. A particular area of vulnerability is the area through the adductor canal as the SFA continues behind the knee. In fact, the area at the adductor canal is a frequent location for SFA disease likely secondary to the torsion and compression forces on the artery itself due to the muscular structure surrounding this canal. In the earlier days of endovascular therapy, we believed that the area to avoid stenting due to the risk of stent crush or stent fracture was near the bony articulation between the femur and the tibia.

We now believe that the area of critical importance is really superior to this point leading up to the adductor canal, which is a frequent location of SFA

lesions. If it is necessary to stent this region, the ability of the stent to withstand the forces present in the SFA is of critical importance. One such device might be the covered, self-expanding GORE VIABAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ). This article describes an interesting case report using this device during the first of two interventions (one in each leg) for a patient with severe claudication symptoms related to significant stenosis of the distal SFA bilaterally. The case was further complicated by the presence of large aneurysms proximal and distal to the stenosis.

CASE REPORT

A 71-year-old man presented with severe claudication bilaterally. He reported that his right leg was slightly worse than his left, and his exertional tolerance was between one to two blocks. He had initially reported

the symptoms to his primary physician, who had ordered a bilateral, lower-extremity arterial ultrasound, which noted bilateral moderate SFA stenosis with ankle-brachial indexes of .92 on the right and .78 on the left. There was no mention of aneurysmal segments on either side. He underwent aortography and runoff as an outpatient by another cardiologist, which showed significant SFA disease complicated by large aneurysmal areas below and above the SFA lesions bilaterally (Figure 1). We elected to treat the left leg first because of the severity of the ankle-brachial index findings and the easier access for this initial procedure—going from right to left in a contralateral fashion.

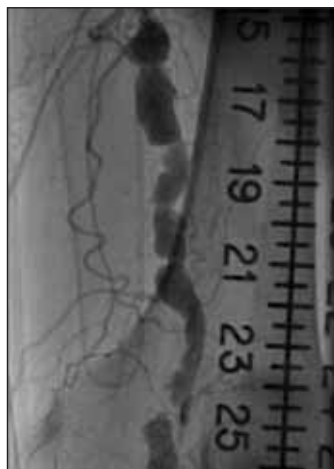


Figure 1. The patient's left SFA, showing multiple aneurysms and severe stenosis.

There was initial consideration of a surgical approach versus possible stenting, which was further complicated by the presence of aneurysms and the location of the distal stenosis and aneurysms impinging upon the critical areas of stent crush and fracture. For the procedure, an 8-F, 45-cm-long sheath (Terumo Medical Corporation, Somerset, NJ) was placed contralaterally, and mapping angiography was performed. The lesion was crossed with mild difficulty with a .018-inch Steelcore wire (Abbott Vascular, Santa Clara, CA) to the peroneal artery. A Volcano IVUS catheter (Volcano Therapeutics, Inc., Laguna Hills, CA) was then used to assess the size of the artery at the tibioperoneal trunk and also to assess the amount of atherosclerosis present at the location where the distal end of the GORE VIABAHN® Endoprosthesis would be placed. In addition, use of ultrasound would allow for more accurate determination of stent size to ensure good apposition at the proximal and distal ends.

To ensure that the stent catheter could be placed into the distal end, angioplasty was performed using a 4-cm X 2-cm Agiltrac balloon (Abbott Vascular) in multiple stenotic areas. Two GORE VIABAHN® Endoprostheses were used (a 6-cm X 15-cm and a 6-cm X 10-cm) and overlapped to the mid SFA. However, angiography performed after stent placement revealed a very small leak into the aneurysm. A 7-cm X 2.5-cm stent was placed, which overlapped into the proximal stent; the proximal portion was postdilated with a 6-mm balloon, and the distal portion was postdilated with a 5-mm balloon (Figure 2). The patient did well after the procedure and had excellent results (Figure 3). Ankle-brachial indexes after the procedure were ≥ 1 after 12 months of treatment. He was placed on a standard aspirin and clopidogrel therapeutic regimen. Because the disease was bilateral, the right SFA was treated similarly with a GORE VIABAHN® Endoprosthesis 2 weeks later, with very good results.

DISCUSSION

The use of covered self-expanding stents to treat long

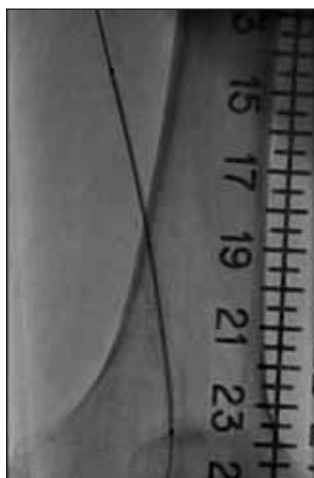


Figure 2. The second GORE VIABAHN® Endoprosthesis was overlapped with the first.

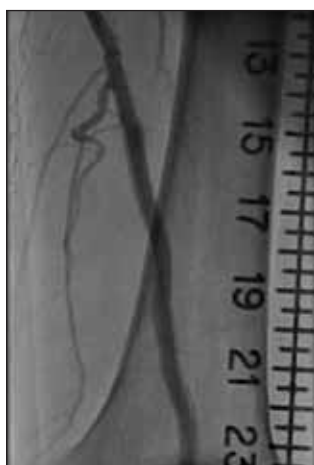


Figure 3. The mid-to-distal SFA after completion of the procedure.

lesions and the areas of the SFA vulnerable to stent crush and stent fractures might be a viable option, especially with regard to in-stent restenosis and the ability of covered stents to better withstand the compression and torsion forces present in the SFA. One possible concern is the risk of acute thrombosis due to use of the covered stent. However, our patient was not placed on warfarin therapy and had done well without acute thrombosis and restenosis at follow-up after 1 year. The patient's medical regimen related to his percutaneous treatment has been the institution of aspirin and clopidogrel. One possible explanation for the lack of acute thrombosis in cases like this might be the better matching of the stent graft to the native artery in relation to the possible mismatch in size of a femoral-to-popliteal bypass graft. The better characteristics of this covered stent might be due to the material actually reinforcing the stent framework while also being more flexible around framework. The fabric also acts to smooth out the stent while it is bent, unlike the scaling one might see with an uncovered stent. The additional advantage of the stent in this particular case was the ability to exclude the aneurysm, which was also of significant concern. In fact, there are many cases of both iliac and SFA disease that are complicated by pre- and poststenotic aneurysms and ulcerated plaques with false aneurysmal channels.

CONCLUSION

Given the challenges of obtaining good long-term results of endovascular therapies in the SFA, particularly with recent data showing frequent stent fractures, the use of covered nitinol stents can be a viable option, with possible better long-term results if the risk of stent fractures can be lowered while obtaining good patency. ■

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GORE VIABAHN®

Endoprosthesis Recanalization of a Complex SFA Lesion

An illustrative case report on the effective use of the GORE VIABAHN® Endoprosthesis.

BY MARK W. MEWISSEN, MD

CASE PRESENTATION

A 62-year-old man presented to the Vascular Center at St. Luke's Medical Center in June 2005 with lifestyle-limiting claudication of the left lower limb. On physical examination, the left popliteal pulse was absent. The left ankle-brachial indexes before and after exercise were 0.5 and 0.2, respectively. Duplex ultrasonography identified a heavily calcified distal superficial femoral artery (SFA) and low velocities in the popliteal artery. Angiography, performed via a right contralateral femoral approach, showed that the distal left SFA was heavily calcified with resulting near-total occlusion of the arterial segment. The distal popliteal artery was relatively free of disease, and the tibial runoff consisted of patent anterior and posterior tibial arteries (Figure 1).

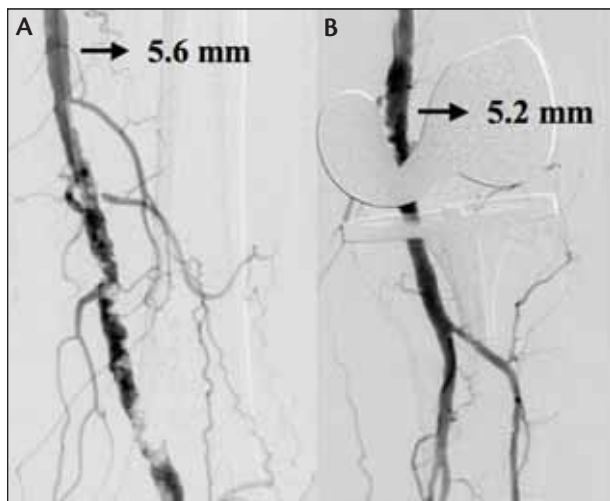


Figure 1. Selective left lower-extremity arteriogram demonstrating a heavily calcified SFA lesion (A). The mid and distal popliteal artery, relatively disease-free and of adequate diameter (>5 mm), accommodate a 6-mm GORE VIABAHN® Endoprosthesis. There is two-vessel runoff, a good predictor of favorable outcome (B).

Using the guidance of a .035-inch Rosen wire (Cook Medical, Bloomington, IN), an 8-F, 45-cm-long sheath was passed over the aortic bifurcation and advanced to the level of the ipsilateral common femoral artery. Using a .018-inch Quick Cross catheter (Spectranetics Corporation, Colorado Springs, CO) for support, a .018-inch, 260-cm-long supportive guidewire (Platinum Plus, Boston Scientific Corporation, Natick, MA) was successfully negotiated across the lesion to allow predilatation using a 3.5-mm diameter, 4-cm-long balloon (Savvy, Cordis Corporation, a Johnson & Johnson company, Miami, FL). This step was necessary to allow passage and deployment of a 6-mm, 15-cm-long GORE VIABAHN® Endoprosthesis (Gore & Associates, Flagstaff, AZ), expanded in place using a high-

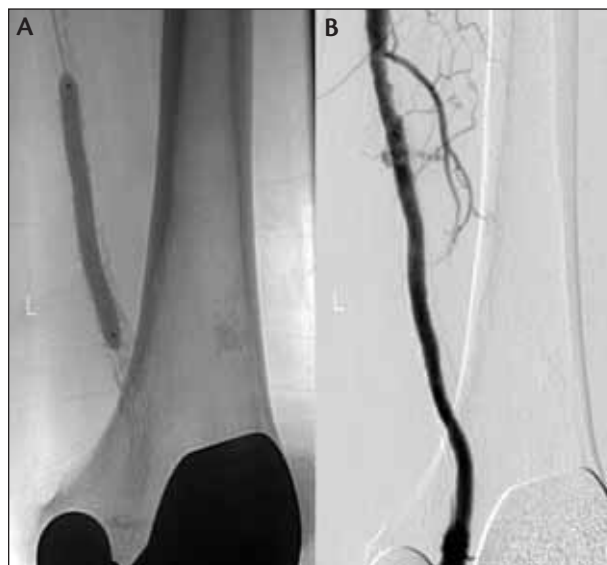


Figure 2. Postdilatation of the 6-mm GORE VIABAHN® Endoprosthesis will help to avoid stent edge dilatation with a high-pressure balloon catheter (A). A poststent deployment and dilatation angiogram shows an excellent technical result (B).

pressure, 5-mm-diameter percutaneous transluminal angioplasty balloon, avoiding dilatation of the stent edges (Figure 2). At 18 months, the patient remains asymptomatic. His ankle-brachial index continues to be normalized. Duplex examination revealed normal arterial waveforms without any significant stenosis.

DISCUSSION

This case, although anecdotal, is in line with several recent reports indicating that outcomes for the GORE VIABAHN® Endoprosthesis exceed results achieved with angioplasty and bare nitinol stenting for complex femoropopliteal arterial lesions. This may be attributable to the expanded polytetrafluoroethylene lining of the stent that probably inhibits the ingrowth of intimal hyperplasia.

Regarding patient and lesion selection, it is important to note that the device requires delivery through a larger-profile sheath (8 F for the 6-mm graft), and that the proximal and distal boundaries of the vessel to be treated must be at least 4.8 mm in diameter. The tibial runoff should also be continuous via at least one patent artery. It is also of paramount importance to avoid dilating the edges of the deployed stent to minimize the development of an edge stenosis, a reported mechanism of stent graft failure. Spot stenting should also be avoided. Extreme care must be exercised when the device is deployed near the orifice of the profunda femoralis artery. High-magnification angiograms in various obliquities must be obtained before stent deployment. Failure to understand the anatomy of the common femoral bifurcation will unavoidably lead to disastrous complications.

The appropriate management of the collateral circulation at the distal segment of a long lesion remains controversial. Some collateral vessels must occasionally be covered if the edges of the graft are to be delivered in relatively disease-free arterial margins. It is believed that the benefits of such technique outweigh the risks of alternative spot stenting strategies, a reported mechanism of early stent graft failure. Furthermore, it is important to flare the stent edges at sites free of plaque. This latter concept also helps to choose the appropriate stent length to ensure exclusion of the diseased segment *in toto*. The multicenter prospective and randomized "Viabahn Versus Bare Nitinol Stent Trial" (VIBRANT), funded by Gore & Associates, will provide additional data regarding the optimal treatment for long SFA lesions. ■

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(Continued from page 12)

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